PPI Influence 11th August 2021

Housekeeping

We are planning on recording this meeting, please let us know if you are not happy with this.

If you're having any problems hearing us you can use the 'chat' function on the right hand side to write a message and alert us to a problem or call Jade (07891348290)

Feel free to a have a mug of tea or coffee handy. Take a break or answer the doorbell, or take a comfort break, as and when you need to.

If there is a lot of background noise during the video call we may mute everyone's microphone just to make it easier for everyone to hear what is being said.

There will be time for questions at the end of each presentation. You can either use the chat function, or speak directly.

What is PPI?

Patient and Public Involvement in research refers to when members of the public work alongside a research team and are actively involved in contributing to the research process.

Public involvement representatives can provide researchers with valuable insights, helping to make health research more relevant to the needs of patients, carers and service users.

Patients and the public can become involved in all stages of the research process including:

- Design and management of studies
- Data collection and analysis
- Dissemination and reporting of findings.

PPI Set Up in the Bristol Trials Centre

Currently we have a Patient Advisory group (PAG), which advises on a wide range of research areas, at a number of different stages of research.

Some studies also have a specific PPI team, who attend study specific meetings.

In the future, we would like to be able to use our PAG as a ‘pool’ of members to approach for new study specific groups.

In this meeting we would like to show you the impact the work you have done with us has had as members of the Patient Advisory Group.

Meeting Agenda	
10:40	Study design: INSPIRE (Dawn Phillips) PURSUIT (Caroline Pope)
10:55	During a study: ARCO (Chloe Beard) SUNFLOWER (Chloe Beard)
11:10	Study Results: VICI (Katie Joyce) ROMIO (Jade Salter-Hewitt)

Any Questions?

PPI feedback in the INSPIRE study

This study was funded by the NIHR HTA Programme (project number 16/140/07). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR HTA or the Department of Health and Social Care.

Study design

Study purpose

- Breathing exercises in patients about to undergo major surgery
- Practice at home for minimum of 2 weeks
- Lung complications after surgery e.g. pneumonia

What is involved?

- Group 1: Breathing exercise leaflet
- Groups 2 & 3: Breathing exercise leaflet **and** breathing device
- Low resistance
- High resistance

INSPIRE PPI

- 3 meetings to date
    - Sept 2018 & March 2019 (in-person)
    - June 2020 (virtually)
- Engaging, dynamic group offered valuable feedback on many aspects of INSPIRE
- Focus today on:
    - Patient Information Leaflet (PIL) layout
    - how the study is presented & explained to patients in terms of the study groups they would be randomised to

IRAS reference: 250345

Inspire

<Trust logo>

Breathing exercises and their effect on lung complications after surgery

This is a summary of the study.

More information can be found in the Patient Information Leaflet on page 2.

Why is the research being done?

Patients who undergo major surgery sometimes develop lung complications after their operation. Lung complications slow recovery and keep patients in hospital longer. We want to know if regular breathing exercises performed **before** surgery can reduce the chances of getting a lung complication. *See page 2.*

What would taking part involve?

Doing breathing exercises **before** surgery.

Complete questionnaires.

You may take part in an optional information study. *See page 3.*

Are there any risks?

There are no known risks involved but if you do have any problems you will be able to contact your local research team.

See page 7.

Can I withdraw from the study?

You can withdraw at any time without providing a reason.

Your medical care will not be affected.

See page 8.

What data will you keep about me, and for how long?

You will be given a unique study number.

We will need your name, date of birth, contact details such as address, phone number and email, NHS number & medical history to do the research and keep in touch with you.

This information will be stored for up to 5 years after the study finishes.

Your data will be stored and used in compliance with current data protection laws. *See page 11.*

Will I benefit?

