# Evaluation of a specific psychosomatic shortterm group intervention for patients with functional/ somatoform complaints in primary care. A cluster randomized controlled trial

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
17/10/2007		Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/10/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
16/07/2013	Mental and Behavioural Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number 01GK0601

# Study information

Scientific Title

### Acronym

speziALL

## **Study objectives**

To determine whether a newly developed specific psychosomatic short-term group intervention for patients with functional/somatoform complaints can effectively be implemented in primary care and leads to improvements in patients' outcomes.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

Ethics Committee of the Medical Faculty, University of Heidelberg. Approved on 19 March 2007 (ref: S-074/2007)

## Study design

Cluster randomized controlled trial.

## Primary study design

Interventional

## Study type(s)

**Treatment** 

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

Functional/somatoform complaints and disorders

#### **Interventions**

All GPs receive a training programme in early diagnosis and management of functional/somatoform complaints in primary care that has already been evaluated.

In addition, a manualised specific psychosomatic short-term group intervention for patients with functional/ somatoform complaints in primary care will be developed. It integrates psychodynamic-interpersonal and cognitive-behavioural elements and emphasizes psychoeducation and resource activation. By experiencing the group process, new perspectives on awareness, self-reference, emotional involvement and relationship patterns shall be opened.

The GPs of the intervention group are trained to conduct the new group intervention in their offices together with a psychosomatic specialist. In each practice of the intervention group the participating patients are treated with the new short-term group intervention. The group format is 10 weekly sessions of ninety minutes each and one booster session. GPs and psychosomatic specialists are supervised in conducting the groups. Patients in the control group receive enhanced medical care.

This trial is carried out in cooperation with:

Prof Joachim Szecsenyi Department of General Practice and Health Services Research University Hospital Heidelberg Vossstr. 2 Heidelberg 69115 Germany

and

Prof Hans-Helmut König
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Germany

### Intervention Type

Other

#### **Phase**

**Not Specified** 

### Primary outcome(s)

Physical quality of life (Physical Component Summary [PCS] of the Short From-36 Health Survey [SF-36]) will be assessed before the intervention and 3 and 9 months after the intervention.

# Key secondary outcome(s))

Patients' characteristics:

- 1. Mental comorbidity (Patient Health Questionnaire, German version [PHQ-D]), assessed before the intervention and 3 and 9 months after the intervention.
- 2. Functional impairment (PHQ-D, SF-36), assessed before the intervention and 3 and 9 months after the intervention.
- 3. Mental quality of life (Mental Component Summary [MCS] of the SF-36), assessed before the intervention and 3 and 9 months after the intervention.
- 4. Health related quality of life (EQ-5D), assessed before the intervention and 3 and 9 months after the intervention.
- 5. Health care utilization, disability days, direct and indirect medical costs (German version of the Client Sociodemographic and Service Receipt Inventory [CSSRI]), assessed before the intervention and 9 months after the intervention.
- 6. Illness perception (Illness Perception Questionnaire [IPQ], Brief Form), assessed before the intervention and 3 and 9 months after the intervention.
- 7. Control beliefs (Illness and Health Locus of Control Questionnaire [KKG]), assessed before the intervention and 3 and 9 months after the intervention.
- 8. Emotional awareness (Toronto Alexithymia Scale [TAS-20]), assessed before the intervention and 3 and 9 months after the intervention.

Additionally the group process will be monitored from the perspective of the patients and the therapists.

The training programme and its effects on GPs' competence will be evaluated, including difficulty experienced by the physician in the physician-patient relationship (Difficult Doctor-Patient Relationship Questionnaire [DDPRQ-10]). The evaluation will be carried out immediately

after the training course, immediately after the group intervention and 9 months after the group intervention.

# Completion date

31/12/2009

# **Eligibility**

## Key inclusion criteria

1,112 General Practitioners (GPs) within 45 minutes outreach around Heidelberg are invited to take part in the trial by letter. The first 36 of them who agree to participate are included in the trial. They are stratified by group experience (yes/no) and training in Psychosocial Primary Care (PPC) (yes/no) and randomly assigned to the intervention or control group.

The GPs recruit patients to participate in the trial according to following inclusion criteria:

- 1. The presence of functional/somatoform complaints (persistent [at least 6 months] bodily complaints for which no sufficient organic explanation can be found)
- 2. The somatoform disorder is the main treatment issue (co-morbidities are allowed)
- 3. Indication for short-term group intervention
- 4. Age 18-70 years
- 5. Distance from the practice to the place of residence not more than around 30 kilometers
- 6. Written informed consent

Patients selected by the GPs are additionally assessed for somatoform disorders by the Patient Health Questionnaire (PHQ-15) and the Whitely-7 (WI-7).

GPs' selection of patients is examined separately to assess its representativeness.

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

# Upper age limit

70 years

#### Sex

All

## Key exclusion criteria

- 1. Ongoing psychotherapy
- 2. Substance abuse (benzodiazepins, alcohol, drugs)
- 3. Severe psychiatric disorder: major depression (PHQ-9), psychosis, dementia or

#### neurodegenerative disorders

- 4. Impairment by severe acute organic disease (Karnofsky index lower than 70%)
- 5. Unable to understand German language
- 6. Ongoing juridical proceedings due to pension or compensation for personal suffering

#### Date of first enrolment

22/10/2007

#### Date of final enrolment

31/12/2009

# Locations

### Countries of recruitment

Germany

# Study participating centre

Department of Psychosomatic and General Clinical Medicine

Heidelberg Germany 69115

# 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

Not defined

#### **Funder Name**

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) Grant Number 01GK0601

# **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?
Results article	results	10/01/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes