

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Effects of digital therapy support using the smartphone application "Migräne-App" (migraine app)

Trial Acronym

Migraine-App Study

URL of the trial

[---]*

Brief Summary in Lay Language

Tension type headache and migraine are - after dental caries - the second and third most prevalent diseases of mankind worldwide. The wide introduction of smartphones allows the use of specific software applications ("apps") for digital therapy support. The "Migräne-App" (migraine app) documents the course of migraine and headache with active data input. It reports back aggregated information from the data set and thereby helps both the patient as well as the treating physician in the verification of treatment success as well as in decisions about therapy adjustments. The migraine app contains reporting functions, an information section as well as self-help tools. In this study, the effects of using the "migraine app" in the practical treatment of migraine and headache patients are examined in a large cohort.

Brief Summary in Scientific Language

Tension type headache and migraine are - after dental caries - the second and third most prevalent diseases of mankind worldwide. The wide introduction of smartphones allows the use of specific software applications ("apps") for digital therapy support. The "Migräne-App" (migraine app) documents the course of migraine and headache with active data input. It reports back aggregated information from the data set and thereby helps both the patient as well as the treating physician in the verification of treatment success as well as in decisions about therapy adjustments. The migraine app contains reporting functions, an information section as well as self-help tools. In this study, the effects of using the "migraine app" in the practical treatment of migraine and headache patients are examined in a large cohort.

An online survey will be developed for the analysis of experiences of the digital therapy support. It contains questions concerning socio-demographic variables, the course of headache disorders, and the previous treatment as well as usage patterns of the migraine app. The survey establishes compliance to a) the recommended therapy, b) the treatment plan, and c) the therapeutic rules devised by the treating physician. The data collected will be compared to traditional pen-and-paper documentation, prior to using the migraine app.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

The datasets generated during and/or analyzed during the current study are available on reasonable request.

Organizational Data

- DRKS-ID: **DRKS00022946**
- Date of Registration in DRKS: **2020/08/26**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **D491/18 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **G43 - Migraine**
- ICD10: **G44.2 - Tension-type headache**

Interventions/Observational Groups

- Arm 1: **Use of "Migräne-App" (migraine-app)**
- Arm 2: **Previous analog headache calendar**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*

Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Non-randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Active control (effective treatment of control group)**
- Purpose: **Supportive care**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Headache days per month. The end point will be recorded comparing the traditional pen-and-paper documentation prior to using the migraine app with the migraine app use at the time of conducting the survey.

Secondary Outcome

Medication days per month. The end point will be recorded comparing the traditional pen-and-paper documentation prior to using the migraine app with the migraine app use at the time of conducting the survey.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Schmerzlinik Kiel, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/07/20**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

G43

G44.2

Use of Migraine-App

Exclusion criteria

none

Addresses

■ Primary Sponsor

Migräne- und Kopfschmerzstiftung gemeinnützige GmbH
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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2018/10/31**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.