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'ThinkCancer!' A trial to see if educational and behavioural workshops can help your general practice team to pick up symptoms and signs of possible cancers as quickly as possible, by referring on to a specialist

Submission date 27/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/02/2023	**Overall study status** Ongoing	
Last Edited 06/03/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Cancer diagnosis can be delayed in primary care. Our goal is to help general practices recognise possible cancers earlier which will lead to better outcomes for patients.
We have developed a unique educational and behavioural package called 'ThinkCancer!'. This involves three workshops for all staff in a practice team. We have tested 'ThinkCancer!' in a small pilot study in Wales, which showed that it can work well in primary care. We learnt important lessons about how the workshops should be delivered, and the best ways to collect information from practices.
Our aim now is to undertake a larger trial with 76 practices to test how well ThinkCancer! works and whether it is cost effective for the NHS. We will assess the effect of ThinkCancer! by measuring the time between a patient first contacting their general practice with a potential cancer symptom and their referral to hospital. A reduction in this time is known to be linked with earlier stage of cancer at diagnosis, needing less treatment, and costing the NHS less overall.
We have worked closely with patients throughout the development of ThinkCancer! and will form a Patient Advisory Group of four to six patients who will help ensure that patient views are fully represented as we interpret the results.

Who can participate?
General practices will primarily be recruited from Wales, topped up with practices from North West of England. We will recruit 8-10 practices from each of the seven Health Boards in Wales, and 8-10 from North West England.

What does the study involve?
Half of the practices will be randomly allocated to receive the intervention.
ThinkCancer! is a whole practice-based behavioural change complex intervention that aims to raise awareness and increase knowledge around current cancer diagnosis guidance. The

intervention is delivered remotely as an educational and quality improvement workshop, via three distinct workshops. The first two workshops are educational sessions, one for all clinical staff (the ‘early diagnosis’ session) and one for non-clinical but patient-facing staff (the ‘cancer aware’ session), allowing exposure to the intervention for all members of practice staff who interact with patients or their carers/advocates in any way. The third session (the ‘safety netting session’) involves the final components of the intervention, the co-production of a bespoke Cancer Safety Netting Plan (CSNP) and the appointment of a Cancer Safety Netting Champion (CSNC).

What are the possible benefits and risks of participating?
In terms of the benefits of the 'ThinkCancer!' intervention at the practice level, better safety netting systems for general practices may result in fewer errors in early cancer diagnosis, and better knowledge and appropriate referral thresholds for GPs may result in more timely and accurate urgent suspected cancer referrals. The whole practice approach to recognising symptoms and signs of cancer includes the GP administrative staff, some of who, might feel uncomfortable with this role. Due to the sensitive nature of the topic, there is a chance that the patient/carer may experience distress during the interview.

Where is the study run from?
Bangor University (UK)

When is the study starting and how long is it expected to run for?
January 2023 to August 2026

Who is funding the study?
Cancer Research Wales and North West Cancer Research (UK)

Who is the main contact?
thinkcancer@bangor.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316593

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 316593

Study information

Scientific Title
ThinkCancer!: A pragmatic randomised controlled phase III trial of a novel behavioural intervention for primary care teams to promote earlier cancer diagnosis with embedded process and economic evaluation

Acronym
ThinkCancer!

Study objectives
The 'ThinkCancer!' general practice based workshop series enable earlier cancer diagnoses more effectively than usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/03/2023, Healthcare Sciences (Post-reg) Ethics and Research Committee (College Road, Bangor, ll572dg, United Kingdom; 01248 383136; healthethics@bangor.ac.uk), ref: 2022-17267
2. Approved 23/08/2023, Health Research Authority IRAS application (Health Research Authority, 2 Redman Place, Stratford,, London, E20 1JQ, United Kingdom; 0207 104 8000; approvals@hra.nhs.uk), ref: IRAS project ID: 316593

Study design
Phase III multicentre pragmatic randomized controlled trial with embedded economic evaluation and process evaluation

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Early diagnosis of cancer in primary care

Interventions
ThinkCancer! is a whole practice-based behavioural change complex intervention that aims to raise awareness and increase knowledge around current cancer diagnosis guidance. The intervention is delivered remotely as an educational and quality improvement workshop, via three distinct workshops. The first two workshops are educational sessions, one for all clinical staff (the 'early diagnosis' session) and one for non-clinical but patient-facing staff (the 'cancer aware' session), allowing exposure to the intervention for all members of practice staff who interact with patients or their carers/advocates in any way. The third session (the 'safety netting session') involves the final components of the intervention, the co-production of a bespoke Cancer Safety Netting Plan (CSNP) and appointment of a Cancer Safety Netting Champion (CSNC).

