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## Effectiveness of a supervised multimodal exercise intervention on persistent Cancer therapy Induced peripheral neuropathy: protocol of the SICILY multicenter randomized controlled trial

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**Background** Exercise has been suggested as a promising non-pharmaceutical intervention for cancer treatment induced peripheral neuropathy (CIPN). However, current evidence is limited to only a few, mostly small, studies with heterogeneous interventions and methodological limitations, and only a limited number of studies focus on chronic CIPN. In addition, data on the cost-effectiveness of exercise programs for CIPN are lacking, limiting the implementation of multimodal exercise programs in clinical practice.

**Objective** To investigate the (cost-)effectiveness of a supervised multimodal exercise program on CIPN burden in patients with persistent CIPN after neurotoxic cancer treatment in a full-scale randomized trial.

**Methods** This multicenter RCT will include 136 patients who completed curative neurotoxic systemic cancer treatment  $\geq 6$  months ago and experience CIPN-interference in daily life. Patients will be randomized (1:1) to an intervention group receiving a novel 12-week supervised multimodal CIPN-specific exercise program, or a wait-list control group receiving the program after a 12-week waiting period. The multimodal program consists of CIPN-specific exercises combining balance, aerobic and resistance exercises twice per week, supervised by a physiotherapist; goal-directed occupational therapy; home-based balance training supplemented with daily hand/feet exercises; and the recommendation to walk  $\geq 30$  minutes on days without scheduled exercise sessions. The primary outcome is patient-reported CIPN burden (EORTC QLQ-CIPN20). Secondary outcomes include CIPN symptoms, disability, mood, fatigue, fear of falling, fear of movement, patient-specific goals, quality of life, physical functioning, physical activity, cost-effectiveness (from a societal perspective) and patient satisfaction. Data will be collected at baseline, 12 weeks (i.e., primary endpoint), and 24 weeks.

**Results** Recruiting since September 2025.

**Conclusion** This trial will provide evidence on the (cost-)effectiveness of a CIPN-specific supervised multimodal exercise program for patients with persistent CIPN.

### Keywords

Peripheral neuropathy, Exercise, Cancer, Quality of life

### Conflict of Interest & Ethical Approval

yes

### Abstract submitters declaration

yes

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