

STUDY No.

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**A trial of pessary self-management compared to standard care in women with pelvic organ prolapse**

## **18-month Questionnaire**

**CONFIDENTIAL**

**We are interested in how using a pessary to manage prolapse affects 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.**

Led by: The University of Stirling, The Nursing, Midwifery & Allied Health Professions Research Unit and St Mary's Hospital, Manchester

*Funded by the NIHR Health Technology Assessment Programme 16/82/01*

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## HOW TO FILL IN THIS QUESTIONNAIRE

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

e.g. 

2	7
---	---

 or 

✓
---

or around the number you wish to select like this

0 1 2 ③ 4

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 

✓
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NEVER 

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- 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 3 months or last 6 months. 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:

**Did you complete this questionnaire at home or in clinic?**

Completed at home 

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Completed in clinic 

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Date questionnaire filled in 

D	D	M	M	Y	Y
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Your date of birth

D	D	M	M	Y	Y
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**Section A****Pelvic floor questions****Pelvic Floor Impact Questionnaire**

Some women find that bladder, bowel, or vaginal symptoms affect their activities, relationships, and feelings. For each question, tick the response that best describes how much your activities, relationships, or feelings have been affected by your bladder, bowel, or vaginal symptoms or conditions **OVER THE LAST 3 MONTHS**.

*Please make sure you tick an answer in all 3 columns for each question.*

How do symptoms or conditions in the bladder/bowel/vagina usually affect your:	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">↓ <b>Bladder</b> (or urine)</div> <div style="text-align: center;">↓ <b>Bowel</b> (or rectum)</div> <div style="text-align: center;">↓ <b>Vagina</b> (or pelvis)</div> </div>		
1. Ability to do household chores (cooking, laundry, housecleaning)?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
2. Ability to do physical activities such walking, swimming, or other exercise?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
3. Entertainment activities such as going to a movie or concert?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
4. Ability to travel by car or bus for a distance greater than 30 minutes away from home?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
5. Participating in social activities outside your home?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
6. Emotional health (nervousness, depression, etc)?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit
7. Feeling frustrated?	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit	<input type="checkbox"/> Not at all <input type="checkbox"/> Somewhat <input type="checkbox"/> Moderately <input type="checkbox"/> Quite a bit

Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol.* 2005;193(1):103-13. doi: 10.1016/j.ajog.2004.12.025. PMID: 16021067.

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## Pelvic Floor Distress Inventory

These questions ask you if you have certain bowel, bladder, or pelvic symptoms and, if you do, **how much they bother you**. Answer these by **circling** the appropriate number. While answering these questions, please consider your symptoms **OVER THE LAST 3 MONTHS**. All questions use the following format with answers from 0 to 4:

<b>Symptom scale:</b>	0 = not present	1 = not at all	2 = somewhat	3 = moderately	4 = quite a bit
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<b>Do you...</b>	<b>Not present</b>	<b>→</b>	<b>Quite a bit</b>
1. Usually experience pressure in the lower abdomen?	0	1	2 3 4
2. Usually experience heaviness or dullness in the pelvic area?	0	1	2 3 4
3. Usually have a bulge or something falling out that you can see or feel in your vaginal area?	0	1	2 3 4
4. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?	0	1	2 3 4
5. Usually experience a feeling of incomplete bladder emptying?	0	1	2 3 4
6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	0	1	2 3 4
<b>Do you...</b>	<b>Not present</b>	<b>→</b>	<b>Quite a bit</b>
7. Feel you need to strain too hard to have a bowel movement?	0	1	2 3 4
8. Feel you have not completely emptied your bowels at the end of a bowel movement?	0	1	2 3 4
9. Usually lose stool beyond your control if your stool is well formed?	0	1	2 3 4
10. Usually lose stool beyond your control if your stool is loose?	0	1	2 3 4
11. Usually lose gas from the rectum beyond your control?	0	1	2 3 4
12. Usually have pain when you pass your stool?	0	1	2 3 4
13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	0	1	2 3 4
14. Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	0	1	2 3 4
<b>Do you...</b>	<b>Not present</b>	<b>→</b>	<b>Quite a bit</b>
15. Usually experience frequent urination?	0	1	2 3 4
16. Usually experience urine leakage associated with the feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	0	1	2 3 4
17. Usually experience urine leakage related to coughing, sneezing or laughing?	0	1	2 3 4
18. Usually experience small amounts of urine leakage (that is, drops)?	0	1	2 3 4
19. Usually experience difficulty emptying your bladder?	0	1	2 3 4
20. Usually experience pain or discomfort in the lower abdomen or genital region?	0	1	2 3 4

Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol.* 2005;193(1):103-13. doi: 10.1016/j.ajog.2004.12.025. PMID: 16021067.

## Section B Pessary questions

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## Pessary use questionnaire

We would like to ask about how you use your pessary. Please answer the following questions thinking about the **LAST 6 MONTHS**. Please complete the questions, even if you have stopped using your pessary.

1. Have you used a pessary for prolapse at any time in the last 6 months?

Yes ☐

*If yes, go to Question 2*

No ☐

*If no, please tell us below why you have stopped using a pessary, then go to Question 8.*

2. Have **YOU** removed your pessary **yourself** in the last 6 months?

Yes ☐

*If yes, please answer Questions 2a, b, c and d*

No ☐

*If no, please go to Question 3.*

2a. Approximately how often did you remove your pessary during the last 6 months? (Please tick **one**)

Once ☐

Once a month ☐

A few  
times ☐

Every day ☐

Other ☐

*For 'Other', please specify below:*

2b. Why did you remove your pessary? (Please tick **all** that apply)

To clean  
the pessary ☐

For  
sexual  
activity ☐

During your  
menstrual  
period ☐

When your  
prolapse symptoms  
were better ☐

☐ To help  
relieve pessary  
problems (e.g.  
pain) ☐

Other ☐

*For 'Other', please specify below:*

2c. Have you received any formal teaching on how to manage your pessary yourself?

Yes ☐

No ☐

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2d. Have **YOU** inserted your pessary in the last 6 months?

No ☐ If no, please go to Question 3.

Yes ☐ If yes, please provide reason for insertiing (Tick **all** that apply below)

After cleaning	<input type="checkbox"/>	After sexual activity	<input type="checkbox"/>	After your menstrual period	<input type="checkbox"/>	When your prolapse symptoms are worse	<input type="checkbox"/>	When pessary problems are better	<input type="checkbox"/>
When doing physical activity/ exercise	<input type="checkbox"/>	Other	<input type="checkbox"/>	For 'Other', please specify:					

3. Are you planning to continue using a pessary to manage your prolapse symptoms?

Yes ☐ If yes, please tell us why

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No ☐ If no, please tell us why

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Not sure ☐

**Below are 4 statements regarding pessaries.** Please tick **one** box for **each** statement (Questions 4 to 7) on how YOU feel (Please complete all questions regardless of which study group you are in)

4. I find pessary changes comfortable.

☐ Strongly agree    ☐ Agree    ☐ Neither agree nor disagree    ☐ Disagree    ☐ Strongly disagree

5. I find pessary changes convenient.

☐ Strongly agree    ☐ Agree    ☐ Neither agree nor disagree    ☐ Disagree    ☐ Strongly disagree

6. I find my pessary care acceptable.

☐ Strongly agree    ☐ Agree    ☐ Neither agree nor disagree    ☐ Disagree    ☐ Strongly disagree

7. Compared to before I took part in this study, my pessary care **now** is:

☐ N/A - I was not using a pessary prior to this study

☐ Very much better    ☐ Much better    ☐ A little better    ☐ No change    ☐ A little worse    ☐ Much worse    ☐ Very much worse

8. Please write here anything you would like to tell us about your experience of pessary care in this trial?

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## Pessary complication questionnaire

Below is a list of problems that you may have encountered since your pessary was fitted. Please tick Yes or No (or where relevant Not Applicable) **for each problem you have experienced in the LAST 6 MONTHS**, and provide details of anything you did, or any treatment that you required, to help the problem.

Have you experienced the following problems:

1. Bothersome vaginal discharge?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
2. Bothersome vaginal smell?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
3. Vaginal pain?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
4. Urine infection (requiring antibiotics)?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
5. Urine incontinence (leakage)?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
6. Difficulty emptying bladder?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
7. Bowel incontinence (leakage)?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	
8. Difficulty emptying bowel?		
Yes	<input type="checkbox"/>	<i>Please give details of anything you did:</i>
		<input type="text"/>
No	<input type="checkbox"/>	

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## 9. Unable to remove pessary?

Yes ☐*Please give details of anything you did:*

No ☐Not applicable ☐

## 10. Difficulty removing pessary?

Yes ☐*Please give details of anything you did:*

No ☐Not applicable ☐

## 11. Difficulty having sex?

Yes ☐*Please give details of anything you did:*

No ☐Not applicable ☐

## 12. Pain during sex?

Yes ☐*Please give details of anything you did:*

No ☐Not applicable ☐

## 13. Pessary fell out

Yes ☐*Please give details of anything you did:*

No ☐

## 14. Vaginal non-menstrual bleeding?

(Please note that a small amount of bleeding during pessary change is not uncommon)

Yes ☐*Please give details of anything you did:*

No ☐

## 15. Other problem not listed above?

Yes ☐*Please give details of anything you did:*

No ☐

## 16. Did you contact your local clinic for advice on any of the above noted problems during the last 6 months?



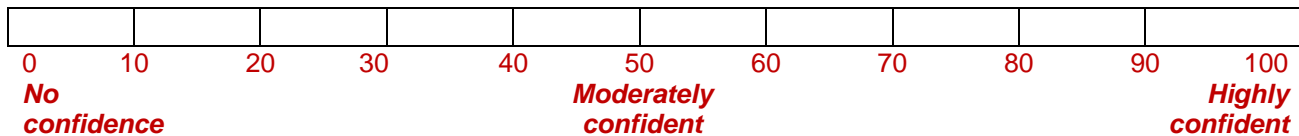
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Yes ☐ No ☐

### Pessary confidence questionnaire

We are interested in knowing how CONFIDENT you feel regarding your ability to change your pessary and how much you feel the pessary will help you. **Even if your pessary is changed in clinic, please tell us how confident you might feel if you were asked to change your pessary yourself.**

**For questions 1-6 below**, please indicate your confidence level, **using the 0-100 scale shown below**. For example, if you feel moderately confident you might write a score of around 55 in the box.



How confident are you that...	Score (0-100)
1. Using a pessary will improve your symptoms of prolapse?	<input type="text"/>
2. Using a pessary will help you avoid (or delay) surgery?	<input type="text"/>
3. Using a pessary will benefit your health and well-being?	<input type="text"/>
4. You can manage problems related to using a pessary?	<input type="text"/>
5. You can (or could if asked) remove your pessary on your own?	<input type="text"/>
6. You can (or could if asked) insert your pessary on your own?	<input type="text"/>

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**Section C****General health and confidence questions**

This section is about your health **in general**

Under each heading, please tick the ONE box that best describes your health TODAY

**MOBILITY**

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

**SELF-CARE**

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

**USUAL ACTIVITIES** (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

**PAIN / DISCOMFORT**

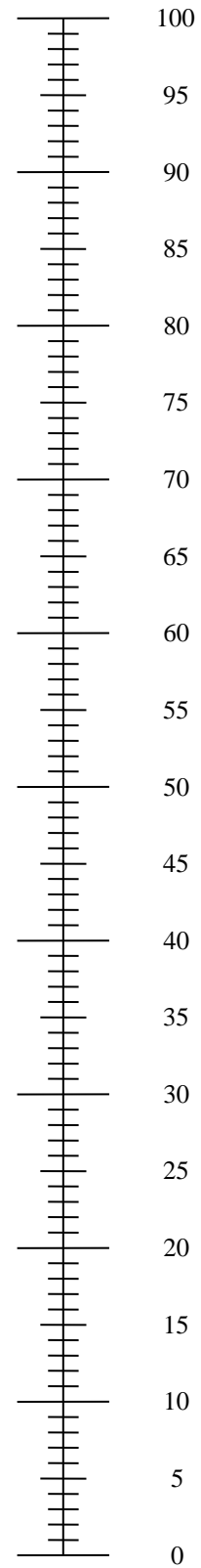
- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

**ANXIETY / DEPRESSION**

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

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The best health  
you can imagine



The worst health  
you can imagine

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- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

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Below is a list of questions that refer to your overall confidence in your ability to cope in demanding situations. For EACH question, please answer by ticking **one** box.

