

# **Improving access to high quality primary care for socio-economically disadvantaged older people in rural areas: a mixed method study**

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# **Abstract**

## *Objectives*

The research objectives were to: 1) explore barriers to primary care access for socio-economically disadvantaged older people in rural areas; 2) develop an intervention to improve access for this group; and 3) test the feasibility of the trial design and intervention.

## *Methods*

A mixed method design, drawing on realist principles and guided by a triangulation protocol, was used to explore barriers for this group using three studies: first, a realist review; second, a qualitative study of semi-structured interviews with older people and focus groups with health professionals; and third, an analysis of the English Longitudinal Study of Ageing using structural equation modelling (SEM). Findings were integrated using a mixed method matrix.

Two strong themes from the integrated theory, the booking system and transport, were identified for intervention. Based on stakeholder dialogues with health professionals and patient representatives, an intervention was developed which was explored in a cluster feasibility trial. The intervention allowed practices to develop their own service changes assisted by a £1500 grant, four development meetings and support manual. The feasibility trial recruited four general practices, with three randomised to intervention and one to usual care.

## *Findings*

The realist review generated a seven-step patient pathway highlighting important contexts and mechanisms. The qualitative study explored barriers, such as engaged telephone lines and limited appointments, and proposed the concept of a social contract, where patients are careful not to bother the doctor in return for goodwill. The cohort study was restricted by limited data but demonstrated the potential of SEM to quantify realist theory.

Participant recruitment in the feasibility study was low (3%), but retention was good (91%) and data collection methods acceptable to participants. Practices were successfully able to develop their own service changes that gave them the freedom, time and resource to be innovative or provided an opportunity to implement existing ideas.

## *Conclusion*

Some vulnerable older people face multiple challenges in accessing primary care. Practices were able to develop their own context-dependent solutions to address local issues.

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# Abbreviations

A+E = accident and emergency  
CFA = confirmatory factor analysis  
CFI = comparative fit index  
CMO = context-mechanism-outcome  
COPD = chronic obstructive pulmonary disease  
COREQ = consolidated criteria for reporting qualitative research  
CRN = Clinical Research Network  
ELSA = English Longitudinal Study of Ageing  
EQ-5D-5L = EuroQol five dimensions questionnaire  
GIS = Geographic Information System software  
GP = general practitioner  
GPPS = GP Patient Survey  
HES = Hospital Episode Statistics  
HSCIC = Health and Social Care Information Centre  
I-ACT = Improving Primary Care Access in Context and Theory  
ICC = intraclass correlation coefficient  
ICECAP-O = ICEpop CAPability measure for Older people  
IMD = Index of Multiple Deprivation  
IQR = interquartile range  
MRC = Medical Research Council  
NA = not applicable  
NatCen = National Centre for Social Research  
NHS = National Health Service  
NICE = National Institute for Health and Care Excellence  
NIHR = National Institute for Health Research  
NSSEC = National Statistics Socio-economic Classification  
PAM = Patient Activation Measure  
PSSRU = Personal Social Services Research Unit  
RAMESES = Realist And Meta-narrative Evidence Syntheses: Evolving Standards  
RCT = randomised controlled trial  
RMSEA = root mean square error of approximation  
SD = standard deviation  
SEM = structural equation modelling  
TLI = Tucker-Lewis Index  
UK = United Kingdom  
VAS = visual analogue scale

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# Publications and statement of authorship

## Publications arising from this thesis

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## Statement of jointly authored publications

The research reported is my own original work, which was carried out in collaboration with others as follows:

Chapter 1: Written by John Ford

Chapter 2: John Ford was the lead author of the following published paper:

Ford JA, Jones AP, Wong G, Clark AB, Porter T, Shakespeare T, Swart AM, Steel N. Improving access to high-quality primary care for socioeconomically disadvantaged older people in rural areas: a mixed method study protocol. *BMJ Open* 2015;5:e009104. doi:10.1136/bmjopen-2015-009104

JF designed the programme of research primarily under the supervision of NS, AJ and GW. TS and TP supported the qualitative aspects, AC the statistics, GB the health economics and AMS the trial. JF drafted the initial manuscript for this publication and the supervisory team commented on their area of expertise.

Chapter 3: John Ford was the lead author of the following published paper:

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JF led and designed this study. He drafted the initial protocol primarily under the supervision of GW, NS and AJ. JF undertook the literature search, screening of abstracts, data collection and analysis. Emerging context-mechanism-outcome configurations were identified by JF and refined through discussion with GW, NS and AJ. JF drafted the initial manuscript with comments and edits from GW, NS and AJ. JF responded to peer review comments with advice from GW, NS and AJ.

Chapter 4: John Ford was the lead author of the following published paper:

Ford JA, Turley R, Porter T, Shakespeare T, Wong G, Jones AP, Steel N. Access to primary care for socio-economically disadvantaged older people in rural areas: A qualitative study. *PLoS ONE* 2018 13(3): e0193952.

JF led and designed this study. He drafted the initial protocol which was refined under the supervision of TS, TP, GW, AJ and NS. JF recruited, consented and interviewed all participants. JF coded the data, which was also independently coded by RT. JF identified the emerging themes with the support of RT, which were refined by TS, TP, GW, AJ and NS. JF drafted the initial manuscript with comments and edits from RT, TP, TS, GW, NS and AJ. JF responded to peer review comments with advice from RT, TP, TS, GW, NS and AJ.

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JF led and designed this study. He drafted the initial protocol which was refined under the supervision of AJ, GW, AC, TP, and NS. JF mapped the realist concepts to available variables with feedback from AJ, GW, AC, TP, and NS. JF linked the two dataset and undertook the initial statistical model with help from AC. The statistical model was refined through discussion with AJ, GW, AC, TP and NS. JF drafted the initial manuscript with comments and edits from AJ, GW, AC, TP and NS. JF responded to peer review comments with advice from AJ, GW, AC, TP and NS.

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JF led and designed this study. He drafted the initial protocol which was refined under the supervision of AJ, GW, GB, AC, ES, AMS and NS. JF recruited practices and patients. JF undertook the baseline visits, development meetings with practices, practice observations and end of study interviews. JF undertook the statistical analysis with the support of AC and health economic analysis with the support of GB. JF drafted the initial manuscript with comments and edits from AJ, GW, GB, AC, ES, AMS and NS.

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# 1 Introduction

In 1948, the Universal Declaration of Human Rights declared that everyone has the right to health care access irrespective of sickness, old age or disability [1]. During the same year, the National Health Service (NHS) was established in the United Kingdom. While the structure and function of the NHS has evolved over the past seventy years, one of the founding principles remains as strong today as ever; access to health care should be free at the point of use, based on clinical need and not an individual's ability to pay [2]. Providing care based on need and free at the point of use has recently been voted by the British Medical Journal readership as the greatest achievement of the NHS over the past 70 years [3].

Recently the NHS has been ranked as the top performing health system compared to ten other comparative countries such as America, Australia, Canada, France, Germany and Norway [4]. While ranked top, the UK was ranked third for access to health care, based on a range of measures of timeliness and affordability, behind the Netherlands and Germany. While access to health care may be good in the UK compared to many countries, inequalities exist. Previous research has found that socio-economically disadvantaged groups, rural communities and older people may find it particularly difficult to access primary care [5]. This research project aims to explore why some rural socio-economically disadvantaged older people face challenges in accessing primary care and develop solutions to help.

## 1.1 What is access?

Ricketts and Goldsmith reviewed the different concepts that have been used to define access to health care [6]. The predominant model, first described in 1974, is the Andersen, Aday and Newman framework [7]. The authors argued that access had been more of a political idea rather than an operational one; often used as a policy goal, rather than being a useful concept in routine service delivery. Therefore, their framework aimed to provide a more systematic approach to conceptualise and operationalise access. The framework moved beyond simply considering the population and health system to the following five dimensions 1) health policy, 2) characteristics of the health service, 3) characteristics of the population at risk, 4) utilisation and 5) consumer satisfaction. Andersen revisited the model 20 years later to emphasise the importance of feedback from utilisation of health services to the predisposing, enabling and need characteristics of the population at risk [8].

The endpoint of this model is utilisation and consumer satisfaction. Several previous studies have also used service utilisation as an endpoint for access [9-11]. Aday and Andersen described utilisation as realised access [7]; an outcome supported by Donabedian who argued that access can be measured by the level of use in relation to need [12]. However conflating access and utilisation

may be overly simplistic. Ricketts and Goldsmith argued that the dynamic processes of learning and adapting in an uncoordinated health system is more important than simply thinking about the structural and resource elements of a health system that lead to utilisation [6]. The authors built on this access theory to propose that patients have a health care career based on their learning from interactions with the system.

Another theoretical model of access was proposed by Penchansky and Thomas in 1981 who summarised access in the following five dimensions: availability, accessibility, accommodation, affordability and acceptability [13]. Levesque and colleagues expanded this model by proposing five corollary abilities of populations that interact with these five dimensions of accessibility: ability to perceive; ability to seek; ability to reach; ability to pay; and ability to engage [14]. The Institute of Medicine added the notion of timeliness and positive outcomes into their definition of access, “the timely use of personal health services to achieve the best possible outcome” [15]. In a UK National Audit Office report on access to general practice, the authors examined four key elements of access which were easier to measure: 1) ability to access general practice close to home, 2) ability to get appointments at the appropriate time, 3) ability to access the surgery at convenient times and in flexible ways and 4) ability to see a preferred health professional [16].

Dixon-Woods and colleagues undertook a critical interpretive synthesis [17], a method which aims to generate theory by drawing on traditional qualitative and quantitative techniques, to explore access to health care specifically for vulnerable groups [18]. The authors argued that the concept of candidacy provides a more useful understanding of access to health care for vulnerable groups, compared to utilisation. Candidacy was defined as how an individual’s eligibility for health care is determined between themselves and the health services through a dynamic and negotiated process.

In this thesis, the Institute of Medicine definition of access is preferred, “the timely use of personal health services to achieve the best possible outcome” [15] because it highlights the importance of timeliness and the best possible outcome. The word “timely” is important because it acknowledges that in some scenarios speed of access is important, but in other situations it is not because of, for example, work commitments or needing to arrange transport. The definition states that the aim of access is to achieve the best possible outcome highlighting that the best outcome may be different for different patients. However, the definition is limited by tying access to the concept of use. An individual may have good access to a service, without necessarily using it. Good access and the knowledge of being able to see a health professional easily reassures, particularly vulnerable, patients that help is available if needed. Therefore, the definition used in this thesis is, *the ability to obtain timely personal health services to achieve the best possible outcome.*

## **1.2 What is the policy context and history of access to primary care in England?**

Despite the challenges in defining access, there has been considerable policy interest in primary care access over the past 20 years. Access to primary care was revolutionised in 1948 with the establishment of the NHS, but it was primarily during the Blair/Brown Government (1997 to 2010) when access to primary care was given substantial policy prominence in the UK [19]. The Blair Government (1997 to 2007) had five main policies to improve access to primary care [20]. First, was the introduction of “one-stop primary care centres” or so-called “polyclinics”. The aim of one-stop primary care centres was to offer a mix of primary and community-based health in larger centres which would be open 12 hours a day, every day of the year. It was intended that these centres would provide a range of services, such as radiology and physiotherapy. Despite promising 150 new centres, only twelve were opened by 2010 when the coalition government (2010 to 2015) halted the programme [21].

Second, walk-in-centres were introduced. These centres did not have the range of facilities as a polyclinic, but allowed patients, irrespective of which practice they were registered with, to see a nurse or GP without booking an appointment. The centres had extended opening in the evenings and weekends. Between 2000 and 2010, more than 230 walk-in-centres were open across England [22].

Third, the Blair Government pledged that patients would be able to see a GP within 48 hours. This had a mixed impact [23]. It forced general practices to re-configure to provide rapid access for patients, helping those with acute problems. However, it also led some general practices to stop advance appointment booking, disrupting continuity. Furthermore, it suggested that speed of access, rather than timeliness, was more important. Despite this target being dropped by the coalition government in 2010, it resurfaced in the Labour general election manifesto in 2015 [24].

Fourth, 2,000 more GPs were promised in 2000 [20] to tackle one of the key issues; a lack of GPs limiting the number of appointments. The promise of more GPs to improve access to primary care was also a theme of the Cameron Government (2010-2017) who pledged to train an additional 5,000 new GPs [25], although this was not as many as Labour’s promise of 8,000 in their 2015 general election manifesto [24].

Finally, NHS Direct, a 24-hour telephone line staffed by nurses, was introduced [26]. The service allowed patients to access health advice from a nurse at any point in the day without going to their own general practice. The coalition government replaced the NHS Direct scheme with NHS 111. The emphasis changed slightly with NHS 111; telephone advisors answered calls rather than nurses and the service focused on acute, but non-urgent, issues.

The coalition government (2010-2015) introduced wide-ranging reforms to the NHS, with the formation of organisations, such as Clinical Commissioning Groups and NHS England [27]. Where Primary Care Trusts has previously commissioned primary care, NHS England assumed this role. It became a key organisation in setting policy for access to primary care, for example, developing policy to increase the number of appointments that can be booked online. Overtime it was recognised that Clinical Commissioning Groups might be better placed to commission primary care in some areas because it would allow better integration of services [28]. Therefore, in a number of areas commissioning of primary care was delegated by NHS England to Clinical Commissioning Groups or a joint arrangement in place [28]. Whilst NHS England retains an important role in national strategic direction for access to primary care, in many areas the Clinical Commissioning Group commissions local services.

One of the key Conservative election pledges in the 2015 general election, at which the Conservative party won a majority, was the delivery of a “seven day NHS”, including 8am-8pm opening of general practices seven days a week [29]. This policy was pre-empted by the 2013 Prime Minister’s Challenge fund. In this programme, £50 million was given to NHS England to fund 20 pilots projects aimed at improving access to general practice and stimulating “innovative ways of providing primary care services” [30]. In 2015/16, £100 million more was provided to NHS England for a further 37 pilot schemes that had to include extended opening as part of the pilot.

In April 2016, the General Practice Forward View was published, which committed an extra £2.4 billion/year to support general practice services in England until 2020/21 [31]. The wide-ranging policy includes changes to workforce, workload, general practice infrastructure and care redesign. The policy aimed to improve access to primary care by increasing access to pre-bookable and same day appointments in evenings and weekends through commissioning an additional 30 minutes consultation capacity per 1000 population. In addition the policy aimed to identify “issues of inequalities in patients’ experience of accessing general practice” and develop “actions to resolve” them [32]. The policy stated that issues relating to inequalities should be undertaken through a Health Equality Impact Assessment. While access to primary care for vulnerable groups has been considered previously, it was given more prominence in the GP Forward View 2016. However, the extent to which commissioners and general practices are able to invest in services to address inequalities, whilst attempting to meet other policy objectives, is unclear.

### **1.3 Why are politicians and decision makers so interested in access?**

One of the main reasons for this considerable policy attention on access to primary care is the perception that improving access to primary care may be a good way to reduce unplanned hospital admissions and A+E attendances, and subsequently reduce costs [33, 34]. Statistics from the



National Audit Office estimated that a typical consultation in general practice costs £21, compared to £124 for a visit to A+E [16]. However, the evidence is mixed – several observational studies have found that general practices which perform better on measures of access to primary care have lower A+E attendances and hospital admissions, but interventions which aim to improve access to primary care appear to have a less of an impact on secondary care use [22, 35-38]. Soljak and colleagues used a national cross-sectional study in England, including more than 98% of general practice, and found that improved access to primary care was associated with lower stroke admissions [36]. Other studies using the GP Patient Survey in England have found that good patient-reported access to primary care was associated with lower self-referred A+E attendances and unplanned asthma admissions [35, 37, 38].

Walk-in-centres aimed to improve access to primary care by allowing patients to see a nurse or doctor at a wide range of times without having to book an appointment. Across England they cost approximately £31million in the first year [22]. The national evaluation found that overall there was no statistically significant difference to A+E attendances [22]. The evaluation found variability in effects, suggesting that improving access through walk-in-centres prevented some attending A+E, whereas for others it may have led to an increased likelihood because of onward referral. There is some weaker evidence that extended access may reduce attendances to A+E for minor conditions. Whittaker and colleagues undertook propensity score matching of 56 practices offering extended opening in Manchester and found a statistically significant reduction in A+E attendances for minor conditions but not for all conditions combined [39].

Access to primary care is also important because it is often viewed by the general public as a marker of the quality and efficiency of the health service, and consequently, the government's performance relating to the NHS. For example, being able to see a GP, especially a regular one, in a timely fashion may be viewed as test of efficiency and effectiveness. It is especially important because 90% of NHS patient contact is through primary care [40].

## **1.4 What is access to primary care currently like in the United Kingdom?**

Considering the policy prominence of access to primary care, what is the current situation? The best source of data on access to primary care in England is the GP Patient Survey [41]. It is a bi-annual survey, commissioned by NHS England and delivered by Ipsos Mori, sent to over two million patients across every practice in England with over 800,000 responses. Over the past 5 years, access to primary care has worsening according to the measures used in the survey [42]. In 2017, 22.5% of patients reported that it was very easy to get through to their surgery by phone, compared to 30.9% in 2012. Similarly, 72.1% of patients in 2017 said they were able to get an appointment, compared to 75.3% in 2012. The proportion of patients who reported that their

overall experience of their general practice was good or very good decreased from 88.3% in 2012 to 84.8% in 2017. Finally, the proportion of people who were able to obtain an appointment with their preferred GP on a regular GP dropped from 41.9% in 2012 to 32.8% in 2017. Importantly, the survey only assesses patient self-reported access and does not consider if access was timely or led to the best outcome possible.

In 2015, the National Audit Office published a "Stocktake of access to general practice in England" [16]. It reported that of the 7,875 general practices in England, the average number of hours per week was 51.4 with a range of 63 to 114 GPs and nurses per 100,000 population. One of the main findings was that there was no good data on the number of consultations. The best estimate, produced by statistical modelling, appeared to be 372 million general practice consultation per year [43].

Part of the reason for the decrease in access may be due to morale and workforce issues within general practice, with the number of full-time equivalent GPs falling by more than 1000 between September 2015 and May 2018 [44]. A recent study of 2,248 GPs in South West England found that 37% reported a high likelihood of quitting direct patient care in the next five years and 54% reported low morale [45]. The chair of the Royal College of General Practitioners, Professor Helen Stokes-Lampard, said the negativity within general practice is the worst she has ever known [46]. Sansom and colleagues undertook a qualitative study of 41 GPs in England, published in 2018 with data collected in 2016 [47]. In the study, GPs reported unrealistic expectations about what general practice can and should deliver, and a lack of understanding from government and professional bodies about the impending workforce crisis.

The GP Patient Survey only covers England and similar data does not exist for Wales and Northern Ireland. Scotland undertakes a similar Health and Care Experience Survey but with different questions [48]. The Scottish survey suggests that while the proportion of patients who have been able to book an appointment within 48 hours has remained stable over the past six years (about 90% of the 133,000 patients completing the questionnaire), the proportion of patients able to book an appointment beyond 48 hours decreased from 80% in 2011/12 to 68% in 2017/18 [49]. Examining the number of fulltime equivalent GPs per head of population is another way of comparing access. In 2017, Wales had the fewest GPs per head of population (0.83 per 1000), compared to Scotland (1.11), Northern Ireland (0.93) and England (0.90) [50]. However, this does not consider the differential health need in these countries, with Northern Ireland and Wales experiencing higher levels of morbidity than Scotland and England in 2016, and England lower premature mortality compared to other UK nations [51]. Despite the lack of data, it is conceivable that the worsening access to primary care seen in England over the past five years would be similar in the other UK nations because the core underlying problems of financial constraint and workforce issues have affected all countries of the UK [52-54].

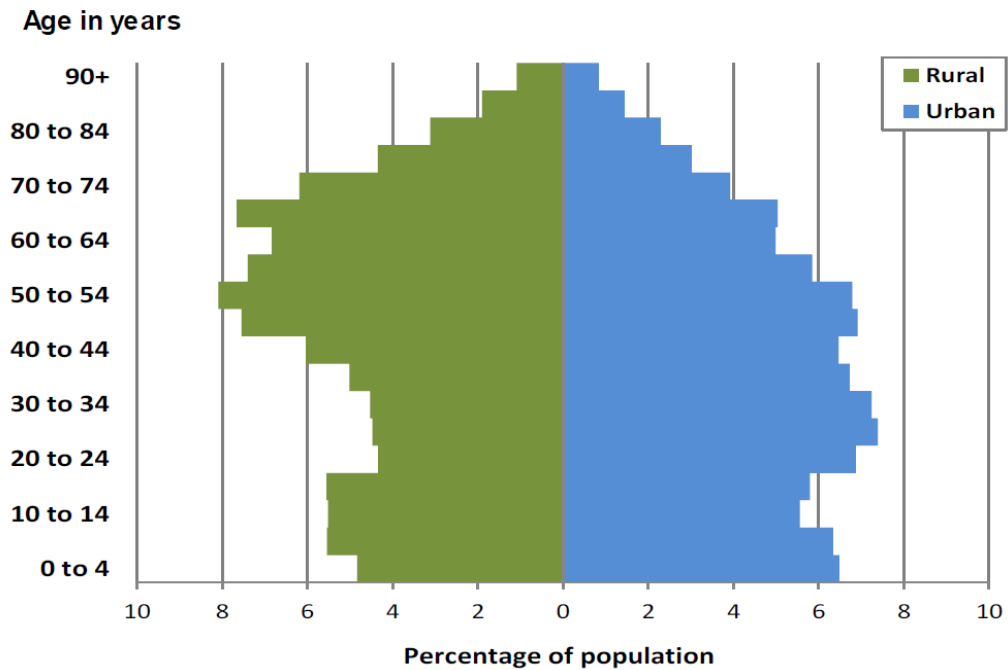
## 1.5 What groups find it most difficult to access primary care?

According to the GP Patient Survey, access to primary care is worsening, but it is likely to be even worse for some vulnerable groups. The National Audit Office stocktake report found that deprived areas tended to have a lower ratio of GPs and nurses to patients and where this ratio was lower it was particularly hard for patients to book and access appointments. The situation is compounded by the number of GPs decreasing faster in deprived areas over the past 10 years compared to areas that are more affluent [55]. The number of GPs and nurses is likely to directly impact the ability to offer timely appointments or provide services that achieve the best possible outcome for patients.

The National Audit Office report also found that in rural areas 37% of patients did not have a general practice within two kilometres [16]. The additional distance to travel to a general practice is particularly important for those who do not have access to a car with the Department for Environment, Food and Rural Affairs estimating that in rural areas one third of people over 85 years old and a quarter of 75 to 84 year olds lived without car access [56].

Currently over nine million people live in rural areas in England (settlements with less than 10,000 resident population) and this number is increasing annually [57]. Figure 1 shows that a higher proportion of people over 50 years old live in rural areas compared with urban areas. In rural areas, the population aged 65 years and over increased by 37% between 2001 and 2015, with the population of over 85 year olds growing fastest [57]. Research undertaken by the Department for Environment, Food and Rural Affairs found that older people in rural areas often preferred to use at first informal networks, such as friends, family or church contacts, rather than using formal support services [58]. However, the report found that these rural social networks appeared to be weakening, leaving some rural older people isolated with difficulty accessing key services, such as primary care.

Figure 1: Percentage of population within age bands by rural-urban classification (Lower Super Output Area) in England, 2016



Source: Statistical Digest of Rural England 2018 [57]

Access to primary care is important for older people because they have a high need for health care [59]. Despite a high prevalence of multiple co-existing medical conditions [60], older people often underuse it relative to need [61]. The largest study estimating the prevalence of multimorbidity from the US, which included over 30 million patients, estimated the prevalence of multi-morbidity (defined as 2 or more conditions) to be 62% in 65-74 year olds, 76% in 75 to 84 year olds and 81% in over 85 year olds [60]. Based on a Scottish cross-sectional study, the prevalence of multimorbidity in those 65 to 84 years old was 65% and for those over 85 years 82% [59].

While rural populations tend, on average, to be more affluent than urban populations, there remains significant pockets of deprivation. More than a sixth of rural pensioners live below the poverty threshold (below 60% of median income); a figure which has increased by 2% between 2012/13 and 2014/15 [57]. Allin and colleagues analysed over 18,000 people in the British Household Panel Survey to assess health service use of people aged over 65 in the UK [62]. They found that older people with lower incomes were significantly less likely compared to more affluent groups to visit a GP, specialist or dentist, but had the greatest need. A review of access to primary care highlighted the compounding effect of reduced car ownership in more disadvantaged areas alongside living further away from health services [5]. The report also highlighted anxieties over safety, availability and cost, for some older people.

While data does not exist on the number of socio-economically disadvantaged older people in rural areas without access to a car, by triangulating the above data sources (proportion of older people living below the poverty threshold in rural areas, proportion of people in rural areas who do not

have access to a car and population of England), it can be estimated that there are about 400,000 people in this group.

From the previous literature it appears that older people, those in rural areas and socio-economically disadvantaged groups face additional challenges in accessing primary care compared to the general population. Interventions are needed to improve access for both the general population, for whom access appears to be worsening, and groups at high risk of poor access, such as socio-economically disadvantaged older people in rural areas.

## **1.6 What currently works to improve access to primary care?**

Two recent major systematic reviews assessed interventions to improve access and included services used in the UK, such as walk in centres, reminder systems, text messaging, multi-lingual services, telephone consulting and advanced access [63, 64]. Comino and colleagues conceptualised access as a dynamic balance between patient need and service provision. The authors identified 317 studies, 75 of which evaluated interventions across three domains of prevention, chronic disease management and episodic care [63]. They found that 55 of the 75 interventions reported positive findings and that interventions with multiple linked strategies targeted at different levels of the health care system were more likely to be effective. Kehle and colleagues defined access as an individual's ability to obtain the health care they need within an appropriate time frame. The authors identified 16 studies to improve access for older people in the US [64]. They found that community-based outpatient clinics, telemedicine and primary care mental health integration improved access. Both reviews highlighted the poor methodological quality of included studies. Furthermore, most interventions were universal and there was a lack of targeted research [63].

Universal interventions that aim to improve access for the whole population, rather than targeting primary care resources at those most in need, have been criticised because they increase access for the so-called 'worried well' and create additional health care demand, without necessarily improving outcomes or health care efficiency [64, 65]. Seven day opening in primary care is a recent universal policy intervention. In an analysis of the GP Patient Survey, it was found that younger people, those who work full time, and those who could not get time off work were more likely to report that weekend opening would help compared to people with Alzheimer's disease, learning difficulties, or problems with walking, washing, or dressing [66]. Therefore, seven day opening may be popular with younger, affluent, working age people but may not benefit those at highest risk of poor access, such as elderly people, those with dementia or disability [65]. Furthermore, the opportunity cost of time and funds is likely to be substantial considering the financial challenges facing the NHS. Together this may reduce the resources available and policy priority for targeted approaches aimed at those who need health care the most.

Research to improve access to primary care requires an understanding of local problems. The National Audit Office stocktake report concluded that it is primarily the working arrangements of individual general practices that influence the ability to get appointments, rather than demographic factors, practice characteristics or staff [16]. An understanding of these individual general practice arrangements is needed to improve access. Therefore, the most useful research evidence to help general practices and commissioners is unlikely to be a single, one-size-fits-all intervention, but a context-dependent intervention that can improve individual general practice working arrangements.

## **1.7 Rationale and aims**

Whilst there is not one agreed definition of access, it is clear that helping patients obtain health care in a timely fashion, to achieve the best possible outcome, is the right thing to do. Furthermore, it may help reduce pressure on other parts of the health service, but the evidence for this is mixed. Despite various policy efforts, access as measured by the GP Patient Survey, appears to be worsening. It is likely to be worse for those patients who face additional barriers, such as vulnerable populations. There is likely to be a magnifying effect when multiple disadvantage coexists, meaning that some socio-economically disadvantaged older people living in rural areas may find it especially difficult to access primary care. This is particularly important because this group is likely to have a high health need. Current initiatives to improve access, such as seven-day opening, are aimed at the whole population, rather than those most in need of health care. While there is a need for interventions to improve access for the wider population, there is little research exploring the barriers, or interventions, for high-risk groups, such as socio-economically disadvantaged older people. Therefore, this research aims to understand how this group access primary care and develop an intervention to improve access for them.

The overall objectives are to:

1. Identify and explore barriers to accessing primary care for socio-economically disadvantaged older people in rural areas
2. Develop a primary care based intervention to improve access for this group
3. Test both the feasibility of the intervention and how it might be evaluated in a definitive trial

## 1.8 Overarching justification of the methodological approach

The pathway an older person takes in their journey to access care may be long, complex, non-linear and dependent on a number of different contexts (e.g. physical, environmental or social). This research aims to unpick some of the complexity of access to primary care for socio-economically disadvantaged older people in rural areas and provide a means of generating more useful information for decision makers. To explore this complexity methods are needed which facilitate contextual understanding. Realist approaches are suited to exploring context and considering ways to improve outcomes.

### 1.8.1 *Philosophical approach*

Realist approaches originate from the philosophy of realism, and in particular Bhaskar's work on critical realism [67]. Bhaskar argued that there is a requirement in science to separate epistemology (study of knowledge and how it is acquired) and ontology (study of the nature of reality), i.e. differentiating between our constantly changing knowledge and relatively unchanging 'real world' which we study. Based on this, he argued that a better ontology is required in science, especially scientific experimentation and our understanding of causation. He highlighted that traditional scientific experimentation is usually undertaken in 'closed systems' where B always follows A, for example in a controlled laboratory setting, however the real world usually involves 'open systems'. In this 'open system', B may follow A, but this is not always true because the real world is complex and dynamic. Therefore to understand the causal relationship between A and B it is key to understand the underlying mechanisms within open systems, i.e. tendencies of the way things act in the real world. While Bhaskar's work was primarily focused on the natural sciences, it has implications for social sciences as well. Pawson and Tilley drew on Bhaskar's work to develop their version of realism (scientific realism) and accompanying approaches [68]. Pawson and Tilley's initial focus was the evaluation of social interventions, but the approaches they developed and pioneered have evolved over the past 20 years to inform a range of areas such as the evaluation of complex health care intervention and literature reviewing.

Realism sits between positivism and constructivism, and has similarities with post-positivism [69]. Broadly speaking, positivism espouses that there is an objective, observable reality governed by natural laws, which is independent of human interpretation. Whereas constructivism argues that everything we know is socially or individually constructed and, therefore, there can be no certainty about reality. Post-positivism shares the assumptions of positivism about an objective, observable reality, but acknowledges that an individual's experiences and perspectives will affect their interpretation. Realism accepts there is a real world, independent of human interpretation, but our knowledge of it is processed through human sense, cognition, language and culture [70]. One key difference between realism and post-positivism is interpretation of causation; realism advocates a

generative understanding (outcomes are produced by unobserved mechanisms which are ‘triggered’ under certain contexts) whereas post-positivism suggests a successionist model (the propensity of one event to lead to an outcome) [71]. Subsequently, realism places more prominence on understanding the contexts and underlying mechanism that are causative compared to a positivist or post-positivist philosophy [72]. Realist approaches are less concerned with understanding if an intervention is successful in achieving an outcome, but rather “what works, for whom, in what circumstances, in what respects and why?” [68]. A key underlying principle of realism is that researchers cannot have certain knowledge of the world or objectivity, but that all knowledge is partial and fallible, and therefore theory generated from a realist perspective is only as good as it is until it is disproved.

Pawson describes realism as a “methodological orientation, or a broad logic of inquiry that is grounded in the philosophy of science and social science” [68]. The logic of realist approaches centres on context-mechanism-outcome (CMO) configurations. In this logic, a mechanism is triggered under a certain context to produce an outcome.

Defining context is important. The Oxford Dictionary defined context as, “the circumstances that form the setting for an event, statement, or idea, and in terms of which it can be fully understood” [73]. This suggests that without context an event, statement or idea may not be fully understood. From a social science perspective, Sayer defined context as “material resources, social structures, including conventions, rules and systems of meaning in terms of which reasons are formulated” [74]. However, within realist approaches context is understood as relating directly to mechanisms and outcomes. The RAMESES projects, which produced quality and publication standards and training materials for realist approaches, defines context in the following way:

Contexts do not refer to places, people, time or institutions per se, but to the social relationships, rules, norms and expectations that constitute them, as well as the resources available (or not). Contexts are therefore bound up with the mechanism(s) through which programmes work, and need to be understood as an analytically distinct but interconnected element of a Context-Mechanism-Outcome configuration [75].

Realist approaches also have a particular understanding of mechanisms, although the fine details of what constitutes realist mechanisms are still debated [76]. Within realism mechanisms are, “causal tendencies whose activation depends on supportive contextual conditions” [76]. They are not always activated, unless certain contexts are present and may interact with each other. They are patterns of how resources (such as material, social, emotional or political) offered by programmes or interventions interact with participants to produce intended or unintended outcomes.

Mechanisms are “hidden, but still real shaped by and interconnected with context” [76].

While both qualitative and quantitative data are used within realist approaches, quantitative techniques are less established. Realist approaches are used in two main methodologies; realist



evaluation and realist review. A realist evaluation uses primary data collection to understand complex interventions [77], whereas a realist review uses a range of published and grey literature [78]. These techniques are pertinent because they mark a shift in thinking about interventions; from a success/failure spectrum to a contextual understanding of whether, why and how, an intervention is more or less likely to work in certain situations.

Whilst this research draws, partly, on realism to answer the research objectives outlined above, the purpose of is not to undertake a philosophical exercise, exploring ontology and epistemology, but rather to take a pragmatic approach aiming to produce evidence that will be of most use to practitioners and policy makers. Therefore, the approach used at each stage is driven by the research question and pursuit of useful evidence, rather than allegiance to a philosophical standpoint.

### 1.8.2 *Mixed methods approach*

Mixed methods, defined as the integration of quantitative and qualitative techniques in the same study or line of inquiry [79], are well-suited to explore the dynamic and iterative concept of access from a realist perspective. It is noteworthy that most previous research looking at access to health care has taken a quantitative approach [9-11]. Few studies have employed qualitative methods [80-82] with even fewer using mixed methods [83].

In the past, mixed methods have faced criticism because the different philosophical underpinnings of qualitative and quantitative research [84], commonly referred to as “paradigm wars” [85]. Quantitative approaches usually assume a positivist perspective and qualitative an interpretivist or constructivist perspective. Giddings and Grant criticised the manner in which mixed method research combines philosophical paradigms, suggesting it is a “Trojan Horse for positivism” [86]. Johnson and colleagues suggest that pragmatism offered the most appropriate philosophical approach for mixed methods [87], but pragmatism itself is subject to substantial philosophical ambiguity. Ong argued that discussions over philosophical perspectives is a “smoke-screen” because in reality researchers rarely take a pure philosophical perspective [88].

Realist approaches are method-neutral because the study design method “should allow collection of data that permit testing the hypothesis” [89]. Mixed methods are well-suited to achieve this since they provide a rich source of data to answer the *what works?*, *for whom?*, *in what circumstances?*, *in what respects?* and *why?* questions [68]. A realist approach is particularly useful in mixed methods because it complements the synthesis process by allowing different techniques to confirm or refute findings. It also provides a consistent philosophical paradigm for mixed methods research that allows both quantitative and qualitative data to be used under one paradigm in the service of developing a realist programme theory of middle-range abstraction.

A further criticism of mixed methods research has been the lack of successful integration of data [90]. O’Cathain described three techniques for integrating data within mixed methods studies: triangulation protocol, following a thread and mixed method matrix [91]. She suggests that the integration of data can occur at the analysis stage or at the interpretation stage. In this research project, a mixed method matrix is used to integrate results from a realist review, qualitative study and cohort analysis into one overall realist programme theory and a triangulation protocol as a framework for the process. More details are given in Chapter 6.

### *1.8.3 Randomised controlled trial approach*

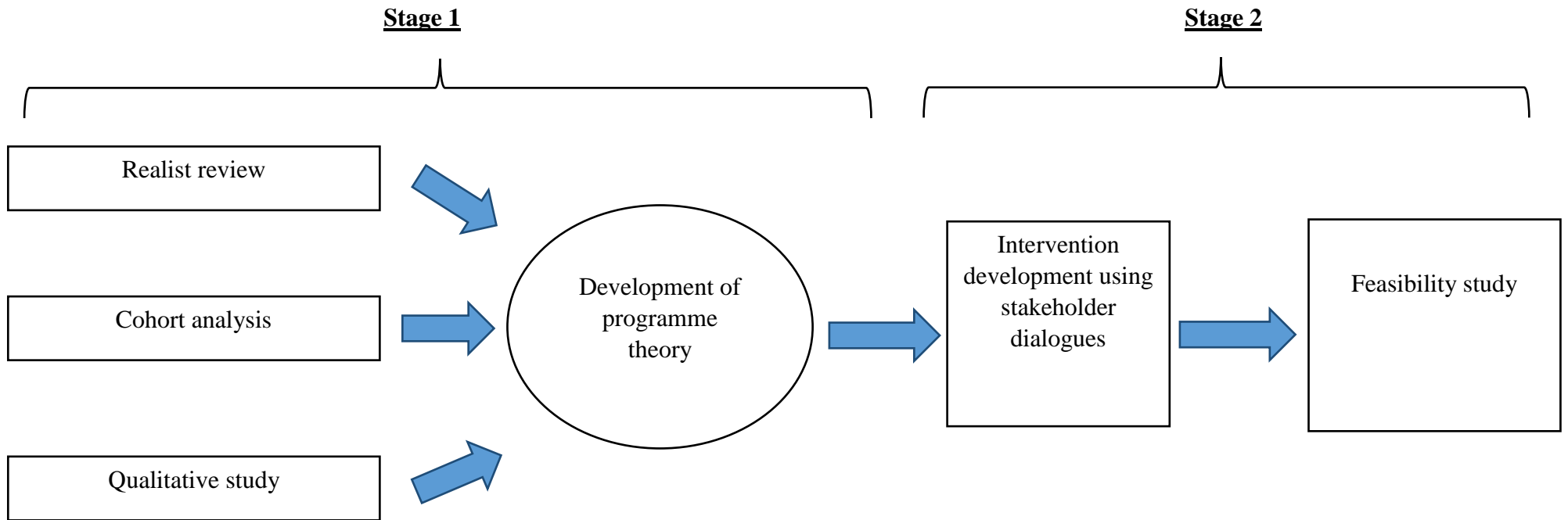
The MRC guidance for evaluating complex interventions recommends that randomised designs should always be considered because “it is the most robust method of preventing the selection bias that occurs whenever those who receive the intervention differ systematically from those who do not, in ways likely to affect outcomes” [92]. The fundamentals of the randomised controlled trial (RCT), randomly allocating individuals or groups to intervention or control, has important advantages compared to observational or quasi-experimental designs. Random allocation provides an adequate counterfactual, reduces the risk of selection bias through self-selection and produces more balanced comparisons between groups. While some have argued that trials should be undertaken where possible [93], others have suggested that RCTs are not always appropriate for complex interventions [94]. Stewart-Brown and colleagues, whilst not denouncing trials of complex interventions, highlighted some of the main concerns, such as difficulties of blinding, challenges selecting appropriate outcomes to power and compare groups, and biased recruitment [95]. Other criticisms have included a failure to understand how and why an intervention works, too much or too little standardisation of the intervention and sometimes an over-reliance on patient-reported outcomes. This has led some to question if a failure to detect a meaningful difference is down to sub-optimal design rather than lack of effect [96]. Criticisms of trials of complex interventions have led to methodological advances, such as the cluster design, stepped wedge design and process evaluations [97, 98]. A trial design is used in this research project because of the essential advantages of providing a suitable counterfactual and reducing selection bias, whilst being able to explore the feasibility of the intervention. A further discussion of trial methodology is included in Chapter 7 (section 7.6.1, page 141) and Chapter 8 (sections 8.3.3 and 8.4.4, pages 152 and 158).

## **1.9 Structure of the research project and thesis**

The research described in this thesis was undertaken in two main stages, as shown in Figure 2. The aims of Stage 1 were to understand the barriers that socio-economically disadvantaged older people in rural areas face in accessing primary care (Objective 1 above) through: a) reviewing the

literature; b) undertaking a qualitative study with older people and health professionals; c) analysing a national cohort study; and d) synthesising the findings from these three studies into one overall realist programme theory. The aims of Stage 2, based on the findings of Stage 1, were to develop an intervention (Objective 2) and test its feasibility while gathering the required information for a definitive trial (Objective 3).

Figure 2: Flow of research project



The thesis contains four original research studies, three of which have been published in peer reviewed journals and the fourth has been submitted for publication. These publications are outlined in the publication and statement of authorship section above (page x). The chapters are largely a replication of the publications with the removal of repetitive text to improve readability. Each publication is presented as a separate chapter with a pre-amble before each. In addition to these chapters, there is a methodological overview chapter (Chapter 2), evidence synthesis chapter (Chapter 6), discussion and conclusion chapter (Chapter 8), statement of impact (Chapter 9) and appendices.

Chapter 2 provides an overview of the proposed methods which was published *a priori* as a protocol in a peer review journal. The rationale and justification of changes are discussed in more detail in Chapter 3, 4, 5, 6 and 8.

Chapter 3 presents a realist review exploring how socio-economically disadvantaged older people in rural areas access primary care (Objective 1 above).

Chapter 4 presents a qualitative study of in-depth interviews with older people and focus groups with health professionals (Objective 1 above).

Chapter 5 presents a statistical analysis of the English Longitudinal Study of Ageing cohort study using Structural Equation Modelling based on the realist theory (Objective 1 above).

Chapter 6 presents a synthesis of the findings from the realist review, qualitative study and cohort study using a mixed method matrix into one overall programme theory and describes the intervention development (Objective 2 above).

Chapter 7 presents the **I**mproving Primary Care **A**ccess in **C**ontext and **T**heory (I-ACT) cluster randomised feasibility trial (Objective 3 above).

Chapter 8 presents an overarching discussion and conclusion highlighting cross cutting themes and important issues and within Chapters 3, 4, 5 and 7 there is a study-specific discussion.

Chapter 9 presents a statement of the impact that has arisen from the research to date.

Appendices are presented at the end of the thesis with additional information on the studies.

## **2 Overview of methods**

### **2.1 Preamble**

This chapter presents an overview of the methods and was published in BMJ Open in 2015 [99] prior to starting data collection for the realist review. It is largely a replication of the publication, except for removal of some text from the Introduction section, the content of which is covered in Chapter 1, and formatting changes to improve consistency. The purpose of this chapter is 1) to give a broad overview of the research describing how the sections relate to each other with detailed methodology presented in Chapters 3, 4, 5 and 7, and 2) provide a baseline to allow readers to understand what was planned and, in subsequent chapters, what was actually undertaken. Changes to the planned methods are described in the relevant chapters.

## 2.2 Chapter summary

The aim of this study is to generate theory of how socio-economically disadvantaged older people from rural areas access primary care, develop an intervention based on this theory and test it in a feasibility trial.

Based on the MRC Framework for Developing and Evaluating Complex Interventions, three methods will be used to generate theory. First, a realist review will elucidate the patient pathway based on existing literature. Second, an analysis of the English Longitudinal Study of Ageing will be completed using structural equation modelling. Third, fifteen semi-structured interviews will be undertaken with patients and four focus groups with health professionals. A triangulation protocol will be used to allow each of these methods to inform and be informed by each other, and to integrate data into one overall realist theory.

Based on this theory, an intervention will be developed in discussion with stakeholders ensuring the intervention is feasible and practical. The intervention will be tested within a feasibility trial, the design of which will depend on the intervention. Lessons from the feasibility trial will be used to refine the intervention and gather the information needed for a definitive trial.

Ethics approval from the regional ethics committee has been granted for the focus groups with health professionals and interviews with patients. Ethics approval will be sought for the feasibility trial after the intervention has been designed.

Findings will be disseminated to the key stakeholders involved in intervention development, to researchers, clinicians and health planners through peer reviewed journal articles and conference publications and locally through a dissemination event.

## **2.3 Introduction**

The United Kingdom, like most high income countries, has an ageing population, with the number of over 65 year olds set to increase by nine million over the next 35 years [100]. An ageing population presents a number of challenges, such as an increasing number of people with chronic health problems and the inevitable impact on health care resource [60]. The triple jeopardy of age, rurality and deprivation leads to increased morbidity but decreased access; an example of the well-known “inverse care law” that states health care provision is inversely related to need [101].

Dowrick and colleagues developed an intervention to improve access to primary care mental health using mixed methods [83]. The authors firstly synthesised evidence from scoping reviews, secondary analysis of qualitative data, stakeholder dialogues, and services user and carer interviews to understand the problems and develop solutions. Based on their findings, the authors developed a three-component model to improve access which included community engagement, primary care quality and tailored psychosocial interventions. The subsequent evaluation found that a multilevel intervention incorporating these three components was most effective.

## **2.4 Aims and justification**

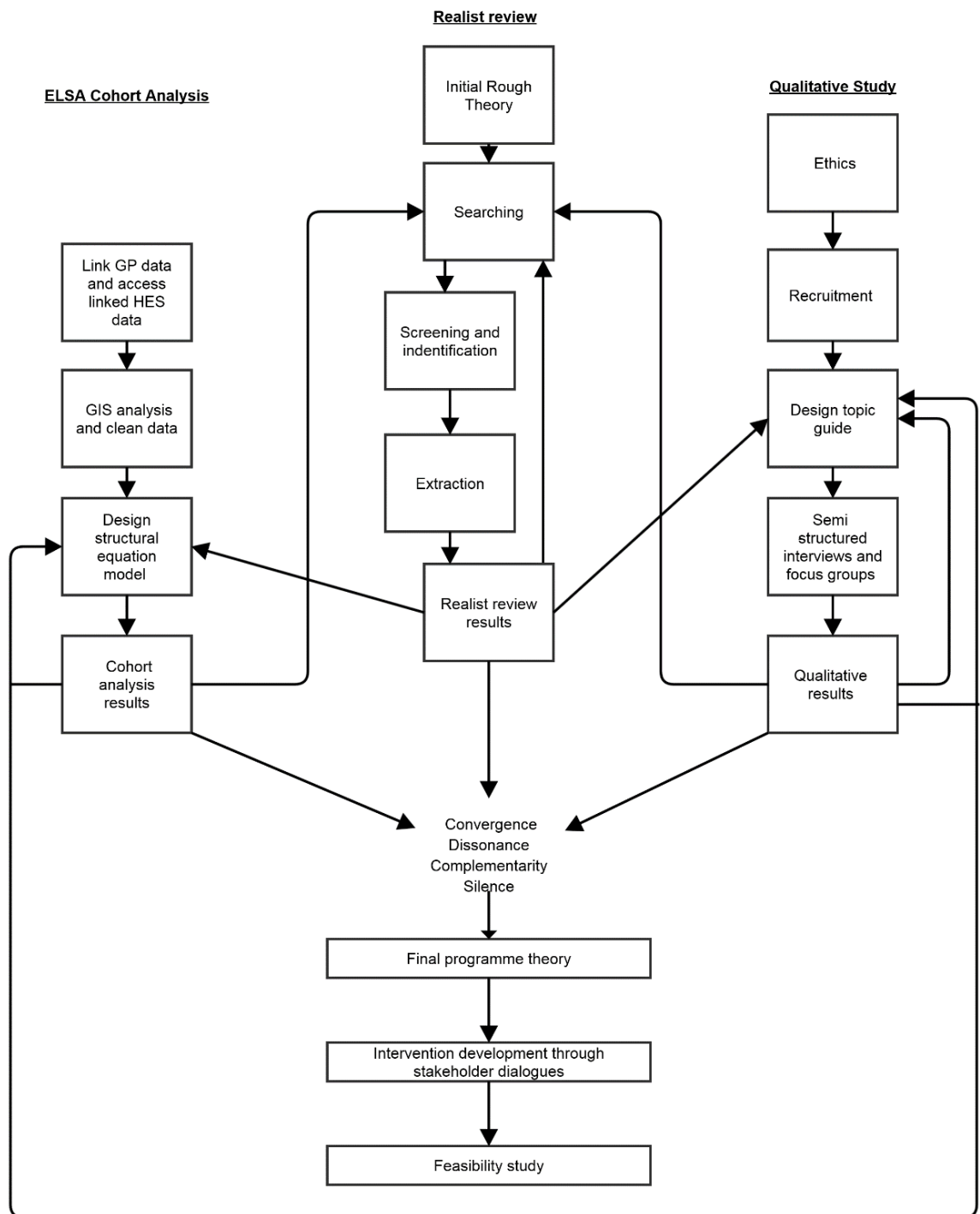
The aim of this study is to develop theory around how socio-economically disadvantaged older people from rural areas access primary care, develop an intervention, and then to test it in a feasibility trial. Here we present a protocol, building upon the methodology used by Dowrick and colleagues [83], for a mixed method study which synthesises evidence across qualitative and quantitative methods using a realist perspective, integrates data using a triangulation protocol and develops an intervention to be tested.

## **2.5 Methods and analysis**

The MRC Framework for Developing and Evaluating Complex Interventions will be used to guide the research [92]. Firstly, theory will be generated using three contrasting but complementary methods to explore the barriers and facilitators to accessing high quality primary care for socio-economically disadvantaged older people in rural areas. The three methods used will be realist literature review, secondary analysis of the English Longitudinal Study of Ageing (ELSA) and qualitative focus groups and interviews. Robust integration of these data will be paramount and Figure 3 shows a triangulation protocol detailing how these data will be integrated. A realist approach will be taken to synthesise and integrate data [68]. This theory will be explored with stakeholders to develop an intervention which will be tested and refined in a feasibility trial.



Figure 3: Triangulation protocol



### 2.5.1 *Realist review*

A realist review allows for the development and refinement of a ‘pathway’ (in realist reviews this is called a programme theory) but also allows for unearthing of the causal processes behind the programme theory (through an analysis of contexts and mechanisms and outcomes) [78]. This is ideally suited to understanding the complexities of the dynamic and iterative concept of access as a balance of patient-side and provider-side components. Realist reviews focus on answering questions such as “how?”, “why?”, “for whom?”, “in what circumstances?” and “to what extent?” access might lead (or not) to changes in quality of care and/or clinical outcomes. Therefore, unlike traditional systematic reviews that concentrate on making judgements (e.g. which intervention is more effective?), realist reviews focus on explanations and understanding.

Initial “rough” programme theory will be generated based on informal searches of the literature and personal content expertise. A more formal literature search will be undertaken in MEDLINE, MEDLINE in process and EMBASE from inception to seek out data to refine the initial “rough” programme theory. Search terms that will be used are shown in Appendix 1. There will be no restriction on study design. Grey literature will be searched using an internet search engine and targeted search of specific websites. All titles and abstracts will be screened. Articles will be included if they consider how socio-economically disadvantaged older people access primary care. Studies will not be restricted to rural areas, since the barriers individuals face in rural areas may not be unique and therefore may be covered in broader studies. Only studies from high income countries will be included. Pawson’s concepts of relevance and rigour will be used to guide document selection [68]. Data from included studies will be coded in QSR NVivo - with coding being both inductive (drawn from the data in the included documents) and deductive (drawn from the programme theory). Analysis and synthesis will focus on a) assigning conceptual categories to the codes (i.e. are these data about context, mechanism or outcome); b) use of the data to configure context, mechanism and outcome (CMO) configurations and; c) use of the data to understand the place and relationships of the CMO configurations with the programme theory. The realist review’s product will be a realist programme theory that is middle-range in abstraction – that is a programme theory that has been empirically tested against data from included documents and is at a level that is testable. During refinement of the realist programme theory we will continue to undertake purposive focused searches informed by the programme theory to seek out relevant substantive theory to corroborate and or add explanatory power. Where relevant, any substantive or formal theory identified from included documents (e.g. locus of control[102]) will be analysed to determine if it relevant to and can add further explanatory power to the realist programme theory we will develop. Reporting of the realist review will adhere to the RAMESES publication standards for realist reviews [103].

### 2.5.2 *Analysis of ELSA*

Findings from the realist review will be explored within ELSA. ELSA is a national, longitudinal, face-to-face interview study of an older people aged 50 and over, initially living in private households. Data cover health, functioning, social participation, and economic position are collected every two years with biological and anthropometric information gathered every four years. First data collection was in 2002 and data collected in 2012/13 has information on approximately 17,000 individuals, of which over 5,000 have participated in all waves of data collection.

In 2013, ELSA was linked with the Hospital Episode Statistics (HES) dataset. HES consists of routinely collected secondary care data and contains admissions, outpatient appointments and A&E attendances in NHS hospitals in England. This enables routinely collected clinical outcomes to be analysed alongside the wealth of participant reported data in ELSA. Added to this linked dataset will be road distance and car travel time from a participant's home to general practice which will be calculated using Geographic Information System software (GIS).

Practice level data will be added from the GP Patient Survey and Health and Social Care Information Centre (HSCIC). The GP Patient Survey collects annual data on patient experience in all general practices in England and was initially established to monitor the NHS from the patient's perspective by collecting a range of patient access factors. Rural index values (combination of average distance from a patient's home to their GP and average population density), deprivation, practice size and Quality Outcomes Framework (QoF) indicators will be added from the HSCIC.

Structural equation modelling (SEM) will be used, based on the theory from the realist review, to explore access in the ELSA cohort linked with HES and general practice data. SEM will be constructed to examine the relationship between access factors, quality of care and secondary care use. SEM allows for theories to be constructed and explored statistically [104]. Primary analysis will be undertaken cross-sectionally using data collected from the most recently available point, Wave 6 (2012) and then subsequently using the longitudinal dataset.

### 2.5.3 *Semi-structured interviews and focus group*

Semi structured interviews will take place with older people and focus groups with health professionals to explore experiences of older people in accessing primary care, discuss findings from the realist review and examine the results from the ELSA analysis.

Fifteen older people who receive a means-tested benefit and live in a rural area will be recruited from two communities with high number of deprived households, pension credit claimants and rurality (based on local authority data). Invitation cards and posters will be distributed in community amenities and groups, such as post offices, grocery stores, public houses, pharmacies,

churches and bowls clubs. A purposive sampling frame will be employed to ensure at least three participants are male, two participants are over 80 years and four participants are from different practices to ensure that the interviews are not dominated by one population group. Participants who are unable to give informed consent will be excluded. Semi-structured interviews will last approximately one hour.

Two focus groups will be undertaken with general practitioners, health care planners and community geriatricians, and two will be undertaken with district nurses, community matrons and case managers. Participants will be recruited through local health providers and the East of England National Institute for Health Research Clinical Research Network. There will be five to six individuals in each of these four focus groups which will last approximately two hours.

The topic guide for the interviews and focus groups will be designed based on the results of the realist review. It will start with open ended questions and progress to more focused questions around findings from the realist review. Hypothetical patient vignettes will be used to explore realist themes. The interviews and focus groups will be audio-recorded and transcribed. Data will be analysed using thematic analysis, using an inductive approach, in QSR NVivo.

#### *2.5.4 Triangulation protocol*

The realist review, ELSA analysis and qualitative component will all explore the contexts that positively or negatively influence access to high quality primary care for socio-economically disadvantaged older people in rural areas, but from different perspectives. Each technique will be informed by, and contribute to, each other. The means by which each method will “talk to each other” is shown in the triangulation protocol in Figure 3. Use of a triangulation protocol has been recommended to integrate mixed methods data [105]. The results from each method will then be synthesised together to form one overarching realist programme theory. By looking for convergence (same results), dissonance (opposing results), complementarity (supportive or explanatory results, but not the same) or silence (no evidence to support or refute) we will be able to further test and refine parts of or the overarching programme theory.

#### *2.5.5 Intervention development*

The integrated theory will contain CMO configurations, as per the realist methodology [68]. The intervention will aim to modify contexts, in order to affect mechanism and subsequent outcomes. An iterative process will be used, based on the interventions from the literature and contexts which could be influenced, to design an initial intervention. As used elsewhere, the intervention will be developed further through stakeholder dialogues [83]. This will involve discussing the results and possible interventions with key stakeholders. Key stakeholders will include NHS England, Norfolk Older People’s Strategic Partnership, HealthWatch and local Clinical Commissioning Groups. A

dialogue analysis template will be created for each encounter and this will be sent back to relevant stakeholder to check for accuracy. The development of the intervention will be tracked to allow a clear understanding of how and why changes have been made. This iterative technique will ensure that the intervention is practical and feasible with face validity.

#### *2.5.6 Feasibility trial*

The design of the feasibility trial will depend on the intervention developed. If the intervention aims to target groups (such as primary care providers) rather than individuals, a cluster design will be used [106]. The purpose of the feasibility trial will be to gather the information needed for a definitive trial and optimise the implementation and use of the intervention. Parameters measured within the feasibility trial will include recruitment and retention, practicality of collecting outcome measures, completeness of data collection and data required for the assessment of cost effectiveness. The trial and intervention will be reported according to CONSORT and TIDieR guidelines [107, 108].

## **2.6 Discussion**

This research aims to develop a specific intervention to improve access to primary care for socio-economically disadvantaged older people in rural areas. Based on the MRC Framework for Developing and Evaluating Complex Interventions, it uses a mixed method approach to provide a coherent and plausible theoretical basis to inform intervention development from a realist perspective. Realist review, ELSA cohort analysis and qualitative focus groups and interviews are used to explore the contexts that influence access to high quality primary care for socio-economically disadvantaged older people in rural areas. These findings will be discussed with stakeholders in order to design an intervention. Finally, the intervention will be tested within a feasibility trial.

#### *2.6.1 Strengths and limitations*

This study will use three methods to look at the same research question, providing corroboration and exploration of findings leading to comprehensive understanding of the issue. This corroboration is consistent with the one philosophical paradigm that is used throughout the mixed methods, realism. Realism highlights the need for theory to be falsified or supported by evidence [68]. The three methods used in this research will allow for theory to be checked for convergence or dissonance. Using a clear and transparent triangulation protocol not only allows for this integration but also enables communication during data collection.

ELSA is a large cohort study established to measure a range of social determinants of health alongside health outcomes in older people providing a rich source of data to explore barriers to health care. Linked with this dataset will be hospital data at an individual level and primary care data at a practice level as contextual variables leading to a wealth of data on the patient pathway.

SEM will be used to analyse theory generated from the realist review. The ability to statistically model theory generated in this way will allow corroboration of results, although not all concepts identified in the realist review may be able to be tested in the linked ELSA dataset. Latent variables may need to be created or concepts excluded to address this problem.

This data will be used in discussions with stakeholders to ensure that the intervention developed is practical, feasible and acceptable. Lessons from the feasibility trial will be used to refine the intervention and gather the information needed for a definitive trial such as practicability of the intervention, recruitment and retention rates and effect sizes and variance required for a sample size calculation.

### *2.6.2 Potential impact*

Improving access to primary care for socio-economically disadvantaged older people in rural areas will hopefully help these individuals better utilise their primary care provider. We anticipate that this will have a positive impact on adherence to chronic disease management and likely help them access the correct urgent care service at an early stage when they become unwell. Preventative measures may then be potentially started earlier reducing hospital admissions and pressure on urgent care services. In turn, this should then reduce health inequalities.

### *2.6.3 Ethics and dissemination*

Ethics approval from the regional ethics committee has been granted for the focus groups with health professionals and interviews with patients. Ethics approval will be sought for the feasibility trial after the intervention has been designed.

Key stakeholders will be made aware of the research through the stakeholder dialogues. The findings of the research will be reported back to each of them. Results will be disseminated to researchers, clinicians and health planners in peer reviewed journal articles and conference publications. One or more dissemination events will be held locally to feedback to participants and contributors to the research.

## **3 A realist review exploring how socio-economically disadvantaged older people in rural areas access primary care**

### **3.1 Preamble**

The previous chapter provided an overview of the methods of the programme of research and this chapter presents the aims, methods, findings and discussion of the first study: a realist review. It was published in *BMJ Open* in 2016 [109]. It is largely a replication of the publication, except for removal of some text from the *Background* section, the content of which is covered in Chapter 1, and formatting changes to improve consistency. The purpose of the realist review was to generate realist theory to understand how socio-economically disadvantaged older people in rural areas access primary care. The theory generated from the realist review contributed the largest proportion to the overall realist programme theory (presented in Chapter 6) and informed the structural equation model used in Chapter 5.

## **3.2 Chapter summary**

### *3.2.1.1 Objective*

The aim of this review is to identify and understand the contexts that effect access to high quality primary care for socio-economically disadvantaged older people in rural areas.

### *3.2.1.2 Design*

A realist review.

### *3.2.1.3 Data sources*

MEDLINE and EMBASE electronic databases and grey literature (from inception to Dec 2014).

### *3.2.1.4 Eligibility criteria for selecting studies*

Broad inclusion criteria were used to allow articles which were not specific but might be relevant to the population of interest to be considered. Studies meeting the inclusion criteria were assessed for rigour and relevance and coded for concepts relating to context, mechanism or outcome.

### *3.2.1.5 Analysis*

An overarching patient pathway was generated and used as the basis to explore contexts, causal mechanisms and outcomes.

### *3.2.1.6 Results*

162 articles were included. Most were from the USA or UK, cross sectional in design and presented subgroup data by age, rurality or deprivation. From these studies a patient pathway was generated which included seven steps (problem identified, decision to seek help, actively seek help, obtain appointment, get to appointment, primary care interaction and outcome). Important contexts were stoicism, education status, expectations of ageing, financial resources, understanding the health care system, access to suitable transport, capacity in primary care, the booking system and experience of health care. Prominent causal mechanisms were health literacy, perceived convenience, patient empowerment and responsiveness of the practice.

### *3.2.1.7 Conclusions*

Socio-economically disadvantaged older people in rural areas face personal, community and health care barriers that limit their access to primary care. Initiatives should be targeted at local contextual factors to help individuals recognise problems, feel welcome, navigate the health care system, book appointments easily, access appropriate transport and have sufficient time with professional staff to improve their experience of health care; all of which will require dedicated primary care resources.



