

Bilaga till rapport

1 (35)

Prioriterade utfall för behandlingsstudier gällande provocerad vulvodyni (vestibulit)/Development of a core outcome set for treatment of provoked vestibulodynia, rapport 362 (2023)

Bilaga 3 Enkäterna/Appendix 3 Surveys

Innehåll i bilagan

Enkät för insamling av bakgrundsinformation från deltagarna/Survey to collect	
background information from participants	2
Enkät 1/Survey 1	6
Enkät 2/Survey 2	23

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Enkät för insamling av bakgrundsinformation från deltagarna/Survey to collect background information from participants



Survey to collect bakground information for participants in the SBU project: Development of a core outcome set for treatment of provoked vestibulodynia.

The following information is being collected so that we can ensure diversity of panel members, which allows us to benefit from as many perspectives as possible.

Responses are anonymous and optional to provide.

Please specify your perspective.

Person with ongoing or past experience of provoked vestibulodynia			
A relative/partner of someone with ongoing or past experience of pro	voked ve	stibulodynia	ì
Healthcare staff			
© Researcher			
Other			
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Please specify			
Gender:			
Age:			
Occupation:			
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xual orientetion			
Prefer not to say			
Heterosexual			
Lesbian/Gay			
Bisexual			
Other:			

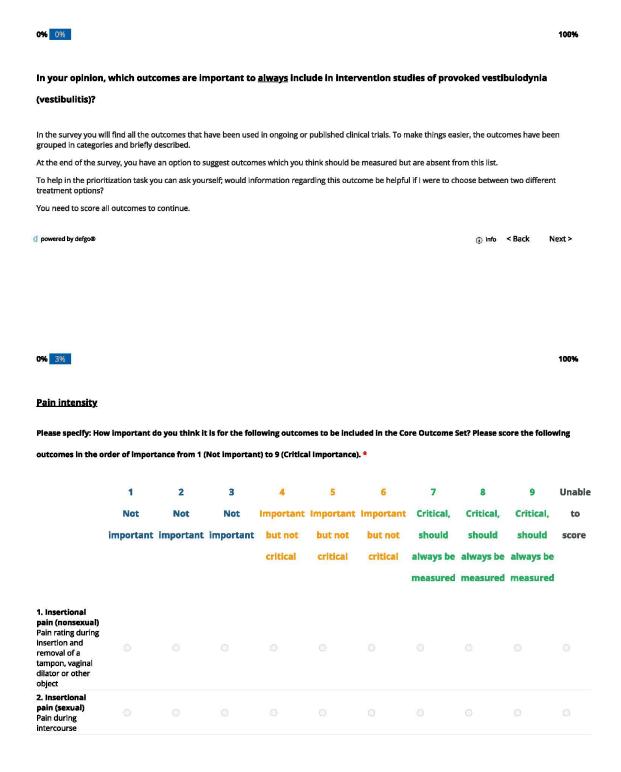
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Enkät 1/Survey 1



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How important do you think it is to include at least 1 of the outcomes above measuring <u>Pain Intensity</u> in the Core outcome set?

*



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Pain Quality and Affect or Pain Temporality

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).*

	1 Not important	2 Not important	3 Not important	5 Important but not critical	6 Important but not critical	 8 Critical, should always be measured	 Unable to score
9. Pain quality How the pain is described							
10. Pain behaviour Behavioural responses when in pain							
11. Pelvic floor response to pressure pain provocation Pelvic floor muscle response to painful pressure applied to the vaginal opening							
12. Time until pain improvement Time from start of treatment until perceived improvement							0

How important do you think it is to include at least 1 of the outcomes above measuring <u>Pain Quality and Affect or Pain Temporality?</u>

*



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Other outcomes related to Pain

