Breaking the vicious cycle of GHB use and relapse: The development of an intervention guideline and piloting project.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28846

Source
Nationaal Trial Register

Brief title
GHB-relapse management

Health condition

GHB use disorder, GHB addiction

Sponsors and support

Primary sponsor: Radboud University Medical Center.
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

To monitor the achievability and viability of the instruction guide.

Secondary outcome

To evaluate the instruction guide and to distinguish subgroup of patients the following data will be retrieved from the patient's file: relapse in GHB-use either duration of abstinence after detoxification, craving, drop-out and duration of treatment, psychiatric problems, quality of sleep, social situation, cognitive functioning and quality of life.

Study description

Background summary

A instruction guide was developed to reduce relapse in GHB-use after detoxification. This instruction guide will be tested in the clinical practice by a pilotstudy. Participants will be recruited at two addiction treatment centres in the Netherlands: Arkin and Novadic-Kentron.

Study objective

Use of gamma-hydroxybutyrate (GHB) can lead to severe dependence or addiction. Patients often relapse in GHB use after detoxification. NISPA, Trimbos Institute and Bonger Institute are developing an instruction guide for relapse management. A systematic inventory of available literature and existing interventions was carried out for the development of this guideline. Results were discussed twice with patients, their significant others and professionals by conducting focus-groups. This procedure has resulted in a draft version of the guideline GHB relapse management which will now be tested in the clinical practice. Therefore, a pilot study has been set up at Novadic-Kentron and Jellinek.

Study design

3-months and 6-months after inclusion patients and their clinician will be interviewed. Data retrieved from patient's file are included in the instruction guide (e.g. MATE-1, GHB-questionnaire, VAS-craving, DASS, MoCa, EQ-5D) and used for monitoring treatment.

Intervention

The instruction guide contains interventions, questionnaires for screening, diagnostics and monitoring, and helping instructions for professionals to reduce the risk of relapse in GHB-use after detoxification. Interventions are tailored and applied depending on patient's need for care.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients diagnosed with a GHB use disorder according to DSM 5; Patients applying for help in one of the participating treatment programs during the study period (Arkin or Novadic-Kentron).

Exclusion criteria

Being under the age of 18 years; insufficient knowledge of the Dutch language; severe psychiatric co-morbidity that would preclude to take part in the process and adherence to the instruction guide; and no informed consent to participate in the pilotstudy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018

Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion Date:	23-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6776
NTR-old	NTR7645
Other	ZonMw : 531004003

Study results