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Prevention of shoulder Problems Trial (PROSPER): exercise to prevent shoulder problems in patients undergoing breast cancer treatment

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Purpose: Shoulder pain and dysfunction are common in women treated for breast cancer. There is some evidence indicating that exercise is safe and may help to prevent shoulder problems. However, previous trials are of low methodological quality and therefore further research is needed to investigate the clinical effectiveness of exercises for women at high risk of developing shoulder problems.

Methods: The PROSPER trial was a pragmatic, multicentre, randomised controlled trial comparing a structured exercise programme with usual care (information leaflet). Women at high-risk (planned axillary node clearance, planned radiotherapy to the axilla and/or supraclavicular area, existing shoulder problems and BMI > 30) of postoperative shoulder problem, ≥ 18 years old and with a confirmed invasive or non-invasive primary breast cancer scheduled for surgery were included. We aimed to randomise 350 women from ten centres across England, with postoperative follow-up at six weeks, six and 12 months post-randomisation. The PROSPER exercise intervention was developed from the available evidence and input from clinical experts and patients. The exercise intervention consisted of three components (exercise, behavioural strategies and physical activity) with a minimum of three face-to-face appointments with a physiotherapist, starting from seven to ten days postoperatively, in addition to another three optional appointments (face-to-face or over the phone). The control group received best practice usual care in the form of written leaflets containing information on exercises, recovery after surgery and treatments for breast cancer. The primary outcome was the Disabilities of the Arm, Shoulder, and Hand (DASH) score at 12 months. Secondary outcomes included DASH subscales, postoperative pain, complications and health-related quality of life. **Results:** We randomised 392 women, from 17 sites, with 196 randomised to each treatment arm. Mean age was 58.1 years and mean BMI was 30.2. Groups were similar for socioeconomic characteristics at baseline. Of 191 women allocated to exercise intervention, 142/191 (74%) received three or more physiotherapy sessions, 38/191 (20%) received up to three sessions and 11/191

(6%) had no treatment. Women randomised to exercise had better arm, shoulder and hand function compared those receiving usual care at 12 months (mean DASH score 16.4 versus 23.9 respectively; adjusted mean difference (MD) -7.01; 95% CI -12.7 to -1.29; $p = 0.017$). This finding was statistically and clinically significant. DASH subscales for activity limitations, participation restriction and impairment improved over time in women receiving exercise compared to usual care. There were no differences in rates of complications between treatment arms.

Conclusion(s): The PROSPER trial found that early structured postoperative exercise was beneficial on outcomes of arm, hand and shoulder function at 12 months for women undergoing breast cancer treatment and who were at high risk of shoulder problems. Early postoperative exercise was safe and did not increase risk of postoperative adverse events.

Implications: The findings of this large multicentre UK trial provide evidence that a structured physiotherapy-led programme can support women on the pathway to recovery from breast cancer treatment. Women having surgery for breast cancer should be offered this clinically effective exercise programme consisting of three to six appointments with a physiotherapist.