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TITLE OF DOCTORAL THESIS

PREPARE: PREoPerative Anxiety Reduction. Development of a brief psychological intervention for the management of pre-surgical anxiety before pancreatic surgery.

S.S.D. M-PSI/08

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Ho cercato di non barcollare; ho fatto passi falsi lungo il cammino.

Ma ho imparato che solo dopo aver scalato una grande collina, uno scopre che ci sono molte altre colline da scalare.

Mi sono preso un momento per ammirare il panorama glorioso che mi circondava, per dare un'occhiata da dove ero venuto.

Ma posso riposarmi solo un momento, perché con la libertà arrivano le responsabilità e non voglio indugiare, il mio lungo cammino non è finito.

-Nelson Mandela-

ABSTRACT

Patients who have to undergo surgical procedures experience high levels of distress due to uncertainty, concern and worry related to the potential physical and mental damage of surgery. Psychological interventions devoted to help patients dealing with these concerns are described in literature, but the reported studies were heterogeneous, mainly based on information giving and patient education, or sometimes on the use of relaxation or mindfulness techniques, and were conducted in different settings, making difficult to compare results.

After a brief narrative review on the factors affecting anxiety in patients undergoing surgery, the thesis describes a new protocol of a short individual psychological intervention, implemented in the unit of the Pancreas Institute of the University Hospital of Verona, with the aim to improve patients' self-efficacy in managing anxiety and their confidence in coping with pancreatic surgery (main outcome). Secondary outcomes are the lowering of "state" anxiety after the psychological intervention and its positive consequences after surgery in terms of: reduction of the number of hospitalization days, the pain perception and the number of complications after surgery.

Methods and analysis: All patients listed for pancreatic major surgery during one year course, were assigned randomly to the psychological intervention or to the control group, once provided the informed consent to participate to the study. Those who were included in the intervention group had the opportunity to talk with a psychologist about personal concerns related to surgery and to learn simple techniques to cope with stress, the day before surgery.

The study was approved by the local Ethics Committee of the Hospital Trust of Verona. Study findings will be disseminated through peer-reviewed publications and conference presentations. Registration details. Protocol version 1, 12th April 2017 Prog. 1288CESC (Appendix 1) Trial registration: ClinicalTrials.gov identifier: NCT03408002

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1. INTRODUCTION

Patients who have to undergo surgical procedures experience high levels of distress (1-3) due to uncertainty, concern and worry related to the potential physical and mental damage of surgery(4). Waiting for surgery induces high levels of anxiety, sometimes associated to depressive symptoms(5). High levels of anxiety can have also negative consequences on postoperative outcomes, in terms of perceived pain and duration of hospitalization(6, 7). Horne *et al.*(8) proved that neglecting psychological effects of distress in patients, other than bringing "unnecessary suffering", has also an economic impact, due to rehospitalisation after discharge.

A source of concern for patients is the perception of loss of control experienced during preoperative period, that is the perception of no power related to the duration of the operation and possible surgical consequences. Thoughts related to postoperative pain, the distance from family during recovery, the fear of loss of autonomy and the worry to die because of the intervention are further components which contribute to patients' stress perception(9).

Therefore potential stressors are both related to the context, such as the degree of information provided to the patient(3, 10) or to patient's psycho-social functioning, such as patient's cognitive style, the behavioural and coping strategies adopted(11-13) and the quality of social support perceived(14).

One of the psychological variables that showed to have higher impact on peri-operative outcomes (i.e. perceived pain, days of hospitalization, use of analgesic drugs, number of readmissions) is clinical anxiety.

Norris et al. (15) reported that pre-operative anxiety ranges between 60% and 92%**.** This implies that clinicians need to identify pre-operative experiences and harbingers of anxiety that may have an impact on patient's post-operative course, their ability to cope with illness and their psychological resiliency.

2. PREOPERATIVE ANXIETY

Anxiety is generally distinguished in: *State Anxiety*, which is the acute emotional state related to a specific event for which a person tends to feel tension, apprehension, nervousness and concern with increased activity of the autonomic nervous system(16) and *Trait Anxiety*, a specific feature of the subject, lasting, characterized by nervousness agitation, greater sensitivity to stimuli and greater reactivity (17). Trait anxiety represents a firmly grounded individual disposition to react coherently to a certain situation, that is, in a largely predictable degree, a reaction of anxiety. When a specific situation matches a patient-inherent facet of trait anxiety, the state anxiety level increases(18).

Preoperative Anxiety can be considered a form of state anxiety and is defined as an unpleasant state of discomfort or tension secondary to a disease for which hospitalization is planned, which is related the waiting condition of undergoing anaesthesia and surgery(19). This condition leads to the perception of worry, fear and uncertainty, which may be associated to depressive symptoms. (1, 3, 5, 20)

A source of intense concern is the perception of loss of control experienced in the pre-operative period, described as the uncertainty about the information related to the duration of the intervention or the possible surgical consequences. Pre-surgery anxiety harbingers are also the expectation of the intervention per se, the concern for mental/physical damage and the possible outcomes of surgery (4). Other concerns include the worry for post-operative pain, the distance from the family during hospitalization, the fear to loose autonomy, the apprehension for the intervention itself and for the risk of death inherent in the operation(9).

2.1 Variables that may affect preoperative anxiety

2.1.1 Socio-demographic variables

Women are more likely to experience pre-operative anxiety. One of the triggers is the distance from the family (4) (21).

Anxiety disorders and depression are reported to be more frequent among older adults(22).

Literature reports that individuals with a higher level of education are more accurate in estimating the risk of surgery (9), whereas those with low literacy perceive higher fear and anxiety(23). Nevertheless, Aykent et al. (24) showed that education does not play a role in the perception of pre-operative anxiety. Other studies report that cultural factors may play a role in the perception of illness, with an effect also on anxiety and depression(25).

2.1.2 Mood condition

Patients with high levels of trait anxiety are generally more nervous, agitated, hypersensitive to stimuli and psychologically more reactive (9). Besides, anxiety, stress, depression, and hostility have a negative effect on health (26).

Kayhan et al. (27) reported that 37.5% of surgical inpatients attending the Meram Faculty of Medicine, Turkey, showed a history of psychiatric disorders. Of these 14.5% showed mood disorders and 24.2% were positive for the presence of anxiety disorders. It has been demonstrated that depressive mood may affect the duration of hospitalization with an average of two more days of hospitalization (28), while high levels of trait anxiety may have an impact on treatment compliance, post-operative pain management and satisfaction with the care received(9, 25)

2.1.3 Coping styles

Coping abilities are related to the cognitive and behavioural efforts adopted by someone to face and manage stressful life events, real or perceived (12, 13, 29, 30). According to Lazarus & Folkman model (31), it consists in the efforts put in place to face internal or external requests based on cognitive and emotional personal resources. Lazarus & Folkman distinguish between problem centred and emotion centred coping strategies (32). Problem centred coping strategies are oriented to the resolution of the problem,

information seeking and active behaviours to change the situation, while emotion centred coping strategies are based on the use of distraction, self-control, the pursuit of social support, positive cognitive evaluations, the assumption of responsibility or avoidance based behaviours (33).

When patients know how to handle stressful situations through the use of good coping strategies, pre-operative anxiety and post-intervention complications are lower (34-38).

2.1.4 Perceived self-efficacy

General self-efficacy is a global trait of personality which contributes to explain individual differences in terms of motivations, attitudes, learning and performance tasks. Self-efficacy refers to the sense of trust that people have in performing a series of actions; the greater their trust, the greater the likelihood that they will commit themselves and bring certain activities to completion (39, 40). Self-efficacy can be considered as the mediator between cognition and action. Studies have related self-efficacy to improved patient participation in care (41) adjustment to illness (42) and adherence (43). As an example on how self-efficacy can contribute to improve health outcomes, literature reports studies which demonstrated that an increased perception of self-efficacy, reduced both self-reported anxiety (44) and autonomic arousal (45, 46) when performing feared tasks, in patients with phobia. The same was demonstrated for pain threshold and tolerance on cold pressure tests (47). Finally, self-efficacy beliefs have been shown to be important predictors for compliance to recommended recovery behaviors in patients with cardiac problems (41, 48-50).

Generalized positive beliefs of self-efficacy serve as a resource factor that buffers distress experiences. A person with low self-efficacy is more vulnerable to distressing experiences, being permanently worried, having weak expectancies of task-specific competence, interpreting physiological arousal as an indicator of anxiety, regarding achievement feedback as an evaluation of personal value, and feeling more responsible for failure than for success (51). Literature reports that patients who show greater confidence in their resources appear more controlled, less anxious and more skilful in managing post-operative pain (52).

In the orthopaedic setting, Heye et al. (2002)(53) showed that patients who underwent an orthopaedic surgery showed a greater sense of self-efficacy if they received indications on how the surgery would take place and how they could act on the recovery process. Magklara et al., (54) in a recent systematic review, concluded that pre-operative self-efficacy was the least consistent predictor of functional outcomes, whereas postoperative self-efficacy was more consistently associated with recovery outcomes such as longer distance ambulation, exercise repetition and frequency, walking speed and disability.

Bandura showed that beliefs about general self-efficacy transformed situations from threatening to safe by decreasing patients' anxiety(55).

Mystakidou K et al. (56) showed that a change in self-efficacy was manly associated with a change in anxiety and to a lesser extent to symptom severity/interference.

Therefore increasing general self-efficacy for managing symptoms and function may be critical to a patient's ability to manage the physical and psychological challenges related to surgical procedures (56.)

2.1.5 Perceived Social support

Perceived Social support is often associated with people's health status (57). High levels of social support are related to experiences of lower preoperative anxiety (58). Social support may be distinguished in "emotional ", that is the verbal and non-verbal communication centred on unspoken emotions, or "informational", that is the search and provision of information on how to manage the problem and to deal with the stress that the situation implies (59). Krohne (57) demonstrated that both types of support have an effect on postoperative outcomes. Specifically, both emotional and information support contribute to reduce anxiety during preoperative period: emotional support impacts on recovery duration; informational support has been marginally associated to the quantitates of anaesthetic used. Khrone et al. (2005)(57) proved also that emotional support is strongly related to pre-operative anxiety and that it exerts a beneficial influence throughout the entire pre-, intra-, and post-operative period.

Studies examining the relationship between social support and hospitalization reported that patients who were followed and supported by family members showed greater adaptation skills(14). Patients who received a greater number of visits showed better post-operative outcomes in terms of lower use of analgesics and fewer days of hospitalization(14). The accessibility of support would alleviate perioperative stress and improve patients' adaptation. Finally, the perception of positive social support was related to lower levels of anxiety in patients with cardiac problems, who had to undergo surgery (60).

2.1.6 Degree of information

Patient education is an essential care component to increase self-management, adherence, and satisfaction.(61) Patient education during peri-operative time helps the patient to understand her condition and the plan of care, to identify and manage potential complications, and to reduce hospital re-admission. This type of information reduces healthcare-associated costs through a decrease in the length of stay and an improvement of self-management after discharge (62).

Stressors, which can lead to an increase in pre-operative anxiety levels are often linked to situational factors (i.e. age, gender, marital status, presence of children), (3, 10). Indeed, patients who receive clear procedural information and instructions on how to behave before surgery show a greater state of psychological well-being, with a reduction in anxiety and stress levels, which positively affect the post-operative period(10).

