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The impact of Therapeutic Exercises on the Quality of Life and Shoulder Range of Motion in Women after a Mastectomy, a RCT.

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Protocol: The Institution Review Board (IRB) of the university and the medical center granted approval for the study. Seventy-six women were approached while waiting for their surgery after approval form their surgeon. Women who showed interest in participating signed a consent form and were then randomly assigned to one of two groups by flipping a coin. Thirty women ended up in the intervention group and 30 in the control group. Figure one details the protocol of the study. The intervention group received pre-surgery education and training on therapeutic exercises in addition to the routine hospital care. The control group, which had 30 patients, received the routine hospital care that did not include any exercise training or education. Routine hospital care included explanation by the surgeon on the surgical procedure with follow up at two and four weeks after discharge. The educational material was developed by the principal investigator (PI) and included a power point and a booklet with instructions on the exercises as well as information about the surgery and what to expect after the surgery. The educational material was based on previous research and adopted to our population after consultation with a panel of experts including two nurses and three physicians. Eligible women were approached while waiting for their appointment with their surgeon. If they showed interest in participating they signed a consent form. The PI explained the study and what is involved in participating including the weekly phone calls for women in the intervention group. Participants were told that they will visited at home by the PI to assess their ROM and to fill out a questionnaire.

The intervention: The intervention consisted of three phases. Phase 1 took place the day prior to surgery at which time the intervention and control, groups completed the QoL-BC survey and shoulder ROM was measured using the goniometer. Phase 2 consisted of one to one education with the intervention group prior to surgery. Education consisted of a power point presentation regarding the therapeutic exercises, information about the surgery and a booklet with pictures of the exercises to take home. In this phase demonstration of the exercises by the researcher with a return demonstration by the patient was done to ensure proper techniques. The researcher called the patients at home every week to ensure that the women were continuing the exercises. Phase 3 was conducted for both groups in the patient's homes and entailed reassessment of shoulder ROM and completing the QoL-BC at the second and fourth week after discharge. All patients completed the study. The exercises included deep breathing as well as shoulder exercises such as extension of the triceps, biceps curl, paddling in sitting position, fluttering with both arms, hands behind neck, forward wall crawls, and side wall crawls.

Patients were instructed to preform 10 repetitions of each exercise during hospitalization, with further guidance at the outpatient follow-up appointment. Shoulder flexion was limited to 90° of active assisted

ROM for the first few days post-surgery and until the drains were removed, then gradually increased after the third postoperative day. Patients were instructed to keep performing the exercises after discharge.

Results

Patient characteristics

There were no differences between groups at baseline. The majority of the patients in both groups were between 35 and 42 years of age, roughly 70% were married, and the majority of patients had a high school or higher education.

Shoulder range of motion scores: While the shoulder ROM scores were not significantly different between groups prior to surgery, there were significant differences at the second and fourth weeks after surgery (Table 2). Flexion at two weeks for the intervention group was 133.80 ± 6.79 and for the control group it was 131.17 ± 2.20, $p = 0.001$, at four weeks it was 167.97 ± 4.09 for the intervention group and 159.92 ± 1.73 for the control group, $p < 0.001$. Extension significantly improved for the study group at two weeks with a mean of 42.77 ± 2.30 versus 38.73 ± 1.46, $p < 0.001$ and at four weeks 53.07 ± 2.12 versus 49.03 ± 1.25, $p < 0.001$. Additionally, abduction demonstrated a significant difference between the study and control groups at two weeks 143.50 ± 4.42 versus 138.57 ± 1.78, $p < 0.001$ and at four weeks 167.03 ± 4.61 versus 159.40 ± 1.69, $p < 0.001$.

Differences between groups on each of the QoL-BC 4 subscales: There were no significant differences between groups at baseline on the QoL survey with both groups having low QoL scores. However, there were significant differences between groups at two and four weeks after surgery on the four subscales (Table 3). Physical well-being was significantly improved with the study group experiencing higher level of physical well-being than the control group; at two weeks, 58.37±6.16 versus 50.23±7.78, $p = 0.001$, and at four weeks 66.67 ± 6.19 versus 54.97 ± 9.55, $p <0.001$. For Psychological well-being there was significant difference between the two groups at two weeks, the study group mean 142.33 ± 15.48 and the control group 122.93±7.34, $p <0.001$, and at four weeks, 169.50 ±26.43 and 145.67 ± 12.44, $p <0.001$. Social well-being at two weeks was significantly higher for the study group 43.57 ± 7.045 versus 29.30 ± 8.30 for the control group, $p <0.001$; and at four weeks 54.33 ± 8.73 for the study group versus 42.33 ± 5.08 for the control group, $p <0.001$. Spiritual well-being was significantly improved at two weeks, with a mean for the study group of 51.07 ± 4.37 versus 44.90 ± 6.05, $p <0.001$; and at four weeks 56.33 ± 3.96 versus 48.93 ± 2.61, $p <0.001$.