

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

<b>Submission date</b> 30/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

**Protocol serial number**  
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

**Study type(s)**

Other

**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(s)**

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

### **Key secondary outcome(s)**

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).

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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)

**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, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

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

## IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/01/2014		Yes	No
<a href="#">Plain English results</a>			24/01/2022	No	Yes