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Effectiveness of Care Bundle Approach on Cardio Respiratory Fitness and Physical Fitness of Patients with Chemotherapy induced Peripheral Neuropathy among Patients receiving Cancer Chemotherapy

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Abstract: ***Chemotherapy induced peripheral neuropathy was diagnosed in approximately 71% of individuals with Cancer (WHO, 2010). A recent meta-analysis study revealed that the total prevalence rate of chemotherapy induced peripheral neuropathy among 4,179 participants receiving neurotoxic chemotherapy was 48% and increased to 68.1%, within the first month of completion of chemotherapy (Seretny, 2014). Aim: To examine the effects of a 12 week aerobic and strength training on chemotherapy induced peripheral neuropathy. Hypothesis: There is a significant improvement in VO_2 max and flexibility test among participants receiving chemotherapy after receiving care bundle approach in experimental group than control group. A true experimental –repeated measure design was used for this study. 120 participants receiving cancer chemotherapy were selected in this study.Simple random sampling technique was used to select 120 participants and were allotted to 60 in either control or experimental group by random table. Result: V_{O2}max: The experimental posttest 3 VO_2 max score was not statistically significant from the control posttest 3 score. (p = 0.469) in males. Flexibility test: The pretest and post test score showed no statistical significant difference in control group. (p=0.151) for males but showed a significant difference (p=0.008) for females.The findings in the present study indicated that combined training did not produce the expected strength and aerobic power benefits to cancer participants***

Keywords: Care bundle approach, V_{O2}Max, Flexibility test, Chemotherapy Induced Peripheral neuropathy

1. Chemotherapy-induced peripheral neuropathy

Chemotherapy induced peripheral neuropathy is generally classified as a series of neuromuscular symptoms, both sensory and motor in nature, that results from nerve damage caused by the neurotoxic effects of chemotherapy drugs for the treatment of cancer (Park et al, 2013). It is estimated that at least 30% of participants who receive paclitaxel, docetaxel, bortezomib, thalidomide, or oxaliplatin will develop a degree of chemotherapy-induced peripheral neuropathy (Airley, 2009). The impact of chemotherapy induced peripheral neuropathy varies and affects participants differently. Chemotherapy induced peripheral neuropathy symptoms may negatively alter a participants's ability to perform routine activities, functions, and behaviors. (Speck et al, 2012).

The purpose of this study was to examine the effects of a 12 week aerobic and strength training intervention on the symptoms of chemotherapy induced peripheral neuropathy.These results suggested that aerobic and strength training contributed to a reduction in chemotherapy induced peripheral neuropathy and also positive influence on cardiovascular fitness (VO_2 max). (Sommerville et al, 2015). The hypoalgesic effect was attributed to a phenomen called exercise induced hypoalgesia (EIH), which has been observed in healthy subjects following acute bouts of exercise. With EIH, pain threshold and tolerance level increases following exercise intensities of 60-75% VO_2max (Levy et al 2008).

A meta analysis study was done to examine the outcomes of a structured, supervised exercise program in reducing symptoms of chemotherapy induced peripheral neuropathy and improving physical fitness and overall QOL. A comprehensive fitness evaluation was administered both before and after the 12-week supervised exercise program. Results revealed that 12-weeks of supervised exercise training helped attenuate symptoms of chemotherapy induced peripheral neuropathy. Overall QOL was significantly improved, and troublesome symptoms related to chemotherapy induced peripheral neuropathy significantly decreased. Thus exercise is an effective tool in managing symptoms of chemotherapy induced peripheral neuropathy. Subjects significantly improved in VO_2 max and muscular endurance following 12-weeks of supervised exercise training. (Wonders, 2014)

2. Materials and Methods

Participants: A true experimental –repeated measure design was used for this study. one hundred and twenty cancer participants receiving cancer chemotherapy were selected in this study. Permission was obtained from the authorities of the hospital to carry out study. The participants were randomly assigned to control and experimental group .This study was approved by the institutional Human Ethics Committee of Saveetha University. (2017/IEC/SU; Dated 11 August 2017) Participants receiving chemotherapeutic agents which cause neurotoxic effects like taxanes (paclitaxel, docetaxel), the vinca alkaloids (vinorelbine), the platinum analogues (cisplatin, carboplatin), and the antimetabolites (capecitabine) with grade I,II,III were selected.Participants who are not able to perform basic activities of daily living such as walking and Participants

with co-morbid diseases that might hamper physical exercise (e.g. heart failure, chronic obstructive pulmonary disease (COPD), orthopaedic conditions and neurological disorders like Cerebro vascular accident and diabetes mellitus were excluded.

