Development of a questionnaire to measure instrumental activities of daily living (I-ADL) in patients with brain tumors

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Primary Objective: The overall aim of this study is to develop a reliable and valid IADL questionnaire for use in brain tumor patients. Parallel versions of this questionnaire will be developed; a patient-based version and a proxy-based version....

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

Summary

ID

NL-OMON44942

Source
ToetsingOnline

Brief title
Measuring IADL in patients with brain tumors

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Brain tumor, primary brain tumor (glioma) and metastatic brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: European Organization for Research and Treatment (EORTC) Quality of Life Group

Intervention

Keyword: - Brain tumor, - Instrumental Activities of Daily Living, - psychometric properties

Outcome measures

Primary outcome

Pilot study

Study parameters including:

- Item selection and generation, resulting in a provisional item list to measure IADL in patients with a brain tumor.

Main study

Study parameters including:

- Item selection and generation, resulting in an item list that will be pre-tested and field tested for psychometric properties, acceptability and cross-cultural applicability in a large international population of brain tumor patients.
- Psychometric properties (of both versions of the questionnaire) such as validity, reliability and responsiveness.
- Measures of agreement between patient and proxy ratings.

Secondary outcome

Pilot study

Baseline characteristics including:

- Patient: age, gender, level of education, tumor type and grade, Karnofsky

Performance Score (KPS), cognitive functioning (if available), date of diagnosis, treatment.

- Proxy: age, gender, level of education, relation to the patient, duration relationship, intensity of contact with the patient.

Main study

Baseline characteristics including:

- Patient: age, gender, level of education, Karnofsky Performance Score (KPS), cognitive functioning (if available), status disease, current treatment, previous treatments,

Specifically for primary brain tumor: tumor type and grade, date of diagnosis, date of recurrence, and for metastatic brain tumor: number of metastases, type of primary tumor, date of diagnosis primary tumor and date of diagnosis brain metastasis.

- Proxy: age, gender, level of education, relation to the patient, duration relationship, intensity of contact with the patient.

Study description

Background summary

Traditional outcome measures used in clinical trials in brain tumor patients (both primary and metastatic) are progression-free and overall survival, next to tumor response on magnetic resonance imaging (MRI). Apart from these outcomes, information on the patient*s functioning and wellbeing has become increasingly important, since in patients who cannot be cured from their disease, the quality of survival is arguably at least as important as the duration of survival.

One way to measure patients* functioning and well-being is with the assessment of a patient*s health-related quality of life (HRQOL). HRQOL is a multidimensional concept covering physical, psychological and social domains, as well as symptoms induced by the disease and its treatment. In addition, measurement of cognitive functioning is nowadays used to objectively assess how the brain tumor patient is doing. Although HRQOL and cognitive functioning are relevant outcome measures in brain tumor patients, these do not provide the complete picture on the patient*s functioning in daily life. HRQOL covers a wide range of domains, but it does not cover activities of daily living (ADL). Moreover, cognitive dysfunction as measured with validated tests, is not easily translated into the patient*s functioning in everyday life. Therefore, an additional measure specifically aimed at measuring ADL is needed.

ADL are divided into two categories, basic activities of daily living (BADL) and instrumental activities of daily living (IADL). BADL include basic skills such as feeding, bathing, dressing, transferring, toileting and continence. IADL on the other hand, include more complex activities such as food preparation, ability to handle finances, shopping, doing laundry, housekeeping, mode of transportation, responsibility for own medication, or using a telephone. These capacities are required for autonomous function within in the society. Because IADL are higher order activities, they may therefore be negatively influenced by a cognitive decline, which is characteristic for brain tumor patients. Therefore, especially limitations in these IADL are informative of the brain tumor patient*s functioning in daily life.

Commonly used ADL scales and questionnaires in brain tumor patients such as the Barthel Index (BI), Karnofsky Performance Score (KPS), Functional Independence Measure (FIM) and the Functional Independence Measure - Functional Assessment Measure (FIM-FAM) only cover BADL and not IADL. Even though the FIM assesses whether there are problems in communication or social cognition, which involve higher order activities, it is not assessed whether this has an influence on activities of daily living. Moreover, these questionnaires have several other limitations, because they were mostly developed in the late 1950s, with more recent revisions in the early 1990s. First of all, advances in technology have changed our daily environment dramatically (for example the use of mobile phones, computers and household appliances). Secondly, quality demands of self-report questionnaires have changed in the meantime. Although most psychometric properties, in terms of reliability and validity, of the questionnaires have shown to be adequate, there are also some limitations. For example, the BI has marked floor- and ceiling effects, potentially limiting its responsiveness to change. It thus seems that there is a need for a new questionnaire, with superior psychometric properties, to measure IADL in patients with brain tumors.

Although there is consensus that patients are the best source to rate their functioning and well-being, proxy ratings should be considered as a potentially appropriate alternative in brain tumor research because proxies might better

judge the patients* functioning in those situations where patients are cognitively impaired or have a very poor health status. Since proxies are often involved in the care of a patient, they have a good picture of the patients* functioning and well-being. Proxy measures could therefore complement or substitute patient self-assessment. In these cases, differences between patient and proxy ratings do not necessarily reflect inaccuracy. However, to date it is unknown if brain tumor patients are able to accurately estimate their own functioning. Therefore, the aim of this study is to develop parallel versions of this IADL questionnaire for brain tumor patients; a patient-based version and a proxy-based version.

Study objective

Primary Objective:
The overall aim of this study is to develop a reliable and valid IADL questionnaire for use in brain tumor patients.
Parallel versions of this questionnaire will be developed; a patient-based version and a proxy-based version.

Secondary Objective:
To determine to what extent patient and proxy ratings on IADL differ. Based on this result, it can be determined if proxy measures are an appropriate alternative in cases where the patient is unable to complete the questionnaire (for example due to cognitive impairments or a poor health status). If appropriate, questionnaires completed by the partner will be used instead of the questionnaires completed by the patient.

Study design

Pilot study
Recently, a new proxy-based questionnaire was developed and validated to measure problems in IADL in patients with early dementia. This questionnaire was developed as a proxy-based questionnaire, because it is known that patients with early dementia are not able to accurately estimate their own functioning. The Amsterdam IADL Questionnaire® consists of 70 items which are divided into 7 different categories; (1) household activities, (2) household appliances, (3) finances, (4) work, (5) computer, (6) appliances, and (7) leisure activities. This questionnaire was developed with input from patients, proxies and professional experts. It was shown that the questionnaire had favorable psychometric properties.
Because there is no gold standard to measure IADL in brain tumor patients, and because of the state-of-the-art properties and the expected similarities in problems in IADL between both patients with dementia and brain tumors, we will evaluate in a pilot study if this questionnaire is also appropriate for brain tumor patients.
First, the items used in the Amsterdam IADL Questionnaire® will be

re-evaluated; it will be established whether these items measure activities that are relevant for brain tumor patients. In addition, new items will be generated. The objective of this pilot study is to develop a new set of items measuring instrumental activities of daily life that are relevant for patients with a brain tumor.
The methods used in this study will resemble the methods that were originally used for the development of the Amsterdam IADL Questionnaire in dementia patients.

Step 1: Evaluation of the activities in the Amsterdam IADL questionnaire®
Ten patients with a primary brain tumor and their proxies (total n = 2 x 10 = 20) as well as professional experts (n=6; 2 neuro-oncologists, 2 specialised neuro-oncology research nurses and 2 neuropsychologists) will be consulted to select the relevant and useful items, which are now used in the Amsterdam IADL Questionnaire. When selecting the items, professional experts should keep in mind three questions; (1) is the activity considered as IADL using the proposed definition (=IADL are complex activities with little automated skills for which multiple cognitive processes are necessary), (2) is the activity likely to be affected in primary brain tumor patients, and (3) is the item clearly defined and formulated? Patients and their proxies only need to answer two questions; (1) is the activity affected during the disease course, and (2) is the activity clearly formulated?

Step 2: Generating new IADL activities
Next, the same experts (n = 6) and another group of patients and their proxies (total n = 2 x 5 = 10) will be consulted to explore activities affected in patients with a primary brain tumor which are not mentioned in the existing Amsterdam IADL Questionnaire®. To do so, in-depth interviews will be conducted using the *sampling to redundancy* criterion, which means that persons will be interviewed until no new themes emerge.

Step 3: Cognitive debriefing
Based on the results obtained in these first two steps, a new set of items will be created that is believed to measure IADL in patients with brain tumors. Then, a new group of patients/proxies will cognitively debriefe this new questionnaire. This group, consisting of 6 brain tumor patients and their proxies (total n = 2 x 6 = 12) will be requested to complete the questionnaire while thinking out loud. With this technique it can be tested whether all questions are interpreted as intended. Ambiguous or incomprehensible questions will be rephrased or omitted from the questionnaire.

This pilot study results in a provisional item list that will be further explored in the main study.

Main study
Phase I: Generation of items

Whether the list of issues identified in the pilot study is sufficient and appropriate for international use remains to be determined. Therefore, the aim of this phase is to extend the work of the pilot study and to compile an exhaustive list of items that measure I-ADL relevant to brain tumor patients (to ensure content validity) in several European countries (Austria, Italy, United Kingdom). Therefore, four sources of information are used in phase I: (1) literature, (2) provisional list of items pilot study, (3) patients and their proxies and (4) health care professionals (HCPs).

