Evidence Profile Q1: Supporting adults who anticipate or live with an ostomy, Second edition

Research Q1 Evidence Profile (Quantitative)

Research question 1: Should access to nurses specialized in wound, ostomy, and continence or no access to nurses specialized in wound, ostomy, and continence be recommended?

Population: All adults (18 & over) anticipating or living with an ostomy.

Intervention: Access to NSWOC.
Comparison: No access to NSWOC.

Outcomes: Peristomal dermatitis/irritation, ostomy leakage, quality of life, readmission rates to hospital, hospital length of stay.

Setting: All healthcare settings

Bibliography: 100, 198, 656, 2047, 2459, 2498, 2505, 10386, 2244

	Quality assessment							Study details	No. of p	articipants			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Access to NSWOC Intervention	Access to NSWOC	No access to NSWOC	Reported effects/outcomes	Certainty	Reference
Peristom	nal dermati	tis or irrita	tion (measured wi	ith: ostomy skin to	ool reporting DE	Γ1)							
1	RCT	serious ^a	not serious	not serious	serious ^b	none	2047: Norway	2047: ERAS² programme - patients receive counseling and extended pre and post op stoma education from ERAS nurses and NSWOC. Pre-op consultations x 2 are 45-60 minutes in duration	14/61	23/61	For every 100 people who have access to NSWOC, 15 fewer will develop peristomal dermatitis/irritation (ranges from 25 fewer to 3 more).	⊕⊕○○ LOW	2047: Forsmo et al. (2016)
2	Quasi- experim ental	very serious °	not serious ^d	not serious	serious e	none	100: United States 2505: North America	100: A pre-operative 2-hour group stoma education class led by NSWOC 2505: Double layer adhesive pouching system coupled with NSWOC consults	2505: participan ts with allergic contact dermatitis had 4.5 DET score at visit 1 and at visit 2, it was 2.4	100: 23 /94 2505: no comparator	Two studies assessed occurrences of peristomal dermatitis or irritation based on clinician observation and use of the ostomy skin tool. Based on one study, for every 100 people who have access to NSWOC, 13 fewer will develop peristomal dermatitis/irritation (ranges from 18 fewer to 4 fewer). Further, mean scores for patients using double adhesive layer pouching system and receiving NSWOC consults, there was a decrease in mean DET¹ score from 4.5 at visit one to 2.4 at visit two.	⊕○○ VERY LOW	100: Stokes et al. (2017) 2505: Erwin- Toth, Thompson & Davis (2012)

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Charling out for men	wing Smalling out for health

			Quality a	ssessment				Study details	No. of p	participants			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Access to NSWOC Intervention	Access to NSWOC	No access to NSWOC	Reported effects/outcomes	Certainty	Reference
1	Systema tic review	seriousf	not serious	serious ^g	serious ^h	none	2244: Spain	2244: Pre-op education and stoma siting by NSWOC	10/123	22/147	For every 100 people who have access to NSWOC, 7 fewer will develop peristomal dermatitis/irritation (ranges from 11 fewer to 2 more).	⊕○○○ VERY LOW	2244: Millan et al. (2010) as cited in Phatak, Li, Karanjawal a, Chang & Kao (2014)
Ostomy	Leakage (r	neasured o	bjectively)			l							
1	Quasi- experim ental	serious i	not serious	not serious	serious ^j	none	100: USA	100: A pre-operative 2-hour group stoma education class led by NSWOC	11/124	19/94	For every 100 people who have access to NSWOC, 11 fewer will experience ostomy leakage (ranges from 16 fewer to 2 fewer).	⊕○○○ VERY LOW	100: Stokes et al. (2017)
Quality o	of Life (mea	asured with	stoma quality of lif	e questionnaire [S	SQOL], 15D, sho	ort form-36 [SF-36],	EQ-5D, Mor	ntreux questionnaire, survey)		•			
1	RCT	serious ^a	not serious	not serious	serious ^k	none	2047: Norway	2047: ERAS² programme - patients receive counseling and extended pre and post op stoma education from ERAS nurses and NSWOCs. Pre-op consultations x 2 are 45-60 minutes in duration.	Ave. baseline score = 0.871 out of 1 Scores dropped from	Ave. baseline score = 0.870 out of 1 Scores dropped from	The study reported that there were no differences between the group that had access to an NSWOC compared to the group that did not have access to an NSWOC. Both groups had significant and clinically important improvement in QOL scores from baseline to 10 days, as well as from 10 days to 30 days.	⊕⊕⊖⊖ LOW	2047: Forsmo et al. (2016)

			Quality as	ssessment				Study details	No. of p	participants			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Access to NSWOC Intervention	Access to NSWOC	No access to NSWOC	Reported effects/outcomes	Certainty	Reference
									baseline to 10 days by 0.0868 Scores improved from 10 days to 30 days by 0.0273	baseline to 10 days by 0.0910 Scores improved from 10 days to 30 days by 0.0322			
4	Quasi- experi mental	serious ¹	not serious ^m	not serious	not serious ⁿ	none	198: Ireland 2498: Turkey 656: Spain 2505: North America	198: follow up visit from NSWOC & use of new appliance (which was not specified) 2498: pre-op group education involving NSWOC 656: inpatient care in hospital with NSWOC 2505: NSWOC consult	198: for 47 participan ts - baseline ave. QOL score 52.5 /100; at f/u ave. QOL score of 61.5/100 2498: Refer to tableo 656: 313 participan ts (EQ-5D scores: pre-op – 0.7902; 3 months f/u – 1.0000) (Montreu	198: No comparison 2498: No comparison 656: 89 participants (EQ-5D scores: preop – 0.7486; 3 months f/u – 0.7406) (Montreux Index	Four studies reported on quality of life by persons with an ostomy receiving support from a NSWOC. Quality of life was measured (using various tools) anywhere from 2 weeks to 3 months after a person received an intervention involving a NSWOC. All studies reported higher scores in quality of life in persons living with an ostomy who had access to an NSWOC. All studies recorded a baseline and post-intervention score and reported a statistically significant improvement in quality of life in persons living with an ostomy.	⊕○○ VERY LOW	198:Chand ler, Buckley, Canty, O'Sullivan & Stuart (2017) 2498: Altuntas et al. (2012) 656: Coca, de Larrinoa, Serrano & Garcia-Llana (2015) 2505: Erwin-Toth, Thompson & Davis (2012)

			Quality as	ssessment				Study details	No. of p	participants			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Access to NSWOC Intervention	Access to NSWOC	No access to NSWOC	Reported effects/outcomes	Certainty	Reference
									x Index scores: pre-op – 68.7/100; 3 months f/u – 74.8/100) 2505: 722 people with ave. baseline score 56.8 and 58.9 at f/u	scores: pre- op – 67.9/100; 3 months f/u – 69.6/100) 2505: No comparison			
Readmis	sion Rate	s to Hospit	al (Measured objec	ctively)		<u> </u>							
1	RCT	serious ^a	not serious	not serious	serious P	none	<u>2047:</u> Norway	2047: ERAS² programme – patients receive counseling and extended pre and post op stoma education from ERAS nurses and NSWOC. Pre-op consultations x 2 are 45-60 minutes in duration.	13/61	11/61	For every 100 people who have access to NSWOC, 4 more will be readmitted (ranges from 8 fewer to 26 more).	⊕⊕○○ LOW	2047: Forsmo, Pfeffer, Rasdal, Sintonen, Korner, & Erichsen (2016)
2	Quasi- experi mental	serious q	not serious	not serious	not serious r	None	100 <u>&</u> 2459: USA	100: A pre-operative 2-hour group stoma education class led by NSWOC 2459: Collaborative lleostomy pathway that includes teaching from NSWOC	100: 19/124 2459: any readmissi on: 9/42 Readmiss ion due to	100: 19/94 2459: any readmission : 57/161 Readmission n due to	100: For every 100 people who have access to NSWOC, 5 fewer will be readmitted (ranges from 11 fewer to 7 more). 2459: For every 100 people who have access to NSWOC, 14 fewer will be readmitted (ranges from 23 fewer to 4 more). 2459: For every 100 people who have access to NSWOC, 15 fewer people	⊕⊕⊖⊖ LOW ^s	100: Stokes et al. (2017) 2459: Nagle et al. (2012)

			Quality a	ssessment				Study details	No. of p	participants			
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Access to NSWOC Intervention	Access to NSWOC	No access to NSWOC	Reported effects/outcomes	Certainty	Reference
									dehydrati on: 0/42	dehydration: 25/161	will be readmitted due to dehydration (ranges from 16 fewer to 3 more).		
Hospital	Length of	Stay (LOS)) (Measured objec	tively)									
1	RCT	serious ^a	not serious	not serious	serious ^t	None	<u>2047:</u> Norway	2047: ERAS² programme – patients receive counseling and extended pre and post op stoma education from ERAS nurses and NSWOCs. Pre-op consultations x 2 are 45-60 minutes in duration.	Participan ts = 61 Median length of stay = 6 days	= 61 Median	The median length of stay was 6 days for patients in ERAS group. For the control group, the median length of stay was 9 days, demonstrating a difference of 3 fewer days (LOS) for persons who had access to NSWOC.	⊕⊕○○ LOW	2047: Forsmo, Pfeffer, Rasdal, Sintonen, Korner, & Erichsen (2016)
3	Quasi- experi mental	serious ^u	not serious	not serious	not serious ^v	none	100. 2459. & 10386: USA	100: A pre-operative 2-hour group stoma education class led by NSWOC 2459:Collaborative Ileostomy pathway that includes teaching from NSWOC	<u>2459:</u> 42	With ave. LOS of 6	Among the three studies, the LOS decreased from 1-3 days when persons had access to an NSWOC, compared to those who did not have access to an NSWOC.	⊕⊕○○ LOW	100: Stokes et al. (2017) 2459: Nagle et al., 2012 10386: Burke, 2017
								10386: Pre-operative stoma siting by a NSWOC for persons undergoing planned ostomy	10386: 85 participan ts with	10386: 43 participants			

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								· ,	ave. LOS of 16 days	with ave. LOS of 19 days			

¹DET: Discoloration, erosion or ulceration, and tissue overgrowth

²ERAS: Enhanced recovery after surgery

Explanations

- a. There was some risk of bias in relation to how the study was conducted (2047). Therefore, we deducted 1 for risk of bias.
- b. The total number of events is less than 300. Therefore, 0.5 deducted for imprecision.
- c. There were very serious concerns in risk of bias for both studies due to missing data, measurement of outcomes and confounding, and as a result we downgraded by 1.5.
- d. Different measures were used to assess for irritation or dermatitis in both studies, so we downgraded by 0.5.
- e. In study 2505, number of events is not clear. Therefore, we downgraded by 0.5.
- f. The systematic review had some overall concerns related to risk of bias based on the AMSTAR -2 tool, therefore we downgraded by 1.
- g. It is unclear if what the control groups across studies consists of in terms of care, therefore we downgraded by 0.5.
- h. The total number of events in is less than 300, therefore we downgraded by 0.5.
- i. Based on ROBINS-I tool, the study had serious concerns related to risk of bias due to limitations in how the study was conducted. Therefore, the study was downgraded by 1 point for risk of bias.
- j. The total number of events was 30, which is less than the optimal number of events (300). We downgraded by 0.5.
- k. The total number of study participants was 122, which is less than the optimum number of participants (400).
- I. There were serious concerns for risk of bias because of confounding and missing data in the majority of studies. Body of evidence was downgraded by 1.
- m. There were some inconsistencies in regards to the majority of the studies using different tools to measure quality of life. Thus, we downgraded by 0.5.
- n. The total sample size of combined articles is 1264, which exceeds the optimal number of participants (400).
- o. Study 2498 Comparison of pre- and post-education SF-36 results

Scales	Pre-education	Post-education	Р
Physical functioning	46.8±9.8	53.1±7.7	0.000
Role-physical	35.7±11.9	44.1±7.0	0.000
Bodily pain	51.9±10.6	56.4±9.1	0.001
General health	48.1±10.6	51.4±11.0	0.006
Vitality	52.3±9.6	54.3±8.8	0.159



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Social functioning	47.7±10.2	51.4±6.5	0.003	
Role-emotional	34.2±14.1	43.8±11.1	0.000	
Mental Health	48.2±10.7	53.2±7.9	0.000	
Summary				
Measures:				
Measures: Physical health	47.2±9.2	52.3±6.9	0.000	

- p. The total number of events was 24, which is less than the optimal number of events (300). Therefore, we downgraded by 0.5.
- q. Both studies had a risk of bias related to how the study was conducted. Therefore, body of evidence was downgraded by 0.5 points
- r. The total number of events is less than the optimal number of events (300), therefore the body of evidence was downgraded by 0.5 points.
- s. Quasi-experimental studies initially have a moderate certainty of evidence due to the nature of their designs. Although inconsistency and indirectness domains were not serious, the body of evidence was rated down for concerns related to risk of bias and imprecision. Hence, the body of evidence was given an overall low certainty.
- t. The total number of participants was less than the optimal number of participants (400). Therefore, we downgraded by 0.5.
- u. There was some risk of bias in relation to how the studies were conducted. Therefore, we deducted 0.5 for risk of bias.
- v. The total number of participants between four studies was 549, which exceeds the optimal number of participants (400).