

BMJ Open Protocol for a feasibility study of a cancer symptom awareness campaign to support the rapid diagnostic centre referral pathway in a socioeconomically deprived area: Targeted Intensive Community-based campaign To Optimise Cancer awareness (TIC-TOC)

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To cite: Smith P, Moody G, Clarke E, *et al*. Protocol for a feasibility study of a cancer symptom awareness campaign to support the rapid diagnostic centre referral pathway in a socioeconomically deprived area: Targeted Intensive Community-based campaign To Optimise Cancer awareness (TIC-TOC). *BMJ Open* 2022;**12**:e063280. doi:10.1136/bmjopen-2022-063280

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-063280>).

Received 31 March 2022
Accepted 22 September 2022



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ABSTRACT

Introduction Rapid diagnostic centres (RDCs) are being implemented across the UK to accelerate the assessment of vague suspected cancer symptoms. Targeted behavioural interventions are needed to augment RDCs that serve socioeconomically deprived populations who are disproportionately affected by cancer, have lower cancer symptom awareness and are less likely to seek help for cancer symptoms. The aim of this study is to assess the feasibility and acceptability of delivering and evaluating a community-based vague cancer symptom awareness intervention in an area of high socioeconomic deprivation.

Methods and analysis Intervention materials and messages were coproduced with local stakeholders in Cwm Taf Morgannwg, Wales. Cancer champions will be trained to deliver intervention messages and distribute intervention materials using broadcast media (eg, local radio), printed media (eg, branded pharmacy bags, posters, leaflets), social media (eg, Facebook) and attending local community events. A cross-sectional questionnaire will include self-reported patient interval (time between noticing symptoms to contacting the general practitioner), cancer symptom recognition, cancer beliefs and barriers to presentation, awareness of campaign messages, healthcare resource use, generic quality of life and individual and area-level deprivation indicators. Consent rates and proportion of missing data for patient questionnaires (n=189) attending RDCs will be measured. Qualitative interviews and focus groups will assess intervention acceptability and barriers/facilitators to delivery.

Ethics and dissemination Ethical approval for this study was given by the London—West London & GTAC Research Ethics (21/L0/0402). This project will inform a potential

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first community-based behavioural intervention that has been designed to improve awareness of vague cancer symptoms and encourage timely symptom presentation for individuals living in socioeconomically deprived communities.
- ⇒ The study has been launched against a challenging backdrop of continued COVID-19 restrictions.
- ⇒ Flexible adaptation of data collection methods is required.
- ⇒ The feasibility of collecting quantitative and qualitative data via telephone will be captured and will enable a rich understanding of remote data collection methods in this study population and context.

future controlled study to assess intervention effectiveness in reducing the patient interval for vague cancer symptoms. The results will be critical to informing national policy and practice regarding behavioural interventions to support RDCs in highly deprived populations.

BACKGROUND

Late-stage diagnosis of cancer contributes to poor survival rates in the UK.^{1 2} Improving cancer diagnosis and time of starting treatment through diagnostic pathways have been an important component of recent national strategies.³ The Model of Pathways to Treatment outlines the patient intervals, which include symptom appraisal and help-seeking.⁴ These intervals represent the time

from detecting a bodily change to recognising a reason to discuss the symptoms with a healthcare professional (appraisal interval), through to the first consultation with a healthcare professional (help-seeking interval). The time taken to appraise symptoms and then seek help, along with symptom management within primary and secondary care, are key determinants of cancer outcomes.⁵ A lack of symptom awareness, negative beliefs surrounding cancer outcomes, barriers to symptom presentation and poor awareness of cancer risk can all lengthen the patient interval.^{6–11} While there are high levels of public awareness for classic alarm symptoms such as unexplained lumps and bleeding, awareness of vague cancer symptoms (such as fatigue, abdominal pain, unexplained weight loss) is poor and, when combined with fear of cancer and fatalism, may contribute to longer patient intervals in socioeconomically deprived populations.¹²

Rapid diagnostic centres (RDCs) aim to expedite investigation of vague cancer symptoms by reducing structural barriers to early diagnosis.^{13–19} General practitioners (GPs) can refer adults over the age of 18 directly from primary care to the RDC for further investigation when cancer is suspected, but no cancer-specific ‘red flag’ symptoms that warrant referral to a site-specific cancer pathway are present. The effectiveness and cost-effectiveness of RDCs have previously been established.^{13 18 20} However, to facilitate earlier diagnosis for people experiencing vague symptoms, targeted behavioural interventions to reduce the patient interval (ie, symptom appraisal and help seeking) are needed.

