

Effect of lymphedema prevention program based on theory of Knowledge-attitude-practice on postoperative breast cancer patients: a randomized clinical trial

Research Proposal

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Data Analysis

SPSS21.0 software was used, a two-sided test was set, and α was set at 0.05. The normality of measurement data was expressed as mean \pm standard deviation ($\pm s$), and two independent sample t-test was used. When not normal, the median and interquartile range [M(Q)] were expressed using the Mann-Whitney U test. Enumeration data were expressed as frequency and constituent ratio using 2 test. Mann-whitney U test was used for grade data.

Table 1 Socio-demographic and clinical characteristics at baseline, by group allocation

Characteristics		Total (n=97)	Intervention Group (n=47)	Control Group (n=50)	t/Z/ χ^2	P
Age (X \pm SD)		50.51 \pm 9.78	50.15 \pm 11.01	50.84 \pm 8.56	-0.344	0.732 ^a
BMI (X \pm SD)		23.50 \pm 2.81	23.32 \pm 2.78	23.67 \pm 2.86	-0.620	0.536 ^a
Marital status (%)	Married	91 (93.8)	44 (93.6)	47 (94.0)	-1.597	0.899 ^c
	Never married	1 (1.0)	1 (2.1)	0 (0.0)		
	Divorced	3 (3.1)	1 (2.1)	2 (4.0)		
	Widowed	2 (2.1)	1 (2.1)	1 (2.0)		
Education level (%)	Junior high school or below	42 (43.3)	21 (44.7)	21 (42.0)	0.282	0.778 ^b
	High school or technical school	25 (25.8)	12 (25.5)	13 (26.0)		
	College or above	30 (30.9)	14 (29.8)	16 (32.0)		
Occupation (%)	Enterprise personnel	18 (18.6)	10 (21.3)	8 (16.0)	-2.156	0.827 ^c
	Peasantry	29 (29.9)	14 (29.8)	15 (30.0)		
	Merchant	15 (15.5)	8 (17.0)	7 (14.0)		
	Technician	13 (13.4)	4 (8.5)	9 (18.0)		
	Unemployed	12 (12.4)	6 (12.8)	6 (12.0)		
	Others	10 (10.3)	5 (10.6)	5 (10.0)		
Monthly income (RMB) (%)	<1500	16 (16.5)	8 (17.0)	8 (16.0)	0.316	0.752 ^b
	1500-3000	35 (36.1)	17 (36.2)	18 (36.0)		
	3001-5000	25 (25.8)	13 (27.7)	12 (24.0)		
	>5000	21 (21.6)	9 (19.1)	12 (24.0)		
Affected extremity (%)	Left	45 (46.4)	19 (40.4)	26 (52.0)	-1.305	0.253 ^c
	Right	52 (53.6)	28 (59.6)	24 (48.0)		
Disease stage (%)	I	38 (39.2)	23 (48.9)	15 (30.0)	1.630	0.103 ^b
	II	43 (44.3)	17 (36.2)	26 (52.0)		

	III	16 (16.5)	7 (14.9)	9 (18.0)		
Operation type (%)	Mastectomy	75 (77.3)	36 (76.6)	39 (78.0)	-0.380	0.931 ^c
	Conserving surgery	17 (17.5)	8 (17.0)	9 (18.0)		
	Mastectomy and rebuild	5 (5.2)	3 (6.4)	2 (4.0)		
Number of axillary lymph nodes extracted [M(Q)]		5.00 (3.00, 19.00)	7.00 (3.00, 21.00)	5.00 (3.00, 17.30)	0.962	0.336 ^b
Time of drainage tube extraction (day) [M(Q)]		9.00 (7.00, 12.50)	8.00 (7.00, 14.00)	10.00 (7.00, 12.00)	0.125	0.901 ^b

Note: ^aIndependent sample test.

^bMann-Whitney U test.

^cChi-square test.

Table 2 Comparison of upper limb lymphedema incidence between two groups after intervention

Lymphedema	Post-test1 (T1)		χ^2	<i>P</i>	Post-test2 (T2)		χ^2	<i>P</i>
	Intervention	Control			Intervention	Control		
	(<i>n</i> =47)	(<i>n</i> =50)			(<i>n</i> =47)	(<i>n</i> =50)		
None (%)	46 (97.9)	48 (96.0)	0.000	1.000	45 (95.7)	46 (92.0)	0.118	0.731
Total (%)	1 (2.1)	2 (4.0)			2 (4.3)	4 (8.0)		

χ^2 =Chi-square test.

Table 3 Comparison of the severity of upper limb lymphedema between two groups after intervention

Lymphedema	Post-test1 (T1)		<i>Z</i>	<i>P</i>	Post-test2 (T2)		<i>Z</i>	<i>P</i>
	Intervention	Control			Intervention	Control		
	(<i>n</i> =47)	(<i>n</i> =50)			(<i>n</i> =47)	(<i>n</i> =50)		
None (%)	46 (97.9)	48 (96.0)			45 (95.7)	46 (92.0)		
Mild (%)	1 (2.1)	2 (4.0)	0.530	0.596	2 (4.3)	3 (6.0)	0.752	0.452
Moderate	0 (0.0)	0 (0.0)			0 (0.0)	1 (2.0)		

(%)				
Severe (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

z=Mann-Whitney U test.

Table 4 Comparison of handgrip strength between two groups after intervention

Group	Pre-test (T0)	Post-test1 (T1)	Post-test2 (T2)	Group	Time	Group × time	ηP^{2*}
	X±SD	X±SD	X±SD	F (P)	F (P)	F (P)	
Intervention	22.02±5.78	18.04±5.77	21.48±5.65	1.975	243.426	27.665	0.371
Control	22.16±5.25	16.18±4.22	19.21±4.30	(0.163)	(<0.001)	(<0.001)	
t	0.122	-2.172	-2.232				
P	0.903	0.032	0.028				

t=Independent sample test.

*=The effect size of the interact (group × time) effect.

Table 5 Comparison of ROM between two groups after intervention

Group	Pre-test (T0)	Post-test1 (T1)	Post-test2 (T2)	Group	Time	Group × time	ηP ² *
	X±SD	X±SD	X±SD	<i>F</i> (<i>P</i>)	<i>F</i> (<i>P</i>)	<i>F</i> (<i>P</i>)	
Flexion							
Intervention	21.26±5.49	119.87±20.49	146.74±16.10	10.646	2332.200	3.289	0.065
Control	19.21±4.30	107.54±24.03	136.74±18.93	(0.002)	(<0.001)	(0.042)	
<i>t</i>	-2.058	-2.712	-2.952				
<i>P</i>	0.042	0.008	0.004				
Extension							
Intervention	60.21±7.79	51.53±10.23	59.96±9.71	3.941	70.293	1.256	0.026
Control	58.12±8.31	46.74±10.35	53.80±8.87	(0.050)	(<0.001)	(0.290)	
<i>t</i>	-1.293	-2.292	-0.674				
<i>P</i>	0.199	0.024	0.097				
Abduction							
Intervention	160.34±11.99	120.60±20.51	147.51±16.99	9.893	190.291	7.038	0.130