Givel et al. (2014)(63) questioned the amount of information to be provided to patients before surgery, showing that it is important not only to generically inform, but it is essential to clarify the amount and the type of information they need to deal with the perioperative period. Adult education is most effective when the content is individualized, when multiple delivery means are utilized, and when delivery occurs in multiple sessions (64).

2.2. The impact of anxiety on perioperative phases (during and after surgery)

2.2.1 Anaesthesia

Higher levels of anxiety prior to surgery have been associated to greater use of sedative drugs during the anaesthesia procedure (20, 65-67), which increases the probability of problems related to anaesthesiology or to post-surgery complications (68). However, evidences are sparse. Some studies used evaluation scales not validated for the measurement of pre-operative anxiety, others did not take into account confounding variables such as the type of surgery and the amount of pre-surgical sedative (19). To overcome these difficulties, Maranets & Kein (1999)(19) adopted the analysis of EEG waves for the evaluation and measurement of the hypnotic components of sedation state induced by anaesthesia. The authors demonstrated that patients with greater preoperative anxiety need more anaesthetic to induce sedation. The same was confirmed by ECG wave patterns.

2.2.2 Perceived post-operative pain

Pain is a component of surgery that frightens patients, leading them to experience intense state anxiety. According to the pain gate theory (69), the pain that a person feels is determined both by a neurophysiological component and by an attitudinal and affective dimension; together these two dimensions influence the transmission and the perception of the sensation of pain. Patients with higher levels of anxiety(70, 71) or with previous negative pain experiences (72) may show higher levels of post-operative pain.

Patients adequately informed before surgery show less apprehension towards pain, feeling thus more able to manage the postoperative period (73) Powell et al. (2016)(74) found that psychological preparation allows post-operative pain reduction (95% CI = 0.35 to 0.06).

2.2.3 Length of Hospitalization

Patients who are poorly informed about their level of health and with higher levels of anxiety are more likely to experience states of emotional distress that can affect the healing process and consequently the number of days of hospital stay after surgery (75-77). A recent meta-analysis (74) suggests that pre-operative psychological preparation reduces by half a day hospitalization time (MD = 0.52 days, 95% CI = 0.82 to 0.22).

2.2.4 Complications and re-hospitalizations

Anxious patients, who have not been provided with any kind of information on the post-operative period and on the procedures necessary for physical recovery, have higher probability to be re-admitted to the hospital and show a greater number of post-operative complications(30). Patients who at the time of discharge received information about what they had to expect, and on how to behave to better recover, once returned at home showed a lower rate of hospital admissions (78).

3. INTERVENTIONS FOCUSED ON PRE-OPERATIVE ANXIETY REDUCTION

A recent meta-analysis published by Powell et al. (74) included 105 studies, conducted between 1970 and 2014 for a total of 10,302 randomized participants, focused on different approaches to help patients in reducing pre-operative anxiety.

Powell et al. (2016)(74) reported a review of randomized clinical trials, conducted in different countries, on subjects who had to undergo cardiology, orthopaedic and abdominal surgery. The approaches described were various in nature: based on information-giving, relaxation techniques, sensory approaches, behavioural instructions, cognitive interventions, emotion and hypnosis based techniques. Most of the literature reported studies aimed at reducing stress and therefore anxiety states through the use of

coping strategies and through psycho-educational techniques combined with coping strategies with the aim to increase the sense of mastery and therefore a reduction in state anxiety.

Most of the studies were based on Cognitive behaviour therapy (CBT) techniques, which aims to influence the thoughts and behaviours that have an impact on the patient emotions (79). The different components of CBT include patient education, problem solving, exposure therapy, cognitive approaches, emotion regulation, and relapse prevention [62]. The different components can be used individually or in combination and are often used over the course of 2 to 4 sessions. Several studies have demonstrated that CBT is safe, well accepted by patients, and effective in reducing anxiety and distress in patients undergoing surgery.(80).

Even if the conclusions of Powell et al. review(74) were still interlocutory, main evidences showed a reduction of postoperative pain, a decrease in the length of hospital stay (mean difference of 0.52 days) and the lowering of negative affect (mainly assessed using anxiety scales).

An overview of the studies that adopted manualized techniques or provided interventions based on evidence-based protocols will be reported in detail in the following paragraphs and in table 1. The described interventions vary in relation to: the health system, the administering personnel (nursing staff with psychological training, health specialists, doctors or psychologists), the informative material provided (informative leaflets, explanatory meetings, CDs containing techniques with relaxation exercises to be performed at home before surgery).

3.1 The first studies

In 1975 Langer(81) conducted a study in which the aim was to compare different combinations of two possible strategies in order to reduce pre-operative stress: cognitive control of adverse events vs information and reassurance provision. The sample was randomized into 4 experimental groups:

1. Group using cognitive control strategy. Following Ellis (1962)(79), patients were advised that attention and thoughts about adverse events may lead to an increase in stress levels. Patients had the opportunity to exercise a sort of control

over their emotions through appropriate instructions. A non-dichotomous (all positive or all negative) view of reality was favoured, leading patients to reflect on the possible presence of more positive alternatives with respect to surgery. Specifically, patients were asked to shift their attention to positive or compensatory aspects related to the operation, such as being in a good hospital, focusing on the possibility of receiving adequate care and the possibility of taking a break from stressors and pressures of daily life to take care for themselves. This strategy did not encourage the rejection of the situation but rather encouraged to maintain an optimistic view of the context taking into account the favourable consequences and to reinterpret the unfavourable ones.

2. Group using information and reassurance provision. This group was given more information about surgery and imaginable post-operative scenarios, with particular attention to the possible pain experienced and was also reassured about the presence of qualified personnel to support patient requests.
3. Group who received both previous interventions.
4. Control group following usual care.

The results showed that the group of patients who learned specific techniques to cope with stress showed better scores compared to the other three groups ("anxiety": $F(1.56) = 5.60$; $p < .05$; "ability to cope": $F(1, 56) = 12.59$; $p < .01$). Greater perception of control showed to contribute to increase stress tolerance levels, effectively reducing the additional stress generated by feelings of impotence.

Felton (1976)(82) proposed a support intervention called "Therapeutic Communication Approach". In this intervention the patient was directed towards actions aimed at his well-being by creating a relationship between the health provider and the patient in an atmosphere in which one could feel free to express his feelings and, at a later stage, to use problem-solving strategies to manage the problematic situation (83). During this intervention, the health provider paid attention to listen the issues reported by the patient and to the non-verbal behaviours which could underlie emotional states or disturbing thoughts. Then the patient's strengths in problem solving were analysed asking to think about past experiences of intense stress that could help in the current

management of the situation (84). Bringing the patient back to positive ways in solving difficult situations in the past helped to focus and to clarify belief patterns that could mobilize positive resources to cope with the pre-operative anxiety experience.

Compared to the control group, who received the usual care or a greater amount of information, the experimental group showed a better adaptation to the situation, reaching a greater sense of agency, self-esteem and tolerating more aggressive states and tension.

3.2 Patients undergoing cardiology surgery

Chronic diseases management programs based on cognitive behavioural interventions have shown a reduction in anxiety, depression and re-hospitalization in patients with myocardial infarction(85).

Furze et al. (2009)(86) proposed a short program administered at home through telephone calls, entitled "Heart Op Program". This study considered two groups of patients: one was given the experimental intervention, while the other followed the usual care. Patients in the experimental group received at home informative material concerning misdiagnoses and myths about cardiovascular diseases, suggestions for secondary prevention and what would happen in the hospital at the time of admission and in the post-operative period. In addition, the program included a CD containing an audio recording with a relaxation technique and a diary for recording the activities performed and the goals achieved in terms of healthy lifestyles before the operation. An operator systematically contacted patients by telephone in order to make sure of adherence to pre-operative treatment, to clarify any doubts about cardiac pathology and to value the achieved objectives. Surprisingly the intervention had no effect on pre-operative anxiety. This unexpected result can be explained if we consider the intense level of anxiety experienced by patients close to surgery, especially if false beliefs or myths regarding the pathology and surgery raise up and are not changed, as did the authors of this experiment, who left the patients free to maintain their usual coping strategies, based on their beliefs.

Dao et al. (2011)(87) examined the applicability of a brief cognitive behavioural

intervention (MADES) to manage anxiety and depressive states in patients who had to undergo coronary artery bypass surgery. It was a manualized approach, consisting of 4 meetings lasting 60 minutes proposed to patients showing anxiety and depression before surgery. During the first meeting, patients had psycho-education on the pathology, the surgery, the post-operative period, the anxiety and depressive states related to the intervention. Moreover, a list of concerns was formulated with the patient, starting from the most intense and proceeding with the less problematic. During the second meeting the goals achieved in terms of learned healthy habits were verified and coping strategies were provided to cope with stress. In the post-operative period, three days after the intervention, attention was paid to the cognitive strategies adopted and to the cognitive distortions related to the pathology still present. The patient continued to be psychologically supported. Five days after the operation, the work carried up to that moment was taken back in hand, the patient was encouraged to maintain the healthy habits acquired and a list of the next objectives to be achieved following the resignation was drawn up. The results showed that the MADES protocol had effects in terms of anxiety (F (1.98) = 17.1; P <.001.) and depression (F (1.98) = 8.69, P. 004.) reduction and also the number of days of hospitalization; whereas the perception of the quality of life did not differ compared to control group.

Recently in Germany, Heilmann (88) proposed a randomized clinical trial (DRKS-ID: DRKS00000696) conducted on patients who had to undergo coronary artery bypass, grafting to reduce pre-operative anxiety by informing patients and providing emotional support. The protocol foresaw that patients increased their capacity to manage emotional aspects to reduce pre-operative anxiety levels, that they could feel free to express their concerns and doubts about the pathology and the operation in order to increase confidence in the medical and nursing staff; and finally they were encouraged to ask for emotional support from family or other significant persons. The interview with the operator took place the day before the operation and lasted 30 minutes. It was an open dialogue, in which the patient was guided to the identification of his personal resources; emphasis was placed on the coping styles used, also passing through the acceptance of the emotional states that were sometimes rejected or denied. Information was provided regarding intensive care, in line with the patient's need for more

information, and instructions were given on how to deal with post-operative pain. The interview focused mainly on the fears expressed by the patient, normalizing them and providing additional information where necessary. The group of patients who took advantage of the psychological intervention before the operation reported a reduction in anxiety levels not only in the pre-operative period (F [1,299] = 14,284, p <0.001), but also five days after intervention with respect to the control group (F [1,199] = 26,215, p <0.001).

