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Patient Centred Assessment Method (PCAM)

Submission date
01/04/2015

Recruitment status
No longer recruiting

Registration date
18/05/2015

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Recent approaches to assessing mental health problems in people with long-term conditions (such as diabetes, coronary heart disease and chronic obstructive pulmonary disease) have not yielded much benefit or acknowledged the broader social problems that might contribute to poor physical and mental wellbeing. The Patient Centred Assessment Method (PCAM) has been developed to enable broad assessment of patient needs and to encourage action based on these needs. This study will assess the acceptability of the PCAM tool for addressing the needs of patients with LTCs in primary care and the feasibility of conducting a full scale study of its effectiveness.

Who can participate?
Patients aged over 18 attending annual reviews by participating nurses at GP practices in NHS Greater Glasgow and Clyde, NHS Grampian and NHS Forth Valley.

What does the study involve?
Eight GP practices will be randomly allocated either to deliver the PCAM intervention or to deliver care as usual. Nurses from practices assigned to PCAM will receive training and other support in the use of PCAM. Patients will be asked to participate in their annual review in the way that they normally would. If they agree to take part, they will be asked to complete an anonymised questionnaire about their review. The questionnaire includes no personal identifying information, only a code which allows it to be matched to other anonymised data, so that the research team cannot know who participants are. After 8 weeks, the NHS will send a follow-up questionnaire to the patient, asking how they are and about any use of services suggested by the nurse. Some patients will be asked if they would like to take part in a brief telephone interview and some will be asked in advance if their review could be audio-recorded.

What are the possible benefits and risks of participating?
Possible benefits would include receiving help or support which otherwise would not be offered or available. There should be no direct risks in participating, because PCAM should be enhancing what is done already.

Where is the study run from?
University of Stirling (UK).

When is the study starting and how long is it expected to run for?
From April 2015 to June 2016.

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

Who is the main contact?
Dr Carina Hibberd

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17283

Study information

Scientific Title
Patient Centred Assessment Method (PCAM): improving nurse-led biopsychosocial assessment of patients with long-term conditions and co-morbid mental health needs

Study objectives
Recent approaches to assessing mental health problems in people with long-term conditions (LTCs) have not yielded much benefit or acknowledged the broader social problems that might contribute to poor physical and mental wellbeing.The Patient Centred Assessment Method (PCAM) has been developed to enable broad assessment of patient biopsychosocial needs and

to encourage action based on these needs. This research will assess the acceptability of the PCAM tool for addressing biopsychosocial needs in patients with LTCs in primary care and the feasibility of conducting a full scale trial of its impact/effectiveness.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=17283

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 3, ref: 168310

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Topic: Diabetes, Primary Care, Cardiovascular disease; Subtopic: Mental Health; Disease: Cardiovascular disease, All Diseases, Heart Failure, Congenital Heart Disease and Pulmonary Hypertension

Interventions
The PCAM aims to provide a systematic language for the integrated assessment of a broad range of physical, mental well-being and social needs. Health and Wellbeing (covering physical health needs; impact of physical health on mental health; lifestyle behaviors; mental wellbeing), Social Environment (covering home safety and stability; daily activities; social networks; financial resources), Health Literacy and Communication (covering understanding of symptoms, self care and healthy behaviour; how engaged patient is in discussions).
These then lead to action-oriented tasks to deal with the identified problem which may include referral or signposting to other professionals or agencies. Nurses will be encouraged to think of the range of supports that are locally available. The research team will also work with the Access to Local Information to Support Self Management project (ALISS) to provide them with a list of potential referral/signposting opportunities which cover the biopsychosocial problems within the PCAM domains. The ALISS Engine acts as a central index for self-management information in Scotland. It is used to collect, organise and share links to community support.

Primary care professionals and people with LTCs will assess the acceptability and implementation requirements of the PCAM through focus groups. We will then conduct a feasibility study for a cluster randomised controlled trial: in 8 GP practices, involving 16 practice nurses, with 50% allocated to deliver the PCAM intervention and 50% to deliver care as usual. Baseline data collection will be conducted before randomisation and will include immediate post-consultation data collection for 10 patients per nurse attending their annual assessment who are willing to take part. Data will include: patient demographics; patient completed evaluation of consultation; patient completed outcome measures; nurse referrals/signposting to services. Patient completed follow-up data will be collected by postal questionnaire 8 weeks after the nurse-led consultation. Practices will then be randomised to receive training and use of the PCAM, or to deliver care as usual. The same data (as at baseline) will be collected for a second group of patients in both PCAM intervention and care as usual practices. A sample of 5 pre/post training audio-recorded consultations will allow analysis of how nurses use the PCAM and whether it changes how they engage in assessments. Follow-up telephone interviews with nurses and patients will reflect on use and impact of the PCAM.

Follow Up Length: 2 month(s); Study Entry: Single Randomisation only

Intervention Type
Other

Primary outcome measure
Recruitment (can nurses and patients be recruited to the study?)

Secondary outcome measures
1. CARE measure; Timepoint(s): 8 weeks follow-up per cohort
2. GHQ; Timepoint(s): 8 weeks follow-up per cohort
3. Nurse referral/ signposting actions; Timepoint(s): 3 months follow-up post intervention
4. PEI; Timepoint(s): 8 weeks follow-up per cohort
5. SF12; Timepoint(s): 8 weeks follow-up per cohort
6. WEMWBS; Timepoint(s): 8 weeks follow-up per cohort

Overall study start date
01/04/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria
Practices
1. Medium to large size practices (4+ GP partners) based in NHS Greater Glasgow and Clyde (NHSGG&C), NHS Grampian, and NHS Forth Valley (NHSFV)
2. Each practice must also be able to recruit two nurses who deliver annual health checks for LTCs (Diabetes Mellitus [DM], Coronary Heart Disease [CHD], or Chronic Obstructive Pulmonary Disease [COPD]).

Patients
All consecutive patients aged over 18 years attending annual reviews by participating nurses will be asked if they would be willing to complete anonymised questionnaires.

Target Gender: Male & Female; Lower Age Limit: 18 years

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 320; UK Sample Size: 320; Description: 16 nurses will be recruited from 8 practices. At baseline and prior to randomisation, each nurse will ask consecutive patients attending for annul reviews to complete questionnaires n=10 completed per nurse (n=160) . Following randomisation and introduction of the intervention the same process will be completed for a further cohort of 10 patients per nurse (n=160).

Total final enrolment
77

Key exclusion criteria
Practices
1. Less than 4 GP partners
2. Unable to recruit 2 nurses
3. Nurses not engaged in conducting annual reviews of patients with long-term conditions

Patients
Adults aged over 18 deemed by practice nurse to be unsuitable to approach due to communication, severe health or severe mental health problems. Nurses will record reasons for exclusion and anonymised demographic details of excluded patients.

Date of first enrolment
01/05/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Research and Enterprise Office
Room 3B1
Cottrell Building
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Sponsor information

Organisation
University of Stirling

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research; Grant Codes: 13/33/16

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018	26/10/2020	Yes	No