Control	160.20±11.72	107.4±25.91	132.26±23.07	(0.002)	(<0.001)	(0.001)	
<i>t</i>	-0.058	-2.770	-3.722				
<i>P</i>	0.954	0.007	<0.001				
Adduction							
Intervention	50.43±8.52	45.00±8.19	48.87±8.24	0.054	40.095	0.472	0.005
Control	49.90±6.43	45.30±7.60	48.12±6.69	(0.817)	(<0.001)	(0.625)	
<i>t</i>	-0.341	0.187	-0.495				
<i>P</i>	0.734	0.852	0.622				
Internal rotation							
Intervention	53.83±7.39	51.15±8.94	53.47±7.33	0.388	11.885	2.833	0.057
Control	53.76±7.06	50.50±7.09	51.66±6.15	(0.535)	(<0.001)	(0.064)	
<i>t</i>	-0.048	-0.397	1.319				
<i>P</i>	0.962	0.692	0.190				
External rotation							
Intervention	64.19±10.65	55.79±9.73	62.21±10.39	1.292	60.940	2.302	0.047
Control	62.86±11.05	53.60±10.54	58.96±10.36	(0.259)	(<0.001)	(1.106)	
<i>t</i>	-0.604	-1.060	-1.534				
<i>P</i>	0.548	0.292	0.126				

t=Independent sample test.

*=The effect size of the interact (group×time) effect.

Table 6 Comparison of DASH scores between two groups after intervention

Group	Pre-test (T0)	Post-test1 (T1)	Post-test1 (T2)	Group	Time	Group × time	η^2 *
	X±SD	X±SD	X±SD	<i>F</i> (<i>P</i>)	<i>F</i> (<i>P</i>)	<i>F</i> (<i>P</i>)	
Intervention	3.00±4.40	29.84±12.47	11.65±6.71	18.978	296.757	11.685	0.199
Control	3.23±3.35	38.00±16.19	18.23±6.65	(<0.001)	(<0.001)	(<0.001)	
<i>t</i>	0.290	2.770	4.845				
<i>P</i>	0.773	0.007	<0.001				

t=Independent sample test.

*=The effect size of the interact (group×time) effect.

Table 7 Comparison of FACT-B scores between two groups after intervention

Group	Pre-test (T0)	Post-test1 (T1)	Post-test2 (T2)	Group	Time	Group × time	ηP ² *
	X±SD	X±SD	X±SD	F (P)	F (P)	F (P)	
Physical well-being							
Intervention	22.81±3.25	18.04±3.31	21.19±3.49	2.789	46.483	0.214 (0.808)	0.005
Control	22.50±4.49	17.36±3.37	20.12±4.06	(0.098)	(<0.001)		
t	-0.390	-1.006	-1.390				
P	0.698	0.317	0.168				
Social/family well-being							
Intervention	19.57±3.90	18.34±4.86	19.58±1.87	7.639	5.483	1.670 (0.194)	0.034
Control	19.28±4.27	16.33±4.87	17.71±2.71	(0.007)	(0.006)		
t	-0.364	-2.038	-3.983				
P	0.730	0.044	<0.001				
Emotional well-being							
Intervention	14.19±3.52	17.26±3.67	18.13±2.59	17.418	25.944	1.463 (0.234)	0.015
Control	13.60±2.39	15.42±2.81	16.06±3.79	(<0.001)	(<0.001)		
t	-0.963	-2.749	-3.151				
P	0.339	0.077	0.002				
Functional well-being							
Intervention	17.23±4.86	16.60±5.12	18.34±2.10	7.328	6.316	1.516 (0.225)	0.031
Control	17.28±5.36	14.44±3.79	16.38±3.88	(0.008)	(0.003)		
t	0.044	-2.344	-3.123				
P	0.965	0.021	0.003				
Breast cancer session							
Intervention	29.02±2.19	22.81±3.34	25.53±3.16	10.276	174.609	7.649 (0.001)	0.137
Control	29.34±2.80	21.42±3.73	22.82±4.38	(0.002)	(<0.001)		
t	0.622	-1.928	-3.476				
P	0.535	0.057	0.001				
Total							

Intervention	102.83±11.25	93.05±11.15	102.77±8.66	19.425	39.240	4.696 (0.010)	0.047
Control	102.00±12.98	84.97±10.03	93.09±12.22	(<0.001)	(<0.001)		
<i>t</i>	-0.333	-3.754	-4.525				
<i>P</i>	0.740	<0.001	<0.001				

t=Independent sample test.

*=The effect size of the interact (group × time) effect.