### 3.3 Background

A review of equality of access to health care in the UK found that rural individuals, older people and those in lower socio-economic groups have poorer access to health care [5]. When these co-exist there is likely to be intersectionality, where complex determinants of health relate, intersect and reinforce each other [110], leading to delayed diagnosis [111], poor quality of care [112], higher mortality [113] and greater inequality [114].

A recent systematic review assessing primary care access [63] categorised barriers as patient factors (e.g. socio-demographics), organisational factors (e.g. appointment system), financial factors (e.g. no health insurance), workforce factors (e.g. technical skills) and geographical factors (e.g. distance to services). As with other reviews [115], this listed the barriers, but did not encompass the dynamic, iterative, and multidimensional nature of access [6, 116]. This reflects the traditional systematic review methodology which aims to pool data to achieve an overall result, rather than explore and explain underlying causal processes.

A realist review seeks to explore the underlying causes for observed outcomes and when these might occur by reviewing published and grey literature [78]. Through a review of the literature, an overarching programme theory is developed which is gradually refined using data drawn from documents included as the review progresses. Within this programme theory, a realist logic of analysis is used to explore outcome patterns. In brief, mechanisms cause outcomes to occur, but the relevant mechanisms will only be ‘triggered’ under the right contexts. When applying a realist logic of analysis, a factor is only assigned the conceptual label of context if there are sufficient data to support the inference that it triggers a mechanism that causes an outcome of interest (i.e. one that is relevant to and found within a programme theory). The analytic building blocks are context, mechanism and outcome (CMO) configurations [68]. These are propositions which describe what works (or happens), for whom and in what contexts and why? Contexts are conditions that trigger or modify the behaviour of mechanisms. In this realist review, we are particularly interested in identifying and understanding the contexts that act as barriers and facilitators of access to primary care.

We aim to use a realist review to explore the contexts that influence access to primary care for socio-economically disadvantaged older people in rural areas by seeking to answer the following questions:

1. What are the barriers and facilitators to accessing high quality primary care for socio-economically disadvantaged older people in rural areas?
2. What are the underlying mechanisms, why do they occur and how do they vary in different contexts?

The purpose is to understand the process of accessing primary care, rather than how to achieve a certain outcome. We did not aim to fully elucidate every underlying mechanism, but rather take a broad overview. The review is not limited to factors which are uniquely rural, since this may overlook important issues such as ease of booking an appointment.

## **3.4 Methods**

### *3.4.1 Programme theory development*

To develop the programme theory an initial rough theory was firstly produced by JF based on prior knowledge and an initial scoping search and subsequently discussed with GW, AJ and NS. For the scoping search, we undertook a narrow search in MEDLINE and search for reports and policy documents using an internet search engine (Google) to identify key resources and understand the breadth of literature on this topic. Documents of interest were read by JF and discussed with the research team. Key theory, such as the Aday and Andersen Framework [7], informed the initial rough theory through the use of their “predisposing”, “enabling” and “need” concepts. Based on our full search, programme theory was developed using a patient pathway that logically mapped out all the steps a patient needed to go through to access primary care. During the review, drawing on the data in the included studies, we then gradually and iteratively refined this patient pathway into a realist programme theory that included CMO configurations.

### *3.4.2 Searching*

The databases MEDLINE, MEDLINE in Process and EMBASE were searched from inception to December 2014. Search terms were initially piloted and refined to increase sensitivity. Search terms used in MEDLINE are shown in the Appendix 1. Grey literature was searched using a search engine (Google) and a targeted search of specific websites (e.g. Kings Fund, Nuffield Trust and Royal College of General Practitioners). References within included documents were screened for relevance.

### *3.4.3 Selection and appraisal of documents*

All titles and abstracts were screened, and articles included if they were judged to possibly contain relevant data on access to primary care in socio-economically disadvantaged older people in rural areas. Studies did not have to include all components (i.e. primary care, deprivation, older people and rural areas) because initial scoping suggested that a narrow inclusion criterion would have excluded important concepts such as ease of booking an appointment. For example, a study was eligible for inclusion if it included both rural and urban areas as long as the concepts described were relevant to socio-economically disadvantaged older people in rural areas. Only studies

published in English were included. Studies primarily focused on care homes or low-income countries were excluded. After titles and abstracts screening, we retrieved the full text of seemingly relevant articles. One author (JF) screened all titles and abstracts. Included studies were re-checked in light of their relevance and extent to which they did actually contain data that would inform programme theory development [68]. The purpose of screening and appraising was not to identify an exhaustive set of studies, but rather reach conceptual saturation in which sufficient evidence is identified to meet the aims of the review [78]. After screening and re-checking, we agreed that conceptual saturation had been reached.

#### *3.4.4 Data extraction and analysis*

Study characteristics were extracted into a pre-specified Excel spreadsheet that was piloted before use and included publication year, country, participants' details, study design, and health care system.

Sections of relevant text were identified from included articles and coded using QSR NVivo [117]. Some codes were derived inductively (originating from the included studies) whereas others were deductive (originating from the initial rough theory). Codes were refined based on emerging concepts throughout the analysis period. Coded text was chosen based on the follow questions:

- 1) Is the section of text referring to context, mechanism or outcome?
- 2) What is the CMO configuration (partial or complete) for it?
  - a) How does this (full or partial) CMO configuration relate to the patient pathway?
  - b) Are there data which support how the CMO configuration relates to the patient pathway?
  - c) In light of this CMO configuration and any supporting data, does the patient pathway need to be changed?
- 3) Is the evidence sufficiently trustworthy and rigorous to change the CMO configuration?
- 4) Is the evidence sufficiently trustworthy and rigorous to justify changing the patient pathway?

An overarching patient pathway was developed from the data using the NVivo coded text and the analysis aimed to find data to corroborate, refute or refine the patient pathway into a realist programme theory by gradually and iteratively building CMO configurations for each step in the patient pathway. To generate the CMO configurations for each step, we started with the outcome and worked backwards. Data and sections of text from the extraction phase were interpreted as relating to context, mechanism or outcome. Most sections of text described the context-outcome process without exploring the underlying mechanism and in these situations, we sought relevant data from other included studies to identify mechanisms. We then made inferences as to what the complete CMO configuration might be for each step. For example, if data were interpreted as relating to context, then the next analytic task was to assess which outcome the context was related

to and what the mechanism might be. Any substantive or formal theory identified during the search was used to assist in programme theory development if relevant. Included studies were re-examined throughout the analysis and programme theory refinement period using an iterative, cyclical process to seek out data to enable judgements to be made about the relevance (contributes to the research questions), rigour (the data used in programme theory development had been generated using methods that were credible and trustworthy) and importance of emerging concepts. In other words, the analysis continually asked whether there were data to warrant modifying a CMO configuration and/or the programme theory.

The CMO configurations were discussed with the research team, which included patient representatives, and these fed into the iterative, cyclical process of searching, data extraction, analysis and programme theory development. Patient representatives were recruited from Older People's Forums in Norfolk and contributed to the design and interpretation of the research. Findings are reported in accordance with the RAMESES publication standards [118]. Ethics approval was not required for this study.

## **3.5 Results**

### *3.5.1 Search results and study characteristics*

In total 3,066 titles and abstracts were screened (Figure 4) leading to full text review of 196 articles. Thirty-four articles were excluded after assessment for relevance and rigour leaving 162 to be included. Most studies were from the USA or UK, cross-sectional in design, not disease-specific and provided subgroups of older adults, socio-economic disadvantaged people, rurality or primary care (Table 1). No studies were found that only included socio-economically disadvantaged older people in rural areas accessing primary care.

Figure 4: PRISMA diagram

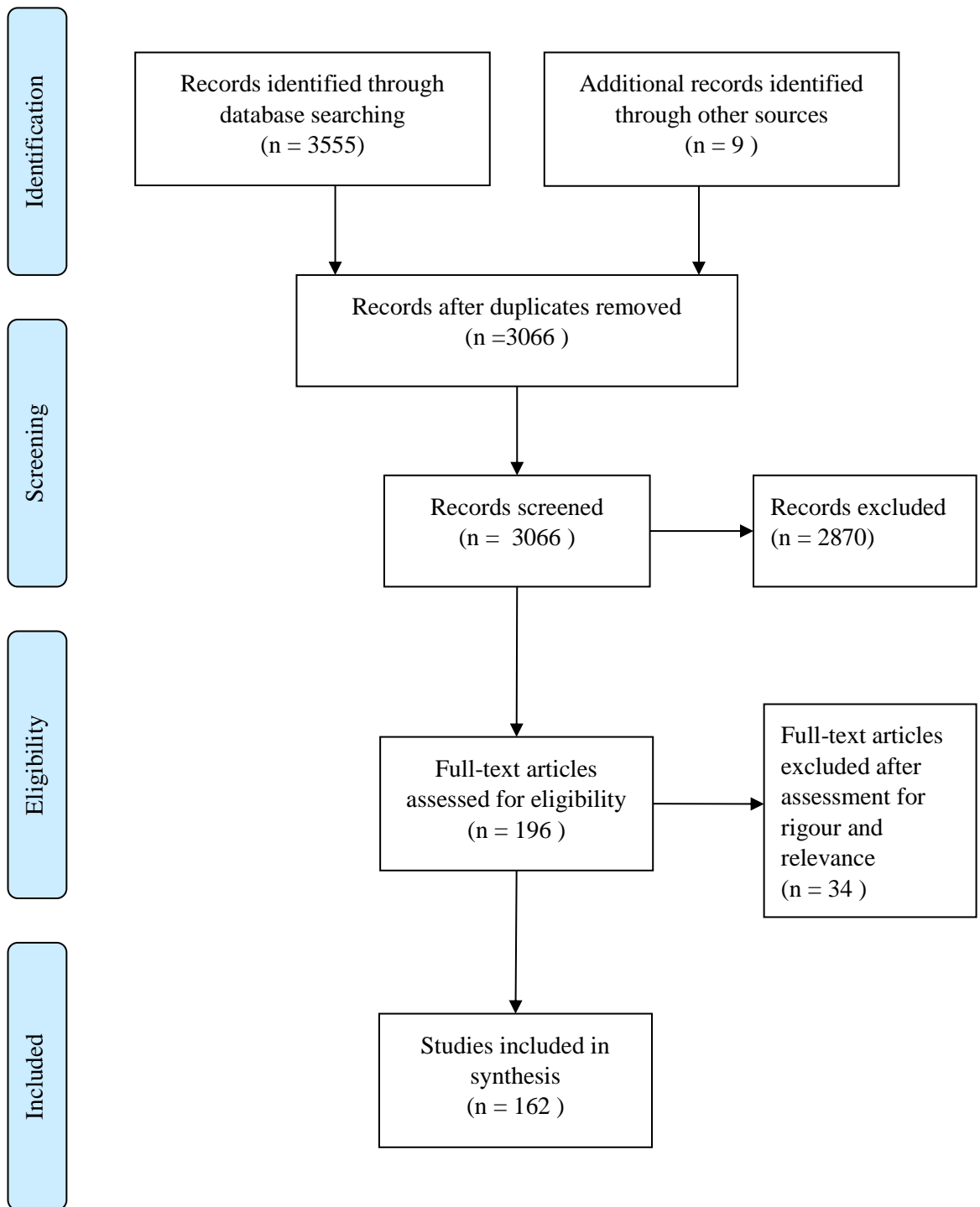


Table 1: Study characteristics

		Number of studies
Country	USA	49
	UK	48
	Canada	19
	Australia	9
	New Zealand	9
	Other	28
Study type	Cross sectional	85
	Analysis of routine data	24
	Qualitative	22
	Cohort	16
	Editorial or discussion paper	3
	Other	12
Health problem	Any health problem	114
	Urgent health problems	10
	Ambulatory care sensitive conditions	8
	Mental health	5
	COPD	3
	Diabetes	3
	Heart disease	3
	Other	16
Age	All adults	111
	Older adults only	51
Socioeconomic position	All adults	150
	Socio-economically disadvantaged only	12
Rurality	Rural and urban	137
	Rural only	13
	Urban only	12
Gender	Both	157
	Female only	4
	Male only	1
Health domain	Primary care only	69
	Primary and secondary	93
Subgroup analysis of relevant population	Yes	114
	No	48
Total		162

### 3.5.2 *From patient pathway to realist programme theory*

Thirty-four articles provided data that were synthesised and used to create the patient pathway (Figure 5) from which the realist programme theory would be iteratively developed. The final step named ‘Outcome’ refers to the result of a primary care interaction such as treatment, referral, reassurance or dissatisfaction. The first three steps (Problem identified, Decision to seek help and Actively seek help) were described in Broadhurst (2003)[119] and used by Kovandzic (2011)[120] in a study exploring access to mental health services for hard to reach groups. The remaining steps were mainly developed from key sources [121-125]. For example, Buetow (2002)[122] summarised previous literature evaluating access to primary care as falling into three categories 1) organisation processes, such as appointment systems, (obtaining an appointment) 2) geographical literature around physical access (getting to the appointment) and 3) social and cultural influences (cutting across both obtaining an appointment and getting to it). These data contributed to the ‘Obtain appointment’ and ‘Get to appointment’ steps.

This patient pathway is transferable to most primary care populations and the concepts described below are particularly relevant to socio-economically disadvantaged older people in rural areas. The patient pathway is shown as a linear pathway for simplicity, but it is clear that access to primary care is considerably more complex and dynamic [121, 126]. For example, a patient with an intermittent problem (such as chest pain) may transit between the first three steps (Problem identified, Decision to seek help and Actively seek help) for days or weeks as they decide if the problem is real, warrants assessment and what the most appropriate service is.

Figure 5: Patient pathway





### 3.5.3 Context-Mechanism-Outcome Configurations

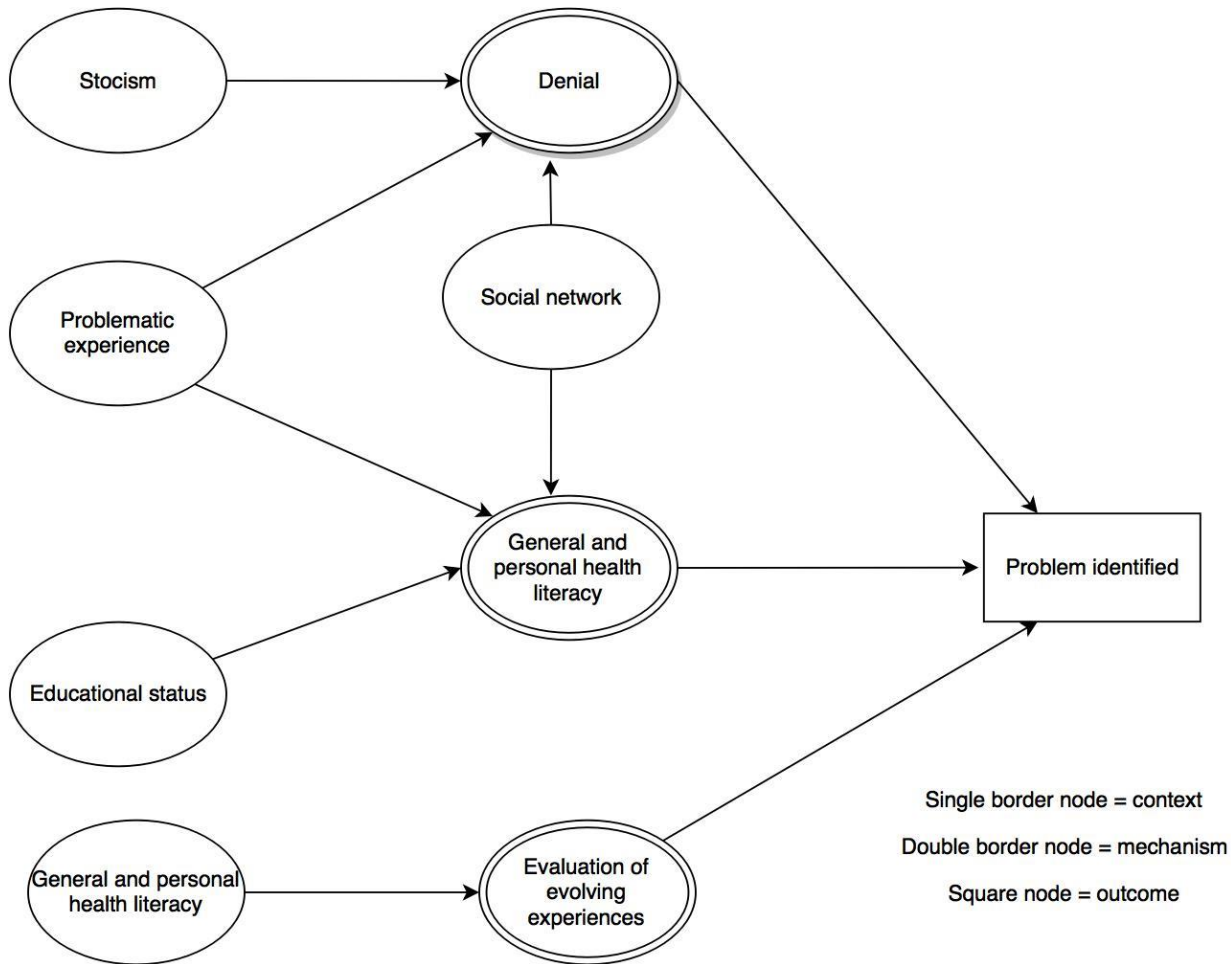
For each of the steps in the patient pathway, we developed CMO configurations which can be found unconfigured in Table 2, Table 3, Table 4, Table 5, Table 6 and Table 7 and configured in Figure 6, Figure 7, Figure 8, Figure 9, Figure 10 and Figure 11. Detailed explanation of how data from the literature contributed to each CMO configuration is shown in Appendix 2.

The first step in the patient pathway is identification of a problem (Table 2 and Figure 6). Some socio-economically disadvantaged older people in rural areas who are experiencing symptoms may not recognise them as a problem because of: poor health literacy [127-129] linked to lower educational status [128, 129] [81](e.g. unaware that unintentional weight loss could be a sign of cancer); low social interaction; or denial [81, 130] because of stoicism [81]. Health literacy will also affect how an individual evaluates their experiences [131].

Table 2: Context-mechanism-outcome configuration for problem identified

Context	Mechanism	Outcome
Educational status [128, 129] Health beliefs [81] Problematic experience [127, 130] Stoicism [81] Social networks [131]	Denial [81, 130] Evaluation of evolving experiences [131] Health literacy [127-129]	Problem identified

Figure 6: Context-mechanism-outcome configuration for problem identified

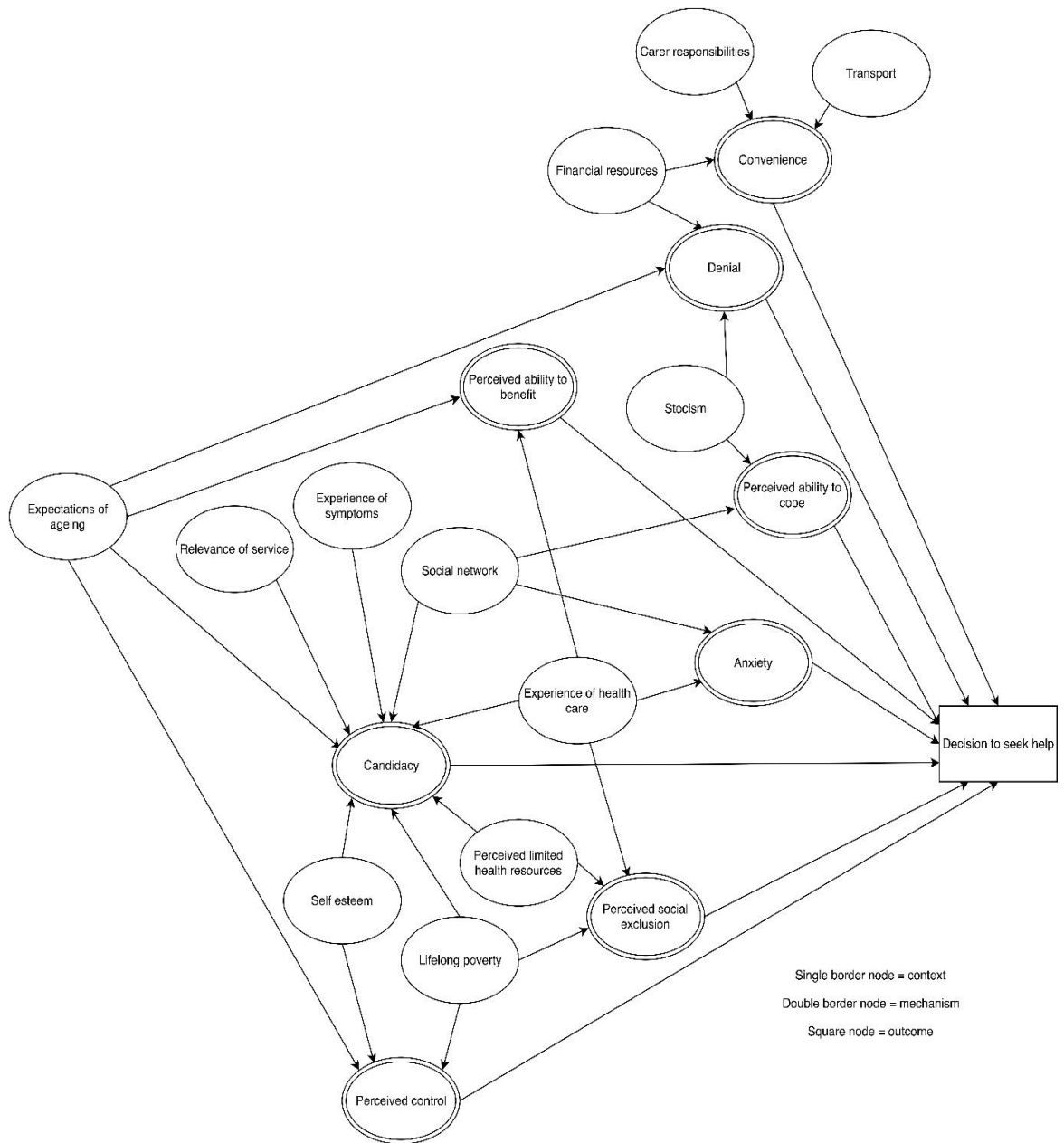


After a problem has been identified, a patient will decide if they should seek help (Table 3 and Figure 7). For this group important mechanisms appear to be candidacy [18, 80, 82, 132, 133], the effort required to attend an appointment [134-136], what the possible consequences will be [127, 137], if the service will meet their need [80, 82, 138] and if they can continue to manage independently without needing to seek health care [80, 130]. Contexts influencing these mechanisms include *personal characteristics*, such as educational status [135], expectations of ageing [80, 82, 132, 139], stoicism [80, 81, 130, 140], and self-esteem [82, 141, 142], *resources available*, such as finances [135, 136, 143], support from friends and family [81], transport [134] and carer responsibilities [144], *perception of the health service* (such as perceived limited resources within health care [80]) and *experience of health care* [18, 80, 145, 146].

Table 3: Context-mechanism-outcome configuration for decision to seek help

Context	Mechanism	Outcome
Carer responsibilities [135, 144]	Anxiety [127, 137]	Decision to seek help
Expectations of ageing [80, 82, 132, 139]	Candidacy [18, 80, 82, 132, 133]	
Experience of health care [18, 80, 133, 138, 145, 146]	Convenience [134-136]	
Experience of symptoms [80, 127, 147]	Denial [140, 143, 148]	
Financial resources [135, 136, 143, 148]	Perceived ability to benefit [80, 82, 138]	
Lifelong poverty [133, 142, 149-151]	Perceived ability to cope [80, 130]	
Perceived limited health resources [80]	Perceived control [139, 141, 145, 149, 150]	
Relevance of services [133, 152]	Perceived social exclusion [80, 146, 151, 152, 154]	
Self-esteem [82, 141, 142]		
Social network [137, 153]		
Stoicism [80, 81, 130, 140]		
Transport [134]		

Figure 7: Context-mechanism-outcome configuration for decision to seek help

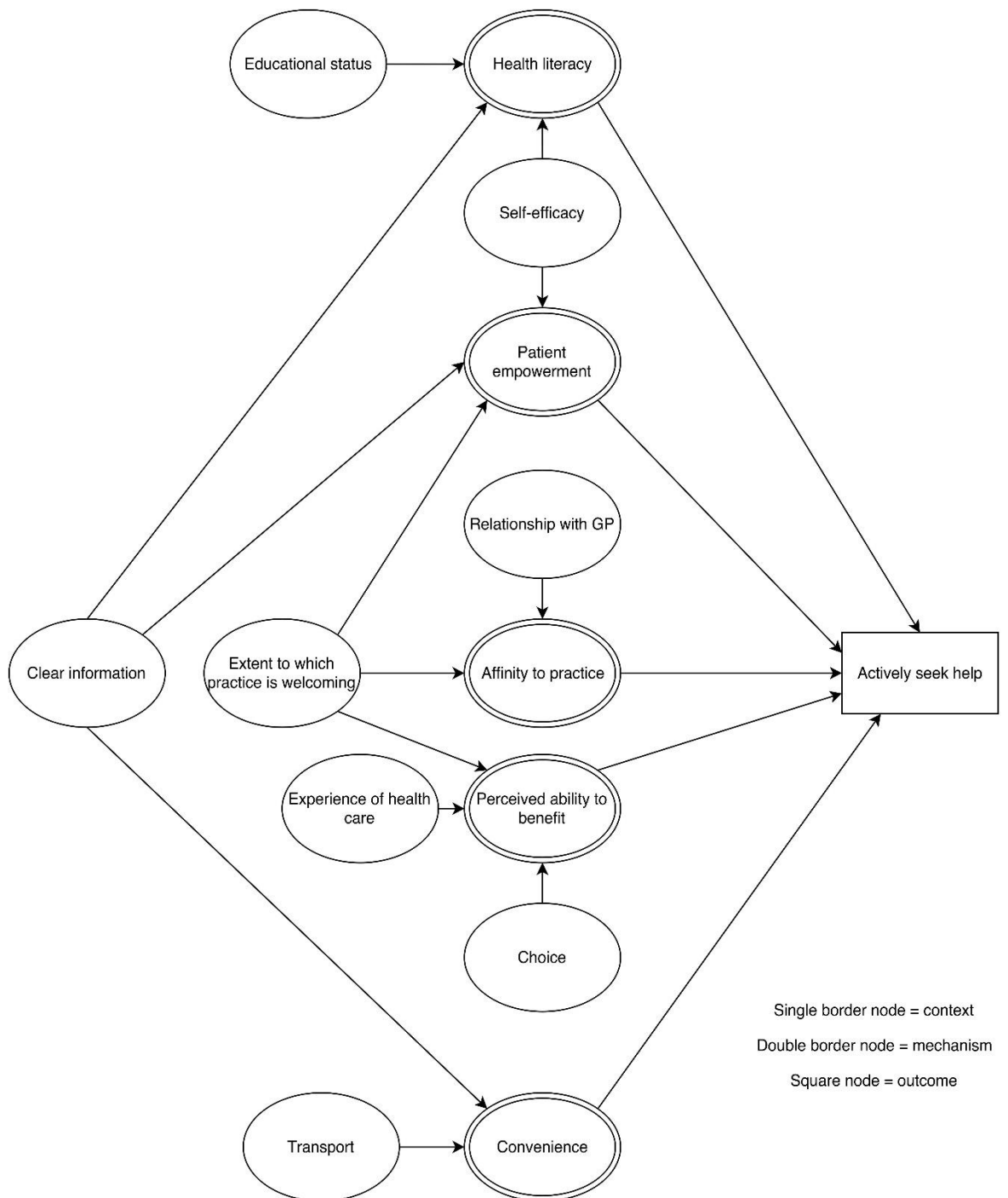


If a patient decides that a problem warrants health care, the next step is to actively seek help (Table 4 and Figure 8). A socio-economically disadvantaged older person in a rural area is more likely to seek help from primary care if they feel a sense of belonging to a practice [81, 130, 135, 155] which they are able to get to easily [129, 152, 156-158], believe it will be of help [129, 130, 159] and are empowered [81, 160, 161]. These mechanisms are influenced by experience of health care [130, 155], educational status [156, 157], personal resources such as self-efficacy [160], and transport [158].

Table 4: Context-mechanism-outcome configuration for actively seek help

Context	Mechanism	Outcome
Choice [129] Clear information [129, 152, 161] Educational status [156, 157] Experience of health care [130, 135] Extent to which practice is welcoming [81, 135, 159] Relationship with GP [130, 155] Self-efficacy [160] Transport [158]	Affinity to a practice [81, 130, 135, 155] Convenience [129, 158] Health literacy [152, 156, 157] Patient empowerment [81, 160, 161] Perceived ability to benefit [129, 130, 159]	Actively seek help

Figure 8: Context-mechanism-outcome configuration for actively seek help

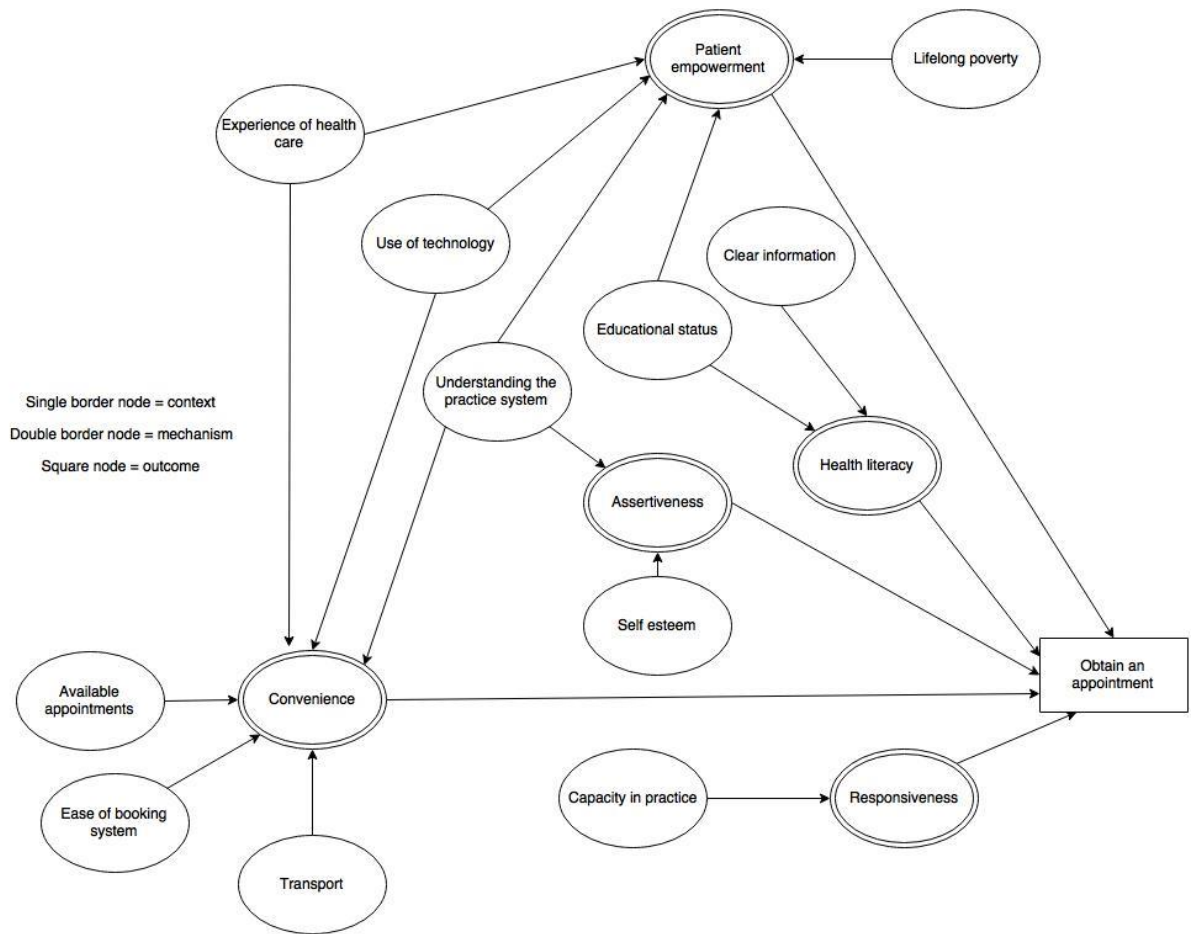


Once the decision to seek primary care is made, a patient is required to obtain an appointment for most primary care services in the UK (Table 5 and Figure 9). Key contexts are available appointments [162], capacity within the practice [122], availability of clear information [120] and ease of the booking system [81]. A socio-economically disadvantaged older person in a rural area is less likely to be able to obtain an appointment if they do not understand the system [120, 163], are not assertive [81, 152], appointments are not available at convenient times [81, 162, 164-168] or the practice is not responsive to their needs [122]. Other contributing contexts include available personal resources (such as transport [167], technology [166, 169, 170], educational status [157, 163] and experience of health care [145, 171]).

Table 5: Context-mechanism-outcome configuration for obtain an appointment

Context	Mechanism	Outcome
Available appointments [162]	Assertiveness [81, 152]	Obtain an appointment
Capacity in practice [122]	Convenience [81, 122, 162, 166, 167, 169, 171]	
Clear information [120]	Health literacy [120, 163]	
Ease of booking system [81]	Patient empowerment [145, 157, 170, 172, 173]	
Educational status [157, 163]	Responsiveness [122]	
Experiences of health care [145]		
Lifelong poverty [172]		
Self-esteem [152]		
Transport [167]		
Understanding the practice system [81, 173]		
Use of technology [166, 169, 170]		

Figure 9: Context-mechanism-outcome configuration for obtain appointment



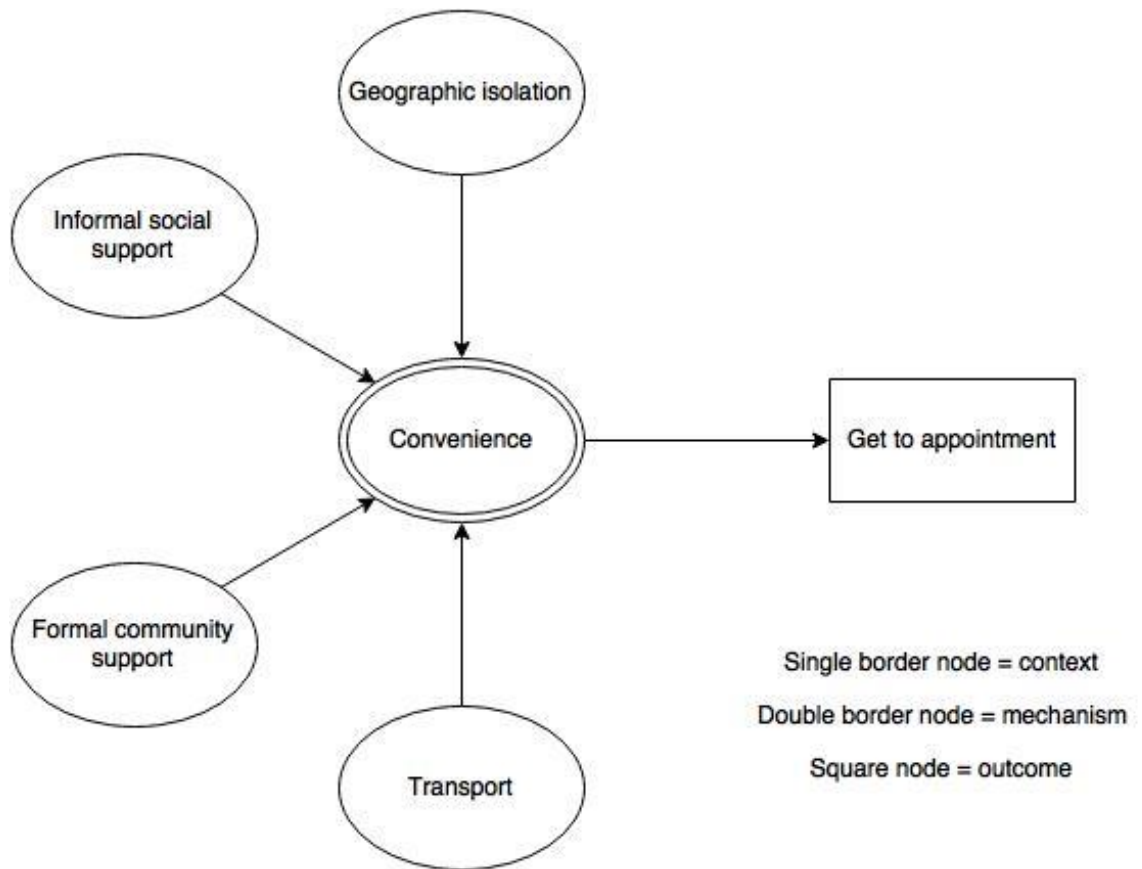


After an appointment is booked, a patient needs to get there (Table 6 and Figure 10). Geographical isolation [174, 175], local support (either social [80] or community [134]) and access to suitable transport [158, 174] are all important in influencing decisions about convenience [80, 134, 158, 174, 175], and subsequent likelihood of attending the appointment for older people in this group.

Table 6: Context-mechanism-outcome configuration for get to appointment

Context	Mechanism	Outcome
Formal community support [134] Geographic isolation [174, 175] Informal social support [80] Transport [158, 174]	Convenience [80, 134, 158, 174, 175]	Get to appointment

Figure 10: Context-mechanism-outcome configuration for get to appointment



The quality of the primary care interaction depends on both patient and clinician factors (Table 7 and Figure 11). A socio-economically disadvantaged older person in a rural area may face problems in articulating the health problem [138, 152, 155] and feeling empowered [81, 176, 177] to negotiate care. These were related to concepts such as continuity of care [138], educational status [155] and experience of health care [81]. The clinician needs to have empathy [155, 178] and capacity within the practice [179], to deliver the care that is required. Capacity includes having sufficient consultation time; evidence suggests that socio-economically disadvantaged people experience shorter consultation times [180] but may have difficulty in articulating health problems, increased anxiety or feel pressured by crowded waiting rooms [181]. Both patient and clinician need equal status [80, 146, 163, 181, 182] which is related to patient trust in the health care system [146, 181], consistency of care [146] and social distance [152, 163, 176, 177, 182].

Table 7: Context-mechanism-outcome configuration for primary care interaction

Context	Mechanism	Outcome
Capacity within practice [179]	Articulation of the health problem [138, 152, 155]	Primary care interaction
Clinician empathy [146, 155, 178]	Empowered clinician [179]	
Continuity of care [138]	Equal status [80, 146, 154, 163, 181]	
Educational status [155]	Patient empowerment [81, 176, 177]	
Emotional distress [178]	Trust [138]	
Experience of health care [81]		
Financial resources [177]		
Perceived ability to benefit [163]		
Perceived discrimination [80]		
Self-esteem [152, 163, 176, 177]		
Social distance [181, 182]		
Trust in health care [146, 181]		

Figure 11: Context-mechanism-outcome configuration for primary care interaction



## **3.6 Discussion**

### *3.6.1 Statement of principle findings*

Socio-economically disadvantaged older people in rural areas face personal, community and health care barriers that limit their access to primary care. Key contexts identified in this review were stoicism, education status, expectations of ageing, financial resources, understanding of the system, access to suitable transport, capacity in primary care, the booking system and experience of health care. Key mechanisms underlying these contexts were health literacy, perceived convenience, patient empowerment and responsiveness of the practice. Realist review proved a useful approach for making sense of some of the complex and dynamic relationship of access because it allows exploration of the underlying mechanisms.

### *3.6.2 Strengths and limitations*

Strengths include a broad search strategy that was not limited to studies of socio-economically disadvantaged older people in rural areas accessing primary care. This reduced the risk of missing major concepts which were not unique but were relevant to this patient group and meant that we could take a broad overview of the topic. Furthermore, the breadth allowed sense to be made of the behaviour of some of the mechanisms under the different contexts reported in the included articles. CMO configurations were discussed with patient representatives to ensure there were no obvious gaps or inconsistencies. The nature of the programme theory developed means that it can be adapted to other populations to help health service design. Our review has demonstrated that, unlike many realist reviews and literature on realist methodologies which focus on a specific intervention or programme, realist reviews can be useful to aid the development of a patient pathway – in this case one that explores drivers and barriers of access to health care.

The main limitation was the lack of evidence specifically focusing on socio-economically disadvantaged older people in rural areas. To overcome this, we took a broad approach and while this meant we did not miss important concepts some issues may not be relevant to this group. Furthermore, a broad approach meant that we had more evidence to support the programme theory. Most of this was from cross sectional studies which generally provided information on context and outcome, whilst qualitative studies provided data on mechanisms. Unsurprisingly there were no randomised controlled trials because, whilst they were eligible, we were not looking at a specific intervention. We did not undertake any formal assessment of the methodological rigour of each manuscript included in the review. However, we did make global judgements about the trustworthiness of data within documents or studies we used to support our inferences. Overall, we judged data to be sufficiently trustworthy to enable refinement of our programme theory.

A further limitation was that the broad approach and nature of the data meant that each CMO configuration could not fully elucidate each complex interaction, nor could we differentiate which contexts or mechanisms were more important than others to achieve desired outcomes. While undertaking a realist review researchers would generally become more focused to contain the large volume of data emerging [118]. We purposefully kept our review broad so as to include data on the whole patient pathway because we believed that a broader programme theory would be more useful in helping us to develop and test any future interventions. Because we were able to achieve sufficient conceptual saturation for the focus of this review, we did not undertake any additional searches. No significant alterations were made to our review processes as the review progressed. Furthermore, it was not always clear what the direction of effect was within the CMOs because the limited literature and therefore we have presented neutral CMOs.

### 3.6.3 *Comparisons with existing literature*

No other reviews exist in this population. Most previous work looking at access to health care (e.g. Hoeck 2013[183], Pong 2011[124]) is based on the Aday and Andersen Framework [7], specifically their description of pre-disposing, enabling and need factors. There are similarities between our programme theory and the Aday and Andersen Framework. For example, most of our concepts could be categorised accordingly, such as educational status (pre-disposing), transport (enabling) and unmet need (need). However, by using realist methodology we were able to explore underlying mechanisms and identify and understand which contexts need to be modified by interventions so as to increase the likelihood that desirable outcomes would occur. The Aday and Andersen Framework lacked this additional level of detail and understanding (and hence coherent rationale) to inform intervention design as it generally only includes contexts and outcomes. Uniquely, we have been able to develop a coherent and transferable explanation of the steps and causal processes (in the form of the realist programme theory) of access to health care using the specific population of socio-economically disadvantaged older people in rural areas. This is important because we will use the findings from our review to design an intervention to address access issues faced by this population group of older people.

A comprehensive review of access to primary care looked quantitatively at whether barriers increased or decreased access for three areas: diabetes, episodic care and Pap testing [63]. Our review has included similar concepts as this review, except for those relating to health insurance because we focused on relevance to the UK. However, we were more focused on understanding the underlying mechanism of, for example, the appointment system, rather than quantitatively describing each barrier. None of these studies mapped out access along a patient pathway from identifying a problem to primary care interaction. In contrast we have developed a patient pathway which; a) allows a more targeted approach to address specific access problems and; b) provides a coherent overview of access to primary care services.

### 3.6.4 Recommendations

Some contexts identified in the review, such as educational status and lifelong poverty, require upstream policy interventions, however contextual factors which may be amenable to health service interventions are detailed below. Not every person will necessarily benefit from all of the below contextual changes, but our findings suggest a focus on these potential barriers.

- Where there is a perception that the health system does not have sufficient resources, messages about the health services aimed at reducing unnecessary health care attendances and promoting self-management should be carefully phrased so that they do not lead to vulnerable groups, who infrequently access primary care, feeling unwelcome or not entitled to health services. For example, a media campaign to encourage use of digital resources may inadvertently lead socio-economically disadvantaged older people without IT skills feeling that health services are not relevant to them.
- Where patients have a negative experience of health care and are at risk of poor access, organisations need to ensure that these experiences are identified and addressed to help those patients remain engaged with the service.
- Where patients have carer responsibilities, opportunities for respite are needed to enable carers to attend appointments.
- Where there are areas with poor public transport, community transport schemes or satellite clinics are needed to help socio-economically disadvantaged older people in rural areas get to their appointment, especially if they do not have a support network.
- Where there is a complex health care system, services should ensure that information is provided in plain English and in a format, which is accessible to vulnerable people, especially regarding how to navigate the system.
- Where practices have over-stretched booking systems, practices need to be responsive to the needs of vulnerable people, such as having a priority, one-stop telephone number or protected appointments at suitable times during the day, as socio-economically disadvantaged older people in rural areas may not be assertive and are often stoical. A balance is needed between simple, clear information and processes for patients while being flexible and able to cater for different needs.
- Where there is limited capacity in primary care, resources need to be prioritised to ensure that health care staff are able to spend the time needed to provide high quality care to vulnerable groups which will improve their experience, keeping them engaged with primary health care.

### 3.6.5 *Conclusion*

Our realist review of access to primary care for socio-economically disadvantaged older people in rural areas identified key contexts such as stoicism, education status, expectations of ageing, financial resources, understanding the system, access to suitable transport, capacity in primary care, the booking system and experience of health care. Important underlying mechanisms were health literacy, perceived convenience, patient empowerment and responsiveness of the practice. Some of these contextual influences on access to care act as barriers across the patient pathway but are amenable to change and interventions should aspire to address them.

Where this chapter has drawn on the published literature to explore access to primary care, the next chapter collects and analyses qualitative data from patients and health professionals to further understand how socio-economically disadvantaged older people in rural areas access primary care.



## **4 A qualitative study exploring how socio-economically disadvantaged older people access primary care**

### **4.1 Preamble**

The previous chapter explored the published literature and this chapter presents the aims, methods, findings and discussion of the second study: a qualitative study of semi-structured interviews with older people and focus groups with health professionals. It was published in PLoS One in 2018 [184]. It is largely a replication of the publication, except for removal of some text from the *Introduction* section, the content of which is covered in Chapter 1. The purpose of the qualitative study was to explore and understand barriers that socio-economically disadvantaged older people in rural areas face in accessing primary care. The findings for this study contributed to the overall programme theory (presented in Chapter 6) and informed the structural equation model used in Chapter 5.

## 4.2 Chapter summary

### 4.2.1.1 Objective

We aim to explore the barriers to accessing primary care for socio-economically disadvantaged older people in rural areas.

### 4.2.1.2 Methods

Using a community recruitment strategy, fifteen people over 65 years, living in a rural area, and receiving financial support were recruited for semi-structured interviews. Four focus groups were held with rural health professionals. Interviews and focus groups were audio-recorded and transcribed. Thematic analysis was used to identify barriers to primary care access.

### 4.2.1.3 Findings

Older people's experience can be understood within the context of a patient perceived set of unwritten rules or *social contract* – an individual is careful not to bother the doctor in return for additional goodwill when they become unwell. However, most found it difficult to access primary care due to engaged telephone lines, availability of appointments, interactions with receptionists; breaching their perceived social contract. This left some feeling unwelcome, worthless or marginalised, especially those with high expectations of the social contract or limited resources, skills and/or desire to adapt to service changes

Health professionals described how rising demands and expectations coupled with service constraints had necessitated service development, such as fewer home visits, more telephone consultations, triaging calls and modifying the appointment system.

### 4.2.1.4 Conclusion

Multiple barriers to accessing primary care exist for this group. As primary care is re-organised to reduce costs, commissioners and practitioners must not lose sight of the perceived *social contract* and models of care that form the basis of how many older people interact with the service.

### **4.3 Introduction**

As people age, the need for access to health care increases. Preventative measures, such as screening, health checks and chronic disease monitoring, leave older people requiring even more health care [59, 185, 186]. Two major systematic reviews, looking at ways to improve access to primary care in the general population, advocate context-specific models [115] targeted at different levels of the health care system [63]. Whilst these are useful general recommendations, they do not provide detailed practical guidance for commissioners and policy makers or for specific population groups; partly due to a limited evidence base. A more focused understanding of the barriers faced by this group is needed to help develop and implement these targeted, context-specific interventions and policies. The perspective of health professionals is important because the quality of services ultimately depends on the local team [187]. In the NHS, this local team is made of primary care staff within a general practice and allied community health professionals who work with the general practice staff. Therefore, our aim is to qualitatively explore barriers to primary care for socio-economically disadvantaged older people in rural areas by both identifying the barriers and understanding how these barriers affect access.

### **4.4 Methods**

#### *4.4.1 Sample and recruitment*

Interviews were undertaken with older people and focus groups with health professionals. Ethical approval was obtained from the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (reference 20142015-43) before the research began (Appendix 3) and for each protocol amendment. Written informed consent was obtained prior to any data collection (consent form Appendix 4, participant information sheet Appendices 5 and 6). Findings are reported in accordance with COREQ guidelines [188].

Participants who lived in a rural area, were over 65 years old and relied on financial support, such as means-tested pension credit, housing benefit or council tax support, were recruited for semi-structured interviews. We specifically did not use the term “benefits” in recruitment material because of socio-cultural connotations. Rurality was defined, using the Office for National Statistics definition, as settlements with less than 10,000 residents [189]. Those in residential care or unable to consent were excluded. We purposively decided to recruit participants through the community rather than primary care organisations to avoid any perception that the research was directly associated with their GP surgery. Our sampling framework aimed at avoiding oversampling of women (criterion: include at least three men), younger participants (criterion: include at least two participants over 80 years old) and people from the same practice (criterion:

include participants from four different GP surgeries). Recruitment and data collection took place between August 2015 and January 2016.

The recruitment strategy evolved throughout the research because of low participation. In the first round of recruitment, three electoral wards in the English rural county of Norfolk, given its large population size and geographic area, were selected based on rurality, household deprivation and pension credit claimants. Posters and/or invitations were displayed in post offices, churches, shops, social clubs and parish newsletters, and this led to recruitment of one participant. For the second round of recruitment, we introduced a £20 shopping voucher, increased the number of electoral wards, amended the invitations and hand delivered approximately 300 invitations; leading to four additional participants. For the third round, the lead researcher (JAF) was interviewed on local radio and discussed the research at local Age UK and older people's forums; leading to an additional two participants. In the fourth round, over four weeks across six pharmacies, about 300 invitations were placed in the pharmacy bags of patients over 65 years old and having their medications delivered; this generated a further eight participants at which data saturation was reached.

For four focus groups, rural health professionals were recruited through the NIHR Clinical Research Network (CRN). The CRN invited general practitioners (GPs) and practice managers from research-active practices in Norfolk and the research lead of Norfolk Community Health Care to identify community health professionals. Health professionals, or their employing organisations, were reimbursed for their time and travel. None of the participants were known to the research team prior to participation, except for one GP who was employed part-time at the University of East Anglia. No participants who contacted the research team subsequently refused to participate or withdrew.

#### *4.4.2 Data collection*

Participants chose to be interviewed at home (n=12) or the University of East Anglia (n=3) while the focus groups were held at the university. All focus groups and interviews followed individual topic guides (Appendix 7). Interviews lasted about one hour and focus groups two. Interviews and focus groups were audio-recorded and transcribed verbatim by an experienced transcriber at the University of East Anglia. Field notes were audio-recorded immediately after the interviews and focus groups and subsequently transcribed. No interviews were repeated.

The interviews and focus groups were conducted by a single male researcher trained in qualitative methods (JAF, qualifications MBChB MSc) whilst a second qualitative researcher (TP) observed two of the focus groups. JAF is a public health doctor, undertaking a PhD, but introduced himself as a researcher looking at access to primary care, not revealing his clinical background to participants unless specifically asked, which happened in one interview.

#### 4.4.3 Data analysis

We analysed the data using thematic analysis, based on the steps outlined by Braun and Clarke [190]. Briefly, this started with familiarisation of the data through repeatedly listening to the interviews and focus groups and reading the transcripts (JAF and RT). Codes were generated by identifying and labelling key sections of text which contained data on access to primary care by two researchers independently (JAF and RT). Similar codes were then independently grouped to form initial candidate themes by the same two researchers (JAF and RT). Themes were refined iteratively through repeated discussions of the data between the two coding researchers, the wider research team, colleagues within the department, and two patient representatives. QSR NVivo was used to code the data [117]. JAF has previously undertaken a realist review in this area [109] and had substantial knowledge of the topic; therefore a constant comparison approach [191] was used to avoid confirmation bias.

To ensure rigour and trustworthiness, we implemented the following measures: 1) coding and generation of initial themes was undertaken independently by two members of the research team (JAF and RT), 2) transcriptions were checked for accuracy by the researcher undertaking the interviews (JAF) and 3) themes were interrogated by the research team and patient representatives. We did not undertake member checking, so as to leave the data as it was captured during the interview.

## 4.5 Findings

In total fifteen participants, six men and nine women were interviewed with an average age of 78 and a range from 67 to 87 years old. Six of these participants were over the age of 80. All participants lived in Norfolk and were registered at ten different GP surgeries.

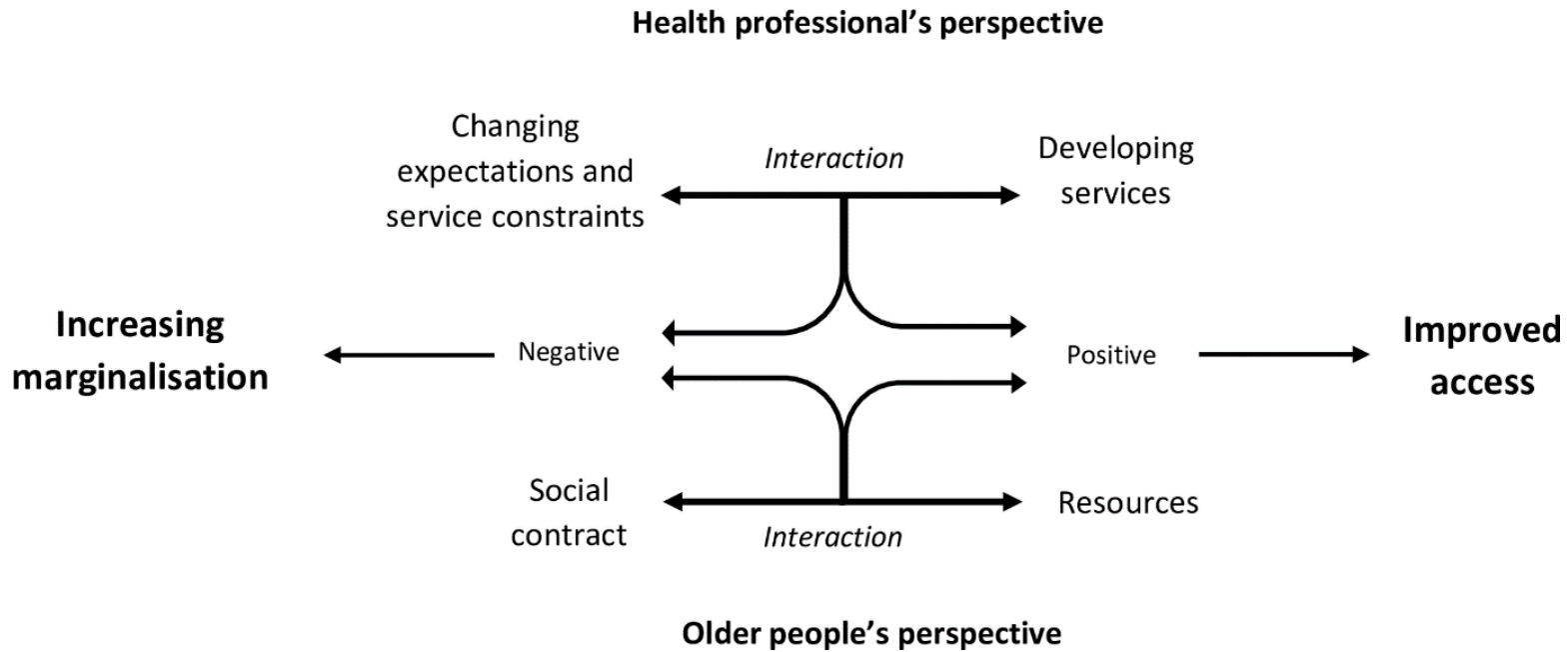
Each of the four focus groups had between three and five participants. There were 16 participants in total: three GPs, four practice managers, five senior community nurses, three district nurses and one community physiotherapist. Two focus groups included only GPs and practice managers, and two community nurses and the physiotherapist.

The perspectives of older people and health professionals are presented, with participant quotes to illustrate each sub-theme. The demographics of interview participants are shown in Table 8, whilst Figure 12 shows a diagrammatic overview of the findings.

Table 8: Demographics of interview participants

Participant number	Age	Gender	Housing type	Distance to GP surgery	Access to a car
1	75	Female	House	7.1 miles	Yes
2	82	Male	Sheltered accommodation	0.3 miles	No
3	83	Female	House	1.1 miles	No
4	73	Female	House	4.4 miles	Yes
5	74	Male	House	4.4 miles	Yes
6	67	Male	House	1.6 miles	No
7	77	Male	House	3.5 miles	Yes
8	76	Female	Sheltered accommodation	0.3 miles	No
9	75	Female	House	2.4 miles	Yes
10	85	Male	House	1.6 miles	No
11	85	Female	House	1.6 miles	No
12	87	Female	House	0.3 miles	No
13	75	Female	House	0.4 miles	No
14	82	Male	House	2.8 miles	No
15	79	Female	House	0.4 miles	No

Figure 12: Older people and health professional's perspective of accessing primary care



#### 4.5.1 Older people's perspective

##### 4.5.1.1 Social contract

Older people's experience can be understood within the context of a patient perceived set of unwritten rules or *social contract*. These social norms are based on reciprocity – older people were careful not to “bother” or waste the doctor's time, on the understanding that their GP surgery (doctors, nurses and receptionists) make special provision for them when unwell. Special provision meant goodwill, such as being flexible about rigid appointment systems or home visits.

Participants saw this in the context of their whole life, inasmuch as they expected the receptionists and GPs to be aware that during their lifetime they were not someone who inappropriately used the service. For example, this participant describes how, because she is careful not to ask for help unnecessarily, the GP does not question when she requests a home visit:

*“I don't come to a doctor unless I'm ill. When I say there's something wrong with me [the GP] knows I don't go their time wasting [because] ... I only go if I'm really not feeling well... He's never queried if we've wanted a call out, never been, “oh, can't you come to the surgery”.” (Pt 13, 75-year-old female)*

Here the participant describes her perception that in return for fulfilling her responsibilities only to attend the GP surgery when necessary, the doctor is willing to undertake a home visit, even if he might query it with other patients. All participants discussed the importance of not bothering, or wasting the doctor's time, unless absolutely necessary. Several participants considered how this attitude had changed in society throughout their life, such as this participant who compared a childhood event to current norms:

*“When I was seven or eight the old man upstairs died because they wouldn't send for a doctor on a Sunday... And this is the thing. I think a lot of people do go and bother, whether it's doctors or hospitals or anybody else, about things which they shouldn't be bothering them with.” (Pt 1, 75-year-old female)*

##### 4.5.1.2 Breach of the social contract

When participants did decide to access primary care, most found it difficult despite being careful not to bother the doctor. Participants articulated a sense of frustration if the practice breached the social contract by not recognising that they were someone who used the service responsibly, thinking carefully before asking to see the doctor. For example, participants shared their dismay about asking for a GP appointment, only for a receptionist to ask what the symptoms were, or if it was something the nurse could have dealt with:



*“I feel that’s rude. I feel like saying it’s nothing to do with you. My first reaction is, ‘it’s not your business. I need to speak to my GP. I’m ringing up about an appointment, I’m not ringing up to tell you what my symptoms are.’” (Pt 6, 67-year-old male)*

Here the participant expected the receptionist to recognise their carefully considered judgement of when to request a doctor’s appointment. In return, they expected the receptionist not to question their decision.

Participants identified difficulties such as engaged telephone lines, availability of appointments, receptionists and home visits. One participant reported having to wait 40 minutes to get through to a receptionist, by which time there were no appointments. Most highlighted the need to negotiate an appointment and usually perceived receptionists as barriers. Several participants described being told “*very firmly*” what they could or could not do. One participant described the receptionists as “*gods*” (Pt 7, 77-year-old male). Some participants described positive experiences of receptionists, but others described negative experiences:

*“I get annoyed with them because I don’t feel that I’m ringing up and wasting their time. They are paid to do a job. They are paid to be polite.” (Pt 15, 79-year-old female)*

Another source of frustration, particularly for those without a car, was being unable to get a home visit or given a telephone consultation instead of a visit.

Some who prioritised this social contract or lacked the resources, skills and/or desire to adapt to service changes were left feeling marginalised; the perceived exclusion from services based on personal characteristics, in particular ageing. For example, this participant described how she felt when contacting the GP surgery, even after careful use of GP services over the course of her life:

*“You just feel so unwelcome and a nuisance, such a nuisance.” (Pt 1, 75-year-old female)*

Other participants felt ostracised, unwelcome or worthless because they were not treated with the respect that they felt they deserved as older people and thoughtful users of the service, such as this participant:

*“You feel that you’re not worth anything. You really feel that all right because you’re elderly you’re not wanted. Ok, curl up in the corner, die quietly. Just leave us alone.” (Pt 15, 79-year-old female)*

This highlights the additional emotional challenges that older people face accessing primary care.

#### 4.5.1.3 *Impact of physical resources and skills*

Having a car was a key resource to being able to get to the GP surgery. Most participants with a car were concerned about what would happen when they could no longer drive, with one reporting that they were planning to move to a new house. For those without a car, the availability of public or community transport was discussed, but most relied on taxis, friends or family. The support provided by an individual's friends and family was important, not only for transport, but also to help with making appointments.

It became evident that personal skills, such as ability to communicate effectively, were important to obtain an appointment. These were often associated with previous experiences, such as type of employment. One participant, who had previously worked in a citizen's advice role, described her personal strategy of negotiating with someone over the phone.