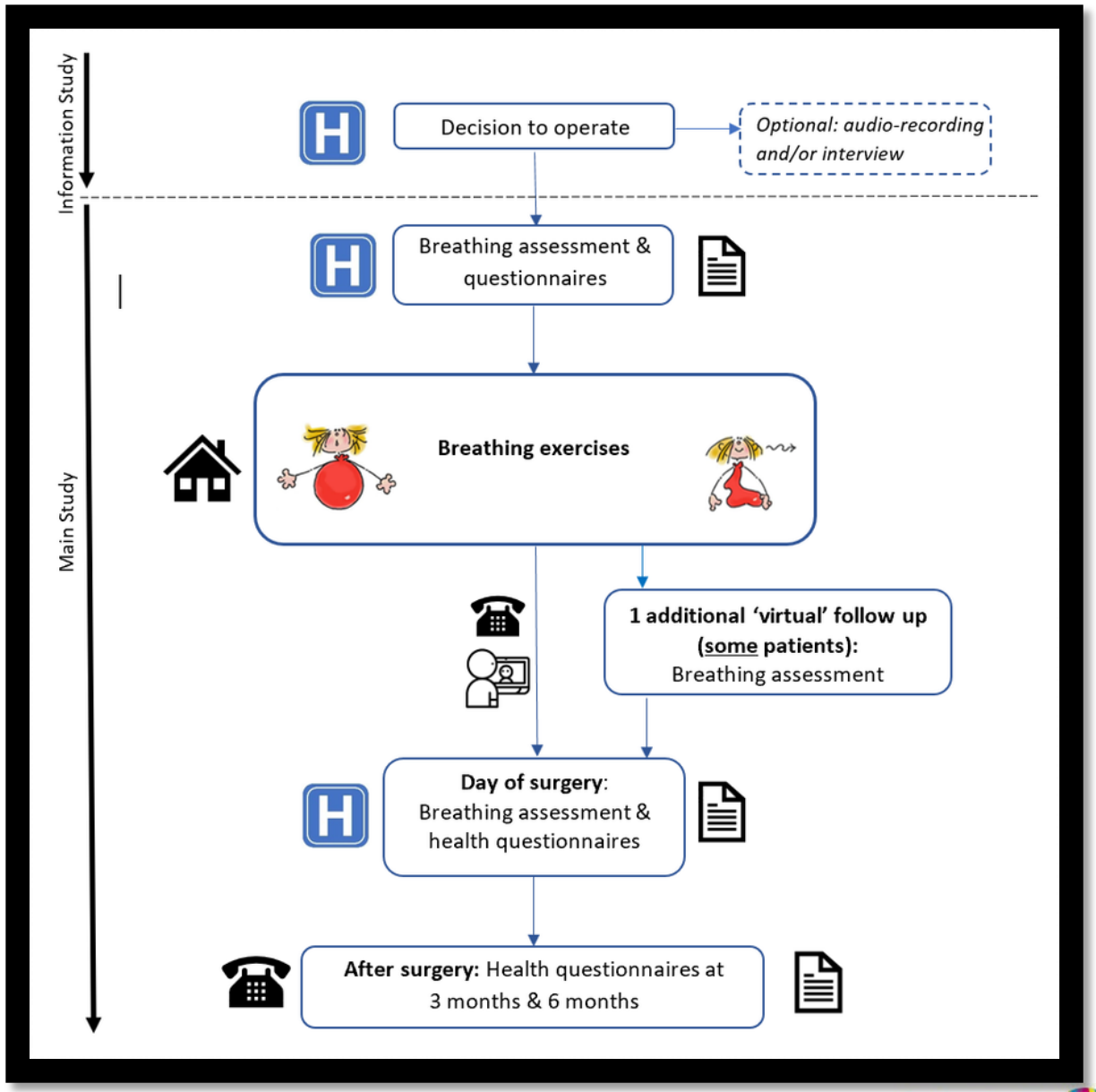
We hope that patients will have fewer lung complications after surgery.

Your recovery time after surgery might be quicker. *See page 7.*

Contact us using the details opposite, or on page 10:

☎ <Name & tel.number>

✉ <email address (if available)>



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Impact of the PPI feedback

Patient Information Leaflet

1. PIL layout suggestions adopted in INSPIRE
2. Adopted by other BTC coordinators for their studies
3. Showcased at staff PPI workshops across Bristol

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Presentation of study groups to patients

1. Research Ethics Committee highlighted dissatisfaction with original study group presentation

   INSPIRE team were able to offer alternative solutions as provided by the INSPIRE PPI team

2. Study successfully approved!

@INSPIRE_Trial

Chief Investigator:
Dr Maria Pufulete

INSPIRE study team:

Dawn Phillips & Mae Hazell

Inspire-study@Bristol.ac.uk

07929 827042 & 07929 827050

Any Questions?

Proper **U**nderstanding of **R**ecurrent **S**tress **U**rinary **I**ncontinence **T**reatment in women

University of BRISTOL
BRISTOL TRIALS CENTRE
NHS North Bristol NHS Trust
Bristol Urological Institute
FUNDED BY NIHR | National Institute for Health Research
TC

What is the PURSUIT study and why is it being done?

