

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

## Trial Description

### Title

**The “Psychosomatic Consultation in the Workplace” - a new model of care at the interface of company-supported mental health care and consultation-liaison psychosomatics**

### Trial Acronym

**PSIB**

### URL of the trial

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### Brief Summary in Lay Language

**Background:** Mental health issues are gaining in importance in the society and economic system. Therefore, new models of care are being established at the interface of company-supported mental health care and conventional outpatient care for people developing mental illnesses. Two large companies (Daimler AG, location Sindelfingen and Untertürkheim, and CASSIDIAN, location Ulm) in cooperation with the local psychosomatic clinics have established the “psychosomatic consultation at the workplace“ in the shape of a consultation liaison model. Our main study goals are: Are there any differences and what are these differences in demographic characteristics, clinical and psychometric factors between patients who use the new offer vs. patients who use the conventional outpatient clinics? Do patients ultimately benefit from the new model of care? How effective do the physicians rate this offer? Where do the physicians see a need for change?

**Methods:** The study takes place in Ulm and in Stuttgart with each site utilizing one outpatient clinic and one company-supported mental health care model (n=280). We use well-established survey instruments (PHQ-SADS, SF-12, WAI, MBI, IS) as well as standardized questions about length of symptoms, number of times the patient / subject has received any mental health / psychotherapeutic care, among others. For the quantitative data analyses, we use uni- and multivariate analytical methods. The qualitative data analysis (expert interviews) will be done using Mayring’s content analysis method. **Discussion:** With the new model yielding easy access for the affected, we are expecting to reach affected patients a lot earlier than with the conventional outpatient model. Based on our results, we seek to optimize the concept of the “psychosomatic consultation at the workplace.“ Once we obtain initial results of the explorative study, we plan to further examine this new model of care and its effectiveness in a long-term clinical trial (RCT).

### Brief Summary in Scientific Language

**Background:** Mental health issues are gaining in importance in the society and economic system. Therefore, new models of care are being established at the interface of company-supported mental health care and conventional outpatient care for people developing mental illnesses. Two large companies (Daimler AG, location Sindelfingen and Untertürkheim, and CASSIDIAN, location Ulm) in cooperation with the local psychosomatic clinics have established the “psychosomatic consultation at the workplace“ in the shape of a consultation liaison model. Our main study goals are: Are there any differences and what are these differences in demographic characteristics, clinical and psychometric factors between patients who use the new offer vs. patients who use the conventional outpatient clinics? Do patients ultimately benefit from the new model of care? How effective do the physicians rate this offer? Where do the physicians see a need for change? **Methods:** The study takes place in Ulm and in Stuttgart with each site utilizing one outpatient clinic and one company-supported mental health care model (n=280). We use well-established survey instruments (PHQ-SADS, SF-12, WAI, MBI, IS) as well as standardized questions about length of symptoms, number of times the patient / subject has received any mental health / psychotherapeutic care, among others. For the quantitative data analyses, we use uni- and multivariate analytical methods. The qualitative data analysis (expert interviews) will be done using Mayring’s content analysis method. **Discussion:** With the new model yielding easy access for the affected, we are expecting to reach affected patients a lot earlier than with the conventional outpatient model. Based on our results, we seek to optimize the concept of the “psychosomatic consultation at the workplace.“ Once we obtain initial results of the explorative study, we plan to further examine this new model of care and its effectiveness in a long-term clinical trial (RCT).

## Organizational Data

- DRKS-ID: **DRKS00003184**
- Date of Registration in DRKS: **2012/01/13**
- 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.: **224/11** , **Ethik-Kommission der Universität Ulm**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1126-7485**

## Health condition or Problem studied

- Free text: **Depression (ICD-10 F30 ff), Anxiety (ICD-10 F40 ff), Somatisation (ICD-10 F45 ff), Burnout Syndrom (ICD-10 Z73)**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F45 - Somatoform disorders**



- ICD10: **Z73 - Problems related to life-management difficulty**
- ICD10: **F34 - Persistent mood [affective] disorders**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F43 - Reaction to severe stress, and adjustment disorders**

## Interventions/Observational Groups

- Arm 1: **Three large companies (2 of them metal-working, 1 security systems) in cooperation with the local psychosomatic clinics have established the “psychosomatic consultation at the workplace“ in the shape of a consultation liaison model.**
- Arm 2: **Patients making use of the outpatients psychosomatic-psychotherapeutic Health Care offered by the cooperating psychosomatic clinic at each site (Ulm and Stuttgart)**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]\***
- Who is blinded: **[---]\***
- Control: **Other**
- Purpose: **Health care system**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Work ability (WAI) (research question 2)  
Identifying different types of patients with specific trait combinations while controlling for the setting (outpatient clinic vs. workplace). (research question 1, cross-sectional part of the study)**