*“As long as I never contradict anybody on the phone I'm fine because they've got feelings as well. I have to say I'm asking because I don't know and not sort of apportion blame as to who did it [because] sometimes there isn't a 'who did it' it's just one of these things.”*  
(Pt 8, 76-year-old female)

Other participants described how conversations with receptionists could escalate and become confrontational.

One participant appeared to have the resources and skills to engage with the system, but not the desire, preferring to retain their existing way of life. For example, she acknowledged the need for a touch telephone to help book an appointment but did not want to conform to the current expectations:

*“It just annoys me. These little things annoy me, so I sort of cling to my phone, but I will have to obviously get one with buttons on at some point.”* (Pt 1, 75-year-old female)

#### 4.5.2 *The health professional's perspective*

##### 4.5.2.1 *Health professionals' views of older people's expectations of the health service and ageing*

The growing expectations of the public was discussed in all focus groups. Health professionals felt that the expectations and needs of the wider population were inconsistent with current patterns of service provision. For example, one health professional described a difficult conversation with a patient who expected a routine GP visit after an operation:

*“It was finding the words to explain that that's how it is now, without saying that's how it is now. She hadn't had an operation for so many years and she'd only ever called her GP*

*if she'd been unwell. And she automatically expected him to call... And that generation that's the least she expected. So, she was really upset." (FG4, community nurse)*

The health professional identifies two reasons for this patient's expectations of a routine home visit after a major operation; first, the system had changed since previous illness and, second, the patient used the service sparingly. This example given by a health professional supports the concept of a perceived social contract from older people.

Conversely, some health professionals reported that many older people from lower socio-economic groups do not seek help because they attribute health problems to ageing, leading to delayed presentation and disengagement with primary care:

*"A lot of them are just thinking they're getting old, so when something doesn't work as well as it used to it's just getting old. They don't think let's go and get it fixed, let's go and get it investigated. That's life - your hearing gets a bit worse, your eyesight gets a bit worse. For them it's expected, so they just don't engage with us." (FG1, GP)*

One health professional felt that some from lower socio-economic groups often had lower expectations of the health service and their own health compared to the wider population:

*"I'd say there's another hard core who are very low service users. They don't expect anything out of life and therefore they don't expect anything out of the health service and they tend not to consult." (FG1, GP)*

The above quotes highlight how health professionals attribute some of the lack of engagement, if not most of it, to the patient rather than the health service.

#### 4.5.2.2 Service constraints

Restricted resources within the health care system, both nationally and locally, was discussed, especially the perception that primary care was being asked to do more without resources to match. This had a direct impact on our group of interest because financial constraints necessitated service reorganisation away from traditional models of care, which are more likely to satisfy a social contract. Health professionals identified other factors which exerted pressure on the service and ultimately access for our population group, such as the increase in recommended preventative medications leading to the medicalisation of ageing and requirement for more health care:

*"Someone wants them to have pills. And whether it's statins or whatever. People are on pills because they are ill, that's one thing, but we've created lots and lots and lots of patients who need pills. So, they're people that we have turned into patients. They're not ill!" (FG2, GP)*

National or regional policies, and enhanced services, added pressure to service delivery. Generally, health professionals were cynical about these and did not feel that they improved services for

disadvantaged older people. For example, policies attempting to promote continuity through a named GP were seen as “*box ticking exercises*” since appointments were rarely available.

Furthermore, several health professionals described how different groups of older people used services, sometimes inappropriately. For example, one GP identified inequalities between healthy older people with good access and ill older people with poor access:

*“I’ve seen the wealthy 70 something who’s making an appointment a week to come and show me some skin blemish that they’re worried about because they have too many holidays on Majorca or whatever. And then I’ve got other people who really struggle to access the service [because] they’ve got transport issues and so on and then when they come they’ve got a long list of things that need sorting out. It seems very inequitable to me.” (FG1, GP)*

#### 4.5.2.3 Need for targeted services for this group

Faced with increased demands and limited resources, health professionals identified the need to re-organise services to reduce costs. These changes often negatively impacted socio-economically disadvantaged older people. Changes included fewer home visits, more telephone consultations, triaging calls and modifying the appointment system, as described by this GP:

*“Over the last four or five years we’ve reiterated our way of people accessing the system umpteen times. So, we now have telephone appointments, we have telephone triage, on the day, open surgery system so there are no pre-booked, [and] a nurse practitioner service.” (FG1, GP)*

However, some re-organisation has led to opportunities. One GP suggested that an outcome of having so many ways of accessing primary care was an ability to accommodate the needs of different older people, such as those without a car. For example, the GP described how a universal approach may miss some groups and how his practice had attempted to address this by becoming more flexible:

*“I think we tend to try and operate a one size fits all service that catches as many people as we can. But we always know that there will be people around the margins of that who fall outside what it’s designed to cope with....One of the things that we have learned over the last decade or so is that we just have to make our system as flexible as we can to take advantage of opportunities because if you have this very rigid system... then somebody says well I want to come to surgery but I can only come at 12 o’clock which is when all the GPs are out on visits.” (FG1, GP)*

Several health professionals described the need for a targeted approach for vulnerable groups, such as disadvantaged older people. However, not all health professionals felt that this should necessarily be a proactive approach which may involve the GP surgery initiating contact with this group, but rather responsive when this group needed help.

Health professionals also identified the need to re-educate how older people use the service by explaining the benefits of attending the practice, rather than requesting a home visit, and discussing the frequency of appointments and legitimate reasons for seeing the doctor.

## 4.6 Discussion

### 4.6.1 *Summary of principal findings*

We found that rural, socio-economically disadvantaged older people's experience of access to primary care can be understood within the context of a *social contract* – an individual is careful not to bother the doctor in return for additional goodwill when they became unwell. However, when participants accessed primary care, most found it difficult due to engaged telephone lines, availability of appointments, interactions with receptionists; breaching their perceived social contract. This left some feeling unwelcome, worthless or marginalised, especially those with high expectations of this social contract or limited resources, skills and/or desire to adapt to service changes. From a health professionals' perspective, barriers included rising demands and expectations, necessitating service development of traditional models of care with less resource. Service developments included fewer home visits, more telephone consultations, triaging calls and modifying the appointment system.

### 4.6.2 *Strengths and limitations*

One strength of our design was collecting data from both service users and health professionals allowing different perspectives of access to primary care. However, we experienced challenges in recruiting this group of hard to reach older people. Recruitment was particularly challenging because we used a community recruitment strategy, compared to recruiting via GP surgeries. We did this so that participants would be less likely to perceive that the research was directly associated with their own GP surgery. However, it made recruitment more difficult and to overcome this challenge we modified our recruitment strategy on three occasions. Our final method, which resulted in most recruits, was to use delivered pharmacy bags to recruit vulnerable older people. This recruitment method that may be applicable to a range of other studies. However, participants recruited using this method may have been more likely to be engaged with primary care and housebound.

We included both men and women and anyone over 65 years old but did not have sufficient data to explore the difference between older men and women [81, 192]. The age of participants ranged from 67 to 87 years old. Those belonging to the 'baby boomer' generation (52 to 71 years old) and 'silent generation' (72 to 93 years old) may have different life experiences and attitudes, but similarly we did not have the data to explore this. Our main inclusion criteria to identify socio-

economically disadvantaged older people was relying on financial support, acknowledging that financial deprivation is only one aspect of disadvantage. Despite receiving financial support, at the interview stage two participants did not appear to fit this group and their data was interpreted with caution. Furthermore, we only undertook four focus groups of health professionals and while similar themes began to emerge in the third and fourth focus groups we were may not have reached full saturation.

Whilst our data came from one area of the UK, we do not have any reason not to think that the concept of a social contract is generalizable to other parts of the UK, although the terms of the reciprocal relationship may be different. Other studies including older people identified similar themes of not wanting to bother the doctor [193] and there is no suggestion that our findings are unique only to our participants. Although areas with low population and GP workforce mobility, such as Norfolk, may facilitate a social contract more than inner city areas. Further research is needed to understand if a social contract exists in other health care systems, such as the US. Previous research from the US has found similar barriers, such as transport, lack of resources, limited health care supply and lack of understanding by doctors [194-198]. However, cost of medical treatment was more important in the US compared to the UK because of different health care systems. The health professionals' perspective is likely to be generalisable across high-income countries because most health care systems are trying to address the challenges of an ageing population, rising demands, increasing costs and financial constraints.

#### 4.6.3 Comparison with other studies

Our findings support the previously described concepts relating to access to services by vulnerable groups of candidacy ("the ways in which patient's eligibility for medical attention and intervention is jointly negotiated between individuals and health services" [17]) and permeability ("the ease with which people can use services" [17]). Health professionals and older people both alluded to the permeability of services, especially concerning availability of appointments, telephone access and receptionists. We found a two-way, dynamic relationship, supported by previous literature [6], between older people's service use affecting practice procedures, and practices informing older people how to best use the service.

The concept of a *social contract* has been applied to health care previously, but at a macro level [199, 200]. Cruess and Cruess argued that members of society expect the medical profession to provide the services of a healer in return for autonomy, trust, status, self-regulation and a functioning health care system [199]. Our findings support the existence of a social contract but enacted at a relational level and for a specific population group.

Bentley undertook a qualitative study using mini-ethnography to explore access to health care for older people living in an English village [80]. The study found that culture, legitimacy and, as

suggested in previous research [192, 201], a retained hierarchical medical model of health care are barriers to access for older people. The authors found that older people did not identify themselves as consumers. We did not find data to support a consumer model either, and our findings support a hierarchical model in which older people do not bother the doctor for minor ailments. Building on this, we found that in return for this hierarchical system older people expect the GP surgery to make special provision when they are ill.

Goodridge and colleagues looked at the experiences of patients with chronic respiratory illness in rural areas of Canada using semi-structured interviews [134]. The authors found several important facilitators to health care, such as distance, relationship with their family doctor, supportive local community and health knowledge. We found that the GP relationship and local social networks were important, but older people in our study highlight the importance of suitable transport options rather than the physical distance to the surgery.

#### *4.6.4 Meaning of findings and policy implications*

In England, Clinical Commissioning Groups have a legal obligation to address health inequalities [202]. Access to services is a key policy area to address inequalities [203]. Policy decisions in relation to access to primary care are challenging because most health services operate within a fixed budget and improving access may lead to increased patient expectations or unnecessary use. One-size-fits-all policies may increase access for the whole population, leading to increased pressure on the system and counterproductively worse access for marginalised groups - a targeted approach is hence needed [63, 115].

There are several reasons why a purely universal approach to improving access to primary care may increase inequalities. Vulnerable groups are likely to have access to fewer resources making it difficult or impossible to take advantage of universal interventions. For example, in our study several participants did not have access to the internet which put them at significant disadvantage for access to online appointments. Differing attitudes to health care are also likely to increase inequalities associated with universal interventions. Older groups, compared to younger, are less likely to view themselves as consumers of health care [134] and therefore may not have the same perception of entitlement associated with being a consumer. For example, a universal GP weekend opening intervention may improve access for younger patients, with fewer health problems, who want health care at the weekend because they are used to consuming other non-health care services seven days a week, rather than for vulnerable older patients. In turn this may stretch health services and further limit access for those who are most vulnerable; compounding the inverse care law.

Undoubtedly universal and targeted approaches should complement each other. A solely targeted approach may help to improve health care for the most vulnerable, but is unlikely to help the

remaining population and may risk worsening their health because limited resources are used on the most vulnerable [204]. This approach may reduce the health gap between best and worst, but the overall health status of the population could worsen. On the other hand, a solely universal approach may increase the overall health status of the population, but increase inequalities. For this reason it can be argued that policy makers should aim to both ‘shift the curve’ (i.e. improve the overall health of the population) and ‘shorten the tail’ (i.e. reduce the health gap) [204].

However there are specific considerations relating to access to primary care. For example, there is difference between need (the ability to benefit from health care) and demand (the expectations of the population). Universal approaches which focus on meeting demand, rather than need, may result in misplaced investment. Previous research has found that deprived older people, compared to affluent groups, tend to visit health and dental services less despite having greater need [61, 205]. Furthermore, supply-induced-demand may occur where providing the whole population with improved access leads to an increased expectations without necessarily increasing the benefits.

Our findings suggest that health professionals support a targeted approach to improving access when vulnerable older people use primary care services, but not necessarily a proactive approach which may, for example, involve outreach activities in the community. We identified various personal and structural resources needed to access primary care, with the most important being transport, social networks and personal skills. An individual’s structural and personal resources was associated with their ability to manage service changes. For example, some older people are unfamiliar with changing staff roles, such as the changing role of a receptionist to include triaging, as well as booking appointments.

A tension exists in the health professional’s views – on one side, ageing is being medicalised, but conversely patients do not consult because they attribute their health problems to ageing. It is likely that the medicalisation of ageing, in part, relates to conditions with incentivised or nationally recommended policies, such as raised cholesterol or blood pressure. It may be that some patients are being contacted to meet incentivised prevention targets, which in turn leads to fewer appointments to fulfil the social contract.

To address the significant financial and workforce challenges within the NHS, there is a drive to deliver primary care within ever larger practices, such as networks, federations or super-partnerships [206]. The effect of these changes is unknown. Our findings suggest a tension between the expectations within a social contract and experiences of older people which is compounded by recent service changes. Reconfiguring services to deliver primary care at scale may lead to socio-economically disadvantaged older people in rural areas feeling more disconnected from primary care, because, if a social contract is present, the older person will continue to carefully use the service but are unlikely to be shown the goodwill they expect in return.



The interface between patient and practice is crucial and many practices have been striving to improve this for a long time. The drive to deliver primary care at scale is likely to make this interface, in the absence of careful planning, less personal. Representative patient groups could help practices to improve the experience of older people. Simple measures may make a significant difference, such as helping practice staff understand the perspective of different patient groups to facilitate a more sensitive approach to the needs of vulnerable groups. This may mean, for some patients, receptionists not asking about a patient's health problem, or having a lower threshold for home visits. A major obstacle is time and resources within primary care; without giving reception staff more time to answer calls and appointments to allocate, older people are likely to continue to have negative experiences.

More community support is needed in rural areas to help with transport, such as community car schemes. Closer collaboration between commissioners and local authorities may help to improve public transport to health care. Furthermore, it may help to protect some appointments which coincide with public transport timetables or when there is limited taxi availability, such as during school drop off and pick up.

#### 4.6.5 Conclusion

We found that rural, socio-economically disadvantaged older people's experience of access to primary care can be understood within the context of a *social contract* – an individual is careful not to bother the doctor in return for additional goodwill when they became unwell. However, the perceived social contract was often breached when participants accessed primary care due to engaged telephone lines, availability of appointments, interactions with receptionists. This left some feeling unwelcome, worthless or marginalised, especially those with high expectations of this social contract or limited resources, skills and/or desire to adapt to service changes. From a health professional perspective, barriers included rising demands and expectations leading to the need to reconfigure services with less resource. As primary care is re-organised to reduce costs, commissioners and practitioners must not lose sight of the perceived *social contract* and models of care that form the basis of how many older people interact with the service.

This chapter has used qualitative data to understand more about how socio-economically disadvantaged older people in rural areas access primary care. The next chapter attempts to quantify the CMO configurations produced from these findings and those of the realist review using structural equation modelling in the English Longitudinal Study of Ageing.

## **5 Exploration of realist theory using structural equation modelling in a linked dataset**

### **5.1 Preamble**

Drawing on the theory generated from the realist review and qualitative study in Chapters 3 and 4, this chapter presents the aims, methods, findings and discussion of the third study: a cohort analysis of the English Longitudinal Study of Ageing using structural equation modelling. It was published in BMC Medical Research Methodology in 2018 [207]. It is largely a replication of the publication, except for removal of some text from the *Background* and *Theoretical underpinning of access to primary care* section, the content of which is covered in Chapter 1, and formatting changes to improve consistency. It was intended that this research would test theory arising from the realist review and qualitative study and generate new theory. However, data limitations meant that only a small proportion of the theory could be tested, and it was not possible to generate new theory. Therefore, the study became more of a methodological paper looking at the use of structural equation modelling to quantify realist theory, rather than robustly testing the proposed theory.

## 5.2 Chapter summary

### 5.2.1.1 Background

Quantitative methods are not well-established in realist approaches, but structural equation modelling (SEM) may be useful to explore CMO configurations. Our aim was to assess the feasibility and appropriateness of SEM to explore CMO configurations and, if appropriate, make recommendations based on our access to primary care research. Our specific objectives were to map variables from two large population datasets to CMO configurations from our realist review looking at access to primary care, generate latent variables where needed, and use SEM to quantitatively test the CMO configurations.

### 5.2.1.2 Methods

A linked dataset was created by merging individual patient data from the English Longitudinal Study of Ageing and practice data from the GP Patient Survey. Patients registered in rural practices and who were in the highest deprivation tercile were included. Three latent variables were defined using confirmatory factor analysis. SEM was used to explore the nine full CMOs. All models were estimated using robust maximum likelihoods and accounted for clustering at practice level. Ordinal variables were treated as continuous to ensure convergence.

### 5.2.1.3 Results

We successfully explored our CMO configurations, but analysis was limited because of data availability. 276 participants were included. We found a statistically significant direct (context to outcome) or indirect effect (context to outcome via mechanism) for two of nine CMOs. The strongest association was between ‘ease of getting through to the surgery’ and ‘being able to get an appointment’ with an indirect mediated effect through convenience (proportion of the indirect effect of the total was 21%). Healthcare experience was not directly associated with getting an appointment, but there was a statistically significant indirect effect through convenience (53% mediated effect). Model fit indices showed adequate fit.

### 5.2.1.4 Conclusions

SEM allowed quantification of CMO configurations and could complement other qualitative and quantitative techniques in realist evaluations to support inferences about strengths of relationships. Future research exploring CMO configurations with SEM should aim to collect, preferably continuous, primary data.

### 5.3 Background

Realist approaches generate testable theories, based on CMO configurations, to explain and understand how an intervention or programme works. They do not oppose quantitative techniques, but their place and purpose is less established within the field. Realist researchers are cautious about quantitative data because of concerns about trying to measure unobservable factors or reducing complex social changes to numerical values [208]. In addition, there are ontological and epistemological concerns about using statistical techniques based on (post-) positivism which seek to compare averages using distributive data assumptions [89].

Structural equation modelling (SEM) is an established quantitative technique which combines both a measurement and structural component [104]. The measurement component allows identification of unobserved, or latent, variables usually through confirmatory factor analysis (CFA). For example, patient empowerment is an unobservable concept, but could be identified from several observed variables, such as confidence in knowing when to seek help, accessing services, raising concerns and finding solutions. These types of latent variables (such as patient empowerment) are generally considered as reflective measures because patient empowerment leads to confidence in knowing when to seek help, accessing services, raising concerns and finding solutions. Formative measures are the opposite and exist when the observed variables causes the latent variable.[209] For example, transport options (formative variable) may be determined by car ownership, availability of public transport and mobility. There is a potential fit here between reflective measures and realist approaches because realist mechanisms are usually conceptualised as being unobservable [210]. Therefore, if we want to be able to measure them, then one possible approach is to use the concept of reflective measures. The structural component of SEM measures the relationship between latent or observable variables along a pre-specified path using regression techniques. While CMOs are configurations, not correlations, they do have a natural sequential order of C-M-O and hence are potentially amenable to measurement.

### 5.4 Justification and study aim

Empirical quantitative data analysis techniques may be an additional means of testing realist theories and hence help to increase their plausibility. We do not propose that quantitative analyses would provide *the answer* or validate realist theory, but rather additional information to allow researchers to explore in more detail what works, for whom, in what circumstances and how. Therefore, our aim is to assess if it is feasible and appropriate to quantitatively model realist theory using SEM and, if so, make some recommendation on how this should be done based on our prior and continuing research on access to primary care.

## 5.5 Theoretical underpinning of access to primary care

Our initial intention in the quantitative analysis was to explore all steps along the patient pathway, however we only had data for one, but arguably the most important, step – obtaining an appointment. The theoretical model developed from the realist review and qualitative data for the ‘Obtain an appointment’ step is shown in Figure 9 (p44) developed from our realist review [109]. In total, there are 23 CMO configurations with seven common mechanisms for this single step. Based on the realist review we were not able to identify which of the CMO configurations had the greatest influence on the outcome of ‘Obtain an appointment’. Here we explore if structure equation modelling might help with this.

## 5.6 Methods

### 5.6.1 Data sources and linkage

A linked dataset was created by merging individual patient data from Wave 6 of the English Longitudinal Study of Ageing (ELSA) and practice data from Wave 7 of the GP Patient Survey; thus, creating a linked dataset of *individual-level* data from ELSA combined with general practice-*level* data from GP Patient Survey.

ELSA is a longitudinal face-to-face interview study of older people aged 50 and over. Data covering health, functioning, social participation, and economic position are collected every two years with biological and anthropometric information gathered every four years. Wave 6 of ELSA (2012/3) has information on 10,601 individuals.

The GP Patient Survey is undertaken by Ipsos MORI (a polling organisation) on behalf of NHS England and collects patients’ views on more than 99% of GP surgeries in England. Wave 7 of the data had two collection periods in summer 2012 and winter 2013. Questionnaires were sent to nearly 2.75 million patients over 18 years old who had been registered at their GP surgery for at least 6 months, across both data collection periods [211]; with 971,232 questionnaires returned (response rate 25.2%). Practice-level results are weighted to more accurately resemble the practice population. Full details of weighting are described elsewhere [211].

GP surgery name and postcode were collected for 52% of participants in Wave 6 of ELSA, enabling linkage with GP Patient Survey. The datasets were linked based GP surgery postcode because this was present in both datasets and was more completely reported than the GP surgery name. Where two practices shared the same postcode, for example because of a shared site, but were lacking a complete surgery name, outputs averaged across both practices were used.

### 5.6.2 *Patient selection*

To be included participants had to be registered with a rural GP surgery, as defined by the Health and Social Care Information Centre, and belong to the lowest socio-economic class of the National Statistics Socio-economic three category classification. Only patients with both GP Patient Survey data and ELSA data were included.

### 5.6.3 *Variable selection and measurement model*

First, all possible variables from ELSA and GP Patient Survey were mapped to our pre-specified theoretical realist model of CMO configurations (i.e. Figure 9, p44). We then, through discussion and looking at previously published studies, identified the best variable for observable concepts, or associated variables for latent concepts, for each individual CMO concept from the dataset. No variables fitted for the following pre-specified theoretical concepts: patient empowerment, clinical problem, public expectations, capacity (in primary care), responsiveness (of primary care), priorities (for primary care), health care expectations, available appointments and home visit policy. Therefore, data were available for nine complete CMOs (i.e. data available for context, mechanism and outcome).

For unobservable concepts with sufficient data availability, confirmatory factor analysis was used to explore the dimensionality of the latent variables. Observable variables which did not statistically significantly contribute to the latent variable were removed. Initially mixed CFAs, combining continuous and categorical data were attempted, but this resulted in significant problems with the models, such as poor model fit or non-convergence. Therefore, ordinal data, such as Likert scales, were treated as continuous variables. In total, there were three latent, one formative variable and eight observed variables as shown in Table 9 and Table 10. Health literacy was not collected in wave 6; therefore, wave 5 data was used. The indicators for each latent variable are described below.

- Healthcare experience was measured using four questions from the GP Patient Survey about quality of care. Other quality of care measures from the GP Patient Survey were dropped because they were highly correlated or did not statistically significantly contribute to the model, such as GP listening or if the patient would recommend the surgery to someone moving to the area. Quality of care measures in ELSA were not included because the low number of patients with data.
- Assertiveness was not measured in the dataset. Therefore, we constructed a latent variable consisting of three variables exploring determination, outgoingness and pride because these have been theoretically linked with assertiveness [212-214].

- Self-esteem was not directly measured in the dataset. Therefore we constructed a latent variable consisting of questions from the Satisfaction with Life Scale, which has a high correlation with self-esteem [215].

Transport was the only formative measure. It consisted of three questions about getting lifts from friends and family, use of public transport and travel time from home to GP surgery. Use of car and community transport were initially included, but these were dropped because of low variance. Travel time was calculated using network analysis within Geographic Information System Software (ArcGIS 10.3). This involved georeferencing the postcodes of both the GP surgery and participant's home, followed by calculating the travel time using an establish network dataset with road data, split by urban and rural motorways, A and B class roads and minor ones.

Table 9: Reflective and formative variables

Theoretical concept	Indicator variables	Measurement scale	Dataset
Reflective variables			
Assertiveness	Feeling determined during past 30 days	5-point scale	ELSA W6
	Describes self as outgoing	4-point scale	ELSA W6
	Feeling proud during past 30 days	5-point scale	ELSA W6
Self-esteem	Reporting life to be close to ideal	7-point scale	ELSA W6
	Reporting conditions in life to be excellent	7-point scale	ELSA W6
	Reporting satisfaction with life	7-point scale	ELSA W6
	Reporting no regrets in life	7-point scale	ELSA W6
	Reporting that he/she has got the important things in life	7-point scale	ELSA W6
Health care experience	Proportion of people who were not overheard in the surgery, or were, but did not mind	Percent	GPPS
	Proportion of people who reported time given by GP was good or very good	Percent	GPPS
	Proportion of people who reported explanation given by GP was good or very good	Percent	GPPS
	Proportion of people who reported the GP involved them in decisions as good or very good	Percent	GPPS
Formative variable			
Transport	How often individual gets lift from friends or family not living with them	6-point scale	ELSA W6
	Road travel time from home to general practice	Continuous	ELSA W6
	How often public transport is used	6-point scale	ELSA W6

ELSA: English Longitudinal Study of Ageing, W6: wave 6, GGPS: GP Patient Survey

Table 10: Observed variables

Theoretical concept	Variable	Type	Dataset
Health literacy	Number of correct health literacy tests	5-point scale	ELSA W5
Education	Level of educational qualification	Categorical	ELSA W6
Technology	Frequency of using the internet	6-point scale	ELSA W6
Convenience	Proportion of people who found the appointment very or fairly convenient	Percent	GPPS
Ease at booking	Proportion of people who would it very or fairly easy to get through to someone at the surgery	Percent	GPPS
Clear information	Proportion of people who know how to contact out of hours	Percent	GPPS
Obtaining an appointment	Proportion that were able to get appointment when needed	Percent	GPPS

ELSA: English Longitudinal Study of Ageing, W5: wave 5, W6: wave 6, GGPS: GP Patient Survey



#### 5.6.4 *Structural model*

The structural equation models included nine complete CMO configurations. We initially undertook a mediation analysis for each individual CMO configuration (data not presented), followed by those CMOs with a common mechanism/mediator (data not presented) and, finally, the full model with all CMOs in the same model. Analysis was clustered at the practice level. The model was analysed using robust maximum likelihoods which estimate robust standard errors that are robust to non-normal data and dependent observations. We used this method because observations were clustered at the practice level and ordinal data treated in a continuous manner. The resulting estimates are standard maximum likelihood estimates. Results standardised by both latent and observed variable variances are used to allow comparison between regression coefficients. Therefore, the standardised regression coefficients should be interpreted as the amount of change in an outcome variable per standard deviation unit of predictor variable.

Model fit was assessed using Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI) and Tucker-Lewis Index (TLI). Based on Hu and Bentler [216], we considered a RMSEA of less than 0.06, CFI and TFI of more than 0.95 as a good fit. The chi-squared value for model fit is not reported because of the use of maximum likelihood estimation with robust standard errors. Only model modifications which could be theoretically justified were made. Based on the modification indices function within MPlus, three minor modifications were undertaken to correlate three factor variables within the self-esteem latent variable which were judged to be theoretically justifiable by the research team. Stata [217] was used to prepare the data and MPlus [218] to undertake the analysis.

## 5.7 Results

Wave 6 of ELSA included 10,601 participants. General practice data was available for 5,482 of these (52%) and basic demographic data between those who did and those who did not have general practice data is shown in Table 11. The group with general practice data had a similar proportion of females but slightly more people aged 60-80 years old or in a higher socio-economic position. Of the 5,482 participants with GP data, 984 belonged to practices which were classified as rural and 4,498 to practices classified as urban. Of the 984 patients belonging to a rural practice, 276 patients were also in the lowest socio-economic class, representing 178 different GP surgeries, and therefore 276 patients were included in the final analysis.

Table 11: Comparison between participants with GP data and those without

Variable		Without GP data (n=5,119)		With GP data (n=5,482)	
		Number	Percent	Number	Percent
Female		2,820	55.1	3,037	55.4
Age (years)	50-54	539	11.3	380	7.1
	55-59	925	19.3	864	16.1
	60-64	865	18.1	1,114	20.7
	65-69	810	16.9	1,058	19.7
	70-74	548	11.5	792	14.7
	75-79	552	11.5	655	12.2
	80+	545	11.4	518	9.6
Socio-economic position	Lower	2,278	42.1	1,921	38.2
	Middle	1,346	24.8	1,275	25.3
	Higher	1,794	33.1	1,835	36.5

The baseline characteristics of included participants are shown in Table 12. There were slightly more females than males. Most people did not have a higher education qualification and their main occupation was routine or semi-routine employment. About one third of participants used public transport at least 2 or 3 times a month. The median road travel time to the GP surgery was 4.80 minutes (inter-quartile range 2.76 to 7.88). Only a third of participants received lifts from friends or family who did not live with them. A third of participants used the internet or email every day and 40% never did. Most people scored highly on the health literacy tests.

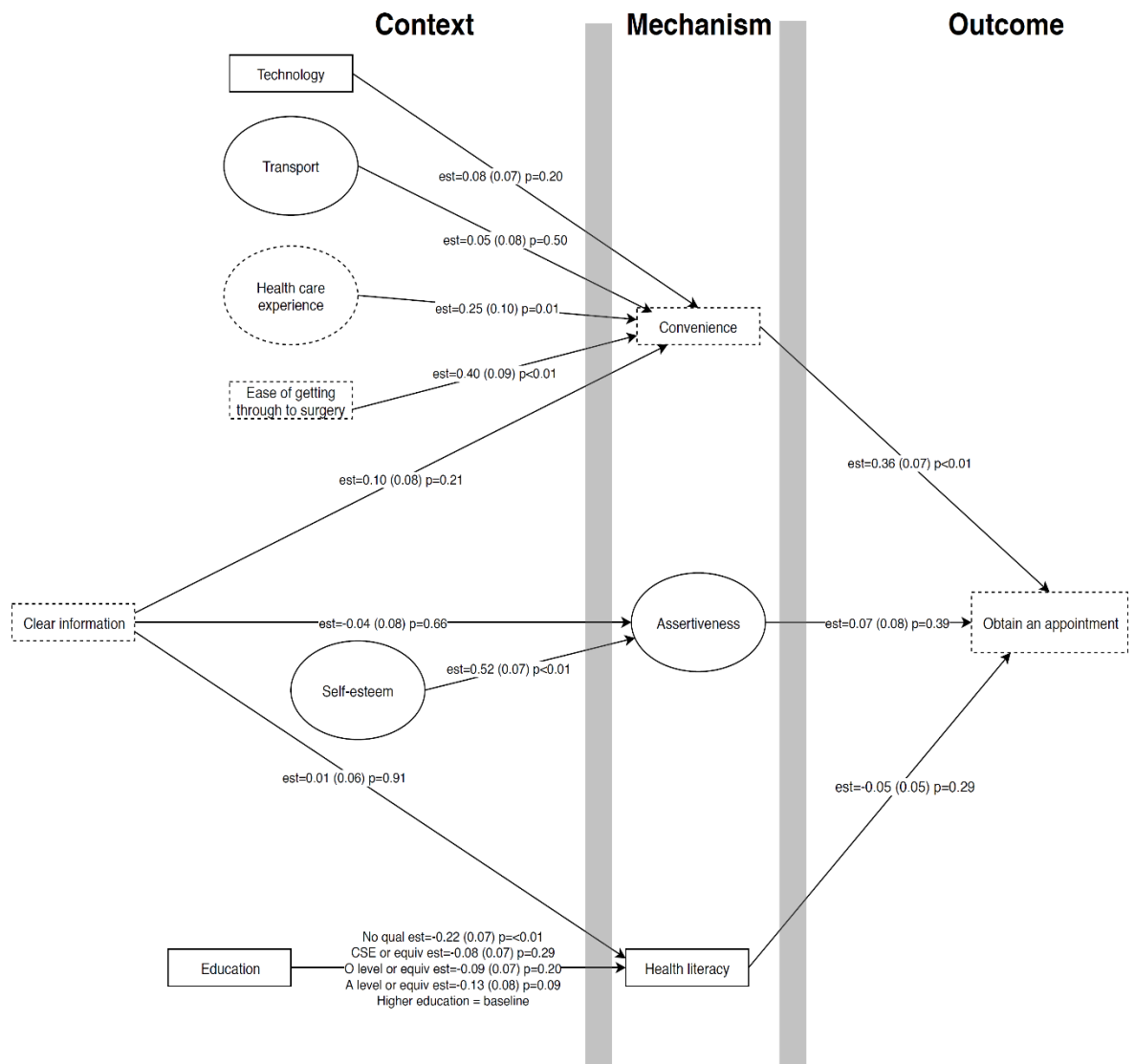
Table 12: Baseline characteristics of included participants (n=276)

Variable		Number	Percent
Female		169	61.2
Age	50-54 years	11	4.0
	55-59 years	27	7.8
	60-64 years	57	20.9
	70-74 years	65	23.6
	75-79 years	47	17.0
	80+ years	35	12.0
	Not available	1	0.4
Educational attainment	No qualification	99	35.9
	CSE or equivalent	24	8.7
	GCE O level or equivalent	63	22.8
	GCE A level or equivalent	22	8.0
	Higher education below degree	36	13.0
	Degree or equivalent	13	4.7
	Not available	19	6.9
Occupation	Routine occupations	74	26.8
	Semi-routine occupations	134	48.6
	Lower supervisory and technical occupations	63	22.8
	Small employers and own account workers	3	1.1
	Not available	2	0.7
Use of public transport	Every day or nearly every day	11	4.0
	Two or three times a week	26	9.4
	Once a week	19	6.9
	Two or three times a month	24	8.7
	Once a month or less	83	30.1
	Never	113	40.9
Road travel time to GP surgery (minutes)		4.80*	2.76 to 7.88**
Frequency of lifts from family or friends not living with them	Every day or nearly every day	1	0.4
	Two or three times a week	17	6.2
	Once a week	22	8.0
	Two or three times a month	17	6.2
	Once a month or less	25	9.1
	Never	194	70.3
Frequency of internet or email use	Every day or almost every day	80	29.0
	At least once a week (but not every day)	42	15.2
	At least once a month (but not every week)	11	4.0
	At least once every 3 months (but not every mth)	4	1.5
	Less than every 3 months	6	2.2
	Never	112	40.6
	Not available	2	7.6
Questions answered correctly in health literacy tests	0	1	0.4
	1	9	3.3
	2	17	6.2
	3	45	16.3
	4	180	65.2
	Not available	24	8.7

n: number, SD: standard deviation, GCE: General Certificate of Education, CSE: Certificate of Secondary Education, \*median \*\*interquartile range

Figure 13 shows the standardised regression coefficients for paths within the structural model, except for the standardised direct regression coefficients from context to outcome which are presented separately in Table 13 to retain clarity. Table 13 also presents the standardised indirect estimates and model fit. Model fit indices showed adequate fit – RMSEA was less 0.06 which is considered a good model fit, but CFI and TLI were less than 0.95 (0.923 and 0.908 respectively) indicating a less than good fit. We did not find any statistically significant direct or indirect effect for seven of the nine CMOs. The strongest association was between the ease of getting through to the surgery and being able to get an appointment. Our results suggest an indirect mediated effect through convenience and the percentage of the indirect effect of the total was 21% (i.e. indirect estimate divided by direct estimate plus indirect estimate =  $0.140/(0.140+0.514) = 0.21$ ). Therefore, patients who reported finding it easier to get through to the surgery were more likely to be able to get an appointment, and about half of this effect (53%) was mediated through the mechanism of convenience. Health care experience was not directly associated with getting an appointment, but there was a statistically significant indirect effect when convenience was added as a mediator (72% mediated effect).

Figure 13: Diagram of the standardised path regression coefficients from context to mechanism and mechanism to outcome for the structural equation model



est = standardised regression coefficients, (brackets) = standard errors, p = two tailed p value

----- = data from the GP Patient Survey

\_\_\_ = data from the English Longitudinal Study of Ageing

▭ = observed variable

○ = latent variable

N.B. Direct regression estimates from context to outcome are provided in Table 4

Table 13: Standardised direct and indirect regression coefficients from context to outcome for the structural equation model

Context	Mechanism	Outcome	Direct effect*		Indirect effect **		Model fit indices***		
			$\beta$	95% CI	$\beta$	95% CI	RMSEA	CFI	TLI
Clear information	Health literacy	Obtain an appointment	0.084	-0.056 to 0.224	0.000	-0.006 to 0.006	0.047	0.923	0.908
Higher education including degree or equivalent			Baseline	NA	Baseline	NA			
GCE A level or equivalent			-0.028	-0.115 to 0.060	0.007	-0.008 to 0.021			
GCE O level or equivalent			-0.026	-0.145 to 0.093	0.005	-0.007 to 0.016			
CSE or equivalent			0.006	-0.072 to 0.085	0.004	-0.006 to 0.013			
No qualification			0.009	-0.126 to 0.144	0.011	-0.011 to 0.032			
Self esteem	Assertiveness		-0.095	-0.213 to 0.024	0.035	-0.045 to 0.116			
Clear information			0.084	-0.056 to 0.224	-0.002	-0.014 to 0.009			
Technology	Convenience		0.080	-0.041 to 0.201	0.029	-0.021 to 0.079			
Health care experience			-0.078	-0.240 to 0.084	0.088	0.018 to 0.158			
Ease of getting through to surgery			0.514	0.407 to 0.620	0.140	0.067 to 0.214			
Transport			0.011	-0.209 to 0.232	0.018	-0.038 to 0.075			
Clear information		0.084	-0.056 to 0.224	0.037	-0.020 to 0.094				

$\beta$ : standardised regression coefficients, CI: confidence intervals, RMSEA: Root Mean Square Error of Approximation, CFI: Comparative Fit Index, TLI: Tucker-Lewis Index, GCE: General Certificate of Education, CSE: Certificate of Secondary Education, NA: not applicable, GCE: General Certificate of Education, CSE: Certificate of Secondary Education, \* direct effect refers to the relationship directly between “Context” and “Outcome”, \*\* indirect effect refers to the relationship from “Context” to “Outcome” through the mediator of “Mechanism”, \*\*\*degrees of freedom = 212

## 5.8 Discussion

### 5.8.1 *Statement of principal finding*

SEM was useful because it enabled a greater understanding of the relative importance of each CMO configurations related to the ‘obtain appointment’ step in our pathway. We found that obtaining an appointment was directly associated with the ease of getting through to the surgery and this effect was mediated through the mechanism of convenience. We also found a mediated effect from previous health care experience to obtaining an appointment through convenience.

### 5.8.2 *Strengths and limitations*

We believe this is the first study to explore CMO configurations using SEM. SEM allows each CMO configuration to be quantified and compared to assess relative strength. The main limitation was the lack of available data. Of the 23 proposed CMOs from our realist review for the ‘obtain an appointment’ step, we were only able to test nine full CMOs. Furthermore, the data included often did not exactly map to the underlying theoretical concept because the data had not been collected specifically to measure the constructs within our study leading to assumptions about data representation. For example, we used internet usage as a proxy for the context of use of technology, however it does not identify those that use the internet to help with primary care access; some may use it frequently for personal emails but never health-related activities. However, by using reflective and formative variables we were able to include more CMOs. There may be different CMO configurations which explain access to primary care for this group than we included. We drew our CMO configurations based on our interpretation of the data from our realist review [109]; remaining true to our underlying theoretical constructs. However, this has necessitated mapping data to concepts which may not perfectly match.

We mixed both individual and practice or organisational level data within the analysis, accounting for this by clustering at the practice level. Merging these two datasets was important because it provided both individual and organisational performance data. Ordinal variables, such as Likert scales, were treated as continuous variables to improve model identification. Health literacy data was not collected in Wave 6 of ELSA, therefore we used data from Wave 5. Our sample was relatively small (n=276), but this is a hard to reach group and obtaining a large dataset is likely to be extremely difficult. Model fit did not meet all the thresholds suggested by Hu and Bentler [216], but were not substantially different. We found a difference between the measures of model fit; RMSEA, the most commonly used measure, showed good fit, but TLI and CFI suggested less than good fit. MacCallum and colleagues have suggested the following thresholds for RMSEA: 0.01 indicates excellent fit, 0.05 good and 0.08 mediocre.[219] Using these thresholds both our



models had good fit. The CFI and TLI measures suggest less than good fit because these indices are affected by the large number of parameters to be estimated within our model. We standardised results, allowing a comparison of strength between different CMOs.

### 5.8.3 *Comparison with other studies*

Realist evaluations can include qualitative and quantitative data collection and analysis, but may be purely quantitative or qualitative [220]. In reality most realist evaluations in health are qualitative in nature and any quantitative analysis focuses on outcomes, tending to either be descriptive or use hypothesis testing to assess statistical significance before and after intervention implementation [221]. Few use more advanced statistical modelling techniques, such as interrupted time series or regression [222, 223]. However, these techniques are used to compare outcomes across time or in different groups, rather than explore the relationship between context, mechanism and outcome configurations. Hawkins suggests propensity score matching as a counterfactual analytical technique to test realist theory without necessitating a randomised controlled trial [224]. However, propensity score matching does not easily allow for latent variables or understanding the relative strengths of CMO configurations.

A key discussion within realist methodology is what constitutes context within the context-mechanism-outcome logic. We have used the RAMESES II explanation of context within this analysis [225]. Here context is conceptualised as not referring “to places, people, time or institutions per se, but to the social relationships, rules, norms and expectations that constitute them, as well as the resources available (or not).” They are seen as “bound up with the mechanism(s) through which programmes work and need to be understood as an analytically distinct but interconnected element of a Context-Mechanism-Outcome configuration”. Therefore, context can be conceptualised as something that triggers a mechanism which in turn generates an outcome. This means that it can be internal or external to an individual, such as self-esteem or ease of getting through to the GP surgery.

Meditation analysis, one component of SEM, has been proposed as a technique for analysing quantitative data within realist methods by three studies, but none have yet reported findings [226-228]. In their protocol, Jamal and colleagues propose mediation analysis to explore mechanisms within a realist RCT. However, their methods have been debated [208]. Van Belle and colleagues argue that mediation analyses follow a successionist model of causal mechanisms (contexts lead to mechanism), rather than a realist generative model of mechanisms (“an unobserved entity, that when activated, generates an outcome of interest” [229]). Within a realist generative model of causation, mechanisms are a combination of reasoning and resources which cause outcomes to happen. Whilst Van Belle and colleagues do not appear to object to mediation analysis *per se*, they do disagree with a “mere variable” approach to analysis. While we agree that taking a purely

variable approach to context-mechanism-outcomes configurations risks missing the rich explanatory benefits of realist approaches, we do not propose that SEM, and by association mediation analysis, should be the sole analysis technique for generating, exploring or assessing the strength of CMO configurations. These techniques could complement analyses of qualitative data, for example, by helping to elucidate the relative importance of a range of CMOs that lead to a similar outcome (as in the case of this paper).

#### *5.8.4 Policy implications*

Hawkins argues that realist methods, and its subsequent theory, should consider both the effect size of CMO configurations and the extent to which they are reusable in complex adaptive systems [224]. Importantly, this would help decision makers by providing an estimated size of effect for each CMO, allowing a more informed decision to be made about which targeted contexts, if improved, would result in a greater change in outcome. These results can then be interpreted alongside financial considerations, qualitative findings and practical issues, such as infrastructure and workforce, to improve the intervention or programme.

#### *5.8.5 Methodological implications*

SEM is a useful technique to explore, and complement, realist theory. Future realist evaluations should consider using it to measure the associations between context and outcome via a mechanism. Some evaluations may benefit from both the measurement (i.e. generation of latent variables) and structural (e.g. mediation analysis) components or only the structural part. The measurement aspect would be most useful in evaluations where there are numerous unobservable or latent concepts.

Using primary data to support the CMO configurations (i.e. collecting data from patients based on a bespoke questionnaire with measures of all the included concepts) would have improved the quality of our study. Our recommendation is that future studies using SEM to explore realist theory should endeavour, where possible, to collect primary data to ensure that concepts are captured sufficiently. Furthermore, continuous variables should be preferred when using SEM to improve model identification. Future research should explore other SEM techniques, such as, growth mixture modelling to explore changes over time, and multiple group comparison to compare groups.

### 5.8.6 *Conclusions*

SEM allows quantification of context-mechanism-outcome configurations within realist theory; complementing qualitative data and descriptive quantitative analysis. Future research is needed to further develop the synthesis of SEM techniques and realist approaches.

This study is the third method, alongside the realist review (Chapter 3) and qualitative study (Chapter 4), used to understand how socio-economically disadvantaged older people in rural areas access primary care. In the next chapter, the findings from these three methods are synthesised into one overall programme theory using a mixed method matrix.

## **6 Synthesis of findings and intervention development**

### **6.1 Preamble**

This chapter presents 1) a synthesis of the findings from the realist review (Chapter 3), qualitative study (Chapter 4) and cohort analysis (Chapter 5), and 2) the intervention development. It describes changes to the planned triangulation protocol, a mixed method matrix comparing the findings from each study, a discussion of any discrepancies between the methods, the final overall programme theory and the intervention development process and outcome. This chapter pulls together findings from Chapters 3, 4 and 5 and shows how the intervention, described in the trial in Chapter 7, was developed.

## 6.2 Introduction

Findings from the realist review (Chapter 3), qualitative study (Chapter 4) and analysis of the English Longitudinal Study of Ageing (Chapter 5) were synthesised using a triangulation protocol and mixed method matrix. A triangulation protocol is a process of gaining a fuller understanding of a problem by using different research methods [91]. Whilst it is described and advocated in the literature, few worked examples exist [91]. Here it is used to describe the overall process of how each method informed, or was informed by, each other method. For example, how findings from the realist review informed the qualitative study and ELSA analysis. Part of the triangulation protocol is a mixed methods matrix, also known as a convergence coding matrix [91]. A mixed methods matrix is a process of comparing findings of different studies to explore convergence, dissonance, complementarity and silence. In particular, it highlights recurrent themes, or meta-themes [105], and any inter-method discrepancy [230]. Inter-method discrepancies are particularly helpful because they can often provide a more in-depth and insightful understanding of the data compared to reporting each method sequentially [230]. Using a triangulation protocol and mixed methods matrix facilitates an overall realist, CMO-based theory to be produced. This is suitable for intervention development because it can highlight contexts that, if modified, may trigger a mechanism leading to an increased likelihood of an outcome.

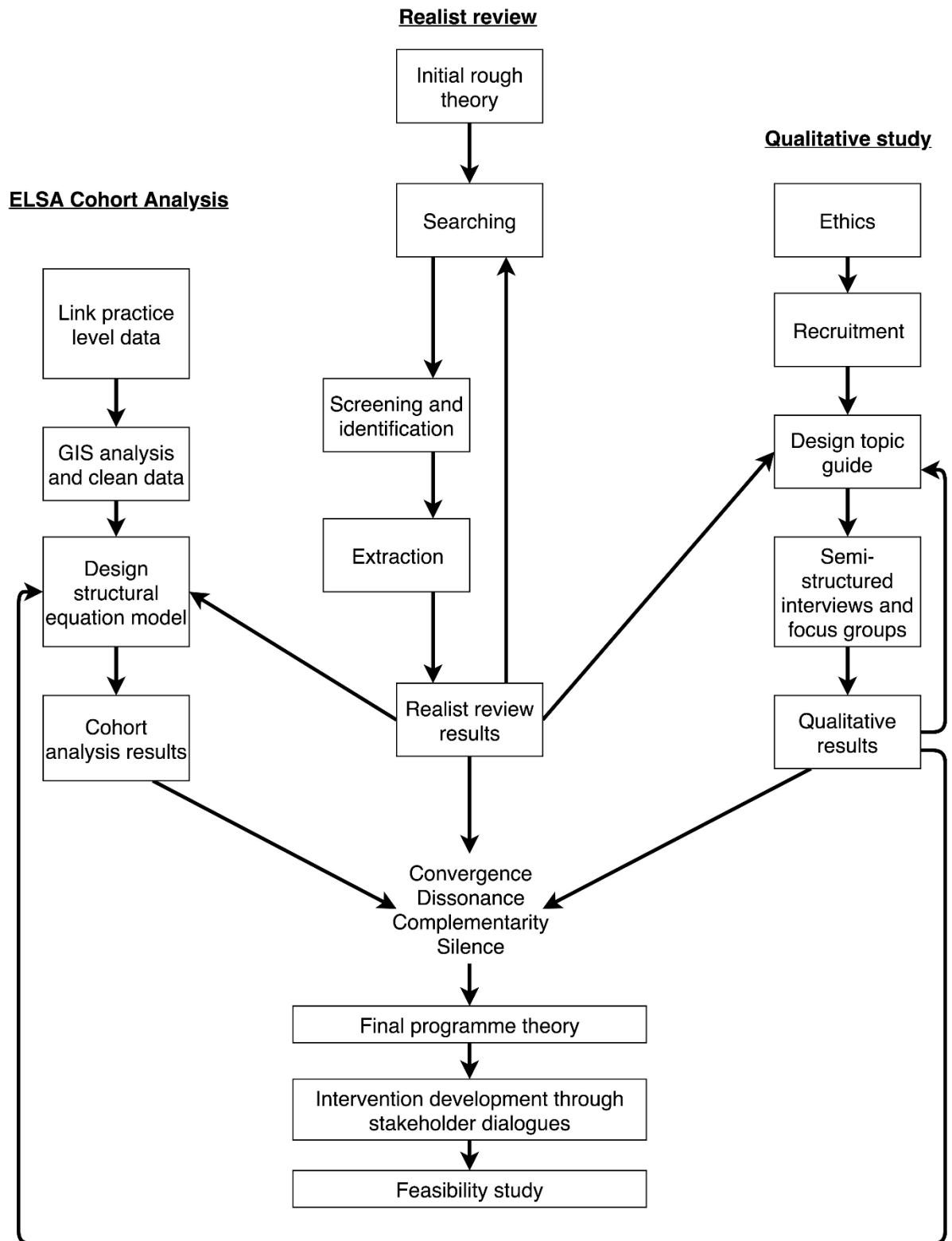
## 6.3 Initial and modified triangulation protocol

The pre-specified triangulation protocol is shown in Figure 3 (page 21). First, a realist review was undertaken which by nature was iterative; initial results led to more searching and re-analysis. The realist review informed the topic guide for the qualitative interviews and focus groups. Data collected from interviews and focus groups were concurrently analysed to allow emerging themes to be explored in subsequent interviews and focus groups. Findings from the realist review and qualitative study were then used to inform the structural equation modelling (SEM).

Two modifications were made to the pre-specified triangulation protocol and the modified triangulation protocol is shown in Figure 14. The modifications were:

1. Due to the sequence of events and delays in accessing data from ELSA it was not possible for the findings of the ELSA analysis to inform the qualitative topic guide.
2. Whilst more literature searching was undertaken based on the findings from the qualitative study and analysis of ELSA, they did not directly inform the realist review findings but were integrated subsequently.

Figure 14: Modified triangulation protocol



## **6.4 Mixed methods matrix**

A mixed method matrix was then used to integrate the findings into one overall realist programme theory of CMO configurations. First, all the CMO configurations from the realist review were listed. The qualitative study used thematic analysis, therefore re-analysis was needed using a realist logic to allow comparison with the realist review. CMO configurations from the qualitative study were then individually compared with the findings from the realist review to consider if they matched (convergence), did not match but supported (complementarity), disagreed (dissonance) or lacked any data (silence). New CMO configurations arising from the qualitative data were added to the mixed methods matrix and data from the realist review re-examined to assess if these CMOs were present.

SEM of ELSA was used in a confirmatory, rather than exploratory, manner (i.e. new CMOs were not generated but CMOs from the realist review and qualitative study were assessed). An exploratory analysis is used in the absence of existing theory where pathways are hypothesised based on clinical experience or logical conjecture from existing evidence. Exploratory SEM was not appropriate here because there was already pre-existing theory based on findings from the realist review and qualitative study. Within the mixed method matrix, non-statistically significant results from the SEM were interpreted as not supporting the proposed CMO (dissonance). However, when building the final overall realist theory dissonance between findings from 1) the realist review and/or qualitative study and 2) the ELSA analysis were not considered because the small sample size in the ELSA analysis may have led to non-statistically significant effects. Therefore, the final theory was produced by combining all CMOs between the realist review and qualitative study where there was convergence, complementarity or silence, and excluding those where there was dissonance.

## **6.5 Findings from mixed methods integration**

The mixed method matrix is shown in Table 14. There were 96 different CMO configurations identified from the realist review and qualitative study. Of these 96 CMO configurations, there were 46 different contexts and 22 different mechanisms across seven different outcomes.

Table 14: Mixed methods matrix

Key = √ - evidence for CMO, = - convergence, + - complementarity, ≠ - dissonance, 0 - silence

Step in pathway	CMO configuration	Realist review	Qualitative study	ELSA analysis
Problem identified	Educational status – health literacy – problem identified	√	0	0
	Health literacy –evaluation of evolving experiences – problem identified	√	+	0
	Problematic experience – denial – problem identified	√	0	0
	Problematic experience – health literacy – problem identified	=	=	0
	Social network – denial – problem identified	√	+	0
	Social network – health literacy – problem identified	√	+	0
	Stoicism – denial – problem identified	√	0	0
	Carer responsibilities - denial - problem identified	0	√	0
	Preventative medicine – medicalisation of ageing – problem identified	0	√	0
Decision to seek help	Carer responsibilities-convenience –decision to seek help	=	=	0
	Expectations of ageing – perceived control –decision to seek help	√	0	0
	Expectations of ageing- candidacy –decision to seek help	√	≠ and +	0
	Expectations of ageing-denial –decision to seek help	√	0	0
	Expectations of ageing-perceived ability to benefit –decision to seek help	√	+	0
	Experience of health care – anxiety – decision to seek help	√	+	0
	Experience of health care – perceived social exclusion –decision to seek help	√	+	0
	Experiences of health care- candidacy –decision to seek help	=	=	0
	Experiences of health care-perceived ability to benefit –decision to seek help	=	=	0
	Experiences of symptoms- candidacy –decision to seek help	=	=	0
	Financial resources-convenience –decision to seek help	√	0	0
	Financial resources-denial –decision to seek help	√	0	0
Lifelong poverty – perceived control –decision to seek help	√	≠	0	



Step in pathway	CMO configuration	Realist review	Qualitative study	ELSA analysis
	Lifelong poverty – perceived social exclusion –decision to seek help	√	≠	0
	Lifelong poverty- candidacy –decision to seek help	√	≠	0
	Perceived limited health resources - candidacy –decision to seek help	√	≠	0
	Perceived limited health resources – perceived social exclusion –decision to seek help	√	≠	0
	Relevance of services- candidacy –decision to seek help	√	≠ and +	0
	Self-esteem – perceived control –decision to seek help	√	0	0
	Self-esteem- candidacy –decision to seek help	√	0	0
	Social networks – anxiety – decision to seek help	=	=	0
	Social networks- candidacy –decision to seek help	=	=	0
	Social networks -perceived ability to cope –decision to seek help	√	+	0
	Stoicism-denial –decision to seek help	√	≠	0
	Stoicism-perceived ability to cope –decision to seek help	√	0	0
	Transport-convenience –decision to seek help	√	+	0
	Changing world – convenience – decision to seek help	0	√	0
	Sparing use of service – candidacy – decision to seek help	0	√	0
	Attitudes to older people – candidacy – decision to seek help	0	√	0
Actively seek help	Choice – perceived ability to benefit – actively seek help	=	=	0
	Clear information – convenience – actively seek help	√	+	0
	Clear information – health literacy – actively seek help	√	+	0
	Clear information – patient empowerment – actively seek help	√	+	0
	Educational status – health literacy – actively seek help	√	0	0
	Experience of health care – perceived ability to benefit – actively seek help	=	=	0
	Extent to which practice is welcoming – affinity to practice – actively seek help	√	+	0
	Extent to which practice is welcoming – patient empowerment – actively seek help	√	≠ and =	0
	Extent to which practice is welcoming – perceived ability to benefit – actively seek help	=	=	0

Step in pathway	CMO configuration	Realist review	Qualitative study	ELSA analysis
	Relationship with GP – affinity to practice – actively seek help	√	≠ and +	0
	Self-efficacy – health literacy – actively seek help	√	0	0
	Self-efficacy – patient empowerment – actively seek help	√	0	0
	Transport – convenience – actively seek help	√	≠ and +	0
Obtain an appointment	Available appointments - convenience -obtain an appointment	=	=	0
	Capacity in practice – responsiveness -obtain an appointment	√	+	0
	Clear information-health literacy-obtain an appointment	=	=	≠
	Ease of booking system-convenience -obtain an appointment	=	=	=
	Educational status-health literacy-obtain an appointment	√	0	≠
	Educational status-patient empowerment-obtain an appointment	√	0	0
	Experience of health care-convenience -obtain an appointment	=	=	=
	Experience of health care-patient empowerment-obtain an appointment	=	=	0
	Lifelong poverty-patient empowerment-obtain an appointment	√	+	0
	Self-esteem-assertiveness-obtain an appointment	√	+	≠
	Transport - convenience -obtain an appointment	=	=	≠
	Understanding the practice system-assertiveness-obtain an appointment	=	=	≠
	Understanding the practice system-convenience -obtain an appointment	√	+	≠
	Understanding the practice system-patient empowerment-obtain an appointment	=	=	0
	Use of technology-convenience -obtain an appointment	=	=	≠
	Use of technology-patient empowerment-obtain an appointment	√	+	0
	Unmet need – social support- obtain an appointment	0	√	0
	Personal skills – patient empowerment- obtain an appointment	0	√	0
	Helpfulness of the receptionist – patient empowerment – obtain an appointment	0	√	0
	Home visit policy – convenience – obtain an appointment	0	√	0
Expectation – convenience- obtain an appointment	0	√	0	

Step in pathway	CMO configuration	Realist review	Qualitative study	ELSA analysis
	Priorities – responsiveness – obtain an appointment	0	√	0
	Public expectations – capacity – obtain an appointment	0	√	0
Get to appointment	Formal community support – convenience – get to appointment	√	0	0
	Geographic isolation – convenience – get to appointment	=	=	0
	Social network – convenience – get to appointment	=	=	0
	Transport – convenience – get to appointment	=	=	0
	Financial resources - affordability – get to appointment	0	√	0
	Mobility – convenience – get to appointment	0	√	0
Primary care interaction	Capacity within practice – empowered clinician – primary care interaction	√	+	0
	Clinician empathy – articulation of health problem – primary care interaction	=	=	0
	Clinician empathy – patient empowerment – primary care interaction	=	=	0
	Continuity of care – articulation of health problem – primary care interaction	√	≠ and =	0
	Continuity of care– equal status – primary care interaction	=	=	0
	Continuity of care– trust – primary care interaction	√	≠ and =	0
	Educational status – articulation of health problem – primary care interaction	√	0	0
	Emotional distress – patient empowerment – primary care interaction	√	0	0
	Experience of health care – patient empowerment – primary care interaction	=	=	0
	Financial resources – patient empowerment – primary care interaction	√	0	0
	Perceived ability to benefit – equal status – primary care interaction	√	0	0
	Perceived discrimination – equal status – primary care interaction	=	=	0
	Self-esteem – patient empowerment – primary care interaction	√	+	0
	Social distance – articulation of health problem – primary care interaction	√	≠ and +	0
	Social distance – equal status – primary care interaction	=	=	0
Trust in health care – equal status – primary care interaction	√	+	0	

A summary comparing agreement or disagreement is shown in Table 15. There were only two CMOs that had convergence among all three methods: 1) past health care experiences (context) triggering perceived convenience (mechanism) leading to an increased likelihood of obtaining an appointment (outcome), and 2) ease of booking system (context) triggering perceived convenience (mechanism) leading to an increased likelihood of obtaining an appointment.

Table 15: Summary of mixed method matrix

<b>Comparison between realist review, qualitative study and ELSA analysis</b>	<b>Number of CMOs</b>
Present in only one method	33
Convergence between realist review and qualitative study	22
Present in realist review and complemented by qualitative study	18
Present in realist review but mixed findings in qualitative	8
Present in realist review but disagreement in qualitative	6
Convergence between realist review and qualitative study but not supported by ELSA analysis	4
Present in realist review, complemented in qualitative findings but not in ELSA analysis	2
Convergence between all methods	2
Present in realist review but disagreement in ELSA analysis	1
<b>Total</b>	<b>96</b>

For 22 CMOs there was convergence between the realist review and qualitative study and for a further 18 the CMO from the realist review was complemented by the qualitative study. Furthermore, for eight CMOs from the realist review there was mixed evidence from the qualitative study, sometimes being support and other times opposed, because of conflicting data from individuals.

For six CMOs, relating to three contexts, there was disagreement between the realist review and qualitative study. These were as follows:

1. Three were related to the context of lifelong poverty. The realist review suggested that the context of lifelong poverty would trigger individuals to have less perceived control over their health care, greater sense of social exclusion and/or feeling ineligible for health services, leading to a decision not to seek health care. However, the qualitative interviews collected data from several individuals who experienced lifelong disadvantaged indicated that lifelong poverty did not trigger these mechanisms, but these individuals reported feeling in control and entitled to health care.
  - Possible explanation: Different populations were examined in the realist review and qualitative study. Two studies contributing data to the CMO from the realist review were 20-year-old cohort studies that used social class as a measure of deprivation [149, 151]. This definition included unskilled workers in the lowest

deprivation category. However, the qualitative study here recruited participants who received means-tested financial support. There may be a difference between disadvantaged individuals who have relied on means-tested support throughout their life and low skilled workers who have not. For example, those who have relied on lifelong means-tested support may be more experienced at engaging with, and navigating, public services.