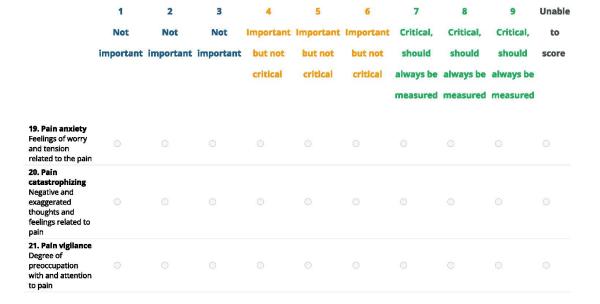
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	1 Not important	2 Not important	3 Not important	and the second of	5 Important but not	6 Important but not	7 Critical, should	8 Critical, should	9 Critical, should	Unable to score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
13. Degree of overlapping pain Degree of comorbid (co- occuring) pain conditions										
14. Pain duration The duration of the pain										
15. Vulvar discomfort Level of discomfort (such as Irritation and burning) felt in the vulva										
16. Multidimensional aspects of pain Pain intensity and quality, and emotional and other aspects (e.g., interpersonal) of pain.										
17. Pain rescue medication Monitoring the use of pain rescue medication during the trial										
18. Pain triggers Physical and psychologically related events that trigger pain events. Includes both positive and negative events										

1 2 3 4 5 6 7 8 Unable Important Important Of critical Of critical Of critical Not Not Not to important important important but not but not but not importance importance score critical critical critical Please specify your d powered by defgo® i Info < Back Next > 0% 25% 100%

How important do you think it is to include at least 1 of the outcomes above measuring Other outcomes related to Pain?

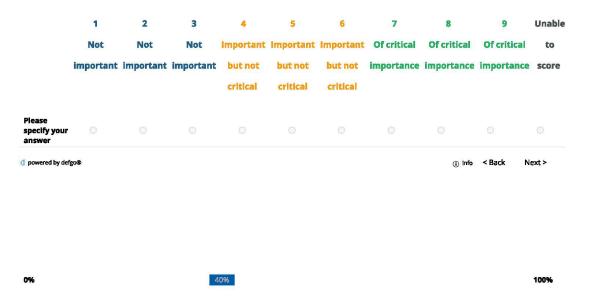
Emontional Functioning-Response to Pain



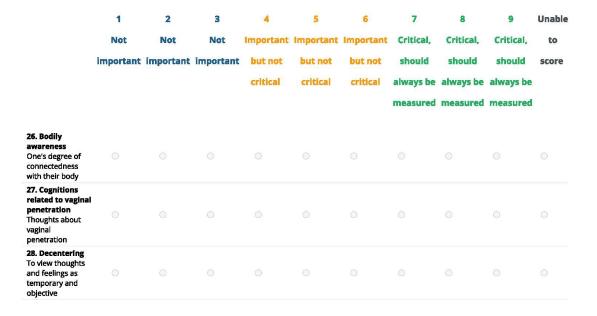
pelf-efficacy Degree of confidence rela o engaging in benetration 23. Tampon nsertion willingness Willingness to nsert a tampo										0
1000 MW	ant do you	think it is to	o include at	: least 1 of th	ne outcomes a	oove measui	ring <u>Emonti</u>	onal Functi	oning-Respo	nse to
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lease specify	unctioning r: How import he order of in 1 Not	ant do you the nportance fro 2	pression link it is for th om 1 (Not imp 3	oortant) to 9 (C 4 t Import	ritical Important 5 tant Importan	e). * 6 t Important	7 Critical,	Set? Please s 8 Critical,	score the follow 9 Critical,	100% wing Unabl
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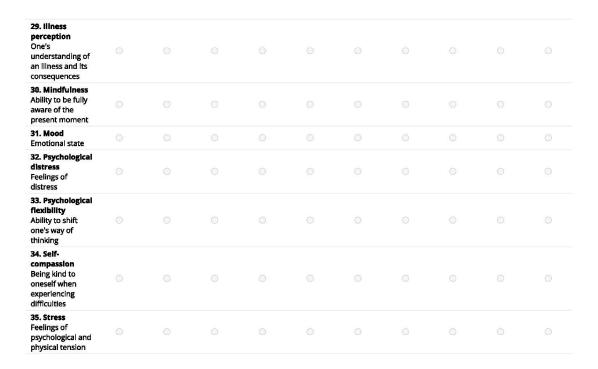
How important do you think it is to include at least 1 of the outcomes above measuring <u>Emotional Functioning</u>.

