Test plan / study protocol

Therapy of Age-related Macular Degeneration Through Training With the Medical Eye Trainer

EK number: 1241/2021 KUK Linz

Data collection during ongoing therapy

Non-interventional study (NIS)

version 3, from 2022/01/22

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3. Short version of the project

With the Medical Eye Trainer (MET) training system, patients suffering from dry age-related macular degeneration (AMD) are treated as part of the clinical routine. The MET system is an application (software) for a standard multimedia device such as a smartphone or tabletC.omputer. The people affected by the disease treat themselves independently once a day for 90 seconds. The planned study will not introduce any new indications or therapynused. Only data from ongoing therapies are collectedt, around to check the effect of the treatment. It haturns around a Non-interventional study (NIS). It doesn't come to any sstudy-specific risk increase, since there are no study-related interventions that go beyond the clinicalhey routine.

4. Scientific background

4.1. General information

AMD is a disease of the eye that is widespread worldwide. According to the Gutenberg health study, around 7,000,000 people in Germany suffer from it. The figures for Austria can be assumed to be 700,000 due to the smaller population. A distinction is made between two forms of AMD, the wet form with 15% and the dry form with 85%. Both types have a high risk of developing significant visual impairment quickly. There are currently only a few therapeutic options for the dry form of the disease. Essentially, nutritional supplement therapy should be mentioned here. This treatment can only reduce the progression of deterioration in 10% of affected people, but it does have a significant side effect profile. This raises the question of completely different treatment approaches. Because of this, the**M.**edical **E.**ye **T**rainer (MET). This is a training device that can easily be used by yourself. The purpose of this new therapy is not to attempt to cure AMD. The eye and brain are trained to better deal with the disease. In a first study on 17 eyes, an improvement in visual performance could even be achieved in 11 cases, the remaining 6 cases showed a stable situation. In no case did it deteriorate. Thus it was possible for the first time not only to slow down this disease, but even to improve ithen. In a second study with a planned number of 150 examinations, this positive effect is to be investigated further. A calculation based on the results of the first study with G * Power gives an optimal number of 150 examinations.

4.2. Risk-benefit assessment

The MET system is in clinicalmStandard use. The patients are subjected to routine checks at the usual intervals. In the planned study there is only one data collection and evaluation. There is therefore no increase in risk. With this data evaluation, the effect of the therapy can be shown more precisely.

4.3. Examiner information

The information collected corresponds to the usual clinical control of the participants.

Only one examiner is planned for the study, so no special information transfer is necessary.

5. Study objective

5.1. aim

The study aims to determine the therapeutic effect of MET im Check ongoing use on the patient.

5.2. Study design

This observational study corresponds to a non-interventional study (NIS) and can therefore not be assigned to a normal phase of a study (I-IV).

The study is being carried out at a center.

5.3. Target parameters

5.3.1. Primary target point

Eyesight improvement

5.3.2. Secondary target point

Improving the quality of life through better handling of the disease.

6. Subject recruitment

6.1. Number of subjects and duration of the study

According to the results of the first study, the calculation with the G * Power system results in a number of 150 eyes. For the study, that number was doubled. The study is planned to last 6 months.

6.2. Selection of subjects

People who are already in therapy. can be taken into account in the data evaluation. In addition, the inclusion of additional test subjects is required. AroundTo keep the recruitment phase short, general practitioners will be informed of the possibility of referring their patients to the study.

6.3. Inclusion criteria

People with dry AMD are included regardless of age. Thus, this value is given as 20-99 years.

6.4. Exclusion criteria

Exclusion criteria are wet AMD, epilepsy and double vision. Other eye diseases are not a problemrepresent.

7. Medical examinations

7.1. Personal data

Only the age is recorded.

7.2. anamnese

Duration of illness, previous therapies.

7.3. Clinical examination

OCT, eyesight, eye status.

7.4. Measurement parameters

Eyesight, fundus.

7.5. type of application

Therapy will from the patient Carried out independently daily and takes 90 seconds per eye.

8. Treatment of the subjects

8.1. Admission to the study

All participants are informed about the study, effects, side effects and risks by means of an information sheet written for the study together with the supervising doctor. Consent is given by mutual signature with clarity and consent.

8.2. Hospitalization

no

8.3. Companion therapy

None

8.4. documentation

The encrypted data can only be viewed and further processed by the examiner. It'll be a complete oneA.nanonymization of the original data is carried out after the data collection has ended. The study will be athttps://clinicaltrials.govregistered and dealt with according to the specifications. These defaults are also used for the publication.

