ISRCTN27782834 https://doi.org/10.1186/ISRCTN27782834

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

Submission date
18/10/2005

Recruitment status
No longer recruiting

Registration date
04/11/2005

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Mental and Behavioural Disorders

[ ] 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.funktional.uni-hd.de

Contact information

Type(s)
Scientific

Contact name
Prof Wolfgang Herzog

Contact details
Thibautstr. 2
Heidelberg
Germany
69115
+49 (0)6221 56 7167
wolfgang_herzog@med.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Health care utilisation

Secondary outcome measures
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

Overall study start date

17/01/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32 GPs; 2000 patients

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
Heidelberg
Germany
69115

Sponsor information

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

Sponsor details
Hannoversche Straße 28-30
Berlin
Germany
10115
+49 (0)1888 57 0
bmbf@bmbf.bund.de

Sponsor type
Government

Website
http://www.bmbf.de

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

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	01/06/2005	11/06/2019	Yes	No
Results article	results	01/06/2005	11/06/2019	Yes	No