Step 1: Literature review
A systematic literature review will be conducted to identify all relevant I-ADL for brain tumor patients, by searching several databases such as PubMed, Embase and PsycInfo. In addition, other sources such as the Quality of Life Group (QLG) item bank (especially role functioning items) and PROQOLID will be searched to identify existing, relevant issues. This search will result in an exhaustive list of relevant I-ADL which will be used to add new issues to the current provisional list of items, or to replace or rephrase inadequate items that are already in the list.

Step 2: Review of current provisional list of items
Twelve patients and their proxies (4 patient-proxy dyads per country; 2 primary and 2 metastatic brain tumor patients), as well as six HCPs (2 per country), will be recruited to review the provisional list of 38 items measuring I-ADL in brain tumor patients. Participants are asked to answer two questions: (1) is the activity likely to be affected in brain tumor patients? and (2) is the item clearly defined and formulated? Moreover, HCPs will answer one additional question: is the activity considered as I-ADL using the proposed?

Step 3: Patient and proxy interviews
Semi-structured interviews will be conducted with 30 (5 interviews * 2 tumor types (primary brain tumor or metastatic brain tumor) * 3 geographical regions) brain tumor patients attending hospital outpatient clinics, and their proxies, to explore all I-ADL affected in brain tumor patients. First, participants will be asked to answer an open question about problems with activities in daily living. Next, participants will be asked to review all activities revealed in the literature search and from the pilot study, and to identify activities that are currently missing. The interview will continue until no new activities arise. Lastly, patients and proxies will be asked to indicate the relevance and importance to their own situation of all these activities on a 4-point Likert scale.

Step 4: Health care professional interviews
Semi-structured interviews will also be conducted with 18 HCPs (2 neuro-oncologists, 2 specialised neuro-oncology research nurses and 2 neuropsychologists per region * 3 geographical regions) in order to explore activities affected in brain tumor patients. HCPs will be asked to indicate if (1) the activities included are considered relevant for this patient group and

(2) if there are missing activities that are considered to be relevant. When HCPs mention that there are irrelevant or missing activities, they should provide a reason. Moreover, HCPs will be asked to identify the 10 activities that mostly determine patients* functioning in daily living and should definitely be included in the final questionnaire.

Step 5: Synthesis
The list of issues from all sources will be reviewed to produce a single, comprehensive list of issues for formulation into the draft questionnaire (in all languages) in phase II. Prior to item selection, specific decision rules will be selected from the available EORTC QLG decision rules.

Step 6: Cognitive debriefing
In another 12 patients and their proxies (4 patient-proxy dyads per country; 2 primary and 2 metastatic brain tumor patients), a debriefing interview will be conducted: the list of issues will be discussed while the participants is asked to think aloud. This may be useful to refine items and avoid ambiguity or other difficulties in the final provisional list.

Phase II: Construction of the item list
The aim of this phase is to construct a draft I*ADL questionnaire resulting from issues identified in phase I. To do so, the list of relevant I*ADL issues will be converted into questions which should be clear, brief and unambiguous. Also, it will be explored if forming multiple item scales is feasible by grouping several items with similar constructs, based on both empirical and conceptual research data. Two versions of the draft questionnaire will be developed: a patient*based version and a proxy*based version. Translations of all questions will be carried out following the European Organistaion of Research and Treatment (EORTC) Quality of Life Group Guidelines for Developing Questionnaire Modules.
Similar to the EORTC QLQ*C30 questionnaire, a 4*point Likert scale will be applied (ranging from *not at all* to *very much*) to assess difficulties in performing the specified activities. In addition to this traditional scoring system, we will add one option (*not applicable*) to each question to account for the fact that some activities are never performed by patients (for example, working). We will do this instead of using conditional questions to lower the response burden. Moreover, questions will refer to the patient*s experience during the past month, because many problems are unlikely to be captured within a one week timeframe.
Lastly, two HCPs who were not involved in the first phase of this study will be consulted to review all items for overlap and clarity.

Phase III: Pre-testing
In phase III, the resulting draft I*ADL questionnaire will be pre*tested in at least 6 countries in 4 main European regions and non-European country (United Kingdom, The Netherlands, Austria, Italy, Poland and Japan. The primary aim of pretesting the questionnaire is to identify and solve potential problems

(phrasing, sequence questions) and to identify missing or redundant questions. Second, preliminary psychometric testing will be performed.
The questionnaire will be administered to brain tumor patients (patient*based version) and their proxies (proxy*based version) who were not involved in the first phase of the project. In addition to completing the questionnaire, respondents will be asked to rate each item on relevance and importance on a 4* point Likert*type scale. Moreover, structured interviews with patients and proxies will be conducted after completion of the questionnaire to determine if the questionnaire is complete and if the questions are acceptable (not too difficult, confusing or upsetting). Finally, both patients and proxies have to indicate 10 items they deem the most important to get insight into which items should be maintained and which might be redundant. Approximately 144 patients (and their proxies) will be recruited in total (24 patients per country).
Patients will be stratified on two important parameters: tumor type (primary or metastatic) and grade (grade II or grade III/IV), and presence of cognitive deficits (present/not present). These cognitive deficits need to be established by objective neuropsychological testing (patients only) and scores will be compared to norm population.

Phase IV: Field testing
The questionnaire and its scale structure will be field-tested in a large, international group of patients in order to determine its acceptability, reliability, validity, responsiveness and cross-cultural applicability. The same 6 countries as in phase III and possibly a 7th country (Croatia) will participate in this phase.
The questionnaire will be filled in by the patients (patient-based version) and the proxies (proxy-based version), which will be followed by the completion of a debriefing questionnaire by each participant to determine the acceptability of the questionnaire. The debriefing questionnaire comprises the following questions: (1) How long did it take you to complete the questionnaire?, (2) Did anyone help you to complete the questionnaire and, if so, what kind of help and how much help was provided?, (3) Were there questions that you found confusing or difficult to answer?, (4) Were there questions that you found upsetting? and (5) Please use the space below if you have other comments about the questionnaire.In addition, patients will also be asked to fill in the Barthel Index (BI) (10 items) and the Medical Outcomes Study Cognitive Functioning Scale (MOS Cog-R) (6 items), necessary for the known* group comparison analyses.
To determine several aspects of reliability and responsiveness, both patients and proxies are requested to complete the all three questionnaires again after approximately two weeks and 3 months.
Lastly, the congruence between patient and proxy rating will be determined. The number of patients and proxies recruited in this phase will be based on the number of items in the questionnaire. We aim to recruit a minimum of 10 patients and their proxies per item in the IADL questionnaire, resulting in a few hundred patients and proxies. Selection of patients should represent the target population. We therefore aim to include patients with primary (both low

and high grade gliomas) and metastatic (both 1-3 and >3 metastases) brain tumors, with and without cognitive deficits and in different stages of their disease and in different treatment stages. This will ensure generalizability of the questionnaire.

Study burden and risks

There are no direct benefits for patients and proxies participating in this study. Nevertheless, their participation will contribute to the development of a valid and reliable questionnaire to measure functioning in daily living of patients with primary brain tumors. Eventually, this questionnaire can be used in clinical trials and also in daily clinical practice. Results of the questionnaire may facilitate treatment decision-making by informing physicians about the value and impact of a specific treatment strategy and it may provide the physician with additional information on the patients* well-being which facilitates communication between the physician and the patient.

On the other hand, participation in this study has possible risks for the patients and their proxies. Patients and proxies are confronted with all problems that the brain tumor patients have with functioning in daily living, which may pose a little psychological burden on them. Moreover, it will cost the patients and proxies time to attend the interviews and complete the questionnaires, although this is expected not to be substantial. Previous experience with the Amsterdam IADL Questionnaire showed limited respondent burden.
The exact burden for patients/proxies depends on the phase of the study. In phase I (generation of items) interviews will be conducted at sereval steps each with new participants. A session will last for approximately 60-90 minutes. Participants in phase III (pre-testing) are requested to complete the questionnaire, they will be interviewed and undergo a neuropsychological assessment. In total this will take approximately 120 minutes. Participants in phase IV (field testing) are requested to complete the questionnaire three times over a period of 3 months (baseline, after 2 weeks and after 3 months). Completing the questionnaire will probably take about 25 minutes. No session will take more than 120 minutes, the respondent burden seems therefore relatively low.

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

Pilot study
(1) Adults; patients and their proxies must be over 18 years.
(2) Patients with histologically confirmed low- or high-grade glioma; WHO grade II diffuse astrocytoma, oligodendroglioma or oligoastrocytoma, WHO grade III anaplastic astrocytoma, anaplastic oligodendroglioma or anaplastic oligoastrocytoma, or WHO grade IV glioblastoma, and their proxies.
(3) The intensity of contact of the proxy with the patient should be in such a way that the proxy clearly knows how the patient is functioning in daily life (daily or weekly contact).;Main study
(1) Adults; patients and their proxies must be over 18 years.
(2) a. Patients with histologically confirmed low- or high-grade glioma; WHO grade II diffuse astrocytoma, oligodendroglioma or oligoastrocytoma, WHO grade III anaplastic astrocytoma, anaplastic oligodendroglioma or anaplastic oligoastrocytoma, or WHO grade IV glioblastoma, and their proxies.
b. Patients with a metastatic brain tumor and a histologically confirmed primary tumor, and their proxies.
(3) The intensity of contact of the proxy with the patient should be in such a way that the proxy clearly knows how the patient is functioning in daily life (daily or weekly contact).

Exclusion criteria

Main study
(1) Patients and proxies without understanding of the official language of the country in which they live.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	27-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2017
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2020
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	NL45243.029.13