ISRCTN22038059 https://doi.org/10.1186/ISRCTN22038059

The feasibility of a brain tumor website

Submission date 19/04/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/05/2013	**Overall study status** Completed	
Last Edited 23/09/2016	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
High-grade gliomas (HGG) are the most malignant type of brain tumors. The 5-year survival is 10 % and a significant part of ongoing research aims to increase survival through surgical and oncological treatments. Accordingly, there is an increasing need for investigating the HGG disease prognosis in order to recommend specific survivorship guidelines for rehabilitative and supportive interventions. The study aims to understand patients and relatives life situation, needs, wishes and preferences for rehabilitative interventions during and after surgical and medical treatment for high grade glioma. Furthermore, the aim is to develop and test a rehabilitative intervention based on patient and family perspectives and existing literature.

Who can participate?
Patients with HGG (WHO grade III and IV) with or without their caregiver.

What does the study involve?
The study is conducted in 2 phases . Phase 1 is an explorative and descriptive interview study of patients and their relatives' life situation and needs for rehabilitation as well as a quantitative evaluation of the patients´ health related quality of life. Phase 2 is a pilot study testing a rehabilitative intervention program. The intervention program is developed from existing intervention literature and the findings from phase 1 of the study.

What are the possible benefits and risks of participating?
Being interviewed by a nurse specialist e.g. about the life situation can have a positive gain for the participants as the interview can help the participants clarify their thoughts. After the interviews it is possible for the participants to ask the nurse specialist any questions that might persist. There are no risks related to participation.

Where is the study run from?
University Hospital of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
May 2012 to May 2015

Who is funding the study?
1. The Center for Integrated Rehabilitation of Cancer Patients (CIRE) (Denmark)

2. The Neuro Center at Copenhagen University Hospital; Rigshospitalet (Denmark)
3. The Danish Cancer Society (Denmark)
4. The Novo Nordisk Foundation (Denmark)
5. Torben and Alice Frimodts Foundation (Denmark)
6. Vera and Flemming Westerbergs Foundation (Denmark)
7. Hetland Olsens Foundation (Denmark)

Who is the main contact?
Karin Piil
Karin.piil@regionh.dk

Contact information

Type(s)
Scientific

Contact name
Mrs Karin Piil

Contact details
University Hospital of Copenhagen
Neurosurgery dept. 3090
Blegdamsvej 9
Copenhagen
Denmark
2100
+ 45 (0)61 27 80 67
Karin.piil@regionh.dk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The feasibility of a brain tumor website among patients with high-grade gliomas and the caregivers

Study objectives
The literature that addresses the supportive, rehabilitative and palliative needs still remains limited and reflects a gap in the existing knowledge regarding the breadth of needs across the disease and treatment trajectory for patients with HGG and their caregivers. This study adds knowledge to the growing body of existing research of the life situation and the longitudinal needs and preferences for rehabilitative and supportive care interventions in patients with HGG and their caregivers. Moreover, we studied the feasibility and safety of an Internet-based intervention. This mixed methods study is divided into two phases. First, a longitudinal, qualitative, explorative and descriptive interview study of the life situation and need for rehabilitation among patients and their caregivers were carried out. Moreover, a quantitative

evaluation of health-related quality of life using patient-reported outcomes was conducted. In the second phase a Danish Brain Tumor Website (BTW) was developed based on professional clinical, scientific knowledge and evidence as well as from the findings from the previous phase. The feasibility and safety was explored in a feasibility study using a mixed methods design including a qualitative semi-structured interview study and statistics regarding the users of the website was extracted using the Google Analytics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Registered by the Danish Data Protection Agency (2007-58-0015) and Danish Data Protection Agency (30-1219/02865) and will be carried out in accordance with the Declaration of Helsinki.
1. No approval needed for phase I.
2. Phase II: The Ethical Committee at the Capital Region of Denmark, ref: H-2-2013-135

Study design
This mixed methods study investigates the feasibility of a newly developed nationwide Danish Brain Tumor Website.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with primary malignant brain tumor of the type high-grade glioma (WHO grade III/VI).

Interventions
Phase I: Participants will be interviewed individually five times over a 12 months period starting at baseline (Test 1: time of diagnosis). Test 2 takes place 5-6 weeks post-operatively, which is approximately 2 weeks after initiation of the oncological treatment. Test 3 is at 28 weeks (after first treatment response scan) and test 4 is at 40 weeks (after second treatment response scan). Test 5 takes place after one year at study end. The patients will be asked to complete questionnaires at all five test points.

Phase II: The intervention program will be developed after phase I. Two separate samples will collected:
1. A nationwide sample studying BTW participation after six months
2. A sample of patients with HGG and their caregivers interviewed three months after being introduced to the BTW.
The interactive Brain Tumor Website (BTW) (hjernekraeftnetvaerk.dk) provides specific HGG information and links to quality websites, a disease and treatment specific dictionary, an ask-the-specialist function, online support groups for sharing experiences and weekly access to an open telephone line with the moderator.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
The primary aim of phase I is to explore the life situation, needs and experiences across the disease and treatment continuum in patients diagnosed with HGG and their caregivers.

The aim of phase II is to study the feasibility of a survivorship program designed from the perspectives in the existing literature and the experiences of the patients and their caregivers obtained in the present study.

Data includes:
1. The number of users
2. Logged-in members
3. Postcodes from which the BTW was accessed
4. Types of devices used to access the BTW
5. Number of first time versus returning users
6. Type of activity (number of sessions, most visited pages, use of telephone support)

Individual telephone interviews were conducted with the participants by the principal investigator and clinical specialist after three months. Using a semi-structured interview guide, participants were asked to share their experiences and evaluation of the BTW.

Key secondary outcome(s))
1. To systematically assess the patients´ needs for rehabilitation along the course of the disease
2. To describe how symptoms are experienced and managed
3. To elucidate the resources of the caregivers and any independent needs related to the patient's disease
4. To gain an understanding of what a survivorship program should comprise
5. To develop a targeted intervention for rehabilitation of patients with HGG and their caregivers
6. Assess safety of the BTW

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. A diagnosis of HGG (WHO grade III/IV) in persons > 18 years of age, either sex that are capable of speaking and understanding Danish and that have a Karnofsky performance score (KSP) > 60 at baseline
2. Caregivers are eligible if they are named by the patient as the most involved caregiver, and will provide written informed consent
3. Access to the Internet

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Karnofsky performance score < 60 at baseline
2. Other types of primary brain tumors than HGG
3. No Internet access
4. No standard treatment

Date of first enrolment
01/05/2012

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Denmark

Study participating centre
University Hospital of Copenhagen
Copenhagen
Denmark
2100

Sponsor information

Organisation
Copenhagen University Hospital

ROR
https://ror.org/05bpbnx46

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Center for Integrated Rehabilitation of Cancer Patients (CIRE) (Denmark)

Funder Name
The Neuro Center at Copenhagen University Hospital, Rigshospitalet (Denmark)

Funder Name
The Novo Nordisk Foundation (Denmark)

Funder Name
Torben og Alice Frimodts Fond

Alternative Name(s)
Torben and Alice Frimodt's Foundation, Torben & Alice Frimodt's Foundation, Torben & Alice Frimodts Fond

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Vera and Flemming Westerbergs Foundation (Denmark)

Funder Name
Hetland Olsen Fund

Alternative Name(s)
Hetland Olsens Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Denmark

Funder Name
Kræftens Bekæmpelse

Alternative Name(s)
Danish Cancer Society, The Danish Cancer Society, DCS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes