Tailored psychological treatment for cancer patients with an adjustment disorder

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23120

Bron
Nationaal Trial Register

Verkorte titel
ADJUST-study

Aandoening

Adjustment disorder

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of this study is psychological distress measured by the Hospital Anxiety

and Depression Scale (HADS)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU
I.M. Verdonck - de Leeuw

+31 20 59 86113

Wetenschappelijk

VU
I.M. Verdonck - de Leeuw

+31 20 59 86113

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	206
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7763
Ander register	METc VUmc : 2019.002

Resultaten