OPAL
optimising pelvic floor exercises to achieve longterm benefits

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

Clinical Assessment Form (CAF) to determine trial eligibility

Study No: | | | | | |

Clinic Date: | d | d | m | m | y | y |

Referral source (tick one):

GP ☐ Consultant ☐ Self ☐ Other _____

1. URINARY SYMPTOMS

Tick those that apply:

Stress UI only ☐

Urgency UI only ☐

Stress and Urgency UI ☐

If both stress and urgency symptoms, which does the patient feel to be more troublesome *(tick one):*

Urge ☐ Stress ☐ Both equally ☐

Ask the woman:

1. How often do you leak urine? *(tick one):*

About once a week or less often ☐ Two or three times a week ☐ About once a day ☐ Several times a day ☐ All the time ☐

2. How much urine usually leaks, whether wearing protection or not? *(tick one):*

a small amount ☐ a moderate amount ☐ a large amount ☐

3. Overall, how much does leaking urine interfere with your everyday life? *(Tick a number between 0 (not at all) and 10 (a great deal))*

0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Clinician Signature..... Designations..... Date.....

2. EXCLUSION CRITERIA

Previous treatment

	Yes	No
Formal PFMT (i.e. one-to-one treatment/assessment) within the last year		

Past Medical History

Pregnant now or within the last 6 months		
Pelvic cancer		
Cognitive impairment affecting capacity to give informed consent		
Neurological disease (Multiple Sclerosis, Parkinson's Disease, Stroke, Motor Neurone Disease, Spinal Injury)		
Nickel allergy		
<18 years old		
Unable to commit to attend 6 appointments		
Participating in other UI research		

3. EXAMINATION (Supine)

Consent

Informed consent to examination obtained *(tick to confirm):* ☐

Chaperone *(tick one):* Accepted ☐ Declined ☐ Unavailable ☐

Latex allergy or sensitivity *(tick one):* Yes ☐ No ☐

Physiotherapist signature _____ Date _____ Time _____

Pelvic floor assessment

Does woman have a prolapse? Yes ☐ No ☐

If yes, is it greater than 1cm outside the vagina on valsalva? Yes ☐ No ☐

Pelvic floor muscle contraction palpable? Yes ☐ No ☐

Oxford rating (*enter 1-5*): ☐

PFM contraction as per the International Continence Society (*tick one*):

Weak ☐ Normal (moderate) ☐ Strong ☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

Clinician Signature…….. Designations…… Date……..

4.RANDOMISATION

	Yes	No
Is this woman eligible based on all inclusion/ exclusion criteria? *(If any shaded box is ticked in sections 1-3 then select No)*	☐	☐
Has the woman signed the study Consent Form?	☐	☐
Has the woman completed the Baseline Questionnaire?	☐	☐
Is the woman returning paperwork to the Trial Office by post instead?	☐	☐
Is this woman willing to be randomised and contacted by the research team?	☐	☐
Is the woman willing to be contacted about taking part in the interview study?	☐	☐
Has the woman been given a 3-day Bladder Diary?	☐	☐
Has the woman been given her next appointment date? (2 week's time)	☐	☐

First appointment is scheduled with;

Nurse ☐ **OR** Physiotherapist ☐

Appointment Date _ _/_ _/_ _ _ _

Appointment Time _ _ : _ _ **am / pm**

Trial group woman randomised to: (tick one) ☐ B ☐ I

5. PATIENT DETAILS

(Patient label can be inserted here if available)

First Name _____ Surname _____

Address _____

_____

Postcode _____ DOB _ _/ _ _/_ _ _ _

CHI No. _____

Contact Details

Tel home _____ Tel mobile _____

Email _____

Permission to leave message: Yes / No Preferred contact method Telephone / email

GP Details

GP Name _____

GP Address _____

_____

- **Please now update screening log and enter details from this form onto to the OPAL website https://www.opaltrial.co.uk/.**
- **Please return a copy of the signed Consent Form and baseline questionnaire to the Trial Office. If the patient is taking away questionnaire for completion provide a pre-paid envelope and advise they post back within 24 hours.**
- **If woman is found to be ineligible or does not wish to take part in the OPAL trial then please update the Screening Log with relevant details and destroy this form in accordance with your local hospital policy.**

Clinician Signature…….. Designations…… Date……..

PFMT

OPAL
optimising pelvic floor exercises to achieve longterm benefits

Study No: | | | | | | |

Date: | d | d | m | m | y | y |

Issued at Appointment: *(please circle)*

1 / 2 / 3 / 4 / 5

Please bring this diary to your next appointment

Pelvic floor muscle exercise diary

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

Your Home Exercise Programme

Pelvic Floor Muscle Exercise Programme (1 + 2 = a session)

Following discussions with my clinician I will:-

1. tighten my pelvic floor muscles and hold as tight as I can for ☐ seconds, relax for ☐ seconds ***and*** repeat this ☐ times

and then

2. tighten my pelvic floor muscles and quickly release them ☐ times

and

3. repeat both exercises 1 & 2 (one session) ☐ times a day for ☐ days each week

In (tick all that apply)

Lying ☐ Sitting ☐ Standing ☐

Additional agreement

- The best time for me to do my exercises is

  _____

- I will contract my pelvic floor muscles every time I

  _____

Signature of clinician: _____

Signature of patient: _____

Date: _____

If you were unable to do the exercises as often as advised please can you say why?

_____

_____

_____

_____

_____

_____

_____

Other comments;

_____

_____

_____

_____

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_____

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_____

_____

OPAL Trial Office;
OPAL Trial Manager, Susan Stratton
susan.stratton@gcu.ac.uk/ 0141 331 3504

Date	Number of PFM sessions	Comment

If you have any concerns with the home exercise programme please contact me;

Clinician Name: _____

Telephone No: _____

Diary Completion Instructions

- Please bring this diary to your next appointment. You will be issued a new diary at each appointment.
- Please write an entry on each day until your next appointment. If you did not perform any PFM sessions do not leave blank. Please enter the date, 0 for PFM sessions and add a comment *(see example on line 2)*

Date	Number of PFM sessions	Comment
02/05/2014	2	Used as advised
03/05/2014	0	Not done

Date	Number of PFM sessions	Comment

Date	Number of PFM sessions	Comment

If you were unable to do the exercises or use the biofeedback as often as advised please can you say why?

_____
_____
_____
_____
_____
_____
_____

Other comments;

_____
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OPAL Trial Office;
OPAL Trial Manager, Susan Stratton
susan.stratton@gcu.ac.uk/ 0141 331 3504

OPAL
optimising pelvic floor exercises to achieve longterm benefits

Study No: | | | | | | |

Date: | d | d | m | m | y | y |

Issued at Appointment: *(please circle)*

1 / 2 / 3 / 4 / 5

Please bring this diary to your next appointment

Pelvic floor muscle exercise and Biofeedback diary

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

Your Home Exercise Programme

Biofeedback Device Programme

Following discussions with my clinician I will:-

Use the biofeedback equipment as programmed once a day for ☐ days each week

Pelvic Floor Muscle Exercise Programme (1 + 2 = a session)

Following discussions with my clinician I will:-

1. tighten my pelvic floor muscles and hold as tight as I can for ☐ seconds, relax for ☐ seconds ***and*** repeat this ☐ times

and then

2. tighten my pelvic floor muscles and quickly release them ☐ times

and

3. repeat both exercises 1 & 2 (one session) ☐ times a day for ☐ days each week

In (tick all that apply)

Lying ☐ Sitting ☐ Standing ☐

Date	Number of PFM sessions (using BF)	Number of PFM sessions (not using BF)	Comment

Date	Number of PFM sessions (using BF)	Number of PFM sessions (not using BF)	Comment

Additional agreement

- The best time for me to do my exercises is _____
- I will contract my pelvic floor muscles every time I _____
- The best time for me to use the biofeedback machine is _____
- I will use my biofeedback machine ___ times a day ___ days each week

Signature of clinician: _____
Signature of patient: _____
Date: _____

If you have any concerns with the home exercise programme please contact me;

Clinician Name: _____

Telephone No: _____

Diary Completion Instructions

- Please bring this diary to your next appointment. You will be issued a new diary at each appointment.
- Please write an entry on each day until your next appointment. If you did not perform any PFM sessions do not leave blank. Please enter the date, 0 for PFM sessions (both columns) and add a comment *(see example on line 2)*

Date	Number of PFM sessions (using BF)	Number of PFM sessions (not using BF)	Comment
02/05/2014	2	1	Used as advised
03/05/2014	0	0	Not done

Date	Number of PFM sessions (using BF)	Number of PFM sessions (not using BF)	Comment

Date	Number of PFM sessions (using BF)	Number of PFM sessions (not using BF)	Comment

Do you have any comments related to your urine leakage ?

If you have any questions about completing the diary please contact:

Clinician Name: _____

Telephone No: _____

THANK YOU FOR TAKING THE TIME TO COMPLETE THE BLADDER DIARY.

PLEASE RETURN IT TO YOUR THERAPIST AT YOUR NEXT APPOINTMENT.

LOCAL NHS LOGO

Study No:

Please bring this diary to your next appointment

Baseline
3 – Day Bladder Diary

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

OPAL
optimising pelvic floor exercises to achieve longterm benefits

Completion Instruction

Please keep this diary to record how your bladder is functioning. Complete the diary for 3 days in a row. Two pages are provided for each day. Skip over the second page if you do not need to use it.

Please complete one line indicating every time you:

- **Have a drink** (complete columns 1 and 2)
- **Go to the toilet to empty your bladder** (complete columns 1, 3 and 4)
- **Leak urine** (complete columns 1, 4, 5 and 6)

If these things happen at the same time you can include them on the same line. Try not to rely on memory but record events as soon after they happen as you can.

We have provided some examples below and more detailed instructions for columns 4 and 5 on the opposite page.

Examples

	1. Time	**2. Drinks**		**3. Trips to the toilet**
		What kind?	How much?	How much urine (mls)
Drink	6.30am	Coffee	1 mug	
Toilet	6.50am			230
Leaked	7.00am			
Toilet & Leaked	7.30am			100

Did you use any pads today? (please tick) - Yes ☑ **No** ☐

4. How strong was your urge to go?					**5. Accidental Leaks**			**6. What were you doing at the time?**
None	Mild	Mod.	Sev.	Leaked.	Small	Mod.	Large	Eg. coughing, walking, having sex,
(tick one)					*(tick one)*			
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If yes, how many times did you change a pad because it was wet ? ☐

Day 3 cont'd

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	2. Drinks		3. Trips to the toilet
	What kind?	How much? (mls)	How much urine (mls)

Did you use any pads today? (please tick) - Yes ☐ No ☐

Completing column 4

Use the following scale to indicate how urgent your need to pass urine was on each occasion:

- **None:** I felt no need to empty my bladder but did so for other reasons.
- **Mild:** I could postpone voiding for as long as necessary without fear of wetting myself.
- **Moderate:** I could postpone voiding for a short while without fear of wetting myself.
- **Severe:** I could not postpone voiding but had to rush to the toilet in order not to wet myself.
- **Leaked:** I leaked before arriving at the toilet.

Completing column 5

Use the following scale to indicate how much urine was leaked:

- A **small leak** would damp your pants/panty liner;
- A **moderate leak** would wet a liner/pants and damp a pad;
- A **large leak** would wet a pad and/or soak inner and outer clothes.

4. How strong was your urge to go? *(see key above)*	5. Accidental Leaks *(see key above)*	6. What were you doing at the time?
None Mild Mod. Sev. Leaked. *(tick one)*	Small Mod. Large *(tick one)*	Eg. coughing, walking, having sex,
☐ ☐ ☐ ☐ ☐	☐ ☐ ☐	
☐ ☐ ☑ ☐ ☐	☐ ☑ ☐	
☐ ☐ ☐ ☐ ☑	☑ ☐ ☐	walking
☐ ☐ ☐ ☐ ☑	☐ ☑ ☐	On way to toilet

If yes, how many times did you change a pad because it was wet ? 3

Day 1

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	**2. Drinks**		**3. Trips to the toilet**	**4. How strong was your urge to go?**	**5. Accidental Leaks**	**6. What were you doing at the time?**
	What kind?	How much? (mls)	How much urine (mls)	None Mild Mod. Sev. Leaked *(tick one)*	Small Mod. Large *(tick one)*	Eg. coughing, walking, having sex
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Did you use any pads today? (please tick) - Yes ☐ **No** ☐				**If yes, how many times did you change a pad because it was wet ?** ☐		

Day 3

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	**2. Drinks**		**3. Trips to the toilet**	**4. How strong was your urge to go?**					**5. Accidental Leaks**			**6. What were you doing at the time?**
	What kind?	How much? (mls)	How much urine (mls)	None	Mild	Mod.	Sev.	Leaked *(tick one)*	Small	Mod.	Large *(tick one)*	Eg. coughing, walking, having sex
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Did you use any pads today? (please tick) - Yes ☐ **No** ☐				**If yes, how many times did you change a pad because it was wet ?** ☐								

Day 1 cont'd

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	**2. Drinks**		**3. Trips to the toilet**	**4. How strong was your urge to go?**					**5. Accidental Leaks**			**6. What were you doing at the time?**
	What kind?	How much? (mls)	How much urine (mls)	None	Mild	Mod.	Sev.	Leaked	Small	Mod.	Large	Eg. coughing, walking, having sex
				(tick one)					*(tick one)*			
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Did you use any pads today? (please tick) - Yes ☐ **No** ☐

If yes, how many times did you change a pad because it was wet ? ☐

Day 2 cont'd

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	**2. Drinks**		**3. Trips to the toilet**	**4. How strong was your urge to go?**	**5. Accidental Leaks**	**6. What were you doing at the time?**
	What kind?	How much? (mls)	How much urine (mls)	None Mild Mod. Sev. Leaked *(tick one)*	Small Mod. Large *(tick one)*	Eg. coughing, walking, having sex
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Did you use any pads today? (please tick) - Yes ☐ **No** ☐				**If yes, how many times did you change a pad because it was wet ?** ☐		

Day 2

Date Form completed: | d | d | m | m | y | y |

Please see pages 2 and 3 for completion guidelines.

1. Time	**2. Drinks**		**3. Trips to the toilet**	**4. How strong was your urge to go?**	**5. Accidental Leaks**	**6. What were you doing at the time?**
	What kind?	How much? (mls)	How much urine (mls)	None Mild Mod. Sev. Leaked *(tick one)*	Small Mod. Large *(tick one)*	Eg. coughing, walking, having sex
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Did you use any pads today? (please tick) - Yes ☐ **No** ☐

If yes, how many times did you change a pad because it was wet ? ☐

STUDY No. | | | | | |

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

BASELINE QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.0 04 Apr 2014

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

e.g. | 2 | 7 | **or** | A | N | N | E | **or** | ✓ |

If you make any errors while completing the form, shade out the box completely and mark the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN ☐ **SOMETIMES** ☑ **NEVER** ☐

Sometimes we would like you to write your answer in your own words, please write these in the boxes provided.

In some questions we would like you to think about different time periods, such as during the last 4 weeks or today. Please check the time periods carefully.

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

You do not have to answer any question if you do not want to.

Thank you for your time in completing this questionnaire. Your answers will be treated with complete confidentiality.

Please start here:

Date questionnaire filled in | D | D | M | M | Y | Y |

Your date of birth | D | D | M | M | Y | Y |

Section A Urine symptoms

Many people experience urinary symptoms some of the time. The questions in this section ask about your experience of urinary symptoms or urine leakage, and how much these bother you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the LAST FOUR WEEKS.

A1 During the night, how many times do you have to get up to urinate (pass water), on average?

- none ☐
- one ☐
- two ☐
- three ☐
- four or more ☐

A2 Do you have a sudden need to rush to the toilet to urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A3 Do you have pain in your bladder?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A4 How often do you pass urine during the day?

- 1 to 6 times ☐
- 7 to 8 times ☐
- 9 to 10 times ☐
- 11 to 12 times ☐
- 13 or more times ☐

A5 Is there a delay before you can start to urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A6 Do you have to strain to urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A7 Do you stop and start more than once while you urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A8 Does urine leak before you can get to the toilet?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A9 How often do you leak urine?

never ☐
about once a week or less often ☐
two or three times a week ☐
about once a day ☐
several times a day ☐
all the time ☐

A10 We would like to know how much urine <u>you think</u> leaks.

How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

A11 Does urine leak when you are physically active, exert yourself, cough or sneeze?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A12 Do you ever leak urine for no obvious reason and without feeling that you want to go?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A13 Do you leak urine when you are asleep?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A14 Do you leak urine when you have sexual intercourse?

- not at all ☐
- a little ☐
- somewhat ☐
- a lot ☐
- not applicable ☐

A15 Tick the one box that best describes how your urine leakage is now:

normal ☐
mild ☐
moderate ☐
severe ☐

A16 Overall, how much does leaking urine interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

A17 Do you wear a pad or other protection because of leaking urine?

yes ☐
no ☐

A17a If yes, how many pads do you wear in an average day (24 hours)?

Enter TOTAL number of pads you wear in 24 hours

Section B Quality of life relating to urine leakage

Below are some daily activities that can be affected by urinary problems. How much does your urinary problem affect you? We would like you to answer every question. Simply tick the box that applies to you.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

B1. To what extent does your urinary problem affect your household tasks (e.g. cleaning shopping, etc.)

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B2. Does your urinary problem affect your job, or your normal daily activities outside the home?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B3. Does your urinary problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B4. Does your urinary problem affect your ability to travel?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B5. Does your urinary problem limit your social life?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B6. Does your urinary problem limit your ability to see/visit friends?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B7. Does your urinary problem affect your relationship with your partner?

not applicable ☐
not at all ☐
slightly ☐
moderately ☐
a lot ☐

B8. Does your urinary problem affect your sex life?

not applicable ☐
not at all ☐
slightly ☐
moderately ☐
a lot ☐

B9. Does your urinary problem affect your family life?

- not applicable ☐
- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B10. Does your urinary problem make you feel depressed?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B11. Does your urinary problem make you feel anxious or nervous?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B12. Does your urinary problem make you feel bad about yourself?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B13. Does your urinary problem affect your sleep?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B14. Do you feel worn out/tired?

never ☐
sometimes ☐
often ☐
all of the time ☐

Do you do any of the following? If so, how much?

B15. Wear pads to keep dry?

never ☐
sometimes ☐
often ☐
all of the time ☐

B16. Be careful how much fluid you drink?

never ☐
sometimes ☐
often ☐
all of the time ☐

B17. Change your underclothes when they get wet?

never ☐
sometimes ☐
often ☐
all of the time ☐

B18. Worry in case you smell?

never ☐
sometimes ☐
often ☐
all of the time ☐

B19. Get embarrassed because of your urinary problem?

never ☐
sometimes ☐
often ☐
all of the time ☐

20. **Overall, how much do urinary symptoms interfere with your everyday life?**
Please ring a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

Section C Bowel symptoms

Many people experience bowel symptoms some of the time. We are trying to find out how many women with urine leakage experience bowel symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS. (*Please cross one box for each question*)**

C1 How often do you have your bowels open?

- three or more times a day ☐
- about twice a day ☐
- about once a day ☐
- two or three times per week ☐
- once a week or less ☐

C2 Are your motions usually…

- watery ☐
- sloppy ☐
- soft and formed ☐
- hard ☐

C3 Do you have difficulty emptying your bowels?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C4 Do you have to rush to the toilet to open your bowels?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C5 Does stool leak before you can get to the toilet?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C6 Overall, how much do your bowel symptoms interfere with your everyday life?
Please cross a number between 0 (not at all) and 10 (a great deal) or "Not applicable"

☐		☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Not applicable		0 not at all	1	2	3	4	5	6	7	8	9	10 a great deal

Section D Prolapse symptoms

Many women experience prolapse symptoms some of the time. We are trying to find out how many women with urine leakage experience prolapse symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS. (*Please cross one box for each question*)**

How often during the last four weeks have you had the following symptoms:		**Never**	**Occasion-ally**	**Some-times**	**Most of the time**	**All of the time**
D1	a feeling of something coming down from or in your vagina?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D2	an uncomfortable feeling or pain in your vagina which is worse when standing?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D3	a heaviness or dragging feeling in your lower abdomen (tummy)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D4	a heaviness or dragging feeling in your lower back?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D5	a need to strain (push) to empty your bladder?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D6	a feeling that your bladder has not emptied completely?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D7	a feeling that your bowel has not emptied completely?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

D8 which of the symptoms above (questions D1 to D7) causes you most bother?

Please enter a number from 1 to 7 in the box, or cross "Not applicable" **D** ☐ Not applicable ☐

D9 Overall, how much do your prolapse symptoms interfere with your everyday life?

Please cross a number between 0 (not at all) and 10 (a great deal)

☐ Not applicable ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

not at all — a great deal

Section E Pelvic floor muscle exercises

Pelvic floor muscle exercises are often recommended to help with urine leakage. They are also known as pelvic floor exercises or Kegels. The exercises involve contracting (tightening and pulling up) the muscles in the area around your vagina. This section asks questions about how confident you are doing pelvic floor muscle exercises. By placing a tick in one box in each row below, please indicate which statements best describe your confidence**.**

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
E1	I believe I can contract my pelvic floor muscles as intensive as I can	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E2	I believe I can contract my pelvic floor muscles for duration of 5 seconds	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E3	I believe I can contract my pelvic floor muscles for duration of 10 seconds	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E4	I believe I can perceive the contraction of the muscle while I am doing pelvic floor muscle exercises	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E5	I believe I can do pelvic floor muscle exercises while doing housework	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E6	I believe I can do pelvic floor muscle exercises anytime I think of it, such as, while driving, riding, or waiting for a traffic light change	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E7	I believe I can contract my pelvic floor muscles before physical exertion, e.g., coughing, laughing	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E8	I believe that pelvic floor muscle exercises can help decrease urine leakage	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E9	I believe that pelvic floor muscle exercises can help avoid (or delay) incontinence surgery	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E10	I believe I can contract my pelvic floor muscles to increase pleasure during sexual intercourse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E11	I believe I can do pelvic floor muscle exercises even without the assistance of biofeedback and/or electrical stimulation	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

E12	I believe I can do pelvic floor muscle exercises daily	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E13	I believe I can do pelvic floor muscle exercises regularly for 3 months	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E14	I believe I can remind myself to do pelvic floor muscle exercises every day	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E15	I believe I can do pelvic floor muscle exercises even when there is a lack of time	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E16	I believe I can do pelvic floor muscle exercises even when I lack energy (too tired)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E17	I believe I can do pelvic floor muscle exercises while watching TV	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

E18 Have you done any pelvic floor muscle exercises over the last month?

Yes ☐ 1 No ☐ 0

E18a If yes, how often did you do the exercises? *(cross one box only)*

A few times a month ☐ 1 A few times a week ☐ 3

Once a week ☐ 2 Once a day ☐ 4 A few times a day ☐ 5

Section F General health TODAY

This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

F1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

F2 Self-care

I have no problems with self-care ☐
I have some problems washing myself or dressing myself ☐
I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

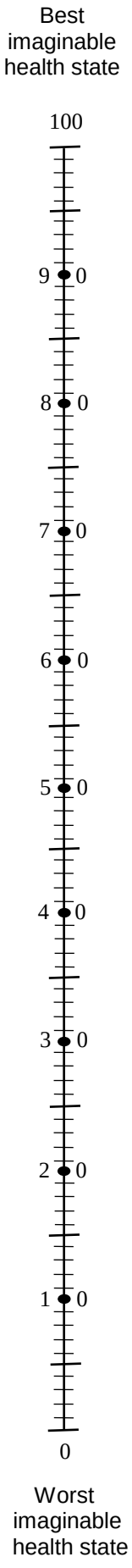
F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Section G Your obstetric history

G1 Please could you tell me a little about the babies you have had?

Number of deliveries ☐☐ (count twins as two separate births)

G2 Year last child born **(year)** ☐☐☐☐

G3 Types of delivery

Number of **normal vaginal** deliveries	☐	Number of **Caesareans before** labour (elective)	☐	Number of **breech** (vaginal) deliveries	☐
Number of **forceps** deliveries	☐	Number of **Caesareans during** labour (emergency)	☐	Number of **vacuum** extraction deliveries	☐

G4 Were any of these twin deliveries?

Yes ☐ No ☐ If **Yes**, enter number of sets of twins: ☐

G5 Please could you give some information about your weight and height?
(Please use whichever units you are familiar with)

What is your average weight now? ☐☐☐ kg OR ☐☐ Stones ☐☐ Pounds

What is your height? ☐☐☐ cm OR ☐☐ Feet ☐☐ Inches

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

Thank you very much for answering these questions. We intend to use the information you have given us for research to help women like yourself who experience urine leakage.

PLEASE GIVE THIS QUESTIONNAIRE TO THE STAFF NOW, OR RETURN IT TO THE TRIAL OFFICE IN THE ENVELOPE PROVIDED.

If you would like any further information or have any queries about the trial, please contact:

The OPAL Trial Office
Tel: 0141 331 3504
E-mail: OpalTrial@gcu.ac.uk

STUDY No. | | | | | |

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

6/12 MONTH QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.1 02 Jul 2014

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

e.g. | 2 | 7 | **or** | A | N | N | E | **or** | ✓ |

If you make any errors while completing the form, shade out the box completely and mark the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN ▒ **SOMETIMES** ✓ **NEVER** ☐

Sometimes we would like you to write your answer in your own words, please write these in the boxes provided.

In some questions we would like you to think about different time periods, such as during the last 4 weeks or today. Please check the time periods carefully.

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

You do not have to answer any question if you do not want to.

Thank you for your time in completing this questionnaire. Your answers will be treated with complete confidentiality.

Please start here:

Date questionnaire filled in | D | D | M | M | Y | Y |

Section A Urine symptoms

Many people experience urinary symptoms some of the time. The questions in this section ask about your experience of urinary symptoms or urine leakage, and how much these bother you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the LAST FOUR WEEKS.

A1 During the night, how many times do you have to get up to urinate (pass water), on average?

- none ☐
- one ☐
- two ☐
- three ☐
- four or more ☐

A2 Do you have a sudden need to rush to the toilet to urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A3 Do you have pain in your bladder?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A4 How often do you pass urine during the day?

- 1 to 6 times ☐
- 7 to 8 times ☐
- 9 to 10 times ☐
- 11 to 12 times ☐
- 13 or more times ☐

A5 Is there a delay before you can start to urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A6 Do you have to strain to urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A7 Do you stop and start more than once while you urinate (pass water)?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A8 Does urine leak before you can get to the toilet?

never ☐
occasionally ☐
sometimes ☐
most of the time ☐
all of the time ☐

A9 How often do you leak urine?

never ☐
about once a week or less often ☐
two or three times a week ☐
about once a day ☐
several times a day ☐
all the time ☐

A10 We would like to know how much urine <u>you think</u> leaks.

How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

A11 Does urine leak when you are physically active, exert yourself, cough or sneeze?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A12 Do you ever leak urine for no obvious reason and without feeling that you want to go?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A13 Do you leak urine when you are asleep?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A14 Do you leak urine when you have sexual intercourse?

- not at all ☐
- a little ☐
- somewhat ☐
- a lot ☐

A15 **Tick the one box that best describes how your urine leakage is now, compared with how it was before you began having treatment within this study:**

- very much better ☐
- much better ☐
- a little better ☐
- no change ☐
- a little worse ☐
- much worse ☐
- very much worse ☐

A16 **Overall, how much does leaking urine interfere with your everyday life?**
Please tick a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

A17 **Do you wear a pad or other protection because of leaking urine?**

- yes ☐
- no ☐

If No, please go to question A18.

A17a **If yes, how many pads do you wear in an average day (24 hours)?**

Enter TOTAL number of pads you wear in 24 hours ☐☐

A17b **Of these pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads YOU PAY FOR yourself ☐☐

A18 **Do you use pads or protectors on your chair or bed in case you leak urine?**

- yes ☐
- no ☐

If No, please go to section B.

A18a If Yes, how many chair or bed pads do you use in an average day (24 hours)?

***Ente*r TOTAL number of chair and bed pads you use in 24 hours** | | |

A18b Of these chair or bed pads, how many do you pay for yourself?
If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads YOU PAY FOR yourself | | |

Section B Quality of life relating to urine leakage

Below are some daily activities that can be affected by urinary problems. How much does your urinary problem affect you? We would like you to answer every question. Simply tick the box that applies to you.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

B1. To what extent does your urinary problem affect your household tasks (e.g. cleaning shopping, etc.)

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B2. Does your urinary problem affect your job, or your normal daily activities outside the home?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B3. Does your urinary problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B4. Does your urinary problem affect your ability to travel?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B5. Does your urinary problem limit your social life?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B6. Does your urinary problem limit your ability to see/visit friends?

not at all ☐
slightly ☐
moderately ☐
a lot ☐

B7. Does your urinary problem affect your relationship with your partner?

not applicable ☐
not at all ☐
slightly ☐
moderately ☐
a lot ☐

B8. Does your urinary problem affect your sex life?

not applicable ☐
not at all ☐
slightly ☐
moderately ☐
a lot ☐

B9. Does your urinary problem affect your family life?

not applicable ☐
not at all ☐
slightly ☐
moderately ☐
a lot ☐

B10. Does your urinary problem make you feel depressed?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B11. Does your urinary problem make you feel anxious or nervous?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B12. Does your urinary problem make you feel bad about yourself?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B13. Does your urinary problem affect your sleep?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B14. Do you feel worn out/tired?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

Do you do any of the following? If so, how much?

B15. Wear pads to keep dry?

never ☐
sometimes ☐
often ☐
all of the time ☐

B16. Be careful how much fluid you drink?

never ☐
sometimes ☐
often ☐
all of the time ☐

B17. Change your underclothes when they get wet?

never ☐
sometimes ☐
often ☐
all of the time ☐

B18. Worry in case you smell?

never ☐
sometimes ☐
often ☐
all of the time ☐

B19. Get embarrassed because of your urinary problem?

never ☐
sometimes ☐
often ☐
all of the time ☐

20. **Overall, how much do urinary symptoms interfere with your everyday life?**

Please tick a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

Section C Bowel symptoms

Many people experience bowel symptoms some of the time. We are trying to find out how many women with urine leakage experience bowel symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS. (*Please tick one box for each question*)**

C1 How often do you have your bowels open?

- three or more times a day ☐
- about twice a day ☐
- about once a day ☐
- two or three times per week ☐
- once a week or less ☐

C2 Are your motions usually…

- watery ☐
- sloppy ☐
- soft and formed ☐
- hard ☐

C3 Do you have difficulty emptying your bowels?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C4 Do you have to rush to the toilet to open your bowels?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C5 Does stool leak before you can get to the toilet?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

C6 Overall, how much do your bowel symptoms interfere with your everyday life?

Please tick a number between 0 (not at all) and 10 (a great deal) or "Not applicable"

☐ Not applicable	☐ 0 not at all	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 a great deal

Section D Prolapse symptoms

Many women experience prolapse symptoms some of the time. We are trying to find out how many women with urine leakage experience prolapse symptoms, and how much they bother them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS. (*Please tick one box for each question*)**

How often during the last four weeks have you had the following symptoms:	**Never**	**Occasion-ally**	**Some-times**	**Most of the time**	**All of the time**
D1 a feeling of something coming down from or in your vagina?	☐	☐	☐	☐	☐
D2 an uncomfortable feeling or pain in your vagina which is worse when standing?	☐	☐	☐	☐	☐
D3 a heaviness or dragging feeling in your lower abdomen (tummy)?	☐	☐	☐	☐	☐
D4 a heaviness or dragging feeling in your lower back?	☐	☐	☐	☐	☐
D5 a need to strain (push) to empty your bladder?	☐	☐	☐	☐	☐
D6 a feeling that your bladder has not emptied completely?	☐	☐	☐	☐	☐
D7 a feeling that your bowel has not emptied completely?	☐	☐	☐	☐	☐

D8 which of the symptoms above (questions D1 to D7) causes you most bother?
Please enter a number from 1 to 7 in the box, or tick "Not applicable" **D** ☐ Not applicable ☐

D9 Overall, how much do your prolapse symptoms interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal)

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Not	0	1	2	3	4	5	6	7	8	9	10
applicable	not at all										a great deal

Section E Pelvic floor muscle exercises

Pelvic floor muscle exercises are often recommended to help with urine leakage. They are also known as pelvic floor exercises or Kegels. The exercises involve contracting (tightening and pulling up) the muscles in the area around your vagina. This section asks questions about how you have been getting on doing pelvic floor muscle exercises and how confident you feel.

E1 Have you done any pelvic floor muscle exercises over the last month?

Yes ☐ No ☐

If No, please continue go to question E8

E1A Have you used a biofeedback machine over the last month?

Yes ☐ No ☐

E2 How often did you do the pelvic floor muscle exercises over the last month? *(tick one box only)*

A few times a month ☐ A few times a week ☐

Once a week ☐ Once a day ☐ A few times a day ☐

E3 Did you do pelvic floor muscle exercises yesterday?
(tick one box only)

No, because I don't remember exactly how to do them ☐
No, because I forgot to do them ☐
No, because I didn't feel like doing them ☐
No, because my urinary leakage wasn't bothering me enough to do them ☐
No, because I was busy doing other things ☐
No, because I was too tired to exercise ☐
No, because the exercises give me an uncomfortable feeling ☐
Yes ☐

E4 How often did you do the exercises yesterday?
(tick one box, and also enter a number if appropriate)

I did not exercise yesterday ☐
I exercised a little, ___times ☐
I exercised now and then, ___ times ☐
I exercised regularly, ___ times ☐

E5 **Did you do the exercises in the last 7 days?**
(tick one box only)

No, because I don't remember exactly how to do them ☐
No, because I forgot to do them ☐
No, because I didn't feel like doing them ☐
No, because my urinary leakage wasn't bothering me enough to do them ☐
No, because I was busy doing other things ☐
No, because I was too tired to exercise ☐
No, because the exercises give me an uncomfortable feeling ☐
Yes ☐

E6 **In the last 7 days, <u>on how many days</u> did you do the exercises?**
(Please tick a number between 0 and 7 days)

0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐
days days

E7 **Give yourself a 'score out of ten' for how well you have exercised in this last week**
Please tick a number between 0 and 10

0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐
very poorly very well

By placing a tick in one box in each row below, please indicate which statements best describe your confidence:

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
E8	I believe I can contract my pelvic floor muscles as intensive as I can	☐	☐	☐	☐	☐
E9	I believe I can contract my pelvic floor muscles for duration of 5 seconds	☐	☐	☐	☐	☐
E10	I believe I can contract my pelvic floor muscles for duration of 10 seconds	☐	☐	☐	☐	☐
E11	I believe I can perceive the contraction of the muscle while I am doing pelvic floor muscle exercises	☐	☐	☐	☐	☐
E12	I believe I can do pelvic floor muscle exercises while doing housework	☐	☐	☐	☐	☐
E13	I believe I can do pelvic floor muscle exercises anytime I think of it, such as, while driving, riding, or waiting for a traffic light change	☐	☐	☐	☐	☐

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
E14	I believe I can contract my pelvic floor muscles before physical exertion, e.g., coughing, laughing	☐	☐	☐	☐	☐
E15	I believe that pelvic floor muscle exercises can help decrease urine leakage	☐	☐	☐	☐	☐
E16	I believe that pelvic floor muscle exercises can help avoid (or delay) incontinence surgery	☐	☐	☐	☐	☐
E17	I believe I can contract my pelvic floor muscles to increase pleasure during sexual intercourse	☐	☐	☐	☐	☐
E18	I believe I can do pelvic floor muscle exercises even without the assistance of biofeedback and/or electrical stimulation	☐	☐	☐	☐	☐
E19	I believe I can do pelvic floor muscle exercises daily	☐	☐	☐	☐	☐
E20	I believe I can do pelvic floor muscle exercises regularly for 3 months	☐	☐	☐	☐	☐
E21	I believe I can remind myself to do pelvic floor muscle exercises every day	☐	☐	☐	☐	☐
E22	I believe I can do pelvic floor muscle exercises even when there is a lack of time	☐	☐	☐	☐	☐
E23	I believe I can do pelvic floor muscle exercises even when I lack energy (too tired)	☐	☐	☐	☐	☐
E24	I believe I can do pelvic floor muscle exercises while watching TV	☐	☐	☐	☐	☐

Section F General health TODAY

This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

F1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

F2 Self-care

I have no problems with self-care ☐
I have some problems washing myself or dressing myself ☐
I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

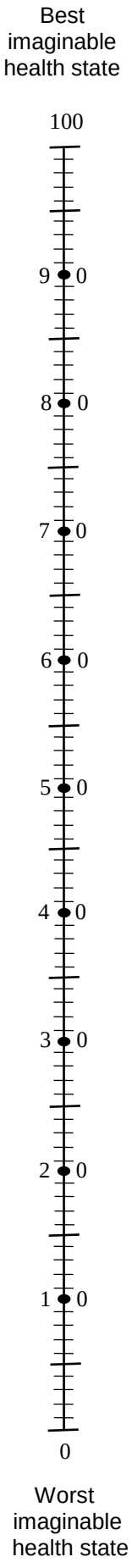
F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Section G Care you have received

When you answer these questions, please think about the care you have received in the LAST 6 MONTHS

G1 Have you seen your family doctor (GP) in the last 6 months?

Yes ☐ **No** ☐

G1a If Yes, approximately how often have you seen your family doctor (GP) in the last 6 months?

Enter number of times seen GP for urine leakage ☐☐

Enter number of times seen GP for any other reason ☐☐

G2 Have you seen a nurse (from your doctor's practice) in the last 6 months?

Yes ☐ **No** ☐

G2a If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 6 months?

Enter number of times seen nurse for urine leakage ☐☐

Enter number of times seen nurse for any other reason ☐☐

G3 In the last 6 months, have you seen NHS HOSPITAL staff <u>for urine leakage</u>?

		If yes, enter number of visits
I have seen a hospital doctor about urine leakage	**Yes** ☐ **No** ☐	**Number of visits** ☐☐
I have seen a hospital nurse about urine leakage	**Yes** ☐ **No** ☐	**Number of visits** ☐☐
I have seen a hospital physiotherapist about urine leakage	**Yes** ☐ **No** ☐	**Number of visits** ☐☐

G4 In the last 6 months, have you received any PRIVATE TREATMENT (for which you had to pay for yourself) <u>for urine leakage</u>?

		If yes, enter number of visits	
I have seen a private doctor about urine leakage	**Yes** ☐	**Number of visits** ☐☐	
	No ☐		
		If yes, enter number of visits	
I have seen a private nurse about urine leakage	**Yes** ☐	**Number of visits** ☐☐	
	No ☐		
		If yes, enter number of visits	
I have seen a private physiotherapist about urine leakage	**Yes** ☐	**Number of visits** ☐☐	
	No ☐		

G5 In the last 6 months, have you been admitted to hospital <u>because of urine leakage</u>?

Yes ☐ **No** ☐

G5a If you were admitted in the last 6 months, how many nights did you stay in hospital?

Enter number of nights in hospital ☐☐

G5b In the last 6 months, have you had an operation <u>for urine leakage?</u>

Yes ☐ **No** ☐

G5c If Yes, please give the name or type of operation and the date:

G6 In the last 6 months, have you taken any medications *(from a doctor, or direct from the chemist's)* <u>for urine leakage</u>?

Yes ☐ **No** ☐

G6a If Yes, please give details of medication received in the last 6 months <u>for urine leakage</u>. Please give drug names (e.g. detrusitol, duloxetine):

G7 Have you had any other treatment or advice <u>for urine leakage</u> in the last 6 months (other than the operation you named in G5c or the drugs you listed in G6a, e.g. vaginal cones)?

Yes ☐ **No** ☐

G7a If Yes, please give details of other treatment or advice received in the last 6 months <u>for urine leakage:</u>

G8 Are you in paid employment?

Yes ☐ **No** ☐

G8a If Yes, approximately how many days off sick have you had <u>for any reason</u> in the last 6 months?

☐☐☐ **Days**

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

Thank you very much for answering these questions. We intend to use the information you have given us for research to help women like yourself who experience urine leakage.

PLEASE RETURN THIS QUESTIONNAIRE TO THE TRIAL OFFICE IN THE ENVELOPE PROVIDED.

If you would like any further information or have any queries about the trial, please contact:

The OPAL Trial Office
Tel: 0141 331 3505
E-mail: OpalTrial@gcu.ac.uk

STUDY No. | | | | | |

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

24 MONTH QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.2 02 Feb 2016

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

e.g. | 2 | 7 | **or** | A | N | N | E | **or** | ✓ |

If you make any errors while completing the form, shade out the box completely and mark the correct one like this:

e.g. If you ticked 'often' but meant to answer 'sometimes':

OFTEN ▒ **SOMETIMES** ✓ **NEVER** ☐

Sometimes we would like you to write your answer in your own words, please write these in the boxes provided.

In some questions we would like you to think about different time periods, such as during the last 4 weeks or today. Please check the time periods carefully.

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

You do not have to answer any question if you do not want to.

Thank you for your time in completing this questionnaire. Your answers will be treated with complete confidentiality.

PLEASE START HERE:

Date questionnaire filled in | D | D | M | M | Y | Y |

What is your average weight now? | | | | **kg** **OR** | | | **Stones** | | | **Pounds**

What is your height? | | | | **cm** **OR** | | | **Feet** | | | **Inches**

Section A Urine symptoms

Many people experience urinary symptoms some of the time. The questions in this section ask about your experience of urinary symptoms or urine leakage, and how much these bother you.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS**.

A1 During the night, how many times do you have to get up to urinate (pass water), on average?

- none ☐
- one ☐
- two ☐
- three ☐
- four or more ☐

A2 Do you have a sudden need to rush to the toilet to urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A3 Do you have pain in your bladder?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A4 How often do you pass urine during the day?

- 1 to 6 times ☐
- 7 to 8 times ☐
- 9 to 10 times ☐
- 11 to 12 times ☐
- 13 or more times ☐

A5 Is there a delay before you can start to urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A6 Do you have to strain to urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A7 Do you stop and start more than once while you urinate (pass water)?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A8 Does urine leak before you can get to the toilet?

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A9 How often do you leak urine?

- never ☐
- about once a week or less often ☐
- two or three times a week ☐
- about once a day ☐
- several times a day ☐
- all the time ☐

A10 **We would like to know how much urine <u>you think</u> leaks.**

How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

A11 **Does urine leak when you are physically active, exert yourself, cough or sneeze?**

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A12 **Do you ever leak urine for no obvious reason and without feeling that you want to go?**

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A13 **Do you leak urine when you are asleep?**

- never ☐
- occasionally ☐
- sometimes ☐
- most of the time ☐
- all of the time ☐

A14 **Do you leak urine when you have sexual intercourse?**

- not at all ☐
- a little ☐
- somewhat ☐
- a lot ☐
- not applicable ☐

A15 Tick the one box that best describes how your urine leakage is now, compared with how it was before you began having treatment within this study (about 2 years ago):

- very much better ☐
- much better ☐
- a little better ☐
- no change ☐
- a little worse ☐
- much worse ☐
- very much worse ☐

A16 Overall, how much does leaking urine interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal)

not at all											a great deal
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
	0	1	2	3	4	5	6	7	8	9	10

A17 Do you wear a pad or other protection because of leaking urine?

- yes ☐
- no ☐

If No, please go to question A18

a. If yes, how many pads do you wear in an average day (24 hours)?

Enter TOTAL number of pads you wear in 24 hours ☐☐

b. Of these pads, how many do you pay for yourself?
If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads YOU PAY FOR yourself ☐☐

A18 **Do you use pads or protectors on your chair or bed in case you leak urine?**

yes ☐

no ☐

If No, please go to section B

a. **If Yes, how many chair or bed pads do you use in an average day (24 hours)?**

Enter TOTAL number of chair and bed pads you use in 24 hours ☐☐

b. **Of these chair or bed pads, how many do you pay for yourself?**
If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads YOU PAY FOR yourself ☐☐

Section B Quality of life relating to urine leakage

Below are some daily activities that can be affected by urinary problems. How much does your urinary problem affect you? We would like you to answer every question. Simply tick the box that applies to you.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS.**

B1 To what extent does your urinary problem affect your household tasks (e.g. cleaning shopping, etc.)

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B2 Does your urinary problem affect your job, or your normal daily activities outside the home?

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B3 Does your urinary problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B4 Does your urinary problem affect your ability to travel?

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B5 Does your urinary problem limit your social life?

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B6 Does your urinary problem limit your ability to see/visit friends?

- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B7 Does your urinary problem affect your relationship with your partner?

- not applicable ☐
- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B8 Does your urinary problem affect your sex life?

- not applicable ☐
- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B9 Does your urinary problem affect your family life?

- not applicable ☐
- not at all ☐
- slightly ☐
- moderately ☐
- a lot ☐

B10 Does your urinary problem make you feel depressed?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B11 Does your urinary problem make you feel anxious or nervous?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B12 Does your urinary problem make you feel bad about yourself?

- not at all ☐
- slightly ☐
- moderately ☐
- very much ☐

B13 Does your urinary problem affect your sleep?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B14 Do you feel worn out/tired?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

Do you do any of the following? If so, how much?

B15 Wear pads to keep dry?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B16 Be careful how much fluid you drink?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B17 Change your underclothes when they get wet?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B18 Worry in case you smell?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B19 Get embarrassed because of your urinary problem?

- never ☐
- sometimes ☐
- often ☐
- all of the time ☐

B20. **Overall, how much do urinary symptoms interfere with your everyday life?**

Please tick a number between 0 (not at all) and 10 (a great deal)

not at all	0	1	2	3	4	5	6	7	8	9	10	a great deal
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Section C Bowel symptoms

Many people experience bowel symptoms some of the time. We are trying to find out how many women with urine leakage experience bowel symptoms, and how much they bother them.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS.** Please tick one box for each question.

C1 How often do you have your bowels open?

- ☐ three or more times a day
- ☐ about twice a day
- ☐ about once a day
- ☐ two or three times per week
- ☐ once a week or less

C2 Are your motions usually…

- ☐ watery
- ☐ sloppy
- ☐ soft and formed
- ☐ hard

C3 Do you have difficulty emptying your bowels?

- ☐ never
- ☐ occasionally
- ☐ sometimes
- ☐ most of the time
- ☐ all of the time

C4 Do you have to rush to the toilet to open your bowels?

- ☐ never
- ☐ occasionally
- ☐ sometimes
- ☐ most of the time
- ☐ all of the time

C5 Does stool leak before you can get to the toilet?

- ☐ never
- ☐ occasionally
- ☐ sometimes
- ☐ most of the time
- ☐ all of the time

C6 Overall, how much do your bowel symptoms interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal) or "Not applicable"

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Not applicable	0 not at all	1	2	3	4	5	6	7	8	9	10 a great deal	

Section D Prolapse symptoms

Many women experience prolapse symptoms some of the time. We are trying to find out how many women with urine leakage experience prolapse symptoms, and how much they bother them.

We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the **PAST FOUR WEEKS.** Please tick one box for each question

How often during the last four weeks have you had the following symptoms:	**Never**	**Occasionally**	**Sometimes**	**Most of the time**	**All of the time**
D1 a feeling of something coming down from or in your vagina?	☐	☐	☐	☐	☐
D2 an uncomfortable feeling or pain in your vagina which is worse when standing?	☐	☐	☐	☐	☐
D3 a heaviness or dragging feeling in your lower abdomen (tummy)?	☐	☐	☐	☐	☐
D4 a heaviness or dragging feeling in your lower back?	☐	☐	☐	☐	☐
D5 a need to strain (push) to empty your bladder?	☐	☐	☐	☐	☐
D6 a feeling that your bladder has not emptied completely?	☐	☐	☐	☐	☐
D7 a feeling that your bowel has not emptied completely?	☐	☐	☐	☐	☐

D8 Which of the symptoms above (questions D1 to D7) causes you most bother?
Please enter a number from 1 to 7 in the box, or tick "Not applicable" **D** ☐ Not applicable ☐

D9 Overall, how much do your prolapse symptoms interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal) or 'Not applicable'

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Not applicable	0 not at all	1	2	3	4	5	6	7	8	9	10 a great deal

Section E Pelvic floor muscle exercises

Pelvic floor muscle exercises are often recommended to help with urine leakage. They are also known as pelvic floor exercises or Kegels. The exercises involve contracting (tightening and pulling up) the muscles in the area around your vagina.

