

# The development, implementation and evaluation of a Psychosocial Intervention for patients treated for NeuroEndocrine Tumors: the PINET study

Published: 24-04-2012

Last updated: 01-05-2024

**Purpose:**The main focus of our study is the development, implementation and evaluation of a self-management intervention for patients treated for pituitary adenomas and patients with endocrine diseases in general.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40080

### Source

ToetsingOnline

### Brief title

PINET

### Condition

- Other condition
- Hypothalamus and pituitary gland disorders

### Synonym

pituitary adenoma, pituitary tumor, primary adrenal insufficiency

### Health condition

Ziekte van Addison, primaire bijnier insufficiëntie

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ipsen Pharmaceuticals

## Intervention

**Keyword:** neuroendocrine tumors, pituitary adenoma, psychosocial intervention, self-management intervention

## Outcome measures

### Primary outcome

Dependent variables:

- Questionnaires on psychological and social aspects (QoL, illness perceptions, coping strategies, self-efficacy, personality traits)
- Questionnaires about general well-being
- Questionnaire about daily functioning: employment status, days absent at work due to their illness and how often they seek medical care.

### Secondary outcome

Explorative data:

- Information focus groups
- Data needs assessment
- Clinical data of previous treatment (including surgery, radiotherapy),
- Clinical data on current status (endocrine status, substitution treatment, and concomitant disease(s) and treatment).
- Data somatic screening (weight, length, blood pressure, heartbeat, hip/waist-ratio)

# Study description

## Background summary

Background:

Pituitary adenomas can cause classical syndromes and result in considerable consequences for the daily lives of affected patients. Recently, studies of our department evaluated that patients treated for pituitary adenomas report an impaired quality of life, a higher prevalence of psychopathology and maladaptive personality traits. Furthermore, they report illness perceptions and coping strategies that may be characterized as inadequate.

The term psychosocial intervention and the term self-management intervention are often used interchangeably. A considerable number of studies stated the effectiveness of a self-management approach in chronic somatic conditions. It can be hypothesized that a psychosocial intervention can stimulate these patients to adapt these factors, which in turn will improve Quality of Life.

Models which are frequently used in psychosocial interventions are the \*Social Cognitive Theory\* (SCT) and the \*Common Sense Model of self-regulation\* (CSM).

## Study objective

Purpose:

The main focus of our study is the development, implementation and evaluation of a self-management intervention for patients treated for pituitary adenomas and patients with endocrine diseases in general.

## Study design

Design:

The development of the selfmanagement intervention will be doen accordign to the focus groups and needs assessment questionnaire. Needs which come up for discussion during the focus groups and data of the needs assessment questionnaire will be used for the design and content of the program.

The effectiveness and practical implications of this intervention will be evaluated in a randomized, controlled trial (RCT).

## Intervention

The proposed psychosocial intervention will be based on the \*Patient Education Program\* (PEP); a behavioural intervention addressing psychosocial topics.

Previous research demonstrated that this program beneficially affect QoL in patients with Parkinson\*s disease and their caregivers. This structured program consist of eight weekly sessions of ninety minutes duration, which include seven different themes (Information, Self evaluation, Health promotion, Stress management, Dealing with anxiety and depression, Social competence, Social

support); during the last session, the intervention will be evaluated. The partners/caregivers of the patients are also involved in the PEP. The participating caregivers in our study will follow the same program, but separately from the patients. Knowledge and skills are being taught in order to improve self-management skills, which supposedly translates into improvements in quality of life, complementing the medical treatment. The method used in the PEP is based on principles of cognitive-behavioral therapy. Interventions such as systematic relaxation training, cognitive restructuring, situational behavioral analysis, and training in social skills are included.

### **Study burden and risks**

We presume patients are willing to participate and therefore experience this program as not aggravating. Before and after the intervention, patients are asked to complete questionnaires. In addition they are asked to fill out these questionnaires after 6 months and 1 year. Completing the questionnaires will take about 1,5 hours. Filling out these questionnaires can be aggravating to same degree.

Participation in this study can improve quality of life. In the worst case quality of life will stay the same. Therefore, no risks are associated to this study.

## **Contacts**

### **Public**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

### **Scientific**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Patients during follow up for pituitary tumors or Addison's disease at the outpatient clinic of the Leiden University Medical Center or the Radboud University Medical Center
- Patients should be in a stable medical situation.

### Exclusion criteria

- Age <18yr, or >75yr
- Currently receiving psychological/psychiatric treatment
- Presence of psychiatric illness

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2013
Enrollment:	180
Type:	Actual

## Ethics review

Approved WMO

Date: 24-04-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 05-06-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 17-09-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 12-11-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 27-11-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 13-01-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 11-03-2015  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 13-07-2016  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL40170.058.12