OPAL TRIAL OFFICE
Nursing, Midwifery & Allied Health Professions Research Unit
Glasgow Caledonian University
GLASGOW G4 0BA
T: +44 (0) 141 331 3504
F: +44 (0) 141 331 8101
www.opaltrial.co.uk

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[clinical team to affix sticker]

Day Month Year

Dear Possible Participant

Information leaflet about a study you MAY be eligible for

We have asked your health care team to enclose this letter and an information leaflet along with your appointment letter.

You have been sent this letter because you are a woman having treatment for urine leakage and **may** be eligible to take part in a study. This study (called the OPAL trial) aims to test two approaches to pelvic floor muscle training (pelvic floor exercises) to see if one approach is better than the other for improving the symptoms of urine leakage. If you have any interest in hearing more about the study, we ask that you read the enclosed Patient Information Leaflet for more detail.

If you decide you do not wish to participate in the trial please inform your therapist or nurse at your routine appointment. This will not affect your future treatment. If, after reading the Information Leaflet and talking with the therapist or nurse, you would like to hear more about the study, a member of the team will spend some time with you going over the study at your appointment.

In the meantime, if you require any further help or information about the trial, do please contact the OPAL Trial Office on 0141 331 3504.

Yours sincerely

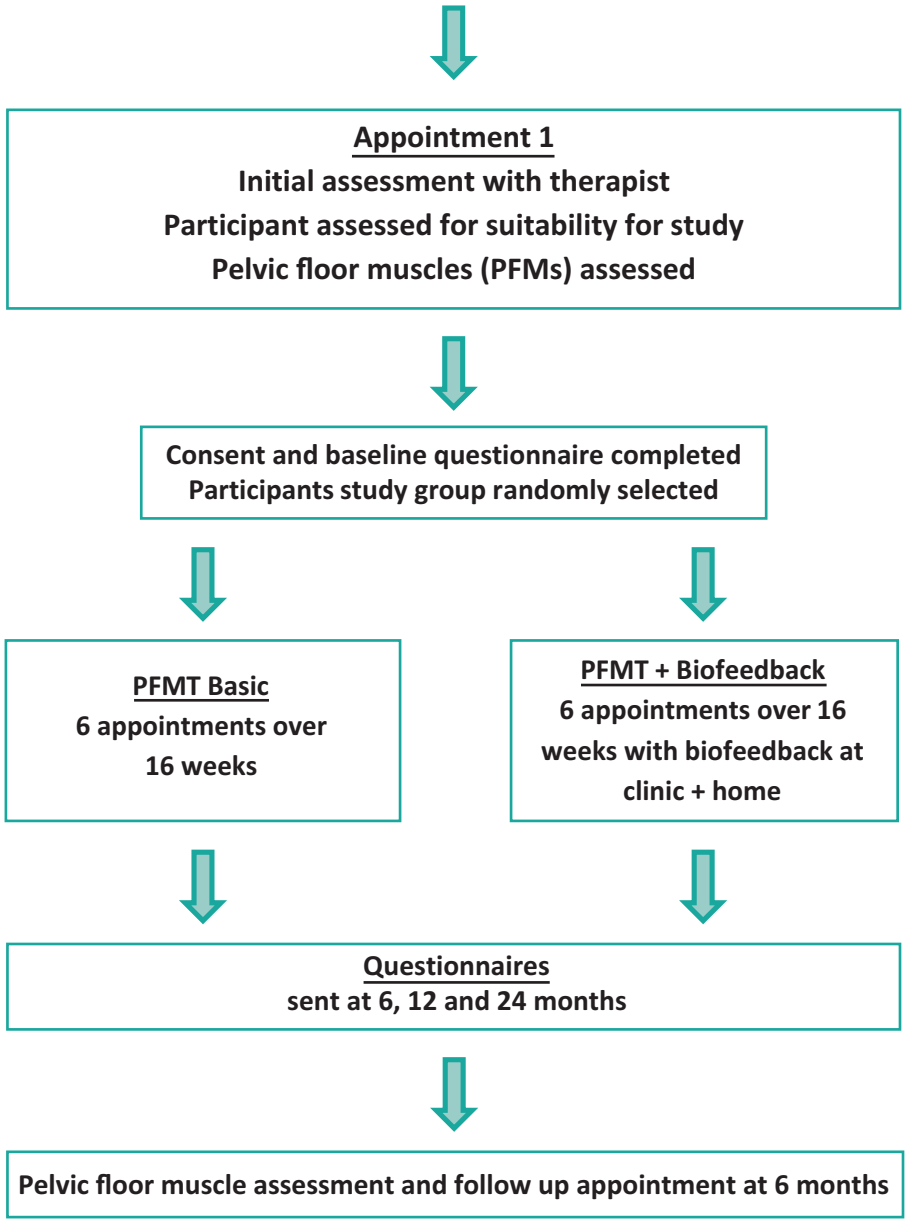
Professor Suzanne Hagen
OPAL Chief Investigator

Miss Susan Stratton
OPAL Trial Coordinator

Local signature to be inserted here

Local Recruitment Officer

Participant Pathway Diagram



OPAL

optimising pelvic floor exercises to achieve longterm benefits

A study comparing pelvic floor muscle exercises with and without the use of computer feedback for women with urine leakage

Patient Information Leaflet

A multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence

McCormick Ref: 1403134

General Patient Information Leaflet: Version 3.0 17.12.2013

Introduction

You are being invited to take part in a research study. Before you decide, 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 and discuss it with others if you wish. One of the research team will go through the information sheet with you and answer any questions that you have. Please ask us if anything is unclear or if you would like more information. Take the time you need to decide whether or not you wish to take part.

What is the purpose of the study?

Urinary leakage is a common, and often distressing problem, for women. There is good evidence that pelvic floor muscle exercises can cure or reduce leakage but it is unclear as to how intensely these exercises need to be undertaken. Sometimes a technique called 'electromyography' biofeedback is used to help a woman perform the exercises. However it is uncertain whether using this technique makes the exercises more effective. This research aims to find out whether doing pelvic floor muscle exercises with biofeedback is any more effective than doing exercises without feedback.

Why have I been asked to take part?

You have been asked to take part because you are a woman with urinary leakage. We are aiming to recruit 600 women. All participants will be asked to attend 6 appointments over 16 weeks, with a continence physiotherapist or nurse. Half of the participants will be taught how to do pelvic floor muscle exercises and will be given a home exercise programme. The other half will, in addition, receive electromyography (EMG) biofeedback at clinic and will be provided with a small hand held EMG biofeedback unit to help with undertaking the exercises at home. The EMG biofeedback uses a vaginal device called a Periform which in clinic is attached to a computer screen that displays the contraction of the muscles as a line graph.

Can I contact a member of the research team for further information?

If you have received this information leaflet you will be offered any opportunity to speak with a researcher when you attend for your appointment. They will be able to provide further information on this study, answer any of your questions and tell you about the next steps should you wish to continue with being part of this study.

If you have any further questions about the study at any stage, please feel free to contact:

Professor Suzanne Hagen
Chief Investigator OPAL Trial
NMAHP RU
Glasgow Caledonian University
G4 0BA
0141 331 8104
s.hagen@gcu.ac.uk

or

Susan Stratton
Trial Manager
NMAHP RU
Glasgow Caledonian University
G4 0BA
0141 331 3504
susan.stratton@gcu.ac.uk

If you would like information about research more generally please contact:

Professor Brian Williams
Director
NMAHP RU
Glasgow Caledonian University
G4 0BA
0141 331 8100
Brian.Williams@stir.ac.uk

Information about the study is available on the following web site:

www.opaltrial.co.uk

Thank you for reading this and considering taking part in this study.

Who is doing this study?

The research is being carried out by a group of experienced doctors, nurses, physiotherapists and researchers from a number of different organisations:

- Nursing, Midwifery and Allied Health Professions Research Unit
- Glasgow Caledonian University, The University of Stirling
- Health Services Research Unit, University of Aberdeen
- Centre for Healthcare Randomised Trials, University of Aberdeen
- The University of Exeter
- The University of Otago, New Zealand
- NHS Greater Glasgow & Clyde
- NHS Grampian
- NHS Ayrshire and Arran

The study is funded by the National Institute for Health Research, Health Technology Assessment Programme.

Who has reviewed this study?

The following groups have reviewed this study and given their approval for it to be carried out:

- West of Scotland Research Ethics Committee
- Each local NHS Board ethics committee and Research & Development department.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

If you decide to take part you are free to withdraw at any time without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the care you receive at any time.

You will not be paid any expenses for your involvement in this study, however a five pound gift voucher will be sent to you with your questionnaires at 12 and 24 months into the study.

What will happen to me if I take part?

At your first scheduled appointment the continence physiotherapist or nurse will ask you some questions, look at your bladder diary, (which will have been sent to you in advance), and a routine vaginal assessment will be undertaken. If you are eligible and interested in the study then a Researcher will give you information about the study and answer any questions you may have. Providing you are still interested they will then give you a consent form and a questionnaire to complete. Once the research office have received these you will then be allocated at random to one of the two groups. Both groups will be seen for 6 appointments over a 16 week period, both will be taught how to do pelvic floor muscle exercises, one group will also use electromyography biofeedback.

At your next and subsequent appointments your continence physiotherapist or nurse will assess your condition and discuss your treatment goals and exercise plan with you. They will make sure you know how to do the pelvic floor muscle exercises. Depending on which group you have been allocated to you will also be asked to use the EMG biofeedback equipment both in clinic and at home. Using a probe inserted into the vagina, EMG biofeedback equipment shows women on a screen what their pelvic muscles do as they exercise.

The continence physiotherapist or nurse will discuss possible reasons for your urinary leakage and lifestyle changes you may be able to make which could also help. During these appointments your progress will be monitored and exercise plan adjusted accordingly.

Some treatment appointments may be audio recorded to find out if the treatment is being delivered as intended. A small number of woman will also be interviewed. A separate Information Leaflet will be given to those selected for Interview.

Please note the audio recordings will be destroyed following transcription.

Questionnaires will be sent to you for completion at 6, 12 and 24 months into the study. You will also be asked to attend for a follow-up vaginal assessment at 6 months. You will be asked to complete a bladder diary over 3 days at the start and end of the study. This will involve keeping a record of liquids you drink , the number of times you go to the toilet or have an accident and how much urine you pass.

How long will I be involved in the study?

You will be involved in the study for 2 years. Your treatment will last for 16 weeks (6 appointments) and we will send the last questionnaire to you 24 months after you enter the study.

What are the possible disadvantages or risks of taking part?

We do not anticipate any risks to you from being involved in the study. All the materials and techniques are already being used in the NHS. Your participation in the study is therefore only to help us evaluate these procedures and should not involve any additional risk. Some people may feel uncomfortable with vaginal examinations but these would be undertaken as part of routine care. Should you decide that this is something you do not wish to have, this will be respected, although you will not be able to take part in the study. This will also not affect the treatment you will receive. Some of the questions may seem invasive but the information is important to us.

What are the possible benefits of taking part?

The treatments you receive may help to reduce your urinary leakage. Taking part in the study will not benefit you further but the information we get from this study may help improve the treatment of women with urinary incontinence.

Will the information I provide be kept confidential?

Yes. All information collected about you will be kept strictly confidential. Paper records will be kept in a locked cupboard, computerised data will be kept on a password protected computer and only those involved in the research will be permitted access to any of the files or data. When the results are published, this will be done in such a way that you will not be identifiable. If quotes from your appointment recording are used, for reports or teaching, you will not be identifiable. If a participant becomes incapacitated during the study, they would be withdrawn and all relevant data collected prior to withdrawal will be retained confidentially.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. In the first instance contact : Susan Stratton, Trial Manager, telephone - 0141 331 3504. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Glasgow and Greater Clyde, Complaints Department, www.nhsggc.org.uk.

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which include professional indemnity insurance for negligence).

What will happen to the results of the study?

The results will help us to understand women's experience of incontinence, treatment and how effective it is. We hope that the results will be published in a number of journals so that others can read and learn from the results of the study. If you wish, when the study is complete we will send you a summary of the findings.

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Trial Ref No.: 11/71/03
Trial Id. No.: | c | c | n | n | n | n |

Consent Form

A multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence.

By signing this form and initialling each box I agree that I have:

Please INITIAL ALL boxes

- been given the Patient Information Leaflet about the study (version 3.0, dated 17/12/13)
- had the opportunity to discuss the study
- received satisfactory answers to any questions I asked
- been given enough information about the study.

☐

I confirm that:

- I am not pregnant
- I am not involved in other research related to my urine leakage.

☐

I understand that:

- my taking part in the study is voluntary and may not benefit my own health
- I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected;
- I may be contacted in the future for long term follow-up of the OPAL study participants.

☐

I understand that I have a 50% chance of receiving pelvic floor muscle training and a 50% chance of receiving pelvic floor muscle training with biofeedback. ☐

I understand that internal vaginal examinations are required as part of pelvic floor muscle training, but these would be required for treatment outside the study also. ☐

I understand that one of my appointments with the therapist/nurse may be audio recorded. ☐

I agree that relevant data and my contact details can be stored, confidentially and securely, by the study office at Glasgow Caledonian University. ☐

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Trial Id. No.: | c | c | n | n | n | n |

I understand that relevant sections of any of my NHS records and data collected during the research, may be looked at by responsible individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

I agree that my GP can be told that I am taking part in this research. ☐

I am willing to be contacted about taking part in the interview study ☐

I am willing to be asked in the future if I would like to take part in other relevant research ☐

I agree to take part in the above study. ☐

Your signature (participant) _____ Date_____

Your name in block capitals _____

To be completed by local team member taking consent
I confirm that I have explained to the person named above, the nature and purpose of the OPAL trial and the treatments involved

Your signature _____ Date_____

Your name in block capitals _____

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School of Nursing, Midwifery and Health
University of Stirling
FK9 4LA
T: +44 (0) 1786 466402
F: +44 (0) 1786 466333
www.opaltrial.co.uk

Title FName SName
Address 1
Address 2
Address 3
Address 4
Post Code

Study Number:
Day Month Year

Dear Ms X

An invitation to take part in an interview study running alongside the OPAL trial

Thank you very much for agreeing to participate in the OPAL trial and for returning your signed consent form and paperwork to the trial office. The trial office has informed us that you are interested in being contacted about participating in the OPAL interview study which is running alongside the trial.

We are undertaking this additional study because we are keen to explore, with women, their experience of urine leakage and of the treatments they receive. We have enclosed a Patient Information Leaflet that gives you more information about what would be involved if you agree to participate. We would be grateful if you would take the time to read the leaflet to help you decide. Please note that you can still be involved in the OPAL trial even if you do not want to take part in the OPAL interview study.

A researcher (Anne Taylor) from the interview study team will call you in a few days to answer any questions you may have and to find out if you would like to take part. In the meantime, if you would like more information about the interview study please contact the OPAL interview study office on 01786 466042.

Yours sincerely

Professor Suzanne Hagen
OPAL Chief Investigator

Dr Carol Bugge
OPAL Interview Study Lead

Woman consents to take part in OPAL trial

⇩

20 women in each treatment group sent information about the interview study

⇩

Woman decides to take part in the interview study

⇩

Interviews take place at:

Prior to treatment: face-to-face interview lasting about 30 minutes

At 6 months: face-to-face interview lasting about 60 minutes

At 12 months: telephone interview lasting about 15 minutes

At 24 months: telephone interview lasting about 15 minutes

McCormick Ref: 1403133

OPAL

optimising pelvic floor exercises to achieve longterm benefits

Exploring women's experiences of symptoms and treatment: An interview study linked to the OPAL trial

Interview Study Patient Information Leaflet

Interview Study Patient Information Leaflet: Version 2.0 17.12.13
Study Number: 11/71/03

Introduction

Thank you for already consenting to be part of the OPAL trial and agreeing to be contacted about taking part in an interview study. The OPAL trial tests two approaches to pelvic floor muscle training (pelvic floor exercises) to see if one approach is better than the other.

You are invited to take part in an additional research study to complement the OPAL trial. Before you decide, it is important for you to understand why this study is being done and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. One of the research team will take 5 to 10 minutes to go through the information sheet with you and answer any questions you have about the study. Please ask us if anything is unclear or if you would like more information. Take the time you need to decide whether or not you wish to take part.

What is the purpose of the study?

This study is based around face-to-face and telephone interviews' with women in the trial. It aims to explore women's experience of urine leakage (urinary incontinence) and of the treatment they receive, as part of the trial, for that leakage.

Why have I been asked to take part?

You have been asked to take part because you are a woman with urine leakage who has agreed to take part in the OPAL trial. We are aiming to talk to approximately twenty women from each treatment group. We are inviting women of different ages, with different types of urine leakage and who live in different areas of the UK.

Can I contact a member of the research team for further information?

If you have received this information leaflet you will automatically be contacted by telephone by a member of the research team (Anne Taylor). She can provide further information on this study, answer your questions and tell you about the next steps should you wish to continue with being part of this study.

If you have any further questions about the study at any stage, please feel free to contact:

Dr Carol Bugge	**OR**	**Dr Anne Taylor**
Senior Lecturer		Research Fellow

University of Stirling
Stirling
FK9 4LA

01786 466109	**OR**	01786 466402

If you would like information about research more generally please contact:

Professor William Lauder
Head of School
School of Nursing, Midwifery and Health
University of Stirling
FK9 4LA

Information about the study is available on the following web site:

http://www.opaltrial.co.uk

Thank you for reading this and considering taking part in this study.

Who is doing this study?

The research is being carried out by a group of experienced doctors, nurses, physiotherapists and researchers from a number of organisations:

- The Universities of Stirling, Exeter and Otago
- Glasgow Caledonian University
- Nursing, Midwifery and Allied Health Professions Research Unit
- Health Services Research Unit, Aberdeen
- Centre for Healthcare Randomised Trials, Aberdeen
- NHS Greater Glasgow & Clyde; Grampian and Ayrshire and Arran

The study is funded by the National Institute for Health Research, Health Technology Assessment Programme.

