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Application for weaning off treatment by General Practitioner (GP) for patients with dependency

Submission date
04/07/2013

Recruitment status
No longer recruiting

Registration date
29/07/2013

Overall study status
Completed

Last Edited
29/07/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research has established the effectiveness of screening, brief intervention and referral to treatment (SBIRT) for patients with alcohol and drug misuse in primary care. Screening large numbers of patients provides an opportunity to engage those who are in need of treatment. Brief interventions can include the provision of brief treatment for patients with less severe substance use disorders (SUDs) and referrals to specialized substance abuse treatment for those with more severe SUDs. General practitioners (GPs) are uniquely positioned to provide SBIRT interventions. Nonetheless, the majority of primary care patients go unrecognized and several studies point to the unwillingness among health care personnel to take on this extra work. In this study a modified SBIRT intervention will be tested. Firstly, to improve GPs treatment motivation and satisfaction for screening a modified version of the Case Finding and Assessment Tool (CHAT) will be used, asking for need for help regarding alcohol, medication, illegal drug or internet misuse and pathological gambling. Need for help may be associated with higher stages of readiness to change, which is regarded as an essential predictor of treatment motivation by GPs. Secondly, GPs in Germany are presently used to referring patients with dependency to a drug helpline. In a previous study only 5% of patients with dependency followed the referral. To increase the number of patients receiving weaning off treatment a new referral path has been established 2011 by the Deutsche Rentenversicherung Mitteldeutschland (DRV-M) facilitating the application for weaning off treatment by the GP without using the drug helpline.

Who can participate?
All GPs in and around the city of Magdeburg who have completed the training Riskanter Alkoholkonsum (SIQ-Modul 9) in 2011 and patients with Allgemeinen Orts Krankenkassen health insurance and screening positive for need for help can participate.

What does the study involve?
Participating GPs will be randomly allocated to either the intervention group or the control group (usual care).
Intervention group GPs will receive information about the new treatment path of applying weaning off treatment in primary care. Each patient indicating a need for help regarding

medication, illegal drug, internet dependency and pathological gambling after screening will be motivated to take weaning off treatment by the GP.
Control group GPs will be informed about a local drug helpline (usual care). Patients screened positive for dependency will be referred to the drug helpline and patients screened positive for hazardous alcohol consumption will be referred to another hospital (Tagesklinik).

What are the possible benefits and risks of participating?
Screening for need for help should improve the treatment motivation of GPs, thus increasing the number of patients that are screened for alcohol and drug misuse/dependency. The new referral path application for weaning off treatment by GPs may lead to an increase in the number of patients successfully referred to weaning off treatment. No risks are expected.

Where is the study run from?
Martin-Luther-University of Halle

When is the study starting and how long is it expected to run for?
The study started in June 2013. GP screening will take six months. The 12-months follow-up will be completed in November 2014.

Who is funding the study?
The study will be funded by the German Pension Insurance (Deutsche Rentenversicherung Mitteldeutschland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Application for weaning off treatment by General Practitioner (GP) for patients with dependency: a cluster randomized controlled trial

Acronym
HELPS

Study objectives
HELPS treatment path - implicating the option for GPs to apply weaning off treatment for patients with dependency in Germany since 2012. More patients will be successfully referred to weaning off treatment when compared to usual care (suggesting treatment via drug helpline).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the Ethics Commission of the University of Halle and the commissioner for data protection of Deutsche Rentenversicherung Mitteldeutschland (DRV-M).

Primary study design
Interventional

Study design
Two arms multicentre cluster randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alcohol, medication, illegal drug or internet dependency pathological gambling, hazardous alcohol consumption

Interventions
Participating GPs will be cluster randomized to intervention and control group.
Intervention group GPs will receive information about the new treatment path of applying weaning off treatment in primary care by practice visit. Each patient indicating need for help regarding medication, illegal drug, internet dependency and pathological gambling after screening will be motivated to take weaning off treatment by the GP. Patients indicating need for help regarding alcohol misuse will be additionally screened for alcohol dependency and hazardous consumption. Patients screened positive for alcohol dependency (CAGE questionnaire score ≥ 2) will be also motivated to take weaning off treatment. Patients negative for alcohol dependency (CAGE < 2) but screened positive for hazardous consumption [Alcohol Use Disorders Identification Test (AUDIT) score ≥ 8] will be referred to another hospital (Tagesklinik).
Control group GPs will be informed about local drug helpline (usual care). Patients screened positive for dependency will be referred to drug helpline and patients screened positive for hazardous alcohol consumption will be referred to another hospital (Tagesklinik).

The cooperating MVZ offers 12 sessions of group therapy for one hour once a week for patients with harmful and hazardous alcohol consumption

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Number of patients using weaning off treatment

Key secondary outcome(s)
1. Number of patients quitting weaning off treatment irregularly
2. Number of patients being abstinent
3. Number of patients with work ability
4. Stage of change alcohol consumption habits
5. Alcohol related expectancies regarding social assertiveness and relaxation and tension reduction

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Need for help regarding alcohol, medication, illegal drug, or internet dependency or pathological gambling after screening
2. 18-67 years of age
3. Allgemeinen Orts Krankenkassen (AOK) health insurance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
67 Years

Sex
All

Key exclusion criteria
1. Refused to give informed consent
2. People who don't have sufficient communication skills

Date of first enrolment
01/06/2013

Date of final enrolment

30/11/2013

Locations

Countries of recruitment
Germany

Study participating centre
Magdeburger Str. 8
Halle
Germany
06120

Sponsor information

Organisation
The German Pension Insurance (Deutsche Rentenversicherung Mitteldeutschland) (Germany)

ROR
https://ror.org/05am9gt90

Funder(s)

Funder type
Government

Funder Name
The German Pension Insurance-Central Germany (Deutsche Rentenversicherung Mitteldeutschland) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration