Newcastle University

The Newcastle upon Tyne Hospitals
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area site participant

Date ☐☐ ☐☐ ☐☐☐☐ (9-16)
dd mm yyyy

INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): a pragmatic multicentre pilot study to assess the feasibility of a future randomised controlled trial

Baseline Questionnaires

INTRODUCTION TO PARTICIPANT QUESTIONNAIRE PACK

We are asking you to complete several questionnaires within this study; these will be given to you to complete at the start, before your investigation and treatment, and then again six months later. This is to allow us to look at various different aspects of the outcome of your investigation and treatment during the study. We are interested in your urinary symptoms and the effect that these symptoms have on the quality of your life. We are also interested in your general health and the costs of your healthcare.

Some of the questions may perhaps seem to be repetitive. This is because we are not yet sure which are the best questionnaires to use in this situation; by using a number of questionnaires at this stage of the research we hope to be in a better position to decide the ideal documents to use in our later larger studies. It is very important to us to have a complete set of information for each participant in the study. Therefore, even if you feel that you have answered a question already, we would be grateful if you would try to respond to all questions in each of the documents.

Please complete the questionnaires and diary **within two weeks** of being given them. Once you have done so, please return the questionnaires and diary to us in the reply paid envelope – no stamp is needed.

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Urinary symptoms

Many people experience urinary symptoms some of the time. We are trying to find out how many people experience urinary 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. Simply tick the box that applies to you.

1. What is your date of birth?

(Please write the date in the box provided. For example, 19 April 1957 would be written as 19 04 57)

day ☐☐ month ☐☐ year ☐☐ 17-22

2a. During the night, how many times do you have to get up to urinate, on average?

none	☐	0
one	☐	1
two	☐	2
three	☐	3
four or more	☐	4

23

2b. How much does this bother you?

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

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

not at all — a great deal

24-25

3a. Do you have a sudden need to rush to the toilet to urinate?

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

26

3b. How much does this bother you?

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

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

not at all — a great deal

27-28

4a. Do you have pain in your bladder?

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

29

4b. How much does this bother you?

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

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

not at all — a great deal

30-31

5a. **How often do you pass urine during the day?**

1 to 6 times	☐	0
7 to 8 times	☐	1
9 to 10 times	☐	2
11 to 12 times	☐	3
13 or more times	☐	4

32

5b. **How much does this bother you?**

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

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

not at all — a great deal

33-34

F score: sum scores 2a-5a ☐☐ 35-36

6a. **Is there a delay before you can start to urinate?**

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

37

6b. **How much does this bother you?**

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

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

not at all — a great deal

38-39

7a. **Do you have to strain to <u>urinate</u>?**

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

40

7b. **How much does this bother you?**

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

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

not at all — a great deal

41-42

8a. **Do you stop and start more than once while you urinate?**

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

43

8b. **How much does this bother you?**

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

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

not at all — a great deal

44-45

V score: sum scores 6a+7a+8a ☐☐ 46-47

9a. **Does urine leak before you can get to the toilet?**

never	☐	0
occasionally	☐	1
sometimes	☐	2
most of the time	☐	3
all of the time	☐	4

48

9b. **How much does this bother you?**

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

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

not at all — a great deal

49-50

10a. **How often do you leak urine?**

never	☐	0
once or less per week	☐	1
two to three times per week	☐	2
once per day	☐	3
several times per day	☐	4

51

10b. **How much does this bother you?**

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

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

not at all — a great deal

52-53

11a. **Does urine leak when you are physically active, exert yourself, cough or sneeze?**

never ☐ 0
occasionally ☐ 1
sometimes ☐ 2
most of the time ☐ 3
all of the time ☐ 4 54

11b. **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal 55-56

12a. **Do you ever leak urine for no obvious reason and without feeling that you want to go?**

never ☐ 0
occasionally ☐ 1
sometimes ☐ 2
most of the time ☐ 3
all of the time ☐ 4 57

12b. **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal 58-59

13a. **Do you leak urine when you are asleep?**

never ☐ 0
occasionally ☐ 1
sometimes ☐ 2
most of the time ☐ 3
all of the time ☐ 4 60

13b. **How much does this bother you?**
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal 61-62

I score: sum scores 9a-13a ☐☐ 63-64

Thank you very much for answering these questions.
Please go on to the next set of questions on the following page.

Quality of life

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.