This section asks questions about how you have been getting on doing pelvic floor muscle exercises and how confident you feel.

E1 Have you done any pelvic floor muscle exercises over the last month?

Yes ☐ No ☐

If No, please go to question E8

a. Have you used a biofeedback machine over the last month?

Yes ☐ No ☐

E2 How often did you do the pelvic floor muscle exercises over the last month?

Tick one box only

- A few times a month ☐
- A few times a week ☐
- Once a week ☐
- Once a day ☐
- A few times a day ☐

E3 Did you do pelvic floor muscle exercises yesterday?

Tick one box only

- No, because I don't remember exactly how to do them ☐
- No, because I forgot to do them ☐
- No, because I didn't feel like doing them ☐
- No, because my urinary leakage wasn't bothering me enough to do them ☐
- No, because I was busy doing other things ☐
- No, because I was too tired to exercise ☐
- No, because the exercises give me an uncomfortable feeling ☐
- Yes ☐

E4 How often did you do the exercises yesterday?

Tick one box, and also enter a number if appropriate

- I did not exercise yesterday ☐
- I exercised a little, .____.times ☐
- I exercised now and then,____.times ☐
- I exercised regularly, ____.times ☐

E5 **Did you do the exercises in the last 7 days?**
Tick one box only

- No, because I don't remember exactly how to do them ☐
- No, because I forgot to do them ☐
- No, because I didn't feel like doing them ☐
- No, because my urinary leakage wasn't bothering me enough to do them ☐
- No, because I was busy doing other things ☐
- No, because I was too tired to exercise ☐
- No, because the exercises give me an uncomfortable feeling ☐
- Yes ☐

E6 **In the last 7 days, <u>on how many days</u> did you do the exercises?**
Please tick a number between 0 and 7 days

☐ 0 days ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 days

E7 **Give yourself a 'score out of ten' for how well you have exercised in this last week**
Please tick a number between 0 and 10

☐ 0 very poorly ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 very well

By placing a tick in one box in each row below, please indicate which statements best describe your confidence:

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
E8	I believe I can contract my pelvic floor muscles as intensive as I can	☐	☐	☐	☐	☐
E9	I believe I can contract my pelvic floor muscles for duration of 5 seconds	☐	☐	☐	☐	☐
E10	I believe I can contract my pelvic floor muscles for duration of 10 seconds	☐	☐	☐	☐	☐
E11	I believe I can perceive the contraction of the muscle while I am doing pelvic floor muscle exercises	☐	☐	☐	☐	☐
E12	I believe I can do pelvic floor muscle exercises while doing housework	☐	☐	☐	☐	☐

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
E13	I believe I can do pelvic floor muscle exercises anytime I think of it, such as, while driving, riding, or waiting for a traffic light change	☐	☐	☐	☐	☐
E14	I believe I can contract my pelvic floor muscles before physical exertion, e.g., coughing, laughing	☐	☐	☐	☐	☐
E15	I believe that pelvic floor muscle exercises can help decrease urine leakage	☐	☐	☐	☐	☐
E16	I believe that pelvic floor muscle exercises can help avoid (or delay) incontinence surgery	☐	☐	☐	☐	☐
E17	I believe I can contract my pelvic floor muscles to increase pleasure during sexual intercourse	☐	☐	☐	☐	☐
E18	I believe I can do pelvic floor muscle exercises even without the assistance of biofeedback and/or electrical stimulation	☐	☐	☐	☐	☐
E19	I believe I can do pelvic floor muscle exercises daily	☐	☐	☐	☐	☐
E20	I believe I can do pelvic floor muscle exercises regularly for 3 months	☐	☐	☐	☐	☐
E21	I believe I can remind myself to do pelvic floor muscle exercises every day	☐	☐	☐	☐	☐
E22	I believe I can do pelvic floor muscle exercises even when there is a lack of time	☐	☐	☐	☐	☐
E23	I believe I can do pelvic floor muscle exercises even when I lack energy (too tired)	☐	☐	☐	☐	☐
E24	I believe I can do pelvic floor muscle exercises while watching TV	☐	☐	☐	☐	☐

Section F General health TODAY

This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

F1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

F2 Self-care

I have no problems with self-care ☐
I have some problems washing myself or dressing myself ☐
I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

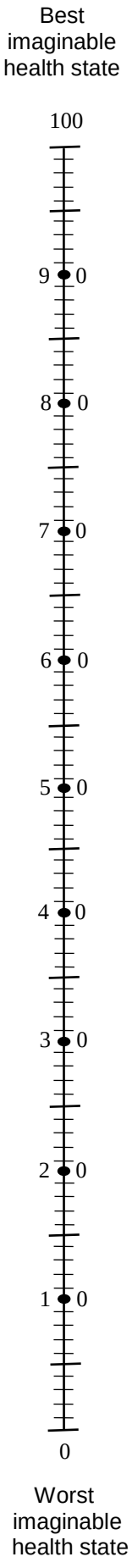
F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Section G Care you have received

When you answer these questions, please think about the care you have received in the **LAST 12 MONTHS**

G1 Have you seen your family doctor (GP) in the last 12 months?

Yes ☐ No ☐

If No, please go to question G2

a If Yes, approximately how often have you seen your family doctor (GP) in the last 12 months?

Enter number of times seen GP for urine leakage ☐☐

Enter number of times seen GP for any other reason ☐☐

G2 Have you seen a nurse (from your doctor's practice) in the last 12 months?

Yes ☐ No ☐

If No, please go to question G3

a If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 12 months?

Enter number of times seen nurse for urine leakage ☐☐

Enter number of times seen nurse for any other reason ☐☐

G3 In the last 12 months, have you seen NHS HOSPITAL staff for urine leakage?

		If yes, enter number of visits
I have seen a hospital doctor about urine leakage	Yes ☐ No ☐	Number of visits ☐☐
I have seen a hospital nurse about urine leakage	Yes ☐ No ☐	Number of visits ☐☐
I have seen a hospital physiotherapist about urine leakage	Yes ☐ No ☐	Number of visits ☐☐

G4 **In the last 12 months, have you received any PRIVATE TREATMENT (for which you had to pay for yourself) <u>for urine leakage</u>?**

		If yes, enter number of visits
I have seen a private doctor about urine leakage	Yes ☐	Number of visits ☐☐
	No ☐	
I have seen a private nurse about urine leakage	Yes ☐	Number of visits ☐☐
	No ☐	
I have seen a private physiotherapist about urine leakage	Yes ☐	Number of visits ☐☐
	No ☐	

G5 **In the last 12 months, have you been admitted to hospital <u>because of urine leakage</u>?**

Yes ☐ No ☐

If No, please go to question G5b

a **If you were admitted in the last 12 months <u>because of urine leakage</u>, how many nights did you stay in hospital?**

Enter number of nights in hospital ☐☐

b **In the last 12 months, have you had an operation <u>for urine leakage?</u>**

Yes ☐ No ☐

If No, please go to question G6

c **If Yes, please give the name or type of operation and the date:**

Type:

Date: D D M M Y Y

G6 **In the last 12 months, have you taken any medications *(from a doctor, or direct from the chemist's)* <u>for urine leakage</u>?**

Yes ☐ No ☐

If No, please go to question G7

a. **If Yes, please give details of medication received in the last 12 months <u>for urine leakage</u>. Please give drug names (e.g. detrusitol, duloxetine):**

G7 **Have you had any other treatment or advice <u>for urine leakage</u> in the last 12 months (other than the operation you named in G5c or the drugs you listed in G6a, e.g. vaginal cones)?**

Yes ☐ No ☐

If No, please go to question G8

a. **If Yes, please give details of other treatment or advice received in the last 12 months <u>for urine leakage:</u>**

G8 **Are you in paid employment**?

Yes ☐ No ☐

If No, please go to section H

a. **If Yes, approximately how many days off sick have you had <u>for urinary leakage</u> in the last 12 months?**

☐☐☐ Days

Section H Your most recent inpatient admission

This section will help us to find out how much it costs you to use health services. We would like to know about your most recent **admission to hospital**. It may have been a long time ago and we understand that you may not remember the exact details. Please just give us your best guess.

H1 Have you been admitted to hospital for your urinary leakage within the last 24 months?

Yes ☐ No ☐

If No, please go to section I

H2 Please tick the box or boxes that describe how you travelled to your most recent hospital admission.

Bus ☐ Hospital car ☐

Train ☐ Ambulance ☐

Taxi ☐ Other (please specify) _____

Private car ☐

H3 If you travelled by bus, taxi or train to your hospital admission what was the total cost of the (one-way) journey?

Please write the cost in the box below.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

H4 If you travelled by private car about how many miles did you travel one-way?

Please write the number of miles in the box below.

Number of miles one-way ☐☐☐

H5 If you travelled by private car and you or a companion had to pay a parking fee how much did this cost?

Please write the cost in the box below.

Expenditure on parking fee (£) ☐☐ - ☐☐ pence

H6 When admitted to hospital how many days were you there?

Please write the number of days in the box below.

Number of days ☐☐

H7 Please tick the box that best describes what you otherwise would have been doing as your <u>main</u> activity during this time if you had not been in hospital?

Housework	☐	Paid work (or business activity)	☐
Childcare	☐	Voluntary work	☐
Caring for relative/friend	☐	Leisure activities	☐
Unemployed	☐	Other (Please specify)	_____

H8 When you were admitted to hospital did anyone come with you? Please tick appropriate box. **Yes** ☐ **No** ☐

If yes, go to Question H9
If no, go to Section i

H9 Please tick the box that best describes the main person who accompanied you to hospital when you were admitted

Partner/ Spouse	☐	Paid caregiver	☐
Other relative	☐	Other (Please specify)	_____
Friend	☐		

H10 Please tick the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you.

Housework	☐	Paid work (or business activity)	☐
Childcare	☐	Voluntary work	☐
Caring for relative/friend	☐	Leisure activities	☐
Unemployed	☐	Other (Please specify)	_____

H11 When admitted how many days did your companion come to visit you? Please write the number of days in the box below.

Number of days ☐☐

Section I Your most recent clinic appointment

This section will help us to find out how much it costs you to use health services. We would like to know about your most recent **clinic appointment (in a hospital or a community clinic)**. It may have been a long time ago and we understand that you may not remember the exact details. Please just give us your best guess.

I1 Have you attended a clinic appointment for your urinary leakage within the last 24 months?

Yes ☐ No ☐

If No, please go to section J

I2 Please tick the box or boxes that describe how you travelled to your most recent clinic appointment.

Bus ☐ Hospital car ☐

Train ☐ Ambulance ☐

Taxi ☐ Other (please specify) _____

Private car ☐

I3 If you travelled by bus, taxi or train to your clinic appointment what was the total cost of the (one-way) journey?

Please write the cost in the box below.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

I4 If you travelled by private car about how many miles did you travel one-way?

Please write the number of miles in the box below.

Number of miles one-way ☐☐☐

I5 If you travelled by private car and you or a companion had to pay a parking fee how much did this cost?

Please write the cost in the box below.

Expenditure on parking fee (£) ☐☐ - ☐☐ pence

I6 When attending your clinic appointment, approximately how long in total did it take you (including time spent at the appointment and travel time there and back)?

Please write the number of hours and minutes in the boxes below.

Number of hours ☐☐ - ☐☐ minutes

I7 Please tick the box that best describes what you otherwise would have been doing as your main activity during this time if you had not been attending the appointment?

Housework	☐	Paid work (or business activity)	☐
Childcare	☐	Voluntary work	☐
Caring for relative/friend	☐	Leisure activities	☐
Unemployed	☐	Other (Please specify)	_____

I8 When you attended your clinic appointment did anyone come with you?
Please tick appropriate box.

Yes ☐ **No** ☐

If yes, go to Question I9
If no, go to Section J

I9 Please tick the box that best describes the main person who accompanied you to your clinic appointment.

Partner/ Spouse	☐	Paid caregiver	☐
Other relative	☐	Other (Please specify)	_____
Friend	☐		

I10 Please tick the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you.

Housework	☐	Paid work (or business activity)	☐
Childcare	☐	Voluntary work	☐
Caring for relative/friend	☐	Leisure activities	☐
Unemployed	☐	Other (Please specify)	_____

Section J — Your most recent GP (doctor/nurse) appointment

This section will help us to find out how much it costs you to use health services. We would like to know about your most recent **GP appointment**. It may have been a long time ago and we understand that you may not to remember the exact details. Please just give us your best guess.

J1 Have you attended a GP appointment for your urinary leakage within the last 24 months?

Yes ☐ No ☐

If No, please go to the next page

J2 Please tick the box or boxes that describe how you travelled to your most recent GP appointment.

Walked ☐ Bus ☐

Cycled ☐ Taxi ☐

Private car ☐ Other (please specify) _____

J3 If you travelled by bus or taxi, what was the cost of the (one-way) fare?
Please write the cost in the box below.

Cost of (one-way) fare (£) ☐☐ - ☐☐ pence

J4 If you travelled by private car about how many miles did you travel one-way?
Please write the number of miles in the box below.

Number of miles one-way ☐☐☐

J5 If you travelled by private car and you or a companion had to pay a parking fee how much did this cost?
Please write the cost in the box below.

Expenditure on parking fee (£) ☐☐ - ☐☐ pence

J6 When attending your GP appointment, approximately how long in total did it take you (including time spent at the appointment and travel time there and back)?
Please write the number of hours and minutes in the boxes below.

Number of hours ☐☐ - ☐☐ Minutes

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

Thank you very much for answering these questions. We intend to use the information you have given us for research to help women like yourself who experience urine leakage.

PLEASE RETURN THIS QUESTIONNAIRE TO THE TRIAL OFFICE IN THE ENVELOPE PROVIDED.

If you would like any further information
or have any queries about the trial, please contact:

The OPAL Trial Office
Tel: 0141 331 3505
E-mail: OpalTrial@gcu.ac.uk

STUDY No. | | | | | |

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

6 MONTH QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.1 02 Jul 2014

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

e.g. | 2 | 7 | **or** | A | N | N | E | **or** | ✓ |

If you make any errors while completing the form, shade out the box completely and mark the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN ▒ **SOMETIMES** ✓ **NEVER** ☐

Sometimes we would like you to write your answer in your own words, please write these in the boxes provided.

In some questions we would like you to think about different time periods, such as during the last 4 weeks or today. Please check the time periods carefully.

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

You do not have to answer any question if you do not want to.

Thank you for your time in completing this questionnaire. Your answers will be treated with complete confidentiality.

Please start here:

Date questionnaire filled in | D | D | M | M | Y | Y |

Section A Urine symptoms

Many people experience urinary symptoms some of the time. The questions in this section ask about your experience of urinary symptoms or urine leakage, and how much these bother you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the LAST FOUR WEEKS.

A9 How often do you leak urine?

- never ☐
- about once a week or less often ☐
- two or three times a week ☐
- about once a day ☐
- several times a day ☐
- all the time ☐

A10 We would like to know how much urine <u>you think</u> leaks.

How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

A15 Tick the one box that best describes how your urine leakage is now, compared with how it was before you began having treatment within this study:

- very much better ☐
- much better ☐
- a little better ☐
- no change ☐
- a little worse ☐
- much worse ☐
- very much worse ☐

A16 Overall, how much does leaking urine interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

Section E Pelvic floor muscle exercises

Pelvic floor muscle exercises are often recommended to help with urine leakage. They are also known as pelvic floor exercises or Kegels. The exercises involve contracting (tightening and pulling up) the muscles in the area around your vagina. This section asks questions about how you have been getting on doing pelvic floor muscle exercises and how confident you feel.

E1 Have you done any pelvic floor muscle exercises over the last month?

Yes ☐ No ☐

E1A Have you used a biofeedback machine over the last month?

Yes ☐ No ☐

Section F General health TODAY

This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

F1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

F2 Self-care

I have no problems with self-care ☐
I have some problems washing myself or dressing myself ☐
I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

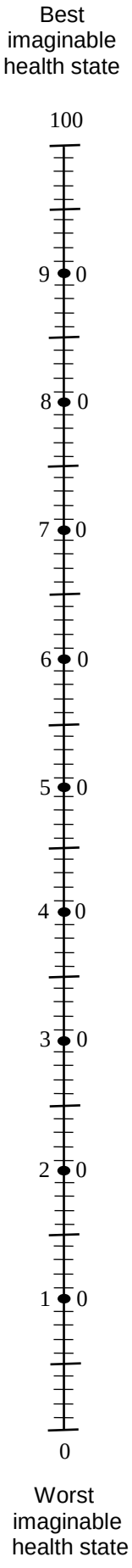
I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



Your own health state today

Email version:
Please write a number from 0-100 in this box

Section G Care you have received

When you answer these questions, please think about the care you have received in the LAST 6 MONTHS

G5b In the last 6 months, have you had an operation for urine leakage?

Yes ☐ **No** ☐

G5c If Yes, please give the name or type of operation and the date:

G6 In the last 6 months, have you taken any medications *(from a doctor, or direct from the chemist's)* for urine leakage?

Yes ☐ **No** ☐

G6a If Yes, please give details of medication received in the last 6 months for urine leakage. Please give drug names (e.g. detrusitol, duloxetine):

G7 Have you had any other treatment or advice for urine leakage in the last 6 months (other than the operation you named in G5c or the drugs you listed in G6a, e.g. vaginal cones)?

Yes ☐ **No** ☐

G7a If Yes, please give details of other treatment or advice received in the last 6 months for urine leakage:

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

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E-mail: OpalTrial@gcu.ac.uk

STUDY No. | | | | | |

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

12 MONTH QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.1 02 Jul 2014

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Please start here:

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Section A Urine symptoms

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How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
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- a large amount ☐

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- much worse ☐
- very much worse ☐

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Please tick a number between 0 (not at all) and 10 (a great deal)

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Section E Pelvic floor muscle exercises

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Yes ☐ No ☐

E1A Have you used a biofeedback machine over the last month?

Yes ☐ No ☐

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This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

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I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

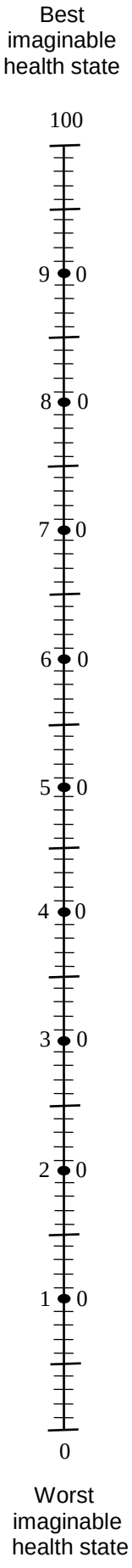
I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



Your own health state today

Email version:
Please write a number from 0-100 in this box

Section G Care you have received

When you answer these questions, please think about the care you have received in the LAST 6 MONTHS

G5b In the last 6 months, have you had an operation for urine leakage?

Yes ☐ **No** ☐

G5c If Yes, please give the name or type of operation and the date:

G6 In the last 6 months, have you taken any medications *(from a doctor, or direct from the chemist's)* for urine leakage?

Yes ☐ **No** ☐

G6a If Yes, please give details of medication received in the last 6 months for urine leakage. Please give drug names (e.g. detrusitol, duloxetine):

G7 Have you had any other treatment or advice for urine leakage in the last 6 months (other than the operation you named in G5c or the drugs you listed in G6a, e.g. vaginal cones)?

Yes ☐ **No** ☐

G7a If Yes, please give details of other treatment or advice received in the last 6 months for urine leakage:

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

Thank you very much for answering these questions. We intend to use the information you have given us for research to help women like yourself who experience urine leakage.

If you would like any further information or have any queries about the trial, please contact:

The OPAL Trial Office
Tel: 0141 331 3505
E-mail: OpalTrial@gcu.ac.uk

STUDY No. | | | | | |

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

24 MONTH QUESTIONNAIRE

CONFIDENTIAL

We are interested in how your urinary symptoms affect your health and everyday life in any way. We would be very grateful if you could complete and return this questionnaire.

Thank you for taking time to help us with our research.

Organisations involved in the trial: Nursing, Midwifery and Allied Health Professions Research Unit
Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit
Glasgow Caledonian University, Universities of Aberdeen, Stirling, Exeter and Otago
NHS Grampian, Greater Glasgow & Clyde and Ayrshire & Arran

Funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA)

Version 3.1 02 Jul 2014

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

e.g. | 2 | 7 | **or** | A | N | N | E | **or** | ✓ |

If you make any errors while completing the form, shade out the box completely and mark the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN ▒ **SOMETIMES** ✓ **NEVER** ☐

Sometimes we would like you to write your answer in your own words, please write these in the boxes provided.

In some questions we would like you to think about different time periods, such as during the last 4 weeks or today. Please check the time periods carefully.

There are no right or wrong answers.

Please try to complete the whole questionnaire even though some questions may appear similar.

You do not have to answer any question if you do not want to.

Thank you for your time in completing this questionnaire. Your answers will be treated with complete confidentiality.

Please start here:

Date questionnaire filled in | D | D | M | M | Y | Y |

Section A Urine symptoms

Many people experience urinary symptoms some of the time. The questions in this section ask about your experience of urinary symptoms or urine leakage, and how much these bother you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the LAST FOUR WEEKS.

A9 How often do you leak urine?

- never ☐
- about once a week or less often ☐
- two or three times a week ☐
- about once a day ☐
- several times a day ☐
- all the time ☐

A10 We would like to know how much urine <u>you think</u> leaks.

How much urine do you <u>usually</u> leak (whether you wear protection or not)?

- none ☐
- a small amount ☐
- a moderate amount ☐
- a large amount ☐

A15 Tick the one box that best describes how your urine leakage is now, compared with how it was before you began having treatment within this study:

- very much better ☐
- much better ☐
- a little better ☐
- no change ☐
- a little worse ☐
- much worse ☐
- very much worse ☐

A16 Overall, how much does leaking urine interfere with your everyday life?
Please tick a number between 0 (not at all) and 10 (a great deal)

not at all 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ a great deal

Section E Pelvic floor muscle exercises

Pelvic floor muscle exercises are often recommended to help with urine leakage. They are also known as pelvic floor exercises or Kegels. The exercises involve contracting (tightening and pulling up) the muscles in the area around your vagina. This section asks questions about how you have been getting on doing pelvic floor muscle exercises and how confident you feel.

E1 Have you done any pelvic floor muscle exercises over the last month?

Yes ☐ No ☐

E1A Have you used a biofeedback machine over the last month?

Yes ☐ No ☐

Section F General health TODAY

This section is about your health **in general**. By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today.**

F1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

F2 Self-care

I have no problems with self-care ☐
I have some problems washing myself or dressing myself ☐
I am unable to wash or dress myself ☐

F3 Usual activities *(such as work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

F4 Pain/discomfort

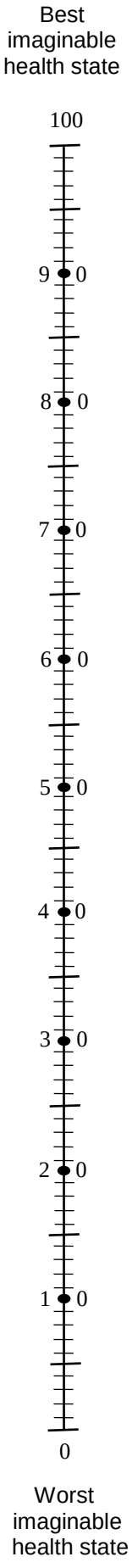
I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

F5 Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



Your own health state today

Email version:
Please write a number from 0-100 in this box

Section G Care you have received

When you answer these questions, please think about the care you have received in the LAST12 MONTHS

G5b In the last12 months, have you had an operation <u>for urine leakage?</u>

Yes ☐ **No** ☐

G5c If Yes, please give the name or type of operation and the date:

G6 In the last 12 months, have you taken any medications *(from a doctor, or direct from the chemist's)* <u>for urine leakage</u>?

Yes ☐ **No** ☐

G6a If Yes, please give details of medication received in the last 12 months <u>for urine leakage</u>. Please give drug names (e.g. detrusitol, duloxetine):

G7 Have you had any other treatment or advice <u>for urine leakage</u> in the last 12 months (other than the operation you named in G5c or the drugs you listed in G6a, e.g. vaginal cones)?

Yes ☐ **No** ☐

G7a If Yes, please give details of other treatment or advice received in the last12 months <u>for urine leakage:</u>

Do you have any comments related to your urine leakage or to the answers you have given? Please feel free to give details in the box below.

Thank you very much for answering these questions. We intend to use the information you have given us for research to help women like yourself who experience urine leakage.

If you would like any further information or have any queries about the trial, please contact:

The OPAL Trial Office
Tel: 0141 331 3505
E-mail: OpalTrial@gcu.ac.uk

Probes

- Please will you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

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

Pre Treatment Interview (Interview A)

RESEARCH QUESTION: To investigate women's experiences of the interventions, both basic and intensive PFMT, to identify the barriers and facilitators which impact on adherence in the short- and long-term, to explain the process through which they influence adherence, and to identify whether these differ between randomised groups.

Probes

- Please will you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Introduction to study and self

Thank you for agreeing to meet with me. We greatly appreciate your willingness to help with the OPAL interview study. The OPAL interview study is about women's experience of UI and how they have got on with the treatment they have been given as part of the OPAL intervention study. I am xxx, one of the researchers on the OPAL study.

Consent

Go over study and what is involved. Do you have any questions for me? Are you still happy to be interviewed and for that interview to be tape recorded? If yes to all – **ask to sign consent**.

Introduction to interview

Today's interview is about your experience of UI and what you hope for from the treatment you are about to have. It will take approximately 30 minutes.

Ice breaker

How is your health generally?

Woman's experience of UI & Symptoms

- When did you start experiencing UI?
- Why do you think it started happening/ what do you think is the cause (Perceived causes)
- Extent of UI symptoms now
- Do symptoms bother you? Extent. Where and when most/least bothersome and why. (anything context/ situation specific).
- Progression over time (both what has happened [past tense] and what they think will happen [will it get better, worse])
- External influences:
    - Where get information about UI? (what you seek/ what you get given / sources e.g. web, magazine, other women etc.)
    - Who else knows about your UI?
    - Explore support from others, who/ what support offered?
    - Does your UI affect others close to you (family, friends)?
- What made her seek help?

Probes

- Please will you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Current Self-Care

- What do you do when you leak urine (explore specific example if possible)
- Do you do anything to manage your UI (deal with it /make it better/ to contain it)
- Does anything you do make it worse
- Anything tried in the past
    - Routines (such as going to the toilet before leaving house/ knowing where toilets are)
    - Containment (use pads etc)
    - Medication
    - Exercise (probe for PFMT specifically and sense of extent to which exercise is generally part of their life)
    - Surgery
- Confidence in managing UI (self efficacy)

Expectations of Treatment

- What do you understand / know about treatment for UI and PFMT in particular
- What do expect the recommended treatment to be? (probe PFMT and for intervention group biofeedback)
- Can you describe what you think the treatment will be like for you? (practical, clinical, feelings)
- What do you hope to get from treatment? (try to identify main outcome wants to change/ why this or these outcome(s) most important to her)
- Expect to happen (processes of health care and do they think/expect improvement or not)
- Want to happen (in this treatment and do they want an operation/medication instead or afterwards)
- Anticipate anything that might influence treatment (e.g. ability to attend, ability to exercise at home)
- what will make it easier for you / what will make it more difficult for you

Closure

Thank you for talking with me today. The interview we have recorded will be removed from the recording device as soon as possible and stored securely. When the interview is typed up (transcribed), all identifying information will be removed. We will study the information you have given us alongside that given by other women. We would like to speak with you again in 6 months time, in that interview we will talk about how you have got on with the treatment. We can come to your home or to the clinic, whichever you would prefer. I will call you to make that appointment; confirm consent to call.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

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

Post Treatment Interview (Interview B)

RESEARCH QUESTION: To investigate women's experiences of the interventions, both basic and intensive PFMT, to identify the barriers and facilitators which impact on adherence in the short- and long-term, to explain the process through which they influence adherence, and to identify whether these differ between randomised groups.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Re-introduction to self, interview, consent

Thank you for agreeing to see me again. We greatly appreciate the help you are giving with the OPAL study. To recap the OPAL interview study is about women's experience of urine leakage and how they have got on with the treatment they have been given. I am xxx, one of the researchers on the OPAL study. Today's interview will take approximately one hour. Are you still happy to be interviewed? Do you have any questions for me before we start?

Ice breaker

How have you been generally since we last spoke?

Symptoms

- Extent of UI symptoms now
- Comparison of symptoms now to 6 months ago (ie pre treatment)
- Perceptions of stages of change (ie when noticed, what changed)
- Why do you think things have changed/not changed? (probe for things in relation to:
    - social [e.g. family support];
    - intervention [were there things about the intervention that the person thinks are related to change];
    - confidence to undertake exercise/ manage leakage [self-efficacy];
    - lifestyle/ self-management (e.g. fluid, dietary changes).

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Intervention

- General views on intervention (How did you find the treatment you received?)
- Probe about PFMT – features positive, features not so helpful
    - What was it like being taught the exercises
    - How did you get on learning the exercises? (check confidence in technique) (mastery)
- For intensive – probe about biofeedback – features positive/ features not so helpful
- What most helpful about the treatment? (probe: exercise/ therapist or nurse/ biofeedback if got it/ feedback on progress etc)
- Did you have any concerns about treatment (probes exercise/ therapist or nurse/ biofeedback if got/ feedback on progress etc)
- Anything change about treatment (probes for exercise etc)? why?
- Experience of service delivery context (appointment system, privacy ….)
- Explore perceptions of relationship with therapist
- Anything outside the service delivery that influenced experience of treatment – external influences
- If they did not complete treatment but remained in study (unlikely I know) why?

Appointments

- Adherence to appointments (did you manage to attend all the appointments)
    - Opinions on number of appointments (too many/ too few)
    - Opinions of exercise asked to do at home – too much/ too little [including biofeedback]
- Factors that affected ability to attend/ not attend scheduled appointments
        - Social influences e.g. family commitments
        - Environmental influences eg. ability to travel?
        - Your own confidence [Self efficacy] influences?

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Self Care

- PFMT undertaken at home:
    - Experience of doing exercise at home (detail – where, when, how often)
    - what was easy? What was difficult?
- If intensive – biofeedback undertaken at home
    - Experience of doing biofeedback as part of exercise regimen at home (detail – where, when, how often)
    - Explore experience with biofeedback and experience without
    - what was easy? What was difficult?
- Any other ways you manage UI?
- Factors influencing adherence to home programme of exercise
    - things that helped you stick with exercise,
    - things that stopped/hampered exercise
    - Did you manage to form a routine for exercise? What was it? How work for you? [questions about maintenance]
    - Were there breaks in your exercise routine (illness/ holiday)? Explore why there was a break and actions taken to re-start exercises (questions about relapse management)?
    - Was there anyone to help you stick to your exercise programme? Or did anyone hinder your ability to do the exercises?
    - Other social influences (such as work commitments etc)
    - Other environmental influences (such as privacy at home etc)
    - How is your confidence to exercise now? Has it changed over time?
    - Do you plan to continue exercising? Explore what will do? How will do?

