C-GALL

PATIENT INFORMATION LEAFLET

The purpose of this study is to compare keyhole gall bladder surgery (laparoscopic cholecystectomy) with medical management in people who suffer from pain due to gallstones but do not have other complications.

INVITATION TO TAKE PART

We would like to invite you to take part in a research study related to gallstones.

Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully, discuss it with your family, friends, or G.P. if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information. Contact details are on the back of this leaflet.

BACKGROUND

Gallstones are very common, with about 10-15% of UK adults suffering from gallstones. However, only 1 in 5 people with gallstones develop symptoms and require medical treatment. The most reported symptom is pain (known as 'biliary colic') in the upper right-hand side of the abdomen. Some people may also suffer from inflammation of the gallbladder (cholecystitis). Painkillers and occasionally antibiotics are prescribed to control gallstone symptoms and surgery is often advised for medically fit patients.

Surgery to remove the gallbladder, known as cholecystectomy, remains the most common treatment. Approximately 70,000 surgical operations for the treatment of gallstones are performed every year in the UK, with significant costs for the NHS.

In the UK, surgery is commonly offered to medically fit people who present at hospital with symptoms or complications due to gallstones. However, up to half of people may not have further symptoms after their initial episode of pain and so surgery may not be necessary. A policy of 'medical management' (painkillers/antibiotics and lifestyle advice) could, therefore, be all that is needed for some people, as they may not experience further episodes of pain.

WHAT IS THE PURPOSE OF THE STUDY?

Most of the current research on gallstones focuses on the surgical management of the disease, less research has been done on 'medical management'. Doctors and surgeons agree that for people who do not have complications there is now a need for a clinical study, which compares surgical management with medical management. This clinical study will help surgeons, patients and health services decision makers understand which is the most effective treatment for people who suffer from pain due to gallstones, but do not have other complications.

We aim to recruit approximately 430 participants. We will collect data throughout the study from all the participants, to see if these two procedures get similar results.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not you take part.

Please take as much time you need to make this decision.

You can read this information leaflet as many times as you wish and ask your doctor (GP or hospital doctor) and/or research nurse as many questions as you like.

If you do decide to take part, you will be asked to sign a form giving your consent to be included in the study. You are free to withdraw from the study at any time without giving a reason. Your decision will not affect the standard of care you receive now or in the future.

WHAT WOULD TAKING PART INVOLVE?

The clinical team (doctor, surgeon, research nurse) in charge of your treatment will give you full information about the study either by discussing it with you in person or by sending you this detailed information booklet by post. If appropriate, a member of the local research team will discuss the study with you at the clinic or contact you by telephone to give you more information and answer any queries you may have.

After taking your time to consider the study and if you agree to take part you will be asked to sign a consent form. You may be asked if your consultation with your consultant can be audio recorded.

Randomisation:

The particular treatment given to each person in the study will be decided by a computer allocation. If you decide to take part in this study, this will mean that neither you nor your doctors can decide which treatment you will receive. There is an equal chance you will be placed into either treatment group. You should only consider participation in the trial if you are willing to accept either of the trial treatments

Questionnaire completion
You will be given a questionnaire before you are randomised that will ask questions about your gallstones and your health and well-being overall. You will then receive subsequent questionnaires approximately every 6 months until the end of the study in 2022. It is very important for you to complete these questionnaires and return them to us to enable the trial to accurately assess the impact of the different treatments. Even if you feel the questions are no longer relevant for you, we still need you to complete them as well as you can and return them to us. This will allow the trial to produce reliable results.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will receive the same health care from your doctors whether or not you choose to participate in the study. By taking part, you will be directly helping us to inform the future treatment of people with uncomplicated gallstones. The results of this study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Risks and complications are possible from both surgical treatment and medical management and participation in this study should not increase those risks.

If you are allocated to the surgical option, a competent and trained surgeon will perform your operation. There are risks associated with surgical procedures and anaesthetics. The team responsible for your care will explain these to you. If you are randomised to the medical management option, then your GP will keep an eye on your symptoms and will keep the surgical team informed if there is any change.

WHAT ARE THE SIDE EFFECTS OF ANY TREATMENT RECEIVED WHEN TAKING PART?

In the UK, surgery is commonly offered to medically fit people presenting with symptoms or complications due to gallstones. However up to half of people with uncomplicated gallstone disease, may not have further symptoms after the initial episode of pain for up to 10 years, and surgery may not be necessary. It is well known that surgical option carries a 10% risk of major and minor complications. Moreover, up to 20% of people who have surgery still experience pain and require on-going pain management. A policy of medical management (painkillers/antibiotics and lifestyle advice) is suggested in this group of people.

In describing the size of a risk, some patients have found the table below a useful way to interpret the numbers.

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a **family**
Common	1/10 to 1/100	One person in a **street**
Uncommon	1/100 to 1/1000	One person in a **village**
Rare	1/1000 to 1/10,000	One person in a **small town**
Very rare	Less than 1/10,000	One person in a **large town**

GENERAL RISKS OF SURGERY

Any surgical procedure has its risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** This is rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss with you in detail.
- **Bleeding:** The risk of major bleeding, which is severe enough to need a blood transfusion, is uncommon but it can happen with any operation.
- **Infection:** The risk of infection at any of the wound sites is common, and you might receive antibiotics in theatre to reduce such risk. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.
- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following day-surgery (affecting less than 1% of those who get a clot). However, there have been deaths following such clots and, therefore, special stockings and/or injection to thin the blood are provided to all patients.

SPECIFIC COMPLICATIONS OF A CHOLECYSTECTOMY

Complication	Risk
Injury to the bowel	0.1% (uncommon)
Bile leak (requiring further surgery, endoscopy)	1-3% (common)
Injury to the bile duct	0.2% (rare)
Major bleeding (>500 ml)	1-2% (common)
Post-operative collections requiring antibiotics or drainage	1-3% (common)

Complication	Risk
Re admission to the hospital	5% (common)
Hernia at the site of port insertion	1% (common)
Severe biliary type pain persisting after surgery	4-9% (common)
Post cholecystectomy diarrhoea	10-15% (common)
Post cholecystectomy syndrome. (Persistent pain requiring further investigations to look for other causes)	13-37% (common)

POSSIBLE COMPLICATIONS FOR PEOPLE ON MEDICAL MANAGEMENT

There is a 0.7% per year risk (uncommon) of developing any of these complications for people on medical management*. (Life time risks are mentioned in the table below.)

Complication	Lifetime risk
Acute inflammation of gallbladder (acute cholecystitis)	10-20% (common)
Infection/pus in gallbladder (empyema)	5-10% (common)
Inflammation of pancreas (acute pancreatitis)	2-5% (common)
Stones in bile duct with or without jaundice	15% (common)
Perforation of the gallbladder	1-2% (common)

*People with gallstones and without symptoms (asymptomatic gallstones) who are NOT offered surgery are also susceptible to 0.3% per year risk (uncommon) of developing similar complications.

If any of these symptoms occur urgent medical attention is required.

It is well known that gallstones, irrespective of symptoms, can cause complications (e.g. pancreatitis/jaundice etc.) and in a minority of people (0.7% risk per year), an emergency hospital admission and further surgical treatment or specific medical procedures may be needed (endoscopy).

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the study is stopped earlier than expected for any reason, you and your doctor will be informed and your continuing care will be arranged.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. All procedures and techniques are already being used in the NHS to treat patients with uncomplicated gallstone disease. Your participation is only to help us evaluate these procedures and should not involve any **additional** risk to you.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (contact details of your local study nurse and the Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

If you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen and NHS Grampian.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action, but you

may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms would be available to you.

If you become unable or unwilling to continue in the C-Gall study, we would withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

We will tell your GP you are taking part, with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsor(s), the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

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~~This~~ We aim to recruit approximately 430~~p~~ participants. We will collect data throughout the ~~UK-wide~~ study ~~will collect data~~ from ~~430~~

all the ~~patients~~ participants ~~over 18 months following either surgical management or medical management~~, to see if these two procedures get similar results.

DO I HAVE TO TAKE PART?
No. It is entirely up to you whether or not you take part.

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WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

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If any of these symptoms occur urgent medical attention is required.

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WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?
If the study is stopped earlier than expected for any reason, you and your doctor will be informed and your continuing care will be arranged.

WHAT IF THERE IS A PROBLEM?
We do not expect any harm to come to you by taking part in this study. All procedures and techniques are already being used in the NHS to treat patients with uncomplicated gallstone disease. Your participation is only to help us evaluate these procedures and should not involve any **additional** risk to you.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (contact details of your local study nurse and the Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this

through the NHS Complaints Procedure. Details can be obtained from your hospital.

If you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen and NHS Grampian.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms would be available to you.

If you become unable or unwilling to continue in the C-Gall study we would withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

We will tell your GP you are taking part, with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsor(s), the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential, and will be held securely in accordance with the Data Protection Legislation. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

IF YOU AGREE TO TAKE PART:

The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen and NHS Grampian will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.abdn.ac.uk/about/privacy or by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

Staff at the hospital who have sent this information leaflet will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Aberdeen and NHS Grampian

and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Staff at the hospital who have sent this information will pass these details to the University of Aberdeen and NHS Grampian along with the information collected from you and your medical records. The only people in the University of Aberdeen and NHS Grampian who will have access to information that identifies you will be people who need to contact you to about study questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Staff at the hospital who have sent this information will keep identifiable information about you from this study for 10 years after the study has finished.

In this study, we aim to collect relevant readmission hospital data from the NHS central registers: in England this is the Health and Social Care Information Centre [HSCIC], in Scotland this is the Information Services Division [ISD], and in Wales this is the NHS Wales Informatics Service [NWIS]. The reason for this is to make sure that we have the correct information about all the participants taking part in this study and ensure that the results are as accurate as possible. In order to do this, we would need to securely send the NHS central registers some information about you (e.g. date of birth, name, and address). They will then match this information to their records and using your study number securely send any hospital readmission data back to the Study Office.

Other researchers may wish to access data from this study in the future, including from outside the UK. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the C-Gall Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

If you develop any concerns over participating in the trial please contact the trial office to discuss these and the different options available to you. You can decide at any time not to carry on with this study, but you should continue attending appointments with your consultant and/or GP as part of your standard care.

If you do withdraw from the study, all information collected up to the point of withdrawal will be kept and used in the analysis. We may also contact you again with a further invitation to take part in other relevant research.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with uncomplicated gallstone disease. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE STUDY?

The University of Aberdeen and NHS Grampian are the study sponsors and have overall responsibility for the management of the

study. The UK government supported National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme funds the study. The research is being carried out by a group of experienced doctors and researchers and is managed from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been approved by the North of Scotland Research Ethics Committee (2).

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and the Research & Development Department of your local hospital, whose roles are to check this research is properly conducted and the interests of those taking part in this study are protected.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the C-GALL study. Please ask us if you have questions or would like more information about the study.

INDEPENDENT CONTACT

If you would like further information on the study from an independent contact, the C-GALL study office can put you in touch with the Chair of the Independent Steering Committee.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

C-GALL Study office Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 438089 Fax: 01224 438165 Email: cgall@abdn.ac.uk Web: https://w3.abdn.ac.uk/hsru/C-GALL	

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Other researchers may wish to access data from this study in the future, including from outside the UK. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the C-Gall Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

If you develop any concerns over participating in the trial please contact the trial office to discuss these and the different options

available to you. You can decide at any time not to carry on with this study, but you should continue attending appointments with your consultant and/or GP as part of your standard care.

If you do withdraw from the study, all information collected up to the point of withdrawal will be kept and used in the analysis. We may also contact you again with a further invitation to take part in other relevant research.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with uncomplicated gallstone disease. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE STUDY?

The University of Aberdeen and NHS Grampian are the study sponsors and have overall responsibility for the management of the study. The UK government supported National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme funds the study. The research is being carried out by a group of experienced doctors and researchers and is managed from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been approved by the North of Scotland Research Ethics Committee (2).

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and the Research & Development

Department of your local hospital, whose roles are to check this research is properly conducted and the interests of those taking part in this study are protected.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the C-GALL study. Please ask us if you have questions or would like more information about the study.

INDEPENDENT CONTACT

If you would like further information on the study from an independent contact, the C-GALL study office can put you in touch with the Chair of the Independent Steering Committee.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

C-GALL Study office Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 438089 Fax: 01224 438165 Email: cgall@abdn.ac.uk Web: https://w3.abdn.ac.uk/hsru/C-GALL	

C-GALL

MEDICAL MANAGEMENT
PATIENT INFORMATION LEAFLET
for NON-SURGICAL PATIENTS

In the C-Gall trial you have been allocated to medical management and this leaflet contains information about your gallstones, advice on diet and information on who to contact for further information, if this is required.

