ISRCTN12595588 https://doi.org/10.1186/ISRCTN12595588

Evaluation of a computer aid for assessing stomach symptoms

Submission date	Recruitment status	[_] Prospectively registered
10/06/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/12/2022	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-computer-aid-to-help-gps-decide-who-needs-further-tests-for-stomach-symptoms

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18331

Study information

Scientific Title
Phase II exploratory randomised controlled trial (RCT) comparing use of electronic clinical decision support (eCDS) for suspected oesophago-gastric cancer in primary care with usual care

Acronym
ECASS

Study objectives
The aim of this study is to test the effects of a computerised clinical decision support (eCDS) tool to assist GPs in selection of patients for gastroscopy for possible OG cancer, and to collect all the relevant data to inform a phase III trial of such a tool.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NE/1179

Study design
Randomised; Interventional and Observational; Design type: Screening, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions
Participants are clustered (at the participating site level) to the intervention arm or usual care.

Practices randomised to the intervention arm will be provided with the oesophagogastric (OG) eRAT, which will be embedded into their clinical system. The eRAT provides a dropdown box

containing an interactive risk calculator, which can be opened at the GP's discretion during the consultation. It allows additional symptoms to be entered and generates a value for the risk of a currently undiagnosed OG cancer, together with guidance on whether or not to refer for further investigation.

Intervention Type
Other

Primary outcome measure
Feasibility; Timepoint(s): 6 months

Secondary outcome measures
All measured at six months from patient recruitment, and will be taken from patient notes (primary and secondary care).

1. Practitioner outcomes: frequency and sustainability of use of eRAT, adherence to recommendations, attitudes to and role of eCDS.
2. Service outcomes: referral rates; use of diagnostic pathways (2WW and direct access gastroscopy, conversion (proportion of referrals with cancer diagnosis) and detection rates (proportion of OG cancers referred through these routes); Time from first consultation to diagnosis with cancer (diagnostic interval)
3. Health economic outcomes based on estimates of resource use
4. Patient outcomes: acceptability of use of eCDS

Overall study start date
01/10/2014

Completion date
28/05/2017

Eligibility

Key inclusion criteria
1. Patients presenting to the GP with symptoms associated with OG cancer (NICE clinical guidelines 17 & 27)
2. Aged 55 years and over
3. Target Gender: Male & Female
4. Aged 55-100

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 3030; UK Sample Size: 3030

Total final enrolment
530

Key exclusion criteria
1. Inability to understand study documentation, for instance because of a lack of English fluency
2. Patients unable to provide informed consent

Date of first enrolment
01/06/2015

Date of final enrolment
28/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS North Durham CCG
Durham
United Kingdom
DH1 5TS

Study participating centre
NHS Durham Dales, Easington & Sedgefield CCG
United Kingdom
TS21 3EE

Study participating centre
NHS Darlington CCG
United Kingdom
DL3 6JL

Study participating centre
NHS Hartlepool & Stockton on Tees CCG
United Kingdom
TS23 2LA

Study participating centre
NHS South Tees CCG
United Kingdom
TS3 6AL

Study participating centre
NHS Cambridgeshire and Peterborough CCG
United Kingdom
CB2 8FH

Study participating centre
NHS Bedfordshire CCG
United Kingdom
MK45 4HR

Sponsor information

Organisation
University of Durham (UK)

Sponsor details
Old Elvet
Durham
England
United Kingdom
DH1 3HP

Sponsor type
University/education

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to report and disseminate the results of the study through peer reviewed scientific journals, internal reporting and newsletters, conference presentations and publications on our websites.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/04/2016		Yes	No
Results article		18/03/2021	10/05/2021	Yes	No
Plain English results			06/12/2022	No	Yes
HRA research summary			28/06/2023	No	No