<u>Anxiety/Depression?*</u>

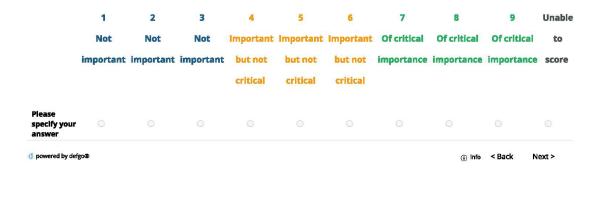


Other outcomes related to Emotional Functioning



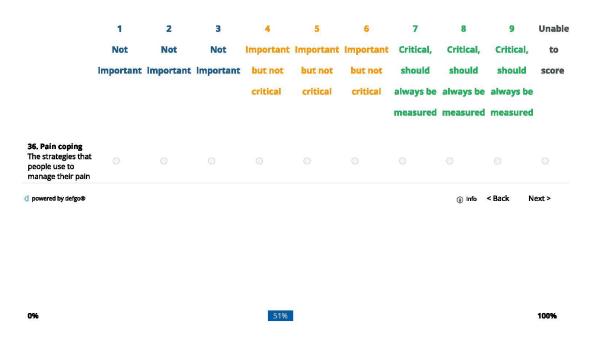


How important do you think it is to include at least 1 of the outcomes above measuring Other outcomes related to Emotional Functioning?*



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Coping

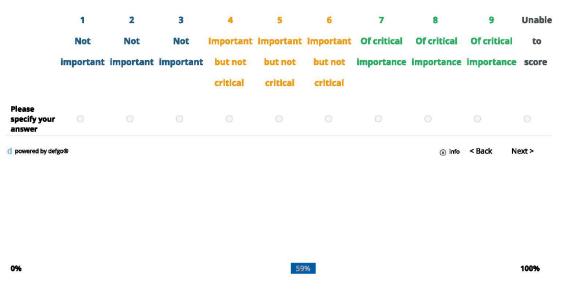


Interpersonal Functioning (i.e. relationships and activities with family, friends, and others)

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
37. Pain related interference on one's life The degree to which the pain interferes with one's life										
38. Relationship quality Quality of relationship with partner										

How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to Interpersonal functioning (i.e. relationships and activities with family, friends, and others)?

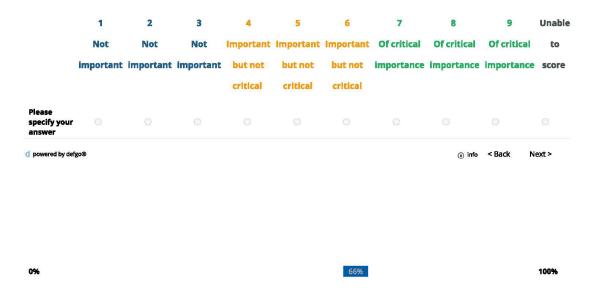


Physical Functioning-Health-Related Quality of Life

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance). *

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
39. Pain Interference on sexual life Degree of interference due to the pain on one's sexual life										
40. Quality of life How satisfied one is with their overall life										

How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to <u>Physical Functioning-Health-Related Quality of Life?</u>*

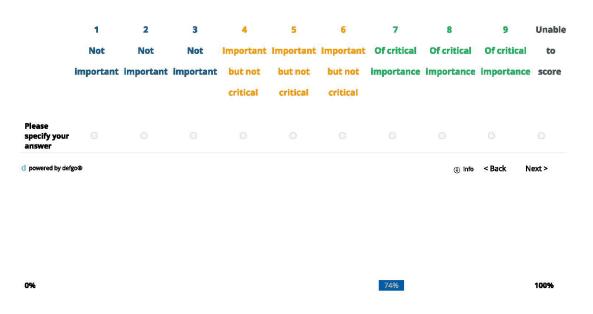


Physical Functioning-Sexual Function

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
41. Attempts to engage in sexual intercourse Sexual intercourse attempts										
42. Frequency of sexual intercourse How often one engaged in sexual intercourse										
43. Information related to sexual function Accuracy of information related to sexual function										©
44. Interest in sexual activity The degree to which one is interested in sexual activity										

