

Evidence Profile Q4: *Supporting adults who anticipate or live with an ostomy, Second edition*

Research Q4 Evidence Profile (Quantitative)

Question 4: Should quality of life assessment or no quality of life assessment be recommended?

Population: Persons living with an ostomy.

Intervention: Quality of life assessment.

Comparison: No quality of life assessment.

Outcomes: Psychological health, self-identity.

Setting: All healthcare settings

Bibliography: 732, 754, 771, 5877, 5788, 4131, 621, 687, 703

Quality assessment							Study details			Reported outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	No. of participants with stoma	No. of participants without stoma			
Psychological health (measured with EORTC QLQ-C30 ¹ , EORTC QLQ-CR38 ² , SF-36 ³ , COH-QOL-Ostomy ⁴ , SQOL ⁵ , SF36v2 ⁶ , HADS ⁸)												
5	Observational	serious ^a	serious ^b	not serious	not serious	none	<u>754:</u> Sweden <u>5877:</u> Iran <u>732:</u> Sri-Lanka <u>771:</u> US	<u>754:</u> 336 participants w/ ave. score of 74.1/100* <u>5877:</u> 64 out of 102 (63%) reported feelings of depression <u>732:</u> About 46% (out of 43 participants) "felt depressed" soon after surgery <u>771:</u> 2329 participants (9.1% felt nervous most of all of the	<u>754:</u> 117 participants w/ ave. score of 80.3/100* <u>5877:</u> No comparison group <u>732:</u> No comparison group <u>771:</u> No information in regards to number of participants,	<p>No studies involved the intervention of a quality of life assessment and a subsequent analysis of outcomes as a result. However, all studies utilized a validated ostomy quality of life assessment tool that measured some aspect of psychological health.</p> <p>Upon assessment, all studies found a negative correlation with those living with an ostomy and psychological/mental health. In studies that compared scores of persons living with a stoma to those without a stoma, it was found that persons living with an ostomy scored less on mental health components. Most studies also found that either majority (or statistically significant amount) of persons living with an ostomy felt nervous or depressed.</p>	⊕⊕○○ LOW	<u>754:</u> Nasvall et al, 2016 <u>5877:</u> Anaraki et al., 2012 <u>732:</u> Jayarajah & Samarasekera, 2017 <u>771:</u> Nichols, 2016 <u>5788:</u> Knowles et al., 2013

Quality assessment							Study details			Reported outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	No. of participants with stoma	No. of participants without stoma			
							5788: Australia	time; 8.8% downhearted or depressed most or all of the time) 5788: 31 people (48% scored more than cutoff for anxiety; 42% scored more than cutoff for depression)	however 6.2% felt nervous most of all of the time; 6.0% felt downhearted or depressed most or all of the time 5788: No comparison group			
Self-identity (measured with EORTC QLQ-C30 ¹ , EORTC QLQ-CR38 ² , SF-36 ³ , COH-QOL-Ostomy ⁴ , SQOL ⁵ , PROMIS ⁹)												
7	Observational	serious ^d	serious ^e	not serious	not serious ^f	none	4131: Netherlands 5877: Iran	4131: 67 participants (average score of 26.1 in sexual functioning; ave. score of 55 sexual enjoyment)** 5877: 102 people (81.4% reported being sexually active before stoma	4131: 76 pts (average score of 44.6 sexual functioning; ave. score of 73.4 sexual enjoyment)** 5877: No comparison group	No studies involved the intervention of a quality of life assessment and a subsequent analysis of outcomes as a result. However, all studies utilized a validated ostomy quality of life assessment tool that measured some aspect of self-identity. All studies reported on sexuality and body image in relation to self-identity. Most of the studies found that living with an ostomy was associated with a negative impact on body image and sexuality. However, a few studies showed that living with an ostomy has no substantial effect, or has an effect to a lesser degree on body image and sexuality.	⊕⊕○○ LOW	4131: Orsini et al., 2012 5877: Anaraki et al., 2012 621: Yilmaz, Celebi, Kaya & Baydur, 2017 687: Abdalla et al., 2016

