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Self assessment of Health And Illness: Research In Neath Gastroenterology unit

Submission date	Recruitment status	[ ] Prospectively registered
04/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/01/2020	Digestive System	[ ] Record updated in last year

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
05/1/110

Study information

Scientific Title
Self assessment of Health And Illness: Research In Neath Gastroenterology unit

Acronym
SHAIRING

Study objectives
The need to involve patients more actively in decisions about their care is recognised in the NHS Plans for England and Wales. Central to this is the ability to measure a patient's progress from their own perspective. This research will give insight into the feasibility and practicality of measuring and using patient-focused outcomes routinely in outpatients.

In the context of a major, multi-centre trial, MINuET (registered with ISRCTN82765705 - http://www.controlled-trials.com/ISRCTN82765705), a simple quality of life measure for use by patients with gastrointestinal disorders, the Gastrointestinal Symptom Rating Questionnaire (GSRQ) has been developed. This is a system-specific questionnaire. It is quick and simple to complete and is applicable to the majority of patients with GI disorders. We hope it will enable the integration of patient-focused measurement into routine clinical practice.

There are three main research questions:
1. In a busy gastroenterology clinic is it feasible for patients routinely to complete electronic questionnaires about their Health-Related Quality of Life (HRQL) - both generic and GastroIntestinal (GI)-specific - and for doctors to use this information? This will be assessed by qualitative interviews of staff and a sub-sample of patients, the proportions of clinic attendees who were eligible and willing to complete electronic questionnaires, and the proportion who successfully completed them among the two groups allocated to do so.
2. Does this intervention improve process of care, notably doctor-patient communication and management decisions? This will be assessed by qualitative interviews, and clinic waiting and consultation times. Limited information on diagnosis and symptoms will be obtained from routine medical records.
3. Does this intervention improve patient outcomes? This will be assessed by a) patient-completed postal questionnaires at baseline, 1 month and 3 months and b) anonymous patient satisfaction questionnaires.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Wales Local Research Ethics Committee, 24/03/2006, ref: 06/WMV02/4

Study design
Single-centre pragmatic randomised controlled trial with repeated measurements

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Gastrointestinal disorders

Interventions
Electronic Health Related Quality of Life Questionnaire (GSRQ/EQ-VAS) - a combination of Gastrointestinal Symptom Rating Questionnaire and EQ-visual analogue scale. The intervention was carried out whenever patients attended clinic visits during the 3-month study follow-up period rather than at planned timepoints.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The Physical and Mental Component Scores from the 36-item Short Form health survey (SF-36), measured at 3 months.

Secondary outcome measures
1. SF-36 scores at 1 month
2. EuroQol (EQ-5D) quality of life questionnaire, filled at recruitment (baseline), 1 month and 3 months
3. Clinic waiting times
4. Length of consultation, taken from routine patient records
5. Patient satisfaction, measured by the Outpatient Medical Interview Satisfaction Scale (OMISS) after each visit to the clinic

Overall study start date
29/07/2006

Completion date
30/09/2007

Eligibility

Key inclusion criteria
All patients attending gastroenterology clinic who are fluent in English and likely to be followed up in the clinic within 3 months.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
500

Total final enrolment
302

Key exclusion criteria
1. Problem is primarily non-gastrointestinal
2. Currently taking part in an HRQL study
3. Frail or seriously compromised (American Society of Anaesthesiologists [ASA] status 4+)

Date of first enrolment
29/07/2006

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Gastroenterology
Port Talbot
United Kingdom
SA12 7BX

Sponsor information

Organisation
Wales Office of Research and Development for Health and Social Care (UK)

Sponsor details
Welsh Assembly Government
Cathays Park
Cardiff

United Kingdom
CF10 3NQ

Sponsor type
Government

ROR
https://ror.org/03w4jzj90

Funder(s)

Funder type
Government

Funder Name
Wales Office of Research and Development for Health and Social Care - Funding Scheme 2005 (UK)

Results and Publications

Publication and dissemination plan
2009 results in: https://doi.org/10.3329/bmrcb.v35i2.2123 (added 03/01/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration