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

Submission date
17/10/2007

Recruitment status
No longer recruiting

Registration date
19/10/2007

Overall study status
Completed

Last Edited
16/07/2013

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.klinikum.uni-heidelberg.de/speziALL.106406.0.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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:

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and

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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
22/10/2007

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Aiming at 242 (2 x 121) patients and assuming a drop-out rate of 20% and further 20% loss to follow-up, initially 378 (2 x 189) patients should be enrolled in the trial.

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
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Sponsor information

Organisation

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

Sponsor details
Hannoversche Strasse 28-30
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Sponsor type
Government

Website
http://www.bmbf.de

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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