DRKS-ID: **DRKS00019825**
Date of Registration in DRKS: **2019/12/03**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

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

Trial Description

Title

A retrospective study of cognitive impairments in general psychiatric patients using a screening instrument

Trial Acronym

ReCog-SCIP

URL of the trial

[---]*

Brief Summary in Lay Language

Attention, memory or information processing disorders can occur in mental disorders such as schizophrenia or affective disorders. Extensive testing batteries are often carried out to investigate these cognitive disorders. This is easier with the SCIP (Screen for Cognitive Impairment in Psychiatry). The SCIP consists of a short test that is simple and easy to use. We have been using the SCIP regularly in our clinic since 2012. Now we want to investigate the mental status of the treated patients and whether it can improve during the course of treatment.

Brief Summary in Scientific Language

Neuropsychological performance deficits are well described in the literature for those suffering from schizophrenia (F2) and affective disorders (F3). Full neuropsychological testing is not very practical in everyday clinical practice. At the same time, an assessment of neuropsychological deficits is of great importance due to the prognostic relevance for therapy and rehabilitation planning as well as occupational and employment perspectives for clinical everyday life. Screening instruments simplify diagnostics. SCIP is a screening instrument for cognitive impairments whose psychometric properties have been well investigated. This was integrated into the clinical routine diagnostics of our general psychiatric wards of the ZfP Südwürttemberg Clinic for Psychiatry and Psychotherapy I at the University of Ulm. In literature, diagnosis-specific differences in neuropsychological examinations are described. There are contradictory results on the stability of neuropsychological problems. Long-term observations of the course of the disease have so far not been described very much, if patients were examined using complex test batteries. Since 2012, the SCIP has been used in clinical diagnostics for the clinical assessment of individual cognitive performance so neuropsychological test results have been available for several years. These are now to be evaluated retrospectively for investigation.

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

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

Yes

Description IPD sharing plan

The study results should be published in a scientific paper. Preparation and submission of the paper is planned for 2020. A further (ethics) application does not have to be submitted.

Organizational Data

- DRKS-ID: **DRKS00019825**
- Date of Registration in DRKS: **2019/12/03**
- 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.: **228/19 , Ethik-Kommission der Universität Ulm**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20-F29 - Schizophrenia, schizotypal and delusional disorders**
- ICD10: **F30-F39 - Mood [affective] disorders**

Interventions/Observational Groups

- Arm 1: **Retrospective observational study of performance in a cognitive screening of patients with F2 diagnosis in longitudinal and cross-section design**
- Arm 2: **Retrospective observational study of performance in a cognitive screening of patients with F3 diagnosis in longitudinal and cross-section design**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Performance of participants in screening (SCIP) from 2012 to 08/2019

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **ZfP Südwürttemberg - Standort Weissenau, Ravensburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/09/26**
- Target Sample Size: **692**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Diagnosis of an F2 or F3 disorder; treated on ward 2053 or 2054 between 01.01.2012 to 21.08.2019

Exclusion criteria

incapable, willing to participate in diagnostics; all other diagnoses

Addresses

■ **Primary Sponsor**

ZfP Südwürttemberg - Versorgungsforschung Klinik I für Psychiatrie und Psychotherapie Universität Ulm
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■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

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): **2020/12/01**
- Number of Participants in Germany after Recruiting complete: **529**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **529**

Trial Publications, Results and other documents

- Further trial documents **Poster DGPPN Czekaj et al. 2012**
- Paper **Schmid et al., 2021**

** 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.*