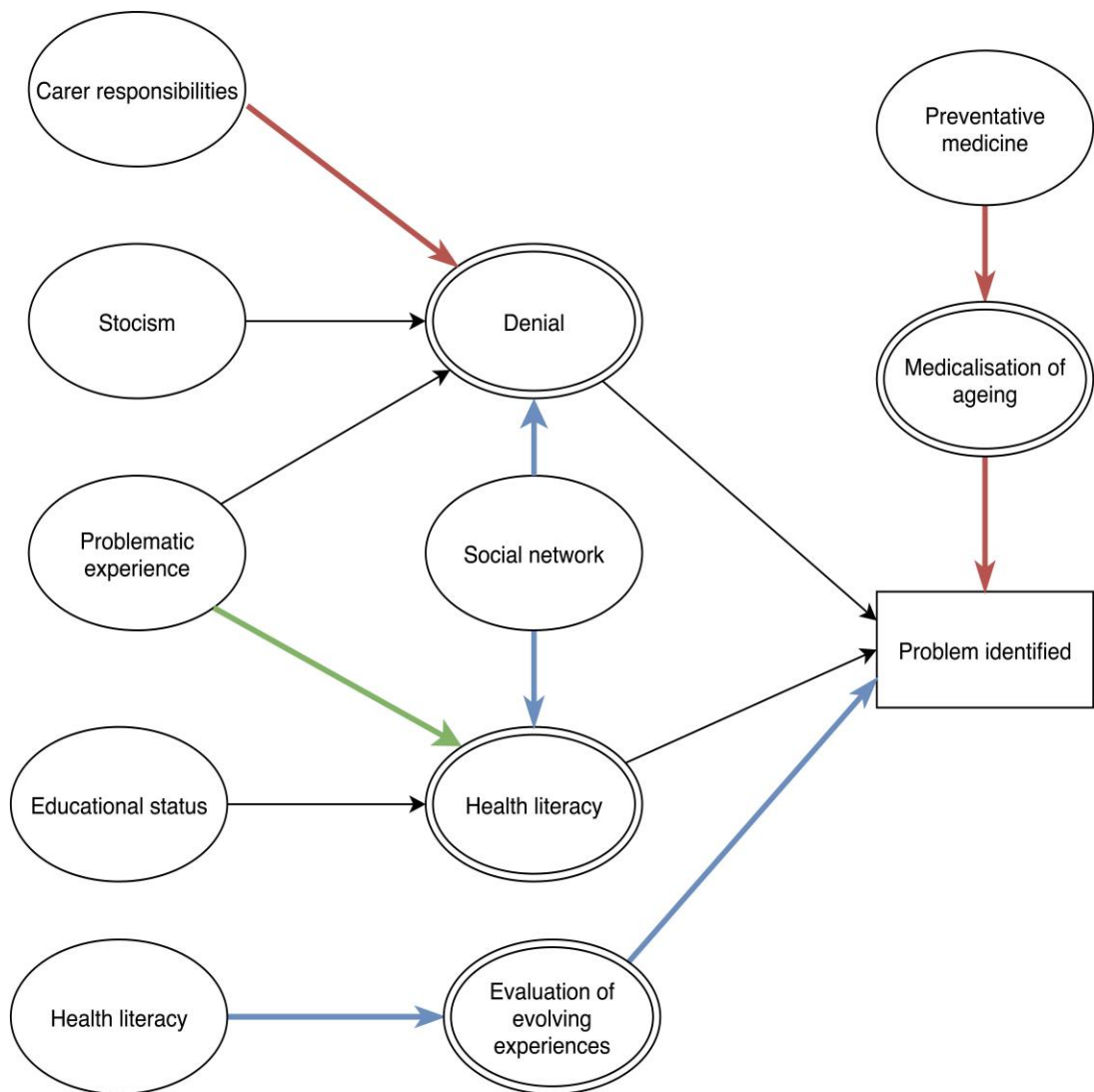
2. Two disagreements arose from the context of perceived limited resources. The realist review suggested that where there are limited resources, socio-economically disadvantaged older people may feel ineligible or excluded from services leading to a decision not to seek help. However, the interviews did not support this; limited resources did not seem to influence an individual's decision to seek help.
  - Possible explanation: The realist review data primarily came from a qualitative study, using mini-ethnography, of older people in a village community in the south of England published in early 2003 with data collection probably in 2001 [80]. The author found that rural, older people were careful not to bother the doctor and in particular were less likely to seek help if they thought the cost to the NHS was high or GPs were particularly busy. In the qualitative study, there was a tension; on one hand participants reported being careful not to unnecessarily visit the doctor, but equally they reported that they would attend if they needed to irrespective of the financial position or business of the GP surgery. The inter-method discrepancy here may have arisen because: 1) the different qualitative techniques used, ethnography and semi-structured interviews generate different data; or 2) a generational difference, because the realist review data included mostly participants who experienced health care pre-NHS as adults, and the qualitative study mostly participants who experienced health care pre-NHS as children or were born after the NHS was established.
3. The final disagreement was related to the context of stoicism. The realist review suggested that in the context of stoicism, individuals might deny knowledge of a health problem and therefore decide not to seek help. Whereas the qualitative interviews suggested that this was not the case and individuals were comfortable acknowledging health problems.
  - Possible explanation: This difference may have arisen because of different health care systems. The realist review data came from an American longitudinal questionnaire of rural patients in relation to cardiac disease [140] in which participants would have paid, either directly or via insurance, for health care. This may have increased an individual's stoicism and reluctance to acknowledge health concerns. Whereas the participants in the qualitative study had health care free at the point of use. Alternatively, it is possible that during the interviews the individual was not aware of a health problem that they were in denial about.

Based on the integration of the data from the different sources it was possible to refine the CMO diagrams arising from the realist review (Figure 6, Figure 7, Figure 8, Figure 9, Figure 10 and Figure 11). These refined diagrams for the final integrated theory are shown in Figure 16, Figure 17, Figure 18, Figure 19, Figure 20 and Figure 21.

Figure 15: Patient pathway



Figure 16: Integrated problem identified diagram



**Key**

- Black – present in realist review but not qualitative study
- Green- agreement between realist review and qualitative study
- Red – new CMO from qualitative study
- Blue – realist review CMO complemented by qualitative study
- Single border node – context
- Double border node – mechanism
- Square node - outcome



Figure 17: Integrated decision to seek help diagram

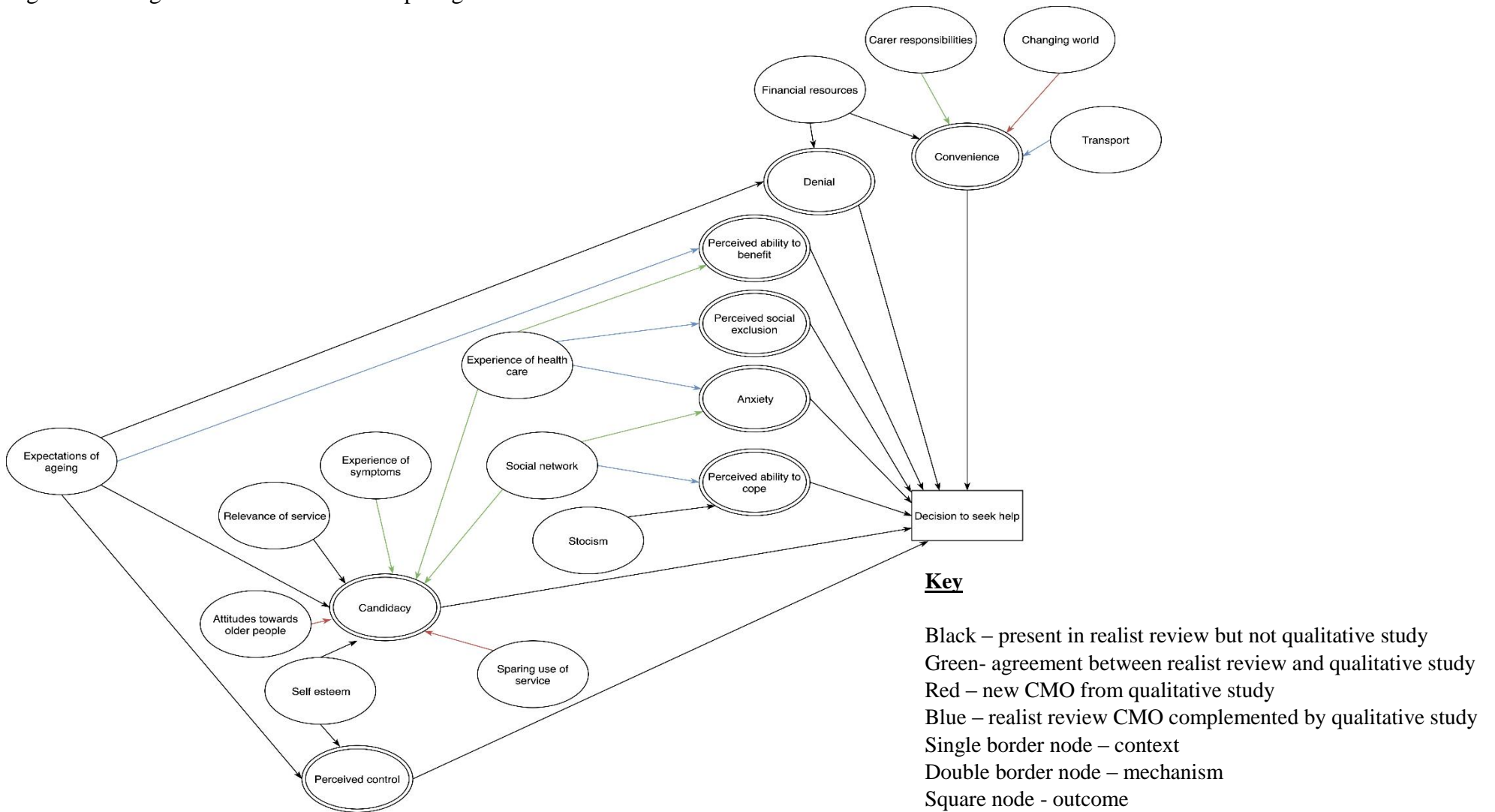


Figure 18: Integrated actively seek help diagram



**Key**

- Black – present in realist review but not qualitative study
- Green- agreement between realist review and qualitative study
- Red – new CMO from qualitative study
- Blue – realist review CMO complemented by qualitative study
- Single border node – context
- Double border node – mechanism
- Square node - outcome

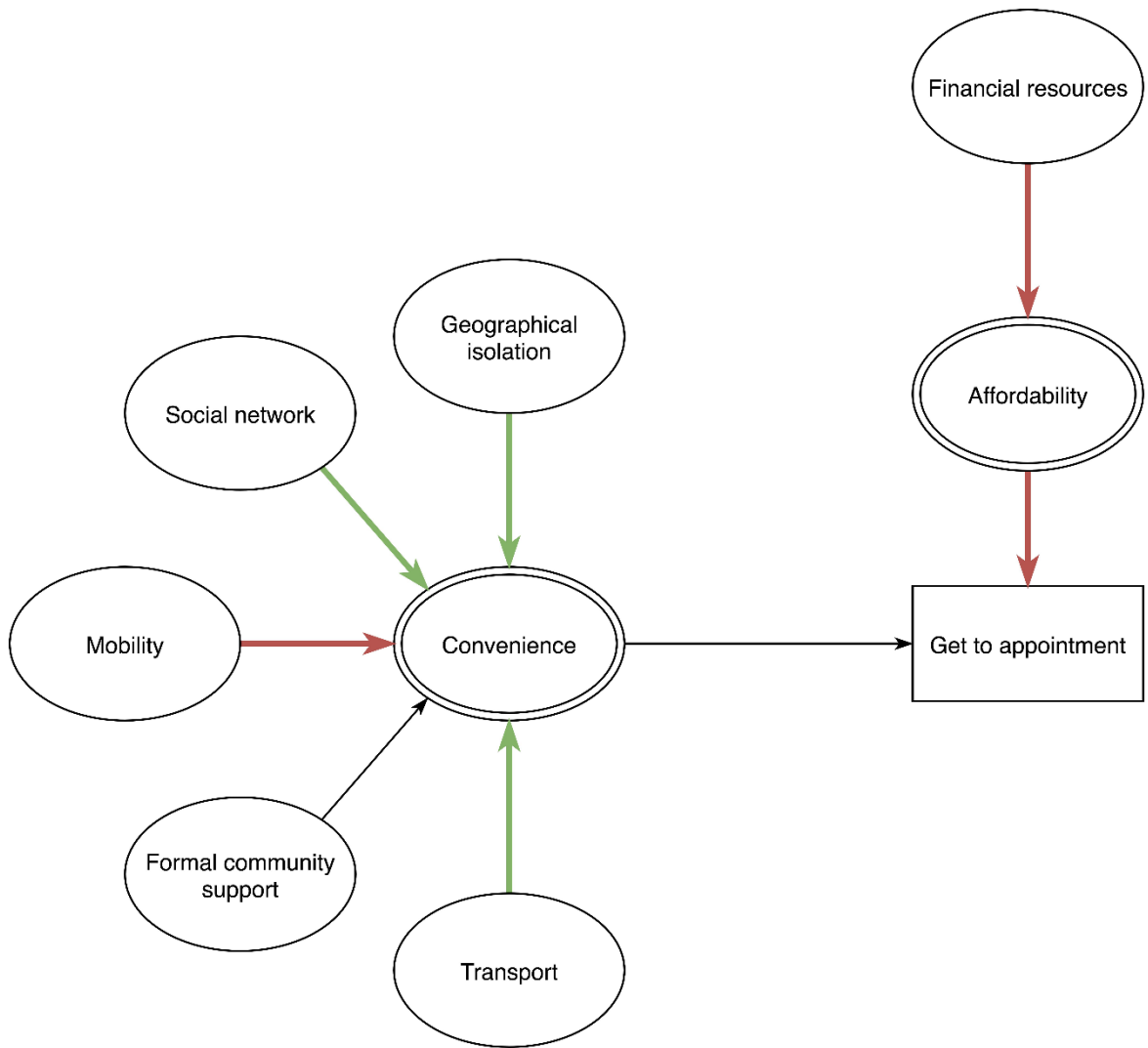
Figure 19: Integrated obtain an appointment diagram



**Key**

- Black – present in realist review but not qualitative study
- Green- agreement between realist review and qualitative study
- Red – new CMO from qualitative study
- Blue – realist review CMO complemented by qualitative study
- Single border node – context
- Double border node – mechanism
- Square node - outcome

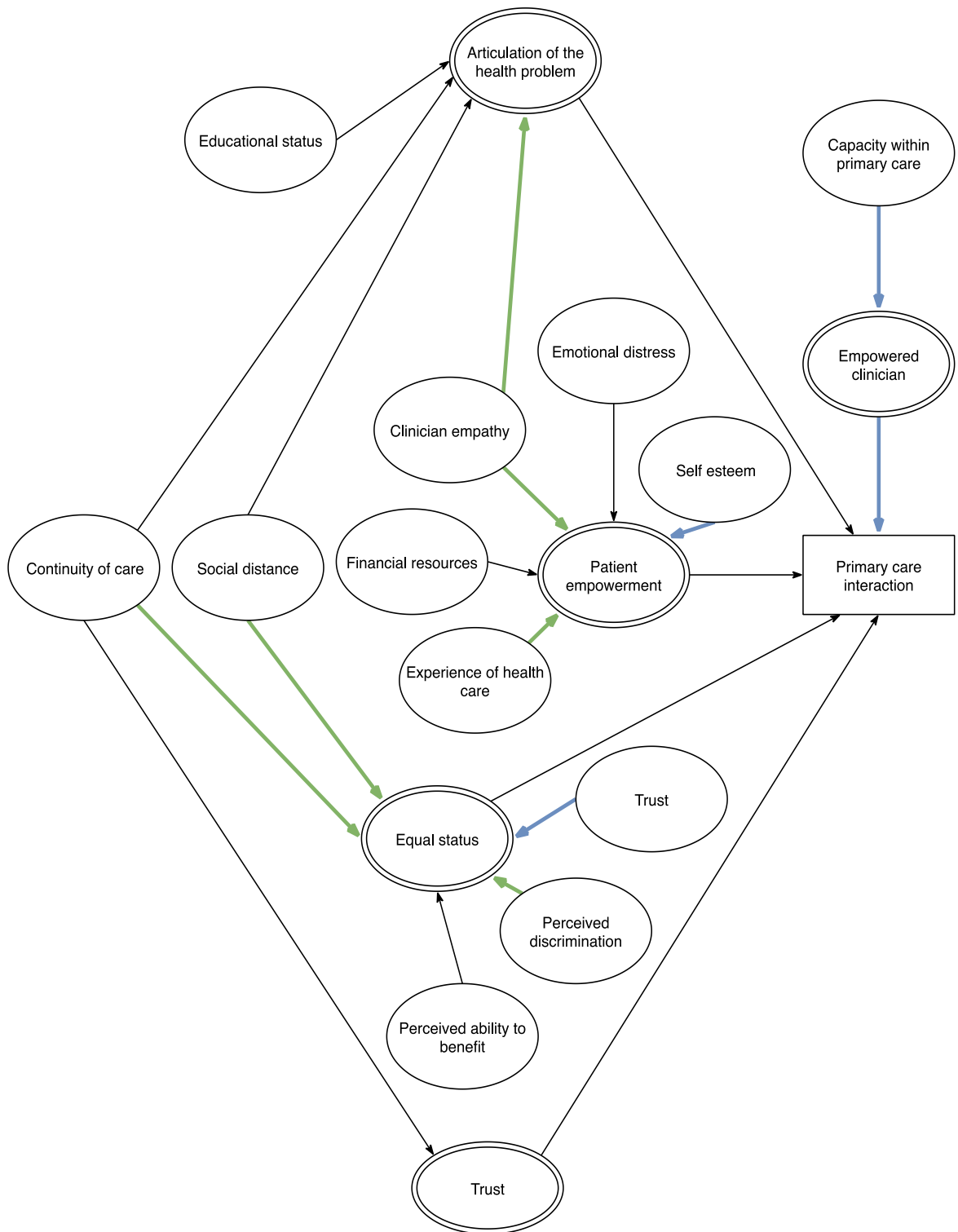
Figure 20: Integrated get to appointment diagram



**Key**

- Black – present in realist review but not qualitative study
- Green- agreement between realist review and qualitative study
- Red – new CMO from qualitative study
- Blue – realist review CMO complemented by qualitative study
- Single border node – context
- Double border node – mechanism
- Square node - outcome

Figure 21: Integrated primary care interaction diagram



**Key**

- Black – present in realist review but not qualitative study
- Green- agreement between realist review and qualitative study
- Red – new CMO from qualitative study
- Blue – realist review CMO complemented by qualitative study
- Single border node – context
- Double border node – mechanism
- Square node - outcome

## 6.6 Intervention development

The intervention was developed through a process of stakeholder dialogues, review of the overall programme theory arising from the realist review, qualitative study and ELSA analysis and discussion within the research team. This section describes the process and how the intervention evolved.

### 6.6.1 *Key requirements for the intervention based on stakeholder dialogues*

Drawing on the overall programme theory, 12 stakeholder dialogues were undertaken with nine general practice staff (three GPs and six practice managers or administrators), one external academic expert and two public and patient representatives. The stakeholder dialogues involved either face-to-face discussions or telephone conversations to discuss the results and potential interventions. The conversations were not recorded, but notes were taken throughout. As ideas emerged, they were discussed in subsequent stakeholder dialogues.

Based on these discussions some key requirements of the intervention started to emerge. First, the intervention had to address an important issue for socio-economically disadvantaged older people in rural areas relating to access; there was little point in trying to tackle a peripheral issue. Second, the practices would need to have influence over, and be able to implement in a short-time frame, any intervention. Third, flexibility was required because each practice had its own unique needs and requirements; one single, rigid intervention was unlikely to be suitable. Finally, and where possible, the intervention should draw on the overall programme theory and incorporate realist principles.

### 6.6.2 *Review of overall programme theory*

The overall programme theory was reviewed to identify the most important barriers which could be influenced by practices in a short time scale. While much of the literature covered health-seeking behaviour, the qualitative study highlighted that booking an appointment and physically getting to the surgery for those without car access were major barriers. Other major barriers included issues, such as previous health care experiences; however, these barriers were felt to be harder to overcome and may not deliver the same benefit. Transport for those without a car and the booking system represented one patient-side and one practice-side barrier and were included in the patient pathway ('Obtain and appointment' Figure 19 and 'Get to appointment' Figure 20). The associated CMO configurations below show that an intervention that modified the context of the ease of the booking system or transport options should trigger the mechanism of convenience and in turn help people to get an appointment or get to the surgery.

- 1) Ease of booking system – convenience – obtain an appointment
- 2) Transport options – convenience – get to appointment

### 6.6.3 *Initial idea for intervention*

During the stakeholder dialogues, the idea emerged of allowing practices, with support, to develop their own intervention. Most practices had ideas of what could be done to improve the booking system and transport or, based on previous experience, knew what was unlikely to work. Allowing practices to develop their own intervention meant that they could develop bespoke service changes to fit in with their own issues, assets and history and it would also complement the realist principles of understanding what works in different contexts.

### 6.6.4 *Evolution of intervention*

The idea was supported and developed in subsequent stakeholder dialogues in the following ways. The practices would need criteria to ensure that interventions could be implemented in a short time frame and it may also be helpful to provide ideas from the published or grey literature. It was clear that the practices would need funding and £1500 was felt to be a reasonable amount compared with other schemes. The conditions of the £1500 were discussed and it was decided that practices would be given the funding irrespective of the amount they spend. For example, a practice may spend £200 or £300, but would still be given the full amount. It was hypothesised that this may lead to more cost-effective interventions because it would incentivise practices to achieve the proposed outcomes at the lowest cost. It may also incentivise practices to make choices which do not involve “out-of-pocket” costs, such as buying new equipment, but rather sunk costs which they are already paying, such as staff time.

Initially the intervention consisted of an evidence brief of the existing literature, service specification and £1500 grant. The purpose of the service specification was to state the objectives of the intervention (improving the booking system and transport) and criteria to ensure that the intervention was deliverable, such as the proposed implementation period. There was concern from some that practices, because of time pressures, may simply choose the quickest and easiest option without proper consideration. To address this concern, four structured development meetings, a logic model and an additional criterion requiring practices to develop an intervention different to current practice were added.

The stakeholder dialogues also identified some concerns. First, some practice managers suggested that practices might be uneasy about improving the booking system to one specific group of the population over another. For example, some were of the opinion that they had a legal duty to deliver an equal service to all registered patients and by modifying the booking system in favour of socio-economically, disadvantaged older people it would be unfair to the rest of the registered

population. However, others acknowledged that this already happens with some services, for example online booking where only patients with the internet can access more appointments. Second, the limited number of appointments available was a core issue and most practices were not able to increase this because of finances, limited workforce or space constraints. Therefore, improving the booking system may have limited benefit because of the lack of appointments. However, it was also felt that improving the efficiency of the booking system or shifting the balance of telephone and face-to-face appointments in certain populations may release resource for patients who are more complex.

#### *6.6.5 Final intervention*

After this iterative process, the final intervention consisted a support package of 1) a support manual with an evidence brief, service specification and logic model, 2) four development meetings and 3) a £1500 grant. There would essentially be two levels of intervention; the trial-level intervention of a support package provided to all intervention practices and a practice-level intervention developed by each practice separately that would, most likely, be different.

This chapter has described how the three studies, a realist review, qualitative study and cohort analysis, were synthesised together and an intervention developed using stakeholder dialogues. The next chapter presents a cluster feasibility trial of the intervention.



## **7 Improving primary care Access in Context and Theory (I-ACT trial): a theory informed randomised cluster feasibility trial using a realist perspective**

### **7.1 Preamble**

Drawing on the intervention developed in Chapter 6, this chapter presents the aims, methods, results and discussion of the fourth study: a cluster feasibility trial looking at how socio-economically disadvantaged older people in rural areas access primary care. It has been submitted for publication (Sept 2018 to *Trials*). It is largely a replication of the submitted manuscript, except for removal of some text from the *Background*, the content of which is covered in Chapter 1, text in the discussion relating to realist RCTs which is discussed in more detail in Chapter 8 (section 8.4.4, page 158), and formatting changes to improve consistency. The purpose of this study was to assess the feasibility of the intervention and the design of the trial.

## **7.2 Chapter summary**

### *7.2.1 Background*

Primary care access can be challenging for older, rural, socio-economically disadvantaged populations. Building on our previous research, here we report the I-ACT cluster feasibility trial which aims to assess the feasibility of trial design and context-sensitive intervention to improve primary care access for this group and so expand our initial theory.

### *7.2.2 Methods*

Four general practices were recruited; three randomised to intervention and one to usual care. Intervention practices received £1500, a support manual and four meetings to develop local, innovative solutions to improve the booking system and transport.

Patients over 64 years old and without household car access were recruited to complete questionnaires when booking an appointment or attending the surgery. Outcome measures at six months included: self-reported ease of booking an appointment and transport; healthcare use; patient activation; capability; and quality of life. A process evaluation involved observations and interviews with staff and participants.

### *7.2.3 Results*

Thirty-four patients were recruited (26 females, 8 males, mean age 81.6 years for intervention group and 79.4 for usual care) of 1,143 invited (3% response rate). Most were ineligible because of car access. Twenty-nine participants belonged to intervention practices and five to usual care. Practice level data were available for all participants, but participant self-reported data was unavailable for three (9%). Fifty-six appointment questionnaires were received based on 150 appointments (37.3%).

Practices successfully designed and implemented the following context-sensitive interventions: Practice A: a stacked phone system and promoting community transport; Practice B: signposting to community transport, appointment flexibility, mobility scooter charging point and promoting the role of receptionists; and Practice C: local taxi firm partnership and training receptionists. Practices found the process acceptable because it gave freedom, time and resource to be innovative or provided an opportunity to implement existing ideas. Data collection methods were acceptable to participants, but some found it difficult remembering to complete booking and appointment questionnaires. Expanded theory highlighted important mechanisms, such as reassurance, confidence, trust and flexibility.

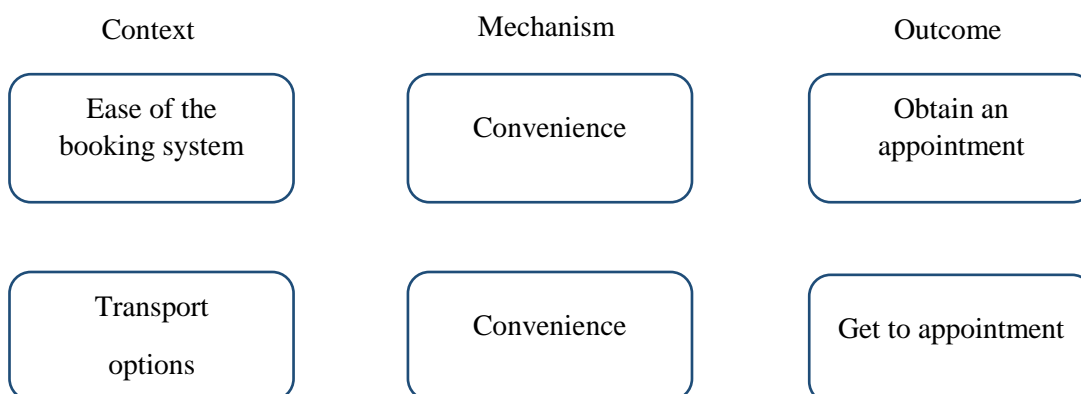
#### 7.2.4 *Conclusions*

Recruiting older participants without access to a car proved challenging, but retention was good. This study design may facilitate a shift from one-size-fits-all interventions to more context-sensitive interventions.

### 7.3 Background

Primary care access can be challenging for older, rural, socio-economically disadvantaged populations. Based on a realist review, qualitative study and analysis of a national cohort study, we identified the booking system and transport for those without car access as important issues suitable for intervention. They were judged to be suitable because GP surgeries could potentially influence or support them in a short time frame. A brief overview of the associated realist CMO configuration is shown in Figure 22. Whilst there is overlap between the concepts of *ease of booking system* and *convenience*; they are different. The ease of the booking system is concerned with how simple and straightforward the process is of booking an appointment based on practice procedures and protocols, whereas convenience is more concerned with the suitability or usefulness of those processes for an individual. For example, a booking system that offers predominantly same day appointments may be viewed as easy, but not convenient for patients without car access who need to arrange transport.

Figure 22: Context-mechanism-outcome configurations associated with the booking system and transport



We designed the I-ACT cluster feasibility trial to assess the feasibility of a trial design and context-sensitive intervention. Specifically, we aimed to 1) assess the recruitment and retention of participants and practices, 2) assess the ability of practices to develop and implement their own service changes and acceptability of the process, 3) assess the acceptability of data collection methods and 4) expand the initial CMO-based theory (Figure 22).

## **7.4 Methods**

### *7.4.1 Study design and practice recruitment*

We undertook a cluster randomised controlled feasibility study. Ethical approval was obtained from the NHS North East National Research Ethics Committee (ref 16/NE/0424 Appendix 8, protocol Appendix 9). We recruited four general practices in Norfolk, England, on a first-come first-served basis via the Eastern Clinical Research Network of research-active practices. Practice eligibility was: a rural practices as classified by the Health and Social Care Information Centre [231], list size of over 7000 and agreement to develop and implement service changes. Each practice was profiled using publicly available data and discussions with practice staff to describe the demographics, organisational structure and issues relating to access.

### *7.4.2 Participant eligibility*

We aimed to recruit 10 participants from each practice for data collection. To be included, participants had to be 65 years or older and have two or more repeat prescriptions at baseline (to only include those with existing health need), 12 or fewer face to face GP or nurse visits over the past 12 months (to exclude frequent attenders who were less likely to have problems using the service) and no household car access. Patients were excluded if they had cognitive impairment, such that written informed consent was not possible, were unable to speak English, or did not usually book their own appointments.

### *7.4.3 Recruitment*

Practices undertook an electronic search to identify patients who met age, medication and primary care visits criteria. It was not possible to search for those without car access, so this eligibility criterion was described in the invitation letter. From the identified patients, 150 were randomly selected for invitation, providing clinical staff judged that they were suitable (e.g. did not have significant cognitive impairment). Later, several additional strategies were introduced to increase recruitment: an additional 150 patients invited, reminder letters sent, and letters of invitations handed out by reception and in-practice pharmacy staff. If patients met the eligibility criteria and were interested, a researcher (JF) visited to obtain written informed consent and collect baseline data (consent from Appendix 10 and participant information sheet Appendix 11).

### *7.4.4 Randomisation*

All participants were recruited prior to randomisation of practices. Norwich Clinical Trials Unit undertook simple, block randomisation using sealed opaque envelopes with a ratio of 3

intervention practices to 1 usual care. Whilst it was not possible to blind participants or practices to the allocation, care was taken by the research team not to inform participants of the allocation.

#### 7.4.5 *Intervention and usual care*

Practices allocated to the intervention arm were asked to improve the ease of the booking system and transport options for socio-economically disadvantaged older people without access to a car. To achieve this, practices were given a support manual (Appendix 12), containing an evidence summary and trial requirements, four development meetings with the lead researcher (JF) over a four-week period and a grant of £1500 as summarised in Table 16. The evolution of the intervention is described in Chapter 6 (section 6.6).

Table 16: Summary of the intervention

<b>Components of the intervention</b>
Support manual containing an overview of the trial, summary of the evidence around access to primary care and requirements the intervention (e.g. must be different to what is currently provided and implementable within three weeks)
Four one-hour development meetings with the lead researcher
£1500 grant provided irrespective of the intervention developed

All practices had two to three months to develop and implement their service changes. The intervention was allowed to be targeted specifically at the group of interest or the whole practice population. Small modifications to the intervention were allowed during the trial period providing the research team was informed. Practices were also asked to consider activity measures to assess implementation of the intervention. All development meetings were audio-recorded and transcribed, and a logic model produced. The practice allocated to usual care did not receive any of the above support.

#### 7.4.6 *Quantitative patient outcomes measures*

The main outcome measures, reflecting the pre-specified CMO configurations and assessed using a 100-point Visual Analogue Scale (VAS), were self-reported transport options, perceived convenience of transport, suitability of transport, ease of booking an appointment, perceived convenience of booking an appointment, and suitability of received appointment. Data were collected at baseline (researcher visit, baseline self-completion questionnaire shown in Appendix 13 as an example), follow-up (postal questionnaire) and every time a participant booked or attended an appointment (postal questionnaire). Other measures collected from participants at baseline and follow up were EQ-5D-5L (EuroQol five dimensions questionnaire) [232], ICECAP-

O (ICEpop CAPability measure for Older people) [233], confidence and trust in their general practice and Patient Activation Measure (PAM) [234]. Patient activation is concerned with the knowledge, skills and confidence a person has in managing their own health. For each of the above measures the difference-in-difference was calculated which is the change between baseline and six months for intervention versus control.

#### 7.4.7 *Qualitative data collection*

At the beginning of the follow-up period, two three-hour observations were undertaken at the reception area of each practice to understand the practice system and identify any important issues which may influence implementation. Written informed consent was obtained and detailed field notes taken.

At follow-up, two group interviews were undertaken at each practice to explore the development and implementation of the service changes, as well as the acceptability of the study design. Furthermore, semi-structured interviews were undertaken with eight participants across all practices to explore the acceptability of the trial design, data collection methods, implementation of the service changes and expand the initial CMO-based theory (Figure 22). Interviews were guided by a topic guide which included discussion of the context, mechanism and outcomes of the initial theory and emerging themes explored in subsequent interviews. Written informed consent was obtained. Interviews were audio-recorded and transcribed.

#### 7.4.8 *Progression*

Progression criteria were set a priori to guide progression to a full trial and were as follows.

Table 17: Progression criteria

Criteria	Threshold
Proportion of participants recruited in each practice	60%
Proportion of participants completing follow-up	50%
Proportion of practices completing follow-up	50%
Proportion of practices being able to successfully develop and deliver a context specific service changes	67%

#### 7.4.9 *Analysis*

Descriptive analysis was used to assess the recruitment and retention of practices and participants. To test the appropriateness of the analysis complete case analysis of key quantitative outcomes was undertaken to compare intervention and usual care for the change between baseline and follow-up using a linear mixed model with practice included as a random effect. The intraclass correlation coefficient was estimated for each outcome, but caution is needed because of the small

number of clusters [235]. Responses to the EQ-5D-5L were converted into utility scores, a scale where zero is equal to death and one is full health, using the crosswalk mapping function [236], as recommended by NICE [237]. Difference in primary care use between intervention and usual care for the six months before the trial and six months follow-up was assessed using a boot-strapped linear mixed model with practice as a random effect to account for the skewed distribution. All analyses were undertaken in Stata 15 [238].

Qualitative data was analysed using two different methods; thematic analysis and a realist logic of analysis. Thematic analysis was used to analyse data relating to acceptability of the intervention development, data collection methods, practice organisation, implementation of the intervention and methodological considerations for a future study. This involved familiarisation, then coding of data using NVivo [117]. Themes were then identified from the codes. A realist logic of analysis was used to expand the initial CMO configurations shown in Figure 22 [239, 240]. To do this, potential booking or transport related contexts associated with obtaining an appointment or getting to the surgery were identified (outcomes). Then data was explored for underlying mechanisms. Only CMO configurations relating to the booking system and obtaining an appointment or transport and getting to the appointment were identified.

Due to the size of the study, we did not undertake a full economic evaluation but did aim to identify the total cost of the intervention and the associated main cost drivers. An NHS perspective was taken and 2016/17 costs in British pounds used throughout. Practices were asked to record on a web-based form any expenditure or time spent on their intervention. These were categorised into one off costs (e.g. development costs) or recurrent costs (e.g. ongoing costs of the intervention) and out of pocket costs (e.g. external training fees) or staff time. Any costs that were no longer incurred as a result of the intervention e.g. previous line rental fees, were also noted. An equivalent annual cost per patient was estimated based on a three-year useful lifetime and discounting of 3.5% for each cost [241]. The number of patients per practice who were older, socio-economically disadvantaged without access to a car per practice were estimated using published sources [57, 242, 243].

Health care utilisation data was collected from electronic patient records by the lead researcher (JF) for six months before and during follow-up. Data collected included: number of GPs, nurse and health care assistant appointments (split by surgery, home or telephone); accident and emergency attendances; hospital admissions (split by emergency or elective); out of hours primary care contact; and ambulance use (split by hear and treat, see and treat or convey). Primary care costs were based on Personal Social Services Research Unit costs [244] and secondary care on NHS Reference costs [245]. Unit costs are shown in Table 18.



Table 18: Unit costs

Activity	Unit Cost	Source
Hourly rate of receptionist	£24.50	PSSRU 2017 – hourly rate for Agenda for Change Band 2 staff extrapolated from average proportion of hourly rate to salary for Band 4, 5 and 6
Hourly rate of practice manager	£30.50	PSSRU 2017 – hourly rate for Agenda for Change Band 4 staff
Hourly rate for dispensary staff	£27.31	PSSRU 2017 – hourly rate for Agenda for Change Band 3 staff extrapolated from average proportion of hourly rate to salary for Band 4, 5 and 6
Signposting a call	£0.20	Personal correspondence from Practice C that it takes on average 30 second of receptionist’s time per call to signpost
Signposting to community transport	£0.80	
Change embargoed slot to suit bus timetable	£0.40	
GP surgery consultation	£31.00	PSSRU 2017
GP home visit	£65.38	Patient contact and travel time based on PSSRU 2015 and hourly rate PSSRU 2017
GP telephone consultation	£24.26	Time based on PSSRU 2015 and hourly rate PSSRU 2017
Nurse surgery appointment	£12.47	Time and hourly cost of direct patient care based on 2015 PSSRU inflated to 2017 costs based on PSSRU inflation indices
Nurse telephone consultation	£4.99	Time and hourly cost of direct patient care based on 2015 PSSRU inflated to 2017 costs based on PSSRU inflation indices
Health care assistant appointment	£3.83	Based on PSSRU 2017 Band 2 nursing hourly rate and 10-minute appointment
111 calls	£7.00	NHS Reference costs 2017
A+E attendance	£148.00	NHS Reference costs 2017
Ambulance call out	£181.00	NHS Reference costs 2017
Ambulance conveyancing	£248.00	NHS Reference costs 2017
Hospital admissions	£313 per day	Excess bed day based on NHS Reference costs 2017

Sources :

PSSRU 2017 [244]

PSSRU 2015 [246]

NHS Reference costs [245]

## **7.5 Results**

### *7.5.1 Recruitment and completion rates*

Fifteen primary care practices were invited, five expressed interest and four were recruited (Figure 23). Of the 1,143 participants invited, 34 were recruited (3% response rate). Twenty-nine participants were registered at intervention practices and five at the usual care practice. Recruitment varied between practices (Table 19) with a range of 5.4% (Practice A with 336 approached and 18 recruited) to 1.7% (Practice C with 238 approached and 4 recruited). Three participants did not complete follow-up (91% completion rate), two of which were from Practice B in the intervention arm and one of which was from the usual care. Fifty-six appointment questionnaires were received based on 150 appointments (37.3%).

Figure 23: Consort flow diagram

N= number of practices, n = number of patients

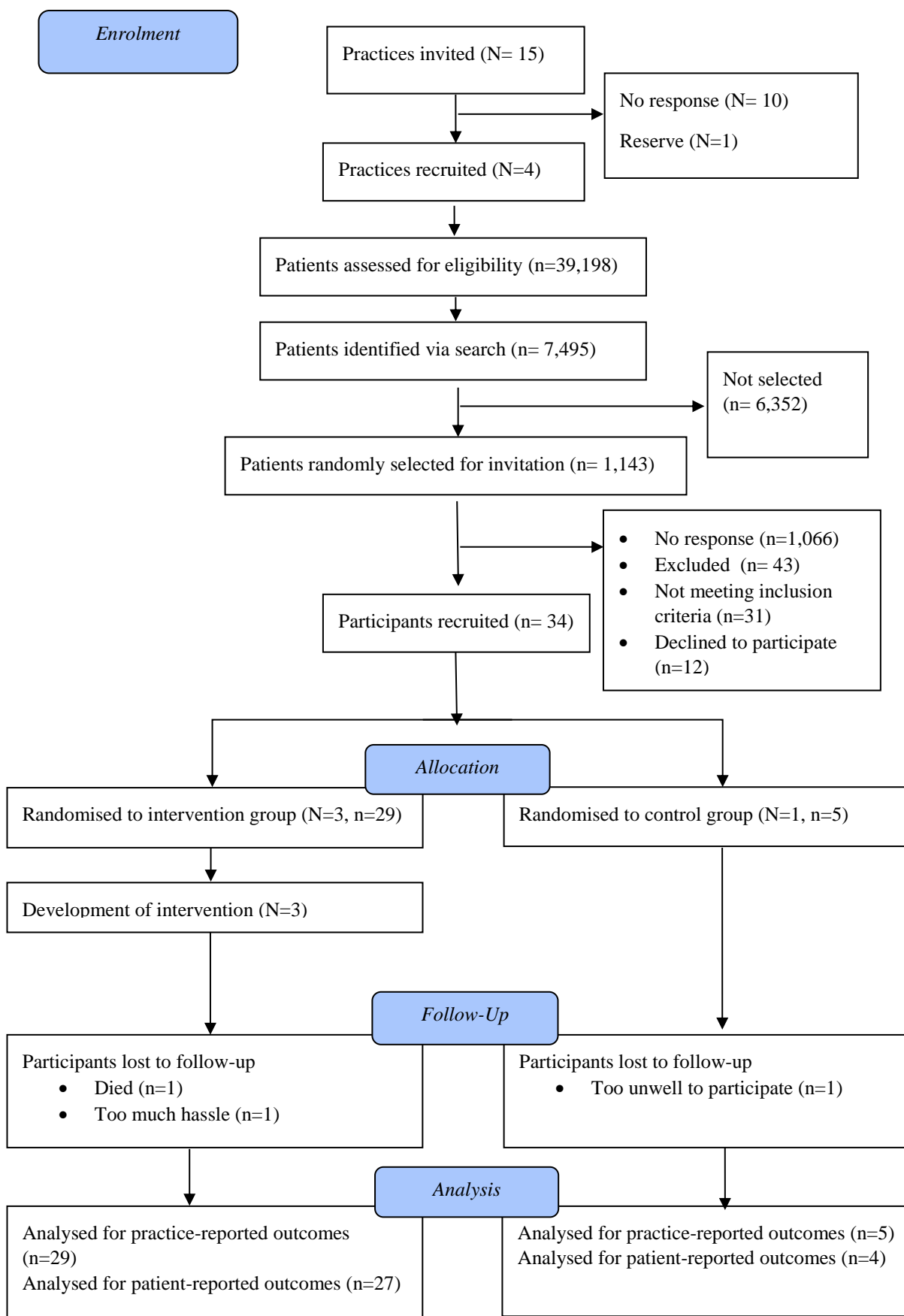


Table 19: Characteristics of included practices

	Practice A	Practice B	Practice C	Practice D
<b>Recruitment to trial</b>				
Eligible (n)	2,408	1,156	1,244	1,188
Invited (n)	336	280	238	289
Recruited (n)	18	7	4	5
<b>Practice characteristics</b>				
Practice population	12,000-13,000	9,000-10,000	8,000-9,000	8,000-9,000
Approximate catchment area (km <sup>2</sup> )	88	101	147	152
Staff profile*	5 GPs, 11 nursing and HCAs staff, 17 admin and receptionist staff	6 GPs, 7 nursing staff and 16 admin and reception staff	7 GPs, 7 nursing staff and 11 admin and reception staff	8 GPs, 6 nursing staff and 8 admin and reception staff
Max no. of staff answering calls	3	4	3	2
<b>Results of GP Patient survey 2016/17</b>				
Very or fairly easy to get through on the phone (%)	53	81	70	100
Very or fairly helpful receptionists (%)	85	100	100	100
Almost always or a lot of the time able to see preferred GP (%)	51	32	89	77
Able to get appointment	94	92	100	100
Appointment same day or next day (%)	56	49	67	58
Very or fairly good overall experience of making an appointment (%)	74	100	90	100
Definitely or probably recommend surgery (%)	82	91	89	100

\*Includes both full-time and part time staff

GP= general practitioner, HCA = health care assistant, n= number

### 7.5.2 Baseline characteristics of patients

The mean age of participants in the intervention was 81.7 years and in usual care 79.4 (Table 20). All participants were white, and most were female. 59% of participants in the intervention practices had completed their education before the age of 16, compared to 20% in usual care. Participants in Practices C and D lived furthest from the surgery and those in Practice A closest. More participants in the intervention arm walked to the surgery or took taxis and more people in the usual care arm relied on lifts from friends or family. All participants in Practices C and D would definitely recommend the surgery compared to 56% in Practice A.

Table 20: Baseline characteristics of included participants

Variable		Practice			Intervention (n=29)	Usual care (n=5)
		A (n=18)	B (n=7)	C (n=4)		
Age, mean (SD)		81.0 (8.7)	84.3 (8.2)	80.0 (4.2)	81.7 (8.0)	79.4 (8.1)
Gender	Female	12 (67%)	7 (100%)	3 (75%)	22 (76%)	4 (80%)
Ethnicity	White - British	18 (100%)	6 (86%)	4 (100%)	28 (97%)	4 (80%)
	White - other	0 (0%)	1 (14%)	0 (0%)	1 (3%)	1 (20%)
Age at completion of education	Before 15 years old	4 (22%)	2 (29%)	2 (50%)	8 (28%)	0 (0%)
	15 or 16 years old	6 (33%)	1 (14%)	2 (50%)	9 (31%)	1 (20%)
	17 to 20 years old	5 (28%)	2 (29%)	0 (0%)	7 (24%)	2 (40%)
	After 21 years old	3 (17%)	2 (29%)	0 (0%)	5 (17%)	2 (40%)
Revised Family Resources Survey	Finances do not impair standard of living in any measures	17 (94%)	7 (100%)	4 (100%)	28 (97%)	5 (100%)
	Finances impair standard of living in 1 or more measures	1 (6%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
Lubben Social Network Scale 6-item, mean (SD)		14.44 (6.05)	14.00 (6.22)	16.00 (6.27)	14.55 (5.93)	15.40 (6.19)
Activities of Daily Living, mean (SD)		1.06 (1.85)	1.00 (1.15)	0.50 (1.00)	0.96 (1.57)	0.80 (1.10)
Instrumental Activities of Daily Living, mean (SD)		0.41 (0.71)	0.57 (0.79)	0.50 (1.00)	0.46 (0.74)	1.00 (1.00)
Distance from home to GP surgery, mean (SD)		0.77 (0.29)	2.09 (2.17)	3.95 (2.34)	1.56 (1.74)	3.58 (2.45)
How do you usually get to the GP surgery?	Walk	7 (32%)	3 (38%)	1 (14%)	11 (30%)	0 (0%)
	Public transport	3 (14%)	1 (13%)	2 (29%)	6 (16%)	2 (25%)
	Taxi	10 (145%)	1 (13%)	2 (29%)	13 (35%)	1 (13%)
	Community transport	0 (0%)	1 (13%)	1 (14%)	2 (5%)	0 (0%)
	Lift from a friend or relative	0 (0%)	0 (0%)	1 (14%)	1 (3%)	3 (38%)
	Home visits only	0 (0%)	2 (25%)	0 (0%)	2 (5%)	1 (13%)
	Other	2 (9%)	0 (0%)	0 (0%)	2 (5%)	1 (13%)
Recommend surgery	No, definitely not	0 (0%)	1 (14%)	0 (0%)	1 (3%)	0 (0%)
	Not sure	1 (6%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
	Yes, probably	7 (39%)	1 (14%)	0 (0%)	8 (28%)	0 (0%)
	Yes, definitely	10 (56%)	5 (71%)	4 (100%)	19 (66%)	5 (100%)

SD = standard deviation

### *7.5.3 Baseline characteristics of practices and profiles*

Practice A had the highest practice population but the smallest catchment area (Table 19). Based on the GP Patient Survey results, Practice A had lowest access scores compared to other practices. All practices had either a dispensary or co-located pharmacy.

Based on the observations at the start of the trial, Practice A had the busiest reception area, with some patients attending the surgery in person because of engaged telephone lines and pressures on the appointment system. Practice B had an existing signposting process, where patients were asked about their health problem and directed to the most appropriate service, meaning that receptionists spent more time on the telephone with each patient but were more deliberate in booking appointments. Practice C reported difficulty with access to taxis, especially during busy school periods. The practice also did not have any nurse specialists, and therefore most appointments were scheduled with GPs, sometimes for issues which could have been dealt with by a different team member. Practice D had a policy of releasing appointments at 8am and 12noon and on one of the observation days an afternoon GP appointment remained unfilled, which staff reported happened occasionally.

### *7.5.4 Intervention development by practices*

Practice A decided to implement a call stacking system, where calls are placed in a queue, and aimed to develop closer links with a community transport provider (Table 21). Practice B incorporated community transport into their signposting, allowed more flexibility for receptionists to move appointments based on bus times, installed a charging point for mobility scooters and promoted the role of receptionists through a practice leaflet. Practice C worked with a local taxi firm to develop a priority hour with corresponding taxi appointment slot and had three external training sessions for receptionists about local services and signposting. The logic model for each practice intervention is shown in Table 22.

Table 21: Summary of interventions developed

Practice	Intervention
A	<ul style="list-style-type: none"><li>• Telephone system to stack calls</li><li>• Linking with, and promoting, community transport</li></ul>
B	<ul style="list-style-type: none"><li>• Signposting to community transport</li><li>• Flexible appointments around bus times</li><li>• Charging for mobility scooters</li><li>• Promoting the role of medical receptionists</li></ul>
C	<ul style="list-style-type: none"><li>• Working with local taxi firm and creating a taxi appointment slot</li><li>• Three external receptionist training sessions about local services and signposting/customer services</li></ul>

Table 22: Logic model for intervention practices

Target population	Assumptions	Practice inputs	Practice activities	Measures	Outputs	Potential outcomes
Practice A						
Patients who do not have transport to get to surgery	Patients find it difficult to get to the surgery leading to poor access	Time to meet with community transport provider  Time to add community transport information to signposting  Time to communicate with receptionists	Set up closer contact with community transport provider  Promote community transport provider at surgery	Number of journeys from community transport to and from surgery	Patients will find it easier to get transport to the surgery Patients will not have to continually redial until they get through to the surgery Fewer patients will attend the surgery to book an appointment	Patients find it easier to get to the surgery  Patients are more satisfied with the booking system
Any patients phoning to book an appointment	Some patients are having to repeatedly dial the surgery because of an engaged telephone line  Some patients may be put off booking an appointment because of the difficulties in the booking system	Funds to install new telephone system	Install new telephone system to stack calls	Data from new telephone system		



Target population	Assumptions	Practice inputs	Practice activities	Measures	Outputs	Potential outcomes
Practice B						
Patients who attend surgery with difficulty but don't have own transport	Some patients can't get appropriate appointments because of lack of transport or knowledge of transport options	Practice manager and administrator time to discuss with reception team  Practice manager and administrator time to add transport to signposting information	Add transport to signposting template Add community transport information to information packs	Data from signposting template and possibly a READ code if signposted to community transport	Patients who attend surgery with difficulty but don't have own transport	Patients supported with transport to get to appointment  Patients supported with transport to get to appointment
Patients who use the bus	Some patients not able to get appointment because of bus times	Receptionist time to include transport in signposting and be flexible with appointments	Communicate with reception team about using embargoed appointments to allow bus travel	Date and recipients of memos and aide memories sent New slot type created for embargoed slots moved to fit in with bus times	Patients who use the bus	Patients with mobility scooters more confident in accessing practice
Patients with mobility scooters who need charging facilities	Some patients don't attend with mobility scooters because they don't have enough battery charge	Receptionist time to facilitate scooter charging and communicate with individual patients	Communicate with reception team about mobility scooter charging Communicate with individual patients about mobility scooter charging	Date and recipients of memos or aide memories sent Details of letters sent	Patients with mobility scooters who need charging facilities	Patients understand more about the role of receptionists
All patients	Patients read the newsletter and practice leaflets	Leaflet about medical receptionists and articles	Promoting role of receptionists	Number of leaflets and newsletters distributed	All patients	

Target population	Assumptions	Practice inputs	Practice activities	Measures	Outputs	Potential outcomes
		about receptionists in the newsletter				
Practice C						
Patients who rely on taxis	Patients find it difficult to book a taxi at certain times of the day	Commitment to prompt a local taxi firm  Administrator time to organise priority hour	Set up formal arrangements with a local taxi firm	Receptionists will record every time a taxi slot is being used for a taxi, possibly with a READ code Taxi firm will provide number of journeys to and from practice over past 12 months and Jan-June 2018	More patients are able to book a taxi Patients have a better understanding of the role of a receptionist Lower number of unnecessary appointments	Patients find it easier to get to the surgery  Patients get better access to the help they need first time  Receptionists more confident in helping patients to the right service
Patients who don't have transport to get to the surgery	Patients may not know about community transport options	Administrator and receptionist time to share information about community transport	Training with local signposting organisation with knowledge about community transport	Number of people attending training	Patients diverted to more appropriate services Increased confidence of receptionists	
Any patient phoning the surgery	Patients are willing to receive advice from receptionists	Time for practice staff to attend triaging and signpost training  Receptionist time to signpost and triage  Funds to pay for training	Training with external company	Number of people attending training		

Practices A and C had out of pocket expenditure (£2262 and £930) for the intervention, whereas Practice B had only staff time costs (Table 23). The annual equivalent cost over a three year lifetime, per older, socio-economically disadvantaged patient without car access (Table 24) for out of pocket costs, was lowest in Practice A (-£13) and highest in Practice C (£2) and staff time costs were lowest in Practice A (£0) and highest in Practice C (£63). Practice A had a monthly cost saving from the new system because of cheaper call rates and the high cost in Practice C reflects the signposting of every call by the receptionists.

Table 23: Total cost of intervention over six-month trial period for each practice

	One off costs			Recurrent costs			Total costs (one off and recurrent)		
	Practice			Practice			Practice		
	A	B	C	A	B	C	A	B	C
Out of pocket costs	£4,680	£0	£930	-£2,418*	£0	£0	<b>£2,262</b>	<b>£0</b>	<b>£930</b>
Staff time	£112	£134	£1,322	£0	£475	£1,329	<b>£112</b>	<b>£610</b>	<b>£2,651</b>
<b>Total costs</b>	<b>£4,792</b>	<b>£134</b>	<b>£2,252</b>	<b>-£2,418*</b>	<b>£475</b>	<b>£1,329</b>	<b>£2,374</b>	<b>£610</b>	<b>£3,581</b>

\* Practice A had a monthly cost saving from the new system because of cheaper call rates compared to their previous contract

Table 24: Equivalent annual cost per socio-disadvantaged older patient without access to a car for each intervention practice

	One off costs			Recurrent costs			Total costs (one off and recurrent)		
	Practice			Practice			Practice		
	A	B	C	A	B	C	A	B	C
Out of pocket costs	£6	£0	£2	-£19	£0	£0	<b>-£13</b>	<b>£0</b>	<b>£2</b>
Staff time	£0	£0	£3	£0	£5	£60	<b>£0</b>	<b>£5</b>	<b>£63</b>
<b>Total costs</b>	<b>£6</b>	<b>£0</b>	<b>£4</b>	<b>-£19</b>	<b>£5</b>	<b>£60</b>	<b>-£12</b>	<b>£5</b>	<b>£65</b>

Note: Assumes a three-year useful lifetime and 3.5% annual discounting

Based on analysis of the intervention development meetings and group interviews with practice staff, the interventions developed ranged from existing ideas which practices were already considering implementing (e.g. a call stacking phone system) to new ideas stimulated by the freedom, time and resource to be innovative (e.g. taxi slots). The process meant that all practices had ownership of their intervention. Practices reported liking the short time scales and deadlines imposed by the intervention development process because of the momentum. All practices found it easier to develop interventions related to the booking system, rather than transport.

### 7.5.5 *Intervention implementation and usual care arm*

Practice A successfully implemented the call stacking system and while they advertised community transport in the reception area, they were unable to establish closer links because of a change in personnel at the community transport provider. Practice B successfully implemented their intervention and at six months receptionists reported signposting to community transport and changing appointments for bus timetables on average once a week. Practice C introduced the taxi slots and had one external training event before the trial began and the two during the six-month follow-up. Activity measures proposed by the intervention practices to assess implementation were not sufficiently robust to interpret. The usual care arm, Practice D, installed a new telephone system during the follow-up period because their previous contract expired. The new system had call stacking as a feature, but it was primarily a financial decision and the practice did not perceive a problem with engaged telephone lines.

### 7.5.6 *Impact of intervention*

Staff in Practice A reported fewer complaints and patients visiting the surgery to make an appointment because of engaged telephone lines after the implementation of call stacking. Participants generally liked the call stacking system because it gave them information about the likely wait and more confidence that the call would be answered. However, both staff and participants stated that more receptionists were needed to answer the calls; for example, 33 patients were queued on one occasion. According to staff in Practice B and C, signposting improved the availability of appointments and GPs liked a reason for the consultation being added to the electronic appointment because this helped identification of emergencies and planning. Some participants liked signposting because they felt it enabled the receptionists to prioritise; others had grown to accept it, while others did not perceive it as the receptionist's role. The only participant in Practice B who used a mobility scooter reported not requiring the charging point during the study period but said that it gave her reassurance. Staff in Practice C reported that the training improved their knowledge about local services, confidence in signposting and dealing with difficult patients. Receptionists reported only rarely using the taxi slots and no participants reported using them.

Table 25 and Table 26 show the monthly change and difference-in-difference for each CMO outcome. Ease of booking an appointment scores improved most in Practice B and C, compared to A and usual care. However, the convenience of booking an appointment increased most in Practice B and usual care with a decrease in Practice C. Transport measures improved in all practices except for Practice C where transport options and ability to get suitable transport decreased.

Table 25: Baseline, follow-up and monthly mean change in visual analogues (score from 0 to 100) for the booking context-mechanism-outcome configuration

		Ease of booking an appointment					Convenience of booking appointment					Ability to book appointment				
		Practice			Intervention total (n=27)	Usual care (n=3)	Practice			Intervention total (n=27)	Usual care (n=3)	Practice			Intervention total (n=27)	Usual care (n=3)
		A (n=18)	B (n=5)	C (n=4)			A (n=18)	B (n=5)	C (n=4)			A (n=18)	B (n=5)	C (n=4)		
Pre-intervention, mean (SD)		52.0 (26.1)	54.3 (26.6)	56.8 (44.5)	53.2 (28.0)	65.4 (20.1)	58.0 (33.1)	65.8 (31.3)	79.3 (25.1)	62.7 (31.6)	64.8 (35.3)	61.4 (26.8)	58.3 (30.3)	74.6 (22.5)	62.6 (26.6)	75.8 (12.7)
Change from baseline to	month 1, mean (SD)	24.4 (17.8)	NA	38.8 (68.2)	28.5 (32.2)	NA	23.4 (19.3)	NA	20.5 (29.0)	22.6 (19.8)	NA	30.6 (17.6)	NA	12.3 (18.0)	24.5 (18.4)	NA
	month 2, mean (SD)	22.4 (27.6)	43.0 (NA)	NA	25.3 (26.4)	-44.0 (NA)	20.6 (21.8)	19.0 (NA)	NA	20.4 (19.9)	-1.0 (NA)	30.9 (12.1)	20.0 (NA)	NA	29.4 (11.8)	-64.0 (NA)
	month 3, mean (SD)	-10.8 (22.6)	24.8 (23.7)	87.3 (NA)	18.5 (39.9)	NA	6.9 (50.2)	1.5 (11.8)	-2.5 (NA)	3.7 (33.7)	NA	14.0 (55.4)	2.3 (29.7)	1.5 (NA)	8.1 (40.1)	NA
	month 4, mean (SD)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	month 5, mean (SD)	14.8 (49.4)	34.0 (NA)	NA	18.0 (44.9)	NA	21.4 (61.4)	-9.0 (NA)	NA	16.3 (56.3)	NA	19.0 (50.8)	34.0 (NA)	NA	21.5 (45.8)	NA
	month 6, mean (SD)	14.7 (25.8)	38.0 (39.0)	87.8 (NA)	24.0 (33.0)	-4.0 (34.1)	8.7 (30.5)	20.7 (41.7)	-0.2 (NA)	10.9 (31.6)	24.0 (16.8)	24.2 (34.0)	37.1 (40.0)	2.7 (NA)	26.0 (34.1)	-17.0 (47.0)
	Final follow-up, mean (SD)	-1.9 (26.8)	25.1 (12.7)	28.3 (52.5)	7.6 (31.6)	6.0 (39.4)	1.2 (23.4)	11.3 (15.9)	-13.3 (21.4)	0.9 (22.4)	22.0 (37.0)	6.1 (31.6)	9.1 (5.9)	-7.9 (7.4)	4.3 (26.6)	2.0 (19.7)
Difference-in-difference without clustering (95% CI)		1.6 (-34.0 to 37.2)					-21.1 (-47.7 to 5.5)					2.3 (-26.3 to 30.9)				
Difference-in-difference adjusted for clustering (95% CI)		7.9 (-38.3 to 54.1)					-21.1 (-46.6 to 4.4)					2.3 (-25.0 to 29.7)				

NA = not applicable, SD = standard deviation

Table 26: Baseline, follow-up and monthly mean change in visual analogues (score from 0 to 100) for the transport context-mechanism-outcome configuration

		Transport options					Convenience of transport					Ability to get suitable transport				
		Practice			Intervention total (n=27)	Usual care (n=3)	Practice			Intervention total (n=27)	Usual care (n=3)	Practice			Intervention total (n=27)	Usual care (n=3)
		A (n=18)	B (n=5)	C (n=4)			A (n=18)	B (n=5)	C (n=4)			A (n=18)	B (n=5)	C (n=4)		
Pre-intervention, mean (SD)		65.5 (27.5)	70.1 (33.7)	71.6 (27.7)	67.5 (28.1)	47.8 (33.4)	69.3 (30.1)	66.9 (38.5)	77.5 (30.5)	69.8 (31.2)	45.4 (30.3)	77.7 (19.7)	61.7 (34.2)	83.1 (22.8)	75.0 (24.1)	75.3 (28.4)
Change from baseline to	month 1, mean (SD)	2.7 (7.6)	NA	-38.5 (5.7)	-11.0 (22.2)	NA	-1.1 (3.3)	0.0 (NA)	-45.0 (NA)	-9.7 (19.9)	NA	14.9 (15.0)	33.0 (NA)	-91.0 (NA)	-2.7 (51.1)	NA
	month 2, mean (SD)	5.0 (9.5)	-13.0 (NA)	NA	2.4 (11.0)	NA	9.9 (21.4)	NA	NA	9.9 (21.4)	NA	16.8 (16.4)	NA	NA	16.8 (16.4)	NA
	month 3, mean (SD)	0.2 (21.5)	-4.2 (12.8)	-42.3 (NA)	-7.8 (21.1)	NA	2.8 (1.8)	3.5 (NA)	NA	3.0 (1.3)	7.5 (NA)	-3.5 (14.5)	NA	NA	-3.5 (14.5)	8.0 (NA)
	month 4, mean (SD)	NA	NA	NA	NA	NA	19.9 (21.4)	-2.0 (NA)	NA	15.5 (21.0)	7.5 (NA)	NA	NA	NA	NA	NA
	month 5, mean (SD)	-15.0 (20.2)	-14.0 (NA)	NA	-14.8 (18.0)	NA	20.0 (21.6)	4.3 (2.5)	-1.0 (NA)	12.5 (18.1)	30.0 (26.2)	-32.5 (43.0)	4.5 (3.5)	-0.5 (NA)	-17.4 (35.9)	24.3 (24.4)
	month 6, mean (SD)	1.0 (35.1)	-6.0 (18.2)	-42.5 (NA)	-2.8 (32.8)	7.3 (14.6)	8.6 (22.1)	5.8 (4.5)	58.0 (NA)	11.7 (23.6)	40.8 (38.7)	7.5 (38.5)	2.0 (NA)	42.0 (NA)	9.9 (36.3)	17.1 (18.7)
	Final follow-up, mean (SD)	6.7 (20.6)	6.1 (15.8)	-9.8 (43.1)	4.6 (22.7)	13.5 (14.3)	4.5 (20.3)	11.4 (21.8)	8.3 (32.3)	6.3 (21.2)	1.0 (12.4)	2.5 (29.3)	20.5 (28.5)	-18.1 (49.4)	2.1 (33.2)	6.6 (21.6)
Difference-in-difference without clustering (95% CI)		-8.9 (-33.1 to 15.4)					5.3 (-17.2 to 27.7)					-4.5 (-40.1 to 31.0)				
Difference-in-difference adjusted for clustering (95% CI)		-8.9 (-32.1 to 14.3)					5.3 (-16.2 to 26.7)					-4.5 (-38.5 to 29.4)				

NA = not applicable, SD = standard deviation

Table 27 shows the difference-in-difference for quality of life, capability and patient activation. Quality of life decreased in all intervention practices but increased in the usual care practice. There was little difference in ICECAP-O scores between intervention and usual care practices. There was a mean drop of 21 points in PAM scores in the usual care arm, but little change in the intervention practices. Intraclass correlation coefficients are shown in Table 28. Self-reported quality of care was recorded at baseline and follow-up but due to small numbers, the data was difficult to interpret (Table 29).