ABOUT YOUR GALLSTONES

Medical management means you won't receive surgical treatment for your gallstones, but you should let your GP know if you notice any troublesome symptoms.

As a general rule, the longer you go without symptoms, the less likely it is that you will have any further problems.

Many people have no further episodes of pain. If you do have further episodes of abdominal pain (biliary colic), treatment depends on how much the pain affects your daily activities. If the episodes are mild and infrequent, you may be prescribed painkillers to control further episodes. You will be given advice about eating a healthy diet and should avoid foods that trigger symptoms to prevent further attacks of pain.

If your symptoms do become more severe and occur frequently, or you develop any complications, then surgery to remove the gallbladder may be recommended after all.

Some people may experience symptoms of bloating and diarrhoea after eating fatty or spicy food. If certain foods do trigger symptoms, you may wish to avoid them in the future.

WHAT ARE GALLSONES?

Gallstones are 'stones' that form in your gallbladder. They are common and can run in families. The risk of developing gallstones increases as you get older and if you eat a diet rich in fat.

References
NHS Choices, Gallstones, 2015
EIDO Healthcare, UG07 Laparoscopic Cholecystectomy, 2016

HOW DO GALLSTONES HAPPEN?

Your liver produces a fluid called bile that is concentrated by, and stored in, your gallbladder. When you eat food, your gallbladder empties bile into your intestines to help digest fats. Stones can develop in bile, particularly if you eat a diet rich in fat.

For some people gallstones can cause severe symptoms, with repeated attacks of abdominal pain being the most common. Pain is due either to stones blocking the gallbladder duct (cystic duct) and preventing your gallbladder from emptying (biliary colic) or to inflammation of your gallbladder (cholecystitis). The pain can be severe enough to need admission to hospital. If this happens surgery might be considered by the medical teams responsible for your care.

DIET AND GALLSTONES

In the past, people with gallstones were sometimes advised to adopt a very low fat diet to stop the gallstones growing.

However, recent evidence suggests this isn't helpful, because rapid weight loss resulting from a very low fat diet can actually cause gallstones to grow.

It is advisable to adopt a healthy and balanced diet based on the Eatwell guide, which can be accessed from https://www.gov.uk/government/publications/the-eatwell-guide. This involves eating a variety of foods – including moderate amounts of fat – and having regular meals.

A healthy diet won't cure gallstones or completely eliminate any symptoms, but it can improve your general health and help control any pain caused by gallstones.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

C-GALL Study office Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 438089 Fax: 01224 438165 Email: cgall@abdn.ac.uk Web: https://w3.abdn.ac.uk/hsru/C-GALL	<<Local centre contact details>>

References
NHS Choices, Gallstones, 2015
EIDO Healthcare, UG07 Laparoscopic Cholecystectomy, 2016

C-GALL
Participant Information Leaflet
Audio-recording of your consultation

Invitation
You are invited to take part in a research study linked to the C-GALL trial. We would like to audio-record the discussion you have with your consultant or research nurse about possible participation in this trial. You can participate in this audio-recording study even if you chose not to participate in the C-GALL trial.

What is the purpose of the audio-recording?
We are interested in understanding how the information about treatment for your gallstones and specifically the C-GALL trial is given to you and the reasons why people take part or not in the C-GALL trial. We plan to use this information to improve training and support to hospital staff which will help people make more informed decisions about taking part in research trials.

Do I have to take part?
It is your decision. If you do agree to take part you can withdraw at any time without giving a reason. Your decision will not affect your current or any future medical treatment or your invitation to take part in the C-GALL trial.

Before you decide, your consultant or the researcher will be happy to discuss any questions you may have about the audio-recording study. You can also contact the researchers conducting this audio-recording study (details below), if you need any further information.

What will happen to me if I take part?
If you agree to take part, your discussion with your consultant or researcher about taking part in the C-GALL trial will be audio-recorded. Your consultant or the researcher will ask you to confirm you consent to recording at the start of the consultation. If you do not wish to be recorded the recording will stop and will be deleted.

What are the benefits/disadvantages of taking part?
There will be no extra benefit to you if you take part in the study but by doing so you will be helping our research to enable us to assess the reasons why people chose to participate (or not) in trials. The audio recordings will be used to help train trial staff to make sure they are giving individuals the information they need in order to decide whether or not to take part in the trial. We do not anticipate any risks posed by participating.

What ethical and data permissions are in place?
North of Scotland Research Ethics Committee, your local hospital and your consultant have given approval for this study to be carried out.

If you agree to take part:
The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen and NHS Grampian will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the

information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.abdn.ac.uk/about/privacy or by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

Staff at the hospital who have sent this information leaflet will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Aberdeen and NHS Grampian and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Staff at the hospital who have sent this information will pass these details to the University of Aberdeen and NHS Grampian along with the information collected from you and your medical records. The only people in the University of Aberdeen and NHS Grampian who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Staff at the hospital who have sent this information will keep identifiable information about you from this study for 10 years after the study has finished.

Will my information be kept confidential?

Your interview will be typed up by University of Aberdeen staff or an external typing company both of who will treat your data confidentially.

What will happen to the results of this study?

All recordings will be anonymised, transcribed and labelled with the C-GALL trial study number only, to ensure confidentiality.
The results will help improve consultations in the C-GALL trial. We may also present the findings at a scientific research meeting and/or scientific publication. You will not be identifiable from any data presented.

Contact Details
Eilidh Duncan
Tel: 01224 438093, email: e.duncan@abdn.ac.uk

Interview study to explore local clinical team members experience of the

C-GALL Trial (C-GALL:Qual)

Participant Information Sheet

What is the purpose of this study?

This embedded research study (called C-GALL:Qual) is interested in exploring why patients decide to participate or not in the C-GALL study and explore the perspectives of C-GALL trial recruiters, specifically with regard to opinions and perspectives on the recruitment and consent process in C-GALL.

The purpose of C-GALL:QUAL is to help the C-GALL trial team better understand what influences patients when they are deciding whether or not to take part in the C-GALL trial and the reasons why trial staff at sites find it easy or difficult to recruit participants in to the trial. You have been invited to take part in this study as you recruit participants to the C-GALL trial and we would like to investigate your opinions and perspectives on the recruitment and consent process in C-GALL.

If you agree to take part in this study, you will be invited to take part in an interview with a researcher to talk about your experience as a recruiter on the C-GALL trial. The discussion would be by telephone at a time that was convenient for you. The discussion would be audio recorded.

Do I have to take part in an interview?

It is your decision about whether or not you wish to take part. If you do agree to take part and then change your mind, you can withdraw at any time without giving a reason.

What happens next?

If you would like to take part, please contact the researcher directly (see contact details in red below) to arrange a convenient time to set up the interview. Before you participate in the discussion with the researcher you will be given an opportunity to ask any additional questions and be asked to sign a consent form.

If you have any questions before you make a decision about whether or not to take part in this study, you can contact the researchers (***Researcher name: email address: telephone number***). You could also contact the C-GALL trial office (details below) if you need any further information.

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping us with our research.

Will my information be kept confidential?

Your interview will be typed up by University of Aberdeen staff or an external typing company both of who will treat your data confidentially.

The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen/ NHS Grampian will keep identifiable information about you for at least 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

What will happen to the results of the study?
We will use the results of this study to help make decisions about the future of the C-GALL trial. The researchers may also report the findings in a scientific journal and at a scientific research meeting. The information that we report would be completely anonymous and would not identify you in any way.

What ethical and data permissions are in place?
This study has been approved by the North of Scotland Research Ethics Committee.

Thank you for reading this leaflet and considering taking part in the qualitative work in C-GALL

Professor Craig Ramsay and Mr Irfan Ahmed
Co-Chief Investigators
C-GALL Trial
Email:cgall@abdn.ac.uk

Participant Information Sheet

Telephone interview study to find out what patients think about options for the management of Gallstones.

Invitation

You were recently asked to take part in a research study called the C-GALL trial. This is a further invitation to take part in a separate interview (via telephone) study running alongside the C-GALL trial.

Before you decide we would like you to understand why this research is being done and what it would involve for you, and help to, answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

The first part of this information sheet tells you the purpose of the study and what will happen. If you are interested, you can read the more detailed information provided in the second section.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to find out about your experience of gallstones (for example, how it impacts on your life) and your perspectives about what is important with regard to treatment of your condition. Different treatments have different outcomes and not all people hope for the same thing but all outcomes may be important. We are looking to speak to about twenty patients to get their point-of-view.

Why have I been invited?
You have been invited because you have gallstones and were invited to take part in the C-GALL trial. Even if you did not take part in the trial we would still like to hear from you. We aim to gather opinions to answer questions about:

1. experience of living with gallstones and concerns during the time of diagnosis
2. expectations about what matters with regards to treatment.

Do I have to take part in an interview?
It is your decision about whether or not you wish to take part. If you do agree to take part and then change your mind, you can withdraw at any time without giving a reason. Your decision will not affect your current treatment or any future medical treatment.

OK, so what happens next?
If you would like to take part, please complete the contact slip over the page and return it in the reply paid envelope. The researchers will then contact you to arrange a convenient time to set up the telephone interview. Before you participate in the discussion with the researcher you will be given an opportunity to ask any additional questions and be asked to sign a consent form.

If you have any questions before you make a decision about whether or not to take part in this study, you can contact the researchers, details below, if you need any further information.

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping us with our research.

Will my information be kept confidential?
Your interview will be typed up by University of Aberdeen staff or an external typing company both of who will treat your data confidentially.

The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen/ NHS Grampian will keep identifiable information about you for at least 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

What will happen to the results of the study?
We will use the results of this study to help make decisions about what outcomes (with regard to treatment) are important to patients and why some outcomes may be more important than others. The researchers may also report the findings in a scientific journal and at a scientific research meeting. The information that we report would be completely anonymous and would not identify you in any way.

What ethical and data permissions are in place?
This study has been approved by the North of Scotland Research Ethics Committee 2.

Please take time to read this information leaflet. Discuss it with your family, friends or your GP if you wish. You can also contact us at any time if there is anything you do not understand or if you would like more information

Lead Researcher
Katie Gillies

Health Services Research Unit
Health Sciences Building, 3rd floor
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Phone: 01224 438159
Email: k.gillies@abdn.ac.uk

Qualitative Researcher
xxxx

Health Services Research Unit
Health Sciences Building, xx floor
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Phone: xxx
Email: xxx

Funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme

Please **INITIAL**

I am willing to be contacted by telephone by a **C-GALL: Qual** researcher to discuss the telephone **Interview** study further: ☐

Name……

Preferred method of contact (please tick and give details as appropriate)

☐telephone……

☐email……

Participant Information Sheet

Telephone interview study to find out what patients think about being invited to participate in a trial.

Invitation

You were recently asked to take part in a research study called the C-GALL trial. This is a further invitation to take part in a separate interview (via telephone) study running alongside the C-GALL trial.

Before you decide we would like you to understand why this research is being done and what it would involve for you, answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to find out **about** patient's experiences of participating in the C-GALL trial. Different treatments have different outcomes and not all people hope for the same thing. We are looking to speak to about twenty patients to get their point-of-view.

Why have I been invited?

You have been invited because you have gallstones and were invited to take part in the C-GALL trial. Even if you did not take part in the trial we would still like to hear from you. We aim to gather opinions to answer questions about:

1. Your thoughts on deciding to participate in the trial, and,
2. Your thoughts on whether to continue participation, and
3. Your opinions about the different treatment options.

Do I have to take part in an interview?

It is your decision about whether or not you wish to take part. If you do agree to take part and then change your mind, you can withdraw at any time without giving a reason. Your decision will not affect your current treatment or any future medical treatment.

OK, so what happens next?

If you would like to take part, please complete the contact slip over the page and return it in the reply paid envelope. The researchers will then contact you to arrange a convenient time to set up the telephone interview. Before you participate in the discussion with the researcher you will be given an opportunity to ask any additional questions and be asked to sign a consent form.

If you have any questions before you make a decision about whether or not to take part in this study, you can contact the researchers, details below, if you need any further information.

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping us with our research. Our research will help understand why people decide not to participate in clinical trials and whether researchers who design clinical trials can make them better for potential participants.

Will my information be kept confidential?
Your interview will be typed up by University of Aberdeen staff or an external typing company both of who will treat your data confidentially.

