Tailored psychological treatment for cancer patients with an adjustment disorder

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23120

Source
Nationaal Trial Register

Brief title
ADJUST-study

Health condition

Adjustment disorder

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is psychological distress measured by the Hospital Anxiety and Depression Scale (HADS)

Secondary outcome

Secondary outcomes of this study are mental adjustment to cancer as measured using the Mental Adjustment to Cancer Scale (MAC)) and health-related quality of life, as measured using the EORTC QLQ-C30. In addition, the cost-utility of the tailored psychological intervention will be investigated. To investigate the cost-utility, all patients will be asked to complete the EQ-5D, iMCQ and iPCQ at all measurement time points.

Study description

Background summary

The prevalence of adjustment disorders among cancer (ex)patients has been reported to be high. Although a large amount of studies have shown evidence for the effectiveness of psychological interventions targeting cancer patients, so far, no study focused on the (cost-)effectiveness of psychological interventions targeting cancer patients with an adjustment disorder. In this study, therefore, a psychological intervention tailored to the individual needs and wishes of the patient will be investigated.

Study objective

It is hypothesized that this tailored intervention is effective in cancer patients with an adjustment disorder compared to a waitlist control group, and potentially cost-saving.

Study design

Patient reported outcome measures will be assessed at baseline (before randomization), and 3 and 6 months after randomization.

Intervention

According to the national guideline “Adjustment Disorder”, the psychological intervention consists of three modules: a module for diagnosis and psycho-education (4 sessions, for all patients) and two additional modules comprising of various types of psychological interventions (maximum of 6 sessions per module, tailored to the individual patient). The three modules are provided as a continuum. After each module there will be assessed if a following module is needed.

Patients in the control group are allowed to receive care-as-usual and receive the tailored psychological intervention after a waitlist period of 6 months.

Contacts

Public
VU
I.M. Verdonck - de Leeuw

+31 20 59 86113
Scientific
VU
I.M. Verdonck - de Leeuw

+31 20 59 86113

Eligibility criteria

Inclusion criteria

Patients are eligible to participate if
1) age ≥ 18 years (no upper age limit)
2) diagnosed with cancer (all types and stages and stages, except non-melanoma skin cancer)
3) patients after the end of primary cancer treatment with curative or palliative intent (all treatment modalities, except for endocrine therapy in breast/prostate cancer)
4) presence of an adjustment disorder as diagnosed with a diagnostic interview

Exclusion criteria

patients who are not able to complete a Dutch questionnaire and Patients with an adjustment disorder who are already receiving psychological treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	206
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-05-2019
Application type:	First submission

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
NTR-new	NL7763
Other	METc VUmc : 2019.002

Study results