- Stress Urinary Incontinence (SUI) is the leaking of urine with physical activity
  - affects ~1/4 women after pregnancy
- Symptoms may come back after treatment – called *recurrent SUI* (or *persistent SUI*)
  - affects quality of life, ability to work and has substantial cost implications

There is no agreement on how best to treat women with recurrent SUI (where their first treatment has failed)

The PURSUIT study is designed to help patients and doctors understand how to treat this (quite common) condition

PPI in PURSUIT

Study Design

Original plan: patients allocated to a specific treatment.

Following PPI: patients are allocated to a treatment group.

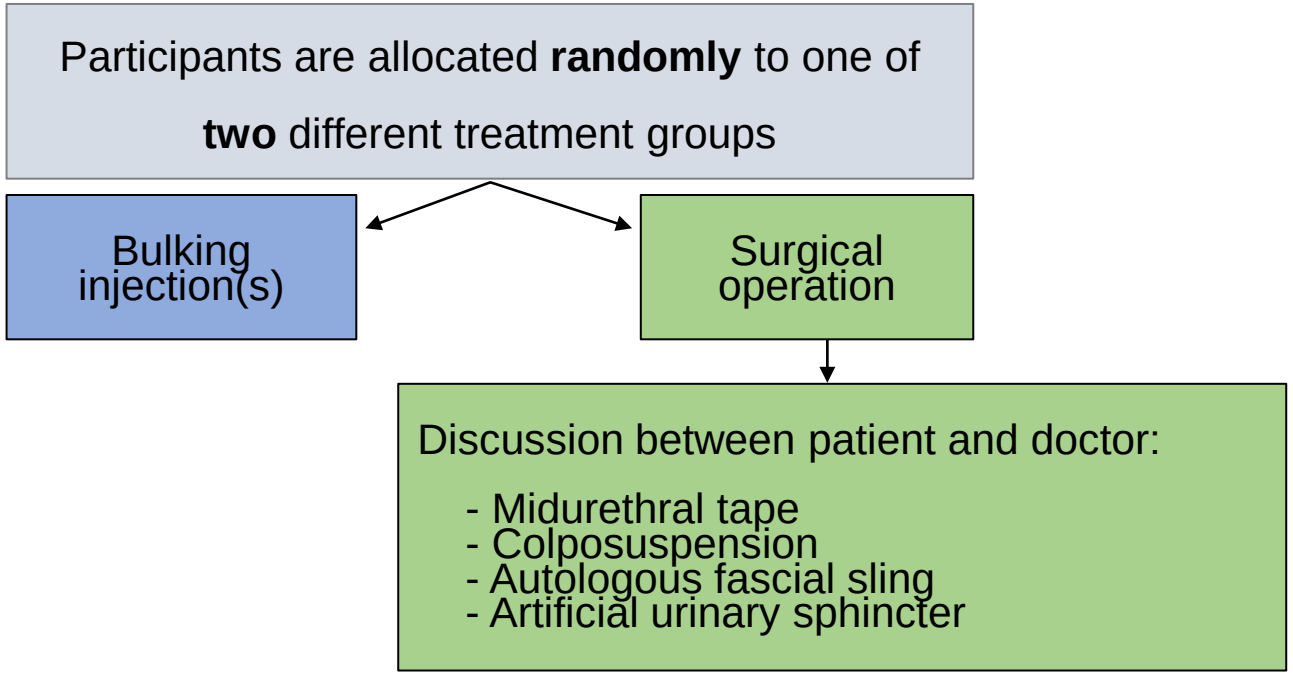
Study Logo

PATIENT ADVISORY GROUP

Study Documents
The PAG group ensured these are easy to read and understand.

PPI representatives
in Trial Management Group and Study Steering Committee

Study design – a clinical trial with 2 'arms'



Main aim

- ✓ To find out whether a surgical operation is better than endoscopic injections – by looking at the patients symptoms (1 year after they are allocated to their treatment group) – Patient Questionnaire

Any Questions?

Patient & Public Involvement (PPI) in the ARCO Consensus Study

What is a Formal Consensus Study?