The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen/ NHS Grampian will keep identifiable information about you for at least 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

What will happen to the results of the study?

We will use the results of this study to help make decisions about how to discuss the trial with future participants. The researchers may also report the findings in a scientific journal and at a scientific research meeting. The information that we report would be completely anonymous and would not identify you in any way.

What ethical and data permissions are in place?

This study has been approved by the North of Scotland Research Ethics Committee 2.

Please take time to read this information leaflet. Discuss it with your family, friends or your GP if you wish. You can also contact us at any time if there is anything you do not understand or if you would like more information

Lead Researcher
Katie Gillies

Health Sciences Research Unit
Health Sciences Building, 3rd floor
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Phone: 01224 438159
Email: k.gillies@abdn.ac.uk

Qualitative Researcher
Jennifer Dunsmore

Health Sciences Research Unit
Health Sciences Building, 3rd floor
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Phone: 01224 438152
Email: Jennifer.dunsmore@abdn.ac.uk

Funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme

Please **INITIAL**

I am willing to be contacted by telephone by an **C-GALL: Qual** researcher to discuss the telephone **Interview** study further: ☐

Name……

Preferred method of contact (please tick and give details as appropriate)

☐telephone……

☐email ……

Participant Information Sheet

Telephone interview study to find out what patients think about options for the management of Gallstones.

Invitation

You were recently asked to take part in a research study called the C-GALL trial. This is a further invitation to take part in a separate interview (via telephone) study running alongside the C-GALL trial.

Before you decide we would like you to understand why this research is being done and what it would involve for you, and help to, answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

The first part of this information sheet tells you the purpose of the study and what will happen. If you are interested, you can read the more detailed information provided in the second section.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to find out what patients think about options for the management of gallstones and their experience of being invited to participate or being in the C-GALL trial. Different treatments have different outcomes and not all people hope for the same thing. We are looking to speak to about twenty patients to get their point-of-view.

Why have I been invited?

You have been invited because you have gallstones and were invited to take part in the C-GALL trial. We are especially interested in talking with you if you chose not to take part in the trial. We aim to gather opinions to answer questions about:

1. considerations when deciding to participate in the trial, and,
2. opinions about the different treatment options.

Do I have to take part in an interview?

It is your decision about whether or not you wish to take part. If you do agree to take part and then change your mind, you can withdraw at any time without giving a reason. Your decision will not affect your current treatment or any future medical treatment.

OK, so what happens next?

If you would like to take part, please complete the contact slip over the page and return it in the reply paid envelope. The researchers will then contact you to arrange a convenient time to set up the telephone interview. Before you participate in the discussion with the researcher you will be given an opportunity to ask any additional questions and be asked to sign a consent form.

If you have any questions before you make a decision about whether or not to take part in this study, you can contact the researchers, details below, if you need any further information.

There will be no extra benefit to you if you do take part in the study but by doing so you will be helping us with our research. Our research will help understand why people decide not to participate in clinical trials, how they can be supported in making the decision about whether to take part or not and whether clinical trials can be designed to make them better for potential participants.

Will my information be kept confidential?
Your interview will be typed up by University of Aberdeen staff or an external typing company both of who will treat your data confidentially.

The University of Aberdeen and NHS Grampian are the co-sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen/ NHS Grampian will keep identifiable information about you for at least 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

What will happen to the results of the study?
We will use the results of this study to help make decisions about how to discuss the trial with future participants. The researchers may also report the findings in a scientific journal and at a scientific research meeting. The information that we report would be completely anonymous and would not identify you in any way.

What ethical and data permissions are in place?
This study has been approved by the North of Scotland Research Ethics Committee 2.

Please take time to read this information leaflet. Discuss it with your family, friends or your GP if you wish. You can also contact us at any time if there is anything you do not understand or if you would like more information

Lead Researcher
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Jennifer Dunsmore

Health Services Research Unit
Health Sciences Building, 2nd floor
University of Aberdeen
Foresterhill
Aberdeen
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Phone: 01224 438131
Email: jennifer.dunsmore@abdn.ac.uk

Funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme

Please **INITIAL**

I am willing to be contacted by telephone by a **C-GALL: Qual** researcher to discuss the telephone **Interview** study further: ☐

Name……

Preferred method of contact (please tick and give details as appropriate)

☐telephone……

☐email……