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## **Effect of a 12-month multidisciplinary rehabilitation intervention on fatigue, work, and health-related quality of life among breast cancer survivors with chronic fatigue –A protocol abstract of the randomized ReCharge Trial.**

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**Background:** Persistent fatigue is a complex and highly distressing late effect after cancer, reported by more than one-third of women treated for breast cancer (BC). Randomized controlled trials (RCTs) investigating the effect of multidisciplinary interventions among cancer survivors with persistent fatigue are lacking. In a recently completed RCT in fatigued lymphoma survivors (the REFUEL-trial), we found that a 12-week multidisciplinary intervention including patient education, exercise, cognitive behavioral therapy (CBT) and nutrition counseling significantly improved level of fatigue, however, this effect did not sustain at 6-month follow-up. We believe that an intervention with longer duration focusing on behavioral change techniques might lead to more sustainable effects. We therefore aim to investigate the effects of a 12-month multidisciplinary rehabilitation program on fatigue BC survivors (BCSs) with persistent fatigue.

**Patients and methods:** A total of 200 BCSs with persistent fatigue, aged  $\leq 70$  years, diagnosed with stage II-III BC in 2019-2024 and  $> 2$  years from curative treatment at Oslo University Hospital or St. Olavs Hospital will be randomized to standard care (n=100) or a 12-month multidisciplinary intervention (n=100). The intervention consists of one digital patient education session, a personalized aerobic exercise program, seven digital CBT-based group sessions and five group based nutritional counseling sessions. The primary outcome is total fatigue assessed by Chalder Fatigue Questionnaire (FQ). Secondary outcomes include other BC related late effects, work, health-related quality of life, cost-utility and cardiorespiratory fitness. Both groups will undergo assessments at baseline, and at 12-, 24- and 36-month post-randomization.

**Expected results and clinical impact:** We hypothesize that the 12-month multidisciplinary intervention will reduce fatigue in BCSs with persistent fatigue, as well as improve other health and functional outcomes. We expect that the results will be valuable for developing and improving healthcare services for cancer survivors with persistent fatigue.

### **Keywords**

persistent fatigue, breast cancer survivors, exercise, cognitive behavioral therapy

### **Conflict of Interest & Ethical Approval**

yes

### **Abstract submitters declaration**

yes

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