Acupuncture in the treatment of Schizophrenia, Depression and Sleep.

No registrations found.

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

Summary

ID

NL-OMON24481

Source
NTR

Health condition

Schizophrenia, Depression, Sleep disorders

Sponsors and support

Primary sponsor: LVR Klinik Bedburg Hau,
Bahnstrasse 6, 47551 Bedburg-Hau
Tel. 0049-2821-813050 (secretary at the clinic, please ask for Frau Bosch)
Fax. 0049-2821-813098

Donders Institute for Brain, Cognition, and Behaviour, Centre for Cognition, Radboud University Nijmegen, Montessorilaan 3, 6525 HR Nijmegen, The Netherlands. Tel: ++492821813050; Fax: ++492821813098
Source(s) of monetary or material Support: P. Bosch works as a buitenpromovenda and is not being paid for the research.

The clinic provides time, patients, space to perform the treatment, and needles but does not provide other funding, nor does the university.

The university provides research collaboration and advises on methods and statistics, moreover provides supervision for the PhD Student.

Intervention

Outcome measures

Primary outcome

The testbattery consists of the following: PSQI, Epworth, RST, BDI, PANSS, Sleep Diary, SF-36, MUPS, number recall (WAIS III), letter number recall (WAIS III), mwt-b.

Tests are filled in or taken in presence of a psychology apprentice. Statistical analysis are performed by an external expert who only receives the numbers. Patient data is kept anonymous at all times. Testing will take place pre and post treatment or waitlistcondition.

Secondary outcome

Followup test three months after post testing.

Study description

Background summary

In this study, the effect of acupuncture on patients with schizophrenia or depression is being studied. Mostly effects on sleep, concentration, memory and affect are studied. This project is conducted in a clinic in Germany and is actually part of a cooperation with the Radboud University Nijmegen. Since it is one of the first studies in this field, the current study is seen as a large pilot that might form the basis for broader future research.

Study objective

Effects of acupuncture (add on) treatment are investigated.

Study design

1. Pre and post treatment;

2. Pre and post waitlist condition;

3. Followup three months later.

Intervention

During 12 weeks the patients will receive acupuncture, once a week during one hour. The

treatment will take place in a room with comfortable chairs. Two acupuncturists will perform treatment, patients will be treated groupwise thereby allowing them to be in (eye) contact with their therapist at all times. Patients are not left alone with the needles inserted.

Contacts

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Eligibility criteria

Inclusion criteria

ICD-10 diagnosis of schizophrenia for one group,
or depression for the other group.

The diagnosis is made by the treating psychiatrist, who, upon concluding that the patient would be suitable for the project, then informs the patient about it.

Exclusion criteria

Addiction, other neurological conditions.

The psychiatrists that inform the patients about the study, also have access to any other diagnosis that the patients might have. Upon entering the study, the exclusion criteria are checked once again in the electronic patient information system of the clinic.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-11-2011
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	NL2984
NTR-old	NTR3132
Other	Ethikkommission der Aerztekammer Nordrhein : 2008331
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
First results (pre treatment) are in progress.