Links between intervention and outcome (if not been explicitly covered through previous content)

- Links between intervention and outcome: what are they perceived to be; how do they make a difference; why do they make a difference?
- What was it like to take part in the research study (more generally)

Closure

Thank you for talking with me today. The interview we have recorded will be removed from the recording device as soon as possible and stored securely. When the interview is typed up, all identifying information will be removed. We will study the information you have given us alongside that given by other women. We would like to speak with you again in 6 months time, that interview is usually undertaken by phone (explore best times to call/ make an appointment to do); confirm consent to call.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

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

12 month Follow-up Interview (Interview C)

RESEARCH QUESTION: To investigate women's experiences of the interventions, both basic and intensive PFMT, to identify the barriers and facilitators which impact on adherence in the short- and long-term, to explain the process through which they influence adherence, and to identify whether these differ between randomised groups.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Re-introduction to self, interview, consent

Is this an OK time to call? Is there another time I can call back?

Thank you for agreeing to talk with me again. We greatly appreciate the help you are giving with the OPAL study. To recap the OPAL interview study is about women's experience of UI and how they have got on with the treatment they have been given. I am xxx, one of the researchers on the OPAL study. Today's interview will take approximately 15 minutes – is it still OK to record? Are you still happy to be interviewed? Do you have any questions for me before we start?

In this interview we will focus on the last six months (that is since we last spoke to you).

Ice breaker

How have you been generally since we last spoke?

Symptoms [maintain focus on comparison to 6 months ago]

- Extent of UI symptoms now/ how bothered by them
- Comparison of symptoms now to 6 months ago (ie post intervention)
- Why do you think symptoms have changed/not changed over the last 6 months? [Focus on issues woman raised at 6 month interview and ask about intervention].

Intervention

- Thinking back to treatment with therapist/nurse, what are your views on it now.
    - PFMT (positive features, less helpful features)
    - Biofeedback (positive features, less helpful features)
- Thinking back to treatment, at last interview you said xxx helped the most. What is your view now?
- Thinking back to treatment at last interview you said xxx concerned you. What is your view now.
- With time having passed, what is it you still remember most vividly from treatment?
- Have you had any other UI treatments? What made you go? How have those treatments been? (link to effect)

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Self Care/ self-exercise [focus on aspects of last 6 months]

- PFMT undertaken at home? :
    - Still doing exercise at home (where, when, how often)
    - what is easy? What is difficult?
- On-going with biofeedback (bought device?) If so explore use– where, when, how often, ease, difficulty
- Any other things you do to manage UI?
- Anything changed in way you exercise since we last spoke – what changed and why?
- Factors influencing adherence to home programme of exercise now that supervised treatment stopped. [possible probes below]
    - things that help you stick with exercise
    - things that stopped/hampered exercise
    - on-going routine? Any breaks? Manage to restart?
    - Other social influences (such as work commitments etc)
    - Other environmental influences (such as privacy at home etc)
    - Spoken with anyone else and has this changed what you do?
- How is your confidence to exercise now? Has it changed over time?
- Do you plan to keep going with exercise longterm? What would help you to do this or to restart if stopped?

Links between intervention and outcome (if not been explicitly covered through previous content)

- Links between intervention and outcome: feeling now about whether or not treatment has made a difference. What are they; how do they make a difference; why do they make a difference?

Closure

Thank you for talking with me today. The interview we have recorded will be removed from the recording device as soon as possible and stored securely. When the interview is typed up, all identifying information will be removed. We will study the information you have given us alongside that given by other women. We would like to speak with you again in a years time, that interview is usually undertaken by phone. Explain will write a month before and then call to find a good time; confirm consent to call.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

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

24 month Follow-up Interview (Interview D)

RESEARCH QUESTION: To investigate women's experiences of the interventions, both basic and intensive PFMT, to identify the barriers and facilitators which impact on adherence in the short- and long-term, to explain the process through which they influence adherence, and to identify whether these differ between randomised groups.

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Re-introduction to self, interview, consent

Is this an OK time to call? Is there another time I can call back?

Thank you for agreeing to talk with me again. We greatly appreciate the help you are giving with the OPAL study. To recap the OPAL interview study is about women's experience of UI and how they have got on with the treatment they have been given. I am xxx, one of the researchers on the OPAL study. Today's interview will take approximately 15 minutes – is it still OK to record? Are you still happy to be interviewed? Do you have any questions for me before we start?

In this interview we will focus on the last year (that is since we last spoke to you).

Ice breaker

How have you been generally since we last spoke?

Symptoms [maintain focus on comparison to 12 months ago]

- Extent of UI symptoms now/ how bothered by them
- Comparison of symptoms now to 12 months ago (ie post intervention)
- Why do you think symptoms have changed/not changed over the last 12 months? [Focus on issues woman raised at 12 month interview and ask about intervention].

Intervention

- Thinking back to treatment with therapist/nurse, what are your views on it now.
    - PFMT (positive features, less helpful features)
    - Biofeedback (positive features, less helpful features)
- With time having passed, what is it you still remember most vividly from treatment?
- Have you had any other UI treatments? What made you go? How have those treatments been? (link to effect)
- Although considerable time has passed since you got the treatment, anything that has stuck with you? Anything you would change?

Probes

- Can you tell me a bit more about that
- Using reflection (ie repeat what person has just said)
- …

Self Care/ self-exercise [focus on aspects of last 12 months]

- PFMT undertaken at home? :
    - Still doing exercise at home (where, when, how often)
    - what is easy? What is difficult?
- On-going with biofeedback (bought device?) If so explore use– where, when, how often, ease, difficulty
- Any other things you do to manage UI?
- Anything changed in way you exercise since we last spoke – what changed and why?
- Factors influencing adherence to home programme of exercise now that some time has passed since treatment. [possible probes below]
    - things that help you stick with exercise
    - things that stopped/hampered exercise
    - on-going routine? Any breaks? Manage to restart?
    - Other social influences (such as work commitments etc)
    - Other environmental influences (such as privacy at home etc)
    - Spoken with anyone else and has this changed what you do?
- How is your confidence to exercise now? Has it changed over last year?
- Do you plan to keep going with exercise longterm? What would help you to do this or to restart if stopped?

Links between intervention and outcome (if not been explicitly covered through previous content)

- Links between intervention and outcome: feeling now about whether or not treatment has made a difference. What are they; how do they make a difference; why do they make a difference?

Closure

Thank you for talking with me today. The interview we have recorded will be removed from the recording device as soon as possible and stored securely. When the interview is typed up, all identifying information will be removed. We will study the information you have given us alongside that given by other women. We would like to speak with you again in a years time, that interview is usually undertaken by phone. Explain will write a month before and then call to find a good time; confirm consent to call.

THERAPIST ASSESSMENT FORM

Prior to photocopying please detach this page from the rest of the Therapist Assessment Form. This page must not be sent to the OPAL Trial Office. It should be re-attached to photocopied records retained for NHS use.

PATIENT DETAILS

Name _____
Address _____
_____
_____

Date of birth ____ / ____/ _____
CHI No. _____
Unit No. _____

Contact Details
Tel home _____
Tel work _____
Tel mobile _____
Email _____
Permission to leave a message **Yes / No**
Preferred method of contact _____

Referrer _____
GP Name & address _____
_____
_____

Occupation _____
If retired, please state previous occupation
_____

Hobbies (active) _____
_____

Hobbies (stopped since UI) _____
_____
_____

Therapist's name _____ Signature_____ Date _____

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

OPAL
optimising pelvic floor exercises to achieve longterm benefits

THERAPIST ASSESSMENT FORM

STUDY NUMBER							
DATE 1ST APPOINTMENT	d	d	m	m	y	y	

1A APPOINTMENT RECORD

Patient contacted by study office re randomisation **Y / N**

Dates	Attended	DNA'd	Cancelled	Rescheduled	Reason for DNA/cancellation
1. _____ / _____ / _____					_____
2. _____ / _____ / _____					_____
3. _____ / _____ / _____					_____
4. _____ / _____ / _____					_____
5. _____ / _____ / _____					_____
6. _____ / _____ / _____					_____

Rearranged appointments:

Comments:

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

1st Appointment - 60 minutes

2A GENERAL MEDICAL HISTORY

Height _____ metres/ feet and inches *(delete as appropriate)*
Weight _____ kilograms/ stones and pounds *(delete as appropriate)*
BMI _____

Smoker **yes / no** If yes, no. per day _____
Chest condition **yes / no** If yes, specify _____
Diabetes **yes / no** Latex allergy or sensitivity **yes / no**

Other significant medical history

Neurological condition **yes / no** If yes, specify _____
Back Pain **yes / no** UTI **yes / no**
IBS **yes / no** Diverticulitis **yes / no**

Dip stick test **yes / no**
Result

Other, please specify _____
Is patient taking medication for UI **yes / no**
If yes, please provide details _____

Is patient taking any other medication **yes / no**
If yes, please provide details _____

2B OBSTETRIC HISTORY

Parity: | |

No. of assisted deliveries _____ Details _____
No. of vaginal deliveries _____ No. of caesarean sections _____
Perineal trauma, specify _____
Heaviest baby (lbs/oz) _____ Currently pregnant **yes* / no**
Planning pregnancy **yes * / no**

*** if yes, contact the OPAL study office on 0141 331 3504**

2C GYNAECOLOGICAL HISTORY

Sexually Active **yes / no** _____
Contraception **yes / no** If yes, please specify _____
Menopause **pre / post / peri** HRT **yes / no** If yes, how long ___ years ____ months
Gynaecological surgery **yes/ no** If yes, please specify _____

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

3A URINARY SYMPTOMS

Present condition	Yes	No	If yes, provide details
any urinary problems?			
stress incontinence?			
frequency?			
urgency?			
urge incontinence?			
nocturia?			
enuresis?			
strain to void?			
feeling of incomplete emptying?			
UTI?			
dyspareunia			
coital UI?			
prolapse?			
other?			

When did you first become aware of urinary problems? _____ years _____ months

Further comments: _____

3B BOWEL SYMPTOMS

Bowel movement frequency per day / week _____

Stool type (Bristol) _____ Does stool type affect symptoms? _____

	Yes	No	Additional Information
Constipation			
Strain to empty bowel			
Digital stimulation			
Perineal support			
Leakage of stool/ liquid/ gas			
Other			

When did you first become aware of bowel problems? _____ years _____ months

Further comments: _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

4 EXAMINATION (Supine)

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

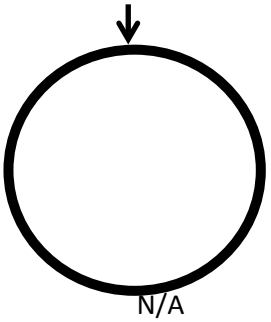
Vaginal Examination

Palpation Sensitivity Pain

	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance (MVC per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____ Repetitions _____

Time used _____ Minutes

Additional / other Information _____

Home Biofeedback

Home unit provided with instruction **yes / no**

Usage discussed and agreed **yes / no**

To be used ____ days per week for ____ sessions

The session consists of;

No of trials ____ held for ____ seconds with ____ seconds relaxation. Threshold ____ Repeated ____ times

Diary leaflets provided **yes / no**

6. ASSESSMENT / TREATMENT / PLAN

Risk Factors UI	yes	no	If yes, provide details below
obstetric history			
occupation / sport			
weight			
smoker / chronic cough			
constipation			
other medical			
Problem list			
SUI			
urgency / UUI			
bowel symptoms			
other e.g. coital UI			
Treatment / advice given			
PFM exercise technique			
anticipatory PFM contraction			
lifting technique			
fluid advice			
smoking cessation advice			
weight loss / dietician referral			
bladder training advice			
defecation			
other advice e.g re altering position for intercourse, gardening etc			
Lifestyle advice sheet given			

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

7. DAILY PFES PROGRAMME RECOMMENDED

length of hold ____ length of relaxation ____ repetitions ____ fast contractions ____

no of times per day ____ no of times per week ____

Position: lying ____ sitting ____ standing ____

If limiting exercise position, please explain _____

_____

PFM & BF programme written in home exercise diary and given to patient **yes / no**

Further comments: _____

Plan/ questions for next time 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

Confirm next appointment:

Date: | | | | | | | Time: | | : | | am / pm

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 1 CHECKLIST

Core Content	YES	NO	If appropriate, at therapist discretion	YES	NO
Beginning					
State your expertise	☐	☐			
Subjective assessment (section 3, TAF)	☐	☐			
Beliefs, emotions and information					
Elicit any inaccurate beliefs about UI and PFMT	☐	☐	Address self-blame and persuade regarding capability for PFMT	☐	☐
Basic verbal and visual explanation			Elicit/support concept of self as role model	☐	☐
• What is SUI, why it happens, and typical progression	☐	☐	Offer feedback about the value of feelings of control	☐	☐
• How PFMT/The Knack works for SUI	☐	☐	Point out links to consumer advocacy sites	☐	☐
Explain use and purpose of BF	☐	☐	Praise willingness to use BF	☐	☐
Offer written information	☐	☐	If of primary concern, explain frequency / urgency and role of PFMT	☐	☐
Teach and confirm PFM contraction					
Teach PFM contraction	☐	☐	If of primary concern, teach **and record** other skills for frequency, urgency, defecation positioning, constipation management	☐	☐
Teach The Knack with a cough	☐	☐			
Objective assessment (section 4, TAF)	☐	☐	Allay anxiety about VE	☐	☐
During VE give feedback on PFM contraction	☐	☐	During VE, remedial teaching to achieve correct PFM contraction	☐	☐
Practice skills					
Teach probe and electrode insertion/removal, turn BF unit on/off	☐	☐	Allay anxiety about BF and its use	☐	☐
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐	☐			
1 / 2 / 3 sets of PFM contractions in _____ body position	☐	☐			
Practise The Knack	☐	☐			
Goal setting and action planning					
Agree PFMT goal for weeks 1 and 2	☐	☐	Agree and record overall treatment outcome goal	☐	☐
Record and both initial PFMT goal in exercise diary	☐	☐			
Encourage The Knack	☐	☐	Suggest one fast contraction every time PFMT remembered	☐	☐
Identify regular time/place for home PFMT	☐	☐			

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Record PFMT action plan in exercise diary ☐☐ Agree BF **behaviour** goal for weeks 1 and 2 ☐☐ Record and both initial BF behaviour goal in exercise diary ☐☐	Persuasion regarding capability for BF ☐☐
Ending Provide exercise diary Set home BF unit to record use ☐☐ Recap agreement to complete home PFMT ☐☐ Recap agreement to use home BF Woman signs for BF; reminded to bring to each appointment ☐☐ Arrange all appointments ☐☐ Print out BF record and staple in TAF ☐☐ Record your plan, if any ☐☐	Praise for intention to do home PFMT ☐☐ Praise for intention to use BF Draw attention to written instructions for BF ☐☐ Offer BF print out to take home ☐☐

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to <u>omit</u> any part of the core content please explain:

If it was appropriate to <u>add</u> something that was not part of the core or optional content please explain:

Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

2nd Appointment - 30 minutes

1 VISIT DETAILS

Date of 2nd appointment ____ / ____ / _____

2 SYMPTOM CHANGE

Has there been any symptom change since previous appointment?

	No change	Better	Worse	N/A
SUI	☐	☐	☐	
Urgency / UUI	☐	☐	☐	☐
Bowel symptoms	☐	☐	☐	☐

Details: _____

_____

Details: _____

_____

Details _____

_____

3 ADVICE FOLLOWED

Has advice given at previous appointment been followed?