Cancer symptom awareness campaigns designed to raise awareness of vague symptoms and counteract negative beliefs about cancer are required to reduce the patient interval in those from a low socioeconomic background.^{21 22} Previous research on use of community symptom awareness campaigns as a mechanism to reduce late-symptom presentation²³ demonstrated the benefits of campaign exposure on symptom presentation and earlier cancer diagnosis.^{24–30} Mass media symptom awareness campaigns can improve GP attendance and referrals for suspected cancer symptoms at a population level³¹; however, these interventions may not be as effective in reaching disadvantaged populations. Targeted behaviour change interventions can improve cancer symptom awareness and presentation in communities most affected by cancer, particularly through the mechanism of social influence.^{32–34} For example, research with a highly deprived UK sample emphasised the importance of a personalised cancer awareness intervention delivered by a trusted lay advisor as a way to improve symptom awareness and encourage earlier help-seeking.^{32 34}

Building on relevant strategies developed in cancer awareness interventions for underserved populations and in line with the updated Medical Research Council (MRC) Framework,³⁵ we will test the acceptability and feasibility of delivering and evaluating a novel, targeted community-based vague cancer symptom awareness campaign to support the RDC pathway.

Aims and objectives

The aim of the study is to assess the feasibility and acceptability of delivering and evaluating the Targeted Intensive Community-based campaign To Optimise Cancer awareness (TIC-TOC) intervention, to determine progression to a future effectiveness trial. The indicative primary outcome measure is the proportion of completed self-report patient interval data. Secondary objectives are to:

1. Assess the feasibility and acceptability of delivering the intervention.
2. Assess the feasibility and acceptability of data collection.
3. Inform data collection requirements for a potential future trial.
4. Investigate the feasibility of collecting data required to undertake a full health economic evaluation in a future trial.

METHODS

Study design and setting

The study will take place between July 2021 and May 2023. We will undertake a mixed-methods feasibility and acceptability study of a targeted cancer symptom awareness campaign. The study will take place at two sites within Wales. Cwm Taf Morgannwg University Health Board (UHB) has been selected as the intervention site and Swansea Bay UHB will be the comparator area. Study sites were selected because they have an active RDC and are areas of high socioeconomic deprivation, with similar deprivation indices.³⁶

Intervention

TIC-TOC is a multifaceted community-based campaign and was developed to optimise entry into the RDC by reducing the patient interval among adults aged over 18 years living in Cwm Taf Morgannwg. The intervention was previously codeveloped and user tested with local stakeholders during January 2019–August 2019 to communicate key messages and highlight six target symptoms: unexplained weight loss, loss of appetite, nausea, persistent fatigue, abdominal pain and ‘feeling different from your usual self’ (online supplemental appendix).

Campaign materials, including poster (figure 1), leaflet and animated video, have been developed and refined through an iterative codevelopment process for adults aged 18 years and over living in a socioeconomically deprived area. The intervention has been theoretically underpinned by the COM-B model³⁷ to increase knowledge of vague cancer symptoms (capability), encourage social diffusion of intervention messages (motivation), modify negative beliefs about cancer (motivation), harness the relational aspects of help-seeking (motivation), provide social support (opportunity) and increase access to a revised referral pathway (opportunity). Initial content and format were derived from existing reviews of barriers to symptom presentation¹² and cancer awareness interventions in deprived communities.^{32 33}



Figure 1 TIC-TOC Campaign poster. Produced by and with permission from *Tiny Wizard Studio Ltd*.

GP, general practitioner; TIC-TOC, Targeted Intensive Community-based campaign To Optimise Cancer awareness.

The intervention is being delivered over a 9-month period (July 2021–March 2022) using multiple dissemination channels, including targeted media-based advertising and community-based advertising, and involving trained lay cancer champions (online supplemental appendix 1) to deliver intervention messages in community settings and online (table 1). Cancer champions will identify community venues of high footfall to distribute intervention materials, prompt symptomatic presentation through opportunistic discussions, deliver educational sessions and engage with pharmacies when delivering TIC-TOC-branded campaign pharmacy bags. They will collaborate with the Health Board and local community third sector organisations to support planning and delivery of engagement activities. Intervention components, mode of delivery and their rationale for inclusion are detailed in table 1. Adaptations to the intervention materials were conducted in line with COVID-19 messaging using preliminary findings from the COVID-19 Cancer Attitudes and Behaviour Study.³⁸ Adaptations included the addition of face masks to campaign characters and changes to wording (eg, ‘contact your GP’ instead of ‘visit your GP’).

Patient and public Involvement

The study team includes two patient/public research partners who will provide input and knowledge at each stage of the study. The research partners have been important for the initial development and set-up of the study. They have provided detailed input on the protocol development and public-facing materials (eg, cancer champion training, poster/leaflet design, questionnaire design and topic guide development) as well as generating ideas on how to engage the target population and support data interpretation. A patient and public involvement representative from the Study Steering Committee will also provide input and knowledge throughout the study.

Outcomes

The indicative primary outcome measure will be the proportion of completed self-report patient interval data questionnaires, with consent rates of $\geq 25\%$ and proportion of missing data $< 20\%$ demonstrating acceptability for progression (table 2). The study’s secondary objectives are to:

- ▶ Assess the acceptability and feasibility of data collection in relation to the following questionnaire measures:
 - Adapted self-reported patient interval (C-SIM) using exact dates where available and estimated dates otherwise.³⁹
 - Participant awareness of cancer symptoms (Cancer Awareness Measure).⁴⁰
 - Participant quality of life (EQ-5D-5L questionnaire).⁴¹
 - Participant healthcare resource use (adapted Client Service Receipt Inventory).⁴²
 - Participant demographic information.
 - Participant smoking and comorbidities including personal experience of cancer.
 - Participant awareness of campaign messages and contamination in the comparator area.
- ▶ Assess the feasibility of delivering the intervention through:
 - Cancer champions.
 - Targeted media-based advertisements.
 - Targeted community-based advertisements.
- ▶ Inform data collection requirements for a potential future trial including the feasibility of collecting linked data by assessing the logistics and acceptability of accessing:
 - Referral rates and the number of cancer/non-cancer diagnoses through the RDCs in the intervention and comparator area.
 - Referral rates and the number of cancer/non-cancer diagnoses through urgent and non-urgent suspected cancer pathways and emergency departments including inpatient, outpatient and emergency departments and cancer registration data in the intervention and comparator areas.

Additionally, compliance to the intervention will be monitored by capturing data on footfall at community

Table 1 Intervention components

Intervention component (mapped onto the COM-B model ³⁷) and rationale	Mode of delivery	Messaging and rationale
1. Prompt earlier presentation with vague cancer symptoms (behaviour).	1. Public facing campaign* leaflet, animated video, events/discussions with cancer champions	<ul style="list-style-type: none"> ▶ Messaging to prompt symptomatic individuals to seek medical help from their GP. ▶ Include information on the timing of the symptoms, based on feedback from stakeholders during co-development: <i>'If you have any of these for 3 weeks or more, contact your GP'</i>.
2. Increase knowledge of vague cancer symptoms (capability). Poor symptom knowledge in deprived communities is associated with prolonged help-seeking ³² .	2a. Public facing campaign*	<ul style="list-style-type: none"> ▶ Focus on the four most common presenting symptoms at the RDC and Danish 'three-legged model'¹³ to reduce the number of symptoms presented: <i>'feeling more tired than usual'</i>, <i>'tummy pain most of the time'</i>, <i>'losing weight for no reason'</i>, <i>'feeling sick for no reason'</i>. Include <i>'if you feel that something just isn't quite right'</i> due to feedback from stakeholders during co-development phase of the intervention.
	2b. Leaflet, animated video and events/discussions with cancer champions	<ul style="list-style-type: none"> ▶ Describe vague symptoms. ▶ Due to feedback from stakeholders during co-development, include a disclaimer that these vague symptoms are not the only cancer symptoms. ▶ Illustrate symptoms on animated video for example, an image of someone with trousers that are too big for <i>'losing weight for no reason'</i>.
3. Modify negative beliefs about cancer (motivation). Fear and fatalism about cancer are associated with prolonged help-seeking in deprived communities. Fear of cancer treatments and misconceptions about cancer influence help-seeking. ³²	3a. Public facing campaign*, leaflet, animated video, events/discussions cancer champions	<ul style="list-style-type: none"> ▶ Messaging requires a treatment focus (ie, <i>'If cancer is found earlier it is easier to treat'</i>) and stigma focus (ie, <i>'Cancer isn't what it used to be'</i>). Concepts combined to: <i>'Be in control of your health. Finding cancer early saves lives. Cancer treatments are more successful if they are started earlier.'</i> The strapline <i>'Be in control of your health'</i> was developed with stakeholders during co-development because of public perceptions that cancer is a death sentence and something that is out of their control. ▶ Stakeholder feedback: avoid phrases such as <i>'catching cancer early'</i> (may reinforce the belief that cancer is contagious) or <i>'don't wait too late'</i> (may increase fear/anxiety about cancer).
4. Reinforce the relational aspects of help-seeking using emotional appeals (motivation). Relationships are a key motivator to help-seeking in the target population through (1) trusting relationships with GPs perceived as welcoming and non-judgmental and (2) the need to maintain good health to care for family. Not feeling worthy of seeking medical help is a key barrier to help-seeking in deprived groups. ³² Interventions are required to increase self-worth and legitimise help-seeking by encouraging symptomatic individuals to seek medical help with symptoms	4a. Public facing campaign*	<ul style="list-style-type: none"> ▶ Images including a friendly GP talking to a patient and/or cartoon characters to depict relationships with friends and family. ▶ Include a range of characters (diverse age and gender) to increase relatability. Stakeholders during co-development preferred characters that appeared representative of the local population. ▶ Social diffusion- include information to prompt people to encourage others in their social network to seek help.
	4b. Leaflet	<ul style="list-style-type: none"> ▶ Use images in addition to wording such as <i>'help your GP to help you'</i> due to perceptions of not wanting to burden the doctor. Explicitly acknowledge that worry about wasting the doctor's time is a barrier to help-seeking and provide practical tips to overcome this barrier.
	4c. Cancer Champions	<ul style="list-style-type: none"> ▶ Provide social support for isolated individuals.

*Public facing campaign includes the following modes of delivery: posters in community centres, posters on buses, targeted Facebook advertising, local radio and newspaper adverts, adverts on local community platforms and printed pharmacy bags. Some of these were changed to be delivered virtually in line with infection control measures during the COVID pandemic.
COM-B model, The Capability, Opportunity, Motivation, Behaviour model; GP, general practitioner; RDC, rapid diagnostic centre.

and online events attended by cancer champions; placement of posters in community venues, supermarket billboards and buses; distribution of pharmacy bags and Facebook metrics (eg, reach of and engagement with targeted advertising). Feasibility parameters and progression criteria are outlined in [table 2](#).

Screening and consent

It was originally envisaged that participants would be approached to participate in the study at the RDC and would be given a paper-based questionnaire to complete. However, as a result of COVID-19 social distancing requirements, patient recruitment and data collection procedures have been adapted, and a more flexible approach to the recruitment methods will be used.

Questionnaire study

All consecutive RDC patients in the intervention and comparator areas will be invited to participate. Patients will be approached by RDC staff during a phone call to book their appointment at the clinic. Staff will gain verbal

consent from potential participants to share their contact details (including name of patient, phone number(s) and date they are due to attend RDC clinic) with the study team. RDC staff will share a list of eligible participants, including names and contact details, via a secure platform to the study team who will be responsible for contacting the potential participants.

An initial phone call will be made to the patient with a view to arranging a convenient time to complete the questionnaire, preferably at the time of the initial phone call and before the patient attends their appointment at the RDC. The preferred method of sending the information sheet will be via email; however, options to receive it via text, a website link or post will also be available. If participants are due to complete their questionnaire in a very short time frame (ie, one that would not allow for sending the participant information sheet), the information will be read out on the telephone and also sent to them via their desired method. Verbal consent will be taken over the phone and potential participants will have

Table 2 Feasibility of delivering TIC-TOC intervention

Feasibility parameter	Method of measurement	Progression criteria
Contamination	Self-report questionnaire data of RDC participants in the comparator area	Low contamination to the comparator area and percentage of people referred who are aware of the intervention: Satisfactory<10% Review in phase 4 10%–20% Fail>20%
Consent provided	Consent rates for study participation	Percentage of patients consenting to participate: Satisfactory≥25% Review in phase 4 15%–24% Fail<15%
Acceptability of questionnaire	Rates of missing data and qualitative interviews with participants	Percentage of the patient questionnaire with missing data (overall): Satisfactory<20% Review in phase 4 20%–40% Fail>40%
Feasibility to collect cost data to inform health economics analysis	Availability and access to intervention implementation costs	Percentage of missing data: Satisfactory<20% Review in phase 4 20%–40% Fail>40%
	Availability and access to subsequent healthcare costs	Percentage of missing data: Satisfactory 20% Review in phase 4 20%–40% Fail>40%
	Assessed by reviewing availability, feasibility and acceptability of patient quality of life measurement	Percentage of participants who completed the questionnaire: Satisfactory>50% Review in phase 4 30%–50% Fail<30% Percentage of missing data: Satisfactory<20% Review in phase 4 20%–40% Fail>40%
Feasibility of delivery	Delivery of targeted media-based adverts	Percentage of targeted media-based adverts placed: Satisfactory >75% Review in stakeholder workshop 50%–75% Fail<50%
	Delivery of targeted community-based adverts	Percentage of targeted community-based adverts distributed: Satisfactory>50% Review in phase 4 30%–50% Fail<30%
	Engagement in the cancer champions' role	Five cancer champions recruited, trained and in post for campaign duration: Satisfactory>75% Review in phase 4 50%–75% Fail<50%
Acceptability of intervention	Acceptability of intervention collected using qualitative data (members of the public and study managers)	Assessed via review of key themes by the Project Management Group
Acceptability of cancer champion role	Acceptability of intervention collected using qualitative data (cancer champions)	Assessed via review of key themes by the Project Management Group
Intervention reach	Footfall at events	Percentage of uptake of public approached: Satisfactory>25% Review in phase 4 15%–25% Fail<15%
	Posters in community venues	Percentage of placement of posters in community venues in the two lowest deprivation quintiles: Satisfactory>50% Review in phase 4 30%–50% Fail<30%
	Engagement with media-based advertising	Review of the total numbers of public engaged
	Demographic data from patients attending the RDC in the intervention area	Percentage of patients attending the RDC in the intervention who are in the two lowest deprivation quintiles: Satisfactory 50% Review in phase 4 30%–50% Fail<30%

Continued

**Table 2** Continued

Feasibility parameter	Method of measurement	Progression criteria
Feasibility to link to routinely collected data	Permission from RDCs, SAIL to access referral and routine data	Yes/no
	Description of governance requirements and assess if feasible in a full-scale trial	Yes/no
	Access to full set of codes to measure referral rates and cancer/non-cancer diagnoses	Yes/no

RDC, rapid diagnostic centre; SAIL, Secure Anonymised Information Linkage.

the opportunity to ask questions prior to completing the questionnaire. Evidence of consent will be logged on the online database on participants' behalf after verbal consent is obtained. If no contact is made after a fifth attempt, then consent will be assumed as declined. At the end of the questionnaire, participants will have a further option to consent to be contacted to take part in a qualitative interview.

Qualitative study

Potential participants will go through the same consent process carried out in the quantitative study. For the qualitative interviews and focus groups, consent will be taken over the phone or in-person depending on COVID-19 restrictions. Interviews and focus groups will explore the acceptability and feasibility of the intervention campaign and evaluation. Interviews will be conducted with patient participants from the intervention and comparator sites to assess potential contamination of other cancer symptom awareness publicities/campaigns. Within the intervention area, acceptability and feasibility will be further explored with interviews with healthcare professionals, cancer champions and the cancer champion managers. There will also be up to two focus groups (or interviews depending on COVID-19 restrictions) with the general public from the intervention area.

Data collection

Cross-sectional questionnaires will be administered to consenting participants who were referred to the RDC in the intervention and comparator areas. A data management plan will outline data collection, management and storage. All data collected will be managed in strict confidence and in accordance with the General Data Protection Regulation (EU 2016/679). Consenting participants will complete the questionnaire over the phone and data will be collected electronically on Online Surveys⁴³ via a computer. Researcher(s) facilitating questionnaire data collection from participants will also keep a diary noting any issues and successes they have during this process to ascertain feasibility of telephone-based data collection.

Up to 30 intervention and 10 control area, patient participants will be recruited for the patient interviews or until data saturation is reached. Post-training and

post-intervention delivery interviews (n=10) will take place with the cancer champions. Ten primary care staff will be interviewed, along with 10 healthcare professionals representing different stages of the referral and care pathway (including community pharmacists and RDC staff). Two focus groups (n=6–8 in each group) with members of the public in the intervention area who have not been referred to the RDC will be conducted. Study managers who train and oversee the cancer champions will also be interviewed. Topics to be explored in the qualitative component of the study are detailed in table 3.

Focus group methodology will enable participants to be shown a slideshow of the intervention materials during data collection to aid recall and prompt discussion about acceptability and influence on awareness/behaviour. Additionally, focus group methodology will help to identify areas of group consensus/discord. Interview data will be collected via telephone, and focus group data will be collected via Microsoft Teams or Zoom or in-person if COVID-19 restrictions allow. Participants will be given a shopping voucher or reimbursed for their time.

Participant selection

All participants must meet the following eligibility criteria:

- ▶ Aged 18 years and over.
- ▶ Either live in the intervention or comparator sites and have been referred to the RDC (questionnaire and/or patient qualitative interviews).
- ▶ Trained as a cancer champion for the study (the cancer champion qualitative entry and exit interviews).
- ▶ A primary care practitioner working in the intervention area for at least 6 months and able to refer to an RDC (primary care interviews). Sampled based on RDC referral rates.
- ▶ Live in the intervention area (public focus group/interviews). Convenience sampling will be conducted via community contacts in Cwm Taf UHB, for example, third sector and Public Health.
- ▶ Either work in the intervention or comparator area for at least 6 months (healthcare professional focus groups/interviews). Community pharmacists will be sampled using convenience sampling through cancer champions and health board links.

Table 3 Topics to be explored during qualitative data collection by participant group

Topic	Qualitative data sources						
	Interviews with RDC patients (n=30)	Interviews with patients from comparator site (n=10)	Serial interviews with cancer champions (n=10)	Interviews with primary care staff (n=10)	Interviews with healthcare professionals (RDC staff and community pharmacists) (n=10)	Focus groups with members of the public (n=2)	Interviews with study managers (n=2)
Exposure and recall of campaign components	X	X	X	X	X	X	
Acceptability and perceived usefulness of intervention components	X	X	X	X	X	X	
Suggestions for campaign improvements	X	X	X	X	X	X	
Perceptions of presenting to GP with vague cancer symptoms	X	X	X		X	X	
Acceptability of data collection methods for evaluation	X	X	X	X	X	X	
Acceptability and feasibility of being referred to the RDC service	X	X					
Acceptability and feasibility of referring patients to the RDC service				X	X		
Influence of the campaign on awareness and behaviour	X	X	X	X	X	X	
Impact of the intervention across time (start, middle and end phases)	X	X	X	X	X	X	
Sustainability of the cancer champion role			X		X		X
How to embed the cancer champion role into existing strategies with current resources			X		X		X
Feedback on training and suggestions for training improvements			X				X
Acceptability of following up future participants using routine data	X	X	X	X	X	X	

GP, general practitioner; RDC, rapid diagnostic centre.

- ▶ Study managers who oversaw the cancer champions, for example, training and day-to-day support (qualitative interviews with TIC-TOC study managers).

Exclusion criteria:

- ▶ Non-English speakers.
- ▶ Unable to provide written or verbal informed consent.

Stakeholder workshop

Stakeholders including third sector and community partners, patient and public representatives from England and Wales, healthcare professionals, service planning leads and academics will be identified through existing contacts, collaborators, health board staff and Public Health Wales. The workshop will involve a facilitated discussion of organisational barriers/enablers to implementing and evaluating the campaign, including potential redesign of the intervention materials to other geographical contexts, sustainability of the cancer champion role and barriers to data collection. Focus group methodology will be used to review study findings against feasibility parameters, identify areas of agreement and disagreement and discuss next steps.⁴⁴ With permission, the meeting will be audio-recorded and transcribed.

Findings will be used to inform decisions about whether to progress to full trial.

Sample size

This feasibility study will determine response rates, estimates of effect sizes and intracluster correlation coefficients for the C-SIM to inform a phase III trial sample size calculation. Based on previous studies,^{45–47} we estimate that a 25% recruitment rate is acceptable to warrant future trial progression. Based on an average 60 patients per month accessing Cwm Taf Morgannwg UHB (Rhondda Cynon Taf and Merthyr but excluding Bridgend) RDC, approximately 360 patients in the intervention area will be invited to participate during the 9-month intervention period and 90 (25%) anticipated to consent to the study. Approximately, 396 patients in the comparator area will be invited to take part in the questionnaire study, based on an average 66 patients per month accessing Swansea Bay RDC, and 99 (25%) are expected to consent to the study. If we identify 756 eligible participants over both areas, we will be able to estimate a participation rate of 25% (n=189) within a 95% CI of +/-3.1%.

ANALYSIS

In accordance with feasibility study design, we will assess the feasibility and acceptability of conducting a full-scale effectiveness trial against feasibility parameters and progression criteria (table 2).

Quantitative analysis plan

The reporting of findings will be in accordance with the Consolidated Standards of Reporting Trials guidelines for pilot and feasibility trials.⁴⁸ We will report the numbers (%) of patients screened, eligible and consented and the completion rates of questionnaires for the intervention and comparator areas. We will characterise the patients recruited by study area according to age, sex, education, deprivation, ethnicity, relationship status, smoking status, comorbidities and cancer experience. Intervention reach (or contamination in the comparator area) will be assessed by the number (%) of individuals by area that have seen, heard or read any adverts, publicity or other types of information in the 9 months of intervention delivery, which focused on cancer. The acceptability of the questionnaire will be assessed from the proportion of completed self-report patient interval data and the secondary outcomes. Descriptive analysis of the questionnaire data and measures will be conducted (numbers (%), median alongside 25th to 75th centiles), including 95% CIs to estimate differences between groups to inform the sample size calculation for a definitive trial. We will describe outcomes by age, gender, ethnicity, comorbidities and education. The acceptability of linking to routine data for a potential future trial will be reported. A detailed statistical analysis plan will be written and signed off prior to analysis.

Qualitative analysis plan

Interviews, focus groups and the stakeholder workshop will be audio-recorded, transcribed verbatim and analysed thematically. Twenty per cent of transcripts will be dual coded to agree coding schedule and assess consistency. Analysis will explore which aspects of the intervention were acceptable to participants, which were feasible to implement and why as well as participant experiences of cancer symptom awareness campaigns. A qualitative data collection and analysis plan will be developed and signed off ahead of data collection and will be frequently reviewed throughout data collection and analysis.

Health economic analysis plan

The health economic component of the study will assess the feasibility of healthcare resource use and quality of life data collection (including a descriptive analysis of missingness, retention and acceptability to patients) to inform a future health economic evaluation and identify the most appropriate analysis framework (eg, cost-effectiveness analysis, cost-utility analysis, cost-consequences analyses). We will also establish the feasibility of gathering all data required to estimate the incremental cost per meaningful reduction in patient interval (according to the planned

primary outcome of a full-scale trial) and incremental cost per quality-adjusted life-year gained in a definitive trial. Availability of published unit costs and finance records will be tested.

We will explore the availability of and access to relevant data required to estimate the costs associated with intervention implementation and potential changes in healthcare resource use following implementation to determine the feasibility of data collection, including intervention implementation costs. Availability and access to subsequent healthcare costs as well as availability and completeness of outcome data (eg, EQ-5D-5L responses) will be assessed. Additionally, we will explore the potential of other outcomes to inform cost-effectiveness analyses and determine a suitable framework for a health economic evaluation in a definitive trial based on the feasibility data.

Ethics and dissemination

Ethical approval for this study was given by the London—West London & GTAC Research Ethics Committee on 29 June 2021, reference number 21/LO/0402. This study has been categorised as low risk. There are no expected adverse events related to the intervention or research procedures and adverse events will not be collected. It may be possible, due to the sensitivity of the topic, that some participants may become distressed while participating. Participants reporting distress will be provided with contact details for the research team and appropriate support organisations as well as signposted to their GP. Participants who become distressed during questionnaire data collection will be reassured and reminded to take their time to answer or that they can skip a question or topic. They will be given the opportunity to take a break and, if required, to stop the questionnaire or interview. The cancer champions and researchers completing data collection will be given training on how to deal with any distress that arises in their conversations with members of the public. They will also be given support by the study team if they feel distressed by their experiences of working on the study.

We will work in partnership with Cancer Research Wales to maximise the potential impact of this study to inform policy recommendations and present findings to lay, academic, clinical and policy audiences. A publication policy has been developed to support dissemination and will provide all study team members with an opportunity to volunteer their ideas and input on planned dissemination. The publication policy will be discussed at regular meetings and updated when necessary.

DISCUSSION

This study aims to explore the feasibility and acceptability of a multifaceted behavioural intervention to improve vague cancer symptom awareness and help seeking in an area of high socioeconomic deprivation. The intervention comprises of lay cancer champions who deliver messages on cancer symptom awareness and early diagnosis to

optimise the pathway into RDCs and improve timely diagnosis of cancer. Intervention materials and messages were coproduced with local stakeholders in Cwm Taf Morgannwg, Wales. Cancer champions (lay members of the local community) have been trained to deliver intervention messages and distribute intervention materials using broadcast media (eg, local radio), outdoor printed media (eg, branded pharmacy bags, posters, leaflets) and social media (eg, Facebook advertisements). This research will build on relevant strategies developed in cancer awareness interventions for disadvantaged populations and in line with the updated MRC Framework.³⁵

The TIC-TOC study was launched against a challenging backdrop of continued COVID-19 restrictions. Our original intention was to collect quantitative data in-person at the RDC and qualitative interviews face-to-face. However, in light of the COVID-19 pandemic and ongoing infection control measures, including changes in the RDC, we were required to substantially alter data collection methods. The feasibility of collecting quantitative and qualitative data via telephone will be captured and will enable a rich understanding of remote data collection in this study population and context. The results will inform optimal methods of implementing and evaluating behavioural interventions to support RDCs in highly deprived populations, during and beyond the pandemic. Findings will be used to inform a potential future trial of effectiveness regarding methods of engaging disadvantaged populations in vague cancer symptom awareness and timely symptom presentation. Results will be critical to informing national policy and practice regarding behavioural interventions to support RDCs, with particular reference to socioeconomically deprived populations.

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Acknowledgements The authors would like to acknowledge the Study Steering Committee members (Chair: Dr Caroline Mitchell; Independent statistician: Professor Victoria Allgar; PPI: Dr Kathy Seddon; Independent expert: Professor Suzanne Scott; Clinician: Dr Brian Nicholson), Professor Richard Neal, Professor Katriina Whitaker and Professor Jon Emery who provide overarching support and oversight of the study conduct. We would also like to acknowledge our lay study members (Ann Maria Thomas and Gareth Newton) for their input on key study documents and intervention material.

Contributors PS and GM are study managers and drafted the manuscript. JT provides senior trial management input. RC-J, HS and BS provide day-to-day statistical and health economic analysis input. RC-J provides statistical expertise and input and supported the sample size calculation and study design. AE provides clinical expertise. ST, CL-B and DC provide expertise and input in study delivery in the RDC and with vulnerable populations. JH and HDQ-S provide qualitative expertise and input and JH maintains an oversight of the qualitative analysis. EC drafted all topic guides and carries out the day-to-day qualitative data collection and analysis. KB and GMM are co-chief investigators and maintain overall oversight and responsibility for the study delivery. All previously mentioned authors and AE, DJ, CL, FVL-W, DH, AW, AMT and GN contributed to the design of the study, have input to the manuscript draft and have read and approved the final version.

Funding The work was supported by Cancer Research Wales (grant number: 2514). This research comes under the auspices of the Health and Care Research Wales funded Primary and Emergency Care Research Centre (PRIME) (517195) and Wales Cancer Research Centre (517190)

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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