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ASPIRE 2: Action to Support Practices Implementing Research Evidence

Submission date	Recruitment status
04/02/2015	No longer recruiting
Registration date	**Overall study status**
20/02/2015	Completed
Last Edited	**Condition category**
08/03/2023	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Plain English summary under review

Study website
http://medhealth.leeds.ac.uk/info/650/aspire//

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18323

Study information

Scientific Title
A cluster-randomised evaluation of adaptable implementation packages targeting high impact clinical practice recommendations in general practice

Study objectives
ASPIRE (Action to Support Practices Implementing Research Evidence) is a NIHR Programme Grant for Applied Research which aims to develop and evaluate an adaptable intervention package to target implementation of 'high impact' clinical recommendations in general practice. The programme focuses on 'high impact' clinical practice recommendations from NICE clinical guidelines and NHS Quality Standards where a measurable change in clinical practice can lead to significant patient benefit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/1393; First MREC approval date 01/12/2014

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Case-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Diabetes, Primary Care; Subtopic: Both, Primary care; Disease: Cardiovascular disease, All Diseases

Interventions
1. Audit and Feedback: This will be by practice and will be repeated regularly during the trial. It will include comparisons with other (anonymised) practices, information to illustrate benefits of changing practice, achievements if possible and educational messages.
2. Computerised Prompts and Decis: These will be built into the existing system or adapted from current SystmOne protocols and the content depends on the recommendation
3. Educational Outreach: Educational sessions using behaviour change techniques

4. GP Appraisal and Revalidation: Practices will be offered a tool kit of materials that will support GPs when preparing for appraisal and/or revalidation
5. Patient Mediated Intervention: Practices will also be provided with materials to assist in their communication with patients concerning the targeted recommendations

Intervention Type
Other

Primary outcome measure
Adherence; Timepoint(s): Adherence will be measures up to 12 mth post randomisaion

Secondary outcome measures
N/A

Overall study start date
27/02/2015

Completion date
06/03/2015

Eligibility

Key inclusion criteria
General practices within the ten Clinical Commissioning Groups (CCGs) in West Yorkshire (Airedale Wharfedale and Craven CCG, Bradford City CCG, Bradford Districts CCG, Calderdale CCG, Greater Huddersfield CCG, Leeds North CCG, Leeds South and East CCG, Leeds West CCG, North Kirklees CCG, Wakefield CCG) will be eligible to
participate in the trial provided they use the IT System, SystmOne clinical software for patient health records.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Planned Sample Size: 144; UK Sample Size: 144

Total final enrolment
144

Key exclusion criteria
1. We will exclude the four general practices which participated in earlier pilot intervention work as they will already have been exposed to active intervention components. We will also exclude general practices where we have already interviewed GPs, nurses and practice managers as part of the intervention development process and which participate

in the planned qualitative process evaluation (which will be the subject of a further protocol and ethics application).
2. Any general practices that do not use SystmOne software for patient health records will also be excluded.

Date of first enrolment
27/02/2015

Date of final enrolment
06/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Trials Research Unit
17 Springfield Mount
Leeds
United Kingdom
LS2 9NG

Sponsor information

Organisation
University of Leeds

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/024mrxd33

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/02/2016		Yes	No
Results article	results	28/02/2020	02/03/2020	Yes	No
Protocol (other)			08/03/2023	No	No
Results article		01/04/2020	08/03/2023	Yes	No
Statistical Analysis Plan			08/03/2023	No	No