45. Mood and Sexual Function Mood and the degree to which one is able to engage sexually and experience pleasure					
46. Non- Intercourse related sexual activity Any activity that is sexually arousing and does not involve intercourse				0	
47. Partner's sexual function Level of partner's sexual function					
48. Sexual activity Any activity that is sexually arousing					
49. Sexual function The degree to which one is able to engage sexually and experience pleasure					
50. Sexual health The level of physical, emotional, and psychological wellbeing related to sexuality					

How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to <u>Physical Functioning-Sexual Function?*</u>

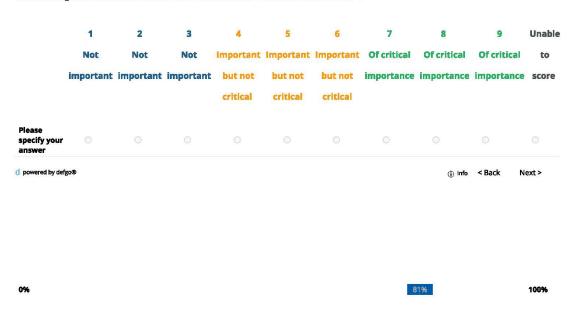


Physical Functioning-Sexual Distress/Sexual Satisfaction/Sexual Function Interference

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).*

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	Important	Important	Important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
51. Pain related sexual interference The degree to which the pain interferes with one's sexuality										
52. Sexual distress How worried and sad one is with their sex life										
53. Sexual satisfaction One's overall perception of positive sexual experiences and pleasure	0	0								

How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to Physical
Functioning-Sexual Distress/Sexual Satisfaction/Sexual Function Interference?*



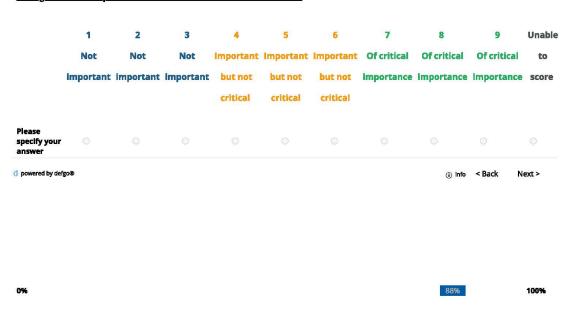
Participant Ratings of Global Improvement and Satisfaction with Treatment

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).*

	1 Not	2 Not Important	3 Not	ini.	5 Important but not	6 Important but not	7 Critical, should	8 Critical, should	9 Critical, should	Unable to score
	important	important	Important	critical	critical	critical		always be		Score
							measured	measured	measured	
54. Treatment credibility Rating of how confident one is with the present treatment									0	
55. Treatment improvement Rating of treatment improvement										
56. Treatment satisfaction Rating of satisfaction with treatment										

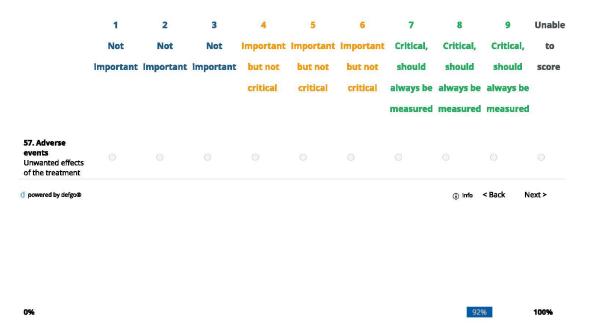
How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to <u>Participant</u>

