

Trial Description

Title

Evaluation of gamification elements for neuropsychological therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the study is to explore the application of game elements in neuropsychological therapy, that is the rehabilitation of cognitive deficits after acquired brain lesions, e.g. memory impairments after stroke. After discharge from the clinic, patients often need to continue their cognitive training tasks at home. Usually, higher motivation and supportive information are needed when there is no longer a therapist available. Which aspect do motivate individuals to continue training? Is it the supply of strategies or rather game-like rewards? In order to explore the mechanisms of motivation, individuals with acquired brain lesion will have the opportunity to train 3 weeks of memory training on an online platform as often and as long as they want to. There will be 4 conditions with varying game elements added to the training program (with/without game elements added on the training tasks and on the online platform). After 3 weeks motivation of the subjects will be analyzed by comparing the number and duration of the training sessions as well as tests and questionnaires on demographic, etiologic and individual personality factors. We assume that more game elements lead to higher individual motivation and better performance in trained and non-trained tasks. In addition, individual experiences and motives as well as cognitive impairment may have an impact on motivation.

Brief Summary in Scientific Language

Frequent and regular cognitive training in inpatient and subsequently in out-patient rehabilitation is important for successful rehabilitation. In home training, patients need a high level of motivation and supportive information as they are no longer supervised by therapists at every session. The aim of this study is to evaluate the efficacy of various motivation strategies to improve neuropsychological therapy for individuals with acquired brain lesion who are undergoing cognitive rehabilitation. Two mechanisms to promote intrinsic motivation are examined: Game elements added in the training program itself and game elements added on the online platform. In addition, the influence of individual characteristics and motives will be explored. All subjects of this study will undergo 3 weeks of an efficient online memory training at home. The number and duration of training sessions can be chosen individually. There will be 4 training conditions with motivation being the varying factor (with/without game elements added on the training tasks and on the online platform). Primary Outcome is the intrinsic motivation induced by the training conditions operationalized by subjective enjoyment of the training program and the number

of individually chosen training sessions. Secondary outcomes are the performance in the trained task and non-trained standardized neuropsychological tests, demographic, etiologic and individual personality factors. The findings of this study will enable the targeted implementation of game elements according to individual motives and disease related characteristics in computer based cognitive rehabilitation.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017680**
- Date of Registration in DRKS: **2019/09/16**
- 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.: **297/19-ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **F06.7 - Mild cognitive disorder**

Interventions/Observational Groups

- Arm 1: **3 weeks of online computer based memory training at home (number and duration of individual choice), game elements are neither added in the training program nor on the online platform.**
- Arm 2: **3 weeks of online computer based memory training at home (number and duration of individual choice), game elements to promote intrinsic motivation are added on the online platform (e.g. avatar, pleasant feedback) but not in the training program.**
- Arm 3: **3 weeks of online computer based memory training at home (number and duration of individual choice), game elements to promote intrinsic motivation are added in the training program (e.g. memory strategies to**



improve competence, larger autonomy in the selection of tasks, integration of relatives to support social relatedness) but not on the online platform.

- Arm 4: **3 weeks of online computer based memory training at home (number and duration of individual choice), game elements to promote intrinsic motivation are added in the training program (e.g. memory strategies to improve competence, larger autonomy in the selection of tasks, integration of relatives to support social relatedness) and on the online platform (e.g. avatar, pleasant feedback).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary Outcome is the intrinsic motivation induced by the training conditions operationalized by a) subjective enjoyment of the training program (5-point Likert scale: "How much did you enjoy the sessions today?"), b) the number and duration of individually chosen training sessions.

Secondary Outcome

Secondary outcomes are: a) the performance in the trained task (e.g. number of correct answers), b) evaluation of subjective enjoyment and effort during the training sessions (5-point Likert scale), c) the performance in standardized neuropsychological tests (MOCA, RWT, VVM), d) demographic variables (age, sex, education), e) etiologic factors (time passed since the injury, etiology, phase of recovery, cognitive deficits), f) experiences with cognitive training and computer based media (5-point Likert scales), g) individual personality factors (BFI-10), h) individual motives and preferred game elements (questionnaires adapted from Tondello et al., 2016), i) evaluation of the implemented game elements/motivational strategies (usability, efficacy). Neuropsychological tests (parameter c) will be assessed at 2 time points: 1. before the beginning of the training phase (max. 1 week in advance; all indicated tests), and 2. after the end of the training phase (max. 1 week later; only RWT and VVM, parallel versions will be applied to control retest effects).

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- University Medical Center **Tagesklinik für Kognitive Neurologie, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/10**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

1) age 18 to 80 years, 2) history of brain damage (e.g. stroke), 3) sufficient knowledge of German language and communication/speech abilities, 4) access to a personal computer with internet connection and private email adress, 5) voluntary participation and informed consent

Exclusion criteria

1) severe deficits regarding cognition, speech, motor function, or psychological condition that interferes with training independently at home (e.g. pronounced aphasia/neglect, acute psychosis), 2) participation in another cognitive training program, 3) insufficient competence (e.g. dementia), 4) pregnancy, 5) breast-feeding women

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

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.