Experimental Phase: A total of 120 participants completed the 12-week home-based exercise program. On the day of admission, the demographic profiles of all participants were obtained by the structural questionnaire. Screening procedures such as echo, ECG, blood investigations, according to the hospital protocol were done Prior to the administration of chemotherapy, and also cardio respiratory, physical fitness was assessed by VO2 max and flexibility test, level of Chemotherapy induced peripheral neuropathy by NCI CTCAEV scale, QOL by European Organization For Research And Treatment Of Cancer scale and knowledge regarding home safety measures by structured questionnaire ie pretest 1st week of first month. During the administration of chemotherapy, the emerging signs of chemotherapy induced peripheral neuropathy wereobserved .the procedure of the intervention of each group was explained. For the control group the qol, chemotherapy induced peripheral neuropathy was assessed without the intervention. After providing the respective intervention for three days ie alternative days the post test was carried out at the end of 3rd week of first month, ,7th week of second month and 11th week of 3rd month. The participants expressed that they felt relaxed after the intervention in experimental group.

Statistics: The V_{O2}max and sit and reach parameters in pre test and post test in control and experimental groups were analyzed by one way analysis of variance .Paired t-test was used to compare the pretest and post test of control and experimental groups.. A probability of 0.05 or less was taken as statistically significant. The analysis and plotting of graphs were carried out using Sigma Plot 13.(Systat Software Inc.,USA)

3. Results

VO_2 max: Figure 8.1 illustrates VO_2 max in control and experimental groups for males. The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of control group is 33.2, 33.8, 34.6, and 36.6 respectively for males. There was a significant difference in control group. ($p< 0.001$) which indicated that participants are aerobically fit. The mean ± SE of pretest, posttest 1, posttest 2, posttest 3 of experimental group is 33.0, 35.8, 37.2, 37.8 respectively. There was a significant difference in experimental group. ($p< 0.001$) which indicated that the participants are fit to do exercises. Figure 8.1 also illustrates the control and experimental pretest scores by comparison using the unpaired t test and t value is reported. There was no statistically significant difference among the groups in pretest score.($p = 0.905$).The control posttest1, VO_2 max score was not statistically significant different from the experimental posttest 1 score.($p = 0.257$), similarly the control posttest 2, VO_2 max score was not statistically significant different from the experimental posttest 2 score.($p = 0.152$), The experimental posttest 3 VO_2 max score was not statistically significant from the control posttest 3 score.($p = 0.469$).

Figure 8.2 illustrates VO_2 max in control, control and experimental group. The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of control group is 23.6, 24.6, 25.9, 27.1 respectively for females. There was a significant difference in control group ($p < 0.001$) which indicated that participants are aerobically fit. The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of experimental group is 27.6, 29.3, 30.6, 32.1 respectively. There was a significant difference in experimental group ($p <0 .001$) which indicated that the participants are fit to do exercises. Figure 8.2 also illustrates the control and experimental pretest scores for females by comparison using the unpaired t test and t value is reported. There was a statistically significant difference among the groups in pretest score.($p=0.005$).The control posttest1, VO_2 max score was significantly different from the experimental posttest 1 score.($p = 0.007$),similarly the control posttest 2 ,VO_2 max score was also significantly different from the experimental posttest 2 score.($p = 0.005$), The experimental posttest 3, VO_2 max score was also statistically significant from the control posttest 3 score.($p = 0.002$).

Figure 8.3 illustrates sit and reach score in control and experimental group for males. The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of control group is 11.0, 11.6, 12.0, and 11.6 respectively for males. There was not a significant difference in control group. ($p = 0.151$) .The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of Experimental group is 13.9, 13.0, 13.0, and 13.4 respectively. There was not a significant difference in experimental group. ($p = 0.813$) which indicated that the participants are fit to do exercises. Fig 8.3 also illustrates the control and experimental pretest scores of males by comparison using the unpaired t test and t value is reported. There was a statistically difference among the groups in pretest score. ($p = 0.003$). The control posttest1, sit and reach score was not significantly different from the experimental posttest 1 score. ($p = 0.196$), similarly the control posttest 2, sit and reach score was not statistically significantly different from the experimental posttest 2 score. ($p = 1.310$), The experimental posttest 3, sit and reach score was not statistically significant from the control posttest 3 score.($p = 0.081$).

Figures 8.4 illustrate sit and reach score in control and experimental group for females. The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of control group is 14.6, 14.8, 15.7 and 15.6 respectively for females. There was not a significant difference in control group. ($p = 0.008$) The mean ± SE of pretest and posttest 1, posttest 2, posttest 3 of experimental group is 17.2, 17.6, 17.2, and 17.8 respectively. There was not a significant difference in experimental group ($p = 0.730$).

The fig 8.4 also illustrates the control and experimental pretest scores by comparison using the unpaired t test and t value is reported. There was a statistically difference among the groups in pretest score.($p < 0.001$)The control posttest1, sit and reach score was significantly different from the experimental posttest 1 score.($p < 0.001$),similarly the control posttest 2 ,sit and reach score was also statistically significantly different from the experimental posttest 2 score.($p = 0.015$), The experimental posttest 3, sit and reach

score was also statistically significant from the control posttest 3 score.(p = 0.002).

4. Discussion

Cancer participants frequently experience loss of physical capacity and well-being when treated for their disease. Strength training combined with aerobic exercise training is believed to be an important intervention for cancer participants who undergo radiotherapy and chemotherapy. Prescribed resistance training at an intensity of 50 to 60% of 1RM is well accepted by participants who report no muscle discomfort when performing physical activities. VO_2 max is the maximum rate of oxygen consumption measured during incremental exercise, which denotes V - volume, O_2 - oxygen, max – maximum and also it reflects the cardio-respiratory fitness. Flexibility was measured via modified sit and reach (Lafayette Flexibility Tester). Standards have been published by the American College of Sports Medicine (Schmitz et al, 2014). A detailed analysis was done in the present study in estimating the VO_2 max. The pretest VO_2 max score was statistically significant in males and females in both the groups, which indicated that the participants in both the groups fulfilled pre fitness evaluation criteria and they can perform the aerobic exercises and physical exercises. In a review of >18 000 participants with CHD in 9 studies stated that the Cardio Rehabilitation Exercise Training on Cardio Respiratory Fitness, where CRF was assessed by several methods (estimated METs, peak VO_2, walking distance, and 6-minute walk test), there was 15% improvement in peak VO_2 and 35% increase in estimated METs and substantial reductions in mortality after CRET, (Franklin et al 2013) . The above findings are similar to the present study, that CRF was assessed by VO_2 max.

A detailed analysis in the present study showed that the experimental group's posttest1, posttest 2, posttest 3 score were not significantly different from the control group in males, but statistically significant was noted between the experimental group posttest1, posttest2 and posttest 3 with the control group pretest among female participants .This gender difference will not influence the study results as maximal aerobic capacity and lung function will not change by either training and non training. The above finding was consistent with the study on effects of a short-term exercise training program on aerobic fitness, fatigue, health perception and activity level of subjects with multiple sclerosis stated that muscle Strength training group demonstrated a significant rightward placement of the aerobic threshold (AT) (VO_2+13%; work rate [WR])+11%), an improvement of health perception (vitality+46%; social interaction+36%), an increase of activity level (+17%) and a tendency to less fatigue. No changes were observed for the control groups. Maximal aerobic capacity and lung function were not changed by either training or non-training in the groups (Mossert et al, 2002).

The experimental posttest 3 VO_2 max score was not statistically significant from the control posttest 3 score. (p = 0.469) in males. The experimental posttest 3, VO_2 max score was also statistically significant from the control posttest 3 score. (p = 0.002). With regards to the aerobic power, the finding is in disagreement with the study by (Vincent et al, 2013) who found an improvement of VO_2 max of 2.21 mL.kg-1·min-1with aerobic exercise at 50 to 60% of HR max for 12 wks in women with breast cancer treated with chemotherapy, but evidences obtained from epidemiological studies indicated that there were no significant differences in HR-average, HR-peak, RPE, average speed, and VO_2 max. (Volaklis et al, 2013). The present study also revealed the same finding.

The purpose of meta analysis study was to examine the effects of a 12 week aerobic and strength training intervention on the symptoms of chemotherapy induced peripheral neuropathy. These results suggested that aerobic and strength training contributed to a reduction in chemotherapy induced peripheral neuropathy and also positive influence on cardiovascular fitness (VO_2 max). (Sommerville et al, 2015).The Effects of Combined Training on Strength and Aerobic Power in Patients with Cancer indicated that there was a significant increase ($P<0.05$) in strength. There was no statistically significant change in VO_2 max. Therefore, while the combined training resulted in an improvement in strength, it did not improve the cancer patients' aerobic capacity.(Bruno et al 2015). The present study also revealed the same finding.

The findings in the present study indicated that combined training did not produce the aerobic power benefits to cancer participants who had undergone radiotherapy and chemotherapy. However, aside from the non-significant change in VO_2 max in particular, the increase in primarily upper limb muscle strength should lead help minimize the hemodynamic response to daily activities. This factor alone should be viewed as a positive outcome when it comes to increasing the participants' longevity and quality of life by decreasing fatigue, muscle wasting, and energy loss in cancer survivors. Hence the hypothesis was accepted.

The study on effects of an individualized prescriptive exercise intervention, administered in-hospital during the treatment-recovery of leukemia participants, on fitness parameters and quality of life demonstrated that an exercise program, consisting of aerobic training, resistance training, and flexibility training, participants to maintain physiology and quality of life while undergoing chemotherapy. (Bradley et al, 2006).

In the present study flexibility was evaluated using the modified sit and reach method among participants receiving cancer chemotherapy. The pretest and post test score showed no statistical significant difference in control group. (p=0.151) for males but showed a significant difference (p=0.008) for females. The pretest and posttest 1, posttest 2, posttest 3 of experimental group showed no statistical significant difference in experimental group for males and also in experimental group for females. Similarly in the present study the flexibility test was assessed by modified sit and reach method as said in above findings.

The detailed analysis was done in present study, the experimental posttest 3, sit and reach score was not statistically significant from the control posttest 3 score for males. But there was a statistically difference among the

group's pretest score (p = 0.003) among male participants. The experimental posttest 3, sit and reach score was also statistically significant from the control posttest 3 score (p=0.002) for females, also noteworthy there was a statistically difference among the groups in pretest score among female participants.

The present study findings were similar to the study conducted by (Schmitz et al 2014) that in the clinical setting flexibility is often assessed using the sit and reach test. It is recommended that cancer participants should participate in active stretching routines as part of a pre-exercise warm up. Surgical complications and fibrosis from radiotherapy should be considered for all resistance exercises. Finally, strength training workouts should incorporate agility work (rapid foot movements, single leg balance exercises foot work agility exercises) following the strength training component.

The findings in the present study indicated that combined training did not produce the expected strength and aerobic power benefits to cancer participants who had undergone radiotherapy and chemotherapy. However, aside from the non-significant change in VO_2 max in particular, the increase in primarily upper limb muscle strength alone should be viewed as a positive outcome when it comes to increasing the participants' longevity and quality of life by decreasing fatigue, muscle wasting, and energy loss in cancer survivors. Hence the hypothesis was accepted.

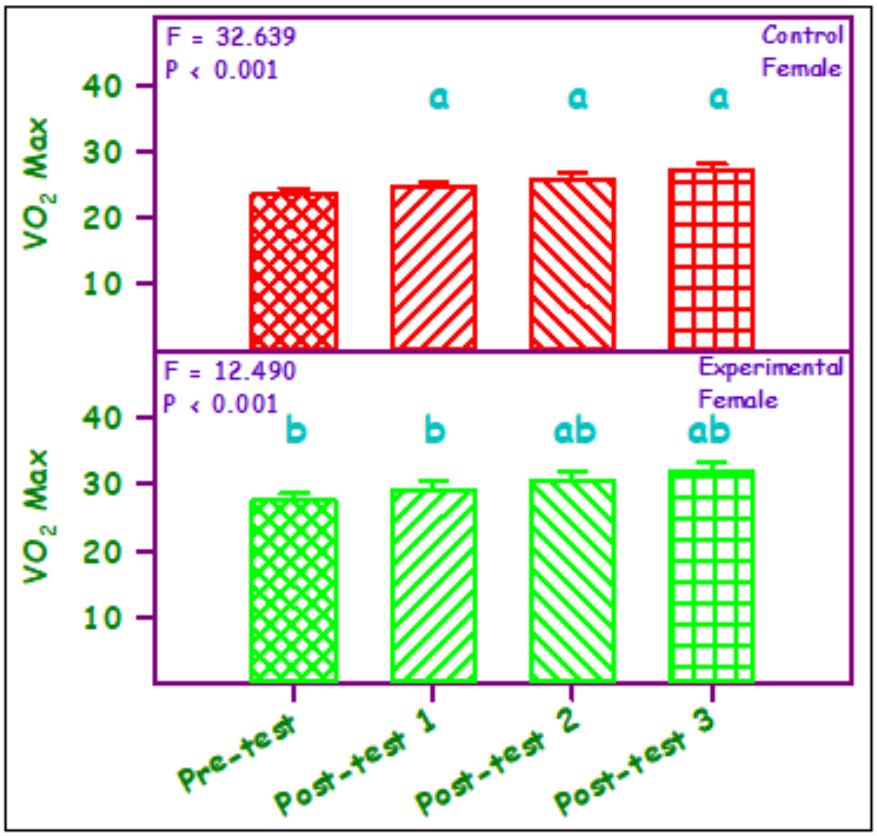

Figure 8.1: Effectiveness of care bundle approach on VO_2 max ml (kg.min) of control and experimental groups, female.
Values are mean ± SE (n = 60 each).
The F and P values are by one way RM ANOVA of the respective groups.
The control and experimental groups are compared by student 't' test.
For the Pre-test the 't' and 'P' values are 2.928 and 0.005 respectively; For the Post-test 1 the 't' and 'P' values are 2.805 and 0.007 respectively; For the Post-test 2 the 't' and 'P' values are 2.950 and 0.005 respectively; For the Post-test 3 the 't' and 'P' values are 3.198 and 0.002 respectively.
a – Significantly different from the respective Pre-test.
b – Significantly different from the respective control group.

