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Diagnosis: Earlier Looking At Your Symptoms - development of a patient-centred tool to measure diagnostic delays

Submission date 30/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/09/2008	**Overall study status** Completed	
Last Edited 24/01/2022	**Condition category** Cancer	

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
SPON 327-06

Study information

Scientific Title
Diagnosis: Earlier Looking At Your Symptoms - development of a patient-centred tool to measure diagnostic delays

Acronym
DELAYS2

Study objectives
This pilot study aims to determine the acceptability (to patients and research nurses), feasibility and validity of a tool to measure patient and primary delays in cancer. In particular this work will:
1. Pilot the recruitment of patients with a recent and established diagnosis of one of seven specific cancers (or groups of cancers) and the administration of the tool by research nurses
2. Assess non-response bias
3. Assess and seek ways to minimize the level of anxiety that may be raised as part of the data collection process
4. Assess completion rates
5. Compare the response to the tool being administered by a research nurse with self-completion facilitated by a research nurse

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East Wales Local Research Ethics Committee. Date of approval: 03/04/2007 (ref: 07/WNo03/1)

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Cancer (breast, colorectal, lung, gynaecological, urological, upper GI, haematological)

Interventions
The participants will be randomly allocated to self-completion vs researcher administration of a tool to measure symptoms prior to a diagnosis. The tool is a document with open and closed questions about symptoms patients have had and how long they have had them for.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To compare the two groups in terms of overall completion rates using an intention to treat analysis

Secondary outcome measures
A comparison will be made between the two modes of the average anxiety levels. This will be assessed after diagnosis as soon as possible, using the Six-item State-Trait Anxiety Inventory (STAI).

Overall study start date
01/09/2008

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Both males and females, age 18+ (no upper limit)
2. Cancer patients with new primary diagnoses of one or groups of the following seven cancers: breast, colorectal, lung, gynaecological, urological, upper gastrointestinal (GI), haematological
3. Patients who are aware of the diagnosis of cancer and confirmed as eligible by Clinical Team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

300

Key exclusion criteria
1. Patients close to death
2. Patients without mental capacity or linguistic capacity to complete the questionnaire

Date of first enrolment
01/09/2008

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
North Wales Clinical School
Wrexham
United Kingdom
LL13 7YP

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor
30-36 Newport Road
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CF24 0DE
+44 (0)2920 875834
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Sponsor type
University/education

Website

http://www.cardiff.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (ref: C8350/A8205)

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
Not provided at time of registration

Intention to publish date

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

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	03/01/2014		Yes	No
Plain English results			24/01/2022	No	Yes