Intervention Type
Behavioural

Primary outcome(s)
1. Primary care interval (PCI - time between first presentation of potential cancer to primary care and referral to secondary care) data. Collected retrospectively by GP research staff or trained nurses, using a Case Report form, for the period 14 to 26 months post-randomisation.
2. Cost-effectiveness in terms of incremental cost per day reduction in PCI and budget impact, collected via health economics data collection sheets/diaries after each GP-educator training event and practice workshop

Key secondary outcome(s))
1. Conversion rate: Collected retrospectively via a Case Report Form sent to the practice, to be completed by the practice manager or allocated staff member for the following intervals: The 12 months prior to randomisation, 2 to 14 months post randomisation
2. USC/2WW referral rate: Collected retrospectively via a Case Report Form sent to the practice, to be completed by the practice manager or allocated staff member for the following intervals: The 12 months prior to randomisation, 2 to 14 months post randomisation
3. Detection rate: Collected retrospectively via a Case Report Form sent to the practice, to be completed by the practice manager or allocated staff member for the following intervals: The 12 months prior to randomisation, 14 to 26 months post-randomisation
4. Cancer stage at diagnosis: Collected retrospectively by GP research staff or trained nurses using a Case Report Form for the following intervals: 14 to 26 months post-randomisation
5. Adherence to NICE NG12 guidelines (NICE, 2015): Guideline interval – the time between patient first meeting any criterion within the NICE NG12 guidelines for referral to diagnosis (Price et al., 2021) collected retrospectively by GP research staff or trained nurses using a Case Report form for the period 14 to 26 months post-randomisation.
6. Factors that contribute to longer Primary Care Intervals for patients diagnosed with cancer: qualitative measures plus subgroup analysis, case note review data collected in summarised form by GP research staff or trained nurses for the period 14 to 26 months post-randomisation.
7. Patient and carer experiences of urgent referral: qualitative measures collected via qualitative interviews with patients and carers; stakeholder interviews will take place between 3 and 6 months, interviews with patients and carers will take place from month 10
8. Mechanisms and contextual factors that drive the implementation of the intervention: practice characteristics and demographics collected at baseline via the practice questionnaire and at 12 months

9. Reach – the proportion of staff members within the practice that attended any of the workshops or had the workshop materials disseminated to them, collected during and after the workshops via workshop registration lists, the NoMAD survey and feedback forms
10. Recruitment – number of practices randomised collected throughout the study period via trial recruitment log
11. Dose – defined as the number of workshop sessions delivered to each practice, collected throughout the workshop delivery period via workshop completion lists
12. The acceptability of the intervention among practice teams: adherence to practice safety netting plan collected through the NoMAD questionnaire, which will be sent to participating practices 2 months post-workshop
13. Acceptability: feedback forms completed by participating staff members immediately following the workshop sessions, nomination of a safety netting champion
NoMAD and workshop notes
14. Whether the ThinkCancer intervention results in increased safety netting, evidenced by NoMAD questionnaire responses, which will be sent to participating practices 2 months post-workshop
15. Cancer-related DATIX information: practice manager to provide cancer-related DATIX information for 2 to 14 months post-randomisation period

Completion date
30/06/2027

Eligibility

Key inclusion criteria
General practices will primarily be recruited from Wales, topped up with practices from North West of England. We will recruit 8-10 practices from each of the seven Health Boards in Wales, and 8-10 from North West England; this conservative estimate is informed by feasibility study recruitment. Wales and North West England have similar regional demography; with higher deprivation and cancer rates compared with other UK areas (NWCR, 2021b, 2021a). If recruitment is challenging, we propose to extend the study into South West England. Networks and contacts established through the feasibility study will be maintained in order to maximise recruitment across Wales, and regional Clinical Research Network (CRN) teams will assist in recruiting the practices across all of the centres.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
99

Key exclusion criteria

All practice types will be included

Date of first enrolment
01/12/2023

Date of final enrolment
17/09/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Bangor University
Wales - North Wales Centre for Primary Care Research
Cambrian 2
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7YP

Sponsor information

Organisation
Bangor University

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Charity

Funder Name
Cancer Research Wales

Alternative Name(s)
Ymchwil Canser Cymru, CRW

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
North West Cancer Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and /or analysed during the current study will be available on request from Dr Nia Goulden (n.goulden@bangor.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Control version 6	10/01/2023	27/01/2023	No	Yes
Participant information sheet	Intervention version 4	10/01/2023	27/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.91		27/01/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes