ThinkCancer! Participant Information Sheet

Research Project 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

IRAS ID: 316593

Research Investigators: Professor Clare Wilkinson and Professor Richard Neal

Introduction and invitation

Thank you for taking the time to read this Participant Information Sheet (PIS). We would like to invite you to participate in today's ThinkCancer! Workshop.

Please read the following information carefully. Feel free to ask questions about anything that is unclear or that you would like more information about. You can ask any of the researchers present during the workshop or you may contact the research team using the contact details below. This information sheet is for you to keep.

About the study

The ThinkCancer! Study, led by Professors Clare Wilkinson and Richard Neal, is part of a programme of research called the Wales Interventions and Cancer Knowledge about Early Diagnosis (WICKED). The overall aims of the WICKED Programme are to improve the quality and consistency of primary care approaches in order to improve timely diagnosis of cancer.

To achieve this, a practice-focused workshop aimed at changing the knowledge, awareness, attitudes and clinical behaviour of primary health care teams has been developed. The ThinkCancer! workshop consists of three separate sessions, delivered online over half a day each focussing on a different element of cancer diagnosis. The workshop has already been tested on a small scale in a feasibility study, which showed that the workshop is achievable to deliver at scale and that we can collect the type of data needed to properly evaluate it.

The best way to find out if the workshop is effective at improving the speed of cancer diagnosis in general practice is to do a randomised controlled trial comparing the workshop to current usual practice. This is a test where, at random, some practices are chosen to receive the ThinkCancer! workshop and others GP practices follow their own usual practice without any changes. We will then ask staff at both groups of GP practices about their experiences as well as collecting data about patient symptoms and referrals, before comparing the results.

You have received this PIS as your practice has been **randomly allocated to take part in the workshop**.

What will taking part involve?

The ThinkCancer! Workshop will comprise separate, themed sessions for clinical and non-clinical staff covering early cancer diagnosis and cancer awareness respectively. These sessions are followed by a whole-team session focusing on the key elements of a practice-specific Cancer Safety Netting Plan, and the appointment of a Cancer Safety Netting Champion at your practice. This Champion will lead on implementing the Cancer Safety Netting Plan within and throughout the practice. In addition, we will provide a handbook to clinical members of staff containing clinical update information and a summary of the latest NICE guidelines on suspected cancer (NG12, 2015).

Before today's workshop your practice manager will have completed a questionnaire in order for us to understand more about your practice characteristics and current safety netting procedures. We tailor the workshop around the responses to this questionnaire. Active discussion will be encouraged throughout the sessions.

The workshop will be delivered online by a GP Educator, who is also a member of the research team. The GP Educator will be accompanied by up to two other research team members, who may note down observations or quotes that arise during the workshop. For people who are unable to attend the workshop on your practice's chosen day, a pre-recorded version will also be available.

At the end of the workshop, you will be asked to complete an evaluation form, giving feedback on the workshop.

We would like to send practice staff members a questionnaire to better understand their experiences of the workshop and how they went on to use the Cancer Safety Netting Plan in their work.

Do I have to take part?

Participation is entirely voluntary and it is up to you to decide whether or not you would like to take part. If you do decide to take part, you will be asked to sign a consent form. If you are happy for us to approach you later on in the study for questionnaire and a telephone interview, please provide your contact details at the bottom of the consent form. We will email you with further details but cannot contact you without your permission. If you provide your contact details you can still decide later on that you do not want to answer the questionnaire or take part in an interview.

You have the right to withdraw at any point in the study. As this is a feasibility study, we would like to gain as much understanding as possible as to why or why not participants decide to take part. Therefore, we will ask any participants who choose to withdraw or not to participate to let us know why, even if the reason may seem unimportant, e.g. logistical

issues. You are not obliged to answer this question and may decline to participate or withdraw without giving a reason.

To withdraw from the study, please let a member of the research team know at any point during the workshop. Alternatively, you can contact the researchers by phone or by email after the workshop has taken place using the contact details below. Any contact details relating to you will be destroyed. Please note that it will not be possible to remove your data after it has been anonymised and incorporated into the final analysis.

What are the possible benefits of taking part?

We hope that you will find the ThinkCancer! workshop useful and enjoyable and that it will lead to improvements in patient care. The findings from the workshop will be used to improve the ThinkCancer intervention further in the future. Furthermore, the workshop provides a potential learning opportunity for all members of staff taking part.

Participating in research and reflecting upon cancer diagnoses may be an activity that clinical staff are able to include in their appraisal portfolios. Certificates of participation can be provided for all staff upon request. Participating GPs are also eligible to receive up to 2 hours accredited CPD.

Are there any disadvantages or risks of taking part?

We do not anticipate any disadvantages or risks to you for taking part.

Confidentiality, Consent and Use of the Data

With your consent, the workshop sessions may be audio recorded and data may also be collected from observations and the feedback evaluation forms. Audio recordings will be transcribed by an experienced external transcription company, with whom we have a confidentiality agreement in place. Other information collected from you will include your name, contact details and the name of your practice. All data will be kept confidential in line with GDPR and any quotes used in reports, publications, presentations or other communication channels will be anonymised so that individual participants and practices are not identifiable outside the immediate research team. All of the data will be kept safe and secure. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Once the study has been completed, we will keep the data for 5 years so we can check the results. If you would like to find out more about how we use your data, please contact us using the details below.

If you decide you want to take part in the workshop, please initial and sign two copies of the attached consent form. **<Different instruction for online consent form>** We will return one copy for your records. By signing the consent form, you are telling us that you:

- Understand what you have read
- Understand that your participation is voluntary
- Consent to take part in the workshop

- Consent to the research described

There will also be the option to consent to providing your contact details, should you wish to receive future communications about the study and if you are willing to receive a questionnaire.

Who is organising and funding this study?

Bangor University is the study Sponsor. The study is funded by Cancer Research Wales and North West Cancer Research.

Complaints and concerns

Should you have any complaints or concerns about the study, please contact us using the contact details below.

Further information and contact details

Further information about the study can be found on our website:
http://wicked.bangor.ac.uk/ **<Website address being updated>**

Please feel free to contact us using the contact details below:

<Trial Manager and RPSO contact details will be included here – TBC>

This study has been reviewed and approved by the Heath Research Authority, Health and Care Research Wales, the Bangor University School of Health Sciences Ethics Committee and local health board R&D department.

Thank you for considering your participation in this workshop.