3.3 Patients undergoing oncological surgery

In 2003 Cheung et al.(89), conducted a trial on a population of patients who were waiting for hysterectomy. The cognitive intervention, proposed before the operation, was based on the theory of Lazarus and Folkman (1984)(31) and provided the teaching of coping strategies through the use of techniques such as distraction and cognitive reappraisal of the situation. Patients in the experimental group were taught how to direct their attention to more favourable aspects of their current situation, in order to be able to distract themselves from the threatening aspects of surgery. Each patient was then encouraged to revaluate the intervention, moving from a threatening vision to a more stimulating (cognitive reappraisal); this activity was intended to help patients recognize any irrational, illogical or any negative self-affirmation as possible triggers that could lead to negative emotional activation. Patients were asked to express their feelings about the operation and to write down what made them anxious. A qualified nurse collaborated with the patients helping them to change their most irrational positions or beliefs into something more rational and useful, reporting the contents on a sheet. Then patients were reminded that if they started to experience negative emotional activation, they could concentrate on the more positive statements identified and written. This type of intervention led the patients of the experimental group to a reduction of state anxiety levels (F = 35.63, P <0.001) and of the perceived pain in the postoperative period (F = 2253.78, P <0.001). Moreover, the patients of the experimental group showed the tendency (even if not statistically significant) to a lesser need of analgesic drugs during the hospital stay.

Parker et al. (2009)(90) conducted a study on cancer patients who had to undergo

prostatectomy. The sample, consisting exclusively of men, was dived into 3 groups: a first group called "stress management" (SM), a second called "supportive attention" (SA) and a third that followed the standard care (SC) and acted as control group. The aim of the study was to test the effects of a brief psychological intervention in the peri-operative period both in the short term and in the long term at 6 and 12 months after surgery.

1. The SM group underwent two individual sessions lasting about 60-90 minutes with a clinical psychologist in the two weeks prior to the operation. The first interview consisted for 60% of the time in providing relaxation skills through the use of diaphragmatic breathing technique and guided imagery. An audio cassette was then delivered with relaxation techniques for practicing at home. During the second meeting the patients were asked to make an exposure in imagination of the day of the operation in order to prepare for both the day of surgery and the subsequent hospitalization. Following exposure to imagination, patients could express their concerns and fears about cancer and surgery; they were suggested problem solving techniques cantered on coping strategies useful to be adopted to increase the sense of self-efficacy through commitment to activities, seeking social support and having realistic expectations with respect to the times of recovery. This group of patients received, before and 48 hours after the operation, two brief reinforcement sessions compared to the acquired skills, reinforcing the use of relaxation and coping strategies.
2. The second group (SA), was interviewed two times for 60-90 minutes by a clinical psychologist, in the two weeks before the intervention. In this case the approach used was supportive in nature and consisted of a semi-structured interview for the collection of information on the patient's psychosocial and medical history. The clinician was limited to listening actively, placing himself in an empathic attitude towards the patient. The aim was to ensure a reassuring environment for the patient so that he could express his fears and concerns. Two short sessions before and 48 hours after the surgery were aimed at allowing the patient to describe his/her experience regarding the intervention and the hospitalization.

3. The control group (SC) followed the standard treatment.

The results showed that the MS group had better outcomes during the peri-operative period compared to the other two groups, in terms of anxiety (Chinese version of State and Trait Anxiety Inventory, p=0.006).

3.4 More recent studies, not included in Powell et al. meta-analysis (74)

In 2016 Rolving (91) compared the clinical and economical effectiveness of a cognitive behavioural rehabilitation strategy with usual care, for patients undergoing lumbar spinal fusion surgery. The psychological intervention was organized into six sessions, each lasting three hours. Patients attended four sessions before surgery, while the fifth and sixth session were placed postoperatively, after three and six months, respectively. The content of each session was pre-specified whit some flexibility to respond to participants' needs. In preoperative sessions, patients were invited to reflect on their moods with respect to the operation, emphasizing the role of the connection between thoughts, emotions and behavior. The content of the second session regarded how to manage pain and coping strategies. In the third meeting, attention was paid to negative automatic thoughts and how they could maintain vicious circles that contribute to increase stress levels. In the last preoperative meeting the patients were helped to manage the pain and stress deriving from their condition by sharing their experiences and expectances. During the follow-up sessions the ways in which patients used cognitive strategies learned during the preoperative period were discussed, highlighting their strengths. This approach proved to be useful in reducing post-operative disability, demonstrating how a holistic approach can be considered useful, effective and economical for the health system.

Third generation Cognitive Behavioural Therapy (CBT) proposes as effective guided imagery, which is a program of directed thoughts and suggestions that guide the imagination to a relaxed and positive state by using descriptive language and the five senses to help the user to visualize the desired change or outcome. Billquist (92) proposed a guided imagery technique to help women to feel more prepared, less anxious, and have higher satisfaction scores after surgery. Patients were divided in a control and an experimental group who received an audio track CD that was designed to

lead patients through their own self-performed guided imagery and relaxation. Patients were asked to listen the CD once a day for the week before their surgery. The patients were evaluated at baseline, during the surgical consent visit, during the day of surgery and at their sixth-week follow-up appointment. Compared with controls, the addition of self-administered guided imagery improved patient preparedness for pelvic floor surgery. Listening to the audio file reinforced the physician's education for the patient and actively involved the patient in preparing herself for the surgical procedure, increasing the perception of self-efficacy and of preparedness for surgery using a ten-point Likert scale.

Powell et al. (74) review did not suggest any approach as elective. However, based on the main results reported in Powell et al. (74) and also on Rolving (91) and Billquist (92) studies, it is possible to hypothesize that techniques related to the third-generation of Cognitive Behavioral approach, which aim to increase the sense of mastery and therefore self-efficacy of patients, might favor anxiety reduction. These interventions are mainly based on imagery, self-awareness, mindfulness and acceptance to commit in a changing action and could be manualized and tested.

Table 1. Studies that provided interventions to reduce pre-operative anxiety

Author	**Methods**	**Interventions**	**Outcomes**
Langer 1975	**Design:** RTC **Sample:** 60 patients **Age:** unknown **Gender:** unknown	**Coping device**: cognitive reframing focusing on positive aspects **Preparatory information:** detailed explanation of anaesthetic procedures and what happens next **Combination:** union of the two previous interventions **Control group:** 20 minutes in which it is explained briefly how anaesthesia takes place	Length of stay
Felton 1976	**Design**: RTC **Sample:** 62 patients who had to undergo major surgery **Age**: from 19 to 71 years **Gender:** unknown	**Therapeutic Communication Approach:** 88 minutes of interview with a nurse who explains the anaesthetic procedures through information material. Examples and behavioural instructions (breathing, correct movements) are provided. **Communication:** 60 minutes of interview with a nurse who fosters expression and responds to the patient's fears and concerns. It favours the re-evocation of past stressful episodes to underline the coping modalities adopted by the patient. **Control group:** 15 minutes interview with a nurse who explains the preoperative and postoperative procedures	Postoperative anxiety (4 days after surgery) Length of stay

Furze 2009	**Design:** RTC **Sample:** 204 patients who will have to undergo coronary artery bypass grafting **Age:** control group 65.29 (sd ±8.51); experimental group 64.8 (sd ±8.51) **Gender:** control group 85% males; experimental group 75% males	**Both groups:** sending home information material on the intervention, a 45-minute interview explaining how to use the material and telephone calls up to the time of admission to make sure that patients follow the program. **Experimental group:** clarification of the false myths about the operation, drafting the objectives to be achieved and teaching a relaxation technique **Control group:** patients describe the experience of the disease, give information on the operating risks, explain the intervention and the procedures to be followed after the operation	Length of stay Postoperative anxiety and depression
Dao 2011	**Design:** RTC **Sample:** 97 patients candidates for coronary artery bypass surgery **Age:** control group 64.2 years (sd ± 11.9); experimental group 62.8 years (sd ± 11.8) **Gender:** control group 79.6% males; experimental group 77.1%	**Managing anxiety and depression using education and skills (MADES):** one week before the operation a manual protocol is proposed for 60-minute heart patients with a clinical psychologist. **Control group:** usual care	Postoperative anxiety and depression immediately after the operation and at 3 and 4 weeks Length of stay
Heilmann 2016	**Design:** RTC **Sample:** 253 patients who are candidates for coronary	**Experimental group:** 30 minute interview the day before the operation. The expression of the patient's fears is encouraged; further information is provided	Anxiety Length of stay

	artery bypass surgery **Age:** experimental group 69 years (sd ± 9.3); control group 67.5 years (sd ± 10.3) **Gender:** experimental group 86.6% males; control group 79.1% males	with respect to the operation. A relaxation exercise is taught using imaginative techniques aimed at the postoperative period. **Control group:** usual care	
Cheung 2003	**Design:** RTC **Sample:** 96 patients candidates for hysterectomy **Age:** 41.72 years (range: 30-55) **Gender:** 100% women	**Experimental group:** it follows the procedure of the control group and in addition the technique of cognitive re-appraisal and cognitive distraction is applied on the aspects considered scary **Control group:** informative material about the surgery is given and behaviours to be explained (movement of the legs, breathing)	Post-operative anxiety at 1 and 3 days after the operation Pain perceived immediately after surgery, at 1 and 2 days later
Parker 2009	**Design:** RCT **Sample:** 159 patients who have to undergo prostatectomy **Age:** supportive attention 60.7 (sd ± 7.2); stress management 59.8 (sd ± 6.9); control 60.9 (sd ± 5.9) **Gender:** 100% male	**Supportive Attention:** two 60/90 minutes interviews with a clinical psychologist who offers a semi-structured interview to the patient 2 weeks before the operation. The clinician shows empathy using reflexive listening. The patient is encouraged to express his own fears. The day of the operation and 48 hours later the patient sees the psychologist for a brief interview **Stress Management**: two 60/90 minutes interviews with a clinical psychologist 2 weeks before the operation. In the first, relaxation techniques (diaphragmatic breathing) and guided imagery are	Emotional state at 48 hours, at 6 weeks, at 6 and 12 months after the operation

		provided. In the second, the patient imagines the day of the operation, explaining his concerns and providing problem solving strategies based on the expressed fears. The day of the operation and 48 hours after the patient sees the psychologist for a brief interview to reinforce the relaxation techniques and the coping strategies learned **Control:** usual care	
Rolving 2016	**Design:** RTC **Sample:** 96 patients undergoing LSF due to degenerative spinal disorders **Age:** 18 to 64 years **Gender:** experimental group 39% males; control group 51.6% males	**Intervention group:** 6 sessions of patient education took place in a conference room at the hospital in a administrative building. 4 sessions were provided before surgery, while 2 after surgery. **Control group**: usual care	Disability Sick Pain Quality of life Coping strategies Readmission to hospital
Billquist 2017	**Design:** RCT **Sample:** 44 women undergo pelvic floor surgery **Age:** 60.9 (range 36-83) **Gender:** all female	**Guided imagery:** standard education + instruction-specific CD developed by a behaviour expert that detailed the day of surgery events and expectations using both guided imagery and relaxations techniques. Participants were asked to listen to the audio CD once a day for the week before their surgery. Control group: standard education	Anxiety level Preparedness Satisfaction with their surgical experience

PART II
Experimental Design

1. AIM OF THE STUDY

The aim of the present study is to test the hypothesis that a short individual psychological intervention can improve patients' self-efficacy in managing anxiety and their confidence in coping with pancreatic surgery (main outcome). The psychological intervention was manualized (see appendix 1) and based on Svensson *et al*.(93) questions and Elan Shapiro's "four elements" protocol for stress management(94), and pointed to increase pre-operative anxiety management, by favouring self-confidence in coping with anxiety. As secondary outcomes, we hypothesized that self-efficacy in managing anxiety would reduce state anxiety before surgery and would lead to better postoperative outcomes such as: a reduction in pain perception, less complications and a reduced duration of the hospital stay.

To our knowledge, this is the first study on pancreatic patients listed for pancreatic major surgery that adopts a manualized psychological preoperative intervention devoted to increase perceived self-efficacy in managing anxiety. Since there are no previous studies, this is a feasibility randomized controlled trial, based on collecting for one year all inpatients candidates to major surgery.

2. MAIN OUTCOMES

Primary outcome

To test the hypothesis that a psychological intervention aimed at the installation of personal resources (see procedures) has effects in terms of *a greater perception of personal self-efficacy* in the management of pre-operative anxiety.

Secondary outcomes:

- We expect that patient state anxiety measured before (t1) and after (t2) the psychological intervention shows a significant decrease at t2 compared to t1;

- We also expect some effects on post-operative variables, namely that patients in the experimental group will show:
    - lower pain perception;
    - fewer complications;
    - a reduced number of days of hospitalization.
- For a subset of patients that will satisfy the inclusion criteria (see procedures), we intend to evaluate the physiological activation in terms of SCR and HRV during the psychological treatment phase. For this subset of patients it will also be verified whether there will be a tuning of the psychophysiological parameters of the therapist and the patient, in terms of therapeutic alliance and if this has an effect on the quality of psychological treatment.

3. METHODS

3.1 Study design and setting

The study is a feasibility Randomized Controlled Clinical trial (95) where half of participants, *Experimental Group* (EG), attend a brief psychological intervention, while the other half follow usual care, *Control Group* (CG).

This study involved the Unit of Clinical Psychology and the Pancreas Institute of University Hospital of Verona (AOUI), which is the first multidisciplinary Italian centre entirely dedicated to diagnosis, treatment and research in the field of pancreatic diseases.

3.2 Sample

All patients listed for major surgery during one year (July 2017-2018) (i.e. splenopancreasectomia, duodenocefalopancreasectomia) at the Pancreas Institute of AOUI in Verona, were considered eligible to enter the study.

Inclusion criteria

- Age between 18 and 80 years
- Ability to provide informed consent
- Scheduled surgical intervention
- General anaesthesia for surgery

Exclusion criteria

Exclusion criteria

- Age lower than 18 and above 80 years old
- Inability to provide informed consent
- Postponement / cancellation of surgery

Dropout criteria

- Withdrawal of consent from the patient
- Cognitive impairment

3.3 Procedure

Standard medical care usually includes a pre-operative counselling session with a surgeon and an anaesthesiologist, CTA, ECG, ECO and blood exams. The major topic of these consultations is the evaluation of general health conditions to undergo surgery, the discussion of the medical procedure and its risks and the explanation of the informed consent sheet. Once clinical evaluations show that surgical intervention is suitable, patients are called back to the hospital the day before surgery on the basis of a surgical list. Surgery can then take place from one up to several weeks after.

Based on standard medical care, the study has been then organized in four time points (T0, T1, T2, T3) as follows (see Figure 1):

- T0: during pre-operative counselling session. Once obtained the informed consent from eligible patients, demographic information was collected using a structured questionnaire. Psychological evaluations were proposed the same day patients attended all clinical evaluations. This to promote patients' participation with the aim

to achieve the adequate enrolment. All psycho-socio-demographic variables were collected by self-administered instruments, for which patients could ask support, if needed. This stage involved the presence of one of the experimenters as an expert psychologist (*DOP*).

Eligible patients were then randomized in a 1:1 ration to one of the two study arms.

- T1: the day before surgery. Subjects in the *Control Group* were informed about surgery procedures, but did not attend any specific psychological intervention on anxiety management (*usual care*). They indicated their perceived self-efficacy in managing anxiety and filled out specific anxiety scales.
- Subjects in the *Experimental Group* indicated perceived self-efficacy in managing anxiety and fulfilled specific anxiety scales before attending the manualized psychological intervention. The *psychological intervention* consists of one consultation lasting about 50 minutes in which patient's concerns about surgery are investigated and managed by a trained psychotherapist (*VM*). During the first part of the consultation the psychotherapist asked open questions inspired by Svensson *et al*.(93) study. The purpose of these questions was to promote the expression and identification of patient's emotional state (i.e. "*Could you describe your mood while waiting for anaesthesia and surgery?*"; "*Could you describe what worries you in particular?*"). The second part of the consultation aimed to reinforce patient's abilities to cope with the situation by using Elan Shapiro's "four elements" protocol for stress management(94) (see paragraph 3.4). T2: within one hour after the psychological intervention (*experimental group only*): perceived self-efficacy in managing anxiety and specific anxiety scales were collected by the same psychotherapist (*VM*).
- T3: After surgery: a description of quality and intensity of physical pain, the length of hospital stays and the number and type of post-operative complications within 30 days were gathered by using the clinical register of the Pancreas Institute. These data were collected by the psychologist and the psychotherapist involved in the study (*VM, OPD*).

3.4 Psychological intervention: the "*Four elements*" protocol for stress management

The purpose of the intervention is to provide a simple technique, easy to implement and applicable at any time, to help patients in managing emotions and psychophysiological aspects of anxiety.

A systematic review, written by Tsimopoulou in 2015 (96) reports different psychological interventions before cancer surgery, all of which can have an effect on post-operative recovery. The psychological interventions mainly reported for stress management regarded relaxation techniques such as breathing, progressive muscle relaxation and meditation, "guided imagery", with participants asked to imagine being at a safe and comfortable place, or are based on problem solving and coping strategies. Given these premises, we identified in the Shapiro protocol, a simple tool that would allow us to use all the main stress management techniques, in order to increase self-efficacy in managing anxiety in our sample of patients.

