

Psychological impact of the Galleri[®] test (sIG(n)al)

Protocol for a longitudinal evaluation of the psychological impact of receiving a cancer signal in the NHS-Galleri trial

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Disclosure

GRAIL, LLC, a subsidiary of Illumina, Inc. are funding the project, which includes all study costs as well as my salary in full through a KCL contract.

The product discussed in this presentation has a CE and a UKCA mark, and will be used within its intended use.

In the US, the Galleri test is an Investigational Device and limited by Federal (or US) law to investigational use. A description of this clinical trial is available on www.ClinicalTrials.gov as required by United States (US) Law.

*GRAIL, LLC, is currently held separate from Illumina, Inc. under the terms of the Interim Measures Order of the European Commission dated 29 October 2021

Why assess psychological impact?

“Screening programmes are effectively judged on whether the benefits to those who get earlier treatment outweigh the harms to those people who get treated unnecessarily, or who are subject to unnecessary anxiety.”

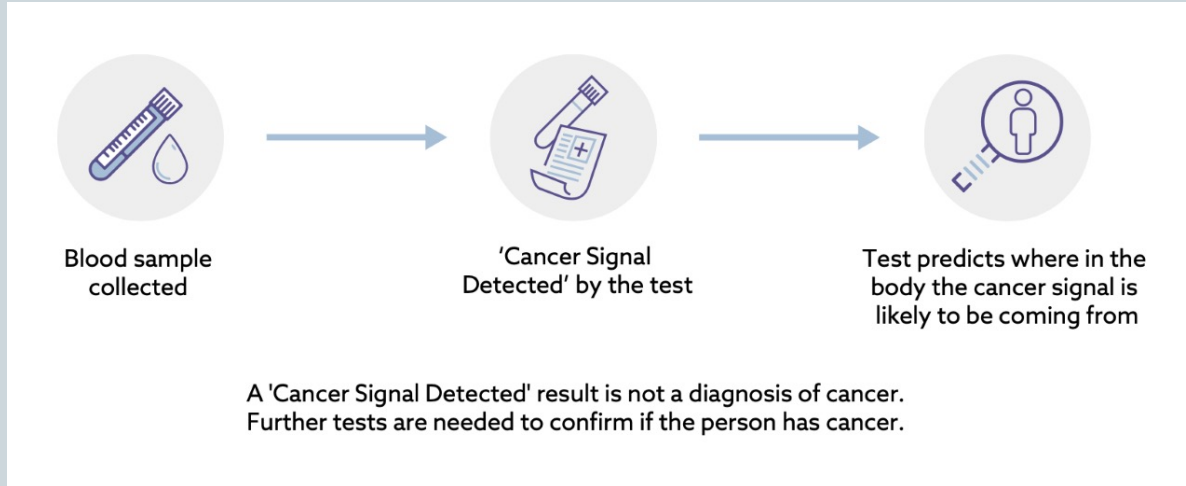
Principles of a national screening programme

1. The screening programme should respond to a recognised need
2. The objectives of screening should be defined at the outset
3. There should be a defined target population
4. There should be scientific evidence of screening programme effectiveness
5. There should be quality assurance, with mechanisms to minimize potential risks of screening
6. The overall benefits of screening should outweigh the harm
7. The programme should integrate education, testing, clinical services and programme management
8. The programme should ensure informed choice, confidentiality and respect for autonomy
9. The programme should promote equity and access to screening for the entire target population
10. Programme evaluation should be planned from the outset

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Multi Cancer Early Detection blood tests



- Uses a simple blood test
- Screens for multiple cancer types
- Complex and varied follow-up after positive screening result
- High test specificity and positive predictive value
- Possible lack of diagnostic resolution

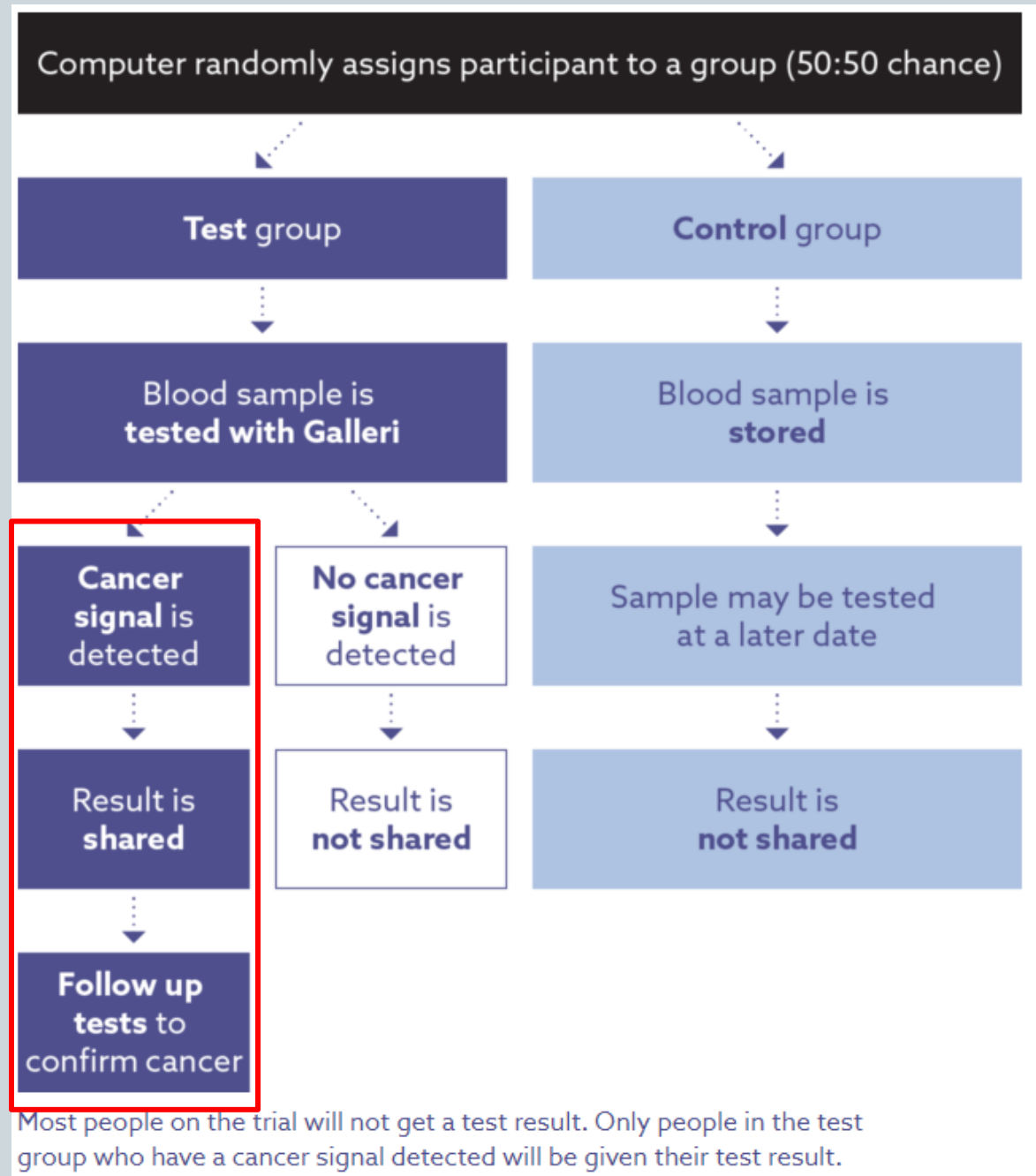
NHS-Galleri Trial



ISRCTN91431511; NCT04241796

More detail about the trial design here: Neal et al. Cancers. 2022. 14(19):4818.

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sIG(n)al objectives

1

To establish levels of anxiety among participants, who have been informed that a cancer signal was detected, shortly after receiving their result

2

To compare longer term anxiety between those subsequently diagnosed with cancer and those who have a diagnostic work-up but no cancer is found, at 6- and 12 month follow-up

3

To explore in depth the experiences of men and women who have a cancer signal detected (using qualitative methods)

Procedure

1st blood test

Cancer signal detected

Phone call with nurse

T1 dispatched with result letter

2-week wait referral pathway

Cancer found OR not found

T2 dispatched 6 months after T1

12-month anniversary of 1st blood test

T3 dispatched 13-15 months after T1 (3 possible versions)

Y1 follow-up attender

Cancer diagnosed

Y1 follow-up non-attender

GRAIL



KINGS COLLEGE LONDON
CANCER PREVENTION
TRIALS UNIT

NHS
Galleri Trial

Psychological Impact of the Galleri Test

Why?

We are interested in people's views and experiences of the Galleri test so we can improve the information and communication we offer to people in the future.

Who?

This survey is sent from King's College London on behalf of the NHS-Galleri Trial and has been asked to complete some of the questions.

What do I need to do?

Simply return the completed survey in the envelope. If you prefer you can also return it by post to <https://edc.grail.com/plog>

This survey is voluntary. Your participation will not affect your care in the NHS-Galleri Trial.

Your data:

Information on how we use your data is on the sheet that came with this survey.

Questions or further information:

If you would like to know more about the survey, please email survey_help@nhs-galleri.com

If you would like to complete the survey in another language, please email survey_help@nhs-galleri.com

By sending your survey to us, you are giving us your consent to use your data for the purposes of the survey.

HOW YOU FEEL RIGHT NOW

A number of statements which people have used to describe themselves are given below.

Read each statement and then tick the appropriate box to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Please make sure you tick only one box for each statement.

Not at all

- I feel calm
- I feel tense
- I feel upset
- I feel relaxed
- I feel content
- I feel worried

YOUR ATTITUDES TO CANCER AND TESTS FOR CANCER MORE GENERALLY

How much do you agree or disagree with each of these statements?

Strongly disagree Tend to disagree Neither agree nor disagree Tend to agree Strongly agree

If someone is meant to get cancer, they will get it no matter what they do

These days, many people with cancer can expect to continue with normal activities and responsibilities

Treatment is very effective in curing cancer

If someone has cancer, it is already too late to get treated

What a person does can determine whether their cancer gets better or worse

Cancer has a major impact on a person's life

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PLEASE ENTER THE PIN

XXX - XXX - XXXX

protected by reCAPTCHA

Privacy Terms

LOGIN

Procedure

2-week wait referral pathway



INTERVIEW STUDY

We would like to talk to some people in more detail about their experiences of taking part in the NHS-Galleri trial.

Are you happy to be contacted about participating in an interview study to talk about your experience?

[If you tick yes, we will send you some more information to help you decide.

We will use your ID number to find your contact details. You do not need to include them with the survey.]

- Yes, please contact me about the interview study
- No, I do not want to participate in an interview study

Interviews planned (n=40)

	Cancer found	No cancer found
Female	N=10	N=10
Male	N=10	N=10

Purposefully sampled to include a range of IMD and age

Primary outcomes

Construct	Validated scale	Timepoints
Anxiety	✓	T1,T2,T3
Emotional, physical and social consequences of screening	✓	T1,T2,T3
	✓	T2,T3
Test-specific concern (single item)		T1,T2 ^a , T3 ^a
Test specific reassurance (single item)		T1,T2 ^a , T3 ^a
Changes in health behaviour		T2, T3 ^a

SPIELBERGER et al. 1983. *Manual for the State-Trait Anxiety Inventory STAI (Form Y)*. Palo Alto, CA: Consulting Psychologists Press.

MARTEAU & BEKKER 1992. *The British journal of clinical psychology*, **31**(3), pp. 301-306.

COCKBURN et al. *Social science & medicine* (1982), **34**(10), pp. 1129-1134.

Secondary outcomes and explanatory variables

Secondary outcomes

Understanding of results
Perceived risk of cancer
Overall experience
Satisfaction with the trial
Satisfaction with care and support
Future intention to have a Galleri test
Decisional regret
Fear of Cancer recurrence

Socio-demographics, health behaviours and experience

Age
IMD
Education
Ethnicity
Born in UK
Marital Status
Smoking/Drinking behaviour
Family experience of cancer
Cancer suspicion

Literacy
Past experience of abnormal screens
Past experience of symptom investigation
Retrospective experience of cancer symptoms
Past experience of anxiety and depression

Cognitions, emotions and behaviours

Information seeking
Coping
Appraisal
Cancer worry
Fatalism
Attitudes to cancer
Unexpectedness
Relief

Clinical outcomes
Cancer diagnosis (ICD-10)
Stage at diagnosis
Treatment

Qualitative materials

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NHS
Galleri Trial

Topic Guide for Interviews

Psychological Impact of the Galleri test

1. Introduction

- Thanks for agreeing to take part
- Introduce self
- Explain what study is about and that interview will last about an hour
- No right or wrong answers.
- Reminder of right to withdraw – confidentiality, anonymity, don't have to answer any questions
- Audio-recording – double check consent.
- Any questions before we start?

2. Interest in the trial

- Can you tell me about why you were interested in the trial?
- How did you find the blood test?
- What did you understand about the test? Any expectations about results?
- Any concerns?

3. Getting your results

- Thoughts/feelings while waiting for your results
- Can you tell me about when you received the result?
- Thoughts/feelings about result
- What did you think the results meant? Expectations about what would happen next

4. Experience of secondary care work-up

- How was your experience of have additional tests after your results? What happened?
- Thoughts/feelings while going through that process?
- Can you tell me about what happened when you found out you had [did not have] cancer? (emotions, expectations re. treatment, feelings about the trial/test, ongoing concerns, understanding of what happens next)

5. Information

- What information do you remember being given before taking part (written or verbally)?
- Thoughts about information provided
- Any information particularly useful? Any information lacking?
- Did you look for information anywhere else (if so where)?
- Suggestions for information needed

6. Looking back at the experience

- Now that you are looking back, how do you feel about taking part in the trial so far?
- How does this compare to other experience of cancer tests/screening?

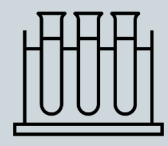
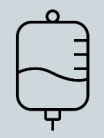
For participants who do not have cancer:

- Thoughts/feelings about having your next blood test at 12 months. Will you go?
- Has your experience changed the way you think about your risk of cancer?
- Any changes in thoughts about going for screening tests in the future?

7. Closing the interview

- Thank you
- Any questions or comments? Anything important to you that you haven't already mentioned?
- Reassure about confidentiality
- What happens next

Data



Jan 2024

Discussion

This work should:

- Improve understanding of the psychological impact of having a cancer signal detected by a MCED test in the context of screening
- Inform the development of procedures, supporting information and interventions to minimise MCED screening-associated anxiety
- Support UK National Screening Committee (UKNSC) recommendations regarding adoption of MCED screening and will support any future roll-out
- Identify if particular population sub-groups may require additional support if MCED testing is implemented at a national level

Limitations of sIG(n)al study

- Volunteer bias where participation requires completion of additional questionnaires
- The trial design has influenced the research questions for the sIG(n)al sub-study
- If MCED testing and return of results is implemented in a different way in practice, our findings may not be fully generalisable

Thank you

Jo Waller

Ninian Schmeising-Barnes

Cancer Prevention Trials Unit