1a. **To what extent does your urinary problem affect your household tasks (e.g. cleaning, shopping, etc.)?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

9

1b. **How much does this bother you?**

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

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

not at all — a great deal

10-11

2a. **Does your urinary problem affect your job, or your normal daily activities outside the home?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

12

2b. **How much does this bother you?**

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

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

not at all — a great deal

13-14

3a. **Does your urinary problem affect your physical activities (e.g. going for a walk, run, sport, gym, etc.)?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

15

3b. **How much does this bother you?**

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

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

not at all — a great deal

16-17

4a. **Does your urinary problem affect your ability to travel?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

18

4b. **How much does this bother you?**

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

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

not at all — a great deal

19-20

5a. **Does your urinary problem limit your social life?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

21

5b. **How much does this bother you?**

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

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

not at all — a great deal

22-23

6a. **Does your urinary problem limit your ability to see/visit friends?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

24

6b. **How much does this bother you?**

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

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

not at all — a great deal

25-26

7a. **Does your urinary problem affect your relationship with your partner?**

not applicable	☐	8
not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

27

7b. **How much does this bother you?**

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

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

not at all — a great deal

28-29

8a. **Does your urinary problem affect your sex life?**

not applicable	☐	8
not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

30

8b. **How much does this bother you?**

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

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

not at all — a great deal

31-32

9a. **Does your urinary problem affect your family life?**

not applicable	☐	8
not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

33

9b. **How much does this bother you?**

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

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

not at all — a great deal

34-35

10a. **Does your urinary problem make you feel depressed?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
a lot	☐	4

36

10b. **How much does this bother you?**

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

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

not at all — a great deal

37-38

11a. **Does your urinary problem make you feel anxious or nervous?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
very much	☐	4

39

11b. **How much does this bother you?**

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

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

not at all — a great deal

40-41

12a. **Does your urinary problem make you feel bad about yourself?**

not at all	☐	1
slightly	☐	2
moderately	☐	3
very much	☐	4

42

12b. **How much does this bother you?**

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

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

not at all — a great deal

43-44

13a. **Does your urinary problem affect your sleep?**

never	☐	1
sometimes	☐	2
often	☐	3
all the time	☐	4

45

13b. **How much does this bother you?**

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

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

not at all — a great deal

46-47

14a. **Do you feel worn out/tired?**

never	☐	1
sometimes	☐	2
often	☐	3
all the time	☐	4

48

14b. **How much does this bother you?**

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

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

not at all — a great deal

49-50

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

15a. Wear pads to keep dry?

never ☐ 1
sometimes ☐ 2
often ☐ 3
all the time ☐ 4 51

15b. How much does this bother you?

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

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

not at all — a great deal 52-53

16a. Be careful how much fluid you drink?

never ☐ 1
sometimes ☐ 2
often ☐ 3
all the time ☐ 4 54

16b. How much does this bother you?

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

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

not at all — a great deal 55-56

17a. Change your underclothes when they get wet?

never ☐ 1
sometimes ☐ 2
often ☐ 3
all the time ☐ 4 57

17b. How much does this bother you?

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

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

not at all — a great deal 58-59

18a. Worry in case you smell?

never ☐ 1
sometimes ☐ 2
often ☐ 3
all the time ☐ 4 60

18b. How much does this bother you?

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

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

not at all — a great deal 61-62

19a. **Get embarrassed because of your urinary problem?**

never ☐ 1
sometimes ☐ 2
often ☐ 3
all the time ☐ 4 63

19b. **How much does this bother you?**

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

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

not at all — a great deal 64-65

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)

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

not at all — a great deal 66-67

Thank you very much for answering these questions.
Please go on to the next set of questions on the following page.

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers 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.

1. How often do you leak urine? *(Tick one box)*

never	0	
about once a week or less often	1	
two or three times a week	2	
about once a day	3	
several times a day	4	
all the time	5	9

2. We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box)

none	0	
a small amount	2	
a moderate amount	4	
a large amount	6	10

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

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal 11-12

ICIQ score: sum scores 1+2+3 13-14

4. When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak	0	15
leaks before you can get to the toilet	1	16
leaks when you cough or sneeze	2	17
leaks when you are asleep	3	18
leaks when you are physically active/exercising	4	19
leaks when you have finished urinating and are dressed	5	20
leaks for no obvious reason	6	21
leaks all the time	7	22

Thank you very much for answering these questions.
Please go on to the next set of questions on the following page.

Urogenital Distress Inventory (UDI)

I. The following symptoms have been described by women who experience accidental urine loss and/or prolapse. Please indicate which symptoms you are now experiencing, and how bothersome they are for you. Be sure to answer all items.

