

# **FUNKTIONAL - Cluster randomised controlled evaluation of a guideline-based curriculum for early diagnosis and treatment of somatoform /functional disorders in general practice**

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|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>18/10/2005   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>04/11/2005 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>11/06/2019       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input checked="" type="checkbox"/> Results          |
|                                        |                                                               | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## **Contact information**

**Type(s)**  
Scientific

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## **Additional identifiers**

**Protocol serial number**  
Funktional-18-10-05

## **Study information**

**Scientific Title**

FUNKTIONAL - Cluster randomised controlled evaluation of a guideline-based curriculum for early diagnosis and treatment of somatoform/functional disorders in general practice

## **Acronym**

FUNKTIONAL

## **Study objectives**

A guideline-based training of general practitioners in early diagnosis and treatment of somatoform/functional complaints leads to improvements for general practitioners (GPs) as well as for patients:

1. Concerning the GPs we expect our intervention to be evaluated as efficient and enhancing competence. We expect the following changes in the trained intervention group in comparison with the waiting control group:
  - 1.1. Change in GPs' attitude towards patients with somatoform/functional complaints
  - 1.2. Higher provider satisfaction
2. Compared to the control group patients of the intervention group are expected to show the following improvements:
  - 2.1. Less dysfunctional health care utilisation
  - 2.2. Greater decrease in their symptomatology (severity and frequency of symptoms) in terms of somatization and comorbid mental disorders (depression, anxiety)
  - 2.3. Better quality of life (QOL)
  - 2.4. Better assessment of their GP's practice and higher patient satisfaction with their doctor
  - 2.5. Extension of the patient's illness explanatory model towards a more biopsychosocial attribution to the illness
3. Regarding both, the GPs and the patients, we expect in the intervention group:
  - 3.1. An improved communication between the GP and his/her patients
  - 3.2. A better doctor-patient-relationship
4. Following a team-oriented approach, we additionally trained the practice nurses of the intervention group in dealing with difficult patients taking particular consideration in such with somatoform/functional complaints. Thereby we expect:
  - 4.1. Change in practice nurses' attitudes towards difficult patients
  - 4.2. A better cooperation between GPs and practice nurses

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Not provided at time of registration

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Somatoform/functional complaints and disorders

## **Interventions**

In this trial we evaluate a training programme for general practitioners in early diagnosis and treatment of functional/somatoform complaints and disorders. The training programme is called FUNKTIONAL-curriculum and was developed in a group of GPs and psychosomatic specialists in order to transform guideline based knowledge into practical skills in dealing with patients with somatoform/functional complaints. The training for the intervention group of 16 GPs extends over a period of 3 months and consists of four modules of 2 x 90 minutes each. 5 months later a 90 minute booster session takes place aiming at exchange of experiences and refreshment of the curriculum contents. The additional module for the practice nurses of the intervention group is arranged in one session over 2 x 90 minutes. The control group, a second group of 16 randomised general practitioners, initially only receives written information material about somatoform/functional disorders and will be trained after data collection.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

Health care utilisation

## **Key secondary outcome(s)**

1. Evaluation of the curriculum
2. GPs' attitudes towards somatisation and provider satisfaction
3. Doctor-patient relationship and patient satisfaction
4. Symptomatology:
  - 4.1. Somatisation
  - 4.2. Comorbidity: depression, anxiety
5. Patients' quality of life
6. Patients' explanatory model, illness perception
7. Practice nurses' attitudes towards difficult patients
8. Team-oriented approach: cooperation between GP and practice nurses

## **Completion date**

03/05/2006

## **Eligibility**

### **Key inclusion criteria**

The participating doctors are general practitioners from the Rhein-Neckar-region. They were stratified by practice location (urban/rural) and training in Psychosocial Primary Care (PPC) (yes/no) and randomly assigned to the intervention group or to the control group.

The following patients of these general practices were included in the study:

1. Aged 18 - 65 years
2. Patient has an appointment with the doctor (not only visits to the practice e.g. to fetch a prescription or to get the regular dose within a substitution therapy)

Among the participating general practitioners there are 16 GPs in the intervention group and 16 GPs in the control group. 2000 patients are to be screened in the practices; 1000 in the

intervention group, 1000 in the control group. We expect about 30% to be screening- positive accordant to our criteria (see inclusion criteria). Accordingly, around 600 patients will have a high symptom load, 300 in the intervention group and 300 in the control group.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

The following patients were excluded from the study:

1. Age younger than 18 years or older than 65 years
2. Patient has no appointment with the doctor (e.g. visits the practice only to fetch a prescription or to get the regular dose within a substitution therapy)
3. Insufficient German language skills (language barrier)
4. Illiteracy
5. Psychosis
6. Mental disability
7. Impairment by severe acute organic disease

**Date of first enrolment**

17/01/2005

**Date of final enrolment**

03/05/2006

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Thibautstr. 2

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# Sponsor information

## Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF])

## ROR

<https://ror.org/04pz7b180>

# Funder(s)

## Funder type

Government

## Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) Grant Number GF GK 01072500

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results       | 01/06/2005   | 11/06/2019 | Yes            | No              |
| <a href="#">Results article</a> | results       | 01/06/2005   | 11/06/2019 | Yes            | No              |
| <a href="#">Study website</a>   | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |