Maintaining health-related quality of life of caregivers of glioblastoma patients: A randomized, two-group, controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON31654

Source
ToetsingOnline

Brief title
Quality of life of informal caregivers of GBM patients

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain cancer., Brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NBTF/Tug McGraw Foundation

Intervention

Keyword: Coping skills intervention, Glioblastoma multiforme, Health-related quality of life, Informal caregiver(s)

Outcome measures

Primary outcome

Indicators of caregivers' health-related quality of life, burden, and mastery

specific to caregiving tasks and patient symptoms will be assessed as primary

outcomes at two-monthly intervals from baseline up till 8 months or patient's

death.

Secondary outcome

Not applicable

Study description

Background summary

Glioblastoma multiforme (GBM) is the most frequently occurring and most aggressive type of malignant primary brain tumor. Despite intensive treatment with neurosurgery, radiotherapy, and chemotherapy, patients with this type of brain tumor invariably experience tumor recurrence. Median patient survival is approximately one year from initial diagnosis. Due to the awareness of the inevitable approaching death of their beloved as well as the fact that GBM patients often demonstrate behavioral, emotional, and cognitive dysfunction early in the course of their disease, caregivers of these patients often bear an incalculable emotional burden for their work. Exhaustion, financial strain, disrupted daily activities, and continuous caregiving contribute to significant mental health morbidity, including anxiety and depression, poor sleep, and even increased cancer risk.

Study objective

This study aims at 1) ascertaining GBM patients* caregiver mastery and burden and 2) determining to what extent a structured psychosocial intervention that teaches coping and problem-solving skills leads to clinically significant improvements in health-related quality of life (HRQOL) of the caregivers of GBM

patients. Concerning the 2nd aim, three questions will be addressed1) does the intervention decrease emotional distress and augment HRQOL? 2) does the intervention improve problem-solving skills? and 3) does the effectiveness of the intervention depend on patient*s HRQOL, tumor, and/or treatment characteristics?

Study design

A randomized, two-group, controlled clinical trial will be undertaken to compare the efficacy of a coping/problem-solving skills intervention (n=36) with standard medical care (n=36) in maintaining overall health-related quality of life and caregiver mastery of GBM patients' informal caregivers.

Intervention

Starting at baseline, individual sessions with caregivers will be held every other week for a maximum of 6 one-hour sessions. The intervention is designed to empower caregivers by enhancing their problem-solving skills and, thereby, increasing their ability to cope with the demands of managing and providing care to the GBM patient.

Study burden and risks

For the informal caregivers, the burden associated with participation consists of (1) completing questionnaires regarding health-related quality of life, caregiver-burden and caregiver-mastery at different points in time during and following the intervention period, (2) (only for the intervention group) participation in the six sessions of the intervention program, either at home or in the hospital. No medical risks are involved. The possible benefits of participation for the intervention group are: (1) better coping skills, (2) better emotion-regulation and, (3) mastery of caregiving.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081 BT Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7

1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) Informal caregiver (partner or intense caregiver, providing at least 21 hours of care per week) of newly diagnosed GBM patiënt, (2) adult (minimum 18 years), (3) written informed consent.

Exclusion criteria

(1) life expectation of the GBM patient of < 3 months, (2) insufficient mastery of the Dutch language, (3) having severe visual impairments (e.g. unable to read the questionaires), (4) inability to understand or apply the skills teached in the intervention due to (a) physical or mental condition(s), (5) inability of care giving due to (a) physical or mental condition(s), (6) having a serious alcohol or drug addiction.

Study design

Design

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

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	21-04-2008
Application type:	First submission
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	NL20592.029.07