Exploratory trial of the WISE approach in primary care

Submission date Recruitment status Prospectively registered 29/04/2010 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 29/04/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 25/07/2013 Other

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 4407

Study information

Scientific Title

Improving outcomes in chronic conditions through effective self-management: exploratory trial of the WISE model in primary care

Acronym

WISE

Study objectives

To test and refine a self care support training intervention for primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oldham LREC approved on the 15th January 2008 (ref: 07/H1011/96)

Study design

Non-randomised interventional and observational process of care qualitative study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

GP practice

Study type(s)

Diagnostic

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: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Two practices to take part in the training. The impact of the training to be assessed by:

- 1. Observations during the training sessions
- 2. Interviews following the training with clinicians and administrative staff
- 3. Four pre- and four post-training recordings of consultations per clinician
- 4. Qualitative interviews with patients:
- 4.1. 20 'think aloud' interviews to explore how patients use a new assessment tool developed for the WISE approach
- 4.2. 25 in depth interviews with patients exploring issues related to self care

Study entry: registration only

Intervention Type

Other

Phase

Phase II

Primary outcome measure

Training is robust and effective for routine delivery in primary care

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/05/2008

Completion date

31/03/2009

Eligibility

Key inclusion criteria

- 1. Diagnosis of diabetes, chronic obstructive pulmonary disease (COPD) or irritable bowel syndrome (IBS)
- 2. Either sex, no age limit

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

Planned Sample Size: 173; UK Sample Size: 173

Key exclusion criteria

- 1. Patients in the palliative care stage of condition
- 2. Those receiving management from a specialist nurse rather than primarily practice nurse or GP
- 3. Mental health problems such as those which reduce capacity to consent and participate

Date of first enrolment

01/05/2008

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Oxford Road Manchester

United Kingdom M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Research and Development office 2nd Floor Christie Building Oxford Road Manchester England United Kingdom M13 9PL

Sponsor type

University/education

Website

http://www.manchester.ac.uk/

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Government

Funder Name

National Primary Care Research and Development Centre (NPCRDC) (UK) (ref: R01135)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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	29/01/2010		Yes	No