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The provision of written information on the management of illness: a cluster randomised trial to examine the impact on primary care services and patient empowerment.

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
13/08/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0096067462

Study information

Scientific Title

Study objectives
To determine the impact of providing written patient information on the frequency, duration and type of patient contact with the primary healthcare team.

To establish the views of both patient and primary care staff on the implications of providing written information in terms of patient empowerment, the patients' level of self care, and the patients' confidence in deciding when to consult a health professional.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Not Applicable: Service delivery

Interventions
The study is a cluster randomised trial. Patients will be allocated to one of the intervention arms or the control arm of the trial by the relevant health professional according to the contents of a prepared unmarked envelope.

Patients in the intervention arms will receive a book describing how to best manage by self care or by contact with a health professional a wide range of common illnesses. Information on supplementary sources of health information will also be available. Those in the control group will receive usual care which may include information or other sources of health information.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measures will be the number of contacts (consultations and telephone calls) between the patient and the primary health care team over a one year period. The length of consultation will be logged using data from the computerised appointment system.

Semi-structured interviews mine the usefulness of the self care book from both patient and practice perspectives.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1998

Completion date
31/12/2003

Eligibility

Key inclusion criteria
The patients to be involved in the study will be randomly selected households from the population of 16,500 patients registered with the Parkbury House Surgery. 800 patients will be invited to participate in each intervention arm, and all occupants of each household will be included (approximately 10% of households.)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria

Patients under the age of 16 will not be used in the random allocation process, and households in which English is not clearly understood will be excluded as the information to be used in the study is available in English only.

Date of first enrolment
01/04/1998

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Parkbury House Surgery
St Albans
United Kingdom
AL1 3HD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
University/education

Funder Name
University of Hertfordshire Research Network (HertNet) / Centre for Research in Primary and Community Care (CRIPACC) (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	01/09/2005		Yes	No