

Participant Study No

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SIMS

Standard vs. Mini-Slings

CONFIDENTIAL

TREATMENT CHOICE QUESTIONNAIRE

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Thank you for taking the time to help us with our research!

We are interested in **YOUR** opinions and preferences for treatment of stress urinary incontinence. We would be very grateful if you would take a moment to read this information and complete the questionnaire that follows.

This questionnaire is being sent to all SIMS trial participants. Participation is entirely voluntary and any information you give us will be treated in complete confidence.

This type of questionnaire may be different to others you have completed but full instructions are provided.

We hope you decide to take part as the results will be used to help women in the future by improving the treatments offered for stress urinary incontinence.

Thank you for your participation.

Guidance notes for questionnaire

This questionnaire asks you to make a series of choices between three different treatments (Treatment A, Treatment B or No Treatment). When deciding how best to answer the questions, you will need to weigh up different aspects of each option. The treatments differ in terms of:

Type of anaesthesia

This relates to the type of anaesthesia that might be used during the treatment

- **General anaesthesia**
- **Local anaesthesia**

Complications

You may or may not experience complications because of your treatment. You may experience:

- **New onset urgency urinary incontinence** – an urgent desire to pass urine and sometimes urine leaks before you have time to get to the toilet.
- **Post-operative intermittent self-catheterisation** – due to temporary problems emptying the bladder fully, short-term self-catheterisation is required for a few days or weeks
- **Dyspareunia** – pain in the pelvis during or after sexual intercourse.
- **Mesh extrusion/erosion** – exposure of mesh through the vaginal wall or nearby organ. This can happen soon, or years after surgery. Sometimes, further surgery might be needed to help relieve pain, or to remove the mesh.
- **None** You would not experience any of these complications

Number of recovery days

This means your usual activities, such as work or leisure, before you had your surgery; **not** usual activities before you had incontinence.

- **3 days**
- **13 days**
- **23 days**
- **33 days**

Level of improvement

This means improvement in your incontinence symptoms after surgery. You may be:

- **Very much improved** - You leak none or only a small amount of urine once a week or less. You never use pads to keep dry.
- **Much improved** - You leak a small amount of urine 2-3 times per week. You mainly leak when you are physically active. You occasionally use pads to keep dry.
- **Improved** - You leak a moderate amount of urine once a day. You mainly leak when you are physically active. You often use pads to keep dry.
- **None** - You leak a moderate amount of urine several times a day. You mainly leak when you cough, sneeze or are physically active. You always use pads to keep dry.

Avoid activities

This means how often you avoid activities due to a fear of leaking urine? Activities might include socialising, physical activity, sex, travel or shopping.

- **Frequently** which means you never avoid activities or that you avoid them: -
- **Occasionally**
- **Rarely**
- **Never**

Cost of treatment

This means all the costs involved with receiving treatment, such as: the cost of the treatment itself, time off work and travel costs such as bus fares or petrol costs or car park charges. We know that you do not have to pay for NHS treatment, but please imagine a scenario where you do. Think about how much each treatment would be worth to you, and whether you would be able and willing to pay for it.

- **£1,000**
- **£2,000**
- **£3,500**
- **£5,000**

Please refer to the guidance notes when you need to.

Section 1 – Your views and experience of treatment

In this section we are interested in your views on treatment.

1. Did you have a preferred type of anaesthetic for treatment of stress urinary incontinence? PLEASE TICK (✓) the box that applies.

No preference <input type="checkbox"/>	Yes – local anaesthetic <input type="checkbox"/>	Yes – general anaesthetic <input type="checkbox"/>
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2. Did you experience any of the following complications as a result of your stress urinary incontinence treatment?

New onset urgency urinary incontinence – an urgent desire to pass urine and sometimes urine leaks before you have time to get to the toilet.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Post-operative intermittent self-catheterisation – due to temporary problems emptying the bladder fully, short-term self-catheterisation is required for a few days or weeks.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Dyspareunia - experience pain in the pelvis during or after sexual intercourse.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Mesh extrusion/erosion – exposure of the tape through the vaginal wall or nearby organ which can occur years after surgery. Requires further surgery to remove the sling.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Did you experience any other complication	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes please write below:		

3. How long did it take to fully recover from surgery for stress urinary incontinence?

Please note this describes the number of days before you could return to your usual activities, such as work or leisure, before you had your surgery; **not** usual activities before you had incontinence

PLEASE SPECIFY HOW MANY DAYS:
(ENTER '0' IF NONE)

Please imagine this situation:

You leak a moderate amount of urine several times a day. You leak when you cough, sneeze or are physically active. Your urinary problem causes you to occasionally avoid activities due to fear of leaking. You always use pads to keep dry from your stress urinary incontinence.