Ratings of Global Improvement and Satisfaction with Treatment?*

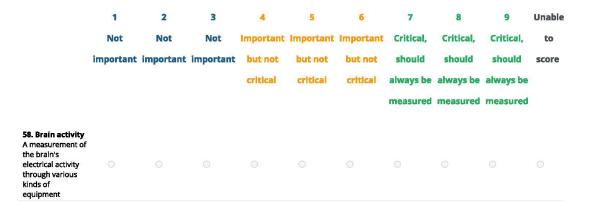


Symptoms and Adverse Events

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).*



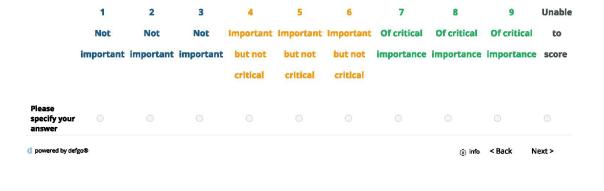
Biological Markers (e.g., assessments based on quantitative sensory testing, imaging, genetic markers, pharmacogenomics, and punch skin biopsy)



59. Inflammation in tissue, nerve fibres or mucosa Measurements of Inflammation and nerve fibres in vulvar tissue samples					
60. Sensation threshold Ability to detect nonpainful pressure applied to the vulva					
61. Tissue blood circulation Changes in the blood circulation in the tissue around the vaginal opening					
62. Vaginal flora Analysis of the content of vaginal microorganisms (microbiome) before and after treatment			0		0
63. Vulvar redness Degree of vulvar redness					

How important do you think it is to include at least 1 of the outcomes above measuring outcomes related to <u>Biological</u>

<u>Markers (e.g. assessments based on quantitative sensory testing, imaging, genetic markers, pharmacogenomics, and punch skin biopsy)?</u>



100%

Do you want to add any additional outcomes?

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In your opinion, which outcomes are important to <u>always</u> include in intervention studies of provoked vestibulodynia (vestibulitis)? In this survey there are a total of 57 outcomes. 51 outcomes were brought forward from Survey 1 and 6 outcomes are new, based on suggestions in Survey 1. To make things easier, the outcomes have been grouped in categories and briefly described. Please note that we have kept the original identification numbering of the outcomes, this mean that there are some numbers missing and that the order is a not always numerical, due to the new outcomes. To help in the prioritization task you can ask yourself; would information regarding this outcome be helpful if I were to choose between two different treatment options? Remember that the goal is to include up to 6 outcomes in the core outcome set, so try to limit the number of outcomes scored as critical (rating scale 7-9). You need to score all outcomes to continue. d powered by defgo® info < Back Next > 0% 6% 100% **Pain intensity** Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical importance).* 1 2 3 5 6 7 9 Unable Important Important Critical, Critical, Critical. Not Not Not to important important but not but not but not should should should critical critical critical always be always be measured measured measured 1. Insertional pain (nonsexual) Pain rating during insertion and removal of a tampon, speculum vaginal dilator or other object

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8. Spontaneous vulvar pain Rating of spontaneous (unprovoked) pain around the vaginal opening						
5. Pelvic muscle pain Pain in pelvic muscles using a standardized pressure device						
4. Provoked vulvar pain by pressure/contact Average pain sensitivity to pressure around the vaginal opening						
3. Pain from treatment Pain evoked by the treatment						
2. Insertional pain (sexual) Pain during sexual activities involving vaginal penetration						

0% 12%

Pain Quality and Affect or Pain Temporality

	1	2	3	4	5	6	7	8	9	Unable	
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to	
	important	important	Important	but not	but not	but not	should	should	should	score	
				critical	critical	critical	always be	always be	always be		
							measured	measured	measured		
9. Pain quality How the pain is described											
10. Pain behaviour Behavioural responses when in pain											

11. Pelvic floor response to pressure pain provocation Pelvic floor muscle response to painful pressure applied to the vaginal opening						
12. Time until pain improvement Time from start of treatment until perceived improvement						
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Other outcomes related to Pain

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
13. Degree of overlapping pain Degree of comorbid (co-occuring) pain conditions										
14. Pain duration The duration of the pain										
15. Vulvar discomfort Level of discomfort (such as irritation and burning) felt in the vulva										
16. Multidimensional aspects of pain Pain intensity and quality, and emotional and other aspects (e.g., interpersonal) of pain.										

