Risk information and informed consent in acupuncture – A proposal from Germany

Sir,

Informed consent has become an important part of medical practice. It requires the communication of information about possible adverse effects of treatment.

Although serious adverse effects of acupuncture seem to be very rare,1 case reports of traumatic complications and indirectly caused side-effects appear regularly in scientific publications.2

Acupuncturists have expressed concern, however, that increased provision of risk information may make patients unduly anxious and change their decisions about treatment.3

It has been our experience that provision of detailed information about possible adverse consequences of treatment can improve patients' understanding and satisfaction without inducing increased anxiety. Meanwhile this has been proven by several studies.4

In our department, patients are enlightened orally and in written form about the risks and possible benefits of the acupuncture therapy. They fill out and sign a form with questions about their medical history and individual risk factors.

In the attached appendix we present our risk information and informed consent forms which we developed especially for acupuncture therapy. Therapists need to know human anatomy.5

Readers are strongly encouraged to discuss this proposal, to shorten it where possible, and to refine it where necessary.

Reference list


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References

Information consultation/Consent
“What you should know...”

Acupuncture

Patient name and address

Please read and answer carefully before the information consultation.

Dear Patient/Parents:

Acupuncture is a very old therapy technique that can be quite beneficial in the treatment of many different illnesses. In this procedure needles are inserted at individually determined points of the body, where they are left for a while. During this period you should attempt to relax. We use exclusively high-quality, sterile disposable articles. To optimize the therapeutic effect, it may be necessary to introduce additional measures, such as e.g. electrical stimulation of the needles or moxibustion, in which the Chinese herb mugwort (Artemisia vulgaris) is ignited. Before the treatment starts, our physicians will discuss your illness with you in a detailed consultation and conduct a comprehensive physical examination. If we are of the opinion that additional diagnostic steps are necessary, we shall discuss the appropriate recommendations with you. We consider it important that you bring all your available examination documents with you to your appointment, so that together we can determine the best possible comprehensive picture of your medical history.

Should you be concerned about side effects?
Acupuncture is a procedure with few side effects; however, as with any other effective therapy, side effects may occur under unfavorable conditions, although severe complications are highly unlikely. However, we consider it important that you be informed about this topic. By carefully filling out the accompanying questionnaire, you help us further reduce the already low risk.

The following list covers the conceivable side effects with comments on their evaluation:

- After acupuncture almost all patients experience relaxation, which is usually perceived as beneficial. Please bear in mind that the ability to drive an automobile may be impaired, so you should use public transportation or allow someone else, for example a relative, to drive.
- Some people react to needle pricks with impaired circulation, up to and including circulatory collapse. Persistent injury has so far not been reported. To minimize the risk, if at all possible we shall perform the therapy with the patient in the lying position.
- Very small bruises at puncture sites occur frequently, because damage to the cutaneous vessels is unavoidable. Further treatment is as a rule not required. If you take blood-thinning medication, please indicate this on the information form.
- In principle, any invasive procedure can produce a localized or spreading infection. We minimize this risk by using sterile disposable needles and by disinfecting especially infection-prone areas, such as e.g. the outer ear. For this reason, please indicate on the questionnaire if you take medication that impairs the immune system or suffer from diabetes or other chronic disease. After the treatment, if you suspect an infection at a puncture site, please come to our office immediately or seek medical attention elsewhere.
- Small nerves may rarely be damaged, which can result in transient, mild paraesthesia. Lesions on larger nerves and vessels are rare, but in certain cases might require further diagnostics and therapy.
• Although damage to internal organs can be almost completely ruled out with our cautious needle technique, it has been reported in medical literature. In such a case, we would naturally respond immediately with adequate measures.
• During moxibustion, burns or allergic reactions to mugwort can occur under unfavorable conditions. You can help us reduce this risk by indicating on the questionnaire whether you have allergies and/or an asthmatic condition.
• Although we use exclusively high-quality, tested acupuncture needles, in rare cases they can break off. In such a case steps would have to be taken to remove the rest of the needle.

During the consultation with your therapist, please ask about anything you wish to know.

