

The meaning of anxiety for patients with a malignant glioma: a grounded theory design

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The aim of this study is to understand what it means to be anxious for adults with a malignant glioma. This study focuses on the lived experience and the underlying processes of the meaning of anxiety. Main question: "What does it mean for..."

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36230

Source

ToetsingOnline

Brief title

Apmag study

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym

malignant brain tumors, malignant glioma's

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: eigen financiën uitvoerend onderzoeker

Intervention

Keyword: Anxiety, Grounded Theory, Malignant gliomas, Palliative patients

Outcome measures

Primary outcome

Primary outcome: The meaning of anxiety => the 'lived experience' and underlying processes of the meaning of anxiety

The 2 main interview questions :

- 1) Please, tell me about your experience from the moment you heard you could not be treated until now
- 2) When you look back at this period, please call times when you have been anxious

Secondary outcome

none

Study description

Background summary

Two percent of all new cancer patients have a primary intracerebral tumor. Approximately 70% of these patients have a malignant glioma. Due to a lack of curative treatment of malignant gliomas, both therapy and care are focused on palliation. In the palliative phase, symptoms are present which negatively affect the quality of life. One of those symptoms is anxiety. There is no scientific knowledge available about what being anxious means for patients with a malignant glioma. It is necessary to understand this unique, individual experience of the patient, because early identification and symptom

mangement requires knowledge, competence and clinical experience of the nurse. By understanding the meaning of anxiety and the specific needs of these patienten, nurses can more focused intervene with knowledge, understanding and empathy.

Study objective

The aim of this study is to understand what it means to be anxious for adults with a malignant glioma. This study focuses on the lived experience and the underlying processes of the meaning of anxiety.

Main question: "What does it mean for patients with a malignant glioma when they are anxious?"

Study design

This qualitative study is based on the principles of Grounded Theory. The study takes place in the home situation of the patient. The initial sample is purposive, aiming for maximum variation. Thereafter, patients are selected purposeful with respect to the emerging theory, until conceptual saturation is reached. To reach conceptual saturation, 10-15 patients are needed. Patients are recruited from a neurological outpatient clinic in the south of the Netherlands.

During three months (January-May 2011) data are collected by one-time, individual semi-structured in-depth interviews, document analysis and a demographic questionnaire. The data are analyzed according to the three phases of GT: open, axial and selective coding. During the data analysis, memos are written.

Study burden and risks

The study has no risks.

The strain for the patient consists of:

- A single in-depth interview of 1 hour
- Completing a demographic questionnaire
- The investigation has no benefits or disadvantages. It is possible that the patient feels comfortable to talk about his illness and related fears.

However, there is a chance that patients have trouble afterwards, because they suddenly have spoken of their fears.

In that case, patients are referred to a social worker.

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

- Good communication skills in Dutch
- adults (18+)
- malignant glioma
- mentally competent
- the patient is aware of the fact that treatment focuses on palliation

Exclusion criteria

- psychiatric disorder with anxiety as the main feature
- cognitive impairment

- aphasia/ phatic problems

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-04-2011

Enrollment: 15

Type: Actual

Ethics review

Approved WMO

Date: 21-02-2011

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL33922.008.10