## Secondary Outcome

**Quality of life (SF-12), clinical symptoms: depression (PHQ-9), somatoform symptom severity (PHQ-15), anxiety (PHQ-7), work related stress (irritationscale, maslach burnout inventory).  
Identifying changes in disease severity, quality of life and ability to work 12 weeks after fist contact,  
Measure for the extent to which recommendations have been implemented,**



**Patient satisfaction,  
Exploration of the feedback received from the company staff (qualitative).**

## Countries of recruitment

- **DE Germany**

## Locations of Recruitment

- University Medical Center **Ulm**
- Medical Center **Stuttgart**
- other **Betrieb, Ulm und Umgebung**
- other **Betrieb, Stuttgart**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/11/01**
- Target Sample Size: **280**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Patients utilising the offer within the course of recruitment**

### Exclusion criteria

**Age < 18 years, no employment (exclusion before data analysis)**

## Addresses

- **Primary Sponsor**

### **Primary Sponsor**

**Universitätsklinik für Psychosomatische Medizin und Psychotherapie Ulm**

**Mr. Prof. Dr. Harald Guendel**

**Am Hochsträss 8**

**89081 Ulm**

**Germany**

Telephone: **0049 (0)731 500 61801**

Fax: **0049 (0)731 500 61802**

E-mail: **med.psychosomatik at uni-ulm.de**

URL: **<http://www.uniklinik-ulm.de/struktur/kliniken/psychosomatische-medizin-und-psychotherapie.html>**

■ **Contact for Scientific Queries**

**Universitätsklinik für Psychosomatische Medizin und Psychotherapie Ulm**

**Ms. Dr. Eva Rothermund**

**Am Hochsträss 8**

**89081 Ulm**

**Germany**

Telephone: **0049 731 500 61848**

Fax: **0049 731 500 61832**

E-mail: **eva.rothermund at uni-ulm.de**

URL: **<http://www.uniklinik-ulm.de/struktur/kliniken/psychosomatische-medizin-und-psychotherapie.html>**

■ **Contact for Public Queries**

**Universitätsklinik für Psychosomatische Medizin und Psychotherapie Ulm**

**Ms. Dr. Eva Rothermund**

**Albert-Einstein-Allee 23**

**89081 Ulm**

**Germany**

Telephone: **0049 731 500 61848**

Fax: **0049 731 500 61832**

E-mail: **eva.rothermund at uniklinik-ulm.de**

URL: **<http://www.uniklinik-ulm.de/struktur/kliniken/psychosomatische-medizin-und-psychotherapie.html>**

## **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.)**

**Abt. Allgemeinmedizin und Versorgungsforschung Koordinierungsstelle Nachwuchsprogramm Netzwerk 'Versorgungsforschung Baden-Württemberg' (gefördert durch das Ministerium für Wissenschaft, Forschung und Kunst in Zusammenarbeit mit dem Ministerium für Arbeit und Sozialordnung, Familie, Frauen und Senioren)**

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Nachwuchsprogramm Netzwerk 'Versorgungsforschung Baden-Württemberg'  
(gefördert durch das Ministerium für Wissenschaft, Forschung und Kunst in  
Zusammenarbeit mit dem Ministerium für Arbeit und Sozialordnung, Familie,  
Frauen und Senioren)  
Mr. PD Dr. Gunter Laux  
Voßstr. 2  
69115 Heidelberg  
Germany**

Telephone: **0049 (0)6221 56 6207**

Fax: **0049 (0)6221 56 1972**

E-mail: **g.laux at med.uni-heidelberg.de**

URL: [---]\*

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**Ltd. Arzt des Betriebsmedizinischen Dienstes Firma CASSIDIAN  
Mr. Dr. med. Marc Krüger  
Landshuterstr. 26  
85716 Unterschleissheim  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/10/31**

## Trial Publications, Results and other documents

- Further trial documents **Studienprotokoll**
- Paper **Effectiveness of psychotherapeutic consultation in the workplace: a controlled observational trial**
- Paper **Improving access to mental health care by delivering psychotherapeutic care in the workplace: A cross-sectional exploratory trial**

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\* *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.*