- Used when evidence is poor - no Randomised Controlled Trials (RCTs)
- Combines the best available evidence with the collective judgement of experts
- ARCO - used to determine which valve choice is best for adults aged 16-60 years with different characteristics (e.g. heart anatomy, existing disease, lifestyle factors, etc.)
    - RCT removes decision from the individual
- PPI fully integrated in the formal consensus process

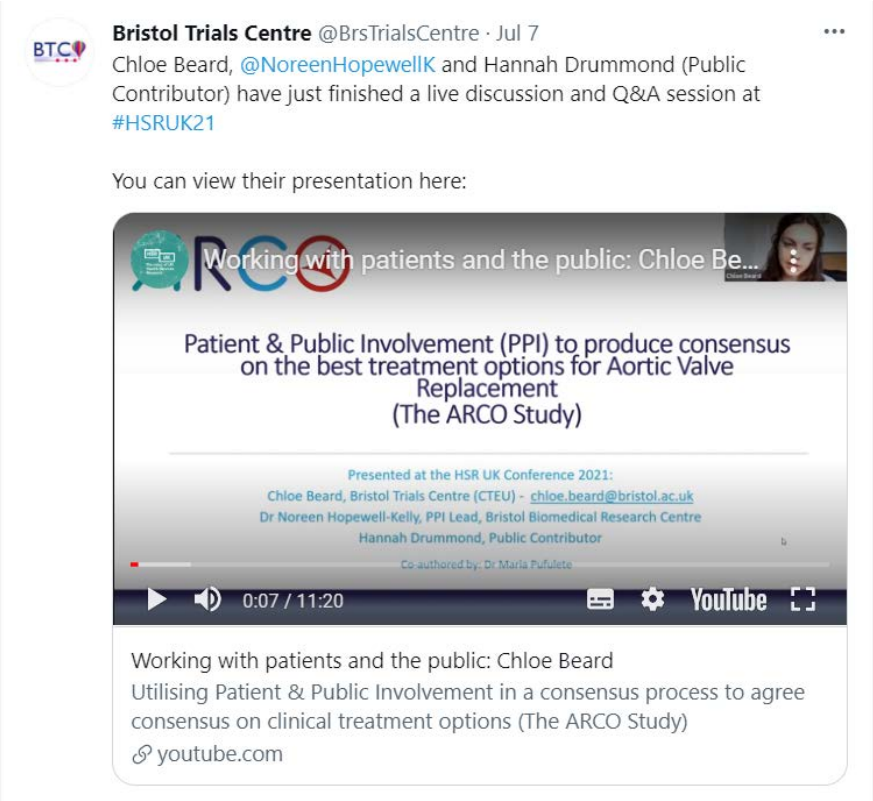
PPI involvement

- Reviewed study survey experts were asked to complete
- Attended formal consensus meeting alongside the experts
- Ensured that clinical scenarios in the formal consensus survey were relevant and representative of the “lived-in” experience
- Identified the most important aspects from the patient point of view on which consensus was needed

PPI involvement continued…

- Most importantly, helped us to develop a template for best practice for PPI in a formal consensus process

- Public Contributor Invited to attend and present at the Health Services Research Conference 2021, alongside members of the study team