Your therapy team

Consent
Please do not fill out and sign until after the information consultation.

I have received and carefully read the information form. I have understood the questions and answered them to the best of my knowledge. Acupuncture therapy and its possible side effects were thoroughly explained to me. My questions were answered completely and intelligibly.

Notes:

☐ After careful consideration I agree to the acupuncture treatment.

☐ I do not agree to the acupuncture treatment. I have been informed that my decision could impede the therapy of my illness.

Bochum, Date:

(Therapist’s signature)

(Patient’s signature)
Questionnaire on the information consultation
“What we should know...”

Acupuncture

Patient name and address

Please read this questionnaire before the information consultation and fill it out as much as possible. Please ask if anything is not clear.

Thank you very much – Your therapy team

Medications

• Are you currently taking medications that influence blood clotting (e.g. aspirin, warfarin or similar drugs)?

☐ yes ☐ no

If yes, which medication(s) and in what dosage?

• Are you currently taking medication that influences the immune system (e.g. steroids or cancer treatment drugs)

☐ yes ☐ no

If yes, which medication(s) and in what dosage?

• Are you currently taking antibiotics?

☐ yes ☐ no

If yes, which antibiotics and in what dosage?

• Are you taking any other medication?

☐ yes ☐ no

If yes, which medication(s) and in what dosage?

Diseases

• Do you suffer from impaired wound healing or a blood coagulation disorder?

☐ yes ☐ no

If yes, which disorder and with which therapy are you being treated?

• Do you now or have you ever had a malignant disease?

☐ yes ☐ no

If yes, which disease, since when and with which therapy are you being treated/were treated?

• Do you now or have you ever had heart disease (e.g. endocarditis or myocarditis,
perforated cardiac septum, valvular disease, myocardial infarction)?

☐ yes  ☐ no

If yes, which disease, since when and with which therapy are you being treated/were treated?

☐ yes  ☐ no

If yes, which allergies and with which therapy are you being treated?

☐ yes  ☐ no

If yes, which allergies and with which therapy are you being treated?

• Do you suffer from diabetes mellitus?

☐ yes  ☐ no

If yes, since when and with which therapy are you being treated?

☐ yes  ☐ no

If yes, from which disease, since when and with which therapy are you being treated?

• Have you ever had an organ or tissue transplantation?

☐ yes  ☐ no

If yes, what and when?

☐ yes  ☐ no

If yes, which organ/tissue and with which therapy are you being treated?

• Do you suffer from a chronic kidney disease?

☐ yes  ☐ no

If yes, from which disease, since when and with which therapy are you being treated?

☐ yes  ☐ no

If yes, which chronic kidney disease and with which therapy are you being treated?

• Do you suffer from a rheumatic disease?

☐ yes  ☐ no

If yes, from which disease, since when and with which therapy are you being treated?

☐ yes  ☐ no

If yes, which rheumatic disease and with which therapy are you being treated?

• Do you or have you ever suffered from a convulsive disorder (epilepsy, convulsions)?

☐ yes  ☐ no

If yes, which convulsive disorder and with which therapy are you being treated?

• Do you or have you ever suffered from a psychological disorder?

☐ yes  ☐ no

If yes, which psychological disorder and with which therapy are you being treated?

• Do you have any known allergies (including neurodermatitis, hay fever)?

☐ yes  ☐ no

If yes, which allergies and with which therapy are you being treated?

• Do you suffer from a chronic lung disease (e.g. asthma, chronic obstructive bronchitis, emphysema)?

☐ yes  ☐ no

If yes, from which disease, since when and with which therapy are you being treated?

• Do you or have you ever suffered from a convulsive disorder (epilepsy, convulsions)?

☐ yes  ☐ no

If yes, which convulsive disorder and with which therapy are you being treated?

• Do you or have you ever suffered from a psychological disorder?

☐ yes  ☐ no

If yes, which psychological disorder and with which therapy are you being treated?

• Do you have any chronic infectious diseases (e.g. hepatitis or HIV)?

☐ yes  ☐ no

If yes, which disease(s)?

Thank you for your cooperation.
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