Internet-based treatment of depressive symptoms in tumor patients.

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Depression is a major health problem in glioma patients, with emotional, cognitive and physical sequelae. Depression in these patients may be associated with increased morbidity and even with poorer survival. In addition, depression is the most...

Ethische beoordeling Positief advies **Status** Werving gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON27351

Bron

NTR

Aandoening

low-grade glioma; low-grade hematological malignancies (non-Hodgkin lymphoma, chronic lymphocytic leukemia); depression

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: KWF Kankerbestrijding/Alpe d'HuZes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in depressive symptoms as measured by the Center for Epidemiological Studies Depression Scale (CES-D).

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Depression is a major health problem in glioma patients, with emotional, cognitive, and physical sequelae. Depression in these patients may be associated with increased morbidity and even with poorer survival. In addition, depression is the most important independent predictor of health-related quality of life (HRQOL) in patients with brain tumours affecting not only patients but also their informal caregivers (i.e., partner, good friend, or family member). The etiology of depression may be due to tumour location, treatment, or patient response to the diagnosis. Treatment of depression usually includes a combination of psychotherapy, group therapy, and medications. Glioma patients, however, are not inclined to seek help for mental health problems. The internet is a medium which is used much easier by glioma patients to seek help for mental health problems. This project is aimed at the development of an internet-based intervention for glioma patients with mild to moderate depression. This type of intervention has been proven to be effective in adult non-cancer populations with mild to moderate depression, but not in glioma patients.

Objectives:

The primary study objectives are:

- 1. To estimate the prevalence of depressive symptoms in glioma patients;
- 2. To determine whether an internet-based guided self-help intervention is effective in reducing symptoms of depression in glioma patients;
- 3. To determine the impact of the intervention on the HRQOL of both glioma patients and their informal caregivers;
- 4. To evaluate the compliance and feasibility of the intervention in this patient population;
- 5. To evaluate the cost-effectiveness of the intervention.

Methods:

We will use an internet intervention based on problem-solving and self-examination therapy which has been proven to be effective, and adapt this intervention for use with glioma patients addressing depression. Glioma patients are guided by a coach to work through the

intervention.

Doel van het onderzoek

Depression is a major health problem in glioma patients, with emotional, cognitive and physical sequelae. Depression in these patients may be associated with increased morbidity and even with poorer survival. In addition, depression is the most important independent predictor of health-related quality of life (HRQOL) in patients with brain tumors affecting not only patients but also their informal caregivers (i.e. partner, good friend, or family member). Treatment of depression usually includes a combination of psychotherapy, group therapy, and medications. Glioma patients, however, are not inclined to seek help for mental health problems. The internet is a medium which is used much easier by these patients. This project is aimed at the development of an internet-based intervention for glioma patients with mild to moderate depression. This type of intervention has been proven to be effective in adult non-cancer populations with mild to moderate depression, but not in glioma patients. Guided self-help over the internet has the possibility to deliver services to large groups of patients. In this sense the proposed intervention is an important addition to existing services in the Netherlands.

Onderzoeksopzet

0 weeks, 6 weeks, 3 months, 12 months.

Onderzoeksproduct en/of interventie

Guided self-help internet intervention focusing on reducing depressive symptoms.

Fifty low-grade glioma patients will be included in the intervention group and 50 low-grade glioma patients will be included in the control group. They will be put on a three month waiting list after which they can also take part in the intervention. Furthermore, 50 patients with low-grade hematological malignancies whose disease does not include the central nervous system will form a control group. They will take part in the internet-intervention.

As web-based intervention we use an adapted version of the website "Allesondercontrole" (Everything under control), an intervention for brief problem-solving which is based on self-examination therapy. The intervention takes five weeks (approximately 15 hours of work in total). During that period, patients describe what they think is important in their lives, make a list of their problems and concerns, and divide these into three categories: unimportant problems (problems which are not related to what is important in their life), important and solvable (these are solved through a six-step procedure of problem-solving), and important but unsolvable (such as loosing someone through death); for each of these problems the patient makes a plan how to cope with this. Patients hand in homework assignments every

week and receive feedback from a personal coach. The coach is not a therapist, but only supports the patient in working through the intervention.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. >18 years of age;
- 2. Presence of either low-grade glioma (grade II) or low-grade hematological malignancies (NHL or CLL);
- 3. Mild to moderate depressive symptoms;
- 4. Internet access and e-mail address.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Major depression, no depressive symptoms, or suicidal intent

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 29-11-2011

Aantal proefpersonen: 150

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 28-12-2011

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 NL3075 NTR-old NTR3223

Ander register KWF Kankerbestrijding : 2010/4804 ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A