Shared decision making with brain tumor patients

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23658

Source
NTR

Brief title
SDM

Health condition

Adult patients with meningioma (50%) or low- (20%) or high-grade (30%) glioma.

Sponsors and support

Primary sponsor: Elisabeth Twee-Steden Ziekenhuis Tilburg (The Netherlands), Tilburg University (The Netherlands).
Source(s) of monetary or material Support: ZonMw - The Netherlands Organization for Health Research and Development, Project number 10070012010006 (Programma Topspecialistische Zorg en Onderzoek ETZ).

Intervention

Outcome measures

Primary outcome

We will evaluate differences in measures of shared decision-making, aspects of quality of life, and symptoms of anxiety and depression in patients after the implementation of the Goings-

On app as compared to the baseline. Furthermore, we will audiotape the first neurosurgical consultation (and the first neuro-oncological consultation will also be audiotaped for most glioma patients) to evaluate differences in content of information discussed and duration of the consultation after the implementation of the Goings-On app as compared to the baseline.

Secondary outcome

As secondary outcomes, we will evaluate the symptoms and personal life goals recorded in the Goings-On app, the frequency and extent of the use of the app by brain tumor patients and their characteristics; as well as the usage of the dashboard by the clinical team, for which patients they use the dashboard, and draw a comparison of the characteristics of the patients for which they use it more versus less.

Study description

Background summary

In brain tumor treatment, we strive for an optimal balance between maximizing tumor reduction to increase survival, and minimizing long-term functional deficits to preserve cognitive skills, socio-professional functioning and aspects of quality of life. Patients have their own specific personal goals they wish to pursue. Cancer patients express the need for more information on late effects of treatment in the decision-making phase, as well as a need for a greater (shared) involvement in the decision-making process. However, research has shown that doctors are often not much aware of patients' personal goals and of the effects of treatment on patient goals, consequently, refrain from discussing how these goals and how these might be affected by any given treatment option. We expect that collecting information about the individual patients' personal goals and providing the clinical care team with this information will not only improve informed decision-making, but also goal-concordant decision-making. Making more accurate information on patient personal goals available better enables balancing and personalizing the gains and losses in terms of functional outcome.

Study objective

Based on previous research in other cancer patients, we hypothesize that when more information is shared on patients' personal goals during treatment decisions, shared decision-making regarding neurosurgical and neuro-oncological treatment, and subsequent aspects of quality of life, will improve and will result in lower symptoms of anxiety and depression as compared to the clinical situation before introduction of the Goings-On app.

Study design

Questionnaires will be administered to all brain tumor patients included in the study following the first neurosurgical consultation, the first neuro-oncological consultation (if applicable),

and 3, 6 and 12 months thereafter.

Intervention

In the first year of the study, patients will receive care as usual. From the second year onwards, we will implement the scientifically developed Goings-On app in clinical practice to identify individual patients' personal goals and symptoms. The Goings-On app allows patients to share more about their personal background with the clinical team by logging individual life goals, goal attainment and symptom burden in a minute a day. The Goings-On app is used from several days before shared neurosurgical or neuro-oncological decision making until 6 months thereafter.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study a participant must meet all of the following criteria:
1) Adult patients (>18 years of age) with meningioma or low- or high-grade glioma who visit the neurosurgical clinic and (from the second year onwards) who are willing and able to use the Goings-On application.
2) Fluent in Dutch.

Exclusion criteria

1) Being a participant in another clinical study that may induce potential contamination of the effects of the other study.

2) Unable physically and/or mentally to fill out the app on a daily basis (a minute a day) and/or fill out (digital) questionnaires.
3) Not agreeing to participate in the evaluations and/or to the use of the related data, and/or to sign for informed consent to use the data from the Goings-On app for this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
We intend to publish the metadata of the study in Tilburg University Dataverse and will employ Data Documentation Initiative (DDI) as the metadata standard for the quantitative and qualitative datasets.

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9256
Other	METC Brabant : METC NW2020-79

Study results