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**Ongoing Trials: Interview with
Florien Boele, MSc, and Martin
Klein, MD, VU University Medical
Center, Amsterdam, about the
Randomised Trial on Internet-Based
Treatment of Depressive Symptoms in
Glioma Patients**

Abacioglu U

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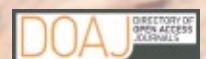


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Interview with Florian Boele, MSc, and Martin Klein, MD, VU University Medical Center, Amsterdam, about the Randomised Trial on Internet-Based Treatment of Depressive Symptoms in Glioma Patients

Ufuk Abacioglu

From the Department of Radiation Oncology, Neolife Medical Center, Istanbul, Turkey

Q: Dear Florian Boele, can you tell us about the ongoing randomised trial on internet-based treatment of depressive symptoms in glioma patients? What are the rationale and background for this trial?

A: Certainly! This project, funded by the Dutch Cancer Society, aims at the development of an internet-based intervention for glioma patients with mild-to-moderate depression. Glioma patients are at an increased risk for depression compared with both the general population and other oncological populations. This may affect brain tumour patients negatively, as in this population, depression has been associated with increased morbidity, poorer survival, and poorer health-related quality of life.

While depression is potentially treatable, depressive symptoms are often overlooked in clinical practice and subsequently undertreated. In addition, standard treatment of depression (antidepressants and/or cognitive behavioural therapy) may encounter specific problems in glioma patients. Glioma patients often take many medications concurrently, which increases the risk for drug interactions. Moreover, psychotherapy usually requires good cognitive functioning in order for the patient to benefit most, while many glioma patients experience cognitive deficits. Therefore, it remains to be determined if either antidepressants or psychotherapy are as effective in glioma patients as they are in the general population and other oncological populations. We want to make an effort in filling this gap in the literature by evaluating the effectiveness of a short, online problem-solving therapy – a form of cognitive behavioural therapy.

This type of intervention has already been proven effective in treating symptoms of depression in the general population. We believe that a problem-solving therapy may be particularly suitable for glioma patients as it is a brief (5 weeks) and practical approach. Moreover, because patients can access the intervention through the internet at any place and at any time, the threshold for participation is low.

Q: What are the objectives of this interesting trial?

A: Our primary goal evidently is to decrease depressive symptoms. Secondary outcome measures include health-related quality of life, fatigue, and patient satisfaction with the intervention offered. We also enquire after health care utilisation and loss of productivity to make an estimation of the cost-effectiveness of the intervention in economical terms.

Q: What is the study population and which patient groups are in the 3 arms?

A: We include adult glioma patients (WHO grade II, III, or IV) with an estimated life expectancy > 3 months who have mild-to-moderate depressive symptoms. Patients are excluded if they have suicidal intent, if they have insufficient mastery of the Dutch language, and if they do not have access to the internet and an e-mail address.

We hope to include 126 glioma patients in total. 63 patients will be randomly assigned to the intervention group – they can start the online therapy straight away. Another 63 will be randomly assigned to a waiting-list control group – they can start online therapy after a waiting period of 3 months. In this way, we can evaluate the effectiveness of the intervention compared with standard care.

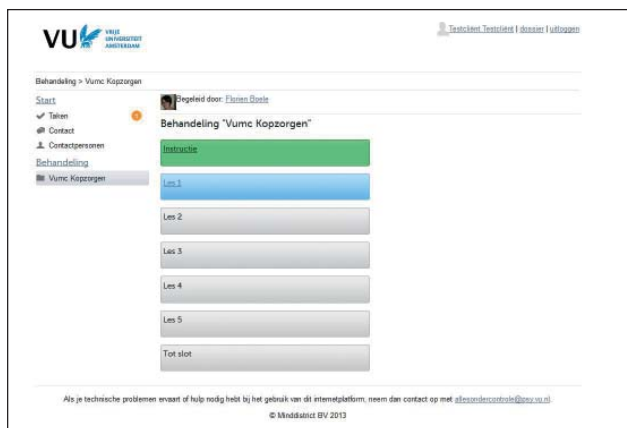
In addition, we hope to include 63 patients with haematological malignancies not involving the central nervous system who are also mildly-to-moderately depressed. They can participate in the intervention straight away. This extra control group will enable us to investigate whether the intervention is equally effective in patients with central nervous system disease and those with other malignancies and a comparable prognosis.