		Not at all true	Hardly true	Moderately true	Exactly true
1.	I can always manage to solve difficult problems if I try hard enough.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	If someone opposes me, I can find the means and ways to get what I want.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	It is easy for me to stick to my aims and accomplish my goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	I am confident that I could deal efficiently with unexpected events.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Thanks to my resourcefulness, I know how to handle unforeseen situations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	I can solve most problems if I invest the necessary effort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	I can remain calm when facing difficulties because I can rely on my coping abilities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	When I am confronted with a problem, I can usually find several solutions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	If I am in trouble, I can usually think of a solution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	I can usually handle whatever comes my way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, *Measures in health psychology: A user's portfolio. Causal and control beliefs*. 1995: 35- 37.

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## Section D Use of NHS National Health Services

The following questions ask you about your use of National Health Services (the NHS) over the **last 6 months**. We are interested in your use of the NHS for your prolapse **and** your overall use of NHS health services.

### For your Prolapse

1. In the last **6 months**, have you been to hospital because of your **Prolapse**? Please tick 'yes' or 'no' for each statement (a) to (f). If you answer 'yes' to any of them, please tell us how many times you used the service.

		Yes	No	
a)	Been to Accident and Emergency (casualty)	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of visits <input type="text"/>
b)	Stayed in hospital overnight	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Nights <input type="text"/>
c)	Had an operation	<input type="checkbox"/>	<input type="checkbox"/>	Type of operation <input type="text"/>
d)	Seen a doctor at a hospital outpatient appointment	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Appointments <input type="text"/>
e)	Seen a physiotherapist at a hospital outpatient appointment	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Appointments <input type="text"/>
f)	Seen a nurse at a hospital outpatient appointment	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Appointments <input type="text"/>

2. In the last **6 months**, have you received care from any of the services below because of your **Prolapse**?

Please tick 'yes' or 'no' for each statement (a) to (g). If you answer 'yes' to any of them, please tell us how many times you used the service.

		Yes	No	Number of times
a)	GP at the surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
b)	GP at your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
c)	Practice Nurse at the surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
d)	Practice Nurse at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
e)	Home visit from district nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
f)	Physiotherapist at the local community clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
g)	Dietician at the local community clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

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### For other health problems

3. In the last **6 months**, have you been to hospital for **other health problems**?

Please tick 'yes' or 'no' for each Statement (a) to (d). If you answer 'yes' to any of them, please tell us how many times you used the service.

		Yes	No	
a)	Been to Accident and Emergency (casualty)	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of visits <input type="text"/>
b)	Stayed in hospital overnight	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Nights <input type="text"/>
c)	Seen a doctor at a hospital outpatient appointment	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Appointments <input type="text"/>
d)	Seen a nurse at a hospital outpatient appointment	<input type="checkbox"/>	<input type="checkbox"/>	Total Number of Appointments <input type="text"/>

4. In the last **6 months**, have you received care from any of the services below for **other health problems**?

Please tick 'yes' or 'no' for each statement (a) to (g). If you answer 'yes' to any of them, please tell us how many times you used the service.

		Yes	No	Number of Times
a)	GP at the surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
b)	GP at your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
c)	Practice Nurse at the surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
d)	Practice Nurse at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
e)	Home visit from district nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
f)	Physiotherapist in a community clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
g)	Dietician at a community clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

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## Prescriptions

5. Over the **last 6 months** have you been prescribed any medications by a GP or hospital doctor for your **prolapse** or any **other health conditions**?

Yes

☐

No

☐

If **Yes**, please write down the name of the medication, the dosage prescribed and how often you take the medication.

Please give the name of the medication (as written on the packaging)	Dosage (e.g. 200mg per day)	How often do you take this? (continue on a separate page if needed)

## Other costs of Prolapse

6. In the **last 6 months**, have you or your relatives/friends paid for any additional care or support because of your **prolapse**?

		Yes	No	How much has this cost altogether in the last 6 months?	Who paid for this?
a)	Employing extra help (e.g. childcare or cleaning)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
b)	Transport to get healthcare (e.g. to go to your GP surgery or hospital)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
c)	Special equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
d)	Other (Please specify below):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<div style="border: 1px solid black; height: 80px; width: 100%;"></div>					

Use this space to add in any additional Prescription details or other costs you would like us to know about



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## Section E Questions on sexual matters

The following questions are of a sensitive nature and we appreciate you completing this section. This information will help us to see to what extent a prolapse and using a pessary affects sexual matters. All information will be kept entirely confidential.

1. Which of the following best describes you:

Not sexually active at all ☐

Go to Question 2

Sexually active with or without a partner ☐

Go to Question 7

### For those who are not Sexually Active

If you engage in sexual activity, please tick this box ☐ and Go to Question 7

2. The following are a list of reasons why you might not be sexually active, for each one please indicate how strongly you agree or disagree with it as a reason that you are not sexually active.

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
a. No partner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. No interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Due to bladder or bowel problems (urinary or faecal incontinence) or due to prolapse (a feeling of or a bulge in the vaginal area)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Because of my other health problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How much does the fear of leaking urine and/or stool and/or a bulging in the vagina (either the bladder, rectum or uterus falling out) cause you to avoid or restrict your sexual activity?

Not at all

A little

Some

A lot

☐
☐
☐
☐

4. For each of the following, please circle the number between 1 and 5 that best represents how you feel about your sex life.

	Rating					
Satisfied	1	2	3	4	5	Dissatisfied
Adequate	1	2	3	4	5	Inadequate

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5. How strongly do you agree or disagree with each of the following statements:

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
a. I feel frustrated by my sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I feel sexually inferior because of my incontinence and/or prolapse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I feel angry because of the impact that incontinence and/or prolapse has on my sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Overall, how bothersome is it to you that you are not sexually active?

Not at all	A little	Some	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### End of Items for those Not Sexually Active

### For those who are Sexually Active

The remaining items in the survey are about a topic that one is not often asked to report on in a survey please answer as honestly and clearly as you possibly can.

7. How often do you feel sexually aroused (physically excited or turned on) during sexual activity?

Never	Rarely	Sometimes	Usually	Always
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. When you are involved in sexual activity, how often do you feel each of the following:

	Never	Rarely	Sometimes	Usually	Almost always
a. Fulfilled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Shame	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Fear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. How often do you leak urine and/or stool with any type of sexual activity?

Never	Rarely	Sometimes	Usually	Always
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Compared to orgasms you have had in the past, how intense are your orgasms now?

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Much less intense	Less intense	Same intensity	More intense	Much more intense
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. How often do you feel pain during sexual intercourse? *(If you don't have intercourse tick this box ☐ and go to the next question.)*

Never	Rarely	Sometimes	Usually	Always
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. Do you have a sexual partner?

Yes ☐ *Go to Question 13*

No ☐ *Go to Question 15*

13. How often does your partner have a problem (lack of arousal, desire, erection, etc.) that limits your sexual activity?

All of the time	Most of the time	Some of the time	Hardly ever/Rarely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. In general, would you say that your partner has a positive or negative impact on each of the following:

	Very positive	Somewhat positive	Somewhat negative	Very negative
a. Your sexual desire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. The frequency of your sexual activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Fear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. When you are involved in sexual activity, how often do you feel that you want more?

Never	Rarely	Sometimes	Usually	Always
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. How frequently do you have sexual desire, this may include wanting to have sex, having sexual thoughts or fantasies, etc.?

Daily	Weekly	Monthly	Less often than once a month	Never
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. How would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low or none at all
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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18. How much does the fear of leaking urine, stool and/or a bulging in the vagina (prolapse) cause you to avoid sexual activity?

Not at all

A little

Some

A lot

☐☐☐☐

19. For each of the following, please circle the number between 1 and 5 that best represents how you feel about your sex life.

Rating

Satisfied	1	2	3	4	5	Dissatisfied
Adequate	1	2	3	4	5	Inadequate
Confident	1	2	3	4	5	Not Confident

20. How strongly do you agree or disagree with each of the following statements:

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
a. I feel frustrated by my sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I feel sexually inferior because of my incontinence and/or prolapse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I feel embarrassed about my sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I feel angry because of the impact that incontinence and/or prolapse has on my sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Rogers, R.G., Rockwood, T.H., Constantine, M.L. et al. A new measure of sexual function in women with pelvic floor disorders (PFD): the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR). *Int Urogynecol J* **24**, 1091–1103 (2013). <https://doi.org/10.1007/s00192-012-2020-8>.

Finally, do you have any comments related to your pessary or prolapse or to the answers you have given? *Please feel free to give details in this box.*

STUDY No.

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Thank you very much for answering these questions. We intend to use the information you have given us to help women like yourself who use a pessary for prolapse.

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