A. Do you experience frequent urination?

1 ☐ Yes 0 ☐ No (skip to B) 9

If yes, how much does it bother you?

0 Not at all ☐ 1 Slightly ☐ 2 Moderately ☐ 3 Greatly ☐ 10

B. Do you experience a strong feeling of urgency to empty your bladder?

1 ☐ Yes 0 ☐ No (skip to C) 11

If yes, how much does it bother you?

0 Not at all ☐ 1 Slightly ☐ 2 Moderately ☐ 3 Greatly ☐ 12

C. Do you experience urine leakage related to the feeling of urgency?

1 ☐ Yes 0 ☐ No (skip to D) 13

If yes, how much does it bother you?

0 Not at all ☐ 1 Slightly ☐ 2 Moderately ☐ 3 Greatly ☐ 14

D. Do you experience urine leakage related to physical activity, coughing or sneezing?

1 ☐ Yes 0 ☐ No (skip to E) 15

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	16

E. Do you experience general urine leakage *not* related to urgency or activity?

1 ☐ Yes 0 ☐ No (skip to F) 17

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	18

F. Do you experience small amounts of urine leakage (that is, drops)?

1 ☐ Yes 0 ☐ No (skip to G) 19

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	20

G. Do you experience large volumes of urine leakage?

1 ☐ Yes 0 ☐ No (skip to H) 21

If yes, how much does it bother you?

0 Not at all	1 Slightly	2 Moderately	3 Greatly	
☐	☐	☐	☐	22

H. Do you experience night time urination?

1 Yes	0 No (skip to I)	
☐	☐	23

If yes, how much does it bother you?

0 Not at all	1 Slightly	2 Moderately	3 Greatly	
☐	☐	☐	☐	24

I. Do you experience bedwetting?

1 Yes	0 No (skip to J)	
☐	☐	25

If yes, how much does it bother you?

0 Not at all	1 Slightly	2 Moderately	3 Greatly	
☐	☐	☐	☐	26

J. Do you experience difficulty emptying your bladder?

1 Yes	0 No (skip to K)	
☐	☐	27

If yes, how much does it bother you?

0 Not at all	1 Slightly	2 Moderately	3 Greatly	
☐	☐	☐	☐	28

K. Do you experience a feeling of incomplete bladder emptying?

1 ☐ Yes 0 ☐ No (skip to L) 29

If yes, how much does it bother you?

0	1	2	3
Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

30

L. Do you experience lower abdominal pressure?

1 ☐ Yes 0 ☐ No (skip to M) 31

If yes, how much does it bother you?

0	1	2	3
Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

32

M. Do you experience pain when urinating?

1 ☐ Yes 0 ☐ No (skip to N) 33

If yes, how much does it bother you?

0	1	2	3
Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

34

N. Do you experience pain in the lower abdomen or genital area?

1 ☐ Yes 0 ☐ No (skip to O) 35

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	36

O. Do you experience heaviness or dullness in the pelvic area?

1		0		
☐	Yes	☐	No (skip to P)	37

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	38

P. Do you experience a feeling of bulging or protrusion in the vaginal area?

1		0		
☐	Yes	☐	No (skip to Q)	39

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	40

Q. Do you experience bulging or protrusion you can see in the vaginal area?

1		0		
☐	Yes	☐	No (skip to R)	41

If yes, how much does it bother you?

0	1	2	3	
Not at all	Slightly	Moderately	Greatly	
☐	☐	☐	☐	42

R. Do you experience pelvic discomfort when standing or physically exerting yourself?

1 ☐ Yes 0 ☐ No (skip to S) 43

If yes, how much does it bother you?

0	1	2	3	
Not at all ☐	Slightly ☐	Moderately ☐	Greatly ☐	44

S. Do you have to push the vaginal walls to have a bowel movement?

1 ☐ Yes 0 ☐ No (skip to T) 45

If yes, how much does it bother you?

0	1	2	3	
Not at all ☐	Slightly ☐	Moderately ☐	Greatly ☐	46

T. Other symptoms?

1 ☐ Yes 0 ☐ No 47

If yes, please describe:

_____

_____

_____

☐☐ 48-51

II. Please go back to page 12 and review all the symptoms listed for question I (A to T). Write the letter of the symptom which has bothered you the most _____ (please write only one letter)

52

Thank you very much for answering these questions.
Please go on to the next set of questions on the following page.

Health Questionnaire

English version for the UK
(validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some 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 with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

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