

SPIRIT Flow Diagram of the LIBRE Study

| TIMEPOINT* | Enrolment | Start | | | | | | Close-out | Follow up |
|---|-----------|--------------------------------|-------------|-----|-----|--------------|--------------|--------------|-----------|
| | SE | V0 | V1 (3Mo) | 6Mo | 9Mo | V2 (12Mo) | V3 (24Mo) | V4 (36Mo) | +12Mo |
| ENROLMENT: | | | | | | | | | |
| Eligibility screen | X | | | | | | | | |
| Informed consent | X | | | | | | | | |
| Randomisation | X | | | | | | | | |
| INTERVENTIONS: | | | | | | | | | |
| <i>[Intervention group "I"]</i> | X | ← Intervention phase V0 – V2 → | | | | | X | X | X |
| <i>[control group "C"]</i> | X | X | X | X | X | X | X | X | X |
| ASSESSMENTS: | | | | | | | | | |
| <i>Clinical Baseline</i> | C+I | | | | | | | | |
| <i>Clinical follow up</i> | | | | | | C+I | C+I | C+I | C+I |
| <i>Spiroergometry</i> | C+I | | C+I | | | C+I | C+I | C+I | |
| <i>Accelerometry</i> | C+I | | C+I | C+I | C+I | C+I | | | |
| <i>Questionnaire "training" (IPAQ-L)</i> | | C+I | C+I | C+I | C+I | C+I | C+I | C+I | |
| <i>Questionnaires "nutrition"</i> | C+I | | C+I | | | C+I | C+I | C+I | |
| <i>Lab</i> | C+I | | C+I | | | C+I | C+I | C+I | |
| <i>Clinical examination</i> | C+I | | C+I | | | C+I | C+I | C+I | |
| <i>Anthropometry "Psychological" questionnaires (EORTC QLQ-C30/BR23, TICS, BKAE, LOT-R)</i> | C+I | | C+I | | | C+I | C+I | C+I | |

C= control group, I= Intervention group, SE= study entry