Who has reviewed this study?

The following groups have reviewed this study and given their approval for it to be carried out:

- West of Scotland Research Ethics Committee
- Each local NHS Board Ethics Committee and Research & Development department

Do I have to take part?

It is up to you to decide if you want to take part in the study. You can continue to take part in the main OPAL trial but decide not to be involved in this additional interview study.

We will telephone you in a few days to discuss the interview study in more detail and answer any questions you have. If, after that, you do decide to take part, we will make an appointment with you for the first interview. At that first interview you will be asked to sign a consent form and will be given a copy of the form to keep.

Participating in this study is completely voluntary and the treatment and standard of care you receive will not be affected in any way if you decide not to take part or if you withdraw from the study at a later date.

You will not be paid any expenses for your involvement in this study.

What will happen to me if I take part?

If you agree to take part in this study, you will be interviewed four times over the next two years.

The researcher will make an appointment with you for the first interview. That appointment can either be at your home or at the clinic **before** your first appointment with the OPAL therapist/nurse who is treating you. That first interview will take approximately 30 minutes. The interviewer will ask you about your experience of urine leakage, what you do to manage your leakage at the moment and what you hope to get from treatment.

The second interview will take place six months after your first appointment, when you have finished treatment. That interview can be at your home or at the clinic. It will take approximately one hour. The interviewer will ask you about your urine leakage symptoms, how you have found the treatment and what you do at home to manage your urine leakage.

The third and fourth interviews are done by telephone and will last approximately 15 minutes each. The interviewer will ask you about your urine leakage symptoms, your on-going views on the treatment you received and what you do to manage your leakage of urine.

Through the four interviews the questions we ask will build on what has been said in your own and other women's interviews.

With your consent, all interviews will be recorded.

How long will I be involved in the study?

You will be involved in the study for the same two years you are involved in the OPAL trial. During that time you will be interviewed four times, twice in person and twice by telephone.

What are the possible disadvantages or risks of taking part?

We do not anticipate any risks to you from being involved in the interview study. Some people may find discussing their urine leakage and treatment upsetting. If you do, you can stop the interview and/or withdraw from the study. However, some people find it helpful to discuss their opinions and feelings.

What are the possible benefits of taking part?

The study may not help you directly but the information we gain may help improve treatment of women with urine leakage in the future.

Will the information I provide be kept confidential?

Yes. Recordings will be securely stored on a password protected University computer. Your identification will be removed from transcripts and any information that you do provide will be seen by the research team only. Women who have taken part will not be identified in any way in the reports. Even if we use quotes of things you have said, it will not be possible for others to identify who said it.

What if there is a problem?

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which include professional indemnity insurance for negligence). If you have a concern about any aspect of this study, ask to speak to the researchers who will do their best to answer your questions [Dr Carol Bugge, 01786 466109]. If you remain unhappy and wish to complain formally, you can do this by using the normal NHS complaints procedures.

What will happen to the results of the study?

The results will help us to understand women's experience of incontinence and of the treatment. We hope that the results will be published in journals so that others can learn from the results. If you wish, when the study is complete, we will send you information about the findings.

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Trial Ref No.: 11/71/03
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Consent Form

Exploring women's experience of symptoms and treatment: An interview study linked to the OPAL trial

By signing this form and initialling each box I agree that I have:

Please INITIAL ALL boxes

- been given the Patient Information Leaflet about the interview study (version x, dated xx/xx/xx)
- had the chance to discuss the study
- received satisfactory answers to my questions
- been given enough information about the study.

☐

I understand that:

- my participation is voluntary and taking part in the study may not benefit my own health
- I am free to withdraw from the study at any time, without giving a reason and without my medical care or legal rights being affected
- I may be contacted in the future for long term follow up.

☐

I understand that:

- a member of the research team will interview me four times over the next two years
- that the interviews will be audio recorded
- that the audio recordings and written versions of the recording will be stored safely and that it will not be possible to identify me to anyone outside the research team.

☐

I agree that:

- relevant data and my contact details can be held, confidentially and securely, by the study office at the University of Stirling;
- my data may be used when presenting the results of the research, including quotes of things I have said, but that that it will not be possible to identify me.

☐

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Trial Id. No.: | c | c | n | n | n |

I agree to take part in the above study. ☐

Your signature (participant) _____ Date_____

Your name in block capitals _____

To be completed by local team member taking consent
I confirm that I have explained to the person named above, the nature and purpose of the OPAL interview study

Your signature _____ Date_____

Your name in block capitals _____