Universitätsklinikum
Knappschaftskrankenhaus Bochum
UKRUB UNIVERSITÄTSKLINIKUM DER RUHR-UNIVERSITÄT BOCHUM

STUDY PROTOCOL

DO POSITIVE SUGGESTIONS DELIVERED THROUGH A SOUND CARRIER DURING GENERAL ANESTHESIA DURING NEUROSURGERY AND ABDOMINAL-GYNAECOLOGICAL SURGERY REDUCE POST-OPERATIVE PAIN AND NAUSEA?

SYNOPSIS

Title of the Study	Do positive suggestions (i.e. music and autogenenous meditation) delivered through a sound carrier during neurosurgery and abdominal-gynaecological surgery reduce post-operative pain and nausea?
Study site	University Hospital Knappschaftskrankenhaus Bochum GmbH In der Schornau 23-25 D-44892 Bochum, Germany
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Investigators **Bochum**	Lisa Grause, RUB: 108012253114 Dr. med. Günther Oprea Dr. med. Sven Asmussen Dr. med. Hartmuth Nowak Dr. med. Felix Ebner Savvas Alaeddine
Monitor	Not applicable
Type of study	Multi-centre, prospective, randomised, double-blinded, controlled, investigational study
Primary endpoint	Pain medication (opiods) needed when patient experiences pain (pain intensity NRS = 3) during the first 2 and 24 hourrs after surgery
Duration of the study	6 months
Participants	Patients who have neurosurgery or abdominal-gynaecological surgery, duration of 1-3 hours, general anaesthesia maintained through volatile anaesthesia
Number of participants	400 patients
Insurance	The study does not need an additional insurance. Any kind of problems and personal injuries occuring during the study will be covered via the hospitals employer's liability insurcance.

Study Protocol

1 Responsabilties and addresses

1.1 Study site

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1.6 Monitor

not applicable

1.7 Sponsor

not applicable

2 Scientific background

2.1 Meaning and importance of therapeutical communication

Communication is of great importance in all areas of general health and medicine. It can assist and improve medical therapies in order to improve health outcomes. Appropriate use of language and conversations tailored to the individual can help to find the most suitable treatment plan for each patient and to get the patient fit again. Positive suggestions can reduce adverse events like pain, nausea and vomiting.

There are some clues that communication has a positive impact on narcotized patients. Apparently, direct talking to the patient but also tape recordings appear to exert this effect.

3 Aim of the study

3.1 Objective of the study

The aim of the study is to find out to what extent intra-operative positive sugggestions delivered to a patient during surgery influence post-operative pain. This will be measured through the patient's requirement of pain medication (opiods) at a defined pain level.

Moreover, it will be tested if patients listening to these tape recordings have a shorter time to awake from surgery compared to the control group. It will also be assessed if the patients of the intervention group have less fear and less disorientation compared to the control group.

Furthermore, it will be tested whether positive suggestions can reduce common post-operative complications like nausea and vomiting.

3.2 Primary endpoint

Requirement of pain medication (opiods) if patient experiences a pain intensity of NRS = 3 during the first 2 and 24 hours after surgery.

4 Recruitment and treatment of participants

4.1 Number of participants

80 per study centre, as there are 5 centres: n = 400

Calculation of the number of cases:

Effect size of the meta-analysis (Rosendahl et al. BMC Anaesth. 2016) and the calculated number of cases (Programm "G Power" of the Uni Düsseldorf):

	Effect size	**number of cases**
Drug use	0.19	212
PONV	0.21	173
Analgesics	0.16	301
Antiemetics	0.22	157

For the primary outcome "pain intensity and requirement of pain medication" 300-400 (= 5 x 80) participants / number of cases appear to be appropriate.

4.2 Duration of the study

The duration of the study for every participant is up to 24 hours after surgery. The whole trial will take place over a period of 6 months.

4.3 Inclusion criteria

Patients who have neurosurgery or abdominal-gynaecological surgery: Duration of the surgery should be between 1 to 3 hours and the patient must obtain volatile anaesthesia. Moreover, the patient has to be aged between 18 and 70 years and must have a risk of post-operative nausea and vomiting (PONV), measured via the "Apfel-Score", of ≥ 2.

4.4 Exclusion criteria

- Massive impairment measured with ASA-Score > 3
- Post-operative requirment of ventilation or requirement of intensive care treatment
- Patients with an epidural catheter
- Patient refuses to participate

4.5 Recruitment of participants

At the University Hospital Knappschaftskrankenhaus Bochum, patients will be recruited from the surgical ward. They must fulfill all the inclusion criteria and none of the exclusion criteria.

4.6 Patient information and Consent

Eligible patients will obtain all relevant information about the study in form of oral expalanation but also in form of an information sheet. This process will occur during the pre-operation discussion. The patient will obtain a copy of the study information sheet.

4.7 Data collection

After ensuring that all participants fulfill all inclusion and none of the exclusion criteria, participants will be randomized into 2 groups and will be pseudo-anonymized. Afterwards, following data will be collected from each patient:

Pre-operative:

- Suggestibility-Score (HGSHS-5)
- PONV-Risk-Score (Apfel)
- Fear Score (STAI-S)
- Pain-Score (NRS)

During and at the end of anaesthesia following data will be collected:

- Depth of anaesthesia (BIS)
- requirement and amount of pain medication
- Duration of surgery
- Time until patient wakes up (termination of sedation until extubation)

Post-operative data collection (2 hours after extubation) in the recovery room:

- Pain-Score (NRS)
- PONV-Score (Wengritzky)
- Antiemetic consum/requirement
- Comfort-Scale (NCS)
- Orientation (time, place, name, situation)
- Requirement of pain medication via patient-controlled analgesia (PCA) or nurse-controlled analgesia (NCA)

On the wards, data will be collected over a period of the first 24 hours post-surgery:

- Pain-Score (NRS)
- PONV-Score (Wengritzky)
- Antiemetic requirments
- Comfort-Scale (NCS)
- Fear score (STAI-S)
- Analgesia requirement via patient-controlled analgesia (PCA) or nurse-controlled analgesia (NCA)

4.8 Documentation

Documentation of the data will be done in pseudo-anonymized form in a written document or electronically.

5 Study process

Methods

The study is a multi-centred, prospective, randomised, double-blinded, controlled trial.

During the pre-operation discussion, the patient will also be informed about the study if he/she is considered as eligible and if patient is willing to participate, consent is gained in a written form. Afterwards, a short form of the Harvard Group Scale of Hypnotic Susceptibility Test (HGSHS-5) will be done in order to assess the suggestibility of the patient: Via tape recordings, the patient will be put into a trance-like state and then, the patient will be asked to perform certain tasks. The patient has the chance to assess on his/her own how well they fulfilled the tasks and how they felt. They should assess the following:

Immobility of the right arm, inability to open the hand, stiffness of the left arm experienced when the patient tries to flex the left arm while the left hand forms a fist, difficulty to communicate and inability to shake the head when asked to do so, catalepsy of the eyes and the inability to open the eyes. If the person fulfills 3 or more of these conditions, he/she is considered as highly suggestible.

Moreover, the risk of post-operative nausea and vomiting will be assessed via the "Apfel-Score". Risk factors for post-operative nausea and vomiting are: female sex, PONV or travelling sickness mentioned in the patient's history, non-smoking status as well as expected requirements in terms of dosage of opiods. The number of risk factors will be added up and if the potential patient scores 2 or higher, he/she can partcipate in the study. If the patient scores 3 in the "Apfel-Score", the patient will obtain an intra-operativ, prophylactical dose of antiemetics. Post-operative nausea and vomiting will be treated with an antiemetic drugs according to lacal standards.

The participants will be randomized into 2 groups. Group 1 will obtain head phones just before the general anaesthesia will start, but nothing will be delivered through these. This group will form the control group. Apart from this, group 1 will obtain exactly the same treatment as group 2 and the treatment will be the standard one. Group 2 will form the intervention group and they will also obtain head phones just before

general anaesthesia sets in. But this time, this group will listen to tape recordings during anaestheisa and surgery. Tape recordings include music, and therapeutical communicatin (autogenic -like). Positive suggestions start with initiation of anaesthesia, will last the whole duration of the surgery and will end with the termination of the anaesthesia.For the intitiation of the general anaesthesia, an opioid will be injected (e.g. sufentanil 0,3 – 0,5 µg/kg body weight), as well as a hypnotic drug (e.g. propofol 2–2,5 mg/kg body weight) and also a muscle relaxant (e.g. rocuronium 0,6 mg/kg body weight), according to local standards. Opioid as well as the muscle relaxant will be given in repetitive doses as required. General anaesthesia will be maintained with a volatile anaesthetic drug, nitrous oxide will not be used. The depth of the aneathesia will be measured via the bispectral index or Narcotrend® and will be kept at a value of 40-60. At the end of surgery the patients receive a non-opiod analgesic drug, according to local standards. Termination of anaesthesia starts when the volatile anaesthetic drug is no longer given to the patient. When the patient finally awakes, extubation should occur.

Parameters of the study will be measured post-operatively within 2 hours and at 24 hours, while the patient is in the post-anaesthesia care unit (PACU) and at the ward, respectively. It is of great importance to document the required dose of analgesics and antiemetics as well as the documentation of pain inensity, PONV, fear and orientation. Pain intensity will be rated via the NRS (numeric rating scale, 0 = no pain at all, 10 = worst imaginable pain).
As a standard post-operative pain therapy suggestion patients with a pain intensity of NRS ≥ 3 will receive intravenous piritramid (0,1mg/kg body weight).
In the first 2 hours after surgery in the recovery room, the patient will be asked about their pain intensity every 15 minutes: „Please rate your pain on a sale from 0 to 10 whereby 0 is no pain at all and 10 is the worst imaginable pain." If the NRS score is ≥ 3, the patient will obtain the same amount of Piritramid on a repetitive basis. The total amount of opioids given will be noted down as well as the type of pain: headache, wound pain, pain on lying, pain of the urinary tract and bladder, etc.
Patients who obtain a Piritramid-PCA (patient-controlled analgesia) will be informed how to use it: "You obtain a pump containing pain killers. You are allowed to use the pump on your own and can influence and control your pain perception. Please assess and document your pain intensity at a regular basis by using a scale from 0 to 10,

whereby 0 is no pain at all and 10 the worst imaginable pain and use the pump when the pain intensity is 3 or higher.” After two hours in the recovery room the present pain intesity will be documented again and the patient will also be asked to rate his/her strongest pain intensity he/she experienced over the last two hours: "On a scale from 0 to 10, what is your pain like at the moment? And what was the maximal pain intensity you have experienced from the end of the operation till right now?"

After 2 hours in the PACU the current, situative fear will be assessed via the STAI-S questionnaire (State-Trait-Anxiety Inventory) and documented.

The patient's well-being (comfort) will be assessed in an analogous way to the pain intensity (NRS), i.e. with the help of a numerical comfort scale reaching fro 0 to 10 wherby 0 mean not feeling comfortable at all and 10 represents feeling absolutely fine and comfortable. Moreover, the patient will be asked about his/her worst value in terms of comfort in the time period from the end of the surgery till right now. The well-being (comfort) will be assessed after 2 hours in the recovery room.

In the PACU, the occurence of post-operative nausea and vomiting will be assessed every 15 minutes just like the pain intensity assessment: "Do you feel sick? If you do, we can give you medication against it.” After 2 hours in the recovery room, the PONV-Impact Scale (Wengritzky) will be obtained as well.

In order to find out about the patient's sense of orientation, the patient will be asked during the first 2 hours in the recovery room if they can tell their name, where they are as well as why there are here and what day it is. For every correct answer, the patient scores 1 point. The sum (0-4) and the time of assessment will be noted.

5.1 Data collection

The measured variables/parameters will be documented electronically or on paper.

5.2 Risk-Benefit assessment

The study is an interventional trial. It aims to assess to what extend therapeutical communication together with music can reduce post-operative complications like pain, nausea and vomiting. As the suggestions delivered are of positive nature no negative consequences are expected. If adverse events occur during or after sugery, corrective actions will be taken as soon as possible.

If the suggestions lead to positive consequences, the participant will profit from these and it is possible that positive suggestions may become standard pain managment during surgery. This way post-operative security and comfort of patients could be increased. As data collection, documentation and anaylsis occurs in pseudo-anonymized form, no conclusions can be drawn from the collected data about the individual patient.

5.3 Adverse events

Adverse events like increase in pain intensity, increase in requirement of analgesia or antiemetic drugs or a longer duration till patient wakes up from anaesthesia will be supervised and treated promptly.

5.4 Termination criteria

5.4.1 Individual termination criteria

The participant has the right to withdraw from the study at any given point without being forced to give a reason for doing so and without having to fear any negative impacts on their on-going treatment if they decide to do so. If the partcipant decides to quit the study, collected data from this patient will be destroyed and no longer used.

5.4.2 Termination of the study

If adverse events like pain intensity, nausea and/or vomiting should increase, the study will be terminated. In order to find out about the impact of the study on those parameters, the collected data will be analysed after inclusion of 200 patients (after half of the total number of cases at each study centre).

6 Biometry / Statistics

6.1 Randomization

The eligible patients willing to participate will be randomized into 2 groups of equal size. Division into these 2 groups will be done via lottery.

6.2 Study question in form of statistics

In this study the hypothesis to prove is: "Positive suggestions during surgery improve post-operative pain perception and intensity"

The null-hypothesis is:

"Positive suggestions during surgery do not improve post-operative pain perception and intensity"

The significance level is $\alpha = 5\%$ ($p < 0.05$).

