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Evaluation of the WISE approach in primary care: improving outcomes in chronic conditions through effective self-management

Submission date	Recruitment status	[_] Prospectively registered
20/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2013	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof David Thompson

Contact details
Department of Gastroenterology
Clinical Sciences Building
Hope Hospital
Stott Lane
Salford
United Kingdom
M6 8HD
david.thompson@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Evaluation of the WISE approach in primary care: improving outcomes in chronic conditions through effective self-management - a two-arm practice-level cluster randomised controlled trial

Acronym
WISE RCT

Study objectives
Is the adoption of the WISE approach to self management support in primary care clinically and cost-effective in the management of patients with existing long-term conditions, compared to routine primary care services?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salford & Trafford Local Research Ethics Committee approved on the 23rd January 2009 (ref: 09 /H1004/6)

Study design
Two-arm practice-level cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Chronic obstructive pulmonary disease (COPD), diabetes or irritable bowel syndrome (IBS)

Interventions
The intervention is designed to encourage practices to adopt a structured and patient-centred approach in their routine management of long-term conditions, providing the practice with skills, resources and motivation to make changes to service delivery in line with the principles of the WISE approach. The planned approach to training combines evidence-based approaches to

changing professional behaviour with approaches to 'normalise' those behaviours in current practice.

The training will seek to impart three core skills to primary care staff:
1. Assessment of the individual patient's needs in terms of their self-management capabilities and current illness trajectory
2. Shared decision making about the appropriate type of support based on that assessment (types include support from primary care, written information sources, generic support groups or condition specific education)
3. Facilitating patient access to support. This may involve signposting patients to various resources which relate to the assessment and shared decision making processes. The training will encompass ways health professionals can negotiate with and guide patients into more appropriate utilisation of health service resources. In the case of IBS, this may also involve referral to psychological treatment services (CBT and hypnotherapy) for eligible patients (so called 'stepped up care').

Training of practice staff takes place over two 3 hour sessions - the effects of the training will be determined through recording patient-level outcomes.

The control group will receive no training.

Follow-up for both arms will be at 6 months and 12 months post-intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Shared decision making
2. Self-efficacy
3. Empowerment
4. Health behaviour
5. Positive attitudes
6. Management options
7. Condition specific quality of life
8. Health related quality of life
9. Service utilisation

Measured at baseline, 6 months and 12 months.

Secondary outcome measures
1. Illness perceptions
2. Health literacy
3. Social capital
4. Shared decision making
5. Self-efficacy
6. Empowerment
7. Health behaviour
8. Positive attitudes

9. Management options
10. Condition specific quality of life

Measured at baseline, 6 months and 12 months.

Overall study start date
01/05/2009

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Diagnosis of chronic obstructive pulmonary disease (COPD), diabetes or irritable bowel syndrome (IBS) (identified from the GP systems using appropriate Read codes and verified by the GP)
2. Sufficient English to be able to complete questionnaires
3. Agreement from the practice that the patient is appropriate for research assessment
4. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,728 diabetic, 1,728 COPD, and 1,728 chronic IBS patients.

Key exclusion criteria
1. In the palliative care stage of condition
2. Receiving management primarily from a specialist nurse rather than a practice nurse or GP
3. Mental health problems such as those which reduce capacity to consent and participate

Date of first enrolment
01/05/2009

Date of final enrolment
01/05/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Gastroenterology
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
R&D office 2nd Floor Christie Build
University of Manchester
Oxford Road
Manchester
England
United Kingdom
M13 9PL
karen.shaw@manchester.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0407-10136)

Funder Name
National Primary Care Research and Development Centre (NPCRDC) (UK)

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	13/05/2013		Yes	No