9. Course of studies

9.1. method

The participants will examined in the Ried im Innkreis hospital and treated with MET. Apart from the usual eye examinations for AMD, none are eligible for the studyzadditional measures necessary. An assessment of the fundus is also accompanied by a **O**ptical **C.**oherence **T**omography (OCT) confirmed the diagnosis. The visual performance for distance (5-6m) and for near (40cm) is determined as an essential factor in the development of the disease.
Participants need their own mobile electronic device with the Apple IOS® or Android® operating system. The MET training system in the form of software will be made available for the duration of the study. Therapy willfrom the patient Carried out independently daily and takes 90 seconds per eye. A success check is planned after two months. The above investigations are repeated here.In addition, the patients are asked about their condition.

9.2. Recording of compliance

By questioning

9.3. Risk-benefit assessment

The first study showed a 34% improvement in eyesight as a result of the therapy; there were no side effects or undesirable effects.

9.4. Unwanted results

By training kcanin rare cases dizziness or double vision are triggered. In previous studies in children it could be shown that these side effects reappear immediately after discontinuation of therapygo awayn. There were no side effects in the first study. The study will be carried out if any side effect occursen ended immediately.
The participant recognizes the side effects himself and is requested to stop the training immediately and contact the test center.

9.5. Control body

onGaround the studieconception nott provided.

9.6. Interim evaluation

Not provided.

9.7. Termination criteria

If undesirable results occur or at the request of the participants.

9.8. Abort the entiren study

For the good and in the interest of the test subjects, the investigator can terminate the study at any time if severe side effects or other unforeseeable circumstances occur. In this case, the ethics committee will be informed.

10. biometrics

10.1. Biometric authority and institution

Prof. Dr. Wolfgang Stürzlinger, VVISE LabD.irector, Simon Fraser University, BC Canada

10.2. Biometric design

Longitudinal comparison of the change

10.3. Sample planning

According to the results of the first study, the calculation with the G * Power system results in a number of 150 eyes. For the study, that number was doubled.

10.4. Data acquisition and evaluation

Entry in Libre Office spreadsheet ® Evaluation in PSPP ®.

10.5. Statistical Methods

T test, Wilcoxon, Smirnov

11. Changes to the study plan

Every change to the test plan must be added as an amendment to every test plan in circulation. All protocol changes must be reported to the ethics committee. In the case of changes to the study plan that are not exclusively of a formal nature and contain changes that are relevant to the test subject, a renewed vote of the ethics committee must be obtained. The patients / test persons must be informed of any changes to the study conditions as part of the information and consent. Any complications and serious adverse events in the course of the research project must be reported to the ethics committee immediately.

12. Ethical and Legal Issues

When carrying out the study, in addition to the Declaration of Helsinki (as amended), the following guidelines and laws must be observed:

Medical Devices Act (MPG)

12. Insurance

It is about eggno Non-interventional study (NIS). These studies were formerly known as the "Observatoryungen ". There was no study-specific increase in riskG, since there are no study-related interventions that go beyond clinical routine. No-fault insurance is taken out for the usual security and legal protection of employees.

13. Archiving and data protection

The anonymisierThe most recent data are archived and backed up in accordance with the General Data Protection Regulation.

14. literature

1. Effect of repetitive visual training in patients with dry age-related macular degeneration

To investigate the efficacy of repetitive visual training with large-field visual stimulation for patients with dry age-related macular degeneration (AMD).

Dr. Robert Hörantner, Jürgen Wolfsgruber, Gerald Stürzlinger... in *Spectrum of ophthalmology(2021)*

2. The Dry Form of Age-Related Macular Degeneration (AMD): The Current Concepts of Pathogenesis and Prospects for Treatment.

Zając-Pytrus HM, Pilecka A, Turno-Kręcicka A, Adamiec-Mroczek J, Misiuk-Hojło M.

Adv Clin Exp Med. 2015 Nov-Dec; 24 (6): 1099-104. doi: 10.17219 / acem / 27093.

3. Age-related macular degeneration therapy: a review.
Ammar MJ, Hsu J, Chiang A, Ho AC, Regillo CD.

Curr Opin Ophthalmol. 2020 May; 31 (3): 215-221. doi: 10.1097 / ICU.0000000000000657.PMID: 32205470