

# RANDOMIZED CONTROLLED TRIAL ON THE EFFECTS OF A SIX-MONTH INTRA-DIALYTIC PHYSICAL ACTIVITY PROGRAM AND ADEQUATE NUTRITIONAL SUPPORT ON PROTEIN-ENERGY WASTING, PHYSICAL FUNCTIONING AND QUALITY OF LIFE IN CHRONIC HEMODIALYSIS PATIENTS

## ACTINUT TRIAL

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### OBJECTIVES

Protein-energy wasting (PEW) is common in hemodialysis patients and is a powerful predictor of adverse outcomes.

Objectives:

- To analyze the impact of an intra-dialytic exercise program combined with nutritional support following current guidelines on nutritional and anthropometric parameters of PEW and its potential to reverse PEW (primary outcome).
- To test the effects of intra-dialytic exercise on functional performances (walking, postural control, and muscular strength), body composition and health-related quality of life in HD patients.

### METHODS

Screening 210 hemodialysis patients of 2 dialysis units Nantes France
21 patients meeting inclusion/exclusion criteria
Nutritional Counseling , Nutritional prescriptions following EBPG Guidelines [2]
Randomisation

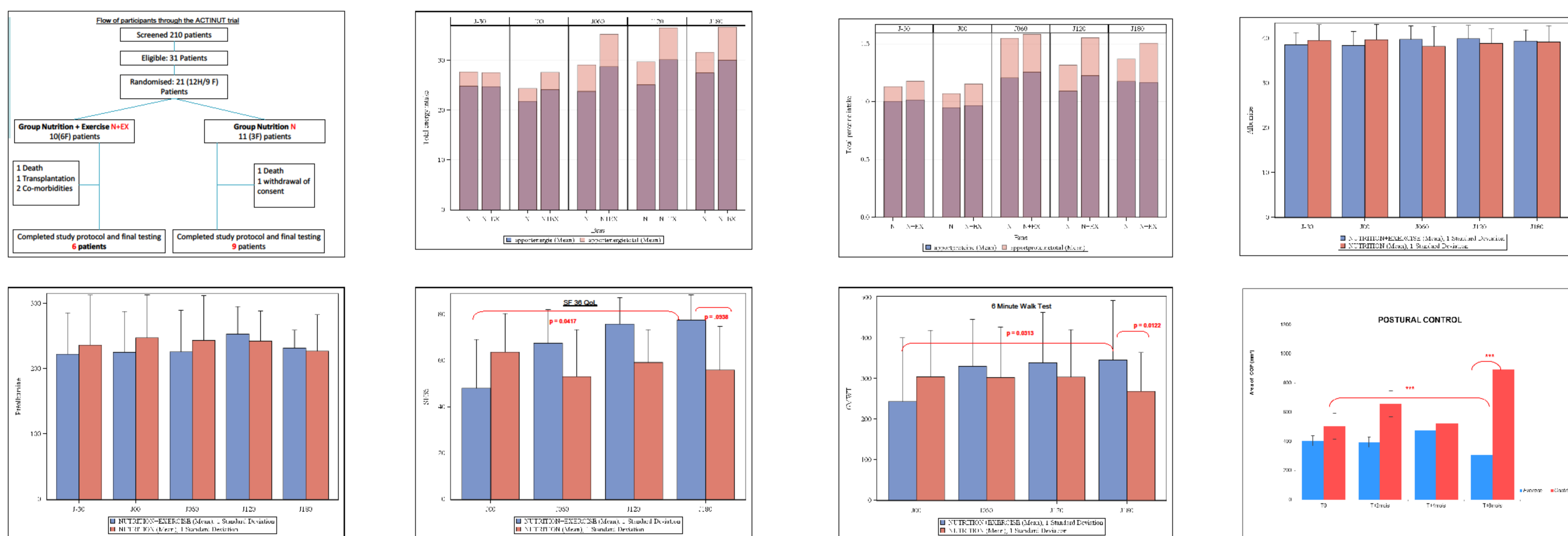
**Nutrition + Intra-dialytic Physical Activity Group (N+EX)**  
**n=10**  
 71.0 years [range 52-89]

**Intervention:**

- Progressive sub-maximal cycling exercise
- 30 minutes during the first half of the dialysis session
- moderate exercise intensity (3/10 on Borg Perceived Exertion scale)
- cycling in supine position
- monitoring of BP and HR

**Nutrition only (control) Group (N)**  
**n=11**  
 69.9 years [range 51-93]

### RESULTS



- Dialysis vintage (years) : 8.6 [0.8-23.8] in N+EX 11.3 [1.3-25.7] in N respectively
- Prevalence of Diabetes: 15 %
- No serious adverse effects of exercise
- **No significant difference in primary outcome (remission of PEW)** between the two groups. Two of 6 patients in N+EX and 4 of 9 patients in N had no longer all criteria of PEW, but only one patient in N had normal albumin, prealbumin and LTI at the end of the study.
- No significant changes were observed between groups over time in measures of serum-albumin, -prealbumin, C-reactive protein, body mass index, lean- and fat-tissue index or quadriceps force
- **There were statistically significant and clinical meaningful increases in self- assessed quality of life (SF36 mean score +61%) and in the Six Minute Walk Test (+ 42 %) in N+Ex while these parameters declined in N.**
- **The postural control** (assessed by the quantity of postural sway) worsened over time in N and **remained stable in N+EX.**

### CONCLUSIONS

The results of this study, made in a limited number of patients, could not show an additive effect of combining intra-dialytic exercise and nutritional support in the treatment of PEW. However this strategy seems safe, well accepted and increases significantly physical performances and quality of life in this frail population of dialysis patients. Further larger-scale studies are necessary in order to investigate long term clinical outcomes.

### REFERENCES:

[1] Fouque D, Kalantar-Zadeh K, Kopple J, Cano N, Chauveau P, Cuppari L, et al: **A proposed nomenclature and diagnostic criteria for protein-energy wasting in acute and chronic kidney disease. *Kidney Int* 2008, 73:391-8.**

[2] Fouque et al, **EBPG Guideline on Nutrition. *Nephrol Dial Transplant* (2007) 22 [Suppl 2]: ii45-ii87.**