

Feasibility and Usefulness of Self-Hypnosis in Patients Undergoing Double-Lung Transplantation During the Pre- and Postoperative Periods: A Randomized Study

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Feasibility and usefulness of self-hypnosis in patients undergoing doublelung transplantation during the pre and postoperative periods:

A randomized study

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INTRODUCTION

Patients undergoing lung transplantation frequently have a long history of chronic disease and face painful and stressful situations. Up to 59% of them describe chronic pain at the time of registration on the waiting list, and about 50% of the patients report chronic pain following surgery. Moreover, as in other surgical settings, major pain experienced during the early postoperative period seems to favor the installation of chronic pain.³ Pain related to specific procedures like physiotherapy and fiberoptic examinations is frequently reported, especially in cystic fibrosis patients.⁴ Major anxiety is also reported, frequently associated with pain. Conventional treatments are sometime insufficient or induce deleterious secondary effects, leading physicians to add alternative and complementary techniques. The beneficial effects of hypnosis for reducing pain and anxiety in patients undergoing surgical or medical procedures, and for treating patients with chronic pain has been reported in several studies.⁵⁻⁷ Hypnosis is characterized by three components: absorption (in a memorized or imaginative experience), dissociation (from the environment), and suggestibility (to the therapist's suggestions).⁸ These components help patients to focus on positive sensations or emotions during a painful or stressful event, to transform the experience of an uncomfortable situation into a more comfortable experience, and to use their own resources to adapt to these situations. Self-hypnosis has been proposed for many years, and since then, studies have reported some positive results in helping patients with pain and anxiety. 9-14 It can be taught through training sessions, and allows the patients to take an active part in the management of their discomfort. Promising results have also been reported in cystic fibrosis patients where the practice of self-hypnosis among other psychological techniques help in adherence to treatment, emotional and social adaptation and health-related quality of life.¹⁵ Two studies have specifically evaluated the interest of teaching self-hypnosis before a scheduled surgical procedure and have reported less pain or anxiety after surgery in the experimental group. 10, 14 However the interest of teaching self-hypnosis before a major unscheduled surgery has never been studied. We hypothesize that implementing the teaching of self-hypnosis in the complex setting of evaluation and preparation of lung transplantation is possible and could improve self-reported pain outcomes, and could secondarily reduce anxiety, and improve self-reported quality of life.

METHODS

Ethics approval

This randomized, open, single-center study was performed in a tertiary care university hospital in accordance with the Declaration of Helsinki. Ethical approval was provided by the Ethical Committee Ile de France XI (reference N° 14028; May 4, 2014; Chairperson L. Salomon, Paris, France). The study was designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT 2010) and published on the Clinical.trials.gov website (NCT02237976; September 12, 2014). The Foch Lung Transplant group attests that they performed all procedures in strict compliance with the International Society for Heart and Lung Transplantation ethics statement.

Study subjects

Patients aged 15 years and over who needed a double-lung transplant were informed of the study at the anesthetic consultation and were included after their registration on the waiting list after they gave their written informed consent. Patients were excluded if they participated in only one self-hypnosis training session before transplantation.

Randomization

The allocation procedure to the self-hypnosis group or to the control group was managed by the sponsor (Direction of the Research Unit, Hôpital Foch). The random allocation sequence, with a 1:1 ratio and blocks of 10, was generated through the site "Randomization.org". Each patient received a unique patient number and a randomization number (patient code). For each subsequent patient, the investigator connected to the www.anesloop.org website using a protected password just after inclusion in the study. This system allocates the patients into groups.

Procedures

Patients referred for a lung transplantation in our center underwent a complete evaluation by the members of the transplantation team including the anesthesiologists specialized in this field. A

psychological evaluation allowed us to assess the acceptance and readiness to the transplant process. Except for a short relaxation technique which is taught during the anesthetic visit, no specific intervention like sessions of mindfulness, relaxation or hypnosis were organized at that time. The patients were referred to a specific pain consultation by a member of the team when the pain was estimated to be not well treated, especially in case of chronic pain or chronic use of opioids.

Our anesthesia technique includes epidural analgesia started just before the surgical incision and is described in detail on the website http://anesthesie-foch.org/protocoles-anesthesie/ (section Anesthesia Foch lung transplant protocol).

Surgery was performed via two successive antero lateral incisions.

During the acute postoperative phase epidural anesthesia was continued for 5 days, monitored twice daily by pain nurses and relayed by oral opioids. Multimodal analgesia was started intraoperatively and continued during the acute phase, including oral pain killers and non-drug analgesic techniques like transcutaneous electrical nerve stimulation (TENS) and auriculotherapy.

Figure 1 summarizes the conduct of the study.

In the self-hypnosis group, two psychologists and two anesthesiologists taught the self-hypnosis technique. All of them had undergone the same 1-year hypnosis training (130 hours) at the University Paris-Saclay and they had more than 8 years of experience at the time of the study. To avoid any discrepancy, and harmonize their technique, they assessed once a month that they had the same practice. They did not use a script during the sessions but all of them performed a 20-minute session with the same type of induction and therapeutic suggestions. Induction was based on regular respiration; focus on surrounding sounds and on specific areas of the body, and therapeutic suggestions were based on the patient's own memories. In one of the sessions, the patients were taught to visualize and imagine themselves in a safe place, in the other session they learnt how to increase their comfort and to "protect" themselves in an uncomfortable situation. For example, the metaphor of a magic glove protecting the hand and the wrist was taught to increase the comfort during blood gas sampling. At the end of the first session, patients received a compact disk (CD) with relaxation and self-hypnosis exercises (SACEM 215517/2013; https://societe.sacem.fr/en) and we recommended that

they practice regularly at home. At least two sessions of teaching had to be performed before the transplantation and there was no limitation to the number of these pretransplantation sessions.

After the transplant the patients were encouraged to use the self-hypnosis technique in different situations: i.e., endoscopic examinations, uncomfortable care, sleep difficulties.

Measurements and Data collection

Figure 1 summarizes the data collected at each time-point.

Pain was assessed by i) the answer to the question "do you think you regularly suffer from pain?"; ii) self-assessment using a visual analogue scale between 0 (no pain) and 100 (worst pain imaginable) at rest and movement; iii) the response to the DN4 questionnaire (neuropathic nature of pain); ¹⁶ iv) the pain related to care. Additionally trait (STAI-Y trait) and state (STAI-Y state) anxiety levels were assessed with the French version of Spielberger's State-Trait-Anxiety Inventory (STAI) ranging from 20 = no anxiety to 80 = maximum imaginable anxiety ¹⁷ and by a visual analogue scale. Adjustment capacities were evaluated by the French version of the Coping Strategies Questionnaire. ^{18, 19} Catastrophism was assessed by the Sullivan questionnaire. ²⁰ Quality of life was assessed by the 12-Item Short Form Survey (SF12 questionnaire). ²¹

Compliance to the self-hypnosis technique was assessed by a questionnaire that was developed specifically and included questions about the practice of self-hypnosis, the circumstances of use and the utilization of the CD.

The short-term outcome of the transplant was indirectly assessed by the length of stay in intensive care after the surgical procedure and the long-term outcome by the volume expired during the first second of forced expiration at the 4th postoperative month.

Data were collected at inclusion, 7 days, one month and 4 months after transplantation.

Regarding the compliance before transplantation, the patients were asked about their preoperative practice on the seventh day after the transplantation.

Outcomes

The main outcome of the study was pain one month after lung transplantation. Secondary outcomes were pain, anxiety, coping, catastrophism, and quality of life at entry and at various time-points up to the 4th month after transplantation. Secondary outcomes also included compliance to the self-hypnosis technique before surgery, in the Intensive Care Unit, one and four months after transplantation.

Statistical analysis

Sample size

Based on a reasonable assumption of a gradual improvement over 6 months of the VSA scale (i.e.,1/6 of the value of the difference decreasing each month), and that at one month, the difference would be 3.7 mm on a 100 mm Visual Analog Scale (VAS) with a standard deviation of 1.55 (with an assumption of a gradual increase in the standard deviation of 5% per month over 6 months). Thus, to detect an average improvement in pain of 33%, for a bilateral alpha risk of 0.05 and a power of 80%, we can define the number of patients to be included as 78.

Statistical methods

All statistical analyses were done on an intention-to-treat basis.

Categorical variables are presented as number (proportion) and compared between groups using Chi2 or Fisher's test as appropriate; continuous variables are presented as median [interquartile range] and compared between groups using the Mann Whitney test.

Repeated-measures mixed-models testing groups were performed to analyze each pain parameter change over time. Post-hoc analysis was performed in case of statistical significance. Comparison of the proportion of patients who practiced self-hypnosis for each period used Chi2 test with post-hoc analysis in case of statistical significance. Bonferroni correction was applied in case of multiple comparisons.

All tests were two-sided. P values of less than 0.05 were considered significant. The statistics were generated using SAS 9.4 software.

Data are available on Dryad website open-access repository (https://doi.org/10.5061/dryad.r7sqv9sbj).

RESULTS

Participants

The study took place from July 2014 to May 2018 and 111 patients were approached for participation. A total of 78 patients gave their consent to the study and were included, 38 in the Control group and 40 in the Self-hypnosis group.

The 40 patients in the self-hypnosis randomization group had at least two training sessions, and 9 out of 40 (22.5%), were able to complete a third session. As planned in the protocol all the patients underwent a "safe place" session and a session to help them managing pain or a sense of discomfort. Subsequent sessions were adapted to the specific needs of each patient.

Double-lung transplantations were performed in 32 cases in the Control group and 36 is the Self-hypnosis group. Eventually, 28 patients in the Control group and 33 in the Self-hypnosis group were evaluated at the 4th postoperative month (**Figure 2**).

Patients' characteristics at entry

Patients' characteristics at entry are resumed in **Table 1** (except for pain scores which are presented in **Table 2**). Most patients had cystic fibrosis or emphysema/chronic obstructive pulmonary disease.

Surgery and postoperative stay in the Intensive Care Unit

The time between the last self-hypnosis session and the transplant was 96 [206] days (extreme values of 3 and 698 days). Fifteen patients out of 32 in the control group and 14 out of 36 in the self-hypnosis group were extubated at their entry in the Intensive Care Unit (ICU) (p=0.51). Duration of ventilation considering only patients having been ventilated in the ICU was 5 [4.7] and 4 [6.0] days in the control group and the self-hypnosis group respectively (p=0.93). Length of stay in the Intensive care unit after the surgical procedure was similar between groups (4.0 [5.0] days in the control group and 5.0 [3.5] in the self-hypnosis group (p=0.09).

Compliance with the procedure of self-hypnosis

The independent practice of self-hypnosis by the patients at different evaluation times is described in detail in **Figure 3**. Practice of self-hypnosis regularly or occasionally was high during the pretransplantation period (76.6%) and decreased significantly during the first week after surgery (p = 0.03). Practice of self-hypnosis rose again 1 and 4 months after the transplant but not in a statistically significant way.

When the 31 patients practicing self-hypnosis were asked about their practice, 13 patients (42%) were very enthusiastic about this technique that helped them in many circumstances, and 21 patients (68%) said that it was difficult to practice alone.

The patients used self-hypnosis mainly in situations of anxiety and breathing related anxiety (20% of them), uncomfortable care, i.e., fiberoptic exam, drain removal, blood sample drawing (16%), pain (16%), sleep disturbances (15%), non-invasive ventilation (6%) or just for training (4%)

The CD was used by 70 % of the patients before the transplant, 7% of them during the first 7 days post-transplant, 23% of them between the 7th day and the first month after the transplant and 39% of them between the first month and the 4th month after the transplant.

Pain

One month after surgery, there was no statistical difference between groups whatever the criterion used, although there was a trend in favor of self-hypnosis: number of patients who declare suffering from pain (p = 0.07, **Figure 4 Panel A**); pain scores measured by VAS at rest (p = 0.16, **Figure 4 Panel B**) and at movement (p = 0.35, **Figure 4 Panel C**). Pain related to care was observed in 12 (42.9%) cases in the control group versus 7 (22.6%) in the self-hypnosis group (p = 0.10). Considering the whole period from entry to postoperative month 4, group-time interactions were not statistically significant whatever the variable concerned (**Table 2**). Of interest is that group effect was never statistically significant opposed to time effect which was significant for the number of patients presenting with pain, the pain score at movement, and not at rest, the number of patients with a neuropathic pain, the number of patients presenting with a pain related to care (p < 0.001 for all). All these variables increased from the early post-operative period (**Table 2**).

Anxiety, coping, catastrophism, and quality of life

Patients of both groups had similar STAI-Y trait scores (37.0 [12.0] in the control group and 39.0 [12.0] in the self-hypnosis group (p = 0.82).

Group-time interactions had no statistically significant effect whatever the concerned variable and group effect was never statistically significant (Table 2). Time effect was significant for the level of anxiety with a decrease at M1 and M4 (p = 0.04), the STAI-Y state score (p = 0.002). Time effect was also significant for three components of coping: catastrophizing (p = 0.007), reinterpreting pain sensations (p < 0.001), and praying (p < 0.001), for all components of catastrophism (rumination, p = 0.005; magnification, p = 0.007; helplessness, p = 0.007; total, p = 0.002), and for both components of the SF12 questionnaire (p < 0.001) (**Table 3**).

Patients of both groups had similar forced expiratory volume during the first second of expiration (% of theoretical value) at the fourth month after surgery: 82.0 [29.0] % in the control group and 84.0 [35] % in the self-hypnosis group (p = 0.85).

DISCUSSION

Our study shows that apart from a tendency to decrease pain and anxiety in the first month following transplantation, self-hypnosis does not alter the post-operative pain profile, anxiety, coping, catastrophism, and quality of life of patients who have had a double-lung transplantation. However, interpretation of these results requires caution due to the variable compliance of the patients to the technique.

Efficacy of self-hypnosis on post-operative pain has already been studied in patients to whom self-hypnosis had been taught preoperatively, and results are favorable to the technique in adolescents who underwent the Nuss procedure to correct pectus excavatum, ¹⁴ and in women undergoing breast surgery who received training in self-hypnosis as a part of a toolkit and used it during 2-week preoperative and postoperative periods. ²² Use of self-hypnosis improved anxiety as demonstrated in cardiac surgical patients undergoing cardio artery by-pass grafting. ¹⁰Implementation of a teaching program of self-hypnosis in the setting of lung transplantation raises many practical problems: i) there is a highly variable delay between final pretransplantation evaluation and the day of surgery; ii) the patients during their stay in the hospital during the final pretransplantation evaluation have to deal with a very tight schedule of various medical consultations and exams; iii) and the remote geographic localization of some patients prevent them from coming to the hospital for repeated sessions. This challenging organization could partly explain the lack of positive results regarding pain and anxiety in our study. One could also hypothesize that the consequences of the major surgical aggression are too great to be modulated by hypnosis.

Adhesion to self-hypnosis was good, especially during the pre-transplant period where 76.6% of our patients reported that they were using it. Continued use of the technique during the post-transplant period is an important issue. In our study, during the first week post-transplant, in the ICU, and despite the commitment of the team, it proved to be difficult for the patients to practice by themselves. Part of this decrease is obviously because 22 of 36 in the self-hypnosis group were not extubated at their entry

in the Intensive Care Unit with a mean ventilation time of 4 days. At this point, use of a CD or MP3 support to help the practice was difficult, some patients were in a difficult condition and hypnosis was not an important concern for the patients and for the team.

During the months following the transplantation, compliance to the self-hypnosis technique rose again. It could be due to the fact, that the team encouraged the patients to use the self-hypnosis technique in different situations: endoscopic examinations, uncomfortable care, sleep difficulties. Many patients told us that practicing self-hypnosis helped them to be more comfortable during acute dyspnea episodes. This can be related to the fact that hypnosis and self-hypnosis have been proposed for patients with severe respiratory disease, especially children with cystic fibrosis and this practice improved peak expiratory flow rate and anxiety after a 4-month period.²³ This technique helped cystic fibrosis patients in relaxation, and control of other symptoms associated with their disease.²⁴ Gradually, the intensivists and the pneumologists discovered the help that self-hypnosis could bring during fiberoptic examination, or other uncomfortable care options, even during the acute period, and encourage the patients to practice it. As some patients did not adhere to the technique, we can also hypothesize that other mind body techniques like mindfulness or meditation could be more suitable for some of them and should be explored in another study.

Strength and weakness

The present study is the first to address the implementation and efficacy of self-hypnosis in patients undergoing lung transplantation and to follow up the patients before and after surgery. The two major strengths of the study are its randomized prospective design and the self-reported measurements of pain and quality of life.

However, some methodological limitations should be discussed.

Analyzing the results of the implementation of self-hypnosis is quite difficult. The results depend on the compliance of the patient to the proposed technique, but also of the effect of hypnosis on pain, anxiety, and other variables. Non-significant results could be due to the lack of practice and / or the lack of efficacy of the technique. Moreover, many other stressors, at this time, could interfere with pain, anxiety, and quality of life. Since our analysis was based on the principle of an intention-to-treat

analysis, it is very difficult to ascertain the usefulness of the technique given the poor compliance to self-hypnosis in the first month following the transplantation (about 30% of the patients).

Coping skills play an important role in the appropriation of the self-hypnosis technique, it would have been interesting to evaluate if age and pathology play a role in this appropriation.²⁵

Although enrolment on a lung transplant waiting list seemed an ideal time to introduce a potentially helpful intervention for pain and anxiety management, this was also a time of huge emotional stress.

This could also explain the high percentage (30%) of screened patients who declined to participate and the absence of subsequent practice for some of patients in the auto-hypnosis arm.

The population may not be representative, either because of the high proportion of patients with cystic fibrosis, which limits the generalization of our results, or because many of the patients had unfounded fear of the word "hypnosis" and refused to be enrolled.

Possibly, the variable delay between sessions and surgery, and the fact that patients received two sessions and others three sessions could induce a heterogeneity between patients and play a role in the lack of benefice of the technique. The long time interval between the last self-hypnosis session and the transplant could explain in part the poor compliance after transplantation and could play a role in the lack of benefit from the technique.

The design of our study did not include following up the patients during the pretransplantation period and the assessment of their learning. Part of them had a regular pretransplantation independent practice but all could have benefited from better support during the waiting period before transplantation either by sending reminders, adding regular telephone calls, ²⁶ or using remote training.²⁷

All the data about the practice and benefit of pretransplantation self-hypnosis practice were collected postoperatively and indications for practicing self-hypnosis were related to pre- and post-transplantation experience. Preoperative collection of data would have necessitated to ask the patients

to come back to our center to fill in some questionnaires or more simply to call them by phone, which was difficult to organize but would have perhaps allowed to individualize specific indications or practice for the preoperative period.

As the study was open, the transplanted and future transplanted patients communicated a lot together, especially using social network for the younger ones. Patients quickly understood that the practice of

self-hypnosis helped a lot when undergoing a painful or stressful examination or care. As a result, one patient wished to leave the study before the transplant while in the control group and wanted to benefit from hypnosis, two other patients wished to benefit from hypnosis during the study while they were in the control group.

Our hypnotic procedure could also be discussed. Our sessions were not standardized with a script as proposed for many clinical trials,¹¹ but we regularly compared and harmonized our practices with a monthly meeting.

Choosing a randomized study methodology and pain as a main goal was perhaps not appropriate. We should perhaps have chosen a different main goal like adhesion to the technique or evaluation of the self-practice, limited our objective to the evaluation of self-hypnosis in painful or stressful post-operative exam or included a qualitative analysis.

Conclusion

This study shows that implementation of self-hypnosis in the very technical setting of lung transplantation is possible. Self-hypnosis seems a potentially beneficial technique. However, our study, which is possibly underpowered and has some important limitations such as a variable compliance to the practice, failed to show an improvement in the patients' experience regarding pain, anxiety and quality of life. A future study should include a more effective training of patients both before and after transplantation.

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FIGURE LEGENDS

Figure 1. Conduct of the study and data collection.

STAI-Y trait: State-trait Anxiety Inventory

STAI-Y state: State-state Anxiety Inventory

SF-12: Short Form 12

Figure 2. Flow chart

Figure 3. Use of self-hypnosis at different evaluation times.

Results are presented as proportions.

Chi-square test was performed to analyze auto-hypnosis use over time.

