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Neurologische Klinik und Poliklinik
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In Assoziation mit dem
Institut für Klinische Neuroimmunologie und dem
Institut für Schlaganfall- und Demenzforschung

Ludwig Maximilians Universität München

LMU

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Introvision in Migraine – IntroMig

NCT03507400

1 Study Protocol

1.1 Research Project

Introvision in Migraine - IntroMig

Clinical Trials Number

NCT03507400

Proposers

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1. 1. Hypothesis

Is Introvision, a technique to reduce stress, effective in reducing the number of headache days per month in patients with episodic migraine (diagnosed according to IHS 3 beta), episodic migraine and episodic tension type headache or chronic migraine 3 months after Introvision (primary outcome measure) compared to the waiting list group. Secondary outcome measures are efficacy in reduction of headache intensity, acute medication, impact of headache (headache impact test -6; HIT-6) and patients‘ overall satisfaction with treatment. Do patients improve in headache self-efficacy, measured with the Headache Management Self-Efficacy Scale Short Form (HMSE-G-SF).

2. Study type

monozentric randomized waiting-list-control study (‚investigator-driven').

3. 3. Study design and discussion of ethic-legal issues

Inclusion criteria:

1. minimum age is 18 years
2. episodic migraine (at least 5 headache days per month), episodic migraine and episodic tension type headaceh (at least 5 migrainous headache days) or chronic migraine (more than 15 headache days per month, out of which at least 8 migrainous headache days for three months), diagnosed according to IHS 3 beta.
3. stable headache-preventative medication
4. stable non-medication preventative measures (for instance regular sports)
5. written informed consent

Exclusion criteria:

1. other symptomatic headaches
2. other primary headaches (Cluster headache, trigeminal neuralgia, idiopathic facial pain, new daily persistent headache)
3. manifest severe depression (BDI-FS > 13 points)
4. drug- or alcohol abuse
5. non-compliance, especially missing entries in the headache diaries
6. active psychosis

For the study, the following data are collected:

- last name, first name, date of birth, age, sex of the patients
- number and intensity of headache days per month, documented in headache diary
- number of days with acute medication against headaches
- Beck-Depression-Inventory: Fast-Screen to document mood
- Headache Management Self-Efficacy Scale Short Form (HMSE-G-SF)
- number of KAW-exercises per week (0-1, 1-3, >3)
- patients‘ global satisfaction with treatment
- HIT-6 questionaire (Headache-Impact-Test) to measure impact of headaches.

According to our previous experience with comparable study designs, we do not expect any lasting psychological stress for the subjects. There are no risks to the physical health of the subjects.

No additional investigations are needed for the study.

Due to the above-mentioned apects no serious adverse events are to be expected. In case of serious adverse events both the director of the clinic as well as the ethics committee will be informed immediately.

4. 4. Ability to agree

The study includes only patients who can decide on their own to participate in the study. Only patients with a minimum age of 18 years will be included. Patients are informed in detail in writing and orally about aims and procedure oft he study. The written information of the study as well as the form for the Declaration of consent are attached to this proposal.

5. 5. Remuneration of subjects and patients, additional costs, insurance

There is no remuneration for participants. Secondary costs due to additional diagnostics or a prolonged hospital stay are not to be expected.

Dr. Monika Empl trains as certified instructor of Introvision, to be able to teach Introvision to study participants. There is no separate remuneration for the investigator, however, if a sponsor is found, an allowance (also for travelling expenses) is provided for the Introvision instructors as well as for the investigator. An enquiry for sponsorship will be sent to the Klaus-Grawe-Foundation, Zurich.

An insurance contract won't be effected, as in this research project no procedures with not very low risks for participants are planned. Study-related trips of the participants to the study are not insured. It is a therapy offer.

6. Data protection

The data protection of the participants is given highest priority: Only the most important personal data are collected (first name, last name, date of birth, age, sex). All collected data will be treated confidentially. They are stored or saved without a name or date of birth under a code number (pseudonymised). Material containing information about individual persons is locked and kept separate from the encoded data. Medical confidentiality and applicable data protection laws are respected. Data analysis is only be carried out by hospital staff, who are all subject to confidentiality. No individualized data will be passed on to a third party. Participants are informed about these procedure. The above mentioned points are explained in the patient information and in particular in the declaration of consent for data protection.

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