Table 27: Mean change between baseline and follow-up in quality of life, capability and patient activation for individual practices, intervention combined and usual care

		Practice			Intervention total (n=27)	Usual care (n=4)	Difference-in-difference (95% CI)
		A (n=18)	B (n=5)	C (n=4)			
EQ5D5L, mean (SD)	Baseline	0.75 (0.20)	0.77 (0.16)	0.88 (0.09)	0.77 (0.18)	0.67 (0.37)	-0.17 (-0.33 to -0.02)
	Follow-up	0.64 (0.23)	0.72 (0.16)	0.83 (0.08)	0.68 (0.21)	0.75 (0.32)	
	Difference	-0.11 (0.14)	-0.05 (0.12)	-0.05 (0.07)	-0.09 (0.13)	0.09 (0.08)	
ICECAP-O, mean (SD)	Baseline	0.81 (0.14)	0.81 (0.10)	0.86 (0.11)	0.81 (0.13)	0.88 (0.15)	-0.01 (-0.14 to 0.11)
	Follow-up	0.73 (0.14)	0.77 (0.10)	0.86 (0.11)	0.76 (0.14)	0.84 (0.18)	
	Difference	-0.08 (0.11)	-0.04 (0.08)	0.01 (0.05)	-0.06 (0.10)	-0.04 (0.04)	
PAM, mean (SD)	Baseline	62.17 (13.40)	56.08 (14.67)	48.27 (6.79)	59.39 (13.52)	79.43 (19.76)	22.88 (5.92 to 39.83)
	Follow-up	60.47 (12.80)	64.86 (14.40)	48.73 (5.95)	59.96 (12.95)	58.10 (15.80)	
	Difference	-1.69 (11.58)	8.78 (12.16)	0.47 (2.43)	0.57 (11.51)	-21.33 (21.20)	

ICECAP-O = ICEpop CAPability measure for Older people. PAM = Patient Activation Measure, SD = standard deviation



Table 28: Intraclass correlation coefficient

Variable	ICC (95% CI)
Ease of booking an appointment	0.18 (0.01 to 0.83)
Convenience of booking appointment	Unable to estimate
Ability to book appointment	Unable to estimate
Transport options	Unable to estimate
Convenience of transport	Unable to estimate
Ability to get suitable transport	Unable to estimate
EQ5D5L	Unable to estimate
ICECAP-O	0.67 (0.00 to 0.96)
PAM	0.08 (0.00 to 0.94)

ICECAP-O = ICEpop CAPability measure for Older people. PAM = Patient Activation Measure, ICC = intraclass correlation coefficient

Table 29: Quality of care at baseline and follow-up for those with complete data

			Practice						Intervention		Usual care	
			A (n=17)		B (n=5)		C (n=4)		(n=27)		(n=3)	
			Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
GP	Giving enough time, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Poor	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	1 (33%)
		Neither	1 (6%)	2 (12%)	1 (20%)	1 (20%)	0 (0%)	1 (25%)	2 (8%)	4 (15%)	1 (33%)	0 (0%)
		Good	6 (35%)	8 (47%)	1 (20%)	0 (0%)	0 (0%)	1 (25%)	7 (27%)	9 (35%)	0 (0%)	1 (33%)
		Very good	9 (53%)	7 (41%)	3 (60%)	4 (80%)	4 (100%)	2 (50%)	16 (62%)	13 (50%)	2 (67%)	1 (33%)
	Listening to you, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Poor	1 (7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	1 (33%)	0 (0%)
		Neither	0 (0%)	0 (0%)	1 (20%)	1 (20%)	0 (0%)	1 (25%)	1 (4%)	2 (8%)	0 (0%)	0 (0%)
		Good	5 (33%)	5 (31%)	1 (20%)	0 (0%)	1 (25%)	1 (25%)	7 (29%)	6 (24%)	0 (0%)	2 (67%)
		Very good	9 (60%)	11 (69%)	3 (60%)	4 (80%)	3 (75%)	2 (50%)	15 (63%)	17 (68%)	2 (67%)	1 (33%)
	Explaining tests and treatments, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Poor	1 (7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)
		Neither	1 (7%)	2 (13%)	1 (20%)	1 (20%)	0 (0%)	0 (0%)	2 (9%)	3 (13%)	1 (33%)	0 (0%)
		Good	5 (36%)	3 (20%)	1 (20%)	0 (0%)	1 (33%)	1 (33%)	7 (32%)	4 (17%)	0 (0%)	1 (33%)
		Very good	7 (50%)	10 (67%)	3 (60%)	4 (80%)	2 (67%)	2 (67%)	12 (55%)	16 (70%)	2 (67%)	2 (67%)
	Involving you in decisions, n (%)	Very poor	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)
		Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
		Neither	2 (15%)	2 (13%)	1 (20%)	0 (0%)	0 (0%)	0 (0%)	3 (14%)	2 (9%)	0 (0%)	0 (0%)
		Good	2 (15%)	5 (33%)	1 (20%)	0 (0%)	1 (25%)	2 (50%)	4 (18%)	7 (30%)		0 (0%)
		Very good	8 (62%)	8 (53%)	3 (60%)	4 (100%)	3 (75%)	2 (50%)	14 (64%)	14 (61%)	3 (100%)	2 (100%)
Treating you with care and	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
	Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
	Neither	0 (0%)	1 (6%)	1 (20%)	1 (20%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)	0 (0%)	0 (0%)	

		Practice						Intervention		Usual care	
		A (n=17)		B (n=5)		C (n=4)		(n=27)		(n=3)	
		Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
concern, n (%)	Good	7 (44%)	3 (19%)	1 (20%)	0 (0%)	1 (25%)	2 (50%)	9 (36%)	5 (20%)	0 (0%)	0 (0%)
	Very good	9 (56%)	12 (75%)	3 (60%)	4 (80%)	3 (75%)	2 (50%)	15 (60%)	18 (72%)	3 (100%)	3 (100%)
Confidence and trust, n (%)	No, not at all	0 (0%)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)
	Yes, to some extent	7 (44%)	5 (29%)	1 (20%)	1 (20%)	1 (25%)	1 (25%)	9 (36%)	7 (27%)	1 (33%)	0 (0%)
	Yes, definitely	9 (56%)	11 (65%)	4 (80%)	4 (80%)	3 (75%)	3 (75%)	16 (64%)	18 (69%)	2 (67%)	3 (100%)
Giving enough time, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Poor	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	Neither	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)
	Good	6 (35%)	8 (50%)	3 (60%)	1 (20%)	1 (25%)	2 (50%)	10 (38%)	11 (44%)	1 (33%)	2 (67%)
	Very good	10 (59%)	8 (50%)	2 (40%)	3 (60%)	3 (75%)	2 (50%)	15 (58%)	13 (52%)	2 (67%)	1 (33%)
Listening to you, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Neither	2 (13%)	0 (0%)	1 (20%)	2 (40%)	0 (0%)	0 (0%)	3 (12%)	2 (8%)	0 (0%)	0 (0%)
	Good	5 (31%)	10 (63%)	2 (40%)	0 (0%)	1 (25%)	2 (50%)	8 (32%)	12 (48%)	1 (33%)	1 (33%)
	Very good	9 (56%)	6 (38%)	2 (40%)	3 (60%)	3 (75%)	2 (50%)	14 (56%)	11 (44%)	2 (67%)	2 (67%)
Explaining tests and treatments, n (%)	Very poor	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Neither	2 (12%)	2 (13%)	1 (20%)	1 (25%)	0 (0%)	0 (0%)	3 (12%)	3 (13%)	0 (0%)	0 (0%)
	Good	5 (29%)	6 (40%)	2 (40%)	0 (0%)	1 (25%)	2 (50%)	8 (31%)	8 (35%)	1 (50%)	1 (33%)
	Very good	9 (53%)	7 (47%)	2 (40%)	3 (75%)	3 (75%)	2 (50%)	14 (54%)	12 (52%)	1 (50%)	2 (67%)
Involving you in decisions, n (%)	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Poor	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)
	Neither	2 (13%)	2 (18%)	1 (20%)	2 (40%)	0 (0%)	0 (0%)	3 (13%)	4 (20%)	0 (0%)	0 (0%)
	Good	5 (33%)	4 (36%)	2 (40%)	0 (0%)	1 (25%)	2 (50%)	8 (33%)	6 (30%)	1 (50%)	0 (0%)

		Practice						Intervention		Usual care	
		A (n=17)		B (n=5)		C (n=4)		(n=27)		(n=3)	
		Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Treating you with care and concern, n (%)	Very good	8 (53%)	4 (36%)	2 (40%)	3 (60%)	3 (75%)	2 (50%)	13 (54%)	9 (45%)	1 (50%)	2 (100%)
	Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Neither	0 (0%)	1 (6%)	0 (0%)	2 (40%)	0 (0%)	0 (0%)	0 (0%)	3 (12%)	0 (0%)	0 (0%)
	Good	6 (40%)	6 (38%)	3 (60%)	0 (0%)	1 (25%)	2 (50%)	10 (42%)	8 (32%)	1 (33%)	1 (33%)
Confidence and trust, n (%)	Very good	9 (60%)	9 (56%)	2 (40%)	3 (60%)	3 (75%)	2 (50%)	14 (58%)	14 (56%)	2 (67%)	2 (67%)
	No, not at all	0 (0%)	1 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)
	Yes, to some extent	3 (18%)	2 (12%)	2 (40%)	2 (40%)	0 (0%)	0 (0%)	5 (19%)	4 (15%)	0 (0%)	0 (0%)
	Yes, definitely	14 (82%)	14 (82%)	3 (60%)	3 (60%)	4 (100%)	4 (100%)	21 (81%)	21 (81%)	3 (100%)	3 (100%)
Recommend surgery, n (%)	No, definitely not	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	No, probably not	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Not sure	1 (6%)	2 (12%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (4%)	3 (12%)	0 (0%)	0 (0%)
	Yes, probably	7 (39%)	6 (35%)	1 (20%)	1 (20%)	0 (0%)	0 (0%)	8 (30%)	7 (27%)	0 (0%)	0 (0%)
	Yes, definitely	10 (56%)	9 (53%)	4 (80%)	4 (80%)	4 (100%)	3 (75%)	18 (67%)	16 (62%)	3 (100%)	3 (100%)

N.B. 'Don't know' or 'Not applicable' responses have not been included.

There was little difference in primary care contact between intervention and usual care in the six months prior to the trial compared to follow-up (Table 30). The main resource cost drivers were unplanned hospital admissions, GP surgery visits and accident and emergency visits (Table 31), but the small numbers and wide variation make it difficult to draw conclusions.

Table 30: Mean change in the number of primary care contacts for six months before follow-up and during follow-up for individual practices, intervention combined and usual care

		Practice			Intervention total (n=29)	Usual care (n=5)
		A (n=18)	B (n=7)	C (n=4)		
Any primary care contact*	Prev 6 months, median (IQR)	3.0 (2.0, 8.0)	2.0 (0.0, 4.0)	3.5 (2.0, 11.0)	3.0 (2.0, 5.0)	3.0 (3.0, 8.0)
	Follow-up 6 months, median (IQR)	3.5 (1.0, 7.0)	3.0 (2.0, 7.0)	2.0 (1.0, 13.0)	3.0 (2.0, 7.0)	3.0 (0.0, 7.0)
	Change between two periods, median (IQR)	0.0 (-1.0, 4.0)	2.0 (0.0, 5.0)	0.0 (-2.5, 3.5)	0.0 (-1.0, 4.0)	-1.0 (-1.0, 0.0)
	Difference-in-difference (95%CI)	0.49 (-2.36 to 3.35)				

\*include surgery appointment, telephone appointment or home visit by GP, nurse or health care assistant

IQR = Interquartile range

Table 31: Resource use activity and associated costs

Resource use		Practice						Intervention total		Usual care	
		A (n=18)		B (n=7)		C (n=4)		(n=29)		(n=5)	
		n	£	n	£	n	£	n	£	n	£
Any primary care contact	Prev 6 months	99	£1,420	14	£367	26	£417	139	£2,203	26	£438
	Follow-up 6 months	93	£1,951	30	£1,145	28	£369	151	£3,464	26	£715
GP surgery visit	Prev 6 months	30	£930	7	£217	5	£155	42	£1,302	8	£248
	Follow-up 6 months	45	£1,395	9	£588	2	£131	56	£2,114	9	£279
GP telephone	Prev 6 months	3	£73	0	£0	0	£0	3	£73	0	£0
	Follow-up 6 months	3	£73	3	£73	0	£0	6	£146	1	£24
GP home visit	Prev 6 months	0	£0	2	£131	0	£0	2	£131	0	£0
	Follow-up 6 months	0	£0	6	£392	0	£0	6	£392	5	£327
Nurse surgery visit	Prev 6 months	19	£237	0	£0	21	£262	40	£499	14	£175
	Follow-up 6 months	36	£449	5	£62	16	£199	57	£711	4	£50
Nurse telephone	Prev 6 months	0	£0	0	£0	0	£0	0	£0	0	£0
	Follow-up 6 months	0	£0	2	£10	0	£0	2	£10	7	£35
HCA surgery visit	Prev 6 months	47	£180	5	£19	0	£0	52	£199	4	£15
	Follow-up 6 months	9	£34	5	£19	10	£38	24	£92	0	£0
Any unplanned secondary care contact	Prev 6 months	8	£14,220	3	£3,607	0	£0	11	£17,827	1	£148
	Follow-up 6 months	11	£533	8	£2,492	0	£0	19	£3,025	2	£4,850
A+E visits	Prev 6 months	5	£740	2	£296	0	£0	7	£1,036	1	£148
	Follow-up 6 months	2	£296	2	£296	0	£0	4	£592	1	£148
Out of hours calls	Prev 6 months	3	£21	0	£0	0	£0	3	£21	0	£0
	Follow-up 6 months	8	£56	3	£21	0	£0	11	£77	1	£7
Ambulance call out	Prev 6 months	0	£0	1	£181	0	£0	1	£181	0	£0
	Follow-up 6 months	1	£181	2	£362	0	£0	3	£543	0	£0
Ambulance conveyancing	Prev 6 months	0	£0	0	£0	0	£0	0	£0	0	£0

Resource use	Practice						Intervention total (n=29)		Usual care (n=5)			
	A (n=18)		B (n=7)		C (n=4)		n	£	n	£		
	n	£	n	£	n	£						
	Follow-up 6 months		0	£0	1	£248	0	£0	1	£248	0	£0
Unplanned hospital admissions n, days	Prev 6 months		3, 43	£13,459	2, 10	£3,130	0,0	£0	5, 53	£16,589	0,0	£0
	Follow-up 6 months		0,0	£0	4, 5	£1,565	0,0	£0	4, 5	£1,565	2, 15	£4,695

### *7.5.7 Staff and participant views on future study design*

Intervention practice staff reported that it might have been useful to learn from other practices. £1500 was viewed as adequate, but not enough for wider transformation. The support manual provided to practices, including evidence summary and examples of possible interventions, was rarely used. At the end of the trial, all intervention practices reported that they were thinking about further developing their interventions (e.g. installing a monitor in reception area to show the number of calls queued), but none had modified the intervention during follow-up. All participants interviewed found the questionnaires quick and easy to complete, although some found it difficult remembering to complete them.

### *7.5.8 Expanding the initial CMO configurations*

Emerging CMO configurations, based on the participant and staff interviews, are shown in Table 32. Important mechanisms were convenience, reassurance, confidence, trust and flexibility. Some CMO configurations were directly related to the interventions developed. For example, when patients are acknowledged and given information when the calling, such as through call stacking (context), this triggers the mechanism of increased confidence of speaking to a receptionist, leading to the outcome of increased likelihood of getting an appointment. Whereas others were not directly related to the interventions, for example, if a GP or nurse tells a patient they need an appointment, this triggers efficient action leading to an increased likelihood of booking an appointment.



Table 32: Expanded context mechanism and outcome configurations

<u>Context</u>	<u>Mechanism</u>	<u>Outcome</u>
<b>Booking system</b>		
Acknowledgement and information (e.g. being held in a queue)	Confidence	Ability to book an appointment
Knowledgeable and empowered receptionists (e.g. effectively signposting with backing from GPs and senior staff)	Trust	
Acceptance of booking system	Engagement	
Primary care staff authorisation of future appointment	Efficient action	
Available appointments with usual doctor	Reassurance and continuity	
Short wait on telephone	Convenience	
<b>Transport options</b>		
Resources to support transport at surgery (e.g. charging point or taxi booking service)	Reassurance	Ability to get to the surgery
Friends, family or neighbours with access to a car	Flexibility	
Familiar transport routine (e.g. using the same taxi firm or bus to travel to the doctors combined with shopping)	Efficiency	
Financial resources and willingness to pay for a taxi	Autonomy	
Suitable public transport routes and times	Convenience	
Ability to walk to surgery	Reassurance	

## 7.6 Discussion

Practices were able to successfully design and implement their own context-sensitive service changes based on a support manual, development meetings and £1500 grant. They found the process acceptable because it gave them the freedom, time and resource to be innovative or provided an opportunity to implement existing ideas. Recruiting older participants without car access proved challenging, with only a 3% response rate, but retention was good. Refined theory highlighted important contexts and mechanisms related to access and the interventions.

### 7.6.1 Strengths and limitations

The overarching realist programme theory (Figure 22) and standardised support package given to intervention practices provided a base from which practices could develop their own service changes. It enabled a comparison between intervention and usual care, whilst also allowing for an understanding of the relative impact of each individual intervention. Profiling and observations were undertaken to understand the characteristics and dynamics of practices. We believe this increases the utility of evidence produced because practitioners can understand what solutions were developed for particular issues and their relative impact. Not only was the trial driven by

realist theory, it also expanded the initial CMO configurations to provide a clearer understanding of access to primary care for this group. Therefore, whilst some participants may have found it difficult to differentiate between ease and convenience, our revised theory has proposed improved CMO configurations. We did not have a primary outcome because we sought to explain the multiple effects of this complex intervention. This is supported by MRC guidance which states that whilst a single primary outcome and small number of secondary outcomes to evaluate complex interventions is the most straightforward from a statistical point of view, this may not provide an adequate assessment of success [92].

Whilst retention was good, the recruitment rate was poor primarily because of the eligibility criteria requiring no car access. Due to the recruitment strategy, it was not possible to estimate the eligible population without access to a car. Furthermore, the proportion of appointment questionnaires returned compared to appointments was 37.3%, although this figure may be underestimated because of joint appointments. Practice A was not able to implement closer links with the community transport provider, but other proposed changes were implemented. Implementation activity measures were not sufficiently robust, but qualitative data on implementation was collected during the end of study interviews.

#### 7.6.2 *Implications for a definitive trial*

Future studies should consider alternative means of collecting data, rather than recruiting individual patients which proved difficult. Intervention practices found it easier to develop interventions relating to the booking system rather than transport, suggesting that wider community and stakeholder action is needed to improve transport. Practices A and C used some of the £1500 grant for out of pocket expenditure, whereas Practice B only had staff time costs. Whilst it could be argued that achieving the outcome at the lowest cost is desirable, practices may have been more innovative if the grant was limited to out of pocket expenditure.

After a few months, it became clear that the taxi slots were not being used, but the practice continued until study completion despite ideas for improvement. Future studies may consider a review period during the trial to allow practices an opportunity to make small modifications with any significant changes incorporated into the analysis plan.

Four criteria for progressing to a full trial were set *a priori*. Three were achieved: there was 91% participant follow-up compared to 50% stated in the progression criteria; all four practices completed follow-up compared to a threshold of two in the progression criteria; and all three practices were able to develop and implement an intervention, compared to a threshold of two in the progression criteria. However, one criteria was not met; two practices recruited less than 60% of target participants (four out of ten and five out of ten) compared to the target of all practices

recruiting 60% or more (six out of ten). As mentioned above the primary reason for this was identifying patients without car access. Whilst the participants recruited to the trial were undoubtedly vulnerable, it is unlikely that sufficient participants could be recruited for a fully powered trial. Therefore a future trial should not restrict eligibility to those without transport or ask practices to specifically develop an intervention to improve transport. Whilst it is expected that this would allow for sufficient recruitment, a pilot study would be required.

### *7.6.3 Comparison with other studies*

Adaptive intervention designs have been used for individual patient management [247-249], but less often for complex interventions. The RADiP trial randomised 795 dental practices in Scotland to either an audit and feedback intervention to improve antibiotic prescribing or control [250]. The intervention practices were then able to develop their own local solutions to improve prescribing habits. The authors found a statistically significant improvement in antibiotic prescribing. Our study has similarities because it allowed intervention practices to develop their own solutions, but arguably for a more complex issue.

Two key linked considerations in the evaluation of complex interventions are standardisation [251] and generalisability [252]. Previous MRC guidance on complex interventions stated that trials should “consistently provide as close to the same intervention as possible” by “standardising the content and delivery of the intervention” in every site [253]. However, the 2008 guidance [92] acknowledges that complex interventions may change and some interventions are specifically designed to adapt to local circumstances [254, 255]. A rigid, standardised intervention which aims to be the same in every setting may subsequently reduce the generalisability because in real life practitioners modify intervention to complement existing practices, policies and services. Our trial design uses middle-range [256], theory of commonly found mechanisms and hence may be more transferable, increasing generalisability.

### *7.6.4 Implications for research and policy*

Practices were successfully able to design and implement context-sensitive interventions and found the process liberating and empowering. Researchers and policy makers should consider giving general practices more opportunities to develop innovative, context-sensitive solutions for local problems, rather than dictating 'one-size-fits all' interventions. However, the process needs managed with dedicated time, resource and willingness from practices.

Research methods need to evolve to generate more useful evidence for decision makers. Katikireddi and colleagues found that most policy initiatives were likely to be ineffective or lacked the evidence to establish effectiveness [257]. This is unsurprising since only 1 in 4 policy makers

report using review articles and evidence summaries or academic journals as a source of information [258]; a finding supported by other researchers [259-261]. Here we present a study design, based on theory and a standardised evidence-based support package that also provides context-sensitive exemplar interventions of the operationalisation of the theory. We believe this design is more likely to produce useful evidence for decision makers because it does not assume that 'one-size-fits all' or judge success based on a single primary outcome, but rather proposes local solutions for local problems explaining their likely effects.

#### 7.6.5 *Conclusion*

Recruiting older participants without access to a car proved challenging, but retention was good. Practices were able to successfully design and implement their own context-sensitive service changes, giving them the freedom, time and resource to be innovative or provided an opportunity to implement existing ideas. It is hoped this study design may facilitate a shift from one-size-fits-all approaches to solutions which are more context-sensitive and facilitate a greater theoretical understanding of the problem and intervention.

## **8 Discussion and conclusion**

A specific discussion section is included at the end of each study chapter discussing the meaning of the findings, comparison with existing literature, strengths and limitations and implications for policy and research (See Chapters 3, 4, 5 and 7). This chapter presents a discussion of the research as a whole, highlighting cross-cutting themes and important issues.

### **8.1 Summary of findings**

There were four main studies within this research. The first three (a realist review, qualitative study and cohort analysis) were synthesised into one overall realist programme theory (Chapter 6) to inform the development of an intervention, which was tested in the fourth study (Chapter 7), a cluster feasibility trial.

The first study, a realist review (Chapter 3), identified articles related to rurality, socio-economic disadvantage or older age and access to primary care. In total, 162 articles were included, most were from the USA or UK, cross-sectional in design and presented subgroup data of rural, socio-economic disadvantage or older age. A seven-step patient pathway was generated with the following steps: problem identified; decision to seek help; actively seek help; obtain an appointment; get to appointment; and primary care interaction. Important contexts were stoicism, education status, expectations of ageing, financial resources, understanding of the health system, access to suitable transport, capacity within the practice, the booking system and experience of health care. Key mechanisms were health literacy, perceived convenience, patient empowerment and responsiveness of the practice.

The second study was a qualitative study of semi-structured interviews with older people and focus groups with health professionals (Chapter 4). From this study, the concept of a social contract, where an individual is careful not to bother the doctor in return for goodwill when they become unwell, was proposed. There were also a number of other issues identified by participants, such as engaged telephone lines, availability of appointments, interactions with receptionists and transport for those without a car. Health professionals described rising demands and expectations but increasing service constraints necessitating reconfiguration.

The third study was an analysis of the English Longitudinal Study of Ageing (ELSA) linked to the General Practice Patient Survey using structural equation modelling (SEM) to explore the aforementioned realist theory (Chapter 5). Limited data meant that analysis was only possible for one-step of the patient pathway; obtain an appointment. The direct effects (context to outcome) and indirect effects (context to outcome via mechanism) were estimated for nine CMO

configuration. Of these, two indirect pathways were statistically significant, 1) ease of getting through to the surgery (context), through the mechanism of convenience to obtaining an appointment (outcome) and 2) health care experience (context), through the mechanism of convenience to obtaining an appointment (outcome).

The final study was a cluster trial assessing the feasibility of the study design and intervention (Chapter 7). After reviewing the overall programme theory for issues which were strong themes and could be influenced by general practices, two issues were identified (booking system and transport). Based on stakeholder dialogues, an intervention was developed which allowed practices asked to develop their own interventions to overcome local problems. To achieve this, intervention practices were given a support package of a manual, four development meetings and a £1500 grant. A range of interventions were developed and implemented, including call stacking, promoting community transport, working with a local taxi firm, receptionist training, incorporating transport into signposting, flexibility with appointments, promoting the role of receptionists and a mobility scooter charging point. The participant recruitment rate was low (3%), mainly because of the eligibility criteria of no car access, but retention was good (91%). Trial design and data collection methods were acceptable to participants and practice staff. Practices found the process acceptable because it gave them the freedom, time and resource to be innovative or provided an opportunity to implement existing ideas.

## **8.2 Strengths and limitations**

The strengths and limitations of each specific study is detailed in Chapters 3, 4, 5 and 7. In this section overarching strengths and limitations, and any study-specific issues not highlighted above, are discussed. However, to re-cap the study-specific strengths and limitations are briefly described below. The realist review covered a breath of literature but lacked detailed exploration of individual CMOs and was limited by a lack of studies focusing on socio-economically disadvantaged older people who also lived in rural areas (section 3.6.2, page 49). The qualitative study, whilst collecting data from patients and health professionals, faced difficulties recruiting patients with the final recruitment strategy of using pharmacy bags raising the possibility of selection bias (section 4.6.2, page 65). Furthermore, the qualitative data did not allow exploration of differences between genders, ages or life events. The cohort analysis was primarily limited by the data meaning that 1) only a small number of the CMOs relating to one outcome could be explored, 2) only a small sample of participants was included and 3) there is a risk that variables used may not have sufficiently capture the concepts within each CMO (section 5.8.2, page 84). Finally, the feasibility trial, whilst having a good retention rate, did not reach the recruitment target, had a relatively low return of appointment questionnaires (37%) and participants may have

found it difficult to differentiate between the concepts of ease and convenience (section 7.6.1, page 141). Practices were able to successfully develop and implement their own intervention, but not all components were equally implemented, and the implementation activity measures devised were not sufficiently robust to allow analysis.

### 8.2.1 *A priori protocol and changes*

A protocol for the research was published *a priori* in a peer-reviewed journal [99] demonstrating what was initially planned and how the research has been modified, reducing the risk of reporting bias. Most changes have been discussed in the above chapters, such as modifying the recruitment strategy in the qualitative study (section 4.4.1, page 55) and restricting the analysis of ELSA (section 5.6.3, page 74). Two changes not discussed in the chapter relating to the cohort analysis were the use of Hospital Episode Statistics (HES) and planned longitudinal analysis (section 2.5.2, page 23). Exploring the impact on unplanned hospital use, such as A+E attendances and unplanned hospital admissions, was initially planned. At the time of writing the protocol, this would have been possible because NatCen, who hold the linked ELSA and HES data, had the data available and approvals. However, before the analysis started the Health and Social Care Information Centre (now NHS Digital) decided to review the approval for the ELSA and HES linked dataset. Despite waiting 16 months and offering to undertake the analysis in the secure data enclave at NatCen, approval was still awaited, and the decision was made to analyse without the HES linkage. A longitudinal analysis was not possible because of the model complexity and small numbers included.

A further change from the protocol was planned stakeholder dialogues with HealthWatch Norfolk, NHS England and local commissioners (section 2.5.5, page 24). The main contact from HealthWatch Norfolk with an interest in access to primary care had moved to a different job, an initial meeting with NHS England commissioners had proved less fruitful than expected and it was not possible to identify someone from a local Clinical Commissioning Group. It proved more valuable speaking to practice managers, GPs and local practice staff, therefore nine stakeholder dialogues were held with this group instead.

An initial aim was to look at access to *high quality* care, acknowledging that simply improving access to health care is not sufficient. The patient pathway included primary care interaction as the final step and the feasibility trial included some measures of patient-reported quality of care (such as being given enough time by the doctor or nurse), however it was not possible to link to objective clinical outcomes, such as improved symptoms, and quality of care could not be explored in depth in the qualitative study.

### 8.2.2 *Identifying disadvantage*

A recurrent issue in the research was identifying older people who experience socio-economic disadvantage defined as “a state of observable and demonstrable disadvantage relative to the local community or wider society or nation to which an individual, family or group belongs” [262]. Disadvantage and deprivation are often used interchangeably. The term deprivation may elicit connotations of personal inadequacy, whereas the term disadvantage is used here because suggests social, economic or political forces outside a person’s control [263]. One issue is that an individual’s deprivation or disadvantage is relative [264]. For example, relative deprivation has been defined, as “a judgment that one or one’s ingroup is disadvantaged compared to a relevant referent, and that this judgment invokes feelings of anger, resentment, and entitlement” [264].

Several proxies are used as objective measures of disadvantage or deprivation. For example, the National Statistics Socio-economic Classification (NSSEC) is used widely in national statistics to measure social class and socio-economic position by categorising people based on their job and level within that job [265]. However, disadvantage is often multi-dimensional involving housing, education, employment and social conditions [262] and using employment, or previous employment, becomes more problematic as people advance through retirement, especially for women who may not have been employed. To capture the multidimensional nature of disadvantage several indices have been used, such as Jarman score [266], Townsend score [267] and Carstairs measure [268]. The Index of Multiple Deprivation (IMD) is the most commonly used nationally and locally [269] as an area-based measure. Based on census data, the IMD includes seven domains, covering issues such as income, employment and barriers to housing and services. However, these indices have been criticised because they do not accurately capture deprivation in rural areas by tending to focus on material disadvantage that is commonest in urban areas [270, 271]. Rural residents may face different challenges such as fuel poverty, limited access to services, poor social networks, low incomes or poor digital connections [272]. Modifications of existing indices for rural areas has successfully highlighted greater heterogeneity and hidden pockets of deprivation in rural areas [273], however this is not widely used and remains an area based measure of deprivation rather than at the individual level.

In the ELSA analysis NSSEC was used because this was the best available measure (section 5.6.2, page 74), in the qualitative study (section 4.4.1, page 55) receiving means-tested financial support and in the feasibility study access to a car in areas with a low IMD postcode score (section 7.4.2, page 113). Whilst all of these are markers of disadvantage, it would have been preferable to have one single definition, and associated measure, which could have been easily applied throughout the research. However, this would have been challenging because it may have resulted in a definition that was too narrow (restricting recruitment), too broad (leading to a failure to recruit the right



types of patients), or too complicated (proving impractical for the cohort analysis or feasibility study). Therefore, one of the limitations of this research is this nebulous concept of disadvantage, with different criteria being used in the different studies.

### 8.2.3 *Recruitment*

Recruitment proved difficult in both the qualitative study and feasibility trial. The primary reason for the difficulty in the qualitative study was identifying people on means-tested benefits and in the feasibility trial was people without access to a car. In both studies, the recruitment strategy evolved to increase recruitment (section 4.4.1 and 7.4.3, page 55 and 113). Undoubtedly trying to recruit hard-to-reach people is challenging, but the majority of those recruited were significantly disadvantaged and vulnerable. With changes to the recruitment strategy, enough participants were recruited to the qualitative study, but not enough to the feasibility trial. In particular, three practices in the feasibility study recruited below target, with one recruiting just four participants. However, on visiting the participants to obtain consent and collect baseline data, most had significant disadvantage, and some were extremely vulnerable. The low participation in some practices made it more difficult to get data on the acceptability and implementation of the service changes.

### 8.2.4 *Mixed methods*

One main strength was the use of mixed methods, combining quantitative and qualitative data to gain a fuller understanding of the issues. Mixed methods were used both in developing the overall programme theory (Chapter 6) and the feasibility trial (Chapter 7). A triangulation protocol and mixed methods matrix was used to integrate both the quantitative and qualitative findings (section 6.3, page 89). Whilst it was possible to integrate the data from the three initial studies, the ELSA analysis was restricted by limited data and did not propose new CMO configurations meaning that the overall programme theory was mostly an integration of the realist review and qualitative data. Furthermore, the findings from the SEM relating to access to primary care were less useful because of issues around mapping variables to concepts and mixing practice and patient level data. For example, the significant CMO configurations contained variables entirely from GP Patient Survey (Figure 13 page 82). Furthermore while model fit was adequate, it was not good, as defined by the existing literature [216]. It would have been preferable to design a survey based on the CMO configurations from the realist review, rather than trying to find variables in ELSA and GP Patient Survey that matched.

A realist approach was suitable for synthesis of mixed method data, but could have been made easier by analysing the qualitative data using a realist logic of analysis rather than thematic

analysis (section 4.4.3, page 57). Thematic analysis was chosen to gain training and experience in one of the more common qualitative analysis techniques, but it meant that the planned hypothetical vignettes were not possible (section 2.5.3, page 23). However, it created methodological inconsistencies. It required re-analyse the qualitative data using the CMO logic of analysis to allow comparison with the realist review. Whilst this was adequate for generating the overall programme theory as described in Chapter 6, it could have been improved by undertaking realist interviews based on the CMO configurations generated from the realist review [240]. This would have necessitated an early choice on what specific CMO configurations to focus on and showing or describing the CMO configurations within the interviews. It may have resulted in more refined overall realist programme theory but may not have produced the concept of a social contract.

Inter-method discrepancies were highlighted and discussed in Chapter 6 (section 6.5, page 91). However, because of the design of the triangulation protocol the discrepancies were identified towards the end of the synthesis process. This meant that there was little opportunity for the discrepancies to be explored in-depth, for example, by including them in the topic guides of the qualitative study. Certain discrepancies arose because some of the literature included in the realist review was older or from a different health system. The age of the study was not formally considered within the realist review, although it was indirectly included during the assessment of relevance and rigour. In retrospect, it may have been more helpful to formally consider the age of the study or limit the search to recent studies because attitudes and behaviour may have changed overtime.

#### *8.2.5 Interventions limited by confines of a trial*

The interventions developed by practices were by nature small-scale improvements to the booking system or supporting better transport for patients. The scale of the intervention was limited by the size of grant, the short timescales for development and implementation and confines of an intervention focusing on a single organisation. It is likely that significant improvements in transport would require large-scale, multi-stakeholder action. For example, increased investment in public and community transport in rural areas and improved funding and more staff in primary care to increase the number of appointments and time spent with patients. Similarly, while the trial interventions may have helped to improve issues, such as engaged telephone lines and signposting, there may be wider systemic issues affecting the ability to book appointments, such as, a lack of funding or qualified GPs.

## 8.3 What do the results mean?

### 8.3.1 *Context is important*

This research project used methods which attempt to accommodate context in relation to how socio-economically disadvantaged older people access primary care. For example, the realist review explored the contextual barriers to primary care that exist (such as stoicism, expectation of ageing, transport and the booking system) and SEM consequently opened the possibility of quantifying the relationship between contexts, mechanisms and outcomes (section 5.8.5, page 86). The feasibility study highlighted some of the different local challenges (such as engaged telephone lines, access for people who use mobility scooters and taxi availability) and possible solutions (such as call stacking, charging points for mobility scooters and working with taxi companies). A key challenge was analysing and interpreting contextual factors in a manageable way; too much depth becomes unwieldy, but not enough depth becomes insensitive. For example, the realist review generated 52 different CMO configurations making the findings difficult to present in a precise manner. A mixed methods approach was used here (section 2.5 and 6.2, page 20 and 89), however other qualitative or quantitative techniques could have been used and may have been more useful. For example, primary data collection through a survey to explore the realist theory would have been considerably better than attempting to map the concepts onto the ELSA variables. Furthermore, ethnography exploring behaviour of older people in rural areas as they access primary care would have provided useful data to complement the interviews and focus groups. Furthermore, the definition of context varies (section 1.8.1, page 11). In realist approaches, contexts can only be fully understood within a context-mechanism-outcome configuration. Therefore, exploration of context in this research was restricted by the confines of the realist CMO logic of analysis.

The feasibility study experimentally used an adaptive intervention based on realist theory, showing that local context-dependent service changes could be developed. This is important because it supports the existing argument that trials of complex interventions should not try to remove contextual confounders but rather acknowledge the open systems of real world contexts [274]. Many trials are designed to minimise differences between arms so that any change in outcomes can be attributed to the intervention rather than another factor or confounder. However, in trials of complex interventions many confounders are related to important local factors. For example, the National Audit Office found that it is primarily the working arrangements of individual general practices that influenced the ability to obtain an appointment, rather than broader workforce or demographic issues [16]. These confounders or contextual factors are important when analysing, interpreting and presenting results because decision makers want to know the settings in which an intervention is more or less likely to work. Without consideration of local factors, interventions

may risk being ineffective because they do not address local issues or fail to engage local practitioners because they are viewed as less relevant.

### 8.3.2 *Quantifying realist theory*

In both the cohort analysis and feasibility trial the underpinning realist theory was quantified. Quantifying CMO configurations is important because it helps differentiate the relative effect of each CMO configuration. Furthermore, the impact and influence of realist theory may be greater with a quantification of CMO configurations because many commissioners, policy makers and practitioners may want to quantify the likely impact of implementing research recommendations. SEM has been proposed by other researchers [227] and is an important step forward in expanding the use of quantitative methods in realist approaches, alongside techniques such as propensity score matching [224]. Importantly, the research presented here suggests that SEM is more likely to be useful when researchers can collect primary data of a continuous nature.

There remain several unresolved barriers to developing quantitative methods in realist approaches. First, the understanding of successionist and generative causation has been debated between realism and statistical modelling [208, 275] as discussed in Chapter 5 (section 5.8.3, page 85). While statistical modelling is usually used within the context a positivist philosophy and successionist model of causation, the statistical process itself does not have a philosophy or view of causation. Using statistical modelling, such as SEM, to measure the association between variables could be undertaken within a generative model of causation to test if an activated mechanism is associated with an outcome. Second, using variables to measure complex, and often unobservable, constructs has been criticised because it oversimplifies concepts [208], as discussed in Chapter 5 (section 5.8.3, page 85). However, this may preclude the use of any quantitative methods and, furthermore, SEM allows the estimation of latent, or unobserved, concepts through factor analysis. SEM may not always be possible because it requires relatively large numbers with ideally primary data collection and it would be challenging to explore emerging or refined CMOs as they arise.

### 8.3.3 *Generating useful evidence*

A key pursuit of this research has been to generate useful evidence for decision makers. The two existing systematic reviews provide some useful ideas to improve access to primary care [63, 64], but considering the multifactorial and dynamic nature of access, it was unlikely that there was going to be a simple solution for such a complex problem [260]. Smith argued that the failure of policy to be evidence-based is related to the fact that generally research communicates ideas, not evidence, to policy makers [276]. So, whilst it would have been preferable to produce a simple

intervention which would be effective in improving access in all, or even most, settings and could be easily translated into policy, this is unlikely to be realistic. It would be more useful to generate an understanding of the problem and propose solutions which are likely to be effective depending on the local issues.

While it may have been possible to achieve some of these aims using a traditional randomised controlled trial design with a robust process evaluation, there are some key differences in the design of the feasibility trial presented here. First, trials of complex interventions are often designed to judge the success or failure of an intervention based on the average difference in a single primary outcome, or occasionally co-primary outcome. A process evaluation is then used to understand the implementation, casual mechanisms and contextual factors [92]. The rationale for primary outcomes is sensible; choosing a primary outcome *a priori* prevents researchers biasing results by choosing favourable outcome measures after the study is completed. Suspicions arise if secondary outcomes are used to justify an intervention in the absence of a positive primary outcome. However, complex interventions work on multiple organisational levels and produce a variety of different and competing positive and negative effects. Judging success based on the average across groups misses those individuals or organisations for which an intervention works particularly well or badly and may leave some to ask, “Did the trial kill the intervention?” [277]. The design of the feasibility trial has experimentally attempted to produce more useful evidence by trying to understand the effects of the intervention, why they occurred and the relative differences between practices, rather than judge success on a single outcome. Importantly this involves mapping of the context and setting [278].

Second, complex interventions tested in trials are often limited by the current policy, organisational landscape or technology available, at the time of trial design. In turn, this may limit the longevity of the evidence. For example, one of the most cited primary care trials in the past 10 years, the COMPETE II trial, randomised patients with type 2 diabetes to shared access with primary care to a web-based, colour coded diabetes tracker across 13 risk factors which delivered brief lifestyle messages [279]. The trial had high internal validity, but since starting in 2002 and publication in 2008, the use of smart phone and tablet apps linked to activity trackers or wearable technology has proliferated. Decision makers in 2018 are less likely to implement this intervention because the technology has been superseded. Some may identify the core components of the intervention, adapting it for use with current technology, but the evidence is weakened because the outcomes presented are inextricably linked with the technology and software that is at least 16 years out of date. In the feasibility trial an overarching realist theory was used which is not tied to any particular policy, technology or organisation. The overarching theory was then operationalised in context-dependent practice interventions because this dynamic adaptation is usually what happens in practice. Theoretically, this process may possibly, if used in a larger scale study,

increase the longevity of the evidence, even if the operationalisation of the overarching theory changes over time.

#### *8.3.4 Challenges and processes in primary care*

Capacity, funding and workforce in primary care were recurrent issues in the realist review, qualitative study and feasibility study. For example, the realist review identified contexts, such as availability of appointments and financial resources, and the qualitative study highlighted the rising demands and expectations coupled with service constraints. The challenges, especially around funding and workforce, facing primary care are well documented [280, 281]. Undoubtedly, new models of delivering primary care at better value are needed more than ever [282].

In the feasibility trial, practices were successfully able to develop and implement their own interventions. The intervention development process was explored in the process evaluation by analysing transcripts of the development meetings and interviews with practices staff. It revealed some information about how decisions are made in primary care. The evidence and policy documents provided to practices at the beginning of the decision-making process were rarely used. It is unclear if this is because the documents were not written or presented in an accessible format, the evidence presented was not relevant or published evidence does not play a major role in decision-making in general practice. Local knowledge and examples from other practices seemed more important than research evidence. In fact, all practices were keen to find out what interventions the other practices had developed. The potential reaction of the GP partnership was an important consideration for all members of staff who were involved in the decision-making process. The short timescales and deadlines appeared to help because it meant there was not enough time for partnership approval, although in every practice the partnership was informed. Whilst this made the process simpler and quicker, it is unclear if the lack of formal partnership buy-in would jeopardise long-term sustainability or larger-scale interventions. Based on this feasibility study, it seems that evidence summaries are less likely to be effective, compared to local information with examples from other similar practices.

#### *8.3.5 Multiple disadvantage and life course influences*

Whilst the realist review and qualitative study highlighted some key issues, such as lack of access to a car, more important was how multiple issues of disadvantage compounded and interacted with each other. For example, lack of car access appeared to be particularly difficult in the absence of a good local social network and /or limited finances. The concept of multiple disadvantage is not new. For example, a separate secondary analysis of ELSA identified five main sources of multiple disadvantage that some older people experience: access problems; low income; loneliness and low

social support; and fear of their local area after dark [283]. It is important to note, that while there are common causes of disadvantage in rural areas, each individual's experience is different.

The influences of an individual's life events on access to primary care in older age was also highlighted by the realist review and qualitative study. Some older people experienced paying for health care before the establishment of the NHS, others had experienced health problems throughout their life, resulting in a good knowledge of the system and potential levers, while for others, their last substantial interaction with health care was when they gave birth half a century ago. The context of lifelong poverty was identified in the realist review as triggering (or not) possible mechanisms of empowerment, perceived social exclusion, candidacy (as defined on page 66) and perceived control. Interestingly in the qualitative study, those individuals who had received state welfare most of their lives had a stronger sense of entitlement to health care than those who had only in later life experienced disadvantage (section 6.5, page 91). It appeared that those who had little interaction with health services during their working lives, but experienced disadvantage in later life found it particularly difficult to navigate and access health care. These "health careers" influence an individual's expectations of, and subsequent access to, health care [6]. For example, an older person's social contract with primary care (section 4.5.1, page 60) may be based on their experience of health care decades ago when primary care had more capacity and flexibility. This differs from a consumer perspective of health care, which has been promoted through health care policy and the introduction of market forces in recent times [80].

Despite disadvantage, most older people included in the qualitative and feasibility trial were resourceful. For example, many of the patients lived alone and went to significant lengths to travel to the surgery. One participant included in the feasibility trial lived by herself and had become increasingly blind but was still able to take bus to the surgery and back. She relied on the bus driver to tell her when she was at the surgery. Another participant would on occasion walk five miles to get to the surgery, and back, because of a lack of public transport and social support. This resourcefulness was particularly powerful for an acute problem; however, for chronic problems with a gradual onset there may be less impetus until disease is more advanced or crisis ensues [284]. The resourcefulness may be associated with previous experiences, employment or other life events (section 4.5.1, page 60). This resourcefulness is an asset and should not be underestimated. An asset-based approach has been advocated for supporting deprived communities [285], but less so on an individual level.

## **8.4 How does this research compare to other published literature?**

A comparison of the each of the individual study findings to existing literature is presented in Chapters 3, 4, 5 and 7, with an overarching comparison here.

### *8.4.1 Understanding access to health services for vulnerable groups*

Dixon-woods and colleagues undertook a critical interpretive synthesis (as discussed in section 1.1, page 1) of access to health care by vulnerable groups [18]. The authors reviewed 199 articles and proposed that the concept of candidacy and permeability (as defined on page 66) would be more useful in understanding access than utilisation. These two concepts fit well with the findings of the realist review and qualitative study, which highlighted a range of dynamic practice and patient side factors. The authors also suggested that candidacy emerges in vulnerable groups within a series of crises, for example emergency department visits, unplanned hospital admissions and out-of-hours care, rather than proactive care with a regular provider. Whilst this may be true for vulnerable groups who often have disorganised lives, such as people who are homeless, the realist review and qualitative study suggested that crises and use of urgent care services were less relevant for socio-economically disadvantaged older people in rural areas. This may be because these individuals have more organised lives, live further away from acute hospitals and experience more chronic disease.

### *8.4.2 Access to mental health services research*

Dowrick and colleagues undertook a similar, but larger, study to this research looking at improving access to mental health services as part of a NIHR Programme Grant for Applied Research [286]. To understand access to mental health services and consider solutions the authors first synthesised seven different sources of evidence: 1) a scoping review of key concepts related to access; 2) a structured review of 105 published studies looking at interventions to improve access for underserved populations; 3) a meta-synthesis of 21 qualitative papers; 4) dialogues with 53 stakeholders; 5) a review of 118 grey literature documents detailing current and planned local services for mental health; 6) a secondary analysis of 92 qualitative interviews exploring barriers and acceptable services for mental health services users; and 7) qualitative interviews with 36 service users and carers. Based on this synthesis, the authors proposed a model, named the AMP model, with the three core components of community engagement, primary care quality and psychosocial interventions. The model was then evaluated through a quasi-experimental design with a no-intervention comparator [287]. This design had essentially three levels of randomisation corresponding to the three core components of the intervention. Initially there were four sites randomised to either community engagement or control. Each site had four practices, which were



subsequently randomised to either primary care training to improve quality of mental health services or control. Finally, 57 patients were randomised across all practices to receive an individual wellbeing intervention. This design allowed the authors to explore each core component individually. The authors found that improved access was associated with the presence of community engagement and primary care training.

This research drew on the strengths of the above research programme, such as, different methods of collecting information about the problem (a realist review, qualitative study and cohort analysis) leading to intervention development. However, here a feasibility trial was undertaken at the end of the programme of research rather than a definitive quasi-intervention study. Dowrick and colleagues developed the AMP model, which may prove a more useful communication tool for commissioners and policy makers designing mental health services, compared to the patient pathway and numerous CMO configurations produced here. The evaluation design used by Dowrick and colleagues was restricted by small numbers, which the authors reported, made their data collection and analysis challenging. The feasibility trial also had small numbers but was not designed to provide definitive conclusions. The authors focused more on qualitative data, compared to quantitative data, making the conclusions difficult to quantify, potentially reducing the ability to compare the relative effectiveness of the interventions. In the feasibility trial here, there was a greater focus on quantitative data, in addition to qualitative data. The methodological challenges faced by Dowrick and colleagues reflect the complications of researching access to health care for hard to reach groups, which was demonstrated in the feasibility trial, such as challenges in recruitment. A less prescriptive approach was undertaken here, allowing practices to develop their own context-dependent solutions. Therefore, there was still a range of interventions operating at different levels and systems (e.g. practice level training, improving taxi services or mobility charging for individual patients), but importantly it was held together by overarching theory. However, in the feasibility trial the interventions were limited to what the practices could influence, whereas Dowrick and colleagues had a multi-stakeholder AMP partnership meaning, significantly, that their intervention could extend beyond one organisation. A key aspect of the Dowrick study was building stakeholder engagement through the AMP partnership. The authors reported that this led to a tension between achieving the aims of the AMP programme while allowing sufficient flexibility to keep stakeholders engaged. Engagement from practice staff developing the intervention here was good, potentially because the practices had more ownership and responsibility for their service changes.

#### *8.4.3 Interventions to improve access to primary care*

In 2012, Comino and colleagues published a review of interventions to improve access to best practice primary care for chronic disease management, prevention and episodic care [63]. The

authors identified 75 evaluated intervention studies, most of which were in Australia, USA and the UK. The interventions were categorised into five groups: 1) practice re-organisation (n=43); 2) patient support (n=29); 3) provision of new services (n=19); 4) workforce development (n=11); and 5) financial incentives (n=9). The authors found that 55 (73%) studies reported positive findings with those interventions using a combination of strategies more likely to report positive results. The interventions developed within the feasibility trial covered many of these categories, for example, there was re-organisation of the booking system, patient support with charging mobility scooters and training of receptionists (workforce development). All practice in the feasibility trial implemented a combination of strategies; however, there were few genuinely new services and the grant was not an incentive because the practices received it irrespective of the intervention or outcome.

Tan and Mays published a systematic review in 2014 of initiatives to improve access to primary and urgent care in England [288]. The authors focused on ten initiatives launched by the New Labour government between 1997 and 2010. From 19 identified studies, the authors found that the new initiatives often overlapped, resulting in complicated care. While the services did improve convenience, there was little evidence of substitution of services by patients and, in fact, the new initiatives were likely to increase overall demand. The authors argued that investment may be more effective if it focused on improving existing services, rather than developing new forms of provision. In the feasibility trial practices developed interventions that complemented their existing services to ensure consistency, for example, one practice developed their signposting process to include community transport.

Kehle and colleagues published a review in 2011 of interventions to improve access to health care for older people, focusing on US interventions [64]. The authors identified 16 studies and identified three interventions that were likely to be effective: community outreach clinics, telemedicine and integration of primary care mental health services improve access. It is less likely that practices would have been able to implement these interventions in the feasibility trial because the timescales were too short (development and implementation over a 2-3 month period), funding was limited (£1500 grant) and the intervention was focused on a single organisation. To allow some of the interventions to be tested, modifications would be needed to the trial design (see section 8.7.3 below) or a different evaluation design used.

#### 8.4.4 *Using realist methods in randomised controlled trials*

Use of realist approaches within a trial have been debated [89, 93, 208, 224, 227, 275]. Bonell and colleagues proposed a “realist RCT” [93], subsequently proposing an example of a realist RCT exploring a whole school intervention aimed at reducing aggression and bullying [227]. Fletcher

and colleagues argued that using realist principles across the phases of the MRC Framework [92] would facilitate better evaluation of complex interventions [289]. Whilst the feasibility trial was not called a realist RCT, it used a realist perspective with similarities and differences to the study proposed by Jamal and colleagues. Their trial assessed a whole-school restorative approach to reducing aggression and bullying in secondary schools. Based on a feasibility study and pilot trial, the authors hypothesised CMO configurations about the intervention *a priori*. These would be refined based on quantitative and qualitative data from a process evaluation. Finally, CMO hypotheses would be tested using mediator and moderator analyses, with CMOs being refined further. The authors argued that this would lead to an evaluation of the intervention effectiveness in context and empirically verified mid-range theory of change.

The feasibility trial here had similarities; first, initial CMO theory was proposed and refined; second, quantitative and qualitative data was used to explore the theory; and third, mediation analyses would have been undertaken with a larger sample size. However, the CMO configurations in the feasibility trial were related to access to primary care, rather than tied to a specific intervention, in this case school based restorative programme. CMOs associated with a specific intervention may be easier to identify and understand. Furthermore, the feasibility trial did not start with a defined programme to be implemented, but rather allowed general practices to develop their own service changes. Therefore, a larger trial using the design presented here would provide empirically verified mid-range theory and examples of context-dependent interventions operationalising the overarching theory.

## **8.5 Personal reflections**

### *8.5.1 Equality of access*

At times during this PhD, I have discussed the merits, or otherwise, of providing additional support to access primary care for vulnerable groups. Some people felt that the responsibility of general practices was to offer services equally to all and it was up to individual patients to take responsibility to seek help, while others that it would be unfair to prioritise one group over another.

On reflection, there may be two possible underlying factors. First, ideological differences in what equality of access means. For some equality of access means equality of opportunity. Since any registered patient can contact the practice and request to see a doctor, irrespective of age, gender, race, socio-economic position, etc., there is equality of access. The responsibility of the general practice is to ensure that everyone who contacts the surgery is seen in an equitable manner, and the

responsibility of the individual is to seek help when unwell. This touches on a broader discourse related to personal versus societal responsibility for health and interactions with health care [290].

Second, from a contractual perspective the onus appears to be on the patient to attend the surgery if they believe themselves to be unwell [44]. Therefore, some general practice staff view their legal responsibility as providing a service to those who request it, rather than proactively undertaking outreach to vulnerable groups, unless specified within an additional or enhanced service. Linked to this may be a concern about the medicalisation of ageing and provision of too much health care, as highlighted by one GP and discussed in the qualitative study (section 4.5.2.1, page 62).

These views on where responsibility lies for access to primary care may have affected the development of transport-related service changes in the feasibility trial. Some practices may not have felt that transport was their responsibility. For example, one practice reported more pressing responsibilities than transport, such as ensuring adequate staffing levels and fulfilling their obligations to NHS England. Alternatively, it may be that practices did not feel able to significantly influence transport. Small changes may be possible, like signposting to community transport or being flexible with appointments, but wider multi-lateral action from the local authority, public transport providers, third sector organisations and community groups would be needed for large-scale change. In retrospect, someone with local transport experience, such as a member of the local authority transport team or community transport provider, could have been invited to attend one of the development meetings to help generate ideas.

My view is that equality of access should be understood as an aspiration to equality of health and delivering care based on clinical need, rather than equality of opportunity. The realist review and qualitative study highlighted a number of contexts and mechanisms that suggest equality of opportunity is a misnomer because barriers exist for some, especially those with high clinical need, as supported by the social determinants of health model [291]. If equality of access is viewed as relating to equality of health, rather than opportunity, it is logical that while health care should remain free at the point of use, efforts to improve access should be proportionally targeted at those with greatest clinical need. For example, rather than investing resources in ensuring that everyone has access to primary care at evenings and the weekend, equality of access and health could be better achieved by identifying those with greatest clinical need and developing additional services to improve access for them.

### 8.5.2 *Realist methods*

Realist approaches appealed to me because of a personal discontentment with traditional systematic reviews of complex interventions which did not appear well-suited to understanding complexity, limiting their usefulness. The freedom to explore contexts within a realist review

meant that I found the reviewing process more interesting and stimulating than a traditional review. The flexibility within the realist review felt more intuitive because the direction of the review was influenced by the data. However, the review generated 52 CMO configurations in total meaning it was difficult to identify or summarise the main findings in a concise manner. In addition, the reproducibility of the realist review findings was unclear. While this may be the case for many quantitative and qualitative studies in health services research, it may be that the variation in realist reviews is greater. In hindsight if I repeated the realist review, only the CMO configurations with the greatest evidence would have been selected with a focus on one component of access rather than access across the patient pathway.

Throughout the PhD, I found differentiating between contexts and mechanisms challenging, especially when it came to assess the concepts within the feasibility study. For example, there appeared to be overlap between the concepts of “ease” (context) and “convenience” (mechanism) in the feasibility trial which made it difficult for readers to differentiate between them. Part of the issue relates to the nature of mechanisms which are, to an extent, unobservable (section 1.8.1, page 11) making them difficult to measure. In hindsight, it may have helped to clearly define and differentiate key concepts within the programme theory, which could then have been provided to participants to help them complete questionnaires. Alternatively, it may be that the tension arises from trying to fit complex mechanisms, such a perceived convenience, within a questionnaire using visual analogues scores.

### 8.5.3 *Feasibility study*

Undertaking a feasibility trial using a realist perspective was methodologically fascinating because of its experimental nature. There was a constant tension between how to analyse and interpret granular context-specific data versus the high-level data, such as the comparison between intervention and control. Developing the intervention with practices was enjoyable because the practices were enthusiastic, motivated and took ownership of the intervention. I felt a strong personal incentive for the feasibility trial to be successful because the design had been my choice. It made me aware of the powerful personal motivators at play when undertaking interventional research and the potential subsequent impact on external validity. For example, if the intervention in the feasibility study was implemented across the NHS the results may be different because the individual facilitating the development meetings may not be as personally invested. On reflection, there is a risk of bias if the individual who is delivering part of the intervention is also the principal investigator. If the trial were to be repeated, it would be better for someone else, not invested in the research, to facilitate the development meetings and work with practices.

## 8.6 Policy implications

Specific policy implications are presented in each study-specific chapter and here overarching policy implications are discussed.

