Measuring impact of Acupuncture treatment on Pain Patients’ Health Status

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29347

Source
NTR

Brief title
MAPPHS

Health condition

Pain, functional disability, subjective well being, use of medication, acupuncture, health status

Sponsors and support

Primary sponsor: Independent project
Source(s) of monetary or material Support: Nederlandse vereniging voor Acupunctuur, NVA

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the ‘MYMOP2-online’ change score. That is, patient reported

scores (7 point scales) of successively: the pain; functional disability due to pain; general wellbeing; medication for the pain.

Secondary outcome

The secondary outcome measure is the database of the acupuncture treatment. That is, frequency; duration; theory; and modality of every single acupuncture treatment.

Study description

Background summary

The number of patients attending acupuncture increased and it is expected that it will rise further in the near future. The WHO is calling member states for more regulation and integration of TC&M in health care. The ICF model used by WHO shows that not the medical diagnosis should be central but rather the meaning the patient himself indicates to health and desired health benefits, as evidenced by well-being, self-reliance and participation. The holistic approach in acupuncture, examines the whole person rather than the illness alone. No protocols, no prescribed treatment, but each individual determines, by mutual agreement, what the desired goals are, and which treatment is most appropriate at that time. There is a huge variety of health problems that people decide to attend acupuncture.

In the present study, the impact of acupuncture on pain patients' health status is being studied. Health status is defined as the degree of pain, functional disability, subjective well being and use of medication.

The present study will be conducted in 25 clinical acupuncture practices in the Netherlands.

In the Netherlands this study is one of the first in this field. It can be seen as a large pilot that might form the basis for more acupuncture research in the future.

Study objective

The primary goal of this observational case series study is to access the changes in health status of pain patients following on acupuncture treatment. Changes will be measured by the 'MYMOP2-online' questionnaire. Health status is defined as the degree of pain, functional disability, subjective well being and use of medication.

The secondary goal is to investigate whether the changes in health status depend on the variability in frequency, duration, theoretical bases and modality of the acupuncture treatment.

Study design

‘MYMOP2-online’ patient questionnaire at first appointment (T0), after four weeks (T1), after 16 weeks (T2)

Database of acupuncture treatment every single treatment.

Intervention

The intervention includes Traditional Chinese Medicine; treatment with needles with eventually additional the use of moxa, massage (tuina/guasha), cupping, elektrostimulation and advice/instruction/exercises about food and lifestyle. Several theoretical bases may underlie the treatment. The acupuncturist choose or combines from a.o. ‘Zangfu’, Five Elements’, ‘Dr. Tan’s Balance Method’, ‘Stems and Branches’, ‘Ashi-points, ‘Earacupuncture’. The treatment is not invasive, which means that nothing will be changed in the usual treatment as a result of this study. In Chinese Medicine the treatment will be tailored to the personal demands and conditions of the patient. The patient will attend the praxis voluntarily. The patient is not assigned to an intervention or control group. The acupuncturist performs the treatment exactly as if no study had taken place. Measurements that will be made during acupuncture treatment reflect common clinical practice.

Contacts

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Eligibility criteria

Inclusion criteria

Acupuncture patients having pain existing more than seven days; attend for acupuncture treatment voluntarily; are 15 years and older; are able to complete a Dutch online questionnaire, completed informed consent.

Acupuncturists who work in The Netherlands for at least 2 years; have a computer in their praxis; speak the Dutch language; completed informed consent.

Exclusion criteria

All other patients attending acupuncturepraxis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2014
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-09-2014
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	NL4635
NTR-old	NTR4787
Other	- : -

Study results