medication during the trial 18. Pain triggers Physical and psychologically related events that trigger pain events. Includes both positive and negative events d powered by defgoth info < Back	Next >
17. Pain rescue medication Monitoring the use of pain rescue	

Emontional Functioning-Response to Pain

	1 Not important	2 Not important	3 Not important	5 Important but not critical	6 Important but not critical	should	8 Critical, should always be measured		
19. Pain anxiety Feelings of worry and tension related to the pain									
20. Pain catastrophizing Negative and exaggerated thoughts and feelings related to pain									
21. Pain vigilance Degree of preoccupation with and attention to pain									
22. Penetration self- efficacy Degree of confidence related to engaging in penetration									
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should

always be always be measured measured measured

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Emotional Functioning-Anxiety/Depression Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance). * Unable 1 Not Not Not Important Important Critical, Critical, Critical, to important important but not but not but not should should should score critical critical critical always be always be always be measured measured measured 24. Anxiety Feelings of worry and tension 25. Depression Feelings of sadness info < Back d powered by defgo® Next > 0% 100% Other outcomes related to Emotional Functioning Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical importance). Unable 3 7 1 2 6 8 Not Important Important Critical, Critical, Critical, to

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critical

but not

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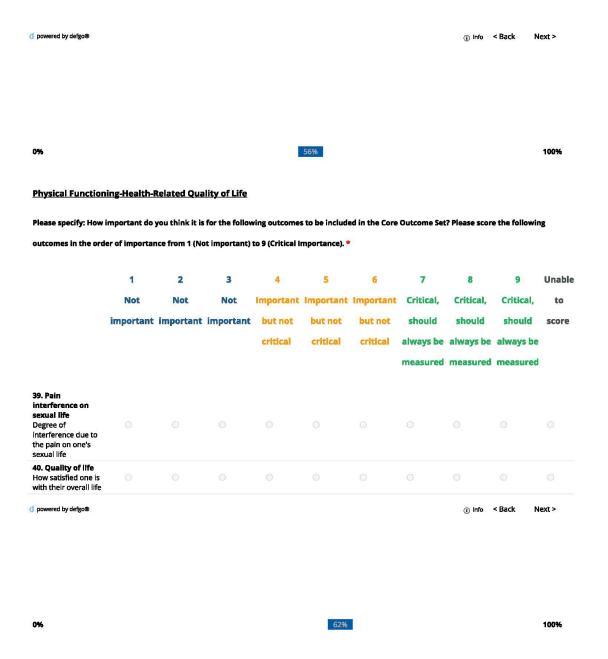
important important

26. Bodily awareness One's degree of connectedness with their body						
27. Cognitions related to vaginal penetration Thoughts about vaginal penetration						
28. Decentering To view thoughts and feelings as temporary and objective						
29. Illness perception One's understanding of an illness and its consequences						
30. Mindfulness Ability to be fully aware of the present moment						
32. Psychological distress Feelings of distress						
33. Psychological flexibility Ability to shift one's way of thinking						
35. Stress Feelings of psychological and physical tension						
64. (New) Sexual self-esteem One's feelings of sexual confidence and sexual worth	0					
65. (New) Shame Feelings of humiliation, remorse, or stigma related to one's sexuality and/or body						
66. (New) Assertiveness Ability to communicate one's needs in general or in relation to one's sexuality.						
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Coping

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).* 3 Unable 1 Important Important Critical, Critical, Critical, Not Not Not to important important important but not but not but not should should should score critical critical critical always be always be always be measured measured measured 36. Pain coping The strategies that people use to manage their pain d powered by defgo® Next > 50% 100% 0% Interpersonal Functioning (i.e. relationships and activities with family, friends, and others) Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical importance). * 1 2 3 6 7 8 9 Unable Important Important Critical, Critical, Critical, Not Not Not to important important important but not but not but not should should should score critical critical critical always be always be measured measured measured 37. Pain related interference on one's life The degree to which the pain interferes with one's life 38. Relationship quality Quality of relationship with partner 67. (New) Thoughts/feelings regarding relationship Openness for a new relationship or new sexpartners, worry regarding existing or new relationships, or feeling of loneliness



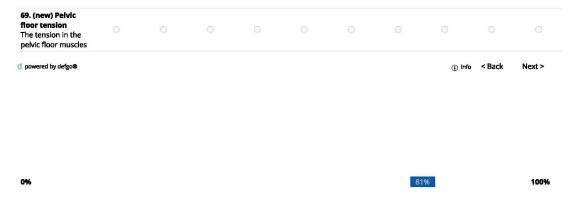
Physical Functioning-Sexual Function

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	Important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
41. Attempts to engage in sexual intercourse Vaginal penetration attempts during sexual activity										
43. Information related to sexual function Accuracy of information related to sexual function										
44. Interest in sexual activity The degree to which one is interested in sexual activity										
45. Mood and Sexual Function Mood and the degree to which one is able to engage sexually and experience pleasure										
46. Non-penetrative sexual activity Any activity that is sexually arousing and does not involve intercourse										
48. Sexual activity Any activity that is sexually arousing										
49. Sexual function The degree to which one is able to engage sexually and experience pleasure										
50. Sexual health The level of physical, emotional, and psychological wellbeing related to sexuality									0	
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Physical Functioning-Sexual Distress/Sexual Satisfaction/Sexual Function Interference

outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance). \star 3 Unable 1 Important Important Critical, Critical, Critical, Not Not Not to important important important but not but not but not should should should score critical critical critical always be always be always be measured measured measured 51. Pain related sexual interference The degree to which with one's sexuality 52. Sexual distress How worried and sad one is with their sex 53. Sexual satisfaction One's overall perception of positive sexual experiences and pleasure d powered by defgo® Next > 0% 75% 100% Other outcomes related to Physical functioning Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical importance).* 1 2 3 9 Unable Important Important Critical, Critical, Critical, Not Not Not to should important important important but not but not but not should should score critical always be always be critical critical measured measured measured 68. (new) Pelvic floor funtion Ability to contract and relax the muscles of the pelvic floor

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following



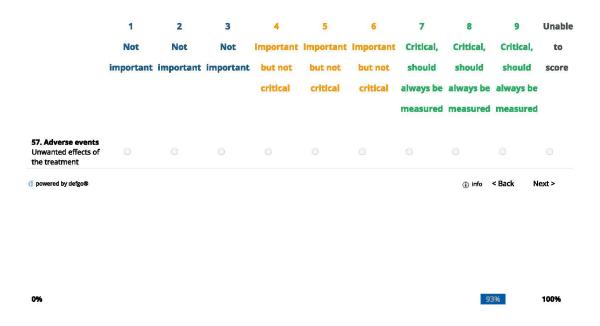
Participant Ratings of Global Improvement and Satisfaction with Treatment

Please specify: How important do you think it is for the following outcomes to be included in the Core Outcome Set? Please score the following outcomes in the order of importance from 1 (Not important) to 9 (Critical Importance).*

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	Important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
54. Treatment credibility Rating of how confident one is with the present treatment										
55. Treatment improvement Rating of treatment improvement										
56. Treatment satisfaction Rating of satisfaction with treatment										
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Symptoms and Adverse Events



Biological Markers (e.g. assessments based on quantitative sensory testing, imaging, genetic markers, pharmacogenomics, and punch skin biopsy)

	1	2	3	4	5	6	7	8	9	Unable
	Not	Not	Not	Important	Important	Important	Critical,	Critical,	Critical,	to
	important	important	important	but not	but not	but not	should	should	should	score
				critical	critical	critical	always be	always be	always be	
							measured	measured	measured	
60. Sensation threshold Ability to detect nonpainful pressure applied to the vulva										
62. Vaginal flora Analysis of the content of vaginal microorganisms (microbiome) before and after treatment										
63. Vulvar redness Degree of vulvar redness										
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