### 8.6.1 *From speed and convenience of access to equality in health*

From a political perspective, policy around access is generally driven by improving the speed or convenience of access. For example, before the 2010 election the Conservative manifesto promised seven-day primary care [292] and the Labour manifesto a reintroduction of the target of being able to see a GP within 48 hours [24]. This focus on speed and convenience is likely to lead to supply-induced demand, where increasing access stimulates additional use of services that would not have otherwise occurred [293]. Without additional investment, this may in turn reduce access to services for those who find it most difficult because resources are stretched further by this additional use.

If access were understood within the context of equality of health, the policy debate would move from trying to ensure everyone could see a doctor quickly, to aspiring to achieve equality of health across society. In turn, this would help to address the inverse care law and help target health care proportional to clinical need. Access driven by need, rather than equality of opportunity, is central to one guiding principle of the NHS, “access to NHS services is based on clinical need, not an individual’s ability to pay” [2]. If access is based on clinical need, then those with greatest need, often vulnerable, marginalised groups, should be able to access more services and policy initiatives should reflect this, while ensuring that health care is freely accessible to all. Vulnerable groups will include socio-economically disadvantaged older people in rural areas, but may also include other groups, such as undocumented migrants, people who are homeless and people from the Gypsy, Roma and traveller communities. Policy initiatives to efficiently treat and manage younger, healthier people with less complex health needs, such as telephone or online consultations with a nurse practitioners or self-referral pathways, may help, if proven to be effective, to free up more resource for those with complex health needs. While technological advances will undoubtedly be important in accessing primary care in the future, many older people do not use technology. Therefore, appointments that are only available for online booking reduce the potentially available appointments for those who do not have internet access.

It is clear that there is not a single aspect of disadvantage, but multiple, that need addressing. Therefore, policies are needed which are able to target multiple levels and areas of disadvantage in rural areas. For example, increasing the number and frequency of bus routes will help some, but

there also needs to be greater support for community transport, taxi availability at key times and accessible parking.

Furthermore, it is unlikely that policy which is highly specified and rigid will be suitable for all areas. This research has highlighted some of the local, organisational and environmental contexts in which people live and practices operate within. Policies need to be sufficiently flexible to allow them to be context-dependent. For example, a hub-and-spoke model to provide access to primary care at weekends has been proposed which would see centralised access of weekend appointments. This may work in urban areas where practices are geographically close together but may be less effective in rural areas where there is often considerable distance between practices.

## **8.7 Future research**

Specific requirements for future research arising from each specific study are detailed in Chapters 3, 4, 5 and 7. Here, an overarching discussion of future research needs and implications for the design of a definitive trial is discussed.

### *8.7.1 Identifying pockets of disadvantage*

Many of the participants included in the research experienced multiple disadvantage and felt marginalised in society. There is a risk that these individuals are missed because on average rural areas are perceived as more affluent. The aforementioned rural modifications to deprivation indices [273] are an important step forward, but may still miss pockets of disadvantage because of the geographic areas used and reliance on measures not specific to rural areas. More research is needed to develop sensitive, small areas measures of rural disadvantage. This type of index could be useful in better identifying geographic areas of disadvantage and better person-specific measures are also needed for use by health and social care professionals. For example, a lack of car access is not routinely recorded in general practice systems in rural areas, but represents an important aspect of disadvantage, especially when co-existing with other challenges, such as living alone or limited financial resources.

### *8.7.2 Robust evaluations of policy decisions*

Research should not just focus on practice-level interventions, but robust evaluations are needed of wider policy decisions, which affect disadvantaged older people in rural areas. For example, the Campaign for Better Transport found that since 2010 local authorities in England and Wales have reduced or withdrawn over 2,400 bus routes due to £78 millions of funding restrictions, but there has been little research looking at the impact on rural communities [294]. Evaluation is also

needed to explore the impact for older people of increased use of technology, for example through online booking or mobile phone apps.

### 8.7.3 *Definitive study*

A larger study is needed to assess if a support package to help practices to develop their own service changes, improves access to primary care for vulnerable older people. Based on the feasibility study, the following modifications for a definitive study are recommended.

1. Transport - recruiting patients without car access was challenging and practices found it difficult to develop interventions to improve transport options, which may require wider multi-stakeholder engagement to make meaningful change. Therefore, a future trial should not restrict eligibility to those without a car or ask practices to develop an intervention specifically related to transport, but they could if this was a local issue with identifiable solution.
2. Support package - a similar support package would be appropriate with a grant, support manual and development meetings. However, modifications are needed. First, the grant would be restricted to out-of-pocket expenses to encourage practices to look outside the practice for innovation. If possible, a larger grant would be made available, in the region of £2000-3000. Second, a shared learning platform would be introduced during the development process to allow practices to learn from each other. This could be a web-based database with some basic details of the practice and proposed intervention. Intervention practices would be allowed to contact each other to optimise their intervention, however this shared learning would only be available midway through the development process to avoid groupthink. Third, the intervention would also include a review three months after implementation to allow practices to make modifications. The analysis plan could include a sensitivity analysis, excluding the first three months. Fourth, a group of facilitators would be trained to support the development meetings by promoting innovative thinking and ensuring interventions developed met trial requirements. Before the development meetings, the facilitators would undertake two observations of the practice reception area and discussions with staff to understand more about the practice. Fifth, the support manual was not widely used, so it would be reduced to only include a list of potential interventions and the service specification.
3. Outcomes – visual analogues scales would be used across the CMO configurations as the main outcomes. This would allow a comparison between intervention and control and relative difference within the intervention group. EQ5D5L, ICECAP-O, PAM and health service use would all be used as ancillary outcomes. Follow-up would be extended to 12 months with data



collection at three and six months. Extending the follow-up period would increase the likelihood of participants experiencing the service changes.

4. Sample size – based on data from the feasibility study a definitive study should recruit 90 practices allocated at a 2:1 intervention: control ratio (60 intervention practices and 30 control) and 2,700 participants which would provide 90% power to detect a difference between the groups of 15 points on the visual analogue scales at 1.67% level of significance. This assumes an ICC of 0.2, average cluster size of 30, and a dropout rate of 10% with level of significance adjusted for multiple testing for three visual analogue scale outcomes. An allocation ratio of 2:1 would be preferable because it would allow for a broader range of interventions to be developed. By removing the transport inclusion criteria, it would be expected that recruitment would be better, although an initial internal pilot would be required.
5. Analysis – with a larger sample size, SEM and multiple group analysis could be used to explore the relationship between intervention and control practices with respect to measures of context, mechanism and outcome. Intervention and control practices would be profile and grouped into similar categories by the research team or statistically using techniques such as latent class analysis or k means clustering [295]. For example, groups may be small rural practices or large urban practices. Similarly, the interventions developed would be grouped into comparable categories to allow a by-practice category and by-intervention analysis. The analysis would provide a comparison between intervention and control according to the overarching theory but would also allow a more granular analysis of the relative differences between types of interventions for different practices. An analysis of the interaction between practice and intervention may also be possible. While it would not be possible to power the study to detect differences between practices, this is also the case with secondary outcomes within traditional randomised controlled trials.
6. Outputs – the aim of the analysis would be to produce useful evidence for decision makers and researchers. Therefore, in addition to the quantitative results, there would also be case studies of what types of interventions practices have developed to overcome specific local problems. This would help practices, commissioners and policy makers understand the range of interventions, and their relative impact, providing key evidence about the possible impact of such an intervention in their locality. Furthermore, the initial theory could be refined and expanded to provide a more in-depth understanding of the problems.

## 8.8 Concluding remarks

Socio-economically disadvantaged older people in rural areas can face multiple disadvantage, reducing their access to primary care. There is no single issue that causes poor access, but a combination of multiple factors of disadvantage that accumulates over time and in place. Exploring the context, and underlying mechanisms, helps to understanding how and why this occurs.

In this research important contexts, mechanisms and outcomes around a patient pathway were identified through a realist review. A qualitative study then explored how some older people are left feeling marginalised from health care because of a breach in their social contract with primary care. Theory from the realist review and qualitative study was then quantified in an analysis of ELSA, although the findings were limited by data availability. Findings from these three studies were then synthesised into one overall programme theory and two key issues identified for intervention: the booking system and transport. Within a feasibility trial practices were given support to develop their own service changes to improve the booking system and transport.

Researchers should strive to produce the most useful evidence possible for decision makers. The feasibility trial was designed to try to overcome some of the issues which limit the usefulness of evidence from trials of complex interventions. The trial design aimed to produce evidence to describe the real-life benefits, drawbacks and potential risks and opportunities associated with the context-dependent intervention. If repeated in a fully powered study, the evidence generated may provide decision makers with empirically verified theory, examples of how the theory has been operationalised, some insight into the likely impact on their population and possible modifications needed to maximise success.

Policy decisions and initiatives relating to access to primary care should aim to address health inequalities, rather than simply focusing on speed and convenience. To improve the health of vulnerable groups, such as socio-economically disadvantaged older people in rural areas, equality of access to primary care may be better understood in terms of equality of health and delivering services based on clinical need, rather than focusing on equality of opportunity.

## 9 Statement of impact

NHS England have used the patient pathway and underlying contexts and mechanisms developed from the realist review, to produce a toolkit called “Improving access for all: reducing inequalities in access to general practice” (<https://www.england.nhs.uk/publication/improving-access-for-all-reducing-inequalities-in-access-to-general-practice-services/>) This toolkit helps individual general practices and CCGs across England to improve access to primary care for vulnerable groups as part of a £2.4 billion per year policy programme, the GP Forward View. One of the seven core requirements within this programme is to address issues of inequalities in patients’ experiences of accessing general practice.

To supplement the toolkit and to highlight some of the themes arising from this research, I have co-produced an animation with NHS England for commissioners and general practices. It highlights how inequalities can arise as patients access primary care and can be accessed here <https://www.youtube.com/watch?v=JCc20BifI5k&t=23s>

The realist review has also supported community health care for vulnerable patients in Ontario, Canada where a Local Health Integrated Network team has used the research to re-design services. In response to the realist review, the lead of the project stated, “Your model and paper on the needs of rural individuals who are medically complex is allowing me to move much quicker on my mandate”.

## References

1. UN General Assembly. Universal declaration of human rights. 1948.
2. England N. The NHS Constitution for England. London: Department of Health 2013.
3. Moberly T. NHS's greatest achievement after 70 years: The BMJ shortlist. *BMJ* 2018:361.
4. Schneider EC, Sarnak DO, Squires D, Shah A, Doty MM. *Mirror Mirror* 2017. 2017.
5. Goddard M. Quality in and Equality of Access to Healthcare Services in England. York 2008.
6. Ricketts TC, Goldsmith LJ. Access in health services research: the battle of the frameworks. *Nurs Outlook* 2005;53(6):274-80.
7. Aday LA, Andersen R. A Framework for the Study of Access to Medical Care. *Health Serv Res* 1974;9(3):208-20.
8. Andersen RM. Revisiting the behavioral model and access to medical care: does it matter? *J Health Soc Behav* 1995;36(1):1-10.
9. Harris MJ, Patel B, Bowen S. Primary care access and its relationship with emergency department utilisation: An observational, cross-sectional, ecological study. *Br J Gen Pract* 2011;61(593):e787-e93.
10. Kerr GD, Higgins P, Walters M *et al.* Socioeconomic status and transient ischaemic attack/stroke: a prospective observational study. *Cerebrovasc Dis* 2011;31(2):130-7.
11. Hassett A, George K. Access to a community aged psychiatry service by elderly from non-English-speaking backgrounds. *Int J Geriatr Psychiatry* 2002;17(7):623-8.
12. Donabedian A. Models for Organizing the Delivery of Personal Health Services and Criteria for Evaluating Them. *The Milbank Memorial Fund Quarterly* 1972;50(4):103-54.
13. Penchansky R, Thomas JW. The concept of access: definition and relationship to consumer satisfaction. *Med Care* 1981;19(2):127-40.
14. Levesque J-F, Harris MF, Russell G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. *International Journal for Equity in Health* 2013;12(1):18.
15. Institute of Medicine. Access to Health Care in America. Washington, DC: The National Academies Press; 1993.
16. National Audit Office. Stocktake of access to general practice in England. London 2015.
17. Dixon-Woods M, Cavers D, Agarwal S *et al.* Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. *BMC Med Res Methodol* 2006;6:35.
18. Dixon-Wood M, Kirk D, Agarwal S *et al.* Vulnerable groups and access to health care: a critical interpretive review. London 2005.
19. Cowling TE, Harris MJ, Majeed A. Evidence and rhetoric about access to UK primary care. *BMJ* 2015:350.
20. Department of Health: The NHS plan: a plan for investment, a plan for reform. In.: The Stationery Office London; 2000.
21. Davies P. Darzi centres: an expensive luxury the UK can no longer afford? *BMJ* 2010:341.

22. Salisbury C, Chalder M, Manku-Scott T *et al.* The National Evaluation of NHS Walk-in Centres. University of Bristol 2002.
23. Simpson JM, Checkland K, Snow S *et al.* Access to general practice in England: time for a policy rethink. *Br J Gen Pract* 2015;65(640):606-7.
24. Labour Party. Britain can be better: The labour party manifesto 2015. 2015.
25. Iacobucci G. What the political parties are pledging on the NHS. *BMJ : British Medical Journal* 2015:350.
26. Pencheon D. NHS Direct: managing demand. *BMJ* 1998;316(7126):215-6.
27. Department of Health. Equity and excellence: liberating the NHS Cm 7881. 2010.
28. NHS England. About primary care co-commissioning. 2018  
[<https://www.england.nhs.uk/commissioning/pc-co-comms/pc-comms/>]: Accessed on 6 Sept 2018.
29. Conservative Party. The Conservative Party Manifesto 2015. Conservative Party; 2015.
30. NHS England. Prime Minister's Challenge Fund. Secondary Prime Minister's Challenge Fund 2014 [<http://www.england.nhs.uk/ourwork/qual-clin-lead/calltoaction/pm-ext-access/>]: Accessed on 7 December 2018.
31. NHS England. GP Forward View. 2016.
32. NHS England. Improving access to general practice. 2018  
[<https://www.england.nhs.uk/gp/gpfv/redesign/improving-access/>]: Accessed on 6 Sept 2018.
33. Purdy S, Griffin T, Salisbury C, Sharp D. Emergency admissions for coronary heart disease: a cross-sectional study of general practice, population and hospital factors in England. *Public Health* 2011;125(1):46-54.
34. Duffy R, Neville R, Staines H. Variance in practice emergency medical admission rates: can it be explained? *Br J Gen Pract* 2002;52(474):14-7.
35. Cowling TE, Cecil EV, Soljak MA *et al.* Access to primary care and visits to emergency departments in England: a cross-sectional, population-based study. *PLoS One* 2013;8(6):e66699.
36. Soljak M, Calderon-Larranaga A, Sharma P *et al.* Does higher quality primary health care reduce stroke admissions? A national cross-sectional study. *Br J Gen Pract* 2011;61(593):e801-7.
37. Fleetcroft R, Noble M, Martin A *et al.* Emergency hospital admissions for asthma and access to primary care: cross-sectional analysis. *Br J Gen Pract* 2016;DOI 10.3399/bjgp16X686089.
38. Cowling TE, Harris M, Watt H *et al.* Access to primary care and the route of emergency admission to hospital: retrospective analysis of national hospital administrative data. *BMJ Quality & Safety* 2016;25(6):432-40.
39. Whittaker W, Anselmi L, Kristensen SR *et al.* Associations between Extending Access to Primary Care and Emergency Department Visits: A Difference-In-Differences Analysis. *PLoS Med* 2016;13(9):e1002113.
40. NHS Digital. Trends in Consultation Rates in General Practice - 1995-2009. 2018  
[<https://digital.nhs.uk/data-and-information/publications/statistical/trends-in-consultation-rates-in-general-practice/trends-in-consultation-rates-in-general-practice-1995-2009#key-facts>]: Accessed on 6 Sept 2018.
41. NHS England. GP Patient Survey. 2018 [<https://gp-patient.co.uk/>]: Accessed on 6 Sept 2018.
42. British Medical Association. Demand in general practice - GP patient survey. 2017  
[<https://www.bma.org.uk/collective-voice/policy-and-research/nhs-structure-and->

- [delivery/primary-and-community-care/demand-in-general-practice](#)]: Accessed on 22 August 2018.
43. Deloitte. Under pressure The funding of patient care in general practice. London 2014.
  44. NHS Digital. General and Personal Medical Services, England : Final 31 December 2017 and Provisional 31 March 2018, experimental statistics. 2018 [<https://digital.nhs.uk/data-and-information/publications/statistical/general-and-personal-medical-services/final-31-december-2017-and-provisional-31-march-2018-experimental-statistics>]: Accessed on 6 Sept 2018.
  45. Fletcher E, Abel GA, Anderson R *et al*. Quitting patient care and career break intentions among general practitioners in South West England: findings of a census survey of general practitioners. *BMJ Open* 2017;7(4).
  46. Wickware C. Negativity in general practice 'is worst I've known', says RCGP chair. 2017 [<http://www.pulsetoday.co.uk/your-practice/practice-topics/employment/negativity-in-general-practice-is-worst-ive-known-says-rcgp-chair/20034954.article>]: Accessed on 6 Sept 2018.
  47. Sansom A, Terry R, Fletcher E *et al*. Why do GPs leave direct patient care and what might help to retain them? A qualitative study of GPs in South West England. *BMJ Open* 2018;8(1).
  48. Scottish Government. Health and Care Experience Survey 2017/18 Results. 2018 [<https://www2.gov.scot/Topics/Statistics/Browse/Health/GPPatientExperienceSurvey>]: Accessed on 7 December 2018.
  49. Scottish Government. How are we performing? 48-hour GP access. 2018 [<https://www2.gov.scot/About/Performance/scotPerforms/NHSScotlandperformance/GP-LDP>]: Accessed on 7 December 2018.
  50. General Medical Council. The state of medical education and practice in the UK. 2017.
  51. Steel N, Ford JA, Newton JN *et al*. Changes in health in the countries of the UK and 150 English Local Authority areas 1990 to 2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet* 2018;392(10158):1647-61.
  52. Rimmer A. Northern Irish GPs warn patients that workforce crisis may mean turning them away. *BMJ* 2017;359.
  53. Royal College of General Practitioners. Primary Care Workforce Survey highlights need for strong action to tackle GP workforce shortage. 2018 [<http://www.rcgp.org.uk/about-us/news/2018/march/primary-care-workforce-survey-highlights-need-for-strong-action-to-tackle-gp-workforce-shortage.aspx>]: Accessed on 7 December 2018.
  54. Appleby J. Is general practice in trouble? ; 2014.
  55. Bostock N. GP workforce falling 50% faster in deprived areas, official data show. 2018 [<https://www.gponline.com/gp-workforce-falling-50-faster-deprived-areas-official-data-show/article/1465701>]: Accessed on 6 Sept 2018.
  56. Department for Environment Food and Rural Affairs. Statistical Digest of Rural England 2013. London 2013.
  57. Department for Environment Food and Rural Affairs. Statistical Digest of Rural England. 2018.
  58. Connors C. Rural Ageing Research Summary Report of Findings. Department for Environment Food and Rural Affairs, 2013.
  59. Barnett K, Mercer SW, Norbury M *et al*. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet* 2012;380(9836):37-43.

60. Salive ME. Multimorbidity in older adults. *Epidemiol Rev* 2013;35:75-83.
61. Asch SM, Sloss EM, Hogan C, Brook RH, Kravitz RL. Measuring underuse of necessary care among elderly medicare beneficiaries using inpatient and outpatient claims. *JAMA* 2000;284(18):2325-33.
62. Allin S, Masseria C, Mossialos E. Inequality in health care use among older people in the United Kingdom: an analysis of panel data. LSE health working papers, 2006.
63. Comino EJ, Davies GP, Krastev Y *et al*. A systematic review of interventions to enhance access to best practice primary health care for chronic disease management, prevention and episodic care. *BMC Health Serv Res* 2012;12:415.
64. Kehle SM, Greer N, Rutks I, Wilt T. Interventions to improve veterans' access to care: a systematic review of the literature. *J Gen Intern Med* 2011;26 Suppl 2:689-96.
65. Ford JA. Extending opening hours in general practice won't improve access for patients most in need. *Br Med J* 2015;350:h1373.
66. Ford JA, Jones AP, Wong G, Steel N. Weekend opening in primary care: analysis of the General Practice Patient Survey. *Br J Gen Pract* 2015;65(641):e792-e8.
67. Bhaskar R. A realist theory of science. Routledge; 2013.
68. Pawson R. Evidence-Based Policy: A Realist Perspective London: SAGE Publications Ltd; 2006.
69. The RAMESES II Project. Philosophies and Evaluation Design. 2017.
70. Wong G, Greenhalgh T, Westhorp G, Pawson R. Realist methods in medical education research: what are they and what can they contribute? *Med Educ* 2012;46(1):89-96.
71. Harré R. The philosophies of science. 1985.
72. Wilson V, McCormack B. Critical realism as emancipatory action: the case for realistic evaluation in practice development. *Nurs Philos* 2006;7(1):45-57.
73. Oxford Dictionary. Definition of context in English. 2018  
[<https://en.oxforddictionaries.com/definition/context>]: Accessed on 6 Sept 2018.
74. Sayer A. Method in social science: revised 2nd edition. Routledge; 2010.
75. The RAMESES II Project. What realists mean by context; or, Why nothing works everywhere or for everyone. 2017.
76. The RAMESES II Project. What is a mechanism? What is a programme mechanism? 2017.
77. Pawson R, Tilley N. Realist evaluation. *Changes* 1997.
78. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review-a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 2005;10 Suppl 1:21-34.
79. Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. *Ann Fam Med* 2004;2(1):7-12.
80. Bentley JM. Barriers to accessing health care: the perspective of elderly people within a village community. *Int J Nurs Stud* 2003;40(1):9-21.
81. Coles R, Watkins F, Swami V *et al*. What men really want: a qualitative investigation of men's health needs from the Halton and St Helens Primary Care Trust men's health promotion project. *Br J Health Psychol* 2010;15(Pt 4):921-39.
82. Shipman C, White S, Gysels M, White P. Access to care in advanced COPD: factors that influence contact with general practice services. *Primary Care Respiratory Journal* 2009;18(4):273-8.

83. Dowrick C, Gask L, Edwards S *et al.* Researching the mental health needs of hard-to-reach groups: managing multiple sources of evidence. *BMC Health Serv Res* 2009;9:226.
84. Gage NL. The paradigm wars and their aftermath a “historical” sketch of research on teaching since 1989. *Educational researcher* 1989;18(7):4-10.
85. Johnson RB, Onwuegbuzie AJ. Mixed methods research: A research paradigm whose time has come. *Educational researcher* 2004;33(7):14-26.
86. Giddings LS, Grant BM. A Trojan horse for positivism?: a critique of mixed methods research. *ANS Adv Nurs Sci* 2007;30(1):52-60.
87. Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a definition of mixed methods research. *Journal of mixed methods research* 2007;1(2):112-33.
88. Ong BN. *The practice of health services research*. Springer; 2013.
89. Marchal B, Westhorp G, Wong G *et al.* Realist RCTs of complex interventions - an oxymoron. *Soc Sci Med* 2013;94:124-8.
90. Lee S, Smith CA. Criteria for quantitative and qualitative data integration: mixed-methods research methodology. *Comput Inform Nurs* 2012;30(5):251-6.
91. O’Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ* 2010;341:c4587.
92. Craig P, Dieppe P, Macintyre S *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.
93. Bonell C, Fletcher A, Morton M, Lorenc T, Moore L. Realist randomised controlled trials: a new approach to evaluating complex public health interventions. *Soc Sci Med* 2012;75(12):2299-306.
94. Berwick DM. The science of improvement. *JAMA* 2008;299(10):1182-4.
95. Stewart-Brown S, Anthony R, Wilson L *et al.* Should randomised controlled trials be the “gold standard” for research on preventive interventions for children? *Journal of Children's Services* 2011;6(4):228-35.
96. Norrie J. Randomised controlled trials of complex interventions. *Trials* 2011;12(1):A142.
97. Barratt H, Campbell M, Moore L, Zwarenstein M, Bower P. Randomised controlled trials of complex interventions and large-scale transformation of services. *Health Services and Delivery Research* 2016;4(16).
98. Moore GF, Audrey S, Barker M *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258.
99. Ford JA, Jones AP, Wong G *et al.* Improving access to high-quality primary care for socioeconomically disadvantaged older people in rural areas: a mixed method study protocol. *BMJ Open* 2015;5(9).
100. Cracknell R. The ageing population: key issues for the 2010 Parliament London 2010.
101. Hart JT. The inverse care law. *Lancet* 1971;1(7696):405-12.
102. Rotter JB. Generalized expectancies for internal versus external control of reinforcement. *Psychol Monogr* 1966;80(1):1-28.
103. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC Med* 2013;11:21.
104. Stein CM, Morris NJ, Nock NL. Structural equation modeling. *Methods Mol Biol* 2012;850:495-512.
105. Farmer T, Robinson K, Elliott SJ, Eyles J. Developing and implementing a triangulation protocol for qualitative health research. *Qual Health Res* 2006;16(3):377-94.



106. DiGuseppi C, Coupland C. The design and use of cluster randomised controlled trials in evaluating injury prevention interventions: part 1. Rationale, design and informed consent. *Inj Prev* 2010;16(1):61-7.
107. Hoffmann TC, Glasziou PP, Boutron I *et al.* Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
108. Moher D, Hopewell S, Schulz KF *et al.* CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2012;10(1):28-55.
109. Ford JA, Wong G, Jones AP, Steel N. Access to primary care for socioeconomically disadvantaged older people in rural areas: a realist review. *BMJ Open* 2016;6(5):e010652.
110. Hankivsky O, Christoffersen A. Intersectionality and the determinants of health: a Canadian perspective. *Critical Public Health* 2008;18(3):271-83.
111. Jones AP, Haynes R, Sauerzapf V *et al.* Travel times to health care and survival from cancers in Northern England. *Eur J Cancer* 2008;44(2):269-74.
112. Solberg LI, Crain AL, Sperl-Hillen JM *et al.* Effect of improved primary care access on quality of depression care. *Ann Fam Med* 2006;4(1):69-74.
113. Jerant A, Fenton JJ, Franks P. Primary care attributes and mortality: a national person-level study. *Ann Fam Med* 2012;10(1):34-41.
114. Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. *Milbank Q* 2005;83(3):457-502.
115. Wakerman J, Humphreys JS, Wells R *et al.* Primary health care delivery models in rural and remote Australia: a systematic review. *BMC Health Serv Res* 2008;8:276.
116. Bauer MS, Williford WO, McBride L, McBride K, Shea NM. Perceived barriers to health care access in a treated population. *Int J Psychiatry Med* 2005;35(1):13-26.
117. NVivo qualitative data analysis Software. In., Version 10 edn: QSR International Pty Ltd; 2012.
118. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: meta-narrative reviews. *BMC Med* 2013;11:20.
119. Broadhurst K. Engaging parents and carers with family support services: What can be learned from research on help-seeking? *Child & Family Social Work* 2003;8(4):341-50.
120. Kovandzic M, Chew-Graham C, Reeve J *et al.* Access to primary mental health care for hard-to-reach groups: from 'silent suffering' to 'making it work'. *Soc Sci Med* 2011;72(5):763-72.
121. Addink RW, Bankart MJ, Murtagh GM, Baker R. Limited impact on patient experience of access of a pay for performance scheme in England in the first year. *European Journal of General Practice* 2011;17(2):81-6.
122. Buetow S, Adair V, Coster G *et al.* Qualitative insights into practice time management: does 'patient-centred time' in practice management offer a portal to improved access? *Br J Gen Pract* 2002;52(485):981-7.
123. Grimsmo A, Siem H. Factors affecting primary health care utilization. *Fam Pract* 1984;1(3):155-61.
124. Pong RW, DesMeules M, Heng D *et al.* Patterns of health services utilization in rural Canada. *Chronic Dis Inj Can* 2011;31 Suppl 1:1-36.
125. Young AF, Dobson AJ, Byles JE. Determinants of general practitioner use among women in Australia. *Soc Sci Med* 2001;53(12):1641-51.

126. Field KS, Briggs DJ. Socio-economic and locational determinants of accessibility and utilization of primary health-care. *Health & Social Care in the Community* 2001;9(5):294-308.
127. Adamson J, Ben-Shlomo Y, Chaturvedi N, Donovan J. Ethnicity, socio-economic position and gender--do they affect reported health-care seeking behaviour? *Soc Sci Med* 2003;57(5):895-904.
128. Allin S, Hurley J. Inequity in publicly funded physician care: What is the role of private prescription drug insurance? *Health Econ* 2009;18(10):1218-32.
129. Beckman A, Anell A. Changes in health care utilisation following a reform involving choice and privatisation in Swedish primary care: a five-year follow-up of GP-visits. *BMC Health Serv Res* 2013;13:452.
130. Tod AM, Read C, Lacey A, Abbott J. Barriers to uptake of services for coronary heart disease: qualitative study. *BMJ* 2001;323(7306):214.
131. Dingwall R, Robertson M. Aspects of Illness. *Behav Cogn Psychother* 1978;6(01):22-.
132. Gardner K, Chapple A. Barriers to referral in patients with angina: qualitative study. *BMJ* 1999;319(7207):418-21.
133. Ebrahim S. Ethnic elders. *BMJ* 1996;313(7057):610-3.
134. Goodridge D, Hutchinson S, Wilson D, Ross C. Living in a rural area with advanced chronic respiratory illness: a qualitative study. *Primary Care Respiratory Journal* 2011;20(1):54-8.
135. Qu H, Platonova EA, Kennedy KN, Shewchuk RM. Primary care patient satisfaction segmentation. *Int J Health Care Qual Assur* 2011;24(7):564-76.
136. Brabyn L, Barnett R. Population need and geographical access to general practitioners in rural New Zealand. *N Z Med J* 2004;117(1199):U996.
137. Horner SD, Ambrogne J, Coleman MA *et al.* Traveling for Care: Factors Influencing Health Care Access for Rural Dwellers. *Public Health Nurs* 1994;11(3):145-9.
138. Camillo P. Understanding the culture of primary health care: implications for clinical practice. *J N Y State Nurses Assoc* 2004;35(1):14-9.
139. Perrig-Chiello P, Perrig WG, Stähelin HB. Health control beliefs in old age—relationship with subjective and objective health, and health behaviour. *Psychol Health Med* 1999;4(1):83-94.
140. Johnson JE, Weinert C, Richardson JK. Rural residents' use of cardiac rehabilitation programs. *Public Health Nurs* 1998;15(4):288-96.
141. Bryant LL, Corbett KK, Kutner JS. In their own words: A model of healthy aging. *Soc Sci Med* 2001;53(7):927-41.
142. Jinks C, Ong BN, O'Neill T. "Well, it's nobody's responsibility but my own." A qualitative study to explore views about the determinants of health and prevention of knee pain in older adults. *BMC Public Health* 2010;10:148.
143. Auchincloss AH, Van Nostrand JF, Ronsaville D. Access to health care for older persons in the United States: Personal, structural, and neighborhood characteristics. *J Aging Health* 2001;13(3):329-54.
144. Arksey H, Jackson K, Wallace AS *et al.* *Access to Health Care for Carers: Barriers and Interventions*. London 2003.
145. Calnan M. Are older people still grateful? *Age Ageing* 2003;32(2):125-6.
146. Mazza D, Shand LK, Warren N *et al.* General practice and preventive health care: a view through the eyes of community members. *Med J Aust* 2011;195(4):180-3.
147. Campbell JL. Patients' perceptions of medical urgency: does deprivation matter? *Fam Pract* 1999;16(1):28-32.

148. Dixon J, Welch N. Researching the rural-metropolitan health differential using the 'social determinants of health'. *Aust J Rural Health* 2000;8(5):254-60.
149. Bosma H, Schrijvers C, Mackenbach JP. Socioeconomic inequalities in mortality and importance of perceived control: cohort study. *BMJ : British Medical Journal* 1999;319(7223):1469-70.
150. Bosma H, van de Mheen HD, Mackenbach JP. Social class in childhood and general health in adulthood: questionnaire study of contribution of psychological attributes. *BMJ : British Medical Journal* 1999;318(7175):18-22.
151. McNiece R, Majeed A. Socioeconomic differences in general practice consultation rates in patients aged 65 and over: prospective cohort study. *BMJ (Clinical research ed)* 1999;319(7201):26-8.
152. Moskowitz D, Lyles CR, Karter AJ *et al.* Patient reported interpersonal processes of care and perceived social position: The Diabetes Study of Northern California (DISTANCE). *Patient Educ Couns* 2013;90(3):392-8.
153. Pescosolido BA. *Advances in Medical Sociology*. JAI Press; 1995.
154. Mathieson J, Popay J, Enoch E *et al.* Social exclusion: meaning, measurement and experience and links to health inequalities: a review of literature (WHO Social Exclusion Knowledge Network Background Paper 1). 2008.
155. Lamb J, Bower P, Rogers A, Dowrick C, Gask L. Access to mental health in primary care: a qualitative meta-synthesis of evidence from the experience of people from 'hard to reach' groups. *Health: an Interdisciplinary Journal for the Social Study of Health, Illness & Medicine* 2012;16(1):76-104.
156. Birch S, Eyles J, Newbold KB. Equitable access to health care: methodological extensions to the analysis of physician utilization in Canada. *Health Econ* 1993;2(2):87-101.
157. Bossuyt N, Van den Block L, Cohen J *et al.* Is individual educational level related to end-of-life care use? Results from a nationwide retrospective cohort study in Belgium. *J Palliat Med* 2011;14(10):1135-41.
158. Comber AJ, Brunson C, Radburn R. A spatial analysis of variations in health access: linking geography, socio-economic status and access perceptions. *International Journal of Health Geographics [Electronic Resource]* 2011;10:44.
159. Underwood SM, Hoskins D, Cummins T, Morris K, Williams A. Obstacles to cancer care: focus on the economically disadvantaged. *Oncol Nurs Forum* 1994;21(1):47-52.
160. Raymond M, Iliffe S, Kharicha K *et al.* Health risk appraisal for older people 5: self-efficacy in patient-doctor interactions. *Prim Health Care Res Dev* 2011;12(4):348-56.
161. Freij M, Weiss L, Gass J *et al.* "Just like I'm saving money in the bank": client perspectives on care coordination services. *Journal of Gerontological Social Work* 2011;54(7):731-48.
162. Bennett KJ, Baxley EG. The effect of a carve-out advanced access scheduling system on no-show rates. *Fam Med* 2009;41(1):51-6.
163. Rogowski J, Freedman VA, Wickstrom SL, Adams J, Escarce JJ. Socioeconomic disparities in medical provider visits among medicare managed care enrollees. *Inquiry* 2008;45(1):112-29.
164. Buetow S, Adair V, Coster G *et al.* Reasons for poor understanding of when and how to access GP care for childhood asthma in Auckland, New Zealand. *Fam Pract* 2002;19(4):319-25.

165. Choi S. Longitudinal changes in access to health care by immigrant status among older adults: the importance of health insurance as a mediator. *Gerontologist* 2011;51(2):156-69.
166. Thommasen HV, Tatlock J, Elliott R, Zhang W, Sheps S. Review of salaried physician visits in a rural remote community - Bella Coola Valley. *Canadian journal of rural medicine : the official journal of the Society of Rural Physicians of Canada = Journal canadien de la medecine rurale : le journal officiel de la Societe de medecine rurale du Canada* 2006;11(1):23-31.
167. Cheung PT, Wiler JL, Lowe RA, Ginde AA. National study of barriers to timely primary care and emergency department utilization among Medicaid beneficiaries. *Ann Emerg Med* 2012;60(1):4-10.e2.
168. Morgan G, Mitchell C, Gallacher J. The perceptions of older people in Wales about service provision. *Qual Prim Care* 2011;19(6):365-8.
169. Choi N. Relationship between health service use and health information technology use among older adults: analysis of the US National Health Interview Survey. *J Med Internet Res* 2011;13(2):e33.
170. Goodall K, Ward P, Newman L. Use of information and communication technology to provide health information: what do older migrants know, and what do they need to know? *Qual Prim Care* 2010;18(1):27-32.
171. Morgan CL, Beerstecher HJ. Satisfaction, demand, and opening hours in primary care: an observational study. *Br J Gen Pract* 2011;61(589):e498-507.
172. Drummond N, McConnachie A, O'Donnell CA *et al.* Social variation in reasons for contacting general practice out-of-hours: implications for daytime service provision? *Br J Gen Pract* 2000;50(455):460-4.
173. Roos NP, Mustard CA. Variation in health and health care use by socioeconomic status in Winnipeg, Canada: does the system work well? Yes and no. *Milbank Q* 1997;75(1):89-111.
174. Jatrana S, Crampton P. Primary health care in New Zealand: who has access? *Health Policy* 2009;93(1):1-10.
175. Turnbull J, Martin D, Lattimer V, Pope C, Culliford D. Does distance matter? Geographical variation in GP out-of-hours service use: an observational study. *Br J Gen Pract* 2008;58(552):471-7.
176. Dixon A, Le Grand J, Henderson J, Murray R, Poteliakhoff E. Is the British National Health Service equitable? The evidence on socioeconomic differences in utilization. *J Health Serv Res Policy* 2007;12(2):104-9.
177. Moffatt S, White M, Stacy R, Downey D, Hudson E. The impact of welfare advice in primary care: A qualitative study. *Critical Public Health* 2004;14(3):295-309.
178. Mercer SW, Jani BD, Maxwell M, Wong SY, Watt GC. Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC Fam Pract* 2012;13(1):1-9.
179. Magan P, Alberquilla A, Otero A, Ribera JM. Hospitalizations for ambulatory care sensitive conditions and quality of primary care: their relation with socioeconomic and health care variables in the Madrid regional health service (Spain). *Med Care* 2011;49(1):17-23.
180. Videau Y, Saliba-Serre B, Paraponaris A, Ventelou B. Why patients of low socioeconomic status with mental health problems have shorter consultations with general practitioners. *J Health Serv Res Policy* 2010;15(2):76-81.

181. Cawston PG, Mercer SW, Barbour RS. Involving deprived communities in improving the quality of primary care services: does participatory action research work? *BMC Health Serv Res* 2007;7:88.
182. Allport GW. *The Nature of Prejudice*. Reading, MA; 1954.
183. Hoeck S, Van der Heyden J, Geerts J, Van Hal G. Equity in GP and specialist contacts by older persons in Belgium. *International Journal of Public Health* 2013;58(4):593-602.
184. Ford JA, Turley R, Porter T *et al*. Access to primary care for socio-economically disadvantaged older people in rural areas: A qualitative study. *PLoS One* 2018;13(3):e0193952.
185. Vegda K, Nie JX, Wang L *et al*. Trends in health services utilization, medication use, and health conditions among older adults: a 2-year retrospective chart review in a primary care practice. *BMC Health Serv Res* 2009;9:217.
186. Schappert SM, Burt CW. Ambulatory care visits to physician offices, hospital outpatient departments, and emergency departments: United States, 2001–02. *Vital Health Stat* 2006;13(159).
187. Cornwell J. *The care of frail older people with complex needs: time for a revolution*. London 2012.
188. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19(6):349-57.
189. Office for National Statistics. Rural/urban definition (England and Wales). 2016 [<http://webarchive.nationalarchives.gov.uk/20160105160709/http://www.ons.gov.uk/ons/guide-method/geography/products/area-classifications/rural-urban-definition-and-la/rural-urban-definition--england-and-wales-/index.html>]: Accessed on 6 April 2017.
190. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology* 2006;3(2):77-101.
191. Boeije H. A Purposeful Approach to the Constant Comparative Method in the Analysis of Qualitative Interviews. *Quality and Quantity* 2002;36(4):391-409.
192. Elias T, Lowton K. Do those over 80 years of age seek more or less medical help? A qualitative study of health and illness beliefs and behaviour of the oldest old. *Sociol Health Illn* 2014;36(7):970-85.
193. Moore A, Grime J, Campbell P, Richardson J. Troubling stoicism: Sociocultural influences and applications to health and illness behaviour. *Health (London)* 2013;17(2):159-73.
194. Averill JB. Voices from the Gila: health care issues for rural elders in southwestern New Mexico. *J Adv Nurs* 2002;40(6):654-62.
195. Goins RT, Williams KA, Carter MW, Spencer M, Solovieva T. Perceived barriers to health care access among rural older adults: a qualitative study. *J Rural Health* 2005;21(3):206-13.
196. Douthit N, Kiv S, Dwolatzky T, Biswas S. Exposing some important barriers to health care access in the rural USA. *Public Health* 2015;129(6):611-20.
197. Iezzoni LI, Killeen MB, O'Day BL. Rural residents with disabilities confront substantial barriers to obtaining primary care. *Health Serv Res* 2006;41(4 Pt 1):1258-75.
198. Borders TF. Rural community-dwelling elders' reports of access to care: are there Hispanic versus non-Hispanic white disparities? *J Rural Health* 2004;20(3):210-20.
199. Cruess SR, Cruess RL. Professionalism and Medicine's Social Contract with Society. *Virtual Mentor* 2004;6(4).

200. Cruess SR, Cruess RL. Professionalism: a contract between medicine and society. *Can Med Assoc J* 2000;162(5):668-9.
201. Cornwell J. *Hard-earned Lives: Accounts of Health and Illness from East London*. Tavistock Publications; 1984.
202. NHS England. *Guidance for NHS commissioners on equality and health inequalities legal duties*. Leeds 2015.
203. Improving Access to General Practice Team. *Improving access for all: reducing inequalities in access to general practice services. A resource for general practice providers and commissioners*. 2017.
204. Woodward A, Kawachi I. Why reduce health inequalities? *2000;54(12):923-9*.
205. Lang IA, Gibbs SJ, Steel N, Melzer D. Neighbourhood deprivation and dental service use: a cross-sectional analysis of older people in England. *Journal of Public Health* 2008;30(4):472-8.
206. Dyson B. *Improving General Practice*. London 2014.
207. Ford JA, Jones A, Wong G *et al*. Access to primary care for socio-economically disadvantaged older people in rural areas: exploring realist theory using structural equation modelling in a linked dataset. *BMC Med Res Methodol* 2018;18(1):57.
208. Van Belle S, Wong G, Westhorp G *et al*. Can “realist” randomised controlled trials be genuinely realist? *Trials* 2016;17:313.
209. Bollen KA, Bauldry S. Three Cs in measurement models: causal indicators, composite indicators, and covariates. *Psychol Methods* 2011;16(3):265-84.
210. Astbury B, Leeuw FL. *Unpacking Black Boxes: Mechanisms and Theory Building in Evaluation*. *Am J Eval* 2010;31(3):363-81.
211. Ipsos MORI. *GP Patient Survey - Technical annex*. London 2013.
212. Tomaka J, Palacios R, Schneider KT *et al*. Assertiveness predicts threat and challenge reactions to potential stress among women. *J Pers Soc Psychol* 1999;76(6):1008-21.
213. Alberti R, Emmons M. *Your perfect right: Assertiveness and equality in your life and relationships*. New Harbinger Publications; 2017.
214. Rathus SA. A 30-item schedule for assessing assertive behavior. *Behav Ther* 1973;4(3):398-406.
215. Pavot W, Diener E. Review of the Satisfaction With Life Scale. *Psychol Assessment* 1993;5(2):164-72.
216. Hu Lt, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Struct Equ Modeling* 1999;6(1):1-55.
217. StataCorp LP: *Stata Statistical Software: Release 13* [Computer software]. In. College Station, TX: StataCorp LP; 2013.
218. Muthén BO, Muthén LK. *Mplus (Version 7)* [Computer software]. Los Angeles, CA: Muthén & Muthén; 2012.
219. MacCallum RC, Browne MW, Sugawara HM. Power analysis and determination of sample size for covariance structure modeling. *Psychol Methods* 1996;1(2):130.
220. Westhorpe G. *Realist Impact Evaluation: An Introduction*. London 2014.
221. Gilmore B, McAuliffe E, Larkan F *et al*. How do community health committees contribute to capacity building for maternal and child health? A realist evaluation protocol. *BMJ Open* 2016;6(11).
222. Mirzoev T, Etiaba E, Ebenso B *et al*. Study protocol: realist evaluation of effectiveness and sustainability of a community health workers programme in improving maternal and child health in Nigeria. *Implement Sci* 2016;11(1):83.

223. Allary C, Bourmaud A, Tinquaut F *et al.* ColoNav: patient navigation for colorectal cancer screening in deprived areas – Study protocol. *BMC Cancer* 2016;16(1):416.
224. Hawkins AJ. Realist evaluation and randomised controlled trials for testing program theory in complex social systems. *Evaluation* 2016;22(3):270-85.
225. Greenhalgh T, Pawson R, Wong G *et al.* What realists mean by context; or, why nothing works everywhere or for everyone. 2017.
226. Gilmore B, Adams BJ, Bartoloni A *et al.* Improving the performance of community health workers in humanitarian emergencies: a realist evaluation protocol for the PIECES programme. *BMJ Open* 2016;6(8).
227. Jamal F, Fletcher A, Shackleton N *et al.* The three stages of building and testing mid-level theories in a realist RCT: a theoretical and methodological case-example. *Trials* 2015;16(1):466.
228. Sharma S, Adetoro OO, Vidler M *et al.* A process evaluation plan for assessing a complex community-based maternal health intervention in Ogun State, Nigeria. *BMC Health Serv Res* 2017;17(1):238.
229. Mahoney J. Beyond Correlational Analysis: Recent Innovations in Theory and Method. *Sociol Forum* 2001;16(3):575-93.
230. Moffatt S, White M, Mackintosh J, Howel D. Using quantitative and qualitative data in health services research – what happens when mixed method findings conflict? [ISRCTN61522618]. *BMC Health Serv Res* 2006;6(1):28.
231. NHS Health and Social Care Information Centre. Indicator Portal. 2016.
232. Herdman M, Gudex C, Lloyd A *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36.
233. Coast J, Flynn TN, Natarajan L *et al.* Valuing the ICECAP capability index for older people. *Soc Sci Med* 2008;67(5):874-82.
234. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood)* 2013;32(2):207-14.
235. Eldridge SM, Costelloe CE, Kahan BC, Lancaster GA, Kerry SM. How big should the pilot study for my cluster randomised trial be? *Stat Methods Med Res* 2016;25(3):1039-56.
236. Nemes S, Garellick G, Salomonsson R, Rolfson O. Crosswalk algorithms for the conversion of mean EQ-5D indices calculated with different value sets. *Scand J Public Health* 2016;44(5):455-61.
237. National Institute for Health and Care Excellence. The guidelines manual. London: NICE 2009.
238. StataCorp LP: Stata Statistical Software: Release 15 [Computer software]. In. College Station, TX: StataCorp LP; 2017.
239. Manzano A. The craft of interviewing in realist evaluation. *Evaluation* 2016;22(3):342-60.
240. RAMESES II Project. The Realist Interview. 2017  
[[http://www.ramesesproject.org/media/RAMESES\\_II\\_Realist\\_interviewing.pdf](http://www.ramesesproject.org/media/RAMESES_II_Realist_interviewing.pdf)]: Accessed on 22 August 2018.
241. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes.* Oxford university press; 2015.
242. Holley-Moore G, Creighton H. *The future of transport in an ageing society.* Age UK, London 2015.

243. Public Health England. National General Practice Profiles. 2018  
[<https://fingertips.phe.org.uk/profile/general-practice>]: Accessed on 22 August 2018.
244. Curtis LM, Burns A. Unit Costs of Health and Social Care 2017. Canterbury 2017.
245. NHS Improvement. NHS Reference costs: User guide 2016-17. 2017  
[<https://improvement.nhs.uk/documents/1978/7 - Reference costs 2016-17 A Guide to using the data.pdf>]: Accessed on 22 August 2018.
246. Curtis LM, Burns A. Unit Costs of Health and Social Care 2015. Canterbury 2015.
247. Nahum-Shani I, Qian M, Almirall D *et al*. Experimental design and primary data analysis methods for comparing adaptive interventions. *Psychol Methods* 2012;17(4):457-77.
248. Almirall D, Nahum-Shani I, Sherwood NE, Murphy SA. Introduction to SMART designs for the development of adaptive interventions: with application to weight loss research. *Transl Behav Med* 2014;4(3):260-74.
249. Klasnja P, Hekler EB, Shiffman S *et al*. Microrandomized trials: An experimental design for developing just-in-time adaptive interventions. *Health Psychol* 2015;34s:1220-8.
250. Elouafkaoui P, Young L, Newlands R *et al*. An Audit and Feedback Intervention for Reducing Antibiotic Prescribing in General Dental Practice: The RAPID Cluster Randomised Controlled Trial. *PLoS Med* 2016;13(8):e1002115.
251. Hawe P, Shiell A, Riley T. Complex interventions: how "out of control" can a randomised controlled trial be? *BMJ* 2004;328(7455):1561-3.
252. Bonell C, Oakley A, Hargreaves J, Strange V, Rees R. Assessment of generalisability in trials of health interventions: suggested framework and systematic review. *BMJ* 2006;333(7563):346-9.
253. Campbell M, Fitzpatrick R, Haines A *et al*. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321(7262):694-6.
254. Patton G, Bond L, Butler H, Glover S. Changing schools, changing health? Design and implementation of the Gatehouse Project. *J Adolesc Health* 2003;33(4):231-9.
255. Patton GC, Bond L, Carlin JB *et al*. Promoting social inclusion in schools: a group-randomized trial of effects on student health risk behavior and well-being. *Am J Public Health* 2006;96(9):1582-7.
256. Merton RK. On theoretical sociology: five essays, old and new. 1967.
257. Katikireddi SV, Higgins M, Bond L, Bonell C, Macintyre S. How evidence based is English public health policy? *BMJ* 2011;343:d7310.
258. Oliver KA, de Vocht F, Money A, Everett M. Identifying public health policymakers' sources of information: comparing survey and network analyses. *Eur J Public Health* 2017;27(suppl\_2):118-23.
259. Atkins L, Kelly MP, Littleford C, Leng G, Michie S. Reversing the pipeline? Implementing public health evidence-based guidance in english local government. *Implement Sci* 2017;12(1):63.
260. Kelly MP, Atkins L, Littleford C, Leng G, Michie S. Evidence-based medicine meets democracy: the role of evidence-based public health guidelines in local government. *J Public Health (Oxf)* 2017;39(4):678-84.
261. McGill E, Egan M, Petticrew M *et al*. Trading quality for relevance: non-health decision-makers' use of evidence on the social determinants of health. *BMJ Open* 2015;5(4):e007053.
262. Townsend P. Deprivation. *J Soc Policy* 1987;16(2):125-46.



263. Shucksmith M, Roberts D, Scott D, Chapman P, Conway E. Disadvantage in rural areas. RURAL RESEARCH REPORT-RURAL DEVELOPMENT COMMISSION 1996.
264. Smith HJ, Pettigrew TF. Advances in Relative Deprivation Theory and Research. *Social Justice Research* 2015;28(1):1-6.
265. Office for National Statistics. Standard Occupational Classification 2010: The National Statistics Socio-economic classification. 2010 [<http://webarchive.nationalarchives.gov.uk/20160106042025/http://www.ons.gov.uk/ons/guide-method/classifications/current-standard-classifications/soc2010/soc2010-volume-3-ns-sec--rebased-on-soc2010--user-manual/index.html>]: Accessed on 6 Sept 2018.
266. Jarman B. Identification of underprivileged areas. *Br Med J (Clin Res Ed)* 1983;287(6385):130.
267. Townsend P, Phillimore P, Beattie A. Health and deprivation: inequality and the North. Routledge; 1988.
268. Carstairs V, Morris R. Deprivation and health in Scotland. *Health Bull (Edinb)* 1990;48(4):162-75.
269. Smith T, Noble M, Noble S *et al*. The English indices of deprivation 2015. London: Department for Communities and Local Government 2015.
270. Bertin M, Chevrier C, Pele F *et al*. Can a deprivation index be used legitimately over both urban and rural areas? *Int J Health Geogr* 2014;13:22.
271. Farmer JC, Baird AG, Iversen L. Rural deprivation: reflecting reality. *Br J Gen Pract* 2001;51(467):486-91.
272. Cloke P, Milbourne P, Thomas C. Living lives in different ways? Deprivation, marginalization and changing lifestyles in rural England. *Transactions of the Institute of British Geographers* 1997:210-30.
273. Fecht D, Jones A, Hill T *et al*. Inequalities in rural communities: adapting national deprivation indices for rural settings. *Journal of Public Health* 2018;40(2):419-25.
274. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implementation Science* 2016;11(1):141.
275. Bonell C, Warren E, Fletcher A, Viner R. Realist trials and the testing of context-mechanism-outcome configurations: a response to Van Belle *et al*. *Trials* 2016;17:478.
276. Smith KE. The politics of ideas: The complex interplay of health inequalities research and policy. *Science and Public Policy* 2014;41(5):561-74.
277. Bird L, Arthur A, Cox K. "Did the trial kill the intervention?" experiences from the development, implementation and evaluation of a complex intervention. *BMC Med Res Methodol* 2011;11:24.
278. Murdoch J. Process evaluation for complex interventions in health services research: analysing context, text trajectories and disruptions. *BMC Health Serv Res* 2016;16(1):407.
279. Holbrook A, Thabane L, Keshavjee K *et al*. Individualized electronic decision support and reminders to improve diabetes care in the community: COMPETE II randomized trial. *CMAJ : Canadian Medical Association Journal* 2009;181(1-2):37-44.
280. Roland M, Everington S. Tackling the crisis in general practice. *BMJ* 2016:352.
281. Majeed A. Shortage of general practitioners in the NHS. *BMJ* 2017:358.
282. Watson J, Salisbury C, Jani A *et al*. Better value primary care is needed now more than ever. *BMJ* 2017:359.

283. Becker E, Boreham R. Understanding the risks of social exclusion across the life course: Older age. National Centre for Social Research 2009.
284. Robb K, Stubbings S, Ramirez A *et al.* Public awareness of cancer in Britain: a population-based survey of adults. *Br J Cancer* 2009;101 Suppl 2:S18-23.
285. Carter MR, Barrett CB. The economics of poverty traps and persistent poverty: An asset-based approach. *The Journal of Development Studies* 2006;42(2):178-99.
286. Dowrick C, Chew-Graham C, Lovell K *et al.* Increasing equity of access to high-quality mental health services in primary care: a mixed-methods study. Southampton (UK) 2013.
287. Dowrick C, Bower P, Chew-Graham C *et al.* Evaluating a complex model designed to increase access to high quality primary mental health care for under-served groups: a multi-method study. *BMC Health Serv Res* 2016;16(1):58.
288. Tan S, Mays N. Impact of initiatives to improve access to, and choice of, primary and urgent care in England: A systematic review. *Health Policy* 2014;118(3):304-15.
289. Fletcher A, Jamal F, Moore G *et al.* Realist complex intervention science: Applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. *Evaluation (Lond)* 2016;22(3):286-303.
290. Resnik DB. Responsibility for health: personal, social, and environmental. *J Med Ethics* 2007;33(8):444-5.
291. McGibbon E, Etowa J, McPherson C. Health-care access as a social determinant of health. *Can Nurse* 2008;104(7):22-7.
292. Conservative Party. The Conservative Party Manifesto 2010. Conservative Party; 2010.
293. Labelle R, Stoddart G, Rice T. A re-examination of the meaning and importance of supplier-induced demand. *J Health Econ* 1994;13(3):347-68.
294. Campaign for Better Transport. Buses in Crisis A report on bus funding across England and Wales 2010 - 2016. London 2016.
295. Ford JA, Kharicha K, Clarke CS *et al.* Service use of older people who participate in primary care health promotion: a latent class analysis. *BMC Health Serv Res* 2017;17(1):176.
296. Tversky A, Kahneman D. Judgment under Uncertainty: Heuristics and Biases. *Science* 1974;185(4157):1124-31.

## Appendix 1: Search strategy used in MEDLINE

1. exp Primary Health care/
2. (primary adj health-care).tw.
3. (general practitioner\* or general practice\* or family practice\* or family practitioner\*).tw.
4. (primary adj2 care).tw.
5. (primary adj healthcare).tw.
6. exp Family Practice/
7. exp General Practitioners/
8. exp General Practice/
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. exp Aged/
11. (old\$ adj2 (people\* or person or adult\$)).tw.
12. elderly.tw.
13. exp frail elderly/
14. 10 or 11 or 12 or 13
15. ((health or social or socioeconomic\$) adj2 (equalit\$ or equit\$ or determinant\$ or disparit\$ or inequality\$ or inequit\$)).tw.
16. (depriv\$ or poverty or poor or socio-economically disadvantage\*).tw.
17. exp Socioeconomic Factors/
18. exp vulnerable populations/
19. exp healthcare disparities/
20. 15 or 16 or 17 or 18 or 19
21. exp Health Services Accessibility/
22. (access or utili?sation).tw.
23. 21 or 22
24. 9 and 14 and 20 and 23

## Appendix 2: Further details of literature underpinning CMO configurations

N.B. Numerous articles contributed to each CMO configuration. Below the CMO configurations are described and an illustrative example given of evidence that underpins the configuration. Contexts are shown in *Italics* and an illustrative example of the supporting literature in **bold**.

### Problem identified

The mechanism of denial to identifying a problem was related with the contexts of stoicism, problematic experience and social network. **Coles 2010** describes results of focus groups with 82 middle aged and older men in a deprived area of the UK [81]. The authors describe how men's attitudes reflect the need to be masculine and stoic, denying pain, sickness and health care (*stoicism*). **Tod 2001** describes patients' experiences of heart disease in 14 semi-structured interviews [130]. The authors found that some patients limit or adapt their lifestyles in order to deny a health care need, such as reducing mild physical activity to avoid chest pain having to see a doctor (*problematic experience*). The Illness Action Model [131] highlights the importance of social interactions, such as someone noticing a problem which had been disregarded which in turn may be accepted, rejected or denied (*social network*).

The mechanism of health literacy (degree to which an individual can understand health information and services based on general or personal knowledge) was related with the contexts of problematic experience, social network and educational status. **Adamson 2003** describes a questionnaire study in which 1350 UK residents were given clinical vignettes and asked about health care utilisation [127]. The authors found that black respondents, those from lower socio-economic groups and women were more likely to report a health seeking behaviour when confronted with an unmet need (*problematic experience*). Research suggests that lower socio-economic groups consult primary care more, but are referred less [128]. This could be because people with lower educational status perceive more problems, have lower thresholds or consult for more minor ailments (*educational status*). **Beckman 2013** presents a secondary analysis of routine data (over 800,000 population) from Sweden [129]. The authors found people from lower income and education groups had worse health outcomes and the authors argue that low health literacy is the likely explanation (*educational status*).

The Illness Action Model [131] contributed to our understanding of the contexts of stoicism, problematic experience, social network and the mechanisms of evaluation of evolving experiences and health literacy. Briefly the model describes the importance of being able to maintain social interactions as a competent partner during an illness or problematic experience. Experiences are iteratively evaluated based on a stock of general and personal knowledge, augmented with social interactions (*evaluation of evolving experiences, health literacy and social network*).

### Decision to seek help

The mechanism of anxiety was linked with the contexts of experience of health care and social network. **Adamson 2003** presents a theoretical model about access to health care based on a questionnaire study (n=1350) [127]. The authors suggest that anxiety leads to seeking health care and is affected by past experience by influencing the interpretation of health care (*experience of health care*). This is supported by Tversky and Kahneman's theory of heuristics and bias for judging uncertainty which suggests that people make judgements based on perceived probability

from previous experiences [296]. **Gardner 1999** presents findings from 16 semi-structured interviews with patients with angina [132]. The authors found that fear of hospitals, operations and medical tests, based on the experience of their peers, was related with barriers to access to health care (*social network*). **Horner 1994** presents findings from semi-structured interviews with 19 rural residents [137]. The authors found that advice from close friends and family contribute to the perceived seriousness of the condition (*social network*).

The mechanism of convenience was linked with contexts of transport, financial resources and carer responsibilities. **Goodridge 2011** presents findings from seven semi-structured interviews with rural residents with COPD [134]. The authors found that the requirement to travel longer distances for rural residents made some people reluctant to seek health care, even in urgent situations (*transport*). **Qu 2011** reported a survey of 479 primary care patients in America [135]. The authors found that a subgroup of patients who were older with less education and a lower income, had a high satisfaction of the convenience (*financial resources*). **Brabyn 2004** looked at access to GPs using Geographic Information Software in New Zealand [136]. The authors suggest that older people, if resources are available, move closer to their General practice to shorten travel time and increase convenience (*financial resources*). A report for the National Co-ordinating Centre for NHS Service Delivery and Organisation by **Arksey 2003** undertook a literature review and consultation to assess the problems carers face in accessing health care [144]. Carers suggested they needed more flexible appointments because of their caring responsibilities (*carer responsibilities*).

The mechanism of denial of the need to seek help was related with financial resources, stoicism and expectations of ageing. **Auchincloss 2001** looked at the National Health Interview Survey of Older People in America. The authors found that access problems increase with decreasing wealth and rurality [143]. The authors argue that a lack of life essentials (e.g. food and housing) would reduce a person's focus on their health needs because of other priorities and this in turn may lead to denial and reluctance to seek help (*financial resources*). **Johnson 1998** analysed 254 questionnaires of rural residents [140] according to the Andersen Framework [7]. The authors argue that the desire to be independent and resistant to outside help leads to a reluctance or denial to seek help until acutely unwell (*stoicism*). **Dixon 2000** presents a discursive comparison of rural and urban health [148]. The authors argue that rural people tend to view health as absence of disease and only seek health care where they believe there is a cure (*expectations of ageing*).

The mechanism of perceived ability to benefit was related with expectations of ageing and experience of health care. **Bentley 2003** describes a mini-ethnographic study in the UK with nine key informants who were rural and elderly [80]. Certain problems were believed to be simply related with ageing which may lead to a decision not to seek health care (*expectations of ageing*). **Camillo 2004** presents an ethnographic study of older women [138]. The author found that many older women, based on previous experience, learnt that often their expectations of health care were not met (*experience of health care*).