4. Please rate how acceptable you think the following levels of improvement are for the above set of symptoms

	Highly unacceptable	Unacceptable	Uncertain	Acceptable	Highly acceptable
Very much improved - You leak none or only a small amount of urine once a week or less . You never use pads to keep dry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Much improved - You leak a small amount of urine 2-3 times per week . You mainly leak when you are physically active . You occasionally use pads to keep dry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved - You leak a moderate amount of urine once a day . You mainly leak when you are physically active . You often use pads to keep dry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
None - You leak a moderate amount of urine several times a day . You mainly leak when you cough, sneeze or are physically active . You always use pads to keep dry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Continuing to imagine the above scenario, how often would you avoid activities due to a fear of urinary leakage? Please note those activities might include socialising, physical activity, sex, travel and shopping.

☐ Frequently

☐ Rarely

☐ Occasionally

☐ Never

Section 2 – What treatment do you prefer?

In this section we want to understand how people choose between different types of treatment. There are 13 questions for you to complete, after the example; please answer them all.

To answer the questions in this section, PLEASE IMAGINE THIS SITUATION:

You leak a moderate amount of urine several times a day. You mainly leak when you cough, sneeze or are physically active. Your urinary problem causes you to occasionally avoid activities due to fear of leaking. You always use pads to keep dry from your stress urinary incontinence.

We would like to understand how a treatment's characteristics affect which treatment, if any, you would choose if you were in the situation described above.

Each choice will describe two treatments that you can receive. We would like you to tell us if you would choose one of the treatments, and, if so, which one.

- In each choice, please imagine that you can only receive one of the two treatments or have no treatment.
- If you choose no treatment, this means that you would not receive treatment and your situation would remain as described above.
- At first glance the choices may appear the same, but in fact each one is different.

We understand that some of the choices will be difficult to make, but there are no right or wrong answers. Your personal opinion is what matters.

ON THE FOLLOWING PAGE THERE IS AN EXAMPLE OF A CHOICE QUESTION, FOLLOWED BY 13 QUESTIONS FOR YOU TO ANSWER.

PLEASE READ THE EXAMPLE BEFORE CONTINUING TO COMPLETE THE REST OF THE QUESTIONNAIRE

EXAMPLE CHOICE QUESTION

To answer the questions in this section, PLEASE IMAGINE THIS SITUATION:

You leak a moderate amount of urine several times a day. You mainly leak when you cough, sneeze or are physically active. Your urinary problem causes you to occasionally avoid activities due to fear of leaking. You always use pads to keep dry from your stress urinary incontinence.

EXAMPLE QUESTION

Please compare the treatments and tick which treatment option you would choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	Pelvic pain during or after sex	None	None
Number. of recovery days	23	3	0
Level of improvement	Much improved	Very much improved.	None
Avoid activities due to fear of leaking	Occasionally	Rarely	Occasionally
Cost to you	£1,000	£3,500	£0
Which treatment would you choose (tick one box only)?	Treatment A <input type="checkbox"/>	Treatment B <input checked="" type="checkbox"/>	No Treatment <input type="checkbox"/>

By choosing Treatment B, this person prefers the procedure done under **local anaesthetic**. They would experience **no complications** as a result of the treatment. It would take them **3 days** to return to work or usual activities. After treatment the person will be **very much improved** and **rarely avoid activities** due to a fear of leaking urine for a **cost of £3,500**.

This person thinks that Treatment B is better than either Treatment A or No Treatment when they have the symptoms described above.

To answer the questions in this section, PLEASE IMAGINE THIS SITUATION:

You leak a moderate amount of urine several times a day. You mainly leak when you cough, sneeze or are physically active. Your urinary problem causes you to occasionally avoid activities due to fear of leaking. You always use pads to keep dry from your stress urinary incontinence.

Choice 1: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	Pelvic pain during or after sex	New urge incontinence	None
Number. of recovery days	3	23	0
Level of improvement	Very much improved	None	None
Avoid activities due to fear of leaking	Occasionally	Rarely	Occasionally
Cost to you	£2,000	£1000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐**Choice 2: Which option would you choose?**

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	New urge incontinence	Pelvic pain during or after sex	None
Number. of recovery days	33	13	0
Level of improvement	None.	None	None
Avoid activities due to fear of leaking	Never	Frequently	Occasionally
Cost to you	£5,000	£3,500	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

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Choice 3: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	Local	General;	None
Type of complication	Pelvic pain during or after sex	New urge incontinence	None
Number. of recovery days	33	13	0
Level of improvement	None	None	None
Avoid activities due to fear of leaking	Occasionally	Frequently	Occasionally
Cost to you	£3,500	£2,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐
Choice 4: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	New urge incontinence	Intermittent catheterisation	None
Number. of recovery days	3	23	0
Level of improvement	Much improved.	Improved	None
Avoid activities due to fear of leaking	Occasionally	Never	Occasionally
Cost to you	£1000	£3,500	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

Choice 5: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	Local	General	None
Type of complication	None	Intermittent catheterisation	None
Number. of recovery days	3	23	0
Level of improvement	None	Very much improved	None
Avoid activities due to fear of leaking	Never	Occasionally	Occasionally
Cost to you	£1,000	£2,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐
Choice 6: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	None	Intermittent catheterisation	None
Number of recovery days	13	33	0
Level of improvement	Very much improved	None	None
Avoid activities due to fear of leaking	Never	Rarely	Occasionally
Cost to you	£2,000	£3,500	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

7: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	Local	General	None
Type of complication	None	Mesh extrusion or erosion	None
Number of recovery days	3	23	0
Level of improvement	Very much improved.	None	None
Avoid activities due to fear of leaking	Never	Frequently	Occasionally
Cost to you	£1,000	£5,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐
Choice 8: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	Local	General	None
Type of complication	Mesh extrusion or erosion	Intermittent catheterisation	None
Number of recovery days	33	3	0
Level of improvement	Much improved	Improved	None
Avoid activities due to fear of leaking	Frequently	Rarely	Occasionally
Cost to you	£2,000	£5,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

Choice 9: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	Intermittent catheterisation	None	None
Number of recovery days	3	13	0
Level of improvement	Improved	Very much improved	None
Avoid activities due to fear of leaking	Frequently	Never	Occasionally
Cost to you	£2,000	£5,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐
Choice 10: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	Mesh extrusion or erosion	Intermittent catheterisation	None
Number of recovery days	23	13	0
Level of improvement	Much improved	Improved	None
Avoid activities due to fear of leaking	Rarely	Frequently	Occasionally
Cost to you	£5,000	£1000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

Choice 11: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	Local	General	None
Type of complication	Pelvic pain during or after sex	Mesh extrusion or erosion	None
Number of recovery days	23	13	0
Level of improvement	Much improved	Improved	None
Avoid activities due to fear of leaking	Frequently	Occasionally	Occasionally
Cost to you	£5,000	£3,500	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐
Choice set 12: Which option would you choose?

	<u>Treatment A</u>	<u>Treatment B</u>	<u>No Treatment</u>
Type of anaesthetic	General	Local	None
Type of complication	Intermittent catheterisation	New urge incontinence	None
Number of recovery days	3	13	0
Level of improvement	None	Much improved	None
Avoid activities due to fear of leaking	Frequently	Occasionally	Occasionally
Cost to you	£3,500	£5,000	£0

Which treatment would you choose (tick one box only)?

Treatment A

☐

Treatment B

☐

No Treatment

☐

13. Thinking about the information and questions in this questionnaire, please tell us how strongly you agree or disagree with each of the following statements.

PLEASE TICK (✓) ONE BOX ONLY WHICH IS CLOSEST TO YOUR OPINION FOR EACH ROW

	Strongly disagree	Disagree	Uncertain	Agree	Strongly agree
I understood the idea of making choices between different treatments					
When choosing between different treatments I needed more information than was provided					
I believe that my choices will have an impact on which treatments are provided in the future					
I found that the available treatment options made sense					
I found that the more questions I answered the easier it was to make a choice					
I found making a choice between different treatments confusing					

Section 3: About you

So we can understand better your answers to the previous questions, we would like to ask a few questions about yourself.

1. Which of these qualifications do you have?

PLEASE TICK (✓) EVERY BOX THAT APPLIES IF YOU HAVE ANY OF THE QUALIFICATIONS LISTED.

Left school with no qualifications	<input type="checkbox"/>
Completed "O" levels or GCSEs	<input type="checkbox"/>
Completed "A" levels	<input type="checkbox"/>
Apprenticeship or vocational training	<input type="checkbox"/>
University degree	<input type="checkbox"/>

2. Which group represents your total income including any benefits received and before any deductions? PLEASE TICK (✓) EITHER WEEKLY OR ANNUAL INCOME

- | | |
|---|---|
| <input type="checkbox"/> Up to £99 per week | <input type="checkbox"/> Up to £5,199 per year |
| <input type="checkbox"/> £100 and up to £199 per week | <input type="checkbox"/> £5,200 and up to £10,399 per year |
| <input type="checkbox"/> £200 and up to £299 per week | <input type="checkbox"/> £10,400 and up to £15,599 per year |
| <input type="checkbox"/> £300 and up to £399 per week | <input type="checkbox"/> £15,600 and up to £20,799 per year |
| <input type="checkbox"/> £400 and up to £499 per week | <input type="checkbox"/> £20,800 and up to £25,999 per year |
| <input type="checkbox"/> £500 and up to £599 per week | <input type="checkbox"/> £26,000 and up to £31,199 per year |
| <input type="checkbox"/> £600 and up to £699 per week | <input type="checkbox"/> £31,200 and up to £36,399 per year |
| <input type="checkbox"/> £700 and up to £999 per week | <input type="checkbox"/> £36,400 and up to £51,999 per year |
| <input type="checkbox"/> £1000 and above per week | <input type="checkbox"/> £52,000 and above per year |
| <input type="checkbox"/> Prefer not to say | <input type="checkbox"/> Prefer not to say |

3. Do you have any comments about this questionnaire?