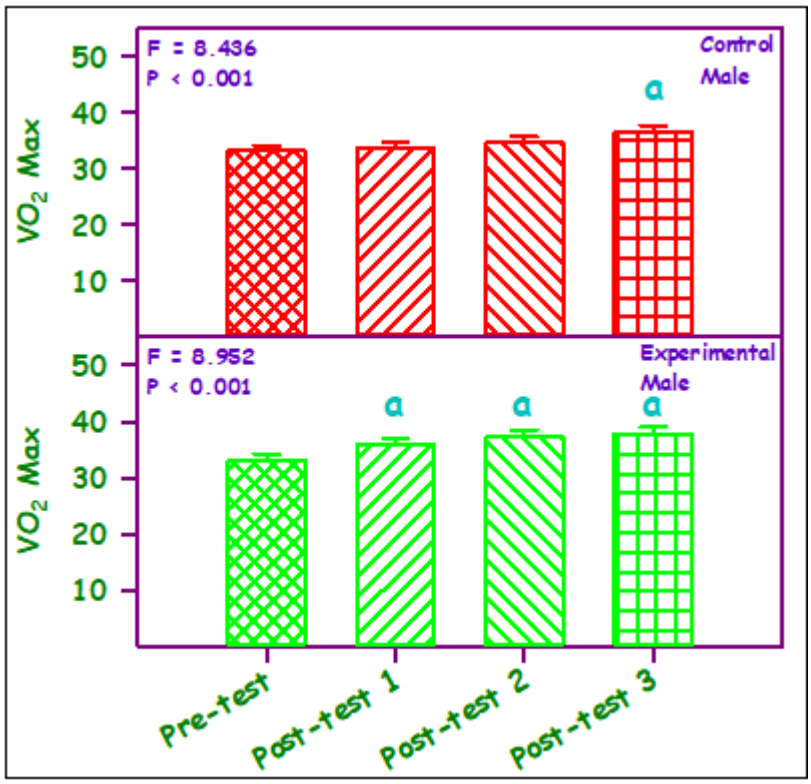

Figure 8.2: Effectiveness of care bundle approach on VO_2 max ml (kg.min) of control and experimental groups, male.
Values are mean ± SE (n = 60 each).
The F and P values are by one way RM ANOVA of the respective groups.
The control and experimental groups are compared by student 't' test.
For the Pre-test the 't' and 'P' values are 0.119 and 0.905 respectively; For the Post-test 1 the 't' and 'P' values are 1.146 and 0.257 respectively; For the Post-test 2 the 't' and 'P' values are 1.452 and 0.152 respectively; For the Post-test 3 the 't' and 'P' values are 0.729 and 0.469 respectively.
a – Significantly different from the respective Pre-test.
b – Significantly different from the respective control group.

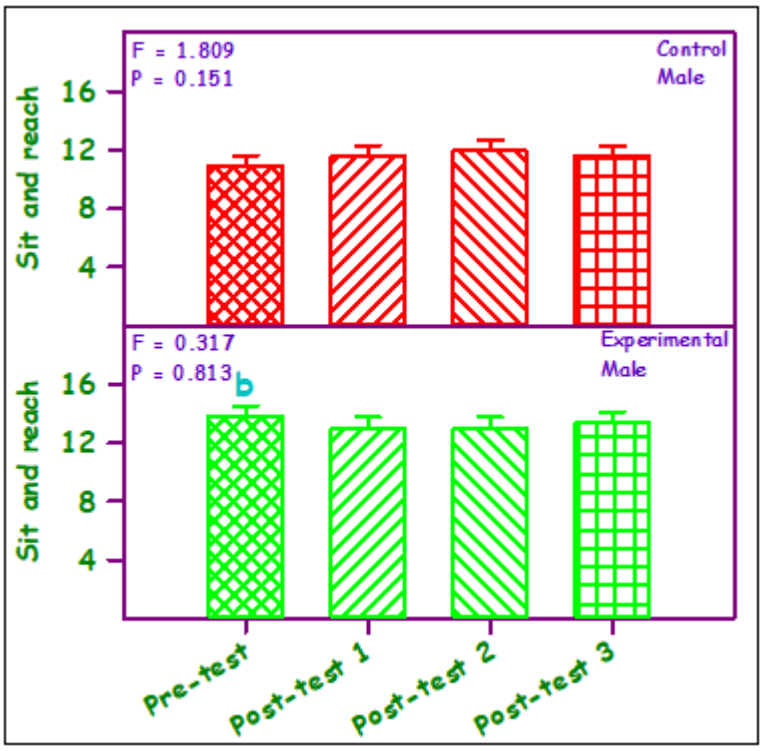

Figure 8.3: Effectiveness of care bundle approach on sit and reach (cm) of control and experimental groups, male.
Values are mean ± SE (n = 60 each).
The F and P values are by one way RM ANOVA of the respective groups.

The control and experimental groups are compared by student 't' test.
For the Pre-test the 't' and 'P' values are 3.103 and 0.003 respectively; For the Post-test 1 the 't' and 'P' values are 1.308 and 0.196 respectively; For the Post-test 2 the 't' and 'P' values are 1.024 and 1.310 respectively; For the Post-test 3 the 't' and 'P' values are 1.774 and 0.081s respectively.
a – Significantly different from the respective Pre-test.
b – Significantly different from the respective control group.