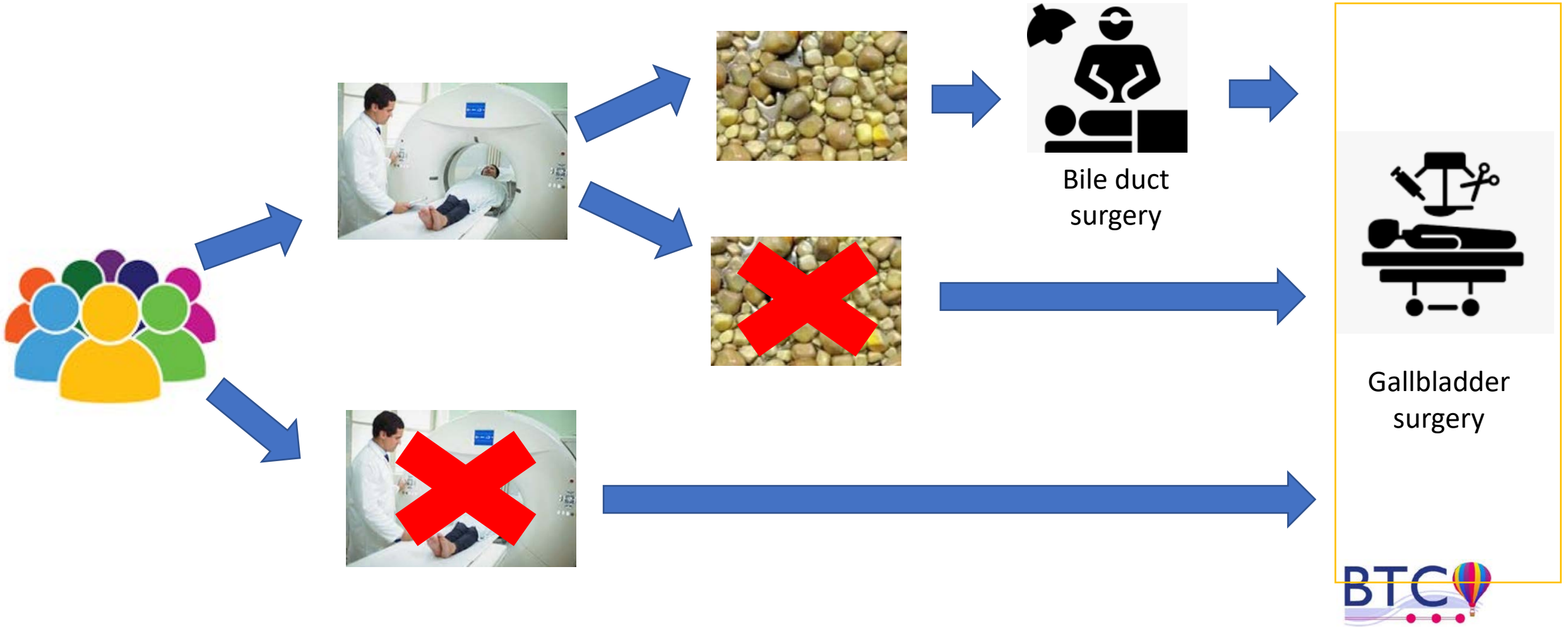
Any Questions?

The Sunflower Study

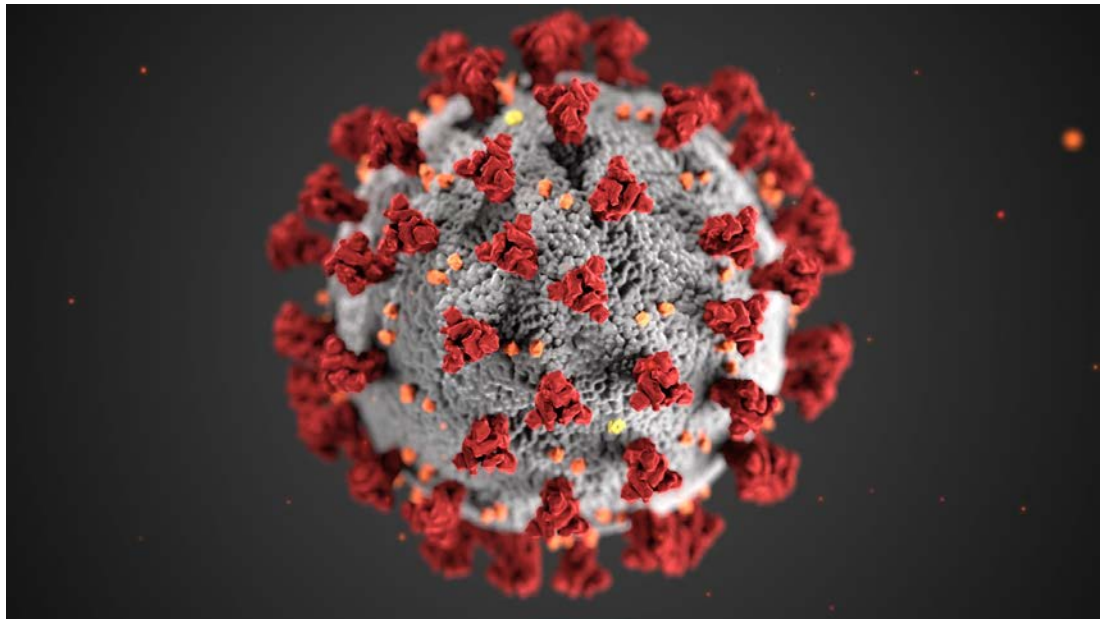
Patient and public involvement

About the study

- Testing whether **testing for bile duct stones** before gallbladder surgery is necessary in patients with low or moderate risk of having stones



Restarting Sunflower during COVID-19 pandemic



- Very supportive
- Trust in hospital staff and processes to protect patients
- No additional information to that already provided

New postal recruitment and consent process

We asked our PPI group:

1. Do you feel that this is an appropriate way to approach patients about Sunflower?
2. Do you feel this process would still allow the patient to give fully informed consent?
3. Do you feel patients would be comfortable only discussing the study by telephone?
4. Do you have any comments on the new version of the participant invitation letter?