*P-value expressed with Bonferroni correction

Figure 4. Evaluation of pain one month after surgery

Panel A: number of patients who declare suffering from pain

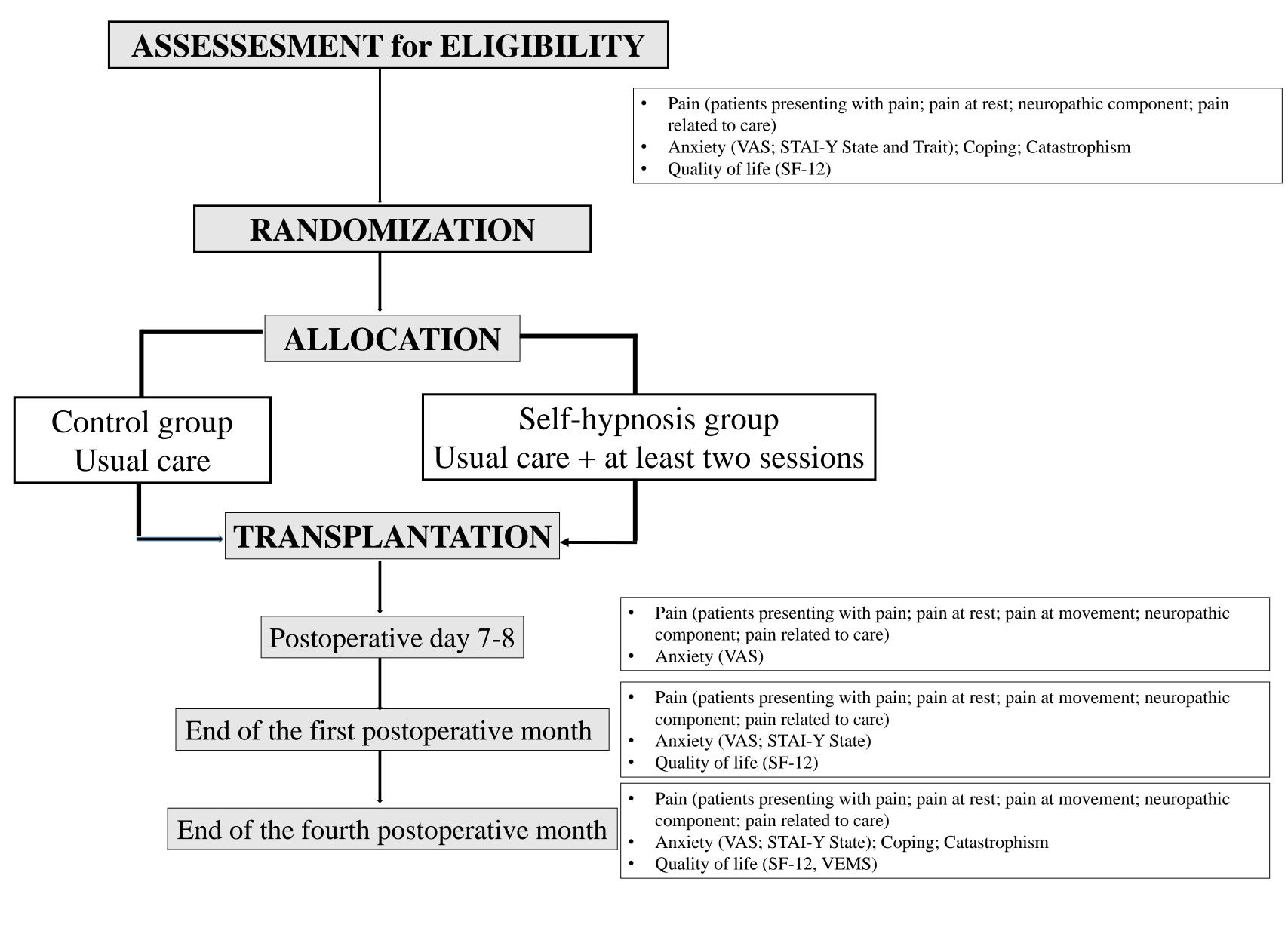
Panel B: pain scores at rest measured by a visual analogue scale

Panel C: pain scores at movement measured by a visual analogue scale

The visual analogue scale is between 0 (no pain) and 100 (worst pain imaginable).

TABLES

- Table 1. Patient characteristics at entry
- Table 2. Evaluation of pain at all postoperative time-points
- Table 3. Evaluation of anxiety, coping, catastrophism, and quality of life at all time-points.



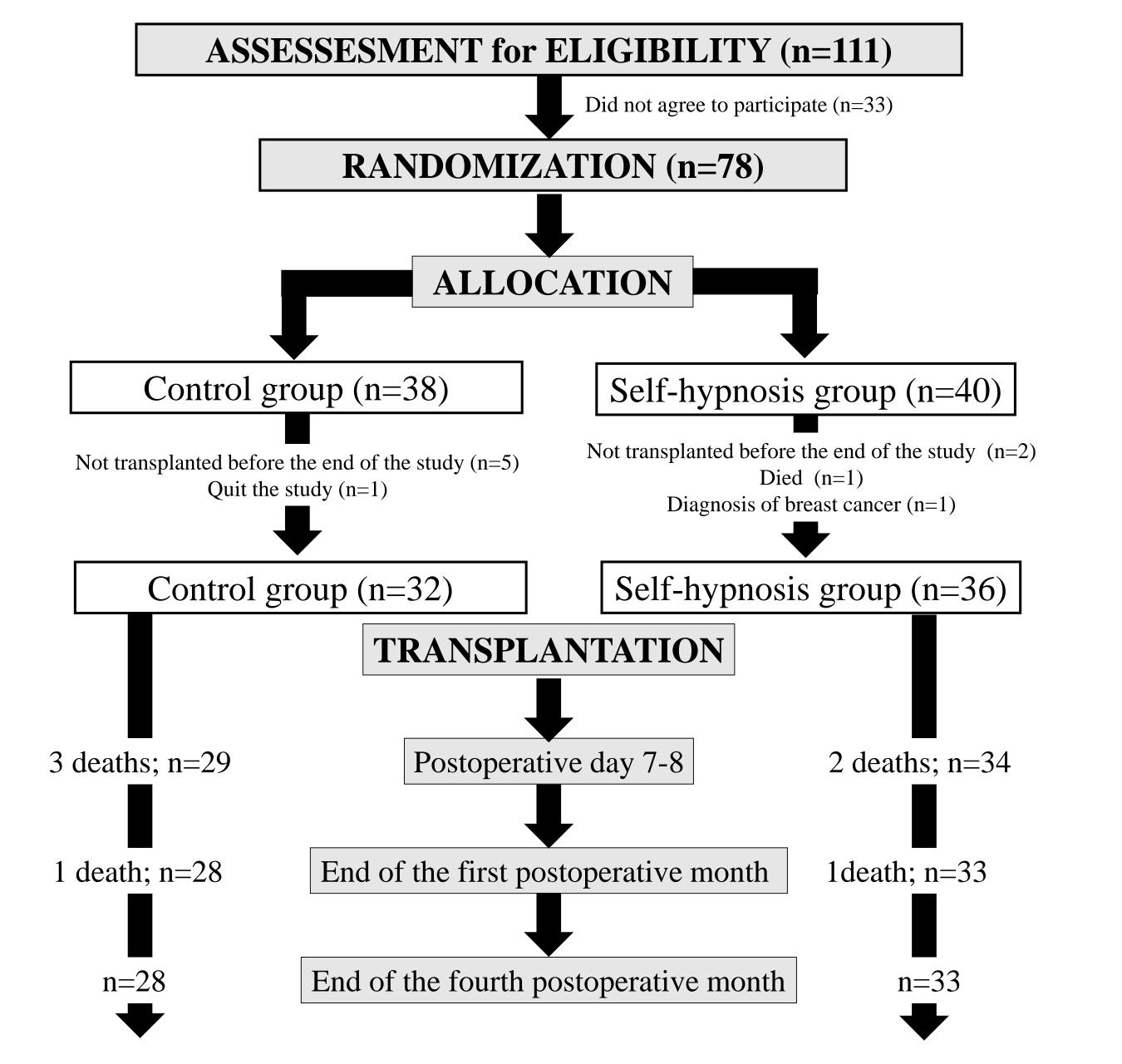
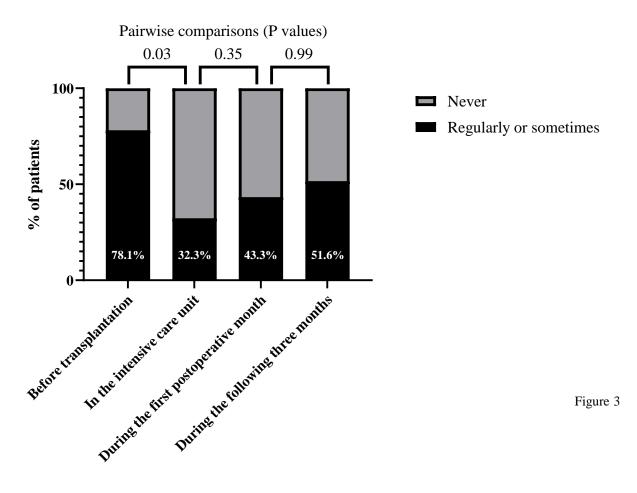
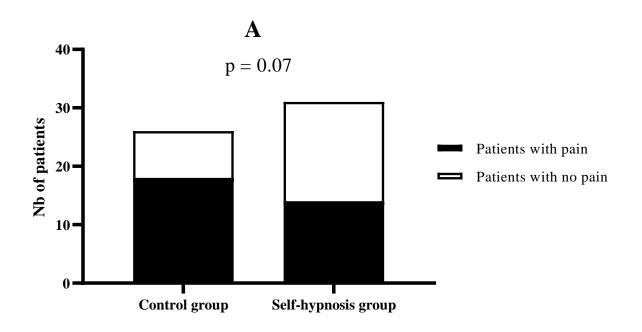
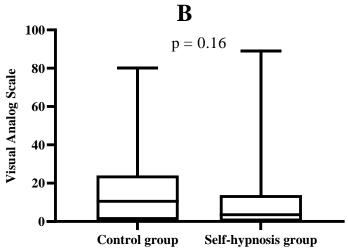


Figure 2

Overal comparison P=0.04







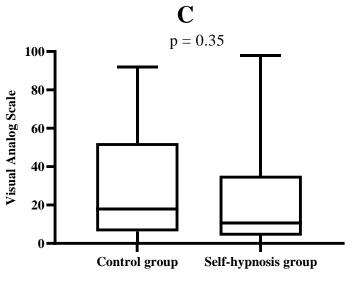


Table 1: Patient characteristics at entry

	Control group	Self-hypnosis group		
	n=38	n=40		
emographics				
Sex, female, number of patients	19 (50.0)	13 (32.5)		
Age, years	42.5 [23]	42 [26.5]		
BMI				
ung pathology, number of patients				
Cystic fibrosis	17 (44.7)	19 (47.5)		
Emphysema or COPD	14 (36.8)	12 (30)		
Other pathologies	7 (18.4)	9 (22.5)		
TAI-Y trait	37.0 [12.0] {37}	39.0 [9.0] {39}		

Results are presented as number (proportion) and median [interquartile range].

In case of missing data, the number of available data is presented as { }.

COPD: Chronic obstructive pulmonary disease

STAI-Y trait: Trait anxiety level¹⁷

Table 2: Evaluation of pain at all postoperative time-points

	Control group Self-hypnosis grou			Mixed mode	el
	n=38	8			
			Group effect	Time effect	Group*Time effect
Patients presenting with pain,			Khi-2 = 1.16	Khi-2 = 1.98	Khi-2 = 2.50
number of patients			p = 0.28	p = 0.16	p = 0.11
At entry	11 (28.9) {38}	13 (32.5) {40}			
Postoperative day 7 or 8	20 (80) {25}	23 (76.7) {30}			
Postoperative month 1	18 (69.2) {26}	14 (45.2) {31}			
Postoperative month 4	13 (50.0) {26}	12 (37.5) {32}			
Pain at rest, VAS, all patients			F ratio 0.05	F ratio 2.04	F ratio 0.84
			p = 0.82	p = 0.11	p = 0.47
At entry	2 [11.0]{36}	3 [23.0]{39}			
Postoperative day 7 or 8	17 [29.0]{28}	13.5 [30.0] {32}			
Postoperative month 1	10.5 [1.5] {28}	3.5 [12.5] {32}			
Postoperative month 4	4 [16.0] {27}	3.5 [13.5] {32}			

Table 2: Continued

	Control group	Self-hypnosis group		Mixed mode	l
	n=38	n=38 n=40			
			Group effect	Time effect	Group*Time effect
Pain at movement, VAS, all patie	ents		F ratio 1.53	F ratio 7.92	F ratio 0.84
			p = 0.22	p < 0.001	p = 0.43
Postoperative day 7 or 8	39.5 [34.0] {28}	38.5 [39] {32}			
Postoperative month 1	18.0 [44.0] {28}	10.5 [30.5] {32}			
Postoperative month 4	19 [57.0] {27}	14 [35.0] {32}			
Neuropathic pain, number of pati	ients with DN4 \geq 4, all patien	ts	Khi- $2 = 0.03$	Khi-2 = 17.06	Khi-2 = 0.01
			p = 0.86	p < 0.001	p = 0.93
At entry	1 (2.6) {38}	2 (5.0) {40}			
Postoperative day 7 or 8	14 (51.8) {27}	11 (34.4) {32}			
Postoperative month 1	10 (35.7) {28}	13 (40.1) {32}			
Postoperative month 4	9 (33.3) {27}	10 (32.2) {31}			
Pain related to care, number of p	atients		Khi- $2 = 0.01$	Khi- $2 = 5.47$	Khi- $2 = 0.35$
			p = 0.93	p = 0.02	p = 0.55
At entry	2 (5.2) {38}	3 (7.5) {40}			
Postoperative day 7 or 8	20 (71.4) {28}	19 (57.6) {33}			
Postoperative month 1	12 (42.9) {28}	7 (22.6) {31}			
Postoperative month 4	8 (29.6) {27}	9 (28.1) {32}			

Table 2: Continued

Values are presented as number (%) and median [interquartile range]. The number of data are presented as { }.

Repeated-measures mixed-models testing groups were performed to analyze each pain parameter change over time. Comparison of preoperative use of painkillers was performed using Fisher's exact test.

VAS: Visual Analog Scale represented by a 100 mm line with anchor statements on the left (no pain) and on the right (extreme pain).

DN4: Neuropathic pain is diagnosed when on the questionnaire the patent answered 'yes' to at least four responses of ten of the DN4 questionnaire¹⁶

Table 3: Evaluation of anxiety, coping, catastrophism, and quality of life at all time-points

	Control group Self-hypnosis group		Mixed model		
	n=38	=38 n=40			
			Group effect	Time effect	Group*Time effect
Anxiety					
Anxiety, VAS			F ratio = 0.83	F ratio = 2.29	F ratio = 0.12
			p = 0.37	p = 0.08	p = 0.94
At entry	19.0 [33.0] {36}	20.0 [26.5] {40}			
Postoperative day 7 or 8	24.0 [49.0] {28}	11.0 [47.0] {31}			
Postoperative month 1	6.5 [25.5] {28}	3.0 [24.5] {32}			
Postoperative month 4	10.0 [34.0] {27}	14.0 [21.0] {27}			
STAI-Y state, score			F ratio = 0.44	F ratio = 5.49	F ratio = 0.11
			p = 0.51	p = 0.005	p = 0.90
At entry	36.0 [22.0] {37}	35.0 [14.0] {39}			
Postoperative month 1	30.5 [13.0] {28}	29.5 [13.0] {30}			
Postoperative month 4	28.0 [18.0] {27}	29 [15.5] {32}			

Table 3: Continued

	Control group Self-hypnosis group	Mixed model			
	n=38	n=38			
			Group effect	Time effect	Group*Time effect
Coping					
Distraction			F ratio = 1.10	F ratio = 0.02	F ratio = 0.01
			p = 0.30	p = 0.90	p = 0.94
At entry	13.0 [6.0] {36}	13.0 [4.0] {38}			
Postoperative month 4	12 [4.0] {27}	13.5 [7.0] {30}			
Catastrophizing			F ratio = 1.61	F ratio = 6.42	F ratio = 1.66
			p = 0.21	p = 0.01	p = 0.20
At entry	6.0 [3.0] {36}	7.0 [4.0] {38}			
Postoperative month 4	5.0 [3.0] {27}	5 [2.0] {30}			
Ignoring pain sensations			F ratio = 1.31	F ratio = 4.06	F ratio = 0.0
			p = 0.25	p = 0.05	p = 0.99
At entry	11.0 [4.0] {36}	10.5 [7.0] {38}			
Postoperative month 4	12.0 [4.0] {27}	12 [5.0] {30}			
Reinterpreting pain sensations			F ratio = 0.06	F ratio = 19.46	F ratio = 0.44
			p = 0.81	p < 0.001	p = 0.51
At entry	7.0 [5.5] {36}	6.5 [6.0] {38}			
Postoperative month 4	3.0 [4.0] {36}	3.0 [3.0] {38}			
Praying			F ratio = 0.02	F ratio = 23.18	F ratio = 2.43
			p = 0.87	p < 0.001	p = 0.12
At entry	6.0 [4.0] {27}	7.5 [5.0] {30}			
Postoperative month 4	3.0 [3.0] {27}	3 [1.0] {29}			

Table 3: Continued

	Control group Self-hypnosis group		Mixed model		
	n=38	n=40			
			Group effect	Time effect	Group*Time effect
Catastrophism					
Rumination			F ratio = 0.10	F ratio = 5.58	F ratio = 0.01
			p = 0.75	p = 0.02	p = 0.93
At entry	5.0 [4.5] {36}	5.0 [6.0] {38}			
Postoperative month 4	2.0 [7.0] {27}	2.5 [6.0] {32}			
Magnification			F ratio = 0.98	F ratio = 6.44	F ratio = 0.03
			p = 0.32	p = 0.01	p = 0.86
At entry	3.0 [4.5] {36}	3.0 [3.0] {38}			
Postoperative month 4	2.0 [4.0] {27}	1.5 [3.0] {32}			
Helplessness			F ratio = 0.84	F ratio = 6.32	F ratio = 0.01
			p = 0.36	p = 0.02	p = 0.91
At entry	4.5 [9.0] {36}	6.5 [7.0] {38}			
Postoperative month 4	3.0 [6.0] {27}	2.0 [7.0] {32}			
Total			F ratio = 0.0	F ratio = 7.44	F ratio = 0.02
			p = 0.95	p = 0.008	p = 0.90
At entry	14.0 [15.0] {36}	15.0 [16.0] {38}			
Postoperative month 4	7.0 [12.0] {27}	7.0 [15.5] {32}			

Table 3: Continued

	Control group Self-hypnosis group		Mixed model		
	n=38	n=40			
			Group effect	Time effect	Group*Time effect
Quality of life - SF12					
Physical health component			F ratio = 2.97	F ratio = 31.99	F ratio = 0.20
summary			p = 0.09	p < 0.001	p = 0.82
At entry	28.5 [8.5] {34}	26.4 [9.8] {38}			
Postoperative month 1	39.2 [12.6] {26}	37.8 [10.6] {27}			
Postoperative month 4	40.7 [21] {27}	40.0 [15.2] {31}			
Mental health component			F ratio = 0.28	F ratio = 10.19	F ratio = 1.03
summary			p = 0.60	p < 0.001	p = 0.36
At entry	43.2 [13.7] {34}	44.9 [16.1] {38}			
Postoperative month 1	49.5 [16.1] {26}	46.4 [23.2] {27}			
Postoperative month 4	55.9 [16.4] {27}	57.0 [10.0] {31}			

Values are presented as number (%) and median [interquartile range]. The number of data are presented as { }.

Repeated-measures mixed-models testing groups were performed to analyze each pain parameter change over time. Comparison of STAI-Y trait score was performed using the Mann Whitney test.

STAI-Y trait: Trait anxiety level¹⁷; STAI-Y state: State anxiety level¹⁷

VAS: Visual Analog Scale represented by a 100 mm line with anchor statements on the left (no anxiety) and on the right (extreme anxiety)

SF-12:Short Form 12