Yes	No	No advice given
☐	☐	☐

Details: _____

_____

4 PFE AND BF PRESCRIBED AT PREVIOUS VISIT AND RECORD OF ADHERENCE

1. Exercise programme followed? **yes / no**
   Length of hold _____ No. of repetitions _____ No. of times per day _____

2. Position? **lying / sitting / standing**

3. PFMT and BF Exercise diary completed? **yes / no**

4. Exercise diary returned? **yes / no**

5. BF programme followed? **yes / no**
   No of trials to do _____ Hold secs _____ Relax secs _____ Threshold _____

6. BF home stats downloaded? **yes / no**
   Trials done _____ Work Average _____ Rest Average _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5 EXAMINATION - NOT COMPULSORY at every appointment, at clinician's discretion. See SOP

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

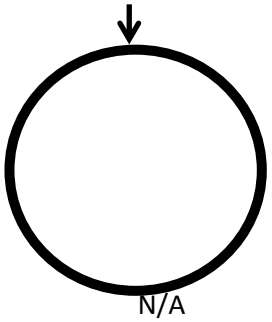
Vaginal Examination

Palpation

	Sensitivity				Pain			
	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Time used _____ minutes

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____

Ramp up/ down _____ Repetitions _____

Additional/ other information _____

Home Biofeedback

Home unit provided with instruction **yes / no**

Usage discussed and agreed **yes / no**

To be used ____ days per week for ____ sessions

The session consists of;

No of trials ____ held for ____ seconds with ____ seconds relaxation. Threshold ____ Repeated ____ times

Diary leaflets provided **yes / no**

7. TREATMENT / PLAN

Treatment / advice given	yes	no	If yes, provide details below
PFM exercise technique			
anticipatory PFM contraction			
lifting technique			
fluid advice			
smoking cessation advice			
weight loss / dietician referral			
bladder training advice			
defaecation			
Other advice eg altering position for intercourse			

Daily PFEs program recommended

length of hold | | length of relaxation | | repetitions | | fast contractions | |

no of times per day | | no of times per week | |

Position: lying | | sitting | | standing | |

If limiting exercise position, please explain _____

PFM & BF program written in home exercise diary and given to patient **yes / no**

Further comments: _____

Plan/ questions for next time 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

Confirm Next appointment:

Date: | | | | | | | Time: | | : | | | am / pm

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 2 CHECKLIST

Core Content		If appropriate, at therapist discretion	
Review	YES NO		YES NO
Invite, reflect back and record woman's observations	☐ ☐	Reflect back any feelings of control	☐ ☐
Remind of cure/improvement probability	☐ ☐	Reassure if no 'changes' (too early)	☐ ☐
Ask about PFMT goal achievement	☐ ☐	Remark on disparity between PFMT goals and actions	☐ ☐
Collect exercise diary	☐ ☐	Praise any PFMT attempts	☐ ☐
Praise any PFMT achievements	☐ ☐	Remark on disparity between BF goal and actions	☐ ☐
Ask about BF behaviour goal achievement	☐ ☐	Praise any BF attempts	☐ ☐
Download home BF unit and save	☐ ☐		
Praise any BF behaviour achievements	☐ ☐		
Problem solving and action planning			
Problem solve to overcome PFMT barriers and increase facilitators	☐ ☐	Elicit regular/repeated prompt for PFMT	☐ ☐
Agree and record PFMT action plan in new exercise diary	☐ ☐	Elicit pros and cons of doing PFMT	☐ ☐
		Elicit level of regret for PFMT non-adherence	☐ ☐
		Challenge prioritisation of PFMT	☐ ☐
		Prompt recall of specific PFMT success	☐ ☐
		Elicit prediction of outcome if PFMT non-adherence	☐ ☐
Invite/address questions about use of BF	☐ ☐		
Problem solve to overcome BF barriers and increase facilitators	☐ ☐	Iterate availability of written instructions for BF	☐ ☐
Agree and record BF action plan in exercise diary	☐ ☐	Persuasion regarding capability for BF	☐ ☐
		Elicit prompt specific to use of home BF	☐ ☐
Rehearse and practice skills			
Woman inserts/removes probe and electrode, turns BF unit on/off	☐ ☐	Allay anxiety about BF and its use	☐ ☐
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐ ☐	Praise willingness to use BF	☐ ☐
		Elicit positive comment about PFM performance based on BF output	☐ ☐
Teach woman how to read BF screen	☐ ☐	Explain/teach skills for other problems such as frequency, urgency, defecation positioning, and constipation management. **Record**.	☐ ☐
1 / 2 /3 sets of PFM contractions in _____ body position	☐ ☐		
Practise The Knack	☐ ☐		
Save and print out BF record. Staple in TAF	☐ ☐	Offer BF printout to take home	☐ ☐

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Goal setting	
Explain that muscles need progression and time to improve function ☐☐	
Make positive comparison between new and baseline BF record ☐☐	
Agree PFMT goal for weeks 3 to 5 ☐☐	Agree and record overall treatment outcome goal ☐☐
Record and both initial PFMT goal in new exercise diary ☐☐	Suggest self-praise for PFMT success ☐☐
Recommend functional use of The Knack ☐☐	Suggest one fast contraction every time PFMT remembered ☐☐
Agree BF behaviour **and output** goals for weeks 3 to 5 ☐☐	
Record and both initial BF goals in new exercise diary ☐☐	Suggest self-praise for BF success ☐☐
Ending	
Invite and address any questions about UI or PFMT ☐☐	Invite and address questions about other symptoms or treatment ☐☐
Provide exercise diary ☐☐	Point out links to consumer advocacy sites ☐☐
Programme home BF unit and set unit to record use ☐☐	Remind woman the BF unit records use ☐☐
Recap agreement to complete home PFMT ☐☐	Praise intention to do home PFMT ☐☐
Recap agreement to complete home BF ☐☐	Praise intention to do home BF ☐☐
Confirm next appointment ☐☐	
Record your plan, if any ☐☐	

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to omit any part of the core content please explain:

If it was appropriate to add something that was not part of the core or optional content please explain:

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

3rd Appointment - 30 minutes

1 VISIT DETAILS

Date of 3rd appointment ____ / ____ / _____

2 SYMPTOM CHANGE

Has there been any symptom change since previous appointment?

	No change	Better	Worse	N/A
SUI	☐	☐	☐	
Urgency / UUI	☐	☐	☐	☐
Bowel symptoms	☐	☐	☐	☐

Details: _____

_____

Details: _____

_____

Details _____

_____

3 ADVICE FOLLOWED

Has advice given at previous appointment been followed?

Yes	No	No advice given
☐	☐	☐

Details: _____

_____

4 PFE AND BF PRESCRIBED AT PREVIOUS VISIT AND RECORD OF ADHERENCE

1. Exercise programme followed? **yes / no**
   Length of hold _____ No. of repetitions _____ No. of times per day _____

2. Position? **lying / sitting / standing**

3. PFMT and BF Exercise diary completed? **yes / no**

4. Exercise diary returned? **yes / no**

5. BF programme followed? **yes / no**
   No of trials to do _____ Hold secs _____ Relax secs _____ Threshold _____

6. BF home stats downloaded? **yes / no**
   Trials done _____ Work Average _____ Rest Average _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5 EXAMINATION - NOT COMPULSORY at every appointment, at clinician's discretion. See SOP

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

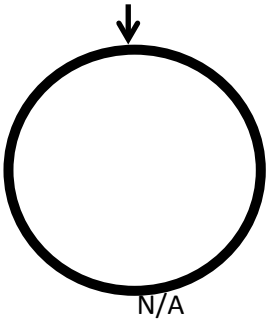
Vaginal Examination

Palpation Sensitivity Pain

	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Time used _____ minutes

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____

Ramp up/ down _____ Repetitions _____

Additional/ other information _____

Home Biofeedback

Home unit provided with instruction **yes / no**

Usage discussed and agreed **yes / no**

To be used ____ days per week for ____ sessions

The session consists of;

No of trials ____ held for ____ seconds with ____ seconds relaxation. Threshold ____ Repeated ____ times

Diary leaflets provided **yes / no**

7. TREATMENT / PLAN

Treatment / advice given	yes	no	If yes, provide details below
PFM exercise technique			
anticipatory PFM contraction			
lifting technique			
fluid advice			
smoking cessation advice			
weight loss / dietician referral			
bladder training advice			
defaecation			
Other advice eg altering position for intercourse			

Daily PFEs program recommended

length of hold | | length of relaxation | | repetitions | | fast contractions | |

no of times per day | | no of times per week | |

Position: lying | | sitting | | standing | |

If limiting exercise position, please explain _____

PFM & BF program written in home exercise diary and given to patient **yes / no**

Further comments: _____

Plan/ questions for next time 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

Confirm Next appointment:

Date: | | | | | | | Time: | | : | | am / pm

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 3 CHECKLIST

Core Content	YES	NO	If appropriate, at therapist discretion	YES	NO
Review					
Invite, reflect back and record woman's observations	☐	☐	Reflect back any feelings of control	☐	☐
Ask about PFMT goal achievement	☐	☐	Suggest leakage diary	☐	☐
Collect exercise diary	☐	☐	Remark on disparity between PFMT goals and actions	☐	☐
Praise any PFMT achievements	☐	☐	Praise any PFMT attempts	☐	☐
Ask about BF behaviour goal achievement (behaviour/output)	☐	☐	Remark on disparity between BF goal and actions	☐	☐
Download home BF unit and save	☐	☐	Praise any BF attempts	☐	☐
Praise any BF achievements	☐	☐			
Problem solving and action planning					
Problem solve to overcome PFMT barriers and increase facilitators including if/then statements	☐	☐	Elicit regular/repeated prompt for PFMT	☐	☐
			Elicit pros and cons of doing PFMT	☐	☐
			Elicit level of regret for PFMT non-adherence	☐	☐
Agree and record PFMT action plan in new exercise diary	☐	☐	Challenge prioritisation of PFMT	☐	☐
			Prompt recall of specific PFMT success	☐	☐
			Elicit prediction of outcome if PFMT non-adherence	☐	☐
Invite/address questions about use of BF	☐	☐	Iterate availability of written instructions	☐	☐
Problem solve to overcome BF barriers and increase facilitators including if/then statements	☐	☐	Elicit prompt specific to use of home BF	☐	☐
			Elicit pros and cons of doing home BF	☐	☐
			Women describes when/where BF done to assess 'environment'	☐	☐
Agree and record BF action plan in exercise diary	☐	☐			
Rehearse and practice skills					
Woman inserts/removes probe and electrode, turns BF unit on/off	☐	☐	Allay anxiety about BF and its use	☐	☐
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐	☐	Praise use of BF	☐	☐
Woman mentally rehearses aloud 1 set of PFM contractions	☐	☐	Elicit positive comment about PFM performance based on BF output	☐	☐
1 / 2 /3 sets of PFM contractions in _____ body position	☐	☐			
Practise The Knack	☐	☐			
Save and print out BF record. Staple in TAF	☐	☐	Offer BF printout to take home	☐	☐

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Goal setting Show ideal 16 week PFMT goal and explain why this much exercise ☐☐ Make positive comparison between new and baseline BF record ☐☐ Agree PFMT goal for weeks 5 to 8 ☐☐ Record and both initial PFMT goal in new exercise diary ☐☐ Recommend functional use of The Knack ☐☐ Agree BF behaviour and output goals for weeks 5 to 8 ☐☐ Record and both initial BF goals in new exercise diary ☐☐	Agree and record overall treatment outcome goal ☐☐ Suggest self-praise for PFMT success ☐☐ Suggest one fast contraction every time PFMT remembered ☐☐ Suggest self-praise for BF success ☐☐
Ending Invite and address any questions ☐☐ Provide exercise diary ☐☐ Programme home BF unit and set unit to record use ☐☐ Recap agreement to complete home PFMT ☐☐ Recap agreement to complete home BF ☐☐ Confirm next appointment ☐☐ Record your plan, if any ☐☐	Praise intention to do home PFMT ☐☐ Praise intention to do home BF ☐☐

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to omit any part of the core content please explain:

If it was appropriate to add something that was not part of the core or optional content please explain:

Therapist's name _____ Signature_____ Date _____ 19

Study Number | | | | | |

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Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Therapist's name _____ Signature_____ Date _____ 20

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

4th Appointment - 30 minutes

1 VISIT DETAILS

Date of 4th appointment ____ / ____ / _____

2 SYMPTOM CHANGE

Has there been any symptom change since previous appointment?

	No change	Better	Worse	N/A
SUI	☐	☐	☐	
Details:				
Urgency / UUI	☐	☐	☐	☐
Details:				
Bowel symptoms	☐	☐	☐	☐
Details				

3 ADVICE FOLLOWED

Has advice given at previous appointment been followed?

Yes	No	No advice given
☐	☐	☐

Details: _____

4 PFE AND BF PRESCRIBED AT PREVIOUS VISIT AND RECORD OF ADHERENCE

1. Exercise programme followed? **yes / no**
   Length of hold _____ No. of repetitions _____ No. of times per day _____

2. Position? **lying / sitting / standing**

3. PFMT and BF Exercise diary completed? **yes / no**

4. Exercise diary returned? **yes / no**

5. BF programme followed? **yes / no**
   No of trials to do _____ Hold secs _____ Relax secs _____ Threshold _____

6. BF home stats downloaded? **yes / no**
   Trials done _____ Work Average _____ Rest Average _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5 EXAMINATION - NOT COMPULSORY at every appointment, at clinician's discretion. See SOP

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

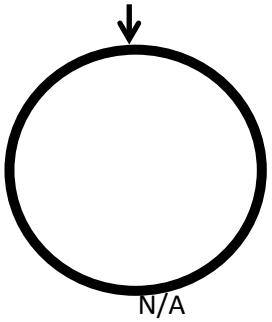
Vaginal Examination

Palpation

	Sensitivity				Pain			
	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Time used _____ minutes

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____

Ramp up/ down _____ Repetitions _____

Additional/ other information _____

Home Biofeedback

Home unit provided with instruction **yes / no**

Usage discussed and agreed **yes / no**

To be used ____ days per week for ____ sessions

The session consists of;

No of trials ____ held for ____ seconds with ____ seconds relaxation. Threshold ____ Repeated ____ times

Diary leaflets provided **yes / no**

7. TREATMENT / PLAN

Treatment / advice given	yes	no	If yes, provide details below
PFM exercise technique			
anticipatory PFM contraction			
lifting technique			
fluid advice			
smoking cessation advice			
weight loss / dietician referral			
bladder training advice			
defaecation			
Other advice eg altering position for intercourse			

Daily PFEs program recommended

length of hold | | length of relaxation | | repetitions | | fast contractions | |

no of times per day | | no of times per week | |

Position: lying | | sitting | | standing | |

If limiting exercise position, please explain _____

PFM & BF program written in home exercise diary and given to patient **yes / no**

Further comments: _____

Plan/ questions for next time 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

Confirm Next appointment:

Date: | | | | | | | Time: | | : | | am / pm

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 4 CHECKLIST

Core Content		If appropriate, at therapist discretion	
Review	YES NO		YES NO
Invite, reflect back and record woman's observations	☐ ☐	Reflect back any feelings of control	☐ ☐
Ask about PFMT goal achievement	☐ ☐	Suggest leakage diary	☐ ☐
Collect exercise diary	☐ ☐	Remark on disparity between PFMT goals and actions	☐ ☐
Praise any PFMT achievements	☐ ☐	Praise any PFMT attempts	☐ ☐
Ask about BF behaviour goal achievement (behaviour/output)	☐ ☐	Remark on disparity between BF goal and actions	☐ ☐
Download home BF unit and save	☐ ☐	Praise any BF use	☐ ☐
Praise any BF achievements	☐ ☐		
Problem solving and action planning		Agree plan to 're-start' PFMT	☐ ☐
Problem solve to overcome PFMT barriers and increase facilitators including **if/then statements**	☐ ☐	Elicit regular/repeated prompt for PFMT	☐ ☐
		Elicit pros and cons of doing PFMT	☐ ☐
Explain consequences of an exercise 'holiday'	☐ ☐	Elicit level of regret for PFMT non-adherence	☐ ☐
Agree and record PFMT action plan in new exercise diary	☐ ☐	Challenge prioritisation of PFMT	☐ ☐
		Prompt recall of specific PFMT success	☐ ☐
		Elicit prediction of outcome if PFMT non-adherence	☐ ☐
Problem solve to overcome BF barriers and increase facilitators	☐ ☐	Elicit prompt specific to use of home BF	☐ ☐
		Elicit pros and cons of home BF	☐ ☐
Agree and record BF action plan in exercise diary	☐ ☐	Women describes when/where BF done to assess 'environment	☐ ☐
Rehearse and practice skills			
Woman inserts/removes probe and electrode, turns BF unit on/off	☐ ☐		
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐ ☐		
Woman mentally rehearses aloud 1 set of PFM contractions including **what she will see on BF screen**	☐ ☐		
1 / 2 /3 sets of PFM contractions in _____ body position **emphasising hold/endurance using template training**	☐ ☐	Elicit positive comment about PFM performance based on BF output	☐ ☐
Practise The Knack	☐ ☐		

Save and print out BF record and staple in TAF ☐☐	Offer BF printout to take home ☐☐
Goal setting Iterate the need for enough exercise for minimum 16-18 weeks ☐☐ Make positive comparison between new and baseline BF record ☐☐ Agree PFMT goal for weeks 8 to 12 ☐☐ Record and both initial PFMT goal in new exercise diary ☐☐ Recommend functional use of The Knack ☐☐ Agree BF behaviour and output goals for week 8 to12 ☐☐ Record and both initial BF goals in new exercise diary ☐☐	Agree and record overall treatment outcome goal ☐☐ Suggest self-praise for PFMT success ☐☐ Suggest one fast contraction every time PFMT remembered ☐☐ Suggest self-praise for BF success ☐☐
Ending Invite and address any questions ☐☐ Provide exercise diary Programme home BF unit and set unit to record use ☐☐ Recap agreement to complete home PFMT ☐☐ Recap agreement to complete home BF ☐☐ Confirm next appointment ☐☐ Record your plan, if any ☐☐	

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to <u>omit</u> any part of the core content please explain:

If it was appropriate to <u>add</u> something that was not part of the core or optional content please explain:

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5th Appointment - 30 minutes

1 VISIT DETAILS

Date of 5th appointment ____ / ____ / _____

2 SYMPTOM CHANGE

Has there been any symptom change since previous appointment?

	No change	Better	Worse	N/A
SUI	☐	☐	☐	
Urgency / UUI	☐	☐	☐	☐
Bowel symptoms	☐	☐	☐	☐

Details: _____

_____

3 ADVICE FOLLOWED

Has advice given at previous appointment been followed?

Yes	No	No advice given
☐	☐	☐

Details: _____

_____

4 PFE AND BF PRESCRIBED AT PREVIOUS VISIT AND RECORD OF ADHERENCE

1. Exercise programme followed? **yes / no**
   Length of hold _____ No. of repetitions _____ No. of times per day _____

2. Position? **lying / sitting / standing**

3. PFMT and BF Exercise diary completed? **yes / no**

4. Exercise diary returned? **yes / no**

5. BF programme followed? **yes / no**
   No of trials to do _____ Hold secs _____ Relax secs _____ Threshold _____

6. BF home stats downloaded? **yes / no**
   Trials done _____ Work Average _____ Rest Average _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5 EXAMINATION - NOT COMPULSORY at every appointment, at clinician's discretion. See SOP

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

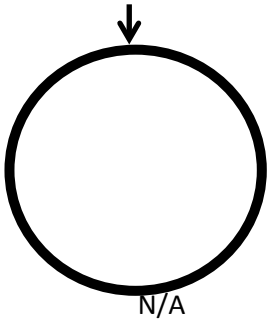
Vaginal Examination

Palpation

	Sensitivity				Pain			
	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Time used _____ minutes

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____

Ramp up/ down _____ Repetitions _____

Additional/ other information _____

Home Biofeedback

Home unit provided with instruction **yes / no**

Usage discussed and agreed **yes / no**

To be used ____ days per week for ____ sessions

The session consists of;

No of trials ____ held for ____ seconds with ____ seconds relaxation. Threshold ____ Repeated ____ times

Diary leaflets provided **yes / no**

7. TREATMENT / PLAN

Treatment / advice given	yes	no	If yes, provide details below
PFM exercise technique			
anticipatory PFM contraction			
lifting technique			
fluid advice			
smoking cessation advice			
weight loss / dietician referral			
bladder training advice			
defaecation			
Other advice eg altering position for intercourse			

Daily PFEs program recommended

length of hold | | length of relaxation | | repetitions | | fast contractions | |

no of times per day | | no of times per week | |

Position: lying | | sitting | | standing | |

If limiting exercise position, please explain _____

PFM & BF program written in home exercise diary and given to patient **yes / no**

Further comments: _____

Plan/ questions for next time 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

Confirm Next appointment:

Date: | | | | | | | Time: | | : | | am / pm

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 5 CHECKLIST

Core Content		If appropriate, at therapist discretion	
Review	YES NO		YES NO
Invite, reflect back and record woman's observations	☐ ☐	Reflect back any feelings of control	☐ ☐
Ask about PFMT goal achievement	☐ ☐	Suggest leakage diary	☐ ☐
Collect exercise diary	☐ ☐		
Praise any PFMT achievements	☐ ☐	Remark on disparity between PFMT goals and actions	☐ ☐
Ask about BF behaviour goal achievement (behaviour/output)	☐ ☐	Remark on disparity between BF goal and actions	☐ ☐
Download home BF unit and save	☐ ☐		
Praise any BF achievements	☐ ☐		
Problem solving and action planning			
Problem solve to overcome PFMT barriers and increase facilitators including **relapse management**	☐ ☐	Elicit regular/repeated prompt for PFMT	☐ ☐
		Elicit pros and cons of doing PFMT	☐ ☐
		Elicit level of regret for PFMT non-adherence	☐ ☐
Agree and record PFMT action plan in new exercise diary	☐ ☐	Challenge prioritisation of PFMT	☐ ☐
		Prompt recall of specific PFMT success	☐ ☐
		Elicit prediction of outcome if PFMT non-adherence	☐ ☐
		Suggest purchase of own BF unit	☐ ☐
Problem solve to overcome BF barriers and increase facilitators including **relapse management**	☐ ☐	Offer information/teaching of alternatives to BF	☐ ☐
		Elicit prompt specific to use of home BF	☐ ☐
Agree and record BF action plan in exercise diary	☐ ☐	Elicit pros and cons of home BF	☐ ☐
		Women describes when/where BF done to assess 'environment	☐ ☐
Rehearse and practice skills			
Woman inserts/removes probe and electrode, turns BF unit on/off	☐ ☐		
BF used throughout practice session with comment on PFM performance	☐ ☐		
Woman mentally rehearses aloud 1 set of PFM contractions including what she will see on BF screen	☐ ☐		
Template or games function offered for 1 / 2 /3 sets of PFM contractions in _____ body position	☐ ☐	Elicit positive comment about PFM performance based on BF output	☐ ☐
Practise The Knack	☐ ☐	Teach self-feedback skills as agreed	☐ ☐
Print out BF record and staple in TAF	☐ ☐	Offer BF printout to take home	☐ ☐

Therapist's name _____ Signature_____ Date _____

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Goal setting Make positive comparison between new and baseline BF record ☐☐ Agree PFMT goal for weeks 12 to 16 ☐☐ Record and both initial PFMT goal in new exercise diary ☐☐ Recommend functional use of The Knack ☐☐ Agree BF behaviour and output goals for weeks 12 to 16 ☐☐ Record and both initial BF goals in new exercise diary ☐☐	Agree and record overall treatment outcome goal ☐☐ Suggest self-praise for PFMT success ☐☐ Suggest one fast contraction every time PFMT remembered ☐☐ Suggest self-praise for BF success ☐☐
Ending Elicit/address uncertainties about health consequences of UI or PFMT ☐☐ Provide exercise diary ☐☐ Programme home BF unit and set unit to record use ☐☐ Recap agreement to complete home PFMT ☐☐ Recap agreement to complete home BF ☐☐ Remind next appointment is last, and will discuss maintenance ☐☐ Confirm next appointment ☐☐ Record your plan, if any ☐☐	

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to <u>omit</u> any part of the core content please explain:

If it was appropriate to <u>add</u> something that was not part of the core or optional content please explain:

Study Number | | | | | |

Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6th Appointment - 30 minutes

1 VISIT DETAILS

Date of 6th appointment ____ / ____ / _____

2 SYMPTOM CHANGE

Has there been any symptom change since previous appointment?

	No change	Better	Worse	N/A
SUI	☐	☐	☐	
Urgency / UUI	☐	☐	☐	☐
Bowel symptoms	☐	☐	☐	☐

Details: _____

_____

3 ADVICE FOLLOWED

Has advice given at previous appointment been followed?

Yes	No	No advice given
☐	☐	☐

Details: _____

_____

4 PFE AND BF PRESCRIBED AT PREVIOUS VISIT AND RECORD OF ADHERENCE

1. Exercise programme followed? **yes / no**
   Length of hold _____ No. of repetitions _____ No. of times per day _____

2. Position? **lying / sitting / standing**

3. PFMT and BF Exercise diary completed? **yes / no**

4. Exercise diary returned? **yes / no**

5. BF programme followed? **yes / no**
   No of trials to do _____ Hold secs _____ Relax secs _____ Threshold _____

6. BF home stats downloaded? **yes / no**
   Trials done _____ Work Average _____ Rest Average _____

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

5 EXAMINATION - To be undertaken at 6th appointment

Informed consent to examination obtained (please tick to confirm) ☐

Chaperone **accepted / declined /unavailable** Latex allergy or sensitivity **yes / no**

Physiotherapist signature _____ Date____/ ____/ _____ Time _____

External Observation

Skin condition _____ Mucosal condition _____

Prolapse visible at rest **yes / no**

Pelvic floor contraction **yes / no** If yes, elevation of vulva perineum & anus **yes / no**

prolapse indrawn with PFM contraction **yes / no / na**

Pelvic floor relaxation **yes / no**

Straining: perineal descent **yes / no** prolapse visible **yes / no / na**

Accessory muscle activity **yes / no** If yes, **adductors / buttocks / abdominals**

Contraction response to cough **yes / no** Descent of perineum with cough **yes / no**

Leakage with cough **yes / no**

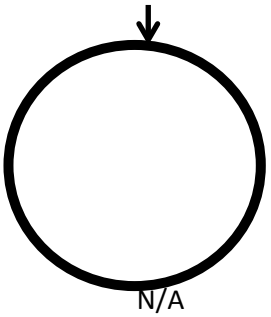
Vaginal Examination

Palpation Sensitivity Pain

	R	L	Ant	Post	R	L	Ant	Post
Superficial								
Deep								

Digital Examination	Vaginal single digit	
SLOW	R	L
Power/ performance per modified oxford scale)		
Endurance (record for strongest side)		
Repetitions (record for strongest side)		
FAST	R	L
Maximum voluntary contraction		
Repetitions (record for strongest side)		

Illustrate view of any prolapse here



	Yes	No	N/A
Contraction response to cough	☐	☐	
Hold with cough	☐	☐	
Is prolapse lifted with PFM contraction	☐	☐	☐

Further comments: e.g. extra instruction to initiate PFM contraction, accessory muscle work, leakage in valsalva etc.

PFM function as per the International Continence Society *(please circle one)*

Relaxation: **Absent** **Partial** **Complete**

Contraction: **Absent** **Weak** **Normal (moderate)** **Strong**

Study Number | | | | | | PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

6. ELECTROMYOGRAPHY BIOFEEDBACK

Clinic

Periform provided with instructions on use, cleaning etc. **yes / no**

Patient introduced to clinic biofeedback **yes / no**

Patient position **Supine / Sitting / Standing**

Time used _____ minutes

Work / Rest test output printed for record **yes / no**

Maximum contraction _____ Endurance _____ Relaxation _____

Ramp up/ down _____ Repetitions _____

Additional/ other information _____

7. TREATMENT / PLAN

Treatment / advice given	yes	no	If yes, provide details below
Discussed satisfaction with treatment			
Discussed continuation with PFM exercises			
Discussed continuation with self – help techniques			
Does the participant intend to continue using BF			

Recommended PFEs programme

length of hold | | length of relaxation | | repetitions | | fast contractions | |

no of times per day | | no of times per week | |

Position: lying | | sitting | | standing | |

If limiting exercise position, please explain _____

Further comments: _____

Plan 1 _____

2 _____

3 _____

Duration of this appointment: | | | | minutes

6 month blinded PFM assessment

Appointment date: | | | | | | | Time | | : | | **am / pm**

Name of therapist to be seen _____

Ensure patient understands that this appointment will be a blinded assessment and will therefore not be with you. The patient cannot discuss which study group they are in with the person examining them or any other hospital staff until after the pelvic floor assessment is complete.

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 6 CHECKLIST

Core Content	YES	NO	If appropriate, at therapist discretion	YES	NO
Review					
Invite, reflect back and record woman's observations	☐	☐	Reflect back feelings of control	☐	☐
Ask about PFMT goal achievement	☐	☐	Suggest leakage diary to monitor symptom change	☐	☐
Collect exercise diary	☐	☐	Remark on disparity between PFMT goals and actions	☐	☐
Praise any PFMT achievements	☐	☐			
Ask about BF goal achievement (behaviour/output)	☐	☐	Remark on the disparity between BF goal and actions	☐	☐
Download BF unit and save	☐	☐			
Praise any BF achievements	☐	☐			
Problem solving and action planning					
Problem solve to overcome PFMT barriers and increase facilitators, including relapse management	☐	☐	Elicit regular/repeated prompt for PFMT	☐	☐
			Elicit pros and cons of doing PFMT	☐	☐
			Elicit level of regret for PFMT non-adherence	☐	☐
Discuss difference between progressive and maintenance PFMT	☐	☐	Challenge prioritisation of PFMT	☐	☐
Record maintenance PFMT action plan in maintenance leaflet	☐	☐	Prompt recall of specific PFMT success	☐	☐
			Elicit prediction of outcome if non-adherence	☐	☐
			If a woman has own BF unit include this in relapse management and action planning	☐	☐
			Offer information/teaching of alternatives to BF	☐	☐
			If woman has own BF unit, elicit prompt specific to use of home BF in maintenance phase	☐	☐
Rehearse and practice skills					
Woman inserts/removes probe and electrode, turns unit on/off	☐	☐	If woman has own BF unit use throughout this appointment	☐	☐
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐	☐	If woman has own BF unit she rehearses aloud 1 set of PFM contractions including what she will see on the BF screen	☐	☐
Woman mentally rehearses aloud 1 set of PFM contractions	☐	☐			
1 / 2 /3 sets of PFM contractions in _____ body position	☐	☐			
Practise The Knack	☐	☐	Elicit positive comment about PFM performance based on BF output	☐	☐

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Print out BF record and staple in TAF ☐☐	Teach self-feedback skills as agreed ☐☐ Offer BF Printout to take home
Goal Setting Make positive comparison between new and baseline BF record ☐☐ Discuss importance of maintenance PFMT ☐☐ Agree maintenance PFMT goal ☐☐ Record and both initial maintenance PFMT goal in maintenance leaflet Recommend functional use of The Knack ☐☐	If woman has own BF unit agree maintenance BF behaviour and output goals ☐☐ If woman has own BF unit suggest self-praise for use ☐☐ Suggest self- praise for PFMT maintenance ☐☐ Suggest one fast contraction every time PFMT remembered ☐☐
Ending Elicit /address uncertainties about health consequences of UI or PFMT ☐☐ Provide maintenance leaflet ☐☐ Reminder of agreement to complete long-term PFMT ☐☐ Offer (re) referral information ☐☐ Remind re trial follow up ☐☐	Praise intention to do long-term PFMT ☐☐ If a woman has own BF unit praise intention to use BF ☐☐ If a woman has own BF unit, recap agreement for long-term BF goals ☐☐

The trial team appreciate that, in the reality of individualised care in clinical practice, there are times when the full treatment protocol is not delivered as planned. If that is the case, please complete the sections below because it is very important for us to understand any variations and why they occurred.

If it was appropriate to omit any part of the core content please explain:

If it was appropriate to add something that was not part of the core or optional content please explain:

Study Number | | | | | |

PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

Further comments: *for example extra instruction to initiate PFM contraction, accessory muscle work*

Thank patient for attending trial physiotherapy sessions and advise them that they will attend for one further BLINDED appointment and receive three further study questionnaires in the post from the trial office.

- **2 months from now, 8 months from now and 20 months from now.**

- **Photocopy this form and keep photocopy for own records.**
- **Return this form and completed patient diaries in the reply paid envelope provided.**