Clinic Poster

<insert local Trust logo>

Are you having Gallbladder surgery?

The Sunflower Study

Testing for bile duct stones before gallbladder surgery

The Sunflower study is taking place in hospitals all over the UK.
It aims to find out whether testing for bile duct stones before gallbladder surgery is necessary or not.
Some doctors test for bile duct stones and others do not.
Both options are considered standard routine care.

What does it involve?

- *We will put everyone who takes part in the study into one of two groups.*
- *One group will have a scan to test for bile duct stones before their gallbladder surgery. If stones are found, these may be removed before surgery.*
- *The other group will not have a scan before their gallbladder surgery.*
- *You may be asked to complete some health questionnaires after your surgery.*

Please ask your local research team for more information about THE SUNFLOWER STUDY

Contact: <insert local contact number>

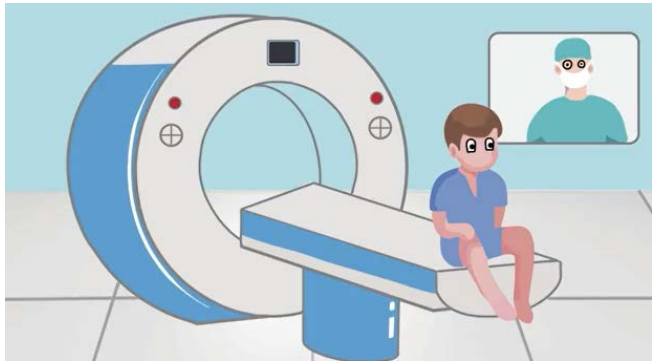
FUNDED BY NIHR | National Institute for Health Research

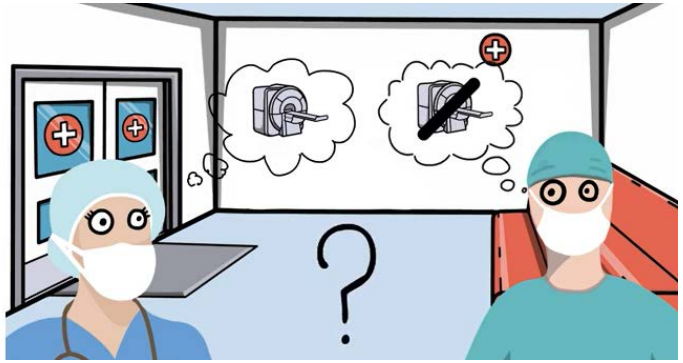
The Sunflower Study is funded by the NIHR HTA Programme (project number 16/142/04). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

University of BRISTOL

SUNFLOWER Poster V0.2 05May2020

Patient Animation





Any Questions?

The VICI Trial

Eplerenone vs placebo to treat chronic central serous chorioretinopathy (CSCR)

- CSCR is a long-term condition where fluid builds up in the eye, behind the retina
- This causes distorted vision which can resolve and recur over time
- Eplerenone is a blood pressure medicine. It was often used to treat CSCR as doctors reported improvements in vision when taking it for blood pressure, though no controlled trial had been carried out to prove whether it worked

Trial overview and results

- VICI recruited 114 patients who were randomly allocated to receive eplerenone or placebo tablets
- Participants attended several follow-up visits at their local clinic where they underwent visual tests, completed questionnaires and scans were taken of their eyes
- We found that there was no benefit to treating CSCR with eplerenone compared to placebo in any of the study tests
- The study had a specific PPI group, all of whom had CSCR

PPI input at end of study

<u>Assisted with drafting the results leaflet to send to participants:</u>

- Advised us to make the background colours lighter to increase contrast/readability

- Provided clear wording for the main result:

"The main study result showed that eplerenone was no better than placebo for treating CSCR. There was no difference in the number of letters people could read with their affected eye."

