Internet-based treatment of depressive symptoms in patients with tumors inside or outside of the central nervous system.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Lymphomas non-Hodgkin's unspecified histology
Study type	Interventional

Summary

ID

NL-OMON39265

Source
ToetsingOnline

Brief title
Internet-based treatment of depressive symptoms in tumor patients.

Condition

- Lymphomas non-Hodgkin's unspecified histology
- Nervous system neoplasms malignant and unspecified NEC
- Respiratory disorders NEC

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: KWF/Alpe D'HuZes

Intervention

Keyword: depression, fatigue, gliomas, internet-based treatment

Outcome measures

Primary outcome

Measures are taken at 0 weeks (pre-test) and after conclusion of the intervention at 5 weeks (post-test), at 3 months follow-up and at 6 and 12 months follow-up for high-grade glioma patients and at 12 months follow-up for low-grade glioma patients. The primary outcome measure is the change in depressive symptoms as measured by the Center for Epidemiological Studies Depression Scale (CES-D). This is a valid and reliable self-report questionnaire used to measure depressive feelings during the past week. The questionnaire consists of 20 propositions, where the respondent indicates how often this proposition applies to him/her (rarely or never, sometimes, regularly, most of the time or always). The sum score lies between 0 and 60. A higher score indicates more feelings of depression. In the general population, people with a score higher than 16 are considered depressed.

Secondary outcome

Secondary outcome measures are quality of life (SF-36, EuroQol, BCM20), symptoms of fatigue (CIS-20), cognitive functioning (a 6-item scale that was developed during the Medical Outcomes Study) and variables that may predict outcome, such as client satisfaction and problem-solving skills. Although a true economic analysis will not be conducted, we will collect data on the costs of the intervention (internet application, costs of the coaches) per patient,

and both in money and hours of working time.

Clinical data to be recorded at study entry will include tumor characteristics (histology, size, site), and treatment history (biopsy, surgery, chemotherapy, corticosteroids, anti-epileptic medication). Additionally, data on potential tumor progression/recurrence and treatment of recurrent tumor (radiotherapy, chemotherapy, corticosteroids) will be collected. AII clinical data will be derived from the medical records and provided by the treating physician or the family physician. Questions on depressive symptoms, quality of life, fatigue, patient satisfaction, problem-solving skills, and data on the costs of the intervention will be presented online in a fixed order. Patients will be allowed to return to any of the measures for review or changes.

Study description

Background summary

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). The etiology of depression may be due to tumor 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.

Study objective

The primary study objectives are:
(1) to determine whether an internet-based guided self-help intervention is effective in reducing symptoms of depression in glioma patients;
(2) to determine the impact of the intervention on the HRQOL of both glioma patients and their informal caregivers (partner, good friend, or family member);
(3) to evaluate the compliance and feasibility of the intervention in this patient population; and
(4) to evaluate the cost-effectiveness of the intervention.

Study design

A web-based intervention that has been proven effective (Allesondercontrole) will be adapted for use by glioma patients.

Fifty low-grade glioma patients will be included in the intervention group and 50 low-grade glioma patients will be included in the waiting list control group. After a three-month period, these patients can also take part in the intervention. Furthermore, 50 patients with hematological malignancies whose disease does not include the central nervous system will form a control group. They will take part in the internet-intervention. Outcome is evaluated before and after the intervention, at 3 and at 12 months follow-up.

Fifty high-grade glioma patients will be included in the intervention group and 50 high-grade glioma patients will be included in the waiting list control group. After a three-month period, these patients can also take part in the intervention. Furthermore, 50 patients with non-small cell lung cancer without metastasis in the central nervous system will form a control group. They will take part in the internet-intervention. Outcome is evaluated before and after the intervention, at 3, at 6 and at 12 months follow-up.

Intervention

As web-based intervention we use the website *Allesondercontrole* (Everything under control), an intervention for brief problem-solving which is based on self-examination therapy. This intervention is already available (only for research purposes, not for the general public) and has been tested in adults with depressive symptoms, anxiety symptoms, and/or stress related symptoms. The website Allesondercontrole (www.ggzelfhulp.nl/index.php?fId=752) can be used in this target population with small adaptations. In a randomized controlled trial with 215 adults, this intervention was found to have significant effects on depression, anxiety and stress/burnout. This is also confirmed in international

studies in which was found that this intervention (as guided self-help) is effective in reducing depression and anxiety symptoms.

The intervention takes five weeks. 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). We think that this intervention is very well suited for glioma patients. First, the intervention is relatively simple and does not require complex skills or understanding of intrapersonal processes (such as changing cognitions). Second, this intervention is exactly about the things glioma patients are thinking about during this phase of their life (what is important for me and how do I solve existing problems). The participants get feedback on the homework assignments every week from a personal coach. The coach is not a therapist, but only supports the patient in working through the intervention. The coaching is given by specialists from Prezens.

After three months, the participants in the control groups who only received information about depression will be offered the same intervention.

Study burden and risks

During the intervention the participants are to spend about 3 hours a week on homework assignments. This means a total of 15 hours for the entire intervention. Additionally, 4 extra hours will be reserved for filling in the questionnaires during the pre- and postmeasures.

The risks of participation in this study are negligible. The control group of glioma patients who do not receive the intervention immediately might be made more aware of their depressive symptoms because of the questionnaires they are asked to fill in. However, we keep track of their CES-D scores. This way we can monitor whether or not the depressive symptoms have gotten worse, in which case we will contact their physician.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Experimental groups:;1: adult (>18 years of age) WHO Grade II low-grade glioma survivors. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account. ;2: adult (>18 years of age) WHO Grade III and Grade IV high-grade glioma patients with an estimated life expectancy of >3 months. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account. ;Control groups:;1: adult (>18 years of age) WHO Grade II low-grade glioma survivors. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account. ;2: adult (>18 years of age) WHO Grade III and Grade IV high-grade glioma patients with an estimated life expectancy of >3 months. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account. ;3. adult (>18 years of age) patients with hematological malignancies without involvement of the central nervous system. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account. ;4. adult (>18 years of age) patients with non-small cell lung cancer without clinical signs of central nervous system involvement. Mild to moderate depressive symptoms (CES-D score >=12). Participants have to have access to internet and an email account.

Exclusion criteria

Suicidal intent

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:	Completed
Start date (anticipated):	30-11-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL36095.029.11