The mechanism of perceived ability to cope was related with stoicism and social network. **Bentley 2003**, in a mini-ethnographic study, found that rural older people would not contact the doctor unless there was significant health problem because they wanted to manage themselves and not burden the NHS (*stoicism*) [80]. Similarly **Tod 2001**, in 14 semi-structured interviews with patients with angina, found that people valued strength, stoicism and the ability to be self-reliant (*stoicism*) [130]. The Network Episode Model [153] highlights the fact that personal social network provide information, advice, emotional support to interpret and access health care (*social network*).

The mechanism of perceived control was related with expectations of ageing, experience of health care, lifelong poverty and self-esteem. **Perrig-Chiello 1999** reported on control in older people

from a cohort study of 442 participants [139]. The authors found that chance or destiny had a dominant role in an elderly person's perspective of health. The authors also found that age is correlated with an increase in external control (*expectations of ageing*). The concept of external control is supported by Rotter's theory of locus of control [102]. In an editorial **Calnan 2003** argues that old age has been medicalised leading to increased dependency and passivity [145]. The biomedical model of health care reinforces these concepts every time an older person seeks help (*experience of health care*). **Bosma 1999a** found in a cross sectional study of 2174 participants from the Netherlands that low control partly originates in adverse socioeconomic conditions during childhood (*lifelong poverty*) [150]. In a subsequent discussion paper **Bosma 1999b** argues that low control is socioeconomic conditions in adulthood contribute to control later in life (*lifelong poverty*) [149]. **Bryant 2001** analysed 22 semi structured interviews of healthy older people [141]. The authors found that an individual's locus of control was closely related with self-esteem (*self-esteem*).

The mechanism of perceived social exclusion was related with lifelong poverty, experience of health care and perceived limited health resources. **Moskowitz 2013** used survey data of 11,105 patients from California [152]. The authors found that socioeconomically disadvantaged people received poorer communication than affluent people. The authors argue that primary care does not make services accessible to socioeconomically disadvantaged patients (*experience of health care*). **McNiece 1999** undertook a secondary analysis of a national survey of almost 72,000 patients [151]. The authors found that socioeconomic differences identified in younger patients persisted into later life (*lifelong poverty*). **Mazza 2011** reported 18 focus groups of people with low socioeconomic status [146]. The authors found that some patients described experiences where GPs were more interested in acute care and less interested in discussing long term preventative care because the doctor did not think it was necessary (*experience of health care*). In the mini-ethnographic study, **Bentley 2003**, described how older rural people were reluctant to use health care and preferred to cope because of the cost to the NHS (*perceived limited health resources*) [80].

The mechanism of candidacy (the ways in which older people's eligibility for medical attention and intervention is jointly negotiated between themselves and health services) was related with perceived limited health resources, experience of health care, expectations of ageing, relevance of services, lifelong poverty, experience of symptoms, social network and self-esteem. **Bentley 2003**, qualitatively looking at rural older people, reported that many felt that the GPs were always busy and this resulted in some playing down symptoms in order to help the GP's workload (*perceived limited health resources and experience of health care*) [80]. **Campbell 1999** in a questionnaire survey of 4999 patients found that patients who thought there was poor GP availability had lower perception of what constituted urgent (*perceived limited health resources*) [147]. **Dixon-wood 2005** in a report to the National Co-ordinating Centre for NHS Service Delivery and Organisation (NCCSDO) describes the concept of candidacy [18]. The authors describe how perceived eligibility is constantly being defined and redefined through experiences (*experience of health care*). **Shipman 2009** reported interviews with older people with COPD, finding that older people often felt there was nothing the GP could do and this resulted in the individual postponing health seeking behaviour (*expectations of ageing*) [82]. **Ebrahim 1996** discussed issues facing marginalised older people [133]. He suggests that the cumulative effect over a lifetime of low incomes and a sense of isolation leads to older people perceiving services as irrelevant and insensitive to their needs (*relevance, lifelong poverty and experience of health care*). [18] **Bentley 2003** in a mini-ethnographic study of rural older people, found that when a symptom and past experience had resulted in, for example, antibiotics, the individual felt more confident to see the doctor again (*previous experience of symptoms*) [80]. The study also found that older people attribute symptoms to a normal part of ageing and do not consider them legitimate reasons to seek health care (*expectations of ageing*). **Coles 2010** in a qualitative study of 82 older deprived

men found that men may legitimise seeking help through a female family member, overcoming the need to 'save face' (*social network*) [81]. **Jinks 2010** undertook semi-structure interviews with 28 older people with knee pain [142]. The authors found that an individual's upbringing or educational achievement effected how confident an individual was to seek health care (*lifelong poverty*). [147]**Shipman 2009** in a qualitative study of older people with COPD suggested a cycle where a worsening condition, led to loss of self-esteem and perception that their need for help is not valid (*self-esteem*) [82].

This CMO configuration was supported by the Network Episode Model which suggests that health seeking behaviour is mediated through social interactions and networks [153]. This could either be through individual social interactions, such as through a personal social network, or at a macro level such as ones ongoing experience of healthcare.

#### Actively seek help

The mechanism of affinity to a practice was related with relationship with GP and extent to which practice is welcoming. **Lamb 2012** used meta-synthesis to look at access problems for hard to reach groups [155]. The authors found that an understanding by the GP of who the patient was and how they related to the worlds they inhabit, based on previous interactions, was fundamental to their relationship with health care (*relationship with GP*). Similarly **Tod 2001** found that if the GP did not have a presence in the community, such as a single handed GP with several surgeries, then patients were more likely to delay seeking help (*relationship with GP*) [130]. **Coles 2010** found that some older men, based on the feel and atmosphere of the practice, felt that they were not welcome at some services (*extent to which practice is welcoming*) [81]. **Qu 2011** undertook a survey to look at the perception of staff in a practice who were not doctors (e.g. receptionists) [135]. In this study 40% of patients (n=479) expressed dissatisfaction about how these staff members facilitated access to doctors (*extent to which practice is welcoming and relationship with GP*).

The mechanism of convenience was related with clear information and transport. **Beckman 2013** in a study of routinely collected Swedish data (n=828,988) looked at access to primary care [129]. The authors argue that having clear information and knowledge of the alternatives are key to attaining the right solution for patients (*clear information*). Several studies described the impact of poor transport on access. One example was **Comber 2011** which combined an attitudes survey with GIS analysis and found that for those who did not own a car, the relative odds of experiencing difficulty in access to GPs was 3.8 times more than those who did own a car (*transport*) [158].

The mechanism of health literacy was related with educational status and clear information. **Birch 1993** used routinely collected data to evaluate access to primary care in Canada [156]. The authors found that low levels of education were related with lower levels of use particular among patients with lower levels of need (*educational status*). Similarly **Bossuyt 2011** in a retrospective cohort study argue that a patient's educational attainment, via the mechanism of health literacy, is related with how health is sought (*educational status*) [157]. **Moskowitz 2013** looked at survey data from 11,105 Americans [152]. The authors found that doctors gave less information to lower socio-economic groups and this in turn is likely to influence how these patients are able to understand and navigate the health care system (*clear information*).

The mechanism of patient empowerment was related with extent to which the practice is welcoming, self-efficacy and clear information. **Coles 2010** found, based on focus groups with 82 socio-economically deprived older men, that increasingly positive experiences with health services led to an increase in assertiveness and empowerment (*extent to which practice is welcoming*) [81]. **Raymond 2011** undertook a cross sectional analysis of a randomised controlled trial of older

people [160]. The authors argue that self-efficacy (an individual's optimistic self-belief) is related with a patient's ability to solve problems and is significantly less likely among women, those with basic education and those living alone (*self-efficacy*). **Freij 2011** undertook 25 qualitative interviews and six focus groups in older adults from America [161]. The authors found that when care co-ordinators gave clear information about available services patients were more confident to use services (*clear information*).

The mechanism of perceived ability to benefit was related with choice, the extent to which the practice is welcoming and experience of health care. **Beckman 2013**, in a Swedish cohort study, argue that choice is important to improving access because patients will be able to choose the best service for them based on availability, geographical location, opening hours, etc [129]. The authors also suggest that the ability to exercise choice is affected by income and/or education (*choice*). **Underwood 1994** reviewed interview transcripts of 46 deprived older people with experiences of cancer [159]. The authors found that some women were made to feel that their concerns about cancer and attendance were unwarranted. This type of experience is likely to make an individual feel unwelcome and of the opinion that primary care cannot meet their needs (*extent to which practice is welcoming*). **Tod 2001** in a qualitative interview of older people with angina found that negative previous experiences of accessing care resulted in a reduced likelihood of accessing the same care again (*experience of health care*) [130].

#### Obtain an appointment

The mechanism of assertiveness was related with understanding the practice system and self-esteem. **Coles 2010** found that older men from deprived areas became more assertive as they learned to deal with the booking system (*understanding the practice system*) [81]. **Moskowitz 2013** argue that perceived social position, influenced by upbringing and life events, affects the assertiveness (*self-esteem*) [152].

The mechanism of convenience was related with available appointments, experience of health care, ease of booking system, understanding the practice system, use of technology and transport. Several studies described the impact of available appointments. For example, **Bennett 2009** report an analysis of routine appointment data (n=43,349), finding that patients who request an appointment but were not able to see their GP or had to wait more than 2 weeks were less likely to keep their appointment (*available appointments*) [162]. **Buetow 2002** presents data on 39 semi-structured interviews of people with asthma and poor access to primary care [164]. The authors compared "patient-centred time" and "practice-centred time", arguing that primary care is often organised around the preferences of the practice rather than patients. For example, the working day and calendar are divided into units of fixed value and practices impose systems of time management designed to meet their needs (*experience of health care*). **Coles 2010** in a qualitative study of older men found that appointment systems were frequently illogical and hard to understand, especially if quick access was required [81]. For example one man was told the next available appointment was in a fortnight, but if he phoned the next day at 8.30am he might be able to get one that day (*ease of booking system*). The study also found that men described having to "break into" the system to be able to successfully navigate it (*understanding the practice system*). **Choi 2011** presents data regarding use of technology from the US National Health Interview Survey (n=27,731) [165]. The authors found that for older people of both genders the increased use of technology was related with increased access to GPs, specialists or allied health professionals (*use of technology*). **Thommasen 2006** in a retrospective cohort study (n=2,378) of patients accessing health services in British Columbia argued that doctors who work in rural areas are likely to rely more on technology, rather than face-to-face appointments, to maximise efficiency [166]. Therefore patients who are able to use technology will find the service more



convenient to access (*use of technology*). **Cheung 2012** analysed 230,258 adults in the US National Health Interview Survey, comparing Medicaid (less affluent) with private insurance (more affluent) beneficiaries [167]. In considering barriers to primary care, the largest difference between these groups was transport and the authors argue that more convenient locations are needed to help Medicaid beneficiaries (*transport*). **Morgan 2011** describes an observational study of 639 general practices in England [171]. The authors argue that satisfaction with a service is based more on convenience than capacity. Improving convenience is likely to improve satisfaction with services and subsequent access (*experience of health care*).

The mechanism of health literacy was related with clear information and educational status. **Kovandzic 2011** presents an analysis of 33 qualitative interviews of how patients with mental health problems access primary care [120]. One of the two main barriers was a lack of effective information that is culturally sensitive with adequate content at the right time (*clear information*). **Rogowski 2008** analysed routinely collected data from older people in the US (n=20,227) [163]. The authors found that patients with low education were less able to navigate health care pathways (*educational status*).

The mechanism of patient empowerment was related with educational status, lifelong poverty, experience of health care, use of technology and understanding the practice system. **Bossuyt 2011** describes a retrospective cohort study of older people who accessed health care at the end of their life (n=2445) [157]. The authors found that less educated people had few transitions throughout the health system and the authors suggest this is because they were unable to organise desired care (*educational status*). **Drummond 2000** describes an analysis of attendees at an out of hours service in Glasgow (n=3193) [172]. The authors argue that patients who are more affluent have developed better negotiating skills over their lifetime and are therefore able to better overcome barriers (*lifelong poverty*). **Calnan 2003** in an editorial argues that older people's experience of health care is medicalised and predominantly biomedical [145]. Therefore ageing is portrayed as a medical problem, re-enforcing dependency and passivity (*experience of health care*). **Goodall 2010** describes findings of eight focus groups with older people living in South Australia [170]. The authors argue that information technology allows patients to engage in a meaningful and empowered manner both in terms of navigating the system and acquiring knowledge (*use of technology*). **Roos 1997** presents an analysis of the socio-economic characteristics and health status in a Canadian study of approximately 600,000 people [173]. The authors suggest that higher socio-economic status results in knowing treatment options and pathways and then being able to better negotiate and ask for a referral when necessary (*understanding the practice system*).

The mechanism of responsiveness was related with capacity within practice. **Buetow 2002** in 29 semi-structured interviews with patients with asthma found that practices were organised around their own capacity needs, rather than patients' needs [164]. The authors describes how practices need to be flexible to address barriers, such as opening hours, traditional appointment systems, intolerance of missed appointments, long waiting times and inadequate consultation lengths (*capacity within practice*).

#### Getting to the appointment

The mechanism of convenience was related with geographic isolation, transport, social network and formal community support. **Jatrana 2009** analysed data from Survey of Family, Income and Employment in New Zealand (n=18,320) and argued that while financial barriers were important to patients, isolation and lack of transportation were especially important to deprived groups (*geographical isolation and transport*) [174]. Furthermore **Turnbull 2008** in a geographic analysis of routinely collected data of out of hours telephone calls compared geographical location,

deprivation and health care use (n=34,229) [175]. The authors found that in rural areas, deprived populations were least likely to receive the health care they needed (*geographical isolation*). Transport was a recurrent theme which several studies discussed. For example, **Comber 2011** in a GIS analysis of 8530 patients in Leicestershire found that patients who did not own a car, compared to those who did, were 3.8 times more likely to experience difficulties over accessing GP (*transport*) [158]. **Bentley 2003** in interviews with older people from rural areas found that the closure of local amenities and public transport led to older people finding it difficult to get to the surgery (*formal community support*) [80]. Furthermore **Goodridge 2011** described semi-structured interviews with older people living in rural areas with chronic respiratory illness [134]. The authors found that patients who did not have a car or access to a local volunteer driver had to wait and depend on the good will of friends or family to get to an appointment (*social network*).

### Primary care interaction

The mechanism of articulation of the health problem was related with educational status, clinician empathy, social distance and continuity of care. **Lamb 2012** presents a meta-synthesis looking at how vulnerable people access health care [155]. The authors found that vulnerable groups find it hard to articulate their problems. This was due to vulnerable groups being unable to communicate using professional models of illness (*educational status*) and doctors being unable to understand where patients are coming from (*clinician empathy*). **Moskowitz 2013** describes an analysis of survey data from the Diabetes Study of Northern California (n=11,105) [152]. The authors found that patients' sense of where they fall in the social hierarchy affected their communication (*social distance*). **Camillo 2004** presents a qualitative, ethnographic study of older women who experienced problems with access to health care [138]. The author found that continuity instilled a strong sense of trust and helped to facilitate better communication (*continuity of care*).

The mechanism of empowered clinician was related with capacity within practice. **Magan 2011** undertook a cross sectional analysis of routinely collected hospital data in 34 health districts in Spain [179]. The authors found that conditions sensitive to primary care intervention were positively correlated with a GP's workload suggesting that as workload increases a GP's ability to intervene decreases (*capacity within practice*).

The mechanism of equal status was related with continuity of care, trust in health care, perceived ability to benefit, social distance and perceived discrimination. **Mazza 2011** presents a qualitative study of 18 focus groups comparing high and low socio-economic status [146]. The authors found that if patients consulted with a number of different GPs it led to conflicting opinions and this resulted in scepticism and uncertainty (*continuity of care and trust in health care*). **Rogowski 2008** in an analysis of routinely collected data of older people in the USA (n=20,227) argued that lower socio-economic groups develop learned beliefs about health care [163]. These might include less confidence in the efficacy of the health care system (perceived ability to benefit). **Cawston 2007** describes participatory action research in a deprived community in Scotland [181]. The authors found that a lack of respect, prejudice or labelling patients based on social group features led to social distance between the doctor and patient (*social distance*). **Bentley 2003** in interviews with older rural people found that some older people did not feel respected in regards to health care and that younger people got better treatment (*perceived discrimination*) [80].

The mechanism of patient empowerment was related with self-esteem, experience of health care, financial resources, clinician empathy and emotional distress. **Dixon 2007** presents a review of literature relating to equity in the NHS [176]. The authors argue that higher socio-economic groups have a louder "voice" because of better education and general self-confidence leading to a greater ability to persuade GPs to meet their needs (*self-esteem*). **Coles 2010** in focus groups with 82 older

deprived men found that their confidence and trust grew with an increasing number of positive experiences (*experience of health care*) [81]. **Moffat 2004** presents findings from 11 semi-structured interviews of people receiving welfare advice [177]. The authors found that financial resources increased choice and control resulting in higher self-esteem and empowerment (*financial resources and self-esteem*). Mercer 2012 reports a questionnaire study of 3,044 patients attending 26 GPs in the UK [178]. The authors found that emotional distress and low GP empathy were associated with lower patient empowerment (clinician empathy and emotional distress).

The mechanism for trust was related with continuity of care. **Camillo 2004** presents a qualitative, ethnographic study of older women who experienced problems with access to health care [138]. The author found that continuity instilled a strong sense of trust and helped to facilitate better communication (*continuity of care*).

The primary care step was supported by Allport's Contact Theory where contact is seen as important to promote understanding and reduce prejudice between groups [182]. This is important because socio-economically disadvantaged patients with low contact with their doctor will have fewer opportunities to reduce prejudice and social distance between themselves and their doctor.

## Appendix 3: Ethical approval for qualitative study

Faculty of Medicine and Health Sciences Research Ethics Committee



John Ford  
MED

Research & Enterprise Services  
West Office (Science Building)  
University of East Anglia  
Norwich Research Park  
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591720

Email: [fmh.ethics@uea.ac.uk](mailto:fmh.ethics@uea.ac.uk)

Web: [www.uea.ac.uk/researchandenterprise](http://www.uea.ac.uk/researchandenterprise)

15/4/15

Dear John

**Title: Access to primary care for socio-economically disadvantaged older people living in rural areas: a qualitative study**  
**Reference 20142015 - 43**

Thank you for your e-mail dated 27/3/15 notifying us of the amendments to your above proposal. These have been considered and we can now confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'M. Wilkinson', is written over a light blue horizontal line.

Mark Wilkinson  
Chair FMH Research Ethics Committee

**Cc: Nick Steel**

## Appendix 4: Consent form for interviews and focus groups

### CONSENT FORM

Title of Project: Improving access to high quality primary care



Name of Researcher: John Ford

	Please initial box
<ul style="list-style-type: none"> <li>I confirm that I have read the information sheet dated 09/06/15 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.</li> </ul>	
<ul style="list-style-type: none"> <li>I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. I understand that the discussion will be audio recorded.</li> </ul>	
<ul style="list-style-type: none"> <li>I agree to take part in the above study.</li> </ul>	

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person  
taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed: 1 for participant; 1 for researcher site file

09/06/15 (version 3)

## **Appendix 5: Participant Information Leaflet for semi-structure interviews**

### **Study Title**

Improving access to high quality primary care

### **Study summary**

At the University of East Anglia we are looking at how people over 65 years old get to and use their GP. We know that some people find it difficult to see their GP. This study aims to identify the common problems and develop solutions.

### **What's involved?**

The study has several parts. Firstly a review of previous research, secondly asking people about their experiences, thirdly analysing a national dataset and finally designing a new service to help overcome these problems.

You've been invited to take part in the second part of the research (speaking to people).

We are looking for people who

- Live in rural areas and are over 65 years old and receive financial support

### **What would taking part involve?**

Taking part will involve a discussion with me for about 1 hour. This will either be at the University or at home, whichever is easiest for you.

I will tell you more about the research again and if you're happy to continue will ask you to sign a consent form.

Then I will ask you about your experiences of getting to see your GP. They will also ask you some focused questions. The discussion will be recorded on a Dictaphone so that I don't have to take detailed notes at the time.

You are free to stop at any point in the discussion, without giving a reason. If you withdraw you will have the option of removing the information you have given up to the point that it has been analysed.

### **What are the possible benefits of taking part?**

Taking part will give you an opportunity to tell your story and contribute to important research which we hope will help older people get in contact with the GP more easily.

You will be reimbursed for the cost of any travel for the research and given a £20 shopping voucher for participating.

### **What are the possible disadvantages and risks of taking part?**

There are very few disadvantages of taking part in this type of research. Anything you say will be anonymised and none of the information will be passed on to your GP or anyone in the NHS.

Sometimes in this type of research issues are discussed which you may feel sensitive about. You do not have to answer any question you do not want to and can stop the discussion at any point, without giving a reason.

If you mention something that I feel would put you or someone else at risk they may have to share that information with someone else.

#### **What will happen the information I provide?**

Your information will be combined with everyone else's and results analysed. This information and basic contact information will be stored on the secure University computer system in case we need to contact you again. It will be reviewed every year and deleted when no longer needed.

We will share the results at conferences and medical journals. Results will also be included my PhD thesis and passed on to people who could use the results to improve health services. No one will be able to identify you from any of the results. The information that you provide will not be passed onto your GP surgery unless I feel that it would put you or someone else at risk.

#### **What will happen to the results?**

The results will be used to design a new service which will be tested. No one taking part in the research will be identifiable from the results. You are very welcome to see a copy of the research report summary. Please contact me (John Ford) if you would like a copy (details below).

#### **Who is funding this research?**

The National Institute for Health Research is providing funding for the whole study.

#### **Who has checked that this study meets national research standards?**

To obtain funding the study underwent a rigorous review process by the National Institute for Health Research. The University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee has also reviewed this research and given a favourable opinion.

#### **Further information**

More information is available on the study website ([www.uea.ac.uk/medicine/research/health-service-research/access-to-research](http://www.uea.ac.uk/medicine/research/health-service-research/access-to-research)). Alternatively please don't hesitate to contact me.

John Ford  
Research Student  
Email: [john.ford@uea.ac.uk](mailto:john.ford@uea.ac.uk)  
Tel: 01603 591743

Date 09/06/15 Version 4

## **Appendix 6: Participant Information Leaflet for focus groups**

### **Study Title**

Improving access to high quality primary care

### **Study summary**

At the University of East Anglia we are looking at how people over 65 years old get to and use their GP. We know that some people find it difficult to see their GP. This study aims to identify the common problems in the system and develop solutions.

### **What's involved?**

The study has several parts. Firstly a review of previous research, secondly speaking to patients and health professionals, thirdly analysing a national dataset and finally designing a new service to help the problems.

You've been invited to take part in the second part of the research (speaking to health professionals).

We are looking for health professionals who fit into one of the following categories: GPs, community matrons/case managers, community geriatricians, commissioners and district nurses. We want a range of professionals and will operate a first-come first-served policy if there is lots of interest.

### **What would taking part involve?**

Taking part would involve attending a focus group with other health professionals for approximately 2 hours at the University of East Anglia. When we meet I will talk through the study again and if you're happy will ask you to sign a consent form.

This discussion will be an opportunity for you to share your experience. Later in the discussion there is likely to be some focus questions. The discussion will be recorded which means we don't need to take detailed notes at the time.

You are free to stop at any point during the focus group, without giving a reason. If you withdraw you will have the option of removing the information you have given up to the point that it has been analysed.

### **What are the possible benefits of taking part?**

Taking part will give you an opportunity to contribute to important research which we hope will shape future services.

You will be reimbursed for the cost of travel and time to take part in the focus group.

### **What are the possible disadvantages and risks of taking part?**

Taking part in this type of research is very low risk. Anything you say will be anonymised and none of the information will be passed on to your GP or anyone in the NHS.

Sometimes in this type of research issues are discussed which are sensitive. You do not have to answer any question you do not want to and can stop the discussion at any point, without giving a reason.



If you mention something that I feel would put you or someone else at risk they may have to share that information with someone else.

**What will happen the information I provide?**

Your information will be combined with everyone else's and results analysed. This information and basic contact information will be stored on the secure University computer system in case we need to contact you again. It will be reviewed every year and deleted when no longer needed.

We will share the results at conferences and journal articles. Results will also be included my PhD thesis. No one will be able to identify you from any of the results. Your responses will not be passed onto your organisation, unless I feel that you or someone else is at risk.

**What will happen to the results?**

The results will be used to design a new service which will be tested. The results are likely to also be report in a journal article and conference publication. No one taking part in the research will be identifiable from the results. If you wish to have a copy of the final results, you can request them from me (details below).

**Who is funding this research?**

The National Institute for Health Research is providing funding for the whole study.

**Who has reviewed this study?**

To obtain funding the study underwent a rigorous review process by the National Institute for Health Research. The University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee has also reviewed this research.

**Further information**

More information is available on the study website ([www.uea.ac.uk/medicine/research/health-service-research/access-to-research](http://www.uea.ac.uk/medicine/research/health-service-research/access-to-research)). Alternatively please don't hesitate to contact me.

John Ford  
Research Student  
Tel: 01603 591743  
Email: [john.ford@uea.ac.uk](mailto:john.ford@uea.ac.uk)

Date 09/06/15 Version 4

# Appendix 7: Topic guide for semi-structure interviews and focus groups

## Interview Topic Guide

### *Introductions*

Explain purpose of discussion – aim to discuss experiences with no right/wrong answers. Discussion will be recorded to help with the analysis. Anything discussed is confidential and won't be shared with anyone, such as your GP, else other than members of the research team. All results will be anonymised. You can stop the discussion at any point and don't need to give a reason. If something is said that I feel may put either you or someone else in direct harm, I will need to discuss it with a colleague. Check with participant expected length of interview. Details of payment of expenses.

Explanation of the structure of the discussion – will last about 1 hr. I will ask questions about your experiences of getting to and seeing the GP. Please be as honest as you can.

1. What do you think about where you live?
2. Tell me about your experiences of getting to and seeing your GP
  - Prompts
    - a. What was your experience of getting an appointment?
    - b. Did you face any challenges in getting to the surgery, if so what were they?
    - c. What made it difficult?
    - d. What made it easy?
3. What do you think is the impact of living in the countryside?
  - Prompts
    - a. Particular difficulties?
4. How might someone's experiences of seeing their GP be affected by having friends or family nearby, or by their financial situation?
  - Prompts
    - a. Would access be harder without friends or family living nearby, if so why?
5. What things would make it easier for you, or someone in your position, to get to and see your GP?
  - Prompts
    - a. Interventions from the realist review will be mentioned, such as telephone consultations and community transport
6. Is there anything else we haven't talk about that you would like to mention?

Thank you for participation

## **Focus group topic guides**

### *Introductions*

Explain purpose of discussion – aim to discuss experiences with no right/wrong answers. Discussion will be recorded to help with the analysis. Anything discussed is confidential and won't be shared with anyone else. All results will be anonymised. You can stop the discussion at any point and don't need to give a reason.

Explanation of the structure of the discussion – will last 2 hours. Please be as honest as possible. If you wish to give examples, please do not mention anything that might be identifiable.

Aim is to have a discussion, so please feel free to challenge each other. Don't need to stick to the script.

Explain that the research is focusing on how older people, especially who are deprived and from rural areas access their GP.

1. What do you think are experiences of older people trying to access their GP?
  - Prompts
    - a. Impact of deprivation
    - b. Impact of rurality
2. Why do you think some older people don't use their GP very often? For example, I'm thinking of someone who might not see their GP for 4 or 5 years and then turn up with a list of problems.
3. Some older people have said that fear or anxiety has stopped them from seeing their GP. Is this something you identify with and, if so, what's been your experience?
  - a. Prompt – examples fear of serious health problem, nursing home, not being able to care for spouse
4. Some older people describe negative experiences of health care in the past which influences who their relationship with health care. Is this something you identify with and, if so, what's been your experience?
  - a. Prompt – loss of trust by misdiagnosis decades ago
5. What do you think would help deprived older people in rural areas get better access to their GP?
  - Prompts
    - a. Telephone consultations, health visitors, protected appointments, challenging anxiety/fear, dealing with negative past experiences
6. Is there anything else we haven't talk about that you would like to mention?

Thank you for participation

## Appendix 8: Ethical approval for I-ACT study



### Health Research Authority

#### North East - York Research Ethics Committee

Jarrow Business Centre  
Rolling Mill Road  
Jarrow  
NE32 3DT

Telephone: 0207 1048091

**Please note:** This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

19 December 2016

Dr John Ford  
Norwich Medical School  
University of East Anglia  
NR4 7TJ

Dear Dr Ford

**Study title:** Improving Primary care Access in Context and Theory (I-ACT trial): A theory informed trial using a realist perspective  
**REC reference:** 16/NE/0424  
**Protocol number:** R109428  
**IRAS project ID:** 218535

The Proportionate Review Sub-committee of the North East - York Research Ethics Committee reviewed the above application via correspondence.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Helen Wilson, nrescommittee.northeast-york@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

## **Ethical opinion**

On behalf of the Committee, the sub-committee gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

### **Conditions of the favourable opinion**

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).*

*Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, [www.hra.nhs.uk](http://www.hra.nhs.uk) or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of management permissions from host organisations.*

### **Registration of Clinical Trials**

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with**

**before the start of the study or its initiation at a particular site (as applicable).  
Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

### **Summary of discussion at the meeting**

#### **Recruitment arrangements and access to health information, and fair participant selection**

Members queried if the GP practices had been identified yet as it may be difficult to get any practices interested.

*It was stated that the practice recruitment process had not commenced yet. However 4 practice managers in Norfolk had been spoken to during the development of the research and each of them seemed keen to participate. It was confirmed that they were particularly interested in having more control over the service changes.*

#### **Informed consent process and the adequacy and completeness of participant information**

Members stated that Question 1 on the Consent Forms should read "satisfactorily".

*It was confirmed that this had been amended.*

Members stated that on the Participant Information Sheet for the trial:-

- under heading "Why have I been invited?" should read "*find it difficult*".
- Page 2 second paragraph "what does it involve" should read "*We will recruit 10 patients from each of 4 GP practices*" as the current wording was not clear on the number of patients involved.

*It was confirmed that these had been amended.*

#### **Suitability of supporting information**

Members stated that a number of the questionnaires involved marking crosses along continuum lines but these lines would need extension across the pages, otherwise it might lead to confusion.

*It was confirmed that the length of the lines had been increased.*

### **Approved documents**

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement [Statement of Activities]		



Copies of advertisement materials for research participants [Poster for practice observations]	1.0	21 November 2016
Covering letter on headed paper [Cover letter]	1.0	21 November 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA Insurance ]		07 June 2016
GP/consultant information sheets or letters [Letter to inform GP of participation]	1.0	21 November 2016
Interview schedules or topic guides for participants [Topic guide for participant interviews]	1.0	21 November 2016
Interview schedules or topic guides for participants [Topic guide for group interviews]	1.0	21 November 2016
IRAS Application Form [IRAS_Form_12122016]		12 December 2016
IRAS Checklist XML [Checklist_12122016]		12 December 2016
Letter from funder [NIHR funding confirmation email]		02 July 2014
Letter from sponsor [Sponsor cover letter]		01 December 2016
Letters of invitation to participant [Letter of invitation to trial]	1.0	21 November 2016
Letters of invitation to participant [Letter of invitation reminder]	1.0	21 November 2016
Letters of invitation to participant [Letter of invitation for participant interviews]	1.0	21 November 2016
Non-validated questionnaire [Questionnaire baseline researcher]	1.0	21 November 2016
Non-validated questionnaire [Questionnaire baseline self-completion]	1.1	12 December 2016
Non-validated questionnaire [Questionnaire booking]	1.1	12 December 2016
Non-validated questionnaire [Questionnaire appointment]	1.1	12 December 2016
Non-validated questionnaire [Questionnaire follow up]	1.1	12 December 2016
Other [Letter reminder at one month]	1.0	21 November 2016
Other [Letter for missed questionnaire]	1.0	21 November 2016
Other [Support manual]	1.0	21 November 2016
Other [Fridge magnet]	1.0	21 November 2016
Other [Schedule of events]		
Other [UEA Professional Negligence Insurance]		07 June 2016
Participant consent form [Consent for trial]	1.1	12 December 2016
Participant consent form [Consent for interviews]	1.1	12 December 2016
Participant consent form [Consent for group interviews]	1.1	12 December 2016
Participant consent form [Consent for observations]	1.1	12 December 2016
Participant consent form [Consent for development meetings]	1.1	12 December 2016
Participant information sheet (PIS) [PIS for participant interviews]	1.0	21 November 2016
Participant information sheet (PIS) [PIS for Observations]	1.0	21 November 2016
Participant information sheet (PIS) [PIS for group interviews]	1.0	21 November 2016
Participant information sheet (PIS) [PIS for trial]	1.1	12 December 2016
Referee's report or other scientific critique report [NIHR DRF Feedback]		
Research protocol or project proposal [Protocol]	1.0	21 November 2016
Summary CV for Chief Investigator (CI) [CV JF]	1.0	21 November 2016
Summary CV for student [John Ford CV]	1.0	21 November 2016

Summary CV for supervisor (student research) [Prof Nick Steel CV]		21 November 2016
Summary CV for supervisor (student research) [Prof Andy Jones CV]		21 November 2016
Summary CV for supervisor (student research) [Dr Geoff Wong CV]		21 November 2016
Validated questionnaire [Questionnaire - PAM]		
Validated questionnaire [Questionnaire - ICECAP-O]		
Validated questionnaire [Questionnaire EQ5D5L]		

### **Membership of the Proportionate Review Sub-Committee**

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **After ethical review**

#### Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

### **HRA Training**

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.



Yours sincerely



pp

**Mrs Janet Hattle**  
**Chair**

Email: [nrescommittee.northeast-york@nhs.net](mailto:nrescommittee.northeast-york@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*"After ethical review – guidance for researchers"*

Copy to: Mrs Tracy Moulton

Mrs Clare Symms, Norfolk & Suffolk Primary & Community Care  
Research Office

## **Appendix 9: I-ACT study protocol**

**Improving Primary care Access in Context and Theory (I-ACT trial): A theory informed trial using a realist perspective**

Version V4.1

Date 14/09/17

Sponsor UEA

Trial registration: ISRCTN18321951

IRAS: NRES 218535 16/NE/0424

## **1 Administrative information**

This document was constructed using the Norwich Clinical Trials Unit (NCTU) Protocol template Version 3. It describes the I-ACT trial, sponsored by University of East Anglia and co-ordinated by NCTU.

It provides information about procedures for entering participants into the trial, and provides sufficient detail to enable: an understanding of the background, rationale, objectives, trial population, intervention, methods, statistical analyses, ethical considerations, dissemination plans and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary.

NCTU supports the commitment that its trials adhere to the SPIRIT guidelines. As such, the protocol template is based on an adaptation of the University College London CTU protocol template (2012) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2012 Statement for protocols of clinical trials (1). The SPIRIT Statement Explanation and Elaboration document (2) can be referred to, or a member of NCTU Protocol Review Committee can be contacted for further detail about specific items.

### **1.1 Compliance**

The trial will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP) as laid down by the Commission Directive 2005/28/EC with implementation in national legislation in the UK by Statutory Instrument 2004/1031 and subsequent amendments, the UK Data Protection Act, and the National Health Service (NHS) Research Governance Framework for Health and Social Care (RGF). Agreements that include detailed roles and responsibilities will be in place between participating practices and NCTU.

Participating sites will inform NCTU as soon as they are aware of a possible serious breach of compliance. For the purposes of this regulation a 'serious breach' is one that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects in the trial, or
- The scientific value of the trial.

### **1.2 Sponsor**

The University of East Anglia is the trial sponsor and has delegated responsibility for the overall management of the I-ACT trial to the UEA Chief Investigator and NCTU. Queries relating to sponsorship of this trial should be addressed to the Chief Investigator or via the trial team.

### **1.3 Structured trial summary**

Secondary Identifying Numbers	Funding reference number: DRF-2014-07-083 IRAS reference number: 218535
Source of Monetary or Material Support	National Institute for Health Research Doctoral Fellowship programme
Sponsor	University of East Anglia, delegated to NCTU
Contact for Public Queries	ctu.enquiries@uea.ac.uk
Contact for Scientific Queries	Dr John Ford

	Norwich Medical School University of East Anglia Chancellors Drive Norwich, NR4 7TJ John.ford@uea.ac.uk 01603 591743
Public Title	I-ACT Study - Improving access to primary care
Scientific Title	Improving primary care Access in Context and Theory (I-ACT trial): A theory informed trial using a realist perspective
Countries of Recruitment	England
Health Condition(s) or Problem(s) Studied	Access to primary care for socio-economically disadvantaged older people living in rural areas
Intervention(s)	<p><i>Intervention</i></p> <p>Provision of a support package including a Support Manual, four weekly development meetings and £1500 to develop and/or deliver practice specific improvement of:</p> <ul style="list-style-type: none"> <li>• ease of the booking system and</li> <li>• transport barriers</li> </ul> <p>for socio-economically disadvantaged older people without access to a car</p> <p><i>Control</i></p> <p>Usual care (defined as accessing the GP surgery in the standard manner)</p>

<p>Key Inclusion and Exclusion Criteria</p>	<p><u>General practice inclusion criteria</u></p> <ul style="list-style-type: none"> <li>• Be classified as rural according to the Health and Social Care Information Centre.</li> <li>• Have a list size of over 7000 patients.</li> <li>• Agree to their practice being profiled. This will involve describing their local system and environment using routinely collected data, practice documentation relating to policies or standard operating procedures and informal discussions with practice staff and patient groups.</li> <li>• Agree to commit to the process of developing their service supported by the research team.</li> <li>• Agreement from a GP or practice manager able to be on-site principal investigator.</li> <li>• Agree to practice observations and a GP, practice manager and two receptionists taking part in a group interview.</li> </ul> <p><u>Trial participant inclusion criteria</u></p> <ul style="list-style-type: none"> <li>• Aged 65 years old or over</li> <li>• Two or more repeat prescriptions</li> <li>• Twelve or fewer consultations in the past 12 months (face-to-face only)</li> <li>• No access to a car within the household</li> <li>• Self-reported difficulty in accessing their general practice</li> </ul> <p><u>Trial participant exclusion criteria</u></p> <ul style="list-style-type: none"> <li>• Significant cognitive impairment that would prevent them providing informed consent, such as dementia</li> <li>• Not able to speak English</li> <li>• Generally do not book their own appointments</li> </ul>
<p>Study Type</p>	<p>The design of this feasibility study is a cluster randomised controlled trial comparing provision of a support package to general practices to improve primary care access over six months in rural socio-economically disadvantaged older people, against usual care.</p>
<p>Date of First Enrolment</p>	<p>Anticipated 01/05/2017</p>
<p>Target Sample Size</p>	<p>40 participants (4 general practices with 10 patients per general practice)</p>
<p>Feasibility objectives</p>	<ul style="list-style-type: none"> <li>• Estimate the size of the eligible patient population</li> <li>• Estimate the recruitment and retention pattern of practices and patients</li> <li>• Assess the feasibility and acceptability of mapping practice profiles</li> </ul>

	<ul style="list-style-type: none"> <li>• Assess the extent to which practices are able to develop and implement a context specific service changes</li> <li>• Assess if the data collection methods are acceptable to patients</li> <li>• Assess the appropriateness of the outcomes measures</li> <li>• Estimate statistical parameters of the key outcome measures to help determine the sample size for the definitive study</li> <li>• Estimate the time and resource requirements</li> </ul>
Feasibility outcomes	<p>The outcomes of the feasibility study will be</p> <ul style="list-style-type: none"> <li>• The proportion of eligible participants within a practice</li> <li>• The proportion of patients recruited</li> <li>• The proportion of patients and practices that withdraw or are lost to follow-up</li> <li>• Statistical parameters of the key outcome measures to inform a sample size calculation for a definitive trial.</li> <li>• Acceptability of data collection methods assessed through professional group and participant interviews</li> <li>• Ability to develop and implement service changes assessed through professional group and participant interviews and activity measures</li> <li>• Ability to profile practices assessed through professional group interviews</li> <li>• Time and resource requirements monitored by the trial team</li> </ul>
Patient outcome measures	<p>This is a feasibility study, as such no primary outcome has been defined. The following outcomes will be collected:</p> <p>Patient reported:</p> <ul style="list-style-type: none"> <li>• Pre-appointment transport options, ease of appointment and perceived convenience,</li> <li>• Post-appointment suitability of received appointment and transport to get to the appointment</li> <li>• Confidence and trust in general practice</li> <li>• Patient Activation Measure (PAM)</li> <li>• Quality of life <ul style="list-style-type: none"> <li>○ EQ-5D-5L</li> <li>○ ICECAP-O</li> </ul> </li> </ul> <p>Routinely recorded:</p> <ul style="list-style-type: none"> <li>• Number and type of health professional contact (health care assistant, nurse, GP or other)</li> <li>• Hospital admissions (safety outcome)</li> <li>• Intervention activity and process measures agreed by research team and practices</li> <li>• Number of referrals</li> <li>• Number of repeat medications</li> </ul>

#### 1.4 Roles and responsibilities

These membership lists are correct at the time of writing; please see terms of reference documentation in the TMF for current lists.

#### 1.4.1 Protocol contributors

Name	Affiliation	Role
Dr John Ford	UEA	Chief Investigator
Prof Nick Steel	UEA	Supervisor
Prof Andy Jones	UEA	Supervisor
Dr Geoff Wong	University of Oxford	Supervisor
Dr Allan Clark	UEA	Statistical advice
Prof Garry Barton	UEA	Health economic advice
Prof Tom Shakespeare	UEA	Qualitative advice
Dr Tom Porter	UEA	Qualitative advice
Prof Ann Marie Swart	UEA	CTU Director and trials advice
Mrs Annie Moseley	None	Patient representative

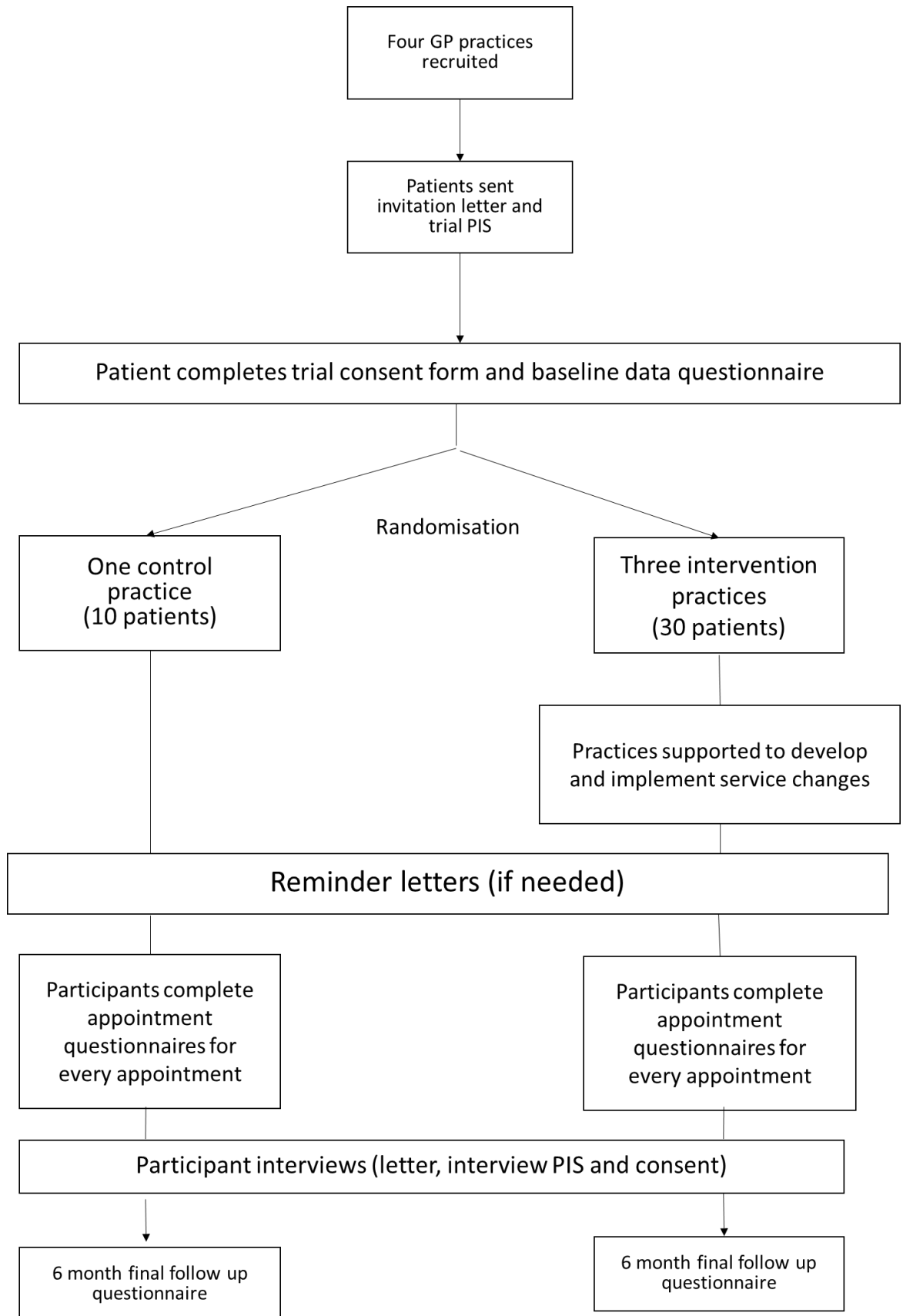
#### 1.4.2 Trial Team

Name	Affiliation	Role and responsibilities
Dr John Ford	UEA	Overall responsibility for day to day management of the trial. Other responsibilities will include: recruiting patients, obtaining consent, collecting quantitative and qualitative data and facilitating practice development meetings.
Dr Erika Sims	UEA	Responsible for providing operational oversight
CTU Data Manager	UEA	Individual responsible for entering data into trial database
CTU Data Programmer	UEA	Programmer responsible for setting up trial database
Martin Pond	UEA	CTU Head of Data Management responsible for oversight of data processes

#### 1.4.3 Trial Management Group

Name	Affiliation	Role and responsibilities
Dr John Ford	UEA	Chief Investigator
Prof Nick Steel	UEA	Supervisor
Prof Andy Jones	UEA	Supervisor
Dr Geoff Wong	University of Oxford	Supervisor
Dr Allan Clark	UEA	Statistical advice
Prof Garry Barton	UEA	Health economic advice
Prof Tom Shakespeare	UEA	Qualitative advice
Dr Tom Porter	UEA	Qualitative advice
Prof Ann Marie Swart	UEA	CTU Director and trials advice
Dr Erika Sims	UEA	Operational oversight
Mrs Hillary Stringer	None	Patient representative
Mrs Annie Moseley	None	Patient representative

## 2 Trial Diagram





### 3 Abbreviations

AE	Adverse Event
CI	Chief Investigator
EQ-5D-5L	EuroQol five dimensions questionnaire
EU	European Union
GCP	Good Clinical Practice
ICECAP-O	ICEpop CAPability measure for Older people
ICMJE	<i>International Committee of Medical Journal Editors</i>
MF	Trial Master File
NCTU	Norwich Clinical Trials Unit
PAM	Patient Activation Measure
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
R&D	Research and Development
REC	Research Ethics Committee
RISP	Research Information Sheet for Practices
TMG	Trial Management Group
TMT	Trial Management Team
ToR	Terms of Reference

### 4 Glossary

Context	Anything external to the intervention which impedes or strengthens its effects
Index of Multiple Deprivation	A measure of deprivation commonly used in the UK in routinely collected statistics that covers seven different aspects of deprivation
Practice profile	A description of the practice that includes patient demographics, current services and policies, workforce, management structure and tensions within the system
Realist methods	Drawing on principles of critical realism, realist methods seek to explore what works, for whom, in what circumstance and why.
Structural equation modelling	A statistical technique used to create latent (unobserved) variables and test causal paths using regression techniques
Support manual	A document that will be given to intervention practices to help them develop their own service changes

## **5 Introduction**

### **5.1 Background and Rationale**

#### **5.1.1 Background to the health problem**

Nine million people live in rural areas in England (settlements with fewer than 10,000 resident population), of which one in five is over 65 years old.(3) The population of over 85 year olds is the fastest growing age group in rural areas.(4) Poverty is high in older rural people with a sixth of rural pensioners living below the poverty threshold (below 60% of median income).(3) Access to primary care for rural people is challenging with one in five living more than 4km from their general practice and one in three pensioner households not having access to a car.(4) Therefore, in English rural areas, there are approximately 651,000 over 65 year olds that do not have access to a car and 316,000 people over 65 years old who live below the poverty threshold.

A review of equality of access to healthcare in the UK found that rural individuals, older people and socio-economically disadvantaged groups have reduced access to healthcare.(5) A compounding effect is likely when these co-exist.(6, 7) Several studies have shown that deprivation, age and rurality are linked to unplanned hospital admissions.(8-11) Duffy and colleagues looked at emergency medical hospital admissions in Scotland using Scottish Morbidity Record data.(8) They found that age and deprivation were the most important factors explaining emergency medical admissions. Local data suggest that one in six unplanned hospital admissions are in residents from rural isolated communities (G Britton, Public Health, Health Intelligence Team, Norfolk County Council).

Reduced access to primary care in this group may be an underlying cause. Soljak and colleagues undertook a national cross-sectional study in England with over 52 million participants and found that improved access to primary care reduced stroke admissions.(12) Another study of 7,856 patients in England found that good patient-reported access to primary care was associated with lower self-referred emergency department attendances.(13) Improving access will enable patients to see their own GP during acute episodes rather than consulting urgent care services.(14)

A recent major systematic review listed barriers to accessing primary care.(15) These were categorised as patient factors (e.g. socio-demographic), organisational factors (e.g. appointment system), financial factors, workforce factors (e.g. technical skills) and geographical factors. However, the review failed to consider the dynamic and iterative concept of access that balances provider-side and patient-side components. Ricketts and Goldsmith reviewed the different concepts which have been used to define access and conceptualised access as dynamic, acknowledging the balance between health service need (patient-side) and health service use (provider-side).(16) They argue that the concept of access is not linear but an iterative process of both patients' learning from prior attempts and their changing perception of need.

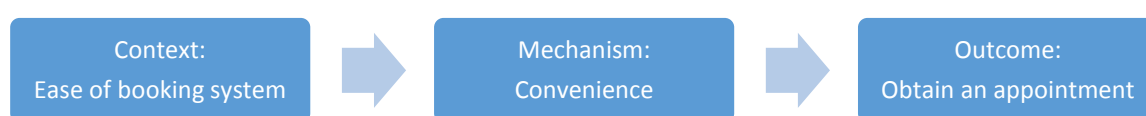
Two recent major systematic reviews assessing interventions to improve access included interventions tested in the UK, such as walk in centres, reminder systems, text messaging, multi-lingual services, telephone consulting and advanced access.(15, 17) It was found that interventions with multiple linked strategies targeted at different levels of the health care system were more likely to be effective. The authors found most interventions were universal and there was a lack of targeted research.(15) Initiatives that increase access to primary care for the whole population, such as walk in centres, have been criticised because they increase access for the worried well and create additional healthcare demand without improving outcomes or healthcare efficiency.(18)

#### **5.1.2 Background to the fellowship**

This feasibility study is the final stage of a NIHR funded doctoral research fellowship.(19) The first two years have been spent generating realist theory about how socio-economically disadvantaged older people in rural areas access primary care. Three steps were undertaken to produce this theory: 1) a realist review of the literature (20) which identified a seven step patient pathway with the associated contextual barriers and drivers at each step, 2) interviews with fifteen older people and four focus groups with health professionals (results being written up for publication) and 3) analysis of the English Longitudinal Study of Ageing using structural equation modelling to quantitatively explore the theory (analysis complete, currently writing up).

These three steps have been synthesised into one overall theory using realist methodology. Realist theory argues that interventions and policies and their evaluation should be context-dependent. Therefore, rather than asking if an intervention works or not, realist approaches aim to explore questions such as “how?”, “why?”, “for whom?”, “in what circumstances?” and “to what extent?”. To answer such questions an analysis technique is used to analyse data building context-mechanism-outcome (CMO) configurations. This entails making interpretations of the gathered data to ascertain its pertinence to: context (C), mechanism (M), outcome (O); and/or the relationships between C, M, and O; and/or the relationships between CMO configurations. An example of a CMO configuration from the realist review is shown in figure 1.

Figure 1: Context-mechanism-outcome configuration example for obtaining an appointment



This feasibility study is informed by a key theoretical proposition from our previous observational and qualitative research. We hypothesise that improving the ease of the booking system and access to suitable transport options for those without access to a car will lead to improved convenience and subsequently obtaining and getting to an appointment.

## 5.2 Objectives

The primary aim of this feasibility study is to test the trial design; providing the necessary information needed to run a definitive trial. Specifically, this will include exploring the following key objectives:

- Recruitment
  - Estimate the size of the eligible patient population
  - Estimate the recruitment and retention pattern of practices and patients
- Setting
  - Assess the feasibility and acceptability of mapping practice profiles
- Intervention
  - Assess the extent to which practices are able to develop and implement a context specific service changes
- Data collection
  - Assess if the data collection methods are acceptable to patients
  - Assess the appropriateness of the outcomes measures
- Sample size
  - Estimate statistical parameters of the key outcome measures to help determine the sample size for the definitive study
- Management
  - Estimate the time and resource requirements

### **5.3 Trial Design**

The design will be a cluster randomised controlled trial. We will compare giving a support package to general practices to develop services to improve primary care access, with usual care over six months in rural socio-economically disadvantaged older people. The five main quantitative self-reported outcomes, based on the underpinning theory, will be pre-appointment transport options, ease of booking an appointment and perceived convenience, and post-appointment suitability of received appointment and transport.

In total four rural practices will be recruited. Three practices will be randomised to the intervention arm and one to the control. The population of interest is older people ( $\geq 65$  years old) with difficulty access the general practice, two or more repeat prescriptions, twelve or fewer nurse or GP consultations in the past 12 months (face-to-face only) and no access to a car within their household. Intervention practices will receive a Support Manual that will inform four development meetings and be given £1500 to develop and/or deliver their own practice-level service changes for this group. The service changes will be aimed at 1) improving the ease of the booking system and 2) helping overcome transport barriers. The Support Manual will contain service specifications, an evidence briefing, an outline for the development meetings and feedback from the practice profiling.

Data will be collected from ten participants in each practice (40 in total).

## **6 Methods**

### **6.1 Site Selection**

The trial sponsor has overall responsibility for site and investigator selection and has delegated this role to Chief Investigator and NCTU.

#### **6.1.1 Study Setting**

The study will take place across four general practices in South Norfolk CCG, North Norfolk CCG or West Norfolk CCG.

#### **6.1.2 Site/Investigator Eligibility Criteria**

To be included practices must meet the following inclusion criteria

- Be classified as rural according to the Health and Social Care Information Centre.
- Have a list size of over 7000 patients.
- Agree to their practice being profiled. This will involve describing their local system and environment using routinely collected data, practice documentation relating to policies or standard operating procedures and informal discussions with practice staff and patient groups.
- Agree to commit to the process of developing their service supported by the research team.
- Agreement from a GP or practice manager able to be on-site principal investigator.
- Agree to practice observations and a GP, practice manager and two receptionists taking part in a group interview.

Once a practice has been assessed as being suitable to participate in the trial, the trial team will provide them with a copy of this protocol.

##### **6.1.2.1 Principal Investigator's (PI) Qualifications and Agreements**

The investigator(s) must be willing to sign the site agreement document to comply with the trial protocol (confirming their specific roles and responsibilities relating to the trial, and that their practice is willing and able to comply with the requirements of the trial). This includes confirmation of appropriate qualifications, agreement to comply with the principles of GCP, to permit monitoring and audit as necessary at the practice, and to maintain documented evidence of all staff at the practice who have been delegated significant trial related duties.

#### 6.1.2.2 Resourcing at practice

The investigator(s) should be able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period. They should also have an adequate number of qualified staff and facilities available for the foreseen duration of the trial to enable them to conduct the trial properly and safely.

Practices will be expected to complete a delegation of responsibilities log and provide staff contact details as described in the NCTU delegation log.

The practices should have sufficient data management resources to allow prompt data return to NCTU.

### **6.3 Participants**

#### 6.3.1 Patient Participants

##### 6.3.1.1 Eligibility Criteria

The population of interest is older people ( $\geq 65$  years old) with difficulty access the general practice, two or more repeat prescriptions, twelve or fewer nurse or GP consultations in the past 12 months (face-to-face only) and no access to a car within their household.

##### 6.3.1.2 Participant Inclusion Criteria

- Aged 65 years old or over
- Two or more repeat prescriptions at baseline search
- Twelve or fewer GP or nurse consultations in the past 12 months (face-to-face only)
- No access to a car within the household at baseline visit
- Self-reported difficulty in accessing their general practice at baseline visit

##### 6.3.1.3 Participant Exclusion Criteria

- Significant cognitive impairment that would prevent them providing informed consent, such as dementia
- Not able to speak English
- Generally do not book their own appointments

#### 6.3.2 Staff participants

##### 6.3.2.1 Eligibility Criteria

GPs, practice managers and practice staff working in the reception area will be eligible to take part in the observations and group interviews.

##### 6.3.2.2 Participant Inclusion Criteria

Only staff working in the reception area will be eligible to take part in the observations.

Only the reception staff and lead GP and practice manager will be eligible to take part in the group interviews.

### 6.3.2.3 Participant Exclusion Criteria

Reception staff recently appointed (within three months) of the proposed group interviews dates will be excluded to ensure that participants have sufficient knowledge of the study.

## 6.4 Interventions

### Intervention group

General practices are often asked to meet targets to improve quality, either as part of the Quality Outcomes Framework, a CQUIN (Commissioning for Quality and Innovation) or enhanced service. This usually involves a commissioner, such as NHS England or a Clinical Commissioning Group, setting a target and providing support and remuneration to achieve it. Each practice has the freedom to decide how to achieve the target. The intervention in this trial uses a similar model; intervention practices will be given two areas of access to target and provided with support and funding to improve their service.

Practices allocated to the intervention arm will be supported to improve the following two areas for socio-economically disadvantaged older people:

- the ease of the booking system
- transport barriers for patients without access to a car

Each practice in the intervention arm will be asked to nominate a GP and practice manager as development leads. A Support Manual will be provided to help intervention practices meet the above objectives for all patients in the population of interest, not just those who are providing data. The Support Manual will include:

- An overview of the trial.
- Service specifications outlining the essential characteristics of the planned changes to ensure that it will meet the research requirements.
- An evidence briefing providing an up-to-date review of the published and grey literature looking at barriers to improve access to primary care and possible interventions.
- An outline of the four development meetings.
- A logic model to support development
- Feedback to practices from the practice profiling.
- Time specific milestones to guide development and implementation.

The support manual will be presented to all intervention practices at an initial induction meeting of practice managers.

The Support Manual will be complimented by:

- Four weekly development meetings for one hour at the practice in which the practice manager and GP will meet with members of the research team to develop their service. The four weekly meetings will consist of:
  1. Problem solving, brain storming and initial actions
  2. Options appraisal, decision-making and next steps
  3. Reviewing decision and completion of logic model
  4. Agreeing service changes and process measures
- £1500 to contribute to the service development and/or delivery

The development meetings will be audio-recorded to help understand the decision-making process. Consent will be obtained from GPs, practice managers and any other staff who attend before audio-recording the meetings. The final service changes will require agreement between the

research team and practice before implementation. The research team will also agree specific activity and process measures to assess implementation.

The logic model produced by the practice and research team will provide a clear description of the service changes and hypothesised causal pathways.

Control group

Participants in practices not randomised to the intervention arm will receive usual care and access the GP surgery in the standard manner.

## **6.5 Outcomes**

Feasibility study measures

The outcomes of the feasibility study will be

- The proportion of eligible participants within a practice
- The proportion of patients recruited
- The proportion of patients and practices that withdraw or are lost to follow-up
- Statistical parameters of the key outcome measures to inform a sample size calculation for a definitive study
- Acceptability of data collection methods assessed through professional group and participant interviews
- Ability to develop and implement service changes assessed through professional group and participant interviews and activity measures
- Ability to profile practices assessed through professional group interviews
- Time and resource requirements monitored by the trial team

Patient outcome measures

The five main quantitative self-reported outcomes, based on the underpinning theory, will be:

- Pre-appointment transport options, ease of booking an appointment and perceived convenience
- Post-appointment suitability of received appointment and transport

Other outcomes include

- Number and type of health professional contact (health care assistant, nurse, GP or other)
- Number of referrals
- Number of repeat medications
- Hospital admissions
- Service activity and process measures agreed by research team and practices
- EQ-5D-5L (EuroQol five dimensions questionnaire)
- ICECAP-O (ICEpop CAPability measure for Older people)
- Confidence and trust in their general practice
- Patient Activation Measure (PAM)

## **6.6 Participant Timeline**

General practices will remain in the study for 10 to 12 months from recruitment. Roughly this is broken down up to 3 months for recruitment and baseline visits, up to 2 months to develop and implement service changes and 6 months with the implemented changes.

Patients will remain in the study for 8 to 9 months from providing consent.

Participants will undergo the following steps

- a) Sent an invitation letter from their general practice and asked to call the research team if interested who will send them the Participant Information Sheet
- b) Screening questions on contacting the research team to check for eligibility
- c) If interested and eligible a baseline visit will be booked
- d) Baseline visit where consent is taken, Baseline Questionnaire completed, trial process explained and participants given several blank Booking and Appointment Questionnaires for use during the trial period
- e) After attempting to book an appointment, successfully or not, participants will be asked to complete the Booking Questionnaire exploring their experiences of the booking system and transport options.
- f) After attending an appointment, participants will be asked to complete an Appointment Questionnaire and post it back to the research team.
- g) In practices allocated to the intervention arm, the six-month trial period will begin once a practice begins to implement change. The control six-month trial period will begin once the first intervention practice begins to implement change.
- h) Within the last 2 months of the trial two participants from each practice will be invited for semi-structured interview.
- i) After six months of follow-up participants will be asked to complete the Follow-up Questionnaire.

#### 6.6.1 Withdrawal

Patient participants

Participants will have the right to withdraw from the study at any time without giving reason. Identifiable data already collected with consent will be retained and used in the study. A reserve list will be created if more than 10 patients from each practice would like to take part. Patients on the reserve list will be contacted if a participant withdraws or become ineligible from the study before the planned changes are implemented.

General practices

If a practice withdraws before service development and/or patients have been recruited another practice will be recruited. Should a practice wish to withdraw after service development and recruitment of patients, data already collected with consent will be retained and used in the study. All participants will be informed of the practice's decision to withdraw and will themselves be withdrawn from the study.

#### 6.6.2 Participant Transfers

If a participant moves from the area during the trial period they will be asked, if willing, to complete the Follow-up Questionnaire.

#### 6.6.3 Trial Closure



Trial closure will be after the last patient has returned the Follow-up Questionnaire six months after implementation of planned changes.

## **6.7 Sample Size**

This feasibility study aims to estimate the important parameters for the sample size calculation for a full trial; no sample size calculation has been undertaken at this stage. There will be four practices and 10 participants from each practice. This was a size that the research team considered to be pragmatic for the scale of this study, and sufficient for collection of in-depth qualitative data as well as indicative quantitative data upon which to base the sample size for the full trial. More practices will be allocated to the intervention arm to provide more information on the feasibility of developing and implementing change. A control practice is necessary to understand how the possibility of being randomised to the control affects patient and practice recruitment and retention.

## **6.8 Recruitment and Retention**

### 6.8.1 General practices

Practices will be recruited with East of England Clinical Research Network (CRN) support using an invitation email and Research Information Sheet for Practices (RISP). Interested practices will be invited to contact the Chief Investigator to discuss participation and practices will be screened in accordance with the inclusion criteria.

### 6.8.2 Patient participants

Prior to randomisation of the practice, and with support from the Chief Investigator, practices will undertake a search to identify patients who are

- 65 years old or over
- Living in a postcode in the highest Index of Multiple Deprivation quartile
- Two or more repeat prescriptions
- Twelve or fewer consultations in the past 12 months (face-to-face, telephone or home visit)

The Chief Investigator will not have access to individual patient information while supporting the search.

From the search 150 patients will be randomly selected for invitation using a random number generator. The practice will screen this list for appropriateness and send an invitation letter. Participants will be asked to contact the research team if interested and will at that stage be sent the participant information sheet. The research team will contact the potential participant after a few days to answer any questions, check eligibility and see if they would like to take part. If willing to proceed, the researcher will arrange a time for the baseline visit, either at home or a location of the participant's choosing, where informed consent will be obtained and Baseline Questionnaire completed. Participants will be recruited on a first-come first-served basis and each practice will aim to recruit ten individuals (40 in total). If ten participants cannot be recruited a reminder letter will be sent and further invitations will be sent based on recruitment need. Potential participants will also be identified from reception staff and searching for those who have their medications delivered. A reserve list will be created if more than 10 patients would like to take part. Patients on the reserve list will be contacted if a participant withdraws or become ineligible from the study before the trial begins. Overall numbers from each step of the recruitment process will be collected throughout to assess eligibility and recruitment and retention.

Participants will be given a fridge magnet as a reminder at the baseline visit. At one month of the trial, participants at all four General practices (intervention and control arms) will be sent a UEA mug as a thank you for taking part and reminder to continue completing questionnaires. No financial incentives will be given to participants.

Every month practices will be asked to send a list of all consultations (face-to-face, telephone or home visit) for each included participant to assess incomplete data. A reminder letter will be sent to participants who have had a consultation but not returned a questionnaire.

### 6.8.3 Staff participants

Staff will be informed of the I-ACT study and associated observations and group interviews at a practice meeting at the beginning of the study. The PI at each site will share the patient information sheets with staff who meet the inclusion criteria for the observations and group interviews at the appropriate time. Staff who are willing to take part will be asked to contact the researcher. The researcher will then arrange a suitable time to obtain consent and undertake the observations or group interviews.

## **6.9 Assignment of Intervention**

### 6.9.1 Allocation

This is a cluster randomised trial. Practices will be randomised using simple block randomisation to ensure that one practice is allocated to the control arm and three to the intervention. Opaque sealed and numbered envelopes will be used. Practices will be randomised after all 10 participants have been recruited and the practice profiled. If participant recruitment is insufficient, participants will continue to be recruited after randomisation until the start of the follow-up period and implementation of service changes.

### 6.9.2 Blinding

It will not be possible to blind participants, clinicians or researchers to the allocation after randomisation.

## **6.10 Data Collection, Management and Analysis**

### 6.10.1 Practice profiling

Prior to randomisation a profile will be created for each practice. The aim is to understand the practice setting at macro (wider organisational factors), meso (practice policies and procedures) and micro (individual relational) levels (21). We will try to elicit the tensions and pressure points within the practice system which may affect the intervention or findings. Profiling information will be used 1) to provide feedback to intervention practices and 2) to provide context when interpreting the findings.

Profiles will include data on practice demographics, GP Patient Survey results, organisational structure, workforce, research experience, previous access issues and services. Information will be gathered from routine publicly available data, a form that practices will complete, practices' policies or Standard Operating Procedures (SOPs) and informal discussions with practice staff and patient groups. Informal discussions will be held with the practice manager, a receptionist, a GP and any patient group about tensions and pressure points within the practice system. These will not be audio-recorded.

### 6.10.2 Data Collection Methods

Quantitative data will be collected from questionnaires and routine practice data at baseline, throughout the trial and follow-up. Qualitative data will be collected through interviews with participants, group interviews with health professionals and observations.

#### 6.10.2.1 Quantitative data collection

The five main quantitative self-reported outcomes, based on the underpinning theory, will be pre-appointment transport options, ease of booking an appointment and perceived convenience, and post-appointment suitability of received appointment and transport. In addition, data will be collected on the number and type of primary care interactions, hospital admissions, activity and process measures as agreed by research team and practices and quality of life (EQ-5D-5L and ICECAP-O).

Participants will complete a Baseline Questionnaire immediately after informed consent has been given. Each participant will be given several Booking and Appointment Questionnaires at the beginning of the trial to complete each time they try to book an appointment and attend the practice. More will be sent if needed. Each time a participant books an appointment, or attempts unsuccessfully, they will be asked to complete the Booking Questionnaire and post it back. After the participant attends an appointment they will be asked to complete the Appointment Questionnaire and post it back. If a participant has a home visit, they will be asked to complete certain questions of the questionnaire. Participants who find it difficult to complete questionnaires, will be offered large print versions or asked to get the help of a friend, neighbour or relative. If this is not possible, a researcher will visit the participant to complete the questionnaire. Participants will only be asked to complete questionnaires for appointments they make for themselves, e.g. not on behalf of someone they care for.

Participants will be asked to complete a final follow up questionnaire at the end of the trial and return it by post.

Baseline data collected from routine practice data for each participant will include:

- Date of birth
- Index of Multiple Deprivation score based on postcode
- Ethnicity
- Gender
- Number and type of health professional (health care assistant, nurse, GP or other) contact over the past 6 months
- Number of referrals over past 6 months
- Number of repeat medications
- Number of hospital admissions over past 6 months

Baseline data collected from participants will include:

- Social support (Lubben social network scale 6 item(22))
- Usual transport and travel time/cost to surgery
- Educational attainment
- Socio-economic status based on Revised Family Resources Survey questions (23)
- Caring responsibilities
- Mobility
- Functioning (ADLs and IADLs)
- EQ-5D-5L
- ICECAP-O
- Confidence and trust in general practice (from GP Patient Survey)

- Patient Activation Measure (PAM)
- Practice access experiences

Validated questions do not exist for some key outcomes, see below. Therefore, visual analogue scales will be used. Outcome data collected from participants using the Booking and Appointment Questionnaires will include:

- Pre-appointment transport options (not validated, VAS will be used)
- Pre-appointment perceived convenience (not validated, VAS will be used)
- Pre-appointment ease of booking an appointment (question from GP Patient Survey questionnaires)
- Details of appointment (questions from GP Patient Survey questionnaires)
- Post-appointment suitability of received appointment (not validated, VAS will be used)
- Post-appointment suitability of transport to get to the appointment (not validated, VAS will be used)
- Cost (no validated questionnaire)
- Confidence and trust in GP or nurse (from GP Patient Survey)
- Patient Activation Measure (PAM, validated questionnaire)

Data collected from practices at six months will include:

- Number and type of health professional contact (health care assistant, nurse, GP or other)
- Number of referrals
- Number of repeat medications
- Hospital admissions
- Activity and process measures agreed by research team and practices

Final follow-up data collected from participants will include:

- Caring responsibilities
- Mobility
- Functioning (ADLs and IADLs)
- EQ-5D-5L
- ICECAP-O
- Confidence and trust in their general practice (from GP Patient Survey)
- Patient Activation Measure (PAM)
- Experiences of access the practice

For the economic evaluation a resource log will be kept throughout the trial to record the resources required for set up and delivery of the planned changes.

#### 6.10.2.2 Qualitative data collection

GPs and practice managers involved in the development meetings will be asked to consent to audio-recording to help understand the decision-making process.

Within the first two months of the trial each practice will be observed for two three-hour periods each to explore how the practice system works and implementation of the planned changes or usual care in control practices. A staff participant information sheet will be sent to reception staff in advance. Informed consent will be obtained in advance of the observation day. A time will be chosen to observe when all staff have consented. Observations will not take place if consent from all staff working in the reception on that day has not been obtained. Posters will be displayed in the surgery explaining the study and that patients have the option of the researcher leaving during their

discussion with the receptionists. The researcher will be located in the practice to observe how the system works in real life. Field notes will be collected during the observations. The researcher will not collect field notes on patients or directly talk to them. Field notes will not be collected on other staff.

In the final 2 months of the trial, two group interviews will be held at each practice. One with the GP and practice manager who were development leads and one with two reception staff. The aim of the group interviews will be to explore how the planned changes worked and any barriers or facilitators to success. Practice staff will be invited and sent a Participant Information Sheet. Consent will be obtained prior to the group interviews. The group interviews will be held at the general practice.

In the final two months of the trial, eight interviews with patient participants will be undertaken, two from each practice. Five participants from each practice will be randomly selected and invited with recruitment on a first come first served basis. The interview will take place at the participant's home or a location of their choosing and last about 1 hour. Consent will be obtained prior to the interview. Each interview will last about one hour and will be audio-recorded with participant consent.

A topic guide, which may evolve based on the service developments, will be used to steer discussions in both the interviews and group interviews. Group interviews with staff and participant interviews will be audio-recorded and transcribed.

All data will be handled in accordance with the Data Protection Act 1998. Verbatim quotes may be used to illustrate key themes. These will be used anonymously

### 6.10.3 Data Management

All data will be stored in a database on a secure server, provided and maintained by the University. The server environment is protected by a firewall and is patched and maintained according to best practice. The physical location of the server is protected by CCTV and security door access. Access to the database will be controlled via unique, personally attributable (i.e. not generic) usernames, password protected, and accessible only to members of the I-ACT trial team at NCTU, and external regulators if requested. Data will be entered in the approved I-ACT database by a member of the I-ACT trial team at NCTU and protected using established NCTU procedures. The database will be developed by NCTU. The database software provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure/missing data. After completion of the trial the database will be retained on the servers of NCTU for on-going analysis of secondary outcomes.

The identification, screening and enrolment logs, linking participant identifiable data to the pseudoanonymised Participant Identification Number (PIN), will be stored securely at the database developed by NCTU, with access controlled on a per-user basis. Access to identifiable and pseudoanonymised data will be stored separately within the database and permissioned accordingly.

Participant contact details will be collected by a member of the research team at the time that the participant calls to express an interest in being part of the study. To collect baseline and follow-up data from the practice records a trial researcher will visit each practice. A secure NHS to NHS email will be used to transfer data securely from practices to the University.

After completion of the trial the identifiable data will be stored for 2 years and pseudoanonymised for 10 years. Paper documents will be stored in a locked filing cabinet and electronic data on the university secure server.

Consent for data collection will include consent to use the data for future research.

The reporting of results (including quotations) will be non-identifiable. An anonymised open access trial dataset may be published after data analysis and dissemination of results.

#### 6.10.4 Analysis plan

The analysis will aim to 1) answer the key feasibility objectives as described in section 5.2 and 2) explore, expand or refine the underpinning theory. A detail statistical, health economic and qualitative analysis plan will be produced and agreed by the TMG prior to data analysis.

##### Feasibility study outcomes

The proportion of eligible participants within a practice and recruitment rate will be estimated from data collected during the recruitment phase. The implementation of planned changes will be assessed using activity data collected from each practice. To inform a sample size calculation for a full trial we will estimate statistical parameters of the key outcome measures. Participant and group interviews will explore the acceptability of data collection methods.

##### Qualitative analysis

Qualitative analysis will be undertaken first followed by quantitative data analysis.

Qualitative data from participant and group staff interviews, development meetings and observations will be analysed using a realist logic of analysis(24). These will be used to explore, firstly, underlying mechanisms of access to primary care, specifically around transport and the ease of the booking system. To do this we will refine the realist programme theory from our previous research describing the barriers this group face accessing primary care. This will involve comparing and contrasting our hypothesised context, mechanism and outcome configurations with the interviews for the trial. Secondly we will explore the processes involved in implementation and delivery of the service changes to refine the logic model from each practice. This will involve generating new context-mechanism-outcome (CMO) configurations based on the information from development meetings, group interviews and observations.

##### Statistical analysis

Building on our previous work the future definitive study will use Structural Equation Modelling (SEM). Based on the underpinning theory, we will compare causal pathways from intervention and control groups. Feasibility study data will be analysed using this technique to assess the suitability of data collected. Due to the small numbers included in the feasibility study, Bayesian methods will be used to estimate preliminary results (25). The multiple group comparison function in MPlus will be used to compare differences between intervention and control groups. The structural component of the SEM will involve mediation analysis with the mechanism of the CMO configuration acting as the mediator. Observed variables will be used where possible, but latent variables may be constructed to help build a better model.

##### Health economic analysis

The economic evaluation will monitor resource-use and health outcomes to identify the key drivers of cost and inform the future definitive study. There will be two primary aims: 1) to compare the estimated cost of initiation and delivery of the service changes with the costs available to each practice and 2) to monitor the data on costs and quality of life e.g. via complete rates, so as to

ensure the full trial will be able to compare the costs of increasing access to primary care with associated quality of life change and health care utilisation. Patient costs will also be estimated using the Appointment Questionnaire.

A discussion group of researchers, practitioners and patients will synthesise and interpret quantitative and qualitative findings in relation to the underpinning theory. The aim will be to assess the interaction between theory and the intervention and control. Drawing on principles of Nominal Group Technique,(26) this will involve group members being given findings from each method in advance, then during a meeting presenting their interpretation of the results and reasoning behind them individually. The varying interpretations will be collected and listed. The team will then undertake a number of rounds of voting with additional discussion until there is consensus on the interpretation of the findings.

## **6.11 Data Monitoring**

### **6.11.1 Data Monitoring Committee**

This is a low risk intervention. No specific risks, untoward incidents or adverse events are anticipated as the intervention aims to improve access to GP services by participants. A risk assessment has been undertaken by the CTU and it has been agreed that a Data Monitoring Committee is not necessary.

Safety outcome variables (hospitalisations) will be collected retrospectively at the end of the follow-up period from routine data. PIs at general practices will be requested to report complaints relating to access to general practices by eligible participants to the TMG. For intervention practices, PI's will be asked to evaluate whether the complaint was related to the service changes. The Trial Management Group will oversee adverse event monitoring.

### **6.11.2 Quality Assurance and Control**

#### **6.11.2.1 Risk Assessment**

The Quality Assurance (QA) and Quality Control (QC) considerations for the I-ACT trial are based on the standard NCTU Quality Management Policy that includes a formal Risk Assessment, and that acknowledges the risks associated with the conduct of the trial and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on: the rights and safety of participants; project concept including trial design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled.

### **6.11.3 Central Monitoring at NCTU**

NCTU staff will review data collection for errors and missing key data points. Consent forms will be reviewed to confirm appropriate completion.

### **6.11.4 Trial Oversight**

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to participant enrolment, consent, eligibility, and allocation to trial groups; adherence to trial

interventions and policies to protect participants; and completeness, accuracy and timeliness of data collection.

#### 6.11.4.1 Trial Management Team

The Trial Management Team (TMT) will be set up to assist with developing the design, co-ordination and day to day operational issues in the management of the trial, including budget management. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TMT terms of reference.

#### 6.11.4.2 Trial Management Group

A Trial Management Group (TMG) will be set up to assist with developing the design, co-ordination and strategic management of the trial. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TMG terms of reference.

#### 6.11.4.3 Trial Sponsor

The role of the sponsor is to take on responsibility for securing the arrangements to initiate, manage and finance the trial.

## **7 Ethics and Dissemination**

### **7.1 Research Ethics Approval**

Before initiation of the trial at any practice, the protocol, all informed consent forms and any material to be given to the prospective participant will be submitted to the HRA and REC for approval. Any subsequent amendments to these documents will be submitted for further approval.

The rights of the participant to refuse to participate in the trial without giving a reason will be respected. Participant will be free to change their mind at any time about participation and follow-up without giving a reason and without prejudicing their further treatment.

### **7.2 Other Approvals**

The protocol has received formal approval and methodological, statistical, clinical and operational support from the NCTU Protocol Review Committee.

### **7.3 Consent**

Consent will be obtained from patients to:

- Contribute data to the trial (obtained at baseline visit)
- Participate in semi-structured interviews (obtained at interview)

Consent will be obtained from practice staff to:

- Audio-record development meetings (obtained from GP and practice manager development leads at first development meeting and any other staff who are present)
- Observe the reception area (obtained from reception staff one week prior to observations)
- Contribute to group interviews (obtained from GP, practice manager and two receptionists at group interview)
-



Participants will be provided with a Patient Information Sheet (PIS) for the trial, interviews and observations. Patient participants will be asked to contact the research team if interested, so will have as long as they need to consider the information. Practice staff will be given the Patient Information Sheet and will be contacted after three working days to enquire about participation. Following a discussion with a researcher, any questions will be satisfactorily answered and if the participant is willing to participate, plans will be made for written informed consent will be obtained. During the consent process it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the trial, at any time and for any reason, without incurring any penalty or this affecting their current or future treatments.

#### **7.4 Confidentiality**

Personal data about patient participants (name, address and telephone number) will usually be collected by a member of the research team at the time that the participant calls to express an interest in being part of the study. This will be stored in a database on a secure server, provided and maintained by the University. The server environment is protected by a firewall and is patched and maintained according to best practice. The physical location of the server is protected by CCTV and security door access. Access to the database will be controlled via unique, personally attributable (i.e. not generic) usernames, password protected, and accessible only to members of the research team who will be responsible for contacting participants. Personal data will be deleted within 2 years of the end of the study.

Personal data about staff participants will be held at a site file at the general practice. Staff participants will be referred to by an anonymised ID and their initials.

#### **7.5 Declaration of Interests**

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the trial.

#### **7.6 Indemnity**

UEA holds insurance to cover participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that UEA has been negligent. However UEA does not have insurance which covers non negligent harm. As this clinical trial is being carried out in a general practice, the general practice continues to have a duty of care to the participant in the clinical trial. UEA does not accept liability for any breach in the general practice's duty of care, or any negligence on the part of practice staff. This does not affect the participant's right to seek compensation via the non-negligence route.

NHS Indemnity does not cover general practices. Indemnity for participants resulting from clinical negligence is provided by the professional indemnity insurance and the practices need to ensure that this covers them when undertaking research activity.

#### **7.7 Finance**

I-ACT is funded as part of a National Institute of Health Research doctoral fellowship (grant number DRF-2014-07-083). It is not expected that any further external funding will be sought.

#### **7.8 Archiving**

Consent for data collection will include consent to use the data for future research. The pseudoanonymised data will be kept for 10 years. Paper documents will be stored in a locked filing cabinet and electronic data on the secure server.

## 7.9 Publication Policy

### 7.9.1 Trial Results

An open evening dissemination event will be held at the University of East Anglia. Participating practices and patients will be invited as well as local GPs, practice managers, commissioners and researchers.

Findings will be presented at the annual Society of Academic Primary Care conference or similar. There will be a main feasibility study journal article published and, if time allows, an accompanying methodological paper.

### 7.9.2 Authorship

Authorship of published articles will be decided based on the ICMJE authorship criteria.

## 7.10 Decision rules for progressing to full trial

The following a priori criteria will be used to support the decision to progress from the design of this feasibility study to seeking funding for a full trial. If recruitment and retention rates are lower than expected amendments may be considered in the full trial to increase them.

- Recruitment of at least 60% of target recruitment in all practices (6 out of 10 patients)
- At least 50% of participants completing follow up
- At least two out of four practices completing follow-up
- At least two out of three practices being able to successfully develop and deliver a context specific service changes

## 8 Protocol Amendments

Version No.	Effective Date	Reason for Change
1.0		New protocol
2.0	31/01/17	<ul style="list-style-type: none"><li>• Change of sponsor representative</li><li>• Addition of NRES reference number</li></ul>
2.1	25/04/17	<ul style="list-style-type: none"><li>• ISRCTN number added</li></ul>
3.0	25/04/17	<ul style="list-style-type: none"><li>• Modification to recruitment strategy</li></ul>
4.0	24/07/17	<ul style="list-style-type: none"><li>• Modification of inclusion criteria and recruitment strategy</li></ul>
4.1	TBC	<ul style="list-style-type: none"><li>• Allow any remaining participants who have been invited to be recruited until service changes are implemented.</li></ul>

## 9 References

1. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleza-Jeric K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Annals of internal medicine*. 2013;158(3):200-7.

2. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ (Clinical research ed)*. 2013;346:e7586.
3. Department for Environment Food and Rural Affairs. *Statistical Digest of Rural England 2013*. London: 2013.
4. Age UK. *Later life in rural England*. London: 2013.
5. Goddard M. *Quality in and Equality of Access to Healthcare Services in England*. York: University of York, 2008.
6. Agabiti N, Picciotto S, Cesaroni G, Bisanti L, Forastiere F, Onorati R, et al. The influence of socioeconomic status on utilization and outcomes of elective total hip replacement: a multicity population-based longitudinal study. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua*. 2007;19(1):37-44.
7. Thorpe JM, Thorpe CT, Kennelly KA, Pandhi N. Patterns of perceived barriers to medical care in older adults: a latent class analysis. *BMC health services research*. 2011;11:181.
8. Duffy R, Neville R, Staines H. Variance in practice emergency medical admission rates: can it be explained? *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2002;52(474):14-7.
9. Reid FD, Cook DG, Majeed A. Explaining variation in hospital admission rates between general practices: cross sectional study. *BMJ (Clinical research ed)*. 1999;319(7202):98-103.
10. Majeed A, Bardsley M, Morgan D, O'Sullivan C, Bindman AB. Cross sectional study of primary care groups in London: association of measures of socioeconomic and health status with hospital admission rates. *BMJ (Clinical research ed)*. 2000;321(7268):1057-60.
11. Thorpe JM, Van Houtven CH, Sleath BL, Thorpe CT. Rural-urban differences in preventable hospitalizations among community-dwelling veterans with dementia. *The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association*. 2010;26(2):146-55.
12. Soljak M, Calderon-Larranaga A, Sharma P, Cecil E, Bell D, Abi-Aad G, et al. Does higher quality primary health care reduce stroke admissions? A national cross-sectional study. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2011;61(593):e801-7.
13. Cowling TE, Cecil EV, Soljak MA, Lee JT, Millett C, Majeed A, et al. Access to primary care and visits to emergency departments in England: a cross-sectional, population-based study. *PloS one*. 2013;8(6):e66699.
14. O'Dowd A. Improving access to GPs will help reduce pressure on emergency departments, says NHS. *BMJ (Clinical research ed)*. 2013;347:f7642.
15. Comino EJ, Davies GP, Krastev Y, Haas M, Christl B, Furler J, et al. A systematic review of interventions to enhance access to best practice primary health care for chronic disease management, prevention and episodic care. *BMC health services research*. 2012;12:415.
16. Ricketts TC, Goldsmith LJ. Access in health services research: the battle of the frameworks. *Nursing outlook*. 2005;53(6):274-80.
17. Kehle SM, Greer N, Rutks I, Wilt T. Interventions to improve veterans' access to care: a systematic review of the literature. *Journal of general internal medicine*. 2011;26 Suppl 2:689-96.

18. Desborough J, Forrest L, Parker R. Nurse-led primary healthcare walk-in centres: an integrative literature review. *Journal of advanced nursing*. 2012;68(2):248-63.
19. Ford JA, Jones AP, Wong G, Clark AB, Porter T, Shakespeare T, et al. Improving access to high-quality primary care for socioeconomically disadvantaged older people in rural areas: a mixed method study protocol. *BMJ Open*. 2015;5(9).
20. Ford JA, Wong G, Jones AP, Steel N. Access to primary care for socioeconomically disadvantaged older people in rural areas: a realist review. *BMJ Open*. 2016;6(5).
21. Murdoch J. Process evaluation for complex interventions in health services research: analysing context, text trajectories and disruptions. *BMC health services research*. 2016;16:407.
22. Gray J, Kim J, Ciesla JR, Yao P. Rasch Analysis of the Lubben Social Network Scale-6 (LSNS-6). *Journal of Applied Gerontology*. 2016;35(5):508-28.
23. McKay S. Measuring material deprivation among older people: Methodological study to revise the Family Resources Survey questions. London: Department for Work and Pensions,, 2008.
24. Manzano A. The craft of interviewing in realist evaluation. *Evaluation*. 2016;22(3):342-60.
25. Emsley R, Dunn G, White IR. Mediation and moderation of treatment effects in randomised controlled trials of complex interventions. *Statistical methods in medical research*. 2010;19(3):237-70.
26. Gallagher M, Hares T, Spencer J, Bradshaw C, Webb I. The nominal group technique: a research tool for general practice? *Family practice*. 1993;10(1):76-81.

## Appendix 10: Main consent form for trial

Practice / Patient Participant Study ID:   /

Please initial  
each box if you  
agree

<b>1</b>	I confirm that I have read and understood the <b>I-ACT study participant information sheet</b> , version number ..... dated ..... for the above study and have had questions satisfactorily answered.	
<b>2</b>	I understand that my participation is voluntary and I am free to withdraw at any time, without giving reasons, and without my care or other legal rights being affected.	
<b>3</b>	If I decide to withdraw before the end of the study, I understand that my information can be removed if it has not yet been processed and analysed.	
<b>4</b>	I give permission for my contact details and a copy of this consent form to be kept confidentially and securely by the research team at the University of East Anglia. I agree that the staff can send me study questionnaires and can contact me by telephone or post.	
<b>5</b>	I give permissions for researchers to collect data from relevant sections of my medical records.	
<b>6</b>	I understand that the information collected about me for this study will be used to support other research in the future, and may be shared anonymously with other researchers.	
<b>7</b>	I agree to take part in the study.	
<b>8</b>	I agree to my GP being informed of my participation in the study.	

Name of participant	Date	Signature
Name of researcher	Date	Signature

4 copies: 1 copy for participant, 1 for project file, 1 for medical records and 1 for CTU

# Appendix 11: Trial participant information sheet

## Improving access to primary care

### I-ACT Study

We would like to invite you to take part in the I-ACT research study run by the University of East Anglia in partnership with your GP practice. It is important that you understand what will be involved and why it is being done. Please take time to read the following information carefully which you may wish to discuss with friends and relatives. Please contact us if you would like more information using the details below. Alternatively if you'd like to discuss it with someone at the GP practice first, please use the contact details on the invitation letter.

#### What is this study about?

We are doing a study to see how best to support people over 65 years old might need when they have to arrange appointments and get to the surgery. There will be four GP practices in this study; three will be supported to find ways that may make it easier for patients to obtain appointments and travel to and from the practice and one will be asked to carry on as usual.

#### Why are we doing this study?

Some people do not find it particularly easy to book an appointment or get to the surgery. We hope this research will help people over 65 years old, in rural areas, to get to and see someone at their GP surgery. This study is the first step as we aim to gather important information about how to plan and run a larger study.

#### Why have I been invited?

Your GP practice is taking part in this study and has identified you as potentially able to take part. We are looking for people who rely on taxis, public transport, community transport, walking or on others who *do not* live with them for transport to the surgery. Unfortunately we're not able to include people with dementia or major memory problems, which would prevent them from consenting or completing questionnaires, or people who can't speak English.

#### How to contact me

If you have any questions about this research or are interested in participating, please contact the study researcher on:

- John Ford (researcher)

### **Do I have to take part?**

No, it is up to you to decide. If you decide to take part and then change your mind, you can stop at any time. Whether or not you take part, you will still have access to the usual services from your GP practice. If you decide *not* to take part it will not harm or affect the care you receive from your GP.

### **What does it involve?**

We will recruit 10 patients from each of the 4 GP practices on a first-come first-served basis. The four GP practices in this study will be randomly split into two groups; three to be in the *intervention* group and one in the *control* group. GP practices in the *intervention* group will be supported by researchers to improve their booking system and transport. Each practice will be able to choose themselves how they do this. The practice in the *control* group will be asked to carry on as usual.

### **What should I do if I wish to take part?**

If you might be interested in taking part in the study, and would like to find out more, please call or email using the details on the first page. You'll be asked a few questions and, if you're eligible to take part, we will arrange the initial meeting. The initial meeting will be held, either at home or a convenient place, to answer any questions you may have and ask you to complete a consent form. At this meeting the researcher will ask you to fill out a questionnaire that should take about 20 mins.

### **What will I need to do if I take part?**

Once your practice has been assigned to either the *control* or *intervention* group, information will be collected for a period of six to nine months. Over that period every time you try to book an appointment or attend an appointment at the surgery we will ask you to fill out a short questionnaire and send it back to us. We will give you paper copies of the questionnaire and envelopes that are already stamped and addressed, so that you can return the questionnaire to us by post, free of charge. We will ask the practice every month if you've had any appointments and send you a reminder in case you've forgotten to complete the questionnaire for us. After about six to nine months we will ask you to complete a final questionnaire.

Towards the end of the study we will want to speak to two patients from each GP practice for about 1 hour to hear their experiences. We will send you a letter with

more information closer to the time. You can choose at that point if you want to take part in the interview.

### **Will I receive any payment for being in this study?**

There is no payment for taking part, but any travel for the initial meeting will be reimbursed.

### **What are the advantages of taking part?**

- If you are in a practice that will be supported to develop ways of improving the service, you may benefit from the new service.
- You are helping us to find out how to improve health care services.
- Even if you are not with an *intervention* practice, your views will help us to find out if the other practices were successful.

### **What are the disadvantages of taking part?**

- You may be disappointed if your practice is not chosen to be in the intervention group.
- The questionnaires will take time to complete and you (or a friend or relative) will need to be able to post them back using the free envelopes.

### **Will my involvement be confidential?**

Yes, the researchers will maintain confidentiality, and will ensure that information gathered during the study is stored in accordance with the 1998 Data Protection Act. Electronic data will be stored on secure computers at the University. You will be given an anonymised number and your name or identifiable data won't be used. Paper information will be locked in filing cabinets in locked offices, and will only be accessible to authorised people. After the study finishes your contact details will be kept for 2 years and anonymised data for 10 years. It is considered best practice to publish an anonymised set of data about a study to help researchers from around the world and we may do this. You will not be identifiable in any reports, dataset or publications.

### **What if there is a problem?**

If you want to withdraw from the study, you can do so at any time without giving a reason. If you withdraw, your information collected can be removed before it is analysed by the research team, but not if you withdraw after it has been analysed. If you have a complaint about the study or how you have been treated, please contact your GP practice or the research team.



### **What will happen to the results of the research study?**

The results will be used to help improve services. We will write up results for the funders (National Institute of Health Research), publications and conferences, as well as for the general public. Full results will be available at <https://www.uea.ac.uk/GPstudy> or you can request a copy which we will send after the study has finished.

### **Who is organising and funding the research?**

The research is funded by the National Institute for Health Research (NIHR). The study has been reviewed by the Research Ethics Committee (Ref: 16/NE/0424). Patient and public representatives have been involved at all stages of the development and review process. The research is sponsored by the University of East Anglia.

### **What do I do next?**

If you are interested in taking part, please call or email the research team on the number given on the front page. Or if you would like to speak to someone at the surgery first please use the contact on the invitation letter.

**Thank you for taking time to read this information about the I-ACT study.**

## **Appendix 12: Support manual for practices**



**I-ACT trial**

**Improving Primary care Access in Context and Theory: A theory informed trial using a realist perspective**

**Support manual for practices**

## **General information**

### *Researcher contact details*

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NR4 7TJ  
01603 591743  
[John.ford@uea.ac.uk](mailto:John.ford@uea.ac.uk)

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01603 591721

### *Research team*

Prof Nick Steel, University of East Anglia  
Prof Andy Jones, University of East Anglia  
Dr Geoff Wong, University of Oxford  
Prof Tom Shakespeare, University of East Anglia  
Prof Ann Marie Swart, University of East Anglia  
Dr Allan Clark, University of East Anglia  
Prof Garry Barton, University of East Anglia  
Dr Tom Porter, University of East Anglia  
Mrs Annie Moseley, patient representative  
Mrs Hillary Stringer, patient representative

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## **Introduction**

This document supports general practices allocated to the intervention arm of the I-ACT trial. The document contains a service specification, describing the necessary components of the service changes, a summary of the literature, an outline to guide the development meetings and a practice profile. This manual is not intended to stand alone, but rather support discussions between practices and the research team.

### *What is this study about?*

This study is about helping socio-economically disadvantaged older people without a car to access their general practice. We've spent the past two years exploring some of the problems that socio-economically disadvantaged older people have accessing their general practice. Two of the main barriers we found were the booking system and transport. We would now like do something to help these patients overcome these barriers. We're planning a randomised controlled trial. But before we can run a full trial we need to undertake a smaller study, known as a feasibility study, to allow us to better understand how we will be able to run the trial.

We realise that every general practice is different, so we're going to let each intervention practice develop a solution. This means that practices can develop something that meets their own local needs.

### *Why is this study important?*

Many people find it difficult to access their general practice, and older people in deprived rural areas may find it particularly difficult. Good access is important for these people who may have high health needs. We know if they can't access their general practice they may be more likely to delay presentation and may be at risk of avoidable complications or hospital admissions.

### *What access problems do this group face?*

Our research has found multiple barriers, such as transport, available appointments and engaged telephone lines. We found that socio-economically disadvantaged older people sometimes feel disconnected with their general practice. They expect a relationship with their general practice based on reciprocity; a mutual understanding that they don't "waste the GPs time" in return for goodwill within the service. Financial and political pressure on primary care has undoubtedly meant that primary care has changed. The mismatch between what this group expect and experience can leave them feeling less welcome.

### *Isn't it unfair to improve access for one particular group?*

Everyone should have equal access to primary care but this isn't always the case and the Inverse Care Law still applies - those with higher health needs often receive less health care. An assertive patient who has access to the internet, drives a car and understands the booking system, undoubtedly gets better access than someone without these resources, such as poorer patients with low health literacy with higher health needs.

### *Why focus just on the booking system and transport?*

Our previous work found multiple barriers across the patient pathway. On speaking to patients two strong barriers were transport for those without a car and the booking system. We also wanted to focus on areas that practices had some control over. While practices can't change bus timetables, they might be able to make links with community transport providers or reconfigure

services for people who depend on buses. This might help more patients attend the practice, rather than relying on home visits.

*Why let intervention practices decide what they want to do themselves?*

Each general practice is unique and the practice staff obviously understand their practice and patients best, so we believe that practices will know best what changes are needed to improve access.

*What types of changes could practices choose?*

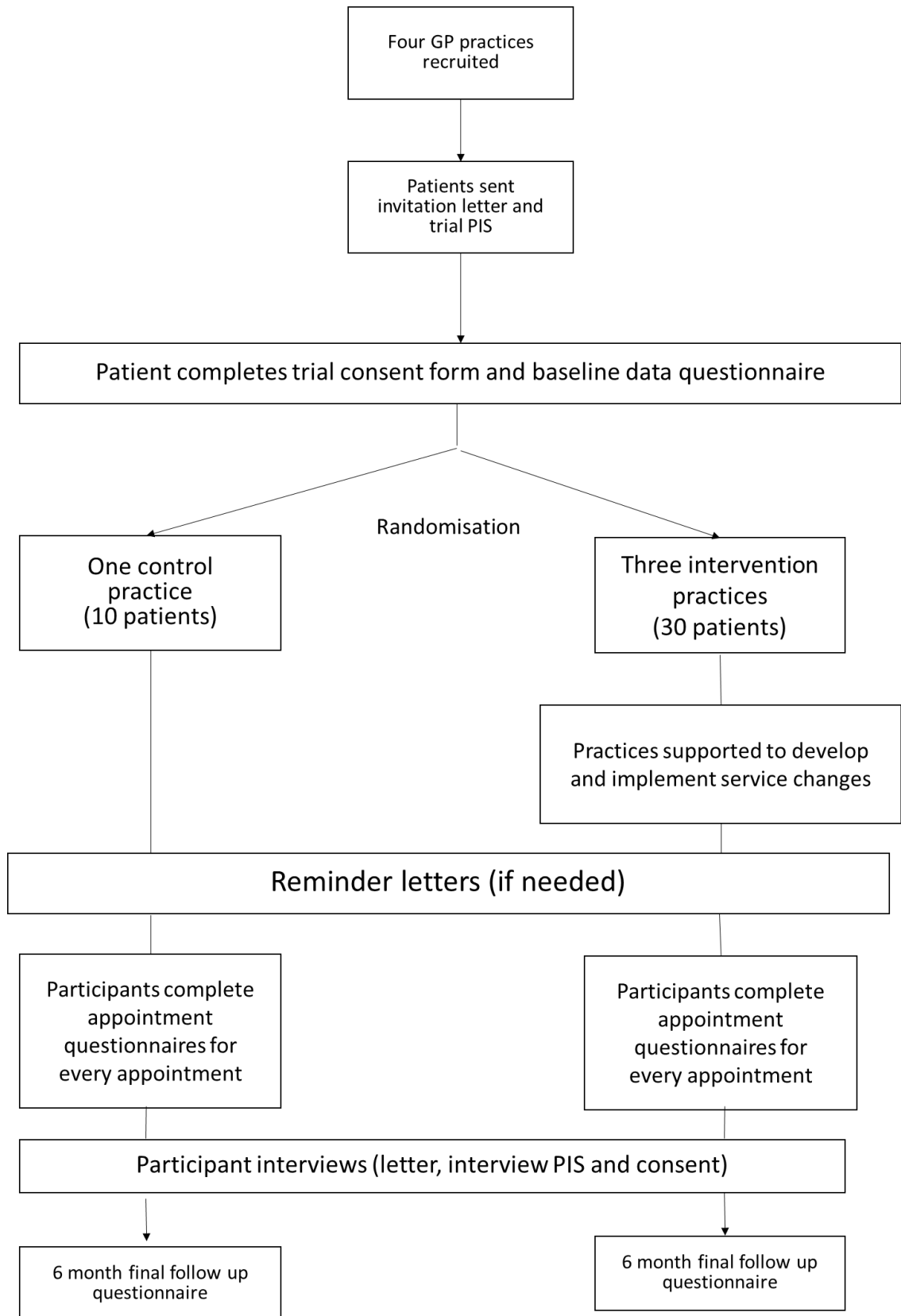
Practices are free to choose any service changes as long as it meets the specifications below. There is an evidence summary in this document which might give practices some ideas. The development meetings will hopefully help this process.

*What will be expected of the practice?*

- Full details are in the RISP, but the main tasks for the intervention practices only are to:
- Allocate one GP and practice manager to be development leads
- Attend an induction meeting for practice managers at UEA
- Participate in four practice development meetings held at the practice
- Develop and implement the service changes
- Collect some basic activity measures

## Trial overview

An overview of the trial is shown below.



## Timeline

Events in bold involve the practices

Week 1: Recruit practices

Week 2-3: Search practice lists

**Week 2-4: Send letters to patients**

Week 2-10: Baseline visits

Week 11: Randomisation

**Week 12: Development meeting 1**

**Week 13: Development meeting 2**

**Week 14: Development meeting 3**

**Week 15: Development meeting 4**

**Milestone 1: Planned changes agreed end of Week 15**

**Week 16-18: Implementation**

**Milestone 2: Planned changes implemented end of Week 18**

Week 19-42: Trial period

**Week 20-21: Observations**

**Week 40-41: Group interviews**

Week 43: Trial closure



## Service specification

The intervention practices' service development must aim to achieve the following two outcomes:

- To improve the ease of the booking system
- To help patients overcome transport barriers

The planned service changes must meet the following criteria. The research team will check to make sure that the planned service changes comply with the criteria.

- It should be different from the access that this group currently receives
- It should be deliverable within the resources available
- It must be possible to introduce the planned changes within 3 weeks of agreement by the research team
- It must comply with the following:
  - The principles and values set out by the NHS Constitution<sup>1</sup>
  - The General Medical Service, Personal Medical Services or Alternative Provider Medical Services contract (depending on local contractual arrangements)
  - Health and Social Care Act 2008 and Care Quality Commission Regulations<sup>2</sup>

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<sup>1</sup> Available at <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>

<sup>2</sup> Available here <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>

## **Evidence brief**

There are two sections to this evidence brief. First, a summary of findings from our initial research and, second, a review of interventions used to improve access across different populations. The intention is to give practices an understanding and examples of what has been used.

### *Our previous research*

Based on interviews with older people and discussions with GPs, practice managers and nurses we've identified the following barriers either on the patient or practice side.

### *The patients' perspective*

#### *Attitudes, expectations and experiences*

Older people discussed the importance of not bothering, or wasting the doctor's time, unless absolutely necessary. When participants did decide to access primary care, most found it difficult. Participants discussed barriers such as engaged telephone lines, availability of appointments, receptionists and home visits. One participant reported having to wait 40 minutes to get through to a receptionist, by which time there were no appointments. Most participants highlighted the need to negotiate an appointment and usually saw receptionists as barriers. Another source of dissatisfaction, particularly for those without a car, was being unable to get a home visit or given a telephone consultation instead.

We found that this group of patients expect a social contract with their GP surgery based on goodwill. Participants articulated a relationship based on reciprocity and goodwill. Patients were careful not to "bother" or waste the GP's time in return for the general practice (doctors, nurses and receptionists) looking after them when in need and being flexible. Participants saw this in the context of their whole life, insomuch as they expected the receptionists and GPs to be aware that during their lifetime they did not use the service inappropriately.

#### *Resources: Transport and social network*

The most important resources mentioned by older people were transport, social networks and personal skills. Having a car was a key resource to being able to get to the general practice. Most participants with a car were concerned about what would happen when they could no longer use it. For those without a car the availability of public or community transport was discussed, but most people relied on taxis or friends or family.

#### *Mismatch between expectations and experiences*

Undoubtedly there was a tension between the expectations and experiences of patients, especially in the context of primary care reorganisation. The combination of lacking, and service changes may lead to a disconnection between patient and practice. For those who lacked the resources, skills and/or desire to adapt in the midst of primary care reorganisation, the unintended consequence was marginalisation; the perceived exclusion from services based on personal characteristics.

### *The health professional's perspective*

#### *Patients' expectations of the health service and ageing*

Health professionals felt that the expectations and needs of the wider population were inconsistent with current patterns of service provision. Conversely, health professionals reported that some patients from lower socio-economic groups do not seek help because they attribute health problems to ageing, leading to delayed presentation and disengagement with primary care

*Doing more for less*

Restricted resources coupled with an expectation to deliver more within the NHS was discussed by all health professionals. National or regional policies and enhanced services added pressure to service delivery. Generally health professionals were cynical about these, especially policies which were not practical in rural areas. Faced with increased demands and limited resources, health professionals identified the need to develop services. Changes included fewer home visits, more telephone consultations, triaging calls and modifying the appointment system.

## Interventions

Here we present a range of interventions used to improve access to primary care. They come from five sources, 1) a systematic review<sup>3</sup>, 2) an independent report by the University of York<sup>4</sup>, 3) report by the Royal College of General Practitioners<sup>5</sup>, 4) the Prime Minister's Challenge Fund<sup>6</sup> and 5) our previous interviews with patients and focus groups with health professionals. A full list can be found at the end of this document. Practice do not have to choose something from this list.

### Practice system

- Telephone triage either by nurse or GP
- Follow-up telephone consultations
- Direct telephone line to clinician or administrator
- Protected appointment at bus times
- Walk in or sit and wait clinics
- GP 'micro teams' involve allocating a shared group of patients to a small number of GPs within a practice
- Case management by a practice nurse
- Disease or group specific clinics
- Health checks

### Computer based interventions

- Patient register for those at risk of poor access
- Reminders for patients and GPs about follow-up appointments
- Computer prompts for clinicians to ask about access

### Workforce

- Clinician or receptionist training

### Community

- Pro-active outreach to those at risk
- Targeted media campaign to raise awareness
- Community-driven patient peer support
- Village agent scheme which signposts patients to resources

## Partnerships

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<sup>3</sup> Systematic review of interventions to enhance access to best practice primary care. BMC HSR 2012

<sup>4</sup> Enhancing access in primary care settings. University of York. 2015. Available at [https://www.york.ac.uk/media/crd/Ev%20briefing\\_Enhancing%20access%20in%20primary%20care.pdf](https://www.york.ac.uk/media/crd/Ev%20briefing_Enhancing%20access%20in%20primary%20care.pdf)

<sup>5</sup> Patient access to general practice: ideas and challenges from the front line. RCGP. 2015. Available at [http://www.rcgp.org.uk/news/2015/february/~/\\_media/Files/Policy/A-Z-policy/Patient-access-to-general-practice-2015.ashx](http://www.rcgp.org.uk/news/2015/february/~/_media/Files/Policy/A-Z-policy/Patient-access-to-general-practice-2015.ashx)

<sup>6</sup> Prime Minister's Challenge Fund Wave 1 and 2. 2016. Available at [http://www.rcgp.org.uk/news/2015/february/~/\\_media/Files/Policy/A-Z-policy/Patient-access-to-general-practice-2015.ashx](http://www.rcgp.org.uk/news/2015/february/~/_media/Files/Policy/A-Z-policy/Patient-access-to-general-practice-2015.ashx)

- Linking with community transport providers
- Working with a third sector organisation
- Partnering with pharmacies to provide care
- Collaborating with district nurses or health visitors

## Development meetings

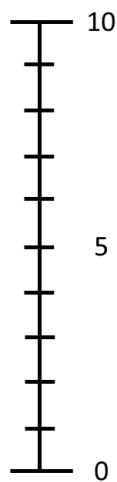
Meeting 1: Problem solving, brain storming and initial actions

Here we will start thinking about some of the problems that your practice might face and possible solutions. You will already have ideas of changes that you could try, but we would like you to take your time to think through the problem as a group.

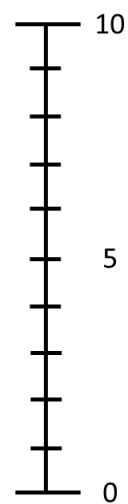
Scale technique

On the scale below, where 10 is the perfect future, where are you just now?

Booking system



Transport



What is helping you to reach that level already?

What issues are stopping you reaching a 10?

## **Brainstorming**

Remember the key rules of brainstorming  
hold off judgment  
be innovative  
strive for quantity  
build on other people's ideas

What would take you a small step higher (e.g. one point)?

What would take you a large step higher (e.g. two or three points)?

**Initial actions**

Choose about three of the ideas above to scope and explore before the second meeting. It might be useful to look back at the service specification.

Note the actions below.



**Meeting 2: Options appraisal, decision-making and next steps**

In this meeting we revisit the options considered in the first meeting. Start by looking at the Logic Model on page 22.

For each of the options list the strengths, weakness, opportunities and threats

Then choose one option to actively pursue and list the next steps.

Option 1:

Strengths	Weaknesses
Opportunities	Threats

Option 2:

Strengths	Weaknesses
Opportunities	Threats

Option 3:

Strengths	Weaknesses
Opportunities	Threats

Option 4:

Strengths	Weaknesses
Opportunities	Threats

Chosen option

Next steps

### **Meeting 3: Review of option and completion of logic model**

Revisit the option chosen at meeting 2. Re-evaluate it.

- Will it meet the objectives?
- Is it practical?
- Will it be possible to implement it in three weeks?
- What resources will be needed?
- What are the risks?
- What steps can be taken to mitigate these risks
- What needs to happen before it can be implemented?

Discuss the logic model below.

Logic model

Target population	Assumptions	Practice inputs	Practice activities	Outputs for each practice	Potential outcomes

#### **Meeting 4: Agree activity and process measures**

Revisit the planned changes.

- Are there any remaining concerns?
- What needs to be done to implement it?

How will we know that the planned changes have been implemented?

What measures can we use? Consider both objective and subjective measures.



### **Practice profiles**

[Research team to complete this section for each individual practice after the profiling stage]

### **National/regional factors (macro)**

[CCG, NHS England and regional factors, such as number of GPs per head of population]

### **Local/practice factors (meso)**

[Practice level factors, such as GP patient survey results, staffing levels, policies, procedures, management structure, etc]

### **Day-to-day within the practice system factors (micro)**

[Dynamics and bottle necks between parts of the practice]

## Detailed literature summary

The level of evidence for each intervention has been graded as high, medium or low.<sup>7</sup> Please note that low means that there is a lack of high quality research, not necessarily that the intervention is ineffective.

### Practice or service re-organisation

Intervention	Level of evidence	Source
Registry-based invitation to non-attenders	Moderate	Systematic review
Telephone triage service (HealthDirect or Health Connect)	Moderate	Systematic review
A computerised diabetes register maintained by the Division; Division mails reminders to GPs for patient recall at various time intervals.	Moderate	Systematic review
Invitation letters for screening test combined with follow up telephone counselling	Low	Systematic review
Implementation of advanced, open, or same day access	High	Systematic review
Computer generated physician and patient reminders for preventive services	Moderate	Systematic review
Telephone consultations for follow-up appointments or reduced proportion of appointments bookable in advance.	Moderate	Systematic review
Computerised screening prompts for physicians combined with tailored print communication (TPC) and tailored telephone counselling for their patients	Low	Systematic review
Implementation of open access appointment system.	Moderate	Systematic review
Telephone consultation or triage	High	University of York report
Placing GPs at the front-end of the service as a means of managing the 'flow' of patients through the system more effectively (Doctor First model)	Moderate	RCGP
GP 'micro teams' involve allocating a shared group of patients to a small number of GPs within a practice – usually two or more doctors and potentially involving a practice nurse	Low	RCGP
Patients with complex needs or unstable conditions are offered a direct line to the clinician with whom they work most closely.	Low	Prime Minister's Challenge Fund
Risk register	Low	Focus groups
Outreach, information and screening during flu days	Low	Focus groups
Extended appointments	Low	Focus groups
Protected appointments at bus times	Low	Interviews

### New service

Intervention	Level of evidence	Source
Implementation of NHS walk-in centres	Moderate	Systematic review
Free-of-charge diabetes screening campaign in pharmacies	Moderate	Systematic review
Nurse facilitator practice support program for preventive health care	Moderate	Systematic review

<sup>7</sup> Quality Assessment Tool for Quantitative Studies. Available at [www.ehpc.ca/index.html](http://www.ehpc.ca/index.html)

Introduction of a women's clinic	Low	Systematic review
Enhanced health risk assessment and feedback to patient	Moderate	Systematic review
Personal health book records for patients	Low	Systematic review
Risk factor assessment through health promotion nurse at practice	Low	Systematic review
Specialist transport services that can help patients (often the frail elderly) who are otherwise unable to travel to their GP surgery to have an appointment at the practice	Low	RCGP
Working with the voluntary sector to reach patient groups who typically report poorer levels of GP access	Low	RCGP
Health checks (similar to checks for those 75+)	Low	Focus groups

#### Workforce

Intervention	Level of evidence	Source
Physician education and prompts for screening	Moderate	Systematic review
Provider training, involvement of nursing staff and new office flow chart system	Moderate	Systematic review
Role substitution – nurse responsibility for first contact and ongoing care for all presenting patients; nurse responsibility for first contact of patients wanting urgent consultations during routine practice hours or out-of-hours; and nurse responsibility for ongoing care of patients with chronic conditions	Moderate	University of York report
Pharmacist services included medication review, education, lifestyle advice, adherence assessment, monitoring and adjusting therapy, predominantly for patients with long-term conditions such as diabetes and hypertension.	High	University of York report
Closer joint working between district nurses and general practices – for example through the use of technology to ensure that district nurses can remotely access and share information about patients with their practice	Low	RCGP
Collaboration with health visitors to visit elderly people	Low	Focus groups

#### Patient support

Intervention	Level of evidence	Source
A neighbourhood-based awareness raising intervention including small group educational sessions, educational material distribution and promotional events.	Moderate	Systematic review
A culturally sensitive media campaign followed by personalised invitation letters in language of recipient	Moderate	Systematic review
Implementation of a culturally appropriate health education outreach program delivered by lay health educators.	Low	Systematic review
A community action program to raise awareness for cervical cancer and screening	Low	Systematic review
A community based health promotion program (Well Women's Check) to raise awareness for PAP testing combined with reminder letters	Moderate	Systematic review

Media campaign and community based promotion	Moderate	Systematic review
Community navigator scheme - trained community navigators are providing support for patients with complex needs in community settings, particularly those who are living on their own. They are helping to signpost individuals to third and voluntary sector organisations, and other local resources, to meet their needs.	Low	Prime Minister's Challenge Fund
Transport plus – community drivers in Norfolk <a href="https://www.norfolk.gov.uk/roads-and-transport/public-transport/community-transport">https://www.norfolk.gov.uk/roads-and-transport/public-transport/community-transport</a>	Low	Interviews
Norfolk Community Transport Association <a href="http://www.ncta.org.uk/find-service/">http://www.ncta.org.uk/find-service/</a>	Low	Interviews
Patient group support	Low	Interviews
Receptionist training	Low	Interviews
Signposting at reception	Low	Focus groups
Advertising the practice in the community	Low	Focus groups

# Appendix 13: Baseline self completion questionnaire for I-ACT study

## Improving access to primary care



**I-ACT Study**

Participant self-completion questionnaire



Practice / Patient Participant Study ID:  /

**This questionnaire is to be completed by participants at the start of the I-ACT study.**

### Family

Thinking about the people to whom you are related by birth, marriage, adoption, etc...

1. How many relatives do you see or hear from at least once a month? Please tick
- |               |                          |
|---------------|--------------------------|
| None          | <input type="checkbox"/> |
| One           | <input type="checkbox"/> |
| Two           | <input type="checkbox"/> |
| Three or four | <input type="checkbox"/> |
| Five to eight | <input type="checkbox"/> |
| Nine or more  | <input type="checkbox"/> |

2. How many relatives do you feel at ease with that you can talk about private matters?
- |               |                          |
|---------------|--------------------------|
| None          | <input type="checkbox"/> |
| One           | <input type="checkbox"/> |
| Two           | <input type="checkbox"/> |
| Three or four | <input type="checkbox"/> |
| Five to eight | <input type="checkbox"/> |
| Nine or more  | <input type="checkbox"/> |

3. How many relatives do you feel close to such that you could call on them for help?

None	<input type="checkbox"/>
One	<input type="checkbox"/>
Two	<input type="checkbox"/>
Three or four	<input type="checkbox"/>
Five to eight	<input type="checkbox"/>
Nine or more	<input type="checkbox"/>

### Friendships

Thinking about all of your friends including those who live in your neighbourhood

4. How many of your friends do you see or hear from at least once a month? Please tick

None	<input type="checkbox"/>
One	<input type="checkbox"/>
Two	<input type="checkbox"/>
Three or four	<input type="checkbox"/>
Five to eight	<input type="checkbox"/>
Nine or more	<input type="checkbox"/>

5. How many friends do you feel at ease with that you can talk about private matters?

None	<input type="checkbox"/>
One	<input type="checkbox"/>
Two	<input type="checkbox"/>
Three or four	<input type="checkbox"/>
Five to eight	<input type="checkbox"/>
Nine or more	<input type="checkbox"/>

6. How many friends do you feel close to such that you could call on them for help?

None	<input type="checkbox"/>
One	<input type="checkbox"/>
Two	<input type="checkbox"/>
Three or four	<input type="checkbox"/>
Five to eight	<input type="checkbox"/>
Nine or more	<input type="checkbox"/>

**Transport to the GP surgery**

7. How do you usually get to the GP surgery?

Tick one or more

drive myself	<input type="checkbox"/>
walk	<input type="checkbox"/>
use public transport	<input type="checkbox"/>
take a taxi	<input type="checkbox"/>
use a community transport scheme (e.g. Dial-a-bus)	<input type="checkbox"/>
get a lift from a friend or relative who lives in the same house as me	<input type="checkbox"/>
get a lift from a friend or relative who does NOT live in the same house as me	<input type="checkbox"/>
do not go to the surgery but get a home visit	<input type="checkbox"/>
Other – please give details	<input type="checkbox"/>

8. Approximately how far is it to your GP surgery (one way)?

\_\_\_\_\_miles

9. If you use a taxi, public transport or community transport, how much does it cost (the fare) you for a return trip to the GP surgery?

£ \_\_\_\_\_ Not applicable

10. Based on the method of transport you use most often, how long does it normally take you to get to the GP surgery (one way)?

\_\_\_\_\_ minutes

**Education**

11. At what age did you complete your education in school or college? Please tick

Before the age of 15 years	
At the age of 15 or 16 years	
Between the age of 17 and 20 years	
After the age of 21 years	

**Caring**

12. Do you regularly help another person with everyday tasks like cleaning, cooking, shopping or dressing?

No (go to question 15)	
Yes	

13. Do you usually share a house with this person?

No	
Yes	

14. Approximately how many hours per week do you help them?

\_\_\_\_\_ hours



**Mobility**

15. By yourself and without using any special equipment, how much difficulty do you have walking for a quarter of a mile?

no difficulty	<input type="checkbox"/>
some difficulty	<input type="checkbox"/>
much difficulty	<input type="checkbox"/>
unable to do this	<input type="checkbox"/>

16. Do you have difficulty doing any of these activities because of a health problem? Exclude any difficulties that you expect to last less than three months

Walking 100 yards	<input type="checkbox"/>
Sitting for about two hours	<input type="checkbox"/>
Getting up from a chair after sitting for long periods	<input type="checkbox"/>
Climbing several flights of stairs without resting	<input type="checkbox"/>
Climbing one flight of stairs without resting	<input type="checkbox"/>
Stooping, kneeling, or crouching	<input type="checkbox"/>
Reaching or extending your arms above shoulder level (either arm)	<input type="checkbox"/>
Pulling or pushing large objects like a living room chair	<input type="checkbox"/>
Lifting or carrying weights over 10 pounds, like a heavy bag of groceries	<input type="checkbox"/>
Picking up a 5p coin from a table	<input type="checkbox"/>
None of these	<input type="checkbox"/>

**Functioning**

17. Please tell us if you have difficulty with any of the following because of a physical, mental, emotional or memory problem.

No difficulty      Some difficulty

Dressing, including putting on shoes and socks		
Walking across a room		
Bathing or showering		
Eating, such as cutting up food		
Getting in or out of bed		
Using the toilet, including getting up or down		
Preparing a hot meal		
Shopping for groceries		
Making telephone calls		
Taking medications		
Managing money, such as paying bills and keeping track of expenses		

### Your experiences of the GP surgery

Last time you saw or spoke to a **GP** from your GP surgery, how good was that GP at each of the following?

	Very Poor	Poor	Neither good nor poor	Good	Very good	Doesn't apply
18. Giving you enough time						
19. Listening to you						
20. Explaining tests and treatments						
21. Involving you in decisions about your care						
22. Treating you with care and concern						

23. Did you have confidence and trust in the **GP** you saw or spoke to?

Please tick

Yes, definitely	<input type="checkbox"/>
Yes, to some extent	<input type="checkbox"/>
No, not at all	<input type="checkbox"/>
Don't know / can't say	<input type="checkbox"/>

Last time you saw or spoke to a **nurse** from your GP surgery, how good was that nurse at each of the following?

	Very Poor	Poor	Neither good nor poor	Good	Very good	Doesn't apply
24. Giving you enough time						
25. Listening to you						
26. Explaining tests and treatments						
27. Involving you in decisions about your care						
28. Treating you with care and concern						

29. Did you have confidence and trust in the **nurse** you saw or spoke to? Please tick

Yes, definitely	
Yes, to some extent	
No, not at all	
Don't know / can't say	

30. Would you recommend your GP surgery to someone who has just moved to your local area?

Yes, would definitely recommend	
Yes, would probably recommend	
Not sure	
No, would probably not recommend	
No, would definitely not recommend	
Don't know	

**Please put an X on the line**

31. Generally speaking, what is your experience of booking an appointment at your GP surgery?

Difficult | \_\_\_\_\_ | Easy

32. Generally speaking, how convenient is the current appointment booking system at the GP surgery?

Inconvenient | \_\_\_\_\_ | Convenient

33. Generally speaking, are you able to get a suitable appointment at the surgery?

No, not at all | \_\_\_\_\_ | Yes, definitely

34. Generally speaking, how are your current transport options to get to the surgery?

Poor | \_\_\_\_\_ | Good

35. Generally speaking, how convenient is it to get to the surgery?

Inconvenient | \_\_\_\_\_ | Convenient