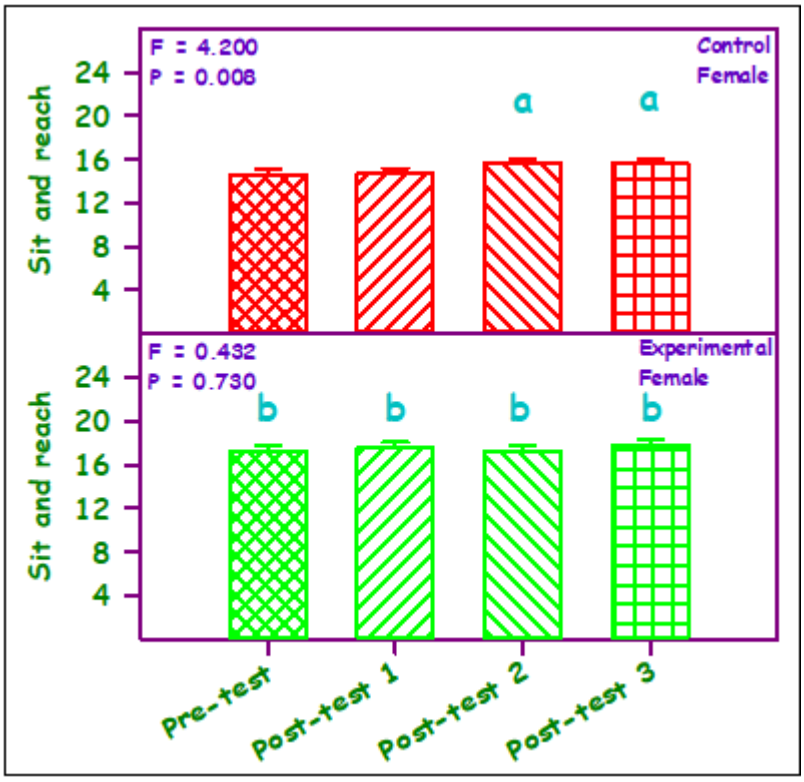

Figure 8.4: Effectiveness of care bundle approach on sit and reach (cm) of control and experimental groups, female.
Values are mean ± SE (n = 60 each).
The F and P values are by one way RM ANOVA of the respective groups.
The control and experimental groups are compared by student't' test.
For the Pre-test the 't' and 'P' values are 3.669 and 0.001 respectively; For the Post-test 1 the 't' and 'P' values are 4.196 and 0.001 respectively; For the Post-test 2 the 't' and 'P' values are 2.501 and 0.015 respectively; For the Post-test 3 the 't' and 'P' values are 3.230 and 0.002 respectively.
a – Significantly different from the respective Pre-test.
b – Significantly different from the respective control group.

5. Conclusion

The study discussed the effectiveness of care bundle approach on cardio respiratory fitness and flexibility. A detailed analysis was done in the present study in estimating the VO_2 max. The pretest VO_2 max score was statistically significant in males and females in both the groups, which indicated that the participants in both the groups fulfilled pre fitness evaluation criteria and they can perform the aerobic exercises and physical exercises. The experimental posttest 3 VO_2 max score was not statistically significant from the control posttest 3 score.(p=0.469) for males but the experimental posttest 3, VO_2 max score was also statistically significant from the control posttest 3 score.(p=0.002).for females . The experimental posttest 3, sit and reach score was not statistically significant from the control posttest 3 score.(p=0.081) for males ,but the experimental posttest 3, sit and reach score was also statistically significant from the control posttest 3 score.(p=0.002) for females. This gender difference will not influence the study results as maximal aerobic capacity and lung function will not change by either training or non training. However, aside from the non-significant change in VO_2 max in particular, the increase in primarily upper limb muscle strength should alone should be viewed as a positive outcome when it comes to increasing the participants' longevity and quality of life by decreasing fatigue, muscle wasting, and energy loss in cancer survivors.

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