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I-ACT Study - Improving access to primary care

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
08/03/2017

Overall study status
Completed

Last Edited
23/05/2019

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nine million people live in rural (country) areas in England, of which one in five is over 65 years old. The population of over 85 year olds is the fastest growing age group in rural areas. Poverty is high in older rural people with a sixth of rural pensioners living in poverty. Access to primary care (first-line healthcare) 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. 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. Previous research has highlighted that socio-economically disadvantaged (poorer) older people in rural areas are at risk of poor access to healthcare. The study team has spent two years understanding why this group may find it difficult to access primary care by reviewing previous research, interviewing older people, conducting focus groups with health professionals and collecting population information. It is possible that improving the ease of the booking system and access to suitable transport options for those without access to a car could help rural older people to access healthcare. This study is looking at a support package to give to GP surgeries, designed to help improve access to primary care for this group. The aim of this study is to test the study procedures to find out if a full-scale trial would be possible.

Who can participate?
Older adults who have difficulty getting to their GP and are on two or more repeat prescriptions.

What does the study involve?
Four GP practices are randomly allocated to one of two groups. One of these practices is allocated to a group that continues to offer usual care to patients. The other three practices are allocated to a group that receive a Support Manual that informs four development meetings and £1500 to develop and/or deliver their own practice-level service changes to their patients. The service changes are aimed at improving the ease of the booking system and helping overcome transport barriers. During the first two months, two three-hour practice observations will take place. In the final two months there will be two group interviews with staff from each practice. In order to obtain information about the effectiveness of the program, data is collected from a random sample of ten patients from each practice. Each time the patient tries to book an appointment or attends the surgery they are asked to complete a questionnaire. Semi-structured interviews are also undertaken with two of the patients recruited from each practice.

What are the possible benefits and risks of participating?
Those taking part may benefit from their GP practice being supported to develop ways of improving the service. This study is very low risk and we don't expect any significant risks for participating taking part.

Where is the study run from?
The study is run from Norwich Medical School and takes place in four GP practices (UK)

When is the study starting and how long is it expected to run for?
September 2016 to May 2018

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

Who is the main contact?
Dr John Ford
jf653@medschl.cam.ac.uk

Study website
www.uea.ac.uk/GPstudy

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33077

Study information

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

Acronym
I-ACT

Study objectives
The aim of this feasibility study is to test the design and collect the necessary information needed to inform a definitive trial investigating the effectiveness of a GP practice a support package to improve access to primary care for socio-economically disadvantaged older people in rural areas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES North East - York Research Ethics Committee, 19/12/2016, ref: 16/NE/0424

Study design
Randomised; Interventional; Design type: Process of Care, Complex Intervention

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Public Health; UKCRC code/ Disease: Other/ Symptoms and signs involving the urinary system

Interventions
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.

Intervention: Practices allocated to the intervention arm will be supported to improve the following two areas for socio-economically disadvantaged older people:
1. Ease of the booking system and
2. Transport barriers
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:
1. An overview of the trial.
2. Service specifications outlining the essential characteristics of the planned changes to ensure that it will meet the research requirements.
3. 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.
4. An outline of the four development meetings.
5. A logic model to support development
6. Feedback to practices from the practice profiling.
7. 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 and £1500 to contribute to the service development and/or delivery. 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
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: Participants in practices not randomised to the intervention arm will receive usual care and access the GP surgery in the standard manner.

During the first two months, two three-hour practice observations will take place. In the final two months there will be two group interviews with staff from each practice.

Intervention Type
Other

Primary outcome measure
1. Pre-appointment transport options, ease of appointment and perceived convenience measured by a self-completed questionnaire designed for the purpose of this study at baseline, 6 months and each time appointment is booked

2. Post-appointment suitability of received appointment and transport to get to the appointment measured by a self-completed questionnaire designed for the purpose of this study at baseline, 6 months and each time appointment is booked

Secondary outcome measures
1. Confidence and trust in GP practice measured by a self-completed questionnaire designed for the purpose of this study at baseline, 6 months and each time appointment is booked
2. Patient Activation Measure (PAM) measured by a self-completed questionnaire designed for the purpose of this study at baseline and 6 months
3. Quality of life (EQ5D and ICECAP-O) measured by a self-completed questionnaire designed for the purpose of this study at baseline and 6 months
4. Number and type of health professional contact measured by routine practice data for trial period from 6 months at baseline and follow-up
5. Hospital admissions measured by routine practice data for trial period from 6 months at baseline and follow-up
6. Intervention activity and process measures agreed by research team and practices measured by routine practice data for trial period from 6 months at follow-up
7. Number of referrals measured by routine practice data for trial period from 6 months at baseline and follow-up
8. Number of repeat medications measured by routine practice data for trial period from 6 months at baseline and follow-up

Overall study start date
01/09/2016

Completion date
30/05/2018

Eligibility

Key inclusion criteria
1. Aged 65 years and over
2. With difficulty accessing the general practice
3. Two or more repeat prescriptions
4. Twelve or fewer nurse or GP consultations in the past 12 months (face-to-face, telephone or home visit)
5. No access to a car within their household
6. Living in a postcode in the highest Index of Multiple Deprivation quartile in the practice

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 56; UK Sample Size: 56

Total final enrolment
34

Key exclusion criteria
1. Significant cognitive impairment that would prevent them providing informed consent, such as dementia
2. Not able to speak English
3. Generally do not book their own appointments

Date of first enrolment
01/04/2017

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Norfolk CCG
Lakeside 400,
Old Chapel Way,
Broadland Business Park,
Thorpe St Andrew
Norwich
United Kingdom
NR7 0WG

Sponsor information

Organisation
University of East Anglia

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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
30/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from John Ford (jf653@medschl.cam.ac.uk). Anonymised individual level data is

available from now until October 2028. Each request will be considered individually based on the purpose and resources required. Consent was obtained to share anonymised data for other research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/04/2019	22/05/2019	Yes	No
HRA research summary			28/06/2023	No	No