in Assoziation mit dem Institut für klinische Neuroimmunologie und dem Institut für Schlaganfall- und Demenzforschung

30.03.2025

Introvision in Migraine – IntroMig

NCT03507400

(Patient Label)

PATIENT INFORMATION and DECLARATION of CONSENT

Introvision in Migraine - Intromig

Contact of the principal investigator:

Dr. med. Monika Empl, Department of Neurology, Department of Neurology, Hospital of the Ludwig-Maximilians-University (LMU) Munich - Großhadern, Marchioninistraße 15, 81377 Munic, Tel.: 089 4400 73906, E-mail: monika.empl@med.uni-muenchen.de

Dear Patient,

You were asked by your doctor to participate in a scientific study on the efficacy of Introvision, a mental self-regulation technique, in migraine and headaches. This study is carried out at Department of Neurology, Hospital of the Ludwig-Maximilians-University (LMU) Munich - Großhadern in cooperation with the University of Hamburg.

This written information is provided in connection with a detailed oral explanation. Your participation in this study is voluntary. Before you decide to agree to participate, it is important that you have fully understood the nature and the course of the study and that you have been informed of your rights. Please do not hesitate to contact one of the doctors listed below for any ambiguity or additional questions.

1. Why is this study carried out?

Stress is a well-known trigger of migraine attacks and headaches. Relaxation procedures such as the progressive muscle relaxation according to Jacobson or biofeedback are recognized therapies for non-drug treatment in migraines and headaches. However, these procedures are not effective in all patients and may reduce stress, but do not solve the cause of stress.
Introvision is a mental self-regulation technique, to reduce and eventually dissolve internal conflicts and blockages, which are often the cause of stress, by means of a mindfulness technique. Introvision has so far been tested on patients with neck tension and tinnitus, but not yet in headache patients. It is to be examined whether this therapy, which is not based on medication, is able to improve migraine or headache.

2. What is covered or investigated in this study?

This study investigates whether Introvision is effective in the treatment of migraines/headaches (Intromig: Introvision in migraine). Patients are assigned at random to the treatment group without waiting time or the control group with a waiting period of at least 6 weeks. When you participate in the study you will attend 6 group sessions to learn the technique of „Konstatierend Aufmerksames Wahrnehmen“ (KAW) (Descriptive attentive perceiving) required for the Introvision and learn more about the Introvision. If you are in the control group, the courses will start at least 6 weeks after the non-waiting group. The KAW is similar to mindfulness exercises. Then you obtain 3 individual sessions from experienced instructors of Introvision, via video conference (Skype) from Hamburg to dissolve your mental blockages. You will be asked to keep a headache diary during the entire study period, in which you document the headaches and

headache strength and the frequency of the exercises in addition to the days with medication againgst headaches. You will also be asked to fill out questionnaires at the beginning of the study, before the 3 individual sessions, after the 3 individual sessions and 3 months after the Introvision sessions, among others on the impact of the headache on your life (HIT-6 test), your mood (BDI-FS), the frequency of KAW exercises, and the changes experienced by the Introvision (Headache Management Self-Efficacy Scale (HMSE-G-SFquestionnaire) as well as the overall satisfaction with the treatment. For the HIT-6 test you need about 5-8 minutes to complete, for the BDI-FS approx. 5 minutes, for the HMSE-G-SFquestionnaire about 5 minutes, for the frequency of the KAW exercises 1 minute as well as for the assessment of overall satisfaction.
Your participation is not associated with any additional examinations and sample withdrawals, and therefore no health risks.
This study project was reviewed by an independent ethics committee and received a positive ethical vote (= consent).

3. What personal benefits or risks do you have due to your participation in this study?

Learning the KAW technique for Introvision and the guided Introvision can have a positive effect on your stress level and possibly reduce the frequency and/or intensity of the headache and thus benefit you directly.

In the case of a positive outcome of the study with proof of efficacy for migraine and headaches, Introvision may become accessible to a larger group of people.

The participation in the study is not associated with any health risks. You will not incur additional charges, costs or visits to the doctor by participating in the study except for the time required for the documentation and meetings. Financial compensation for participation in this study is not foreseen. A fault-independent insurance was not concluded.

4. Can participation in this study be terminated at any time?

Participation in this scientific examination is voluntary and requires your written consent. You can cancel your participation at any time without giving any reason. In this case, all data already collected would be deleted and the questionnaires or the headache diary would be disposed of according to data protection regulations. As a result, this decision has no adverse consequences, nor does it damage the trustful relationship between you and your doctors. Please inform the doctors mentioned below in writing about this decision.
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5. What happens to the collected data?

The collected data will be handled strictly confidentially. The study complies with the rules on medical confidentiality and data protection. Personal data and findings about you are collected, stored and always transmitted encrypted (pseudonymisised), i.e. neither your name nor your initials nor your birth date appear in the pseudonym (= encryption code). The encryption is done by a sequential series of numbers, which is created according to the order of the study entry. Access to the encryption code is limited to the heads of the study: Dr. Monika Empl and Prof. Dr. Andreas Straube.

The documents will be kept in our clinic until completion and final evaluation (three years from the beginning of the study). In the case of publications of the study results, the confidentiality of the personal data is guaranteed.

Thank you for your help with this research project!

6. Who can you contact if you have further question?

If you have any further questions, please contact the physicians responsible for the study:

Dr. med. Monika Empl, Prof. Dr. med. Andreas Straube, Department of Neurology

Hospital of the Ludwig-Maximilians-University (LMU) Munich - Großhadern

Telephone: 089-4400-0

E-mail-adresses: monika.empl@med.uni-muenchen.de

Andreas.Straube@med.uni-muenchen.de

Declaration of consent

I have received and read the patient information; I have also been informed orally. All my questions were answered. I declare that

I agree with participating in the study Introvision in migraines and headaches – Intromig. I can revoke my consent at any time without giving any reason.

Date*		Signature of the patient	

* The date must be entered by the person himself

Data Protection Declaration

I declare that

I have been informed that, in the course of the study, personal data, mainly medical findings, are recorded on electronic data carriers and, after an encryption (pseudonymation) which does not allow any inferences to my identity, stored and evaluated. If the data is used for a publication, then no inference is possible.

I have been informed that I can revoke the consent at any time without giving any reason and that the data collected will be destroyed.

With my signature I declare that I agree with the collection and use of personal data and results data in accordance with the patient information.

Date*		Signature of the patient	

* The date must be entered by the person himself

Date		Doctor's signature	