

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

Submission date 04/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/01/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration