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

Thank you for taking the time to read this Participant Information Sheet (PIS).
Please read the following information carefully. Feel free to ask questions about anything that is unclear or that you would like more information about using the contact details below. This Participant 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 - focussing on cancer awareness, cancer diagnosis and cancer safety netting. 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 practices that have received the workshop to usual practice. This is a test where, at random, some practices are chosen to receive the ThinkCancer! workshop and others 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 been given this PIS as your practice has agreed to take part in the ThinkCancer! Study and has been **randomly allocate to the control group**. This means that your practice will continue to follow usual practice.

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 are interested in taking part in an interview, please let your practice manager know or contact us directly (details can be found below). We will email you with further details and arrange a convenient date and time.

If you decide to take part in an interview you have the right to withdraw at any point. 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 anyone who chooses 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. 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?

There will be no direct benefits to you from taking part in the study, but we hope that it will lead to improvements in patients care. The findings from the interviews will help us to understand more about usual practice and may be used to develop the workshops further in the future. In addition, control practices will be able to access the ThinkCancer! workshop materials and a pre-recorded version of the workshop once they have completed their participation in the study.

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 interviews will be audio recorded and transcribed verbatim 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 five 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.

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 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, details can be found 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 taking part in this study.