6.3 Analysis of data during the study itself

During the study itself, data will be analyzed after 200 patients, the data will be analyzed and the number of cases as well as the effect size may be reconsidered if required.

6.4 Planned analysis methods

It will be tested if the collected data is normally distributed and for this the Kolmogorov-Smirnov tests will be used. Analysis of the results for the used drug doses (mean ± SD) will be done via the student t-test, the PONV will be analysed via the chi^2–Test and the propotions of pain intensity between intervention and control group will be analysed via the Mann-Whitney U-Test. A p-value < 0.05 will be considered as statistically significant.

7 Altertions in the study protocol

If any alterations in the study protocol have to be made, the study protocol has to gain another ethical approval by the ethical commision of the Medical Faculty of Ruhr-University Bochum.

8 Ethical and legal remarks

8.1 Declaration of Helsinki

The study respects the latest declaration of Helsinki.

8.2 Consent

Participation at this study is voluntary. Patients / Participants will be informed beforehand about the process of the study and will receive all relevant information about the study. Clarification will be done verbally and in a written form, i.e. the potential participant will obtain a form in which the most important and all relevant facts concerning the study are mentioned. Consent is given via a signature on the consent sheet (see appendix). The particpant has the right to withdraw from the study at any time of the study process without having to give a reason for doing so or fearing disadvantages in his/er ongoing medical treatment.

8.3 Data protection

The names of the patients / participants and all personal data as well as information and documents will be handled with respect of the doctor-patient confidentiality and the condtions mentioned in the "Bundesdatenschutzgesetzes (BDSG)". Data obtained from patients / participants will be passed on - if needed - only in pseudo-anonymized form. No unauthorised person will have the chance to gain insight into the original documents.

8.4 Vote of the ethical commission

This study protocol was handed to the ethical commision of the Medical Faculty of the Ruhr-University Bochum in order to be ratified.

8.5 Insurance

The study does not require any additional insurance. Any personal injury or any problems will be covered by the hospital’s employer's liability insurrance.

8.6 Funding

This study is partly is partly supported by de.NBI, a project of the German Federal Ministry of Education and Research (BMBF) [grant number FKZ 031 A 534A]

8.7 Signatures

Dean of the study / Clinical director for anaesthesia, intensive-care medicine and pain therapy	*Prof. Dr. med. M. Adamzik*
Principal investigator	*Dr. med. G. Oprea*
Medical director	*Prof. Dr. med. R. Viebahn*

9 References

„Efficacy of therapeutic suggestions under general anaesthesia: a meta-analysis of randomized controlled trials“. (*Rosendahl, Koranyi, Jacob, Zech, Hansen*, BMC Anaesth 2016. Therapeutical suggestions and hypnosis appear to be the most effective psychological intervention forms in order to improve intra- and post-operative patient outcomes. (*Montgomery* 2002, *Schnur* 2008, *Tefikow* 2013, *Kekecs* 2014).

In a meta-analysis concerning this topic *Rosendahl et al.* assessed the efficency of therapeutic suggestions during general anaesthesia with regards to a number of post-operative outcomes: post-operative nausea, vomiting, analgetic drug dosage requirements, requirement of anti-emetics, pain intensity, psychological stress (e.g. fear, depression) and recovery (e.g. mobility). The reason for using intra-operative suggestions is that during general anaesthesia the central auditory system stays intact. Therefore, the nervous system can still process auditory stimuli (*Clark* 1973, *Madler* 1991).

The meta-analysis used 32 randomised-controlled studies which fulfilled following criteria: The participants in the trials were adults and were grouped into intervention and control groups. Only intra-operative, but no pre- or post-operative suggestions were used in any of these 32 studies. Participants had general anaesthesia and after surgery, various outcomes were assessed by themselves and other people. This way, data from 1,111 patients who were in the intervention groups (mean age: 47.7) and 991 patients who were in the control group (mean age: 47.2) was collected and analyzed. 32% of all intervention groups (i.e. 12 intervention groups) obtained affirmative, postive suggestions, 3% of all intervention groups (i.e. one group) received non-affirmative, positive suggestions and 38% of all intervention groups (i.e. 14 groups) received non-affirmative and affirmative suggestions. In 51% (i.e. 19 groups) of all intervention groups, these suggestions were supported by music and other noises. In 56% of all control groups (i.e. 18 groups) the participants received headphones but did not hear anything at all, 22% of all control groups (i.e. 7 groups) listened to music or noises, and 7 control groups listened to textes read out of e.g. a cooking book or listened to the history of the hospital. Moreover, different anaesthetic drugs were used

in these different trials. In the intervention group, the outcome was slightly, but still statistcally significantly different compared to the control group suggesting that positive suggestions have positive impact on post-operative outcomes.

There was a siginificant effect on post-operative nausea and vomiting (effect size = 0.21, CI 95% [0.07; 0.36]) as well as requirements of anaelgetic drugs (effect size = 0.16, CI 95% [0.06; 0.26]) (*Merikle und Danemann* 1996). There was a slight significant effect visible in post-operative anti-emetic drug requirement (effect size = 0.22, CI 95% [- 0.003; 0.45]) and recovery (effect size = 0.11, CI 95% [-0.01; 0.24]). No statistically significant effect was detected in terms of pain intensity (effect size = 0.04, CI 95% [-0.04; 0.12]) and psychological stress (effect size = 0.03, CI 95% [-0.11; 0.16]).

The effects detected in terms of analgetic drug requirement, recovery, pain intensity and psychological stress were similar in all groups used in the meta-analysis, but differences were seen in terms of post-operative nausea and vomiting as well anti-emetic drug requirement. However, no confounding factor could be found explaining the differences seen in the latter mentioned outcomes. Affirmative suggestions led to higher effects than non-affirmative ones (*Mayo* 2014). The usage of different analgestics did not lead to any differences in the impact of suggestions.

The meta-analysis concluded that suggestions during general anaesthesia causes siginificant, positive effects on the mentioned outcomes. Negative effects triggered by the suggestions could not be detected. Hence, suggestions are a possible intervention tool in order to improve post-operative outcomes and are not pricy. So far, it is not clear what form and type of suggestion is the most effective one (*Kekecs* 2014, *Dawson* 2001, *Jelicic* 1993, *Williams* 1994).

Maroof M, Ahmed SM, Khan RM, Bano SJ, Haque AW. Intra-operative suggestions reduce incidence of post hysterectomy emesis. *J Pak Med Assoc* 1997

This study contained 50 ASA I und ASA II patients who were grouped into intervention and control group: The intervention group who received intra-operative positive suggestions showed statistically siginficant improvement in terms of nausea (control group 60%, intervention group 36%, $p < 0.05$). The requirement for anti-emetics was also statistically higher (control group 66.6%, intervention group 22.2% $p < 0.05$). The study suggests that therapeutical suggestions could be an alternative to anti-emetic therapy.

