Trial Description

Title

Online Rehab-Need Test (OREST): Practicability, acceptance and usefulness of an active program (self-test) to screen for the need of medical rehabilitation among individuals covered by the German statutory pension insurance scheme in Baden-Württemberg and the Rhine Region.

Trial Acronym

OREST

URL of the trial

https://www.imbi.uni-freiburg.de/SEVERA/Projekte/aktuell/orest

Brief Summary in Lay Language

In Germany, those who want or need medical rehabilitation generally need to apply for it. Whether it is approved depends on numerous legal factors (from the insurance provider's perspective) and personal factors. Those concerning the latter include the actual need for rehabilitation, a positive rehabilitation prognosis, and the person's ability to participate in rehabilitation. It is the responsibility of those paying for the rehabilitation to determine a patient's individual need for it. There is, however, no active screening mechanism to assess who might need it. The aim of this project is to design and assess in practice a web-based, interactive screening program (self-test) to determine the potential need for rehabilitation. A web-based self-test of this type could facilitate the access to medical rehabilitation, especially for those thus far inadequately served by such a service. It would also enable a fairer distribution of service and involve the insured more deeply with their insurance provider. Should this screening program prove effective, it could feasibly be incorporated in the insurance providers' standard procedures.

Brief Summary in Scientific Language

Planned is a randomized, controlled intervention study (RCT). 8.000 individuals aged 40to 54 years and covered by the German statutory pension insurance scheme in Baden-Württemberg and the Rhine region will either be given information about the self-test in the internet (intervention group), or will function as the control group. The actual use of the screening program will be documented for 22 months. Afterwards, the "accounts" of both groups will be examined, that is, the extent to which each group applied for rehab, what kind of rehabilitation, and their employment status and/or duration of workers' disability payments.
Due to delays in the study schedule the observation period of 24 months was shortened to 22 months.
The evaluation of the program's acceptance by means of website statistics and a brief online-questionnaire (initially the secondary endpoint) has been cancelled after objections concerning data protection have been made (demand to collect as few data as possible on the website).

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006344**
- Date of Registration in DRKS: **2015/04/15**
- 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.: **40/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1164-0887**

Health condition or Problem studied

- Free text: **Need of rehabilitation**

Interventions/Observational Groups

- Arm 1: **Intervention group: receives written information on the possibility of testing online their need for rehabilitation at www.rehabedarfstest.de (including the password).**
- Arm 2: **Control group: receives no information about the website www. rehabedarfstest.de. They can apply for rehab using the standard procedure.**

Characteristics

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

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **Active control (effective treament of control group)**
- Purpose: **Screening**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Our primary endpoint is to measure how often rehabilitation applications are made and approved during the study's observation period. After 22 months have passed, we will have access to the accounts of the 8000 insurees and inquire about (1) death, (2) medical rehabilitation services applied for and approved (application date, type of service being applied for, how the service is carried out, and the start and end of rehabilitation), (3) occupational status and time on disability, and (4) how many applications for and authorization of workers' disability have been submitted. The authorization of rehabilitation applications will be our main criterium for determining whether the application was worthwhile (= „correctly positive“).
Furthermore, results from the self-tests will be assessed for potential problems and compared with (population-based) norms (i. e., the „Lübeck cohort“; WAI-norms).

Secondary Outcome

No secondary outcome.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/08/01**
- Target Sample Size: **8000**
- Monocenter/Multicenter trial: **[---]***
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **54 Years**

Additional Inclusion Criteria

Basis for the randomization process is a cohort of individuals insured by the German statutory pension insurance scheme of Baden-Württemberg and the Rhine Region aged between 40 and 54 years (cutoff day) who fulfill the insurance providers' prerequisites for a rehab measure. Half of our sample will consist of insurees with and without previous rehabilitation experience (the intervention group's last rehabilitation measure must not have been more than 4 years ago).

Exclusion criteria

[---]*

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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- **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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  URL: **http://www.deutsche-rentenversicherung.de/Rheinland/de/Navigation/0_Home/Impressum_node.html**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***

- Study Closing (LPLV): **2019/06/18**
- Number of Participants in Germany after Recruiting complete: **7980**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **7980**

Trial Publications, Results and other documents

- Paper **Mittag O, Brendel L, Schlöffel M,. Pollmann H (2017). Testung und Kalibrierung eines Fragebogensets zur späteren webbasierten Erfassung von Rehabilitationsbedarf bei Versicherten der Deutschen Rentenversicherung (Online-Rehabedarfstest). Prävention und Rehabilitation, 29 (2), 62 - 69.**
- Paper **Schlöffel M, Kampling H, Fichtner U, Farin-Glattacker E, Pollmann H und Mittag O (accepted 23.09.2020). Online-Rehabedarfstest (OREST): Wirksamkeit einer Einladung zu einem proaktiven Screening (Selbsttest) auf Bedarf an medizinischen Rehabilitationsmaßnahmen bei Versicherten der Deutschen Rentenversicherung Baden-Württemberg und Rheinland. Die Rehabilitation (accepted).**

** 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.*