Trial Description

Title

National survey on health care provision for depression in primary care: A nested intervention study

Trial Acronym

VERA/NILS

URL of the trial

http://www.psychologie.tu-dresden.de/i2/klinische/Studien/vera/index.html

Brief Summary in Lay Language

The NILS study is an intervention study nested within a national research project led by the Institute of Clinical Psychology and Psychotherapy of the Technische Universität Dresden, Germany, in collaboration with the German Alliance against Depression (‘Bündnis gegen Depression e.V). The VERA project aims to describe the status quo of health care provision for depression in primary care settings in Germany. The VERA project is supported by stakeholder associations (Stiftung Deutsche Depressionshilfe), the Saxonian association of general practitioners (Sächsische Gesellschaft für Allgemeinmedizin), the center for evidence-based health care provision (Zentrum für evidenzbasierte Gesundheitsversorgung) and a large health insurance company in Germany (AOK PLUS). The VERA project is funded by the German Ministry of Health. In March 2014, field work in five selected regions in Germany started, assessing about 269 general practitioners and their patients. It was explored, how many individuals are affected by physical and mental health problems, and what the determinants for health care provision in these primary care patients are.
NILS examined in a random sample of 87 general practitioners of the VERA project, whether already available low-threshold supportive guideline-oriented interventions improve the detection of and health care provision for patients with depression.

Brief Summary in Scientific Language

The VERA study is a multi-stage, national prospective-longitudinal study to depict the status quo of health care provision for depression in German primary care settings and aims to examine the implementation of the S3 guideline for unipolar depression in primary care, focusing in particular on provision-related aspects (awareness, knowledge, acceptance, adherence, promoting/repressing factors), patient-related aspects (age, gender, type/ severity of depression) as well as aspects related to interfaces across the German health care system (from primary care to specialized care, effects by region). A random sample of 269 general practitioners clustered by regions across Germany was examined, of which 87 were randomly selected for the nested intervention study NILS. It is the aim of NILS to examine the utility and effects of low-threshold supportive guideline-oriented interventions to improve dissemination and adherence in a random subsample of general practitioners.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005666**
- Date of Registration in DRKS: **2014/02/11**
- 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.: **EK 392102013 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F34 - Persistent mood [affective] disorders**
- ICD10: **F38 - Other mood [affective] disorders**

Interventions/Observational Groups

- Arm 1: **Random selection of 46 general practitioners of the VERA project and allocation to low-threshold supportive guideline-oriented interventions to improve S3 guideline adherence: evaluation of effects based on main project; Study materials are : Desktop-Guidelines for diagnoses, differential diagnoses, therapy algorithms, access to web-based psychiatrist consultation, depression case documentation protocols (DeMol), depression screening questionnaires (PHQ)**
- Arm 2: **Matched wait-list control group**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Control group receives no treatment**
- Purpose: **Health care system**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

(1a)Adherence towards S3 guidline: based on indicators related to S3-guidline key points, i.e., type/frequency/duration of medical and non-medical treatments; education, shared decision-making, duration/frequency of monitoring, referral to specialized care if appropriate
(1b) Diagnosis: clinical diagnoses at reference day (clinical judgement; validity of diagnoses and severity), depressive symptoms / depressive disorder based on self-reports using international established and evaluated measurements (DSQ, PHQ)

Secondary Outcome

(1) course of depressive symptoms: see primary endpoints, (2) S3 guideline adherence during follow-up period (see primary endpoints), improvement of S3 guided health care provision due to intervention (medium effect), (3) cost-benefit ratio of S3 guided health care provision: health care utilization and costs, determination of incremental cost-effectiveness-relation of guideline-oriented health care provision.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutschlandweit**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/25**

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- Target Sample Size: **12000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

The patient sample consists of all patients at a reference day (or two half-days) consulting their primary care doctor for a visit.

Exclusion criteria

Exclusion criteria: age < 18 years, no consultation (i.e. retrieve prescription only), physical or mental condition undermines processing of questionnaires (i.e. dementia, emergency case, severe pain), questionnaires can only be processed with help from others (i.e. sensory/motor deficits, no glasses), lack of informed consent.

Addresses

- **Primary Sponsor**

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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.)**

Mit der Abwicklung der Fördermaßnahme beauftragt hat das BMG denProjektträger im DLR, Gesundheitsforschung
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Status

■ Recruitment Status: **Recruiting complete, follow-up continuing**

- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*