Q: Which scales do you use to assess the patients' psychological status?

A: The Center for Epidemiological Studies Depression Scale (CES-D) will be used to assess depressive symptoms. During our screening process, we also evaluate suicidal ideation with the Beck Scale for Suicide Ideation (BSS) and we exclude patients who may have suicidal intent. They are subsequently referred to their general physicians.

Q: What types of interventions are performed when a patient is diagnosed as having depressive symptoms in the trial?

A: The intervention is an adapted version of “Everything Under Control”, which has been shown effective in improving depression, anxiety, and stress/burnout in the general population [1]. The original intervention has been adapted to suit patients with brain tumours: additional information about the disease and treatment and its psychological impact on daily life has been included, and examples of the assignments have been made disease-specific. The highly structured intervention protocol includes 5 modules with texts and exercises. During the online course, patients define what is important in their lives. They also make a list of their problems and concerns, and they identify whether or not these are related to what they feel is truly important. Problems are then divided into 3 distinct categories: unim-



An overview of the online course as a participant will see it. Completed modules will turn green, active modules are blue. With kind permission from Minddistrict BV.

portant problems, problems that are important, but solvable, and problems that are important, but unsolvable. For each of these problems, patients make a plan on how to cope with them, guided by methods explained in the modules. During the intervention, a personal coach provides feedback on the completed assignments. The coach (either myself or trained and supervised Master students) only supports the patient in working through the intervention, but does not provide additional therapy.

Q: *Is this a nationwide study in the Netherlands? Which groups and how many centres participate in the trial?*

A: Yes, I am happy to say it is. The Dutch Society for Neuro-Oncology supports our trial, as do various patient organisations and 17 hospitals throughout the Netherlands. We are very grateful for their support and their efforts in informing patients about our trial.

Q: *What is the extent of burden and risks associated with participation?*

A: During the intervention, the participants are to spend about 3 hours a week on the assignments. This means a total of 15 hours for the entire intervention. Additionally, 4 extra hours will be reserved for completing the questionnaires during the pre- and post-assessments. The risks of participation in this study are negligible. The control group of glioma patients who do not receive the intervention immediately might be made more aware of their depressive symptoms because of the questionnaires they are asked to complete. However, we keep track of their CES-D and BSS scores. This way, we can monitor whether or not their depressive symptoms worsen, in which case we will contact their respective physicians.

Q: *How is the recruitment and when do you expect to reach the accrual goal? When can we get the first results?*

A: As in most randomised controlled trials on treating psychological symptoms, accrual is progressing slowly. So far, we have received 188 completed depression screening questionnaires, which equals an estimated 5–10 % of the patients who received our information brochure. So far, we have included 77 glioma patients and 18 patients with a haematological malignancy. Efforts to improve accrual are still ongoing, and we



The research team: Martin Klein (left) and Jaap Reijneveld (right) standing in the back, Florian Boele (left) and Irma Verdonck-de Leeuw (right).

will continue to include patients until May 2015. Our data collection will subsequently be completed in August 2016, but we hope to report on the short-term effects of the intervention around December 2015. In the meantime, we would be more than happy to share our knowledge and experience with those who are interested in initiating comparable studies in this exciting field of research.

Thank you very much!

Reference:

1. van Straten A, Cuijpers P, Smits N. Effectiveness of a web-based self-help intervention for symptoms of depression, anxiety, and stress: randomized controlled trial. *J Med Internet Res* 2008; 10: e7.

Florien Boele, MSc, is the study coordinator and Dr Martin Klein is the principal investigator of the trial with the working title “Internet-based treatment of depressive symptoms in patients with tumours inside or outside of the central nervous system”.

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