McLintock TTC, Aitken H, Downie CFA, Kenny GNC. Postoperative analgesic requirements in patients exposed to positive intraoperative suggestions. *Br Med J* 1990

This is a randomied, double-blinded study consisting of 63 female patients who were divided into control and intervention groups. Outcomes assessed were pain intensity and morphine requirements 24 hours after surgery. The study highlighted a statistically siginficant reduction in morphine requirements in the intervention group: The intervention group needed on average 51.0mg (CI 95% [42.1; 60.0]), the control group needed on average 65.7 mg (CI 95% [55.6; 75.7 mg]). Pain intensity was similar in intervention and control group.

Nilsson U, Rawal N, Unestahl LE, Zetterberg C, Unosson M. Improved recovery after music and therapeutic suggestions during general anaesthesia: a double-blind randomised controlled trial. *Acta Anaesthesiol Scand* 2001

This study is a randomised, double-blinded study containing 90 female aptients who had hysterectomy and who underwent at the same time general anaethesia. The first interventin group received intra-operative suggestions combined with music and this group then needed less analgetic drugs than the control group. The second intervention group received only intra-operative music and this intervention group considered the analgesia more effective than the control group. Therefore, they became mobile faster. At the point of discharge both intervention groups were less exhausted compared to the control group. In terms of nausea and time till discharge

no differences could be detected between control and intervention group.

Kekecs Z, Nagy T, Varga K. The effectiveness of suggestive techniques in reducing postoperative side effects: a meta-analysis of randomized controlled trials*. Anesth Analg*, 2014

This is a meta-analysis reviewing 26 studies with regards to post-operative pain intensity, nausea and fear as well as post-operative analgetic drug requirement if positive suggestions were used. The suggestions led to a significant effect in terms of reduction of pain intensity (effect size = 0.25; CI 99% [0.00-0.50] P = 0.010) and fear (effect size = 0.40; CI 99% [0.13; 0.66] p < 0.001), but not in terms of nausea and requirements of analgetic drugs.

Williams AR, Hind M, Sweeney BP, Fisher R. The incidence and severity of postoperative nausea and vomiting in patients exposed to positive intra-operative suggestions*. Anaesthesia* 1994

This is a double-blinded study including 60 patients, who had gynaecological surgery. The intervention group suffered siginificantly less from nausea and vomiting in the first 24 hours after surgerycompared to the control group.

Eberhart LHJ, Döring HJ, Holzrichter P, Roscher R, Seeling W. Therapeutic suggestions given during neurolept-anaesthesia decrease post-operative nausea and vomiting. *Eur J Anaesthesiol* 1998

This is a randomised, double-blinded study. The intervention group showed a reduction in nausea and vomiting (intervention group: 30.6% vs. control group: 68.6%).

Evans C, Richardson PH. Improved recovery and reduced postoperative stay after therapeutic suggestions during general anaesthesia. *Lancet* 1988

A randomised double-blinded study containing 39 female patients: Out of these, 19 received suggestions. All 39 patients underwent hysterectomy. The patients grouped into the intervetnion group recovered faster could be discharged earlier than the ones from the control group and suffered from a shorter period of pyrexia compared to the control group.

Lebovits AH, Twersky R, McEwan B. Intraoperative therapeutic suggestions in day- case surgery: are there benefits for postoperative outcome. *Br J Anaesth* 1999

This study included 70 patients who had surgery for hernia: They were divided into intervention and conrtol groups. In terms of pain intensity after surgery, there was no significant difference between intervetnion and control, but the intervention group complained less about nausea and vomiting (control group: 15%, intervention group 4%; $p < 0.02$). This difference became less siginificant in the long run. Anyway, during the whole stay at hospital, the intervention group suffered from less adverse events (e.g. headache) after surgery.

Myles P.S., Wengritzky R., Simplified postoperative nausea and vomiting impact scale for audit and post-discharge review. *Br J Anaesth 2012*

Myles und Wengritzky show in their study how to use the PONV and explained how to identify clinically significant cases. The frequnecy of vomiting hereby highlights the intensity of nausea. Clinically strong PONV are considered if the score is > 5.

10 Appendix

10.1 Text of suggestions

Positive suggestions- text

Part A (duration:19 minutes;will be repeated several times; starts with induction of anaesthesia and ends with end of anaesthesia)

(Music)
You are sleeping now
and can relax and make yourself comfortable,
save energy and take a rest,
as you are safe and in a well-protected environment.
Everything that you will hear, see and feel will help to speed up your recovery.
This way, your body can concentrate on its recovery as well.

And we will be by your side.
You can hear my voice, you will here it all the time during the surgery,
so that you can concentrate on it,
what i am telling you is of great importance for you,
your recovery and your health.

Every breath you take will be more and more supported by the medical ventilator and will take over the work of respiration for you so that you can save all your energy for the time later on, after the surgery, so that you can breathe the fresh air later on.
With each time you breathe out, you can also free yourself from any worries, fears and burdens.
You can relax and gain calmness, confidence and build up energy needed for the process of recovery.

The surgery is going well. The surgeon and anaesthetist are confident and pleased.
Everything is going nicely, calm and professional.
The medical staff are specialised in their job. They know exactly what they are doing and know how to provide the best care for you.
Everything is ready for the perfect treatment.

All requirements for the best and safest surgery are fulfilled.

The highest priority is your safety and well-being is and the anaesthetist and the health care professionals are there to ensure your safety and well-being.
They will be by your side at any point in time until you fully recovered from the surgery.
They will provide the best care for you.
It is all planned: the medication you will require and everyone knows what to do in order to provide best treatment for you for any situation.
We will always be there for you.
Your essential bodily functions are strictly and permanently controlled.

The regular squeaking originates from the monitor and shows that your heart beat is regular. Your blood pressure is absolutely perfect as well.
The essential part is done by yourself and your body. The staff around you will just ensure that the conditions are optimal.
As you and your mind can take a rest now, your body can concentrate on its self-protection and self-recovery.
All your organs, your heart, and your blood vessels work in concordance.

(indirect suggestions delivered by another speaker)
Perfect! Your patient here appears to be absolutely well. Perfectly stable and calm. The patient is handling the situation in an amazing manner. This will lead to a quick recovery and the patient can be happy that the surgery was such a success.
Are you happy?
Absolutely. This is running smoothly and perfectly.
Perfect!

Listen carefully to what I have to tell you know!
You know that this surgery is of great importance for you
and while the procedure here is done carefully , the recovery room and also the ward get prepared for your arrival over there.

And while the surgery is taking place, you can shut yourself away and dream of a place where you experience pure wellness and comfort.
Your body is aware that a calm and confident mind are the key to a perfect recovery

and your subconsciousness profits from this as well: Your subconsciousness can then perfectly balance your hormone levels, the bodily process for recovery, the immune system, the sleep pattern and all other key processes required to ensure perfect health.
Your subconsciousness is doing a great job.

Let's talk about the time after the surgery:
In case you experience any pressure at the site of surgery, then you can conclude that this is a sign of recovery. Tissue repair started. Your white blood cells are busy at this side now and will guarantee best wound healing. Moreover, they recruited other cells, activated messenger substances in order to provide best cure and good perfusion so that all essential nutrients can get to the site as quickly as possible.
You are well looked after.
You will notice that any kind of tension and fear would increase pain. Therefore, it is better to relax and ensure that the part of the body where surgery took place is well protected. Relax and take a step back.
It is normal that you can feel at which part of your body the surgery took place. But your body will fix this area so that you will be fit and healthy again. It is enough to notice that the signals sent out from the area of incision will become less and less. Once you notice this, you can move on.
It is great to know that your body and every single cell, know exactly what their job and function is so that they can perform in an outstanding manner without needing your attention in order to do so. You have time to focus on more pleasant situations in life .
While your body is working on its recovery and the health professionals take care of everything, you can back out and relax at a calm place. Enjoy this and only now and then, you may hear that professionals do their job in order to get you back to best health.

What else can you expect from the time after surgery?
Step by step, your body will regain its full function, your blood circulation will run perfectly smoothly again as well as your digestion.
Saliva will be produced and you will be able to swallow,
and you will be able to drink.
Everything will be fine.
You will notice complete sense of well-being.

You can think about what you would love to eat now
and prepare your stomach which relaxed up to this point for the arrival of food.

What else should be mentioned?
There were fears and worries. They are normal as they aim to protect you .
Now,after surgery, they are unnecessary and useless as your process of recovery already started and as you are safe and comfortable.
Recovery has already started and will go on and on without needing help.

Your body is doing an amazing job!
You can do it!
And we will be there for you and by your side.
You are safe

Moreover, once the surgery is over,
you are going to be able to breathe on your own again.
You can breathe a sigh of relief.
You can take a deep breath in and out
in order to free your airways.
You will notice how energy will speed through your body.

We are all confident that you will be fine after surgery, so you can be confident as well.
The medication provided for you will prevent nausea, vomiting and pain and they will work well, so that you can feel comfortable.
In the upcoming days and weeks after surgery you will be free of complications and burdens.
You will feel relaxed, happy and calm.
Any type of sensation which you might feel will not influence your well-being. It will only be a note for you telling that your body is working on its recovery and repair.
Your body will find its balance again.
Everything is going to be perfect.

Teil B (duration: 12 minutes, will only be played once; will start when general anaesthesia ends)
Surgery went well and is about to finish now.

Your recovery process has already started.
You could relax and save energy.
Now, it is time to bring you back to the here and now.
All fears and worries that aimed to protect you are of no use and of no necessiy.
You are safe and in best care.
All kind of pain which should protect you are unnecessary as you get the best treatment and support.
Any sort of nervousness which could upset your digestive tract is unnecessary as well as everything is working perfectly well. You can chew, swallow and drink. So, you can look forward to have a proper meal. What would you love to eat now?
You will enjoy the food and it will help you to regain strength and power.
Your stomach is fine,
your kidneys do their job,
the wound is healing
your body is perfectly regulating itself .
You can breath
And with every breath you take, your recovery proceeds as well.
With every breathing out, you can get rid of your fears, anxiety and worries.
You are going to get stronger and stronger.
You will notice how you get more and more aware of the environment surrounding you.
You will now eventually wake up and can move yourself.
You are able to orientate yourself. Everything is just the way it is meant to be.
Health care professionals are there to protect and support you.
Your recovery process can go on.
The time in hospital will be fine.
It is awesome to be cared for in such a perfect, warm-hearted manner! Perfect!

10.2 Patient information sheet

Patient's name:……..... date of birth:……

Dear Patient,

you are currently staying at our hospital and you will undergo surgery which will require general anaesthesia. Therefore, you fulfill the most important criteria, and have the chance to become a participant of the study "Can positive suggestions delivered through a sound carrier during general anaesthesia reduce post-operative pain, nausea and time required to awake from genera anaesthesia?" if you decide to do so.

The aim of the study is to investigate whether listening to positive suggestions during general anaesthesia during surgery can improve post-operative outcomes , i.e. reduce complications like pain intensity, nausea and vomiting and reduce the time needed to awake from general anaesthesia.

Background of the study

The topic "communication" is of great importance in all areas concerning Health Care and can support patients during their therapies and treatments.

Up to date, there are several hints that special forms of positive suggestions can speed up recovery , i.e. to help the patient to get well again within a shorter period of time. Moreover, there is evidence that negative outcomes like nausea can be reduced with the use of positive suggestions. Apparently, this does not only occur through direct conversation between the doctor and the patient, but also via tape recordings delivering positive suggestions to the patient during general anaesthesia: The subconsciousness appears to be able to process the auditory input despite anaesthesia.

What does this mean for you?

After any kind of operation, there is the risk that patient's experience pain at the operating site, as well as nausea and vomiting. Furthermore, it can take some time until you fully wake up from anaesthesia and can fully orientate yourself (soll das in meiner Studie auch getestet werden?). The study "Can positive suggestions delivered through a sound carrier during general anaesthesia reduce post-operative pain, nausea and time required to awake from genera anaesthesia?" will explore to what extent positive suggestions delivered to you during surgery can improve the outcomes of the above mentioned aspects. The delivered text is a purely positive one, i.e. only contains positive and confident context. These positive suggestions should help you to feel better and more comfortable after surgery and to reduce complications and adverse outcomes like intense pain or nausea and vomiting. Consequently,

it is not expected that participation in this study will cause any negative effects or will put you at any medical risk.
In order to analyse how efficient and to what extent the positive suggestions can influence your health, the participating patients will be divided into two groups. One group will receive headphones at the beginning of the anaesthesia but the headphones in this group will be just dummies and the participants allocated to that group will not listen to anything at all. They will form the control group. The participants allocated to the other group will also receive headphones once anaesthesia is induced and in this group, the headphones work, i.e. patients in this group will be exposed to positive suggestions during the whole surgery (=intervention group). By comparing the outcomes, i.e. pain intensity and nausea/vomiting between the intervention and control group, one will investigate the efficiency of the therapeutical communication (=positive suggestions).
Apart from this, both groups will be treated the same.
This study is a double-blinded trial, which means that neither the doctor treating you nor you as a participant know which group you were allocated to: So you will not know whether you will be part of the intervention or control group. This way study results will not be influenced by this kind of knowledge.
There will be random allocation of participants into intervention and control group. This way, it can be assured that the group composition is quite similar.
You will get the normal standard medical treatment no matter what study group you are in and even if you decide not to take part in the study at all as the participation at this study is voluntary.

Risks and complications:
This study is a pure observational study.There will not be any additional medical examinations done or any additional blood samples taken. Hence, there is no additional medical risk for you if you decide to participate at this study. As the participants in the intervention group will only listen to positive suggestions, no negative effects will be expected.
All patients will be supervised carefully during and after surgery so that one can intervene quickly if any negative effects should occur.

Insurance cover
There is no requirement for any additional insurance as the participants are not put at any increased risk when participating at the study.

Data protection
Your data concerning your medical condition will be stored in a pseudo-anonymised form, and

will be stored as implicated by guidelines for at least 15 years. This means, that the your study data will only exists in form of a general data set. Therefore, any inferences to your data will only be possible in case of an emergency requiring access to your data and this would require a disproportionate, immense amount of effort. As the case may be, study data will be passed on to other centres of the multicentred trial or future co-operation partners (hosptials, universities, research facilities), but the data will only be passed on in pseudo-anonymised form.
The connection between your personal data and the pseudo-anonymised collected data will be a randomisation code, which only a few authorised people will know and which will not be passed on to other people. All data will be destroyed 15 years after the study ended.
Every single person that will care for you during the whole process of the trial, will respect the confidentiality law and are aware of the data secrecy. Thereby, only the doctor treating you, the leader of the study, the deputy and the medical student will be able to access the data and only they will be allowed to use and analyse the data. Moreover, these people will not be informed which randomisation code represents your data in particular. This way pseudo-anoymisation will be guaranteed.
However, the pseudo-anonymisation also leads to the consequence that you will not be able to get any further details about your specific study data results.

Voluntariness

Participation at this study is voluntary. You can withdrawal from this study any time you feel it is appropriate to do so, i.e. whenever you want to without having to say why you decided to do so. In case you do decide to drop out of the study, all data collected from you up to this point will be destroyed. If you decide to withdrawal from this study, this will not influence your medical treatment in any way.
Of course, you can refuse to participate at the study straight away when you get the offer to particpiate: In this case, you do not need to fear any adverse consequences at all. You will always be guaranteed standard medical treatment.

Availability of the prinicpal investigator

In case of any questions, the doctors of the clinics can help you to solve these. If any concerns cannot be solved this way, the dean of the studies called Dr. Oprea can be called (telephone: +49 (234) 299 - 3001).
If you are ready to participate in the study, you are kindly asked to sign the consent form after a detailed discussion about the frelevant aspects of the study.

Consent and data privacy statement

I hereby consent that my data concerning my person, my diagnosis & medical examination can be used for the above mentioned study.
I am aware that my data will be handled with care & that the data policy will be respected at any point in time.
I am well informed about the study, the aim of the stud and also about the study process and know that the participation at this study does not put me at an increased risk of adverse incidents.
I am aware that my data will get pseudo anonymized and that due to this, identification of my person by looking at the study data will not be possible unless an immense amount of effort is done. Therefore, there is no chance for me, as a participant, to have an insight into the studying result.
I have read and understood the information sheet. I had the opportunity to ask questions and to get further explanations to remove ambiguity.
I consent voluntarily to participate in this study .I know that I can withdrawal from the study at any point without having to mention any reason why I decided to do so, and without having to fear any disadvantages in my further medical treatment if I decide to do so.

Comments:……

……	……	…….
(name of the participant)	(signature of the participant)	(place, date)
……	……	…….
(name of the doctor)	(signature of the doctor)	(place, date)

10.3 Staff information sheet

Dear staff members working for the clinics in the areas anaesthesia, intensive care medicine and pain therapy, we want to focus again on therapeutical communication as a possible tool for standard care. Therefore, our patients should have the chance to listen to positive suggestions during surgery in order to experience less pain, nausea and vomiting after surgery. These suggestions should be delivered to the patient via certain communication techniques as well as nonverbal communication.

We are taking part in multicentered trial investigating therapeutical communication and its effects on post-operative pain intensity as well as nausea and vomiting. In order to reduce post-operative pain, nausea and vomiting, postive suggestions will be delivered to patients during surgery. These suggestions will be delivered through headphones.

With the help of the study, we aim to investigate whether listening to previously recorded verbal content during surgery can lead to reduction in requirement of general anaesthesia and reduce post-operative adverse events like nausea and vomiting. All participants will be continuously supervised, pain intensity will be rated by the patient and post-operative nausea and vomiting (=PONV) will be rated via a simple yes-no-question.

For reducing pain, patient will get standard pain treatment (opiods, painkillers, ...). In order to reduce the feeling of sickness, patients will receive anti-emetics as required. So, this treatment will be standard pain and anti-emetic treatment. All results will be handled with care and with respect of the data protection law as well as confidentiality. Moreover, patient data will get anonoymized.

Aim of this study is, to find out whether positive suggestions should become part of standard peri-operative treatment and to find out whether we can improve patient outcomes by using this form of therapeutical communication.

Thanks in advance.
Yours sincerely, Dr. med. Günther Oprea
Prinicipal investigator (Bochum)

10.4 Harvard Group Scale Of Hypnotic Susceptibility Test

HGSHS-5 – A short version of the HARVARD GROUP SCALE OF HYPNOTIC SUSCEPTIBILITY Tests

INTRODUCTION

Hello. Before we start, I would like to mention a few facts. For this, I would like you to ask to make yourself comfortable. Did you know that even in everyday life we sometimes experience a "natural trance state"? For example when you look out of the window or when you go for a long walk and you feet appear to walk on their own without you having to think about it, when you think about your last holiday trip, your last visit at hospital. In those moments we do not think in a rational way, but think in terms of pictures and meomries. In those states we react more emotional and also exhibit a more responsive bodily response / body language.
When such a trance-like state is initiated for therapeutical purposes, then this state is called "hypnosis": hereby, it is of importance to mention that hypnosis is not used for manipulation, but helps you as an individual to become more able to process ideas and to react to stimuli without being distressed by any external factor.

Now, we want to test for scientific purposes how correspondent you are to positive suggestions and for trance-like states. During this hypnosis we will not ask you to perform anything you would be ashamed of and your privacy and human dignity will be respected all the time. The best thing to do is just to relax and to listen to the test and the process.

INDUCTION

Please take a seat and make yourself comfortable. Your hands should be place on your lap. That's great. Just relax and look at your hands, fix them with your gaze. please focus on a specific point on one of your hands. it does not matter what type of point you fix and in what area it is located.Just go for one point. Great...just let your hands go floppy and fix your selected point. The following instructions will help you to relax and to enter the hypnosis. entspannen Sie die Hände und fixieren Sie deutlich den gewählten Punkt. Relax and feel comfortable. Please focus with your eyes the selected point on your hands and do not let it go while you listen to me carefully. Your ability to enter and experience hypnosis is depndent on how carefully you listen, on how ready you are to experience the hypnotic state anf how cooperative you are as well as how concentrated you ook at the point on your hand. If you listen carefully to what I say you will find out how easy it is to experience a trance-like state. A trance- like state is absolutely normal. In a way, you are under hypnosis whenyou watch a good film. You can experience the state when you are stunned by something. In these moments you forget about your surrounding. This is what we would like you to do right now as well. Just let go... This state is usually considered as pleasurable and comfortable.

Please relax and continue to focus on the spot on your hand. If your eyes are about to fix something else, then do not mind and just bring your attention back to the selected spot. You might find out that the spot becomes blurry or changes its colour. This is absolutely fine.If you feel sleepy, this is okay. Just accept it and continue to fix the point on your hand with your eyes. But there will be a point in time where you cannot concentrate on the ppint anymore as it will be too exhausting and you will be unable to keep xour eyes open. You want to close your eyes or they might close without you having any control over it. Just let this happen. While I will continue talking, you will become more and more sleepy. You will notice that I will give you further suggesgtions for closing your eyes, but do not mid about this.

The following suggestions are for particpants who need slightly longer. You can just continue to relax.

Just continue to feel comfortable and concentrate about your musculature. Relax all your muscles and let them go floppy. The muscles in your legs will go floppy...the muscles in your feet will get floppy....just let your arms go floppy...the hands and

fingers. Relax the muscles in your neck...the muscles in your tummy...just relx. relax...just relax and let it go.

As you relax more and more, you might have the feeling that your body becomes heavier and heavier. Your arms feel heavy, your legs feel heavy...your fingers...your feet. Like metal Your legs feel heavy and floppy...really heavy and floppy. Your arms are heavy and floppy...your arms are heavy,so heavy....your whole body feels heavy Your eye lids are extremely heavy. And you feel heavy and sleepy.Relaxed and at ease. Your breathing slows down...slowly and regularly. You become more and more tired and sleepy. Your eyes are tired of fixing the spot on your hand. You have the feeling that your eyes get wet as if you are about to cry and your eye lids are so heavy. Soon, your eyes will close without you having to do anything to to so.Your ees are exhausted from starring at the spot. So exhausted. It would be awesome to close the eyes. You would love to close your eyes just to be able to fully relax. You would loe to listen to my voice while you are in a sleepy state. You will soon reach the point where you can no longer resist the urge to close your eyes...the will just close on their own...

You feel relaxed, comfortable and fully at ease....you are fully relaxed. A pleasurable feeling of being safe and warm and a great feeling of heaviness....you are sleepy and tired....tired and sleepy...sleepy....sleepy...sleepy. Listen to my voice.

Your gaze gets blurry....it is difficult to get a clear picture of your surrounding. Your eyes are exhausted. The exhaustion is massive and get more and more, more and more. Your eye lids are geavy. Heavier.Heavier than ever before. You have the feeling as if weights are pulling your eye lids down and cause them to close your eyes. Your sight gets blurry....close your eyes...possibly they ae aleready closed.

Your eyes are closed now...or would close soon now...it is not necessary to force them to stare any more. Even if your eyes are not closed yet, you have fixed the spot on your hand and you feel relaxed and sleepy. Just allow yourself to close your eyes. Exactly. Close your eyes. Close them. Let it happen. Close your eyes now.

You are relaxed and comfortable, but you will relax even more. Much more.

Your eyes are closed now. You will keep your eyes closed, until I will tell you something else, i.e. till I tell you to wake up...- You feel completely relaxed and sleepy and you listen to my voice. Listen to my voice carefully. Concentrate to what I say...even focus your thoughts on what I say...just listen- you will become more and more relaxed ad sleepy. Soon, you will be completely relaxed but will no longer hear me. You will not

wake up till I tell you to do so. I will start counting now. For each number, you will feel how you dive to sleep...deeper and deeperI. A relaxing sleep whch will give you time to recover and in which you will be able to do all those things I will ask you to do.

1...you will fall into a deep sleep....2....deeper and deeper,a healthy sleep...3...4...deeper and deeper....5...6...7....You fall asleep more and more, a deep sleep. Nothing will disturb you. Just listen to my voice, just listen to what this voice tells you to focus on. Please pay attention to what my voice tells you and to what things i ask you to focus on...8-9-10-11 - 12....deeper and deeper, a deep sleep...
13 - 14 - 15.... Despite you are sleeping deeply, you can hear me really well. You will always be able to listen to me no matter how deep you think you are asleep... 16 - 17 - 18 .... deep sleep, fully asleep. Nothing can disturb you. You will experience a lot of things i will tell you to do so.... -19 - 20. Deep sleep! You will only wake up when I tell you to do so. You want to sleep and will experinece, what I will describe you soon. Pay attention to what I tell you and wait and see what happens. Just let it happen even if it is not the way you might expect it to be like.

IMMOBILITY OF THE RIGHT ARM

You are relly relaxded right now. The heaviness which have experienced from time to time spreads across your whole body. Now I would like you to concentrate on your right arm and hand...right arm and right hand are heavy as well...and as you imagine the heaviness of your right arm and right hand you can feel how the right arm and right hand become even more and more heavy. Now your arm is heavy. Relyy heavy...lie metal...you may want to test how heavy your arm is and you might want to try to lift ...it might be too heavy to lift or you may be able to lift it, but only slightly...why don't you test how heavy it is? ...Try to lift your hand just try to lift it. (10 SECONDS SHOULD GO BY)

Good. That's enough...relax again.You have experienced the resistance as you tried to liftyour hand...which is caused by the fact that you are in a fully relaxed and floppy state. Now you can let your hand relax. If you wanted to, you could lift your arm up right now but you do not have to do so. Just relax....fully relax. Relax. Only relax.

FINGER CLOSURE (time: 1'40")

Now something different...put your hands together and interlace your fingers...interlace

your fingers and push your hands together, tightly...interlace your figers...pressure your hands against reach other...strongly..really storong...Notice how your fingers interlace more and more, your fingers are interlaced so much that you ask yourself if you will ever be able to part them again at all...try to part your hands from each other...just try to do so... (10 SECONDS SHOULD GO BY)

That's enough....relax...you have noticed how difficut it was to initiate the separation of your hands. Your hands are no longer bound to each other... You can part them now. Put your hands back to the starting position... relax.

RIGIDITY OF THE ARM (LEFT)

Please place your left arm in front of you..fully extended and build a fist. Forwards...exacly this way...great...now form a fist...a tight fist. Pay attention to your left arm and imagine that your left arm gets stiffer and stiffer... absolutely stiff..and now realise how your arm gets more and more rigid. it is stiff. hard and infelxible. Like an iron bar...and you know...you feel that it is impossible to flex your arm...try to do so...test how stiff, rigid and hard it is...try to flex it... (10 SECONDS SHOULD GO BY).

That's enough. Do not continue to flex your arm and relax. Do not try to flex your arm anymore...realx. You could feel the stiffness which required a lot of force to flex your arm...atask which is usually really easy to perform. You could feel the increaing stiffness and rigidity. But now your arm is no longer stiff. Put your arm back to its former postion ...just relax, your whole body should relax. While your arm relxes, your whole body does so just as well.

INHIBITION TO COMMUNICATE

You are now fully relaxed...absolutely relaxed...deeply relaxed...just imagine how difficult it would be to start a conversation in a siutation just like this...possibly just as difficult as it would be if you were sleeping...even saying no or shaking the head to say no...I guess you will find it really difficult just to shake your head right now...just try to do so... (10 SECONDS SHOULD GO BY).

That's good...do not go on to try to do so. relax You have felt the resistance while you were trying to do a simple normal action. Now you are able to shake your head so much easier and fast...try to shake your head gently...great...now relax, just relax.

CATALEPSY OF YOUR EYES

Your eyes have been closed for a little while now while you remained in the relaxed state. Your eyes are closed. Tightly. Really tightly. I will soon ask you to open your eyes...if you try to open your eyes you will have the feeling as if your eye lids were clued together. Fully clued. Even if you tried to open them, you would only do so for a really short period of time before closing them again just to avoid that anything would disturb your concentration. But i believe that you are not able to open your eyes...not even for a short period of time possilby, you would like to try to open your eyes now, just to open your eyes for a short time despie the fact that your eye lids feel so heavy and so tightly closed. Try to open your eyes...just try to do so... (10 SECONDS SHOULD GO BY).

Great. Do no longer try to do so. The eyes should close now. Close them tightly. You had the chance to experience how tightly your eyes are closed. Now relax. Your eyelids will no longer feel that sticky and you would be able to open them right now if you wanted to do so. But please let them closed. Relax. Relax and keep your eyes shut.

TERMINATION

Please listen carefully to what I say now. I will soon start to count from 20 backwards till 1. Meanwhile, you will gradually wake up but you will mainly stay in a trnace like state like you are right now. You will only fully open your eyes when I say "5".When I am at the number 1 you will be fully awake and in a normal state. You will feel relaxed and as if you had a good recovery and relaxing sleep. I will start counting backwards now. You will not open the eyes till I reach the number 5- not earlier than this- and you will not be fully awake till you hear gthe number 1. When i come to say 1, you are fully awake. Ready?

20 - 19 - 18 - 17 - 16 - 15 - 14 - 13 - 12 - 11 - 10 - 9 - 8 - 7 - 6 - 5 - 4 - 3 - 2 - 1.

Your eyes are open now. You are fully awake.

(CONTIUNE TO SPEAK ONLY 10 SECONDS AFTER THIS)

And now please take the assessment form. You are asked to assess if you were able to perform the suggestions and whether an observer would have seen any kind of actions. Just consider what you think what happened. Answer the questions by either ticking A or B.

10.5 Assessment HGSHS-5

Assessment tool for

HGSHS-5

(short version of Harvard Group Scale of Hypnotic Susceptibility Test)

Study: ……

Test institution: ……

Tester: …… **Date:**……

Test person: ……

Contact dates: ……

Sex: male female **Alge:** ……

Test result NS MS HS

OBJECTIVE, EXTERNAL REACTIONS

You can read now the following 5 suggestions from the test you just did. We would kindly ask you to assess whether an observer would have seen yo performing the suggestions if the observer were in your room while you were in the trnce-like state.We want to see first of all how you would rate your reaction. Sometimes you might be insecure or you even may have to guess. But please give a jdgement for each of the performance.

After short descriptions of each of the fight suggestions you will see two possible answers "A" or "B". Please tick for each suggestion one answer "A" or "B". <please answer each "question" depending on which alternative you think is right. Please answer each question as only this way the questionnaire can be used and assessed in an appropriate manner.

1. Immobility of the right arm

   First of all you sholud concentrate on the heaviness of your right arm and then you should try to lift your right arm. Do you think that somebody watching you trying to do this could see that you lifted your arm more than 3 cms (before the examiner ended the task)?

   Please tick:

   ◯ A: I have not lifted my arm more than 3 cms.

   ◯ B: I have lifted my arm more than 3 cms.

2. Finger closure

   Afterwards, you should interlace your fingers and relaise how tightly they were bound to each other. Then you were asked to separate your hands. Do you think that an observer could see that your hands fully parted (before you should put your hands onto the armrest)?

   Please tick:

   A:My fingers were not fully parted before I was asked to place them onto the armrest.

   ◯ B: My fingers were fully separated.

3. Stiffness of your arm

   You were asked to hold your arm in front of you and to form a fist. You should realise how stiff and rigid your arms became. Then you were asked to form a fist with your left hand. You shold realise how stiff your arm was and you were asked to flex your arm. Do you think that an observer could see that your arm flexed less than 5 cms (before the examiner ended the task)?

   Please tick:

   A: My arm was flexed less than 5 cms.

   B: My arm was flexed more than 5 cms.

4. *<u>Inhibition to communicate</u>*

   Afterwards you were asked to think about how heavy it is to shake your head in order to say "no". Do you think an observer would have seen you shaking your head (before the examiner ended the task?)

   Please tick:

   A: I did not shake my head in an obvious way.

   B: I did shake my head in an obvious manner.

5. *<u>Eye closure</u>*

   Finally , you were asked to find out how tightly your eye lids were closed so that you could not open them. Do you think that an observer would have been able to see how your eyes opened (before the examiner ended the task)?

   Please tick:

   A: My eyes did not open at all.

   ◯ *B: My eyes did open.*

5.7 STAI-S Test

In order to assess fear.

1. I am calm.	1	2	3	4
2. I feel secure.	1	2	3	4
3. I am tensed	1	2	3	4
4.I am worried.	1	2	3	4
5. I feel liberated.	1	2	3	4
6. I am excited.	1	2	3	4
7. I am worried that sth. could go wrong.	1	2	3	4
8. I feel rested	1	2	3	4
9. I am concerned	1	2	3	4
10. I feel at ease.	1	2	3	4
11. I am self-confident.	1	2	3	4
12. I am nervous.	1	2	3	4
13. I have the jitters	1	2	3	4
14. I am clenched.	1	2	3	4
15. I am relaxed	1	2	3	4
16. I am content.	1	2	3	4
17. I am afraid.	1	2	3	4
18. I am overwrought.	1	2	3	4
19. I am cheerful	1	2	3	4
20. I am jolly	1	2	3	4

5.8 PONV Impact Scale

P. S. Myles, R. Wengritzky

G1. Did you have to vomit or gag?

0. Not at all
1. Once
2. Twice
3. Three times or more

G2. Did you have a feeling of nausea (a strange feeling in your tummy and the wish to vomit)? If so, did this feeling occur during activities of everyday life like standing up, getting out of bed, moving in bed, walking or eating?

0. Not at all
1. Sometimes
2. Often or most of the time
3. The whole time

In order to calculate the PONV Impact Scale score, the numerical answers from question 1 and 2 are added up. A PONV Impact Scale score larger than five defines clinically important PONV.