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Improving the care of people with long term conditions (ENHANCE)

Submission date 05/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/08/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 22/09/2021	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Long-term conditions (LTCs) are important determinants of quality of life (QoL) and healthcare costs worldwide. Osteoarthritis (OA) is the most common musculoskeletal condition in older adults and is very commonly seen in patients with other LTCs. Likewise, anxiety and depression are frequently diagnosed in the same patient with other LTCs including OA. However these conditions are seldom prioritised by patient or clinician resulting in higher levels of disability, poorer prognosis and increased health care costs. The aim of this study is to examine the feasibility and acceptability of an integrated approach to LTC management, tackling the under-diagnosis and under-management of OA-related pain and anxiety and/or depression in patients with other LTCs in primary care.

Who can participate?
Adults aged 45 years and older due for their LTC review (asthma/COPD/hypertension or ischemic heart disease/diabetes).

What does the study involve?
Four practices participate in this pilot trial. Each practice operates as both a control practice and as an intervention practice. During their control period, practices provide usual best current care for LTC reviews. During their intervention period they provide usual best current care for LTC reviews and also integrate case finding, assessment and negotiation of a management plan for anxiety / depression / joint pain. All participants are followed up at 6 weeks and 6 months. Interviews with about 20 patients and audio recordings of about 40 LTC review consultations are done with those that have received a LTC review during practice intervention periods..

What are the possible benefits and risks of participating?
No risks have been identified.

Where is the study run from?
Four GP practices in the NIHR Clinical Research Network: West Midlands area of NHS North Staffordshire and NHS Stoke on Trent (UK).

When is the study starting and how long is it expected to run for?
September 2014 to December 2106

Who is funding the study?
Arthritis Research UK Primary Care Centre of Excellence, a NIHR Research Professorship (NIHR-RP-2014-04-026) and the National Institute of Health Research Collaborations for Leadership in Applied Health Research and Care West Midlands (NIHR CLAHRC WM).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
19369

Study information

Scientific Title
Improving the care of people with long term conditions: a pilot stepped wedge randomised controlled cluster trial

Acronym
ENHANCE 2015

Study objectives
For many conditions adherence to guidelines is incentivised by the Quality and Outcomes (QoF) component of the General Practice contract. For some conditions not included in QoF (e.g. osteoarthritis (OA), chronic pain, anxiety), or those conditions with more subjective outcomes (e. g. depression), care frequently remains suboptimal and health needs often go unidentified. As Goodwin et al (2010) note “chronic disease management approaches that identify patients on the severity of a single condition may miss multi-morbid patients who stand to benefit greatly from improved co-ordination of care”. This pilot trial will examine the feasibility and

acceptability of an integrated approach to Long Term Condition (LTC) management by tackling the under-diagnosis and under-management of OA related pain (knee, hip, hand and foot) and anxiety and/or depression in patients aged 45 years and over with other LTCs in primary care (asthma / COPD / hypertension or ischemic heart disease / diabetes), within what we have called an 'ENHANCE' LTC review. This study is a pilot stepped wedge randomised controlled cluster trial that will include 4 GP practices within NIHR Clinical research Network: West Midlands (NIHR CRN: West Midlands). We aim to recruit 300 patients aged 45 years and over with a LTC. A theoretically informed mixed methods approach will be employed using participant self reported questionnaires, a medical record review, an 'ENHANCE' EMIS template, qualitative interviews and audio recordings of the 'ENHANCE' LTC review. This pilot trial will inform us about the feasibility and acceptability of running a full scale randomised trial, including information about the recruitment and response rates. In addition, this pilot involves interviewing GPs, practice nurses to assess their views and experiences of the ENHANCE LTC review.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Greater Manchester East Research Ethics Committee , 06/05/2015, ref: 15/NW/0335

Primary study design
Interventional

Study design
Randomised; Interventional and Observational; Design type: Screening, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Health services and delivery research; Subtopic: Health services and delivery research; Disease: All Health services and delivery research

Interventions
1. Usual care (control): Whilst some practices deliver their LTC reviews within dedicated clinics, others provide a more ad hoc appointment system. While we won't be asking practices involved to alter the content of their usual LTC reviews during the control period, we will be asking the practices to book some of their patients due for their LTC review into dedicated study consultations per week. During the control period the practice nurse introduces the study to patients and hands them a study pack to take away and complete.
2. The 'ENHANCE' LTC review (intervention): During the intervention period, trained practice nurses will deliver the 'ENHANCE' LTC review during the dedicated study clinics, supported by the 'ENHANCE' EMIS template.
The core components of the 'ENHANCE' LTC review are:
2.1. LTC review consultations set up especially for the research study
2.2. Usual LTC reviews extended by an extra 15 minutes to integrate:
2.2.1. Case finding for anxiety / depression / joint pain
2.2.2. Assessment of anxiety / depression / joint pain
2.2.3. Negotiation of a management plan which might include facilitating self-management support or signposting / referral to services within or outside the practice

2.3. An ‘ENHANCE’ review summary card for patients
2.4. An ‘ENHANCE’ EMIS template to support the review
A modified LTC review template specifically developed for the study will be embedded within the EMIS system at practice level. The practice nurse will access this template allowing key information to be recorded and the fidelity of the training and content of the ‘ENHANCE’ review to be assessed.

Intervention Type
Other

Primary outcome(s)
Health outcome EQ-5D-5L; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire

Key secondary outcome(s)
1. Symptoms of depression PHQ-9; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
2. Symptoms of anxiety GAD-7; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
3. Pain Intensity; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
4. Bothersomeness; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
5. Pain interference; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
6. Health perceptions; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
7. Satisfaction of LTC review GPAQ Nurse Assessment; Timepoint(s): Collected at baseline via self-reported questionnaire
8. Content of LTC consultation; Timepoint(s): Collected at baseline via self-reported questionnaire
Health Care Utilisation; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire
9. Work performance; Timepoint(s): Collected at baseline, 6 weeks and 6 months via self-reported questionnaire

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patients due for their LTC review for asthma / COPD / hypertension or ischemic heart disease / diabetes
2. Registered with the participating GP practices during the specified trial period for that practice
3. Aged 45 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
318

Key exclusion criteria
1. Vulnerable patients (i.e. patients on the practice register for severe enduring mental ill health (e.g. schizophrenia /bipolar), significant cognitive impairment (e.g. dementia), and/or terminal illness)
2. Patients who reside in a nursing home and have alternative arrangements for LTC care
3. Patients unable to read and speak English (cover letters, the Participant Information Sheet and questionnaires are in English. The postal questionnaires will have a contact name and telephone number that participants can call to discuss any difficulties or help required with completion of the consent form or the questionnaire. In addition, all interviews will be conducted in English)

Date of first enrolment
13/07/2015

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Keele
Arthritis Research UK Primary Care Centre
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Sponsor information

Organisation
University of Keele

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	21/09/2021	22/09/2021	Yes	No
Protocol article	protocol	01/01/2015	22/07/2020	Yes	No
HRA research summary			28/06/2023	No	No