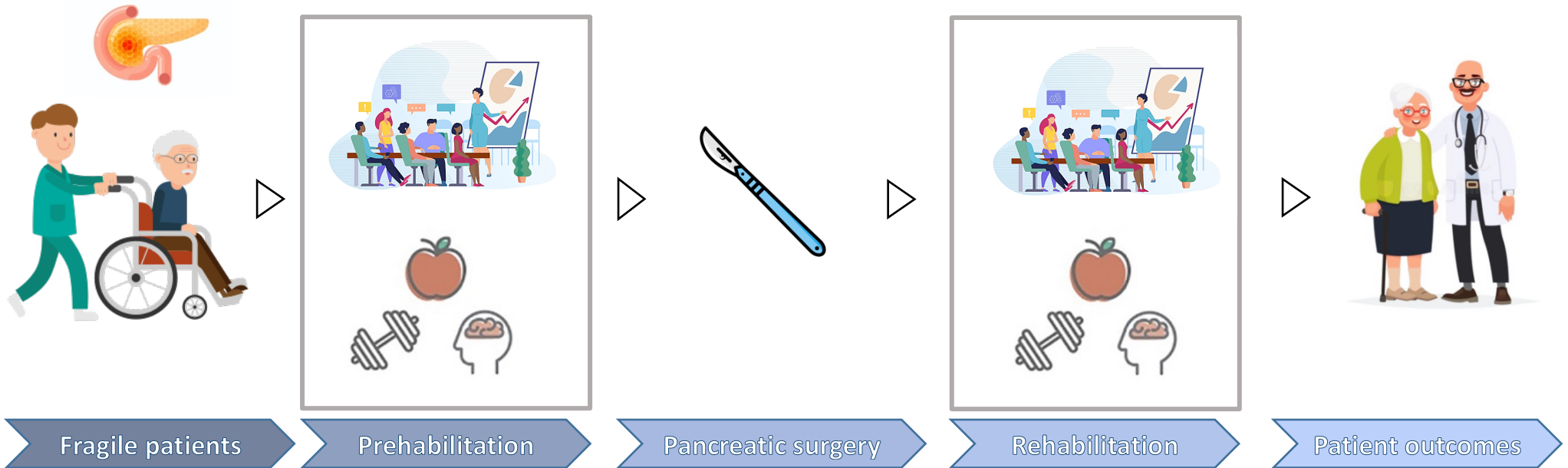


# PREFITS studies: Prehabilitation and REhabilitation for Fragile patients In pancreaTic Surgery

## Primary objective

The aim of the PREFITS studies is to assess the optimal pre- and rehabilitation for fragile patients after pancreatic surgery and what the role of pancreatic enzyme suppletion is in combination with validated and standardized pre- and rehabilitation.



## Background

Standardized prehabilitation and rehabilitation is suggested to have a positive effect on patient outcomes after surgery<sup>1-3</sup>, especially for fragile patients<sup>4-6</sup>. However, this effect is still unclear for patients after major and minor pancreatic surgery.

## Methods

The PREFITS studies include a consensus meeting following three studies in a step-up approach.

## PREFITS-Pilot



**20 patients**  
(10 major and 10 minor pancreatic surgeries)



## PREFITS-1 RCT



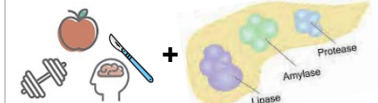
VS



## PREFITS-2 RCT



VS





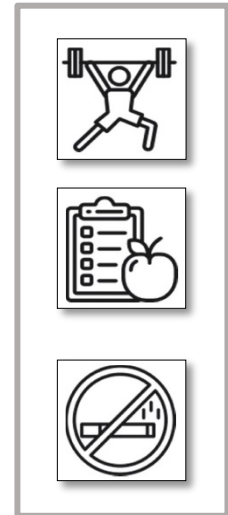
# PREFITS studies: Prehabilitation and REhabilitation for Fragile patients In pancreaTic Surgery

## Primary objective

To assess the effect of prehabilitation and rehabilitation on the postoperative outcomes and quality of life for fragile patients after pancreatic surgery

## Background

In recent years, research has shown that standardized prehabilitation and rehabilitation is suggested to have a positive effect on patient outcomes after surgery<sup>1-3</sup>, especially for fragile patients<sup>4-6</sup>. However, this effect is still unclear for patients after major and minor pancreatic surgery. In addition, the development of exocrine pancreas insufficiency after pancreatic resection is suggested to play a role in prolonged postoperative recovery due to nutritional deficiencies<sup>7</sup>, which could be improved by the suppletion of pancreatic enzymes during pre- and rehabilitation. The aim of the PREFITS studies is to assess the optimal pre- and rehabilitation for fragile patients after pancreatic surgery and what the role of pancreatic enzyme suppletion is in combination with validated and standardized pre- and rehabilitation.



## Methods

The PREFITS studies include a consensus meeting following three studies in a step-up approach. With a multidisciplinary consensus meeting, using the SIGN50 methodology, the optimal pre- and rehabilitation will be discussed. The feasibility and implementation of the created pre-/rehabilitation program will be assessed in the PREFITS-pilot study, whereafter, the PREFITS-1 RCT will be executed to assess the effect of the created standardized program. Last, the addition of pancreatic enzyme suppletion to the created pre-/rehabilitation program will be investigated in the PREFITS-2 RCT.

## Participants

Patients  $\geq 65$  years, undergoing pancreas resection, with Fried Frailty index  $> 1$ , comorbidities and poor mobility and/or diminished endurance.

### Multidisciplinary consensus

SIGN50 methodology to assess best pre-/rehabilitation program

Systematic literature review

Consensus meeting with:

- Surgery
- Oncology
- Gastroenterology
- Physiotherapy
- Dietary

### PREFITS-Pilot

Prospective cohort study in Fondazione Poliambulanza (IT)

Inclusion of 20 patients:  
pancreatoduodenectomy (N = 10)  
distal pancreatectomy (N = 10)

Intervention: pre-/rehabilitation program

Outcomes:

- Time to functional recovery
- Comprehensive Complication Index, CCI
- Delayed gastric emptying rate
- Readmission rate
- Quality of Life

### PREFITS-1: RCT

Multicenter, randomized trial to assess the effect of pre- and rehabilitation on the postoperative outcomes and quality of life

Pre- and rehabilitation **VS** no intervention  
With stratification for (neo-)adjuvant therapy

Outcomes:

- Time to functional recovery
- Comprehensive Complication Index, CCI
- Delayed gastric emptying rate
- Readmission rate
- Quality of Life

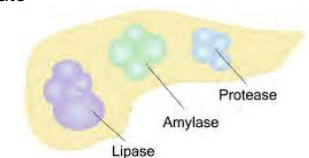
### PREFITS-2: RCT

Multicenter, double-blind, randomized trial to assess the effect on supplementing pancreatic enzymes on the outcomes of pre- and rehabilitation program in pancreatic surgery

Pre-/rehabilitation with supplementation of CREON pancreas enzymes **VS** pre-/rehabilitation with placebo

Outcomes:

- Time to functional recovery
- Comprehensive Complication Index, CCI
- Delayed gastric emptying rate
- Readmission rate
- Quality of Life





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