Quality assessment							Study details			Reported outcomes	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	No. of participants with stoma	No. of participants without stoma			
							<p><u>621</u>: Turkey</p> <p><u>687 & 703</u>: US</p> <p><u>732</u>: Sri Lanka</p> <p><u>754</u>: Sweden</p>	<p>surgery, only 33.3% resumed sexual activity after surgery)</p> <p><u>621</u>: 57 people (Scores were lowest on sexuality/body image: 43.86 ±17.42)</p> <p><u>703</u>: Refer to table^h</p> <p><u>732</u>: 9/27 resumed sexual activity after surgery</p> <p><u>754</u>: Refer to tableⁱ</p>	<p><u>621</u>: No comparison group</p> <p><u>687</u>: Refer to table^g</p> <p><u>703</u>: Refer to table^h</p> <p><u>732</u>: No comparison group</p> <p><u>754</u>: Refer to tableⁱ</p>			<p><u>703</u>: Sun et al., 2016</p> <p><u>732</u>: Jayarah & Samarasekera, 2017</p> <p><u>754</u>: Nasvall et al., 2017</p>

1. EORTC QLQ-C30: Designed by the European Organization for Research and Treatment of Cancer to assess quality of life of cancer patients overall
2. EORTC QLQ-CR38: Designed by the European Organization for Research and Treatment of Cancer to assess quality of life for colorectal cancer
3. SF-36: Health related quality of life questionnaire
4. COH-QOL-Ostomy: City of Hope Quality of Life – Ostomy Questionnaire
5. SQOL: Stoma quality of life scale

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6. SF36v2: Version 2.0 of the SF36 (health related quality of life questionnaire)
7. SIBD: Short Inflammatory Bowel Disease Questionnaire
8. HADS: Hospital Anxiety and Depression Scale
9. PROMIS: Patient Reported Outcomes Measurement Information System

*Higher scores demonstrate better mental health

**Score out of 100; higher scores demonstrate better sexual functioning/enjoyment

Explanations

- a. Studies were assessed using the ROBINS-I tool. No studies adjusted for potential confounders. Therefore, the body of evidence was downgraded by 1.
- b. Although all study results were consistent in that living with an ostomy correlated with poor psychological health, there was inconsistency in the measurement tools among all studies. Therefore, the body of evidence was downgraded by 0.5.
- c. The total sample size for all studies was 3008, which exceeds the optimal size of 400 participants.
- d. Studies were assessed using the ROBINS-I tool. Most studies did not control for potential confounders. Therefore, the body of evidence was downgraded by 1.
- e. The study results were inconsistent in regards to the correlation of living with an ostomy and self-identity. There inconsistency in the tools used to measure quality of life among studies. With these considerations, the body of evidence was downgraded by 0.5.
- f. The total sample size for all studies was 6,182, which exceeds the optimal size of 400 participants.
- g. Age-adjusted and disease activity-adjusted means of PROMIS[®] Scores for Sexual Interest and Satisfaction Among Patients with and without Ostomy stratified by Gender:

Gender	Sexual Function Domain	Patients without Ostomy – Adjusted Mean (SE)	Patients with Ostomy – Adjusted Mean (SE)
Men	Sexual interest (n=270)	48.7 (0.6)	48.5 (1.7)
	Sexual satisfaction (n=280)	48.2 (0.4)	46.1 (1.5)
Women	Sexual interest (n=956)	40.4 (0.4)	40.8 (1.3)
	Sexual satisfaction (n=711)	46.7 (0.3)	47.5 (1.1)

- h. Reports of sexual inactivity in ostomy group versus anastomosis group based on year of surgery:

Year of surgery	Ostomy status**	Reports of Sexual Inactivity
Before January 1, 2000	Ostomy group	51%
	Anastomosis group	29%
After January 1, 2000	Ostomy group	69%
	Anastomosis group	58%

** total number of persons with ostomy = 181 & total number of persons with anastomosis = 394

- i. EORTC QLQ-CR38² comparison of mean values in groups with and without a permanent stoma:

Function	Mean value	Number of persons
Body image		
Stoma	74.8	314
No stoma	87.2	103
Sexual functioning		
Stoma	87.3	298
No stoma	82.3	92
Sexual enjoyment		
Stoma	62.9	85

No stoma	58.5	41
Male sexual problems		
Stoma	54.0	160
No stoma	43.1	38
Female sexual problems		
Stoma	25.6	20
No stoma	25.0	15