- Highlighted the outcomes that mattered most as a patient living with CSCR:
  - Vision in low light conditions
  - Resolution and recurrence of condition

PPI input at end of study

<u>Ideas/advice for future research:</u>

- Noted that the follow-up questionnaire used in the VICI trial seemed geared towards someone with much worse vision than patients with CSCR actually experience

- All group members agreed they would like to see a clinical trial carried out for Photodynamic therapy, which is another potential treatment option for CSCR

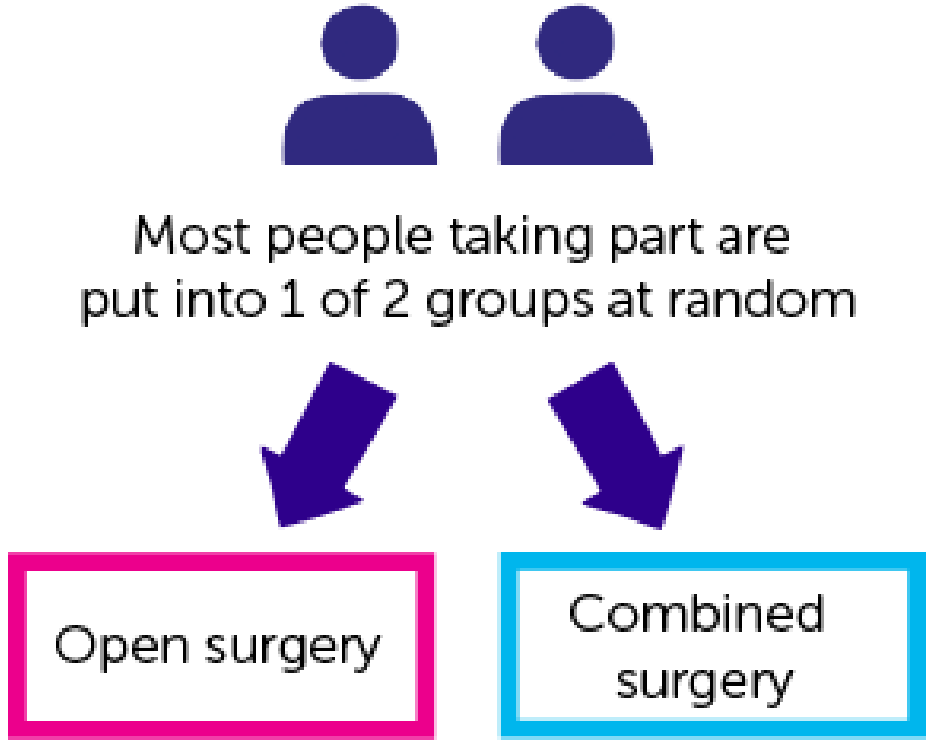
Any Questions?

The ROMIO Study

Patient and Public Involvement

About the Study

Comparing **open** and **combined open and keyhole** surgery for people with cancer of the food pipe (oesophageal cancer)



Sharing the Study Results

- Timing & phasing of results
- Which results to share
- Which patient/public groups need to be kept up to date, and how to do this
- Types of materials

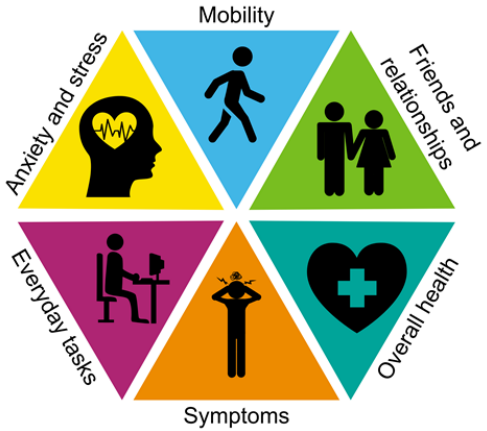
PPI meeting, January 2020

Which Results to Share

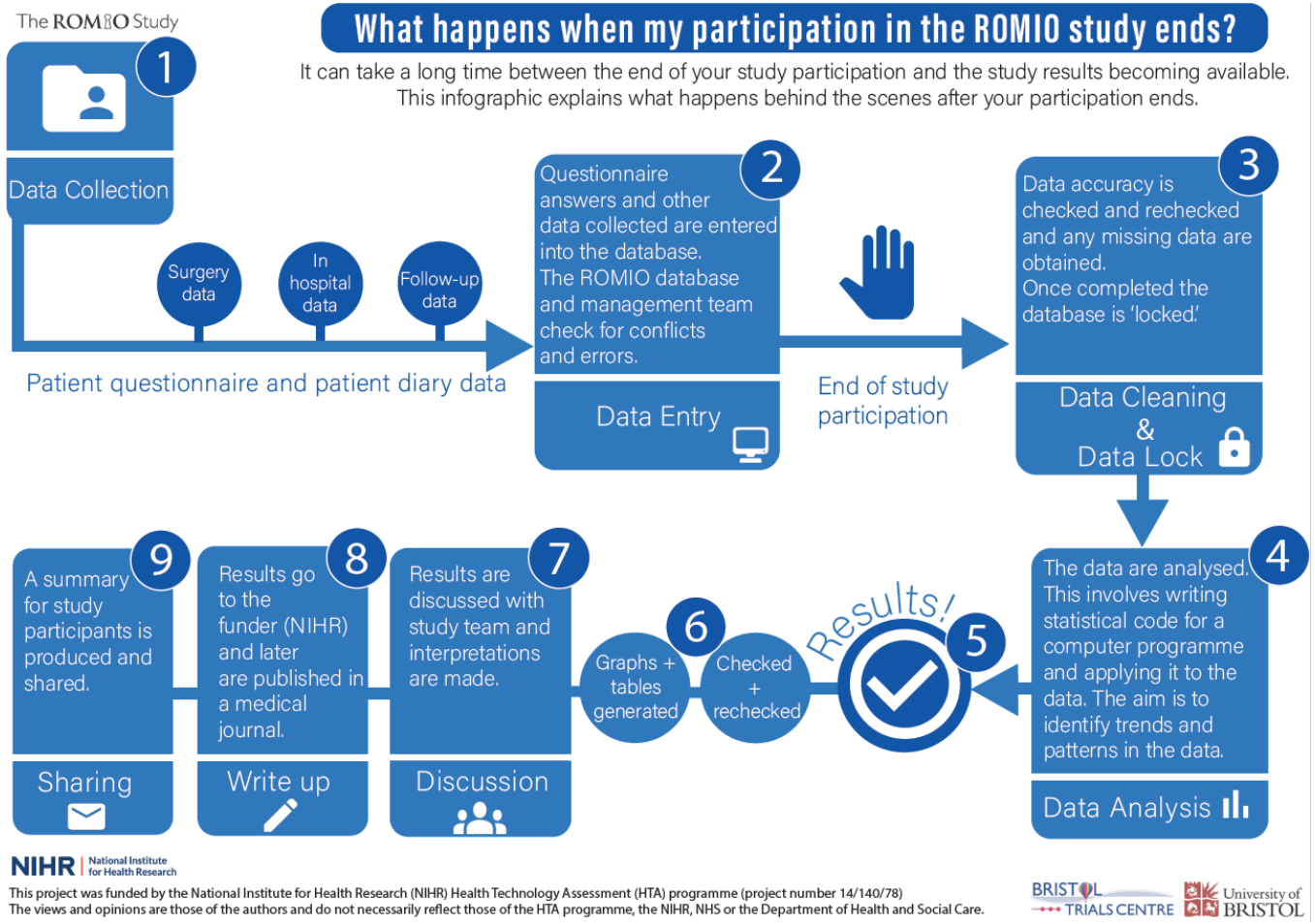
Main question: Does the surgical approach make a difference to patients' physical activities up to 3 months after surgery (as reported by patients)?

We are also interested in:

- Complications – during hospital stay and at home
- How long patients stayed in hospital
- Pain after surgery
- Lung capacity after surgery
- How other aspects of quality of life are affected (over 2-3 years)
- Survival
- Cost to the NHS (over 2-3 years)
- Whether patients knew which surgery they had
- How the surgery was done



Keeping Study Participants Up to Date



The ROMIO Study Newsletter

Issue 3, Winter 2020

Sharing the Study Findings

The ROMIO first findings will soon be ready!

We plan to share the first findings of the study with you in a leaflet in Spring 2021. The leaflet will be sent to you in the post. It will describe whether we saw any differences in recovery after surgery between the different types of surgery. It will also include some other findings that our patient and public advisory group have told us you may be interested to hear about. We are working to make sure we have all the information we need to finish this analysis. This includes making sure our data is complete and accurate before we complete the analysis. We hope the enclosed leaflet explains why there is a delay before we can share the findings. It also describes what is happening at the moment, and after your participation finishes.

BTC

Results Materials – under development

Funder website
(plain English summary)

twitter

Twitter schedule
(public tweets & links)

Bristol Trials Centre website
(detailed summary)

BTC

Any Questions?

Thank you for attending today

Next Steps:
- Any feedback or questions, please email Jade
- Expense forms will be sent to PPI Representatives