The technique consists essentially in four short and self-asserting frames. It refers to the sequence of the four elements (earth, air, water, fire), which is easy to remember. It starts from grounding (earth), continues with controlled breathing exercises (air), salivation induction (water) and the detection of a "safe place" image among patient memories (fire). Subjects experiment these techniques together with the psychologist and comment the effect they perceive. At the end of the consultation, patients are provided with a painted bracelet, which acts as a reminder to practice the exercise during moments of greater stress.

The application of this protocol of psychological intervention, which takes place in a single session, appears to be in line with the dynamics of the surgical department in question and with the type of patient candidates for the operation. The times between preoperative visits and hospitalization are very tight, and it must also be considered that most patients come from different places in Italy, which is why hospitalization takes place the day before the operation.

3.5 Study measures

Before surgery the following self-report, paper-and-pencil questionnaire were proposed:

T0 pre-operative counselling session

- ***Socio-demographic schedule***

  Information regarding gender, age, scholarship, family status and employment, disease status and any medication taken using a schedule specially designed for the survey.

- ***State-Trait Anxiety Inventory (STAI-Y2)***

  The State-Trait Anxiety Inventory Y2 form (Spielberger et al, 1983(17); Italian version Pedribassi, Santinello 1989(97)) is a self-assessment questionnaire composed by 20 items on a Likert scale ranging from 1 (not all) to 4 (much). The questionnaire evaluates the level of trait anxiety, which is how one feels usually. We measured trait anxiety, as it was supposed to be a confounding variable; if subjects tend to be anxious, it is expected that in specific situations, state anxiety (secondary outcome) may be higher. The internal consistency for trait scale vary from .85 to .90; the test-and-retest sensibility after one month is about .82. Total scores ranges from 20 to 80 points and a threshold value of anxious symptomatology is stated at 40 points. Using a scalar criterion, it is possible to define a severity level: from 40 to 50 mild anxiety, from 51 to 60 moderate anxiety, over 60 serious anxiety level.

- ***Patient Health Questionnaire (PHQ-9)***

  PHQ-9 (98) is a self-report questionnaire developed specifically for use in primary care. It is used for screening, diagnosis, monitoring and measurement of depression severity. PHQ-9 consists of 9 items corresponding to the symptoms of major depression according to the Diagnostic and Statistical Manual of Psychiatric Disorder IVth edition (99). The range score is between 0 to 27 points and the cut-off is set at a score of 10. The sensitivity (0.84) and the specificity (0.78) of the instrument are recognized as optimal to highlight depression of clinical relevance. Scores indicate the severity of depression: from 5 to 9

minimum depressive symptoms/subthreshold depression, from 10 to 14 minor depression/minor major depression, 15 to 19 moderate major depression and at least scores over 20 indicate severe depression(33).

- ***The Brief Coping Orientation to Problems Experienced (Brief COPE)***

  The Brief COPE is a tool to assess coping styles. It is a short version of the COPE version developed by Carver (1989)(100) and it consists of 28 items divided into 14 scales composed, each, of 2 items. The Brief COPE was created to evaluate a wide variety of coping strategies by referring to a series of distinct ways of solving problems and modulating emotions. The items are evaluated on a 4-point scale where 1 indicates "I do not usually do this" and 4 “I usually do just that". The scale aims to evaluate the coping styles of either normal or subject affected by different pathologies.

- ***General Self Efficacy Scale (GSES)***

  General Self-Efficacy Scale (GSES)(101). evaluates perceived ability in managing different stressful life events. The Italian version of GSES was translated by Sibilia(102). It is a unidimensional scale of 10 items on a Likert scale from 1 (no at all true) to 4 (totally true). The total score ranges from 10 to 40. The highest scores indicate a greater degree of self-efficacy. The analysis conducted on samples from 23 countries found an internal consistency ranging from .76 to .90 (Cronbach’s alpha).

- ***Multidimensional Scale of Perceived Social Support (MSPSS)***

  The MSPSS(103) is a multidimensional scale and the Italian version preserves the original structure, based on three factors which correspond to three different sources of support: family, friends and a significant person. It consists of 12 items scored on a 7-point Linkert scale(104). The instrument has the desirable characteristics for an accurate measurement of perceived social support: the reliability of Cronbach's alpha is of .90 for the total scale, .94 for the Family dimension, .93 for the Friends dimension and .94 for the Other Significant size.

- ***Functional Assessment of Cancer Therapy – General (FACT-G) and Functional Assessment of Chronic Illness Therapy-Fatigue (FACT-F)***

  FACT-G(105) is a questionnaire composed by 27 items on 4 points Likert scale ranging from 0 "nothing at all" to 4 "very much", divided into four subsections: physical wellbeing (PWB), social wellbeing (SWB), emotional wellbeing (EWB) and functional wellbeing (FWB). The timing of administration is almost 10 minutes.
- FACIT-F(105) is a FACT-G subscale. It is one-dimensional questionnaire that explores specifically the impact of Cancer Related Fatigue. It is composed by 13 item on a four points Likert scale ranging from 0 "nothing at all" to 4 "very much". The timing of administration is about 5 minutes. For its brief and the good psychometric proprieties, it is considered as a good tool to ensure Cancer Related Fatigue. Using both scales, FACIT-F and FACT-G, it is possible to reach information about Cancer Related Fatigue and the quality of patient's life.

Finally, the interest in receiving psychological support was evaluated by a yes/no dichotomous question: "*How much would you like to have psychological support to better deal with surgery anxiety?*"

All these measurements at t0 were collected to better describe the sample and because some of them (age, education level, gender and trait anxiety) were possible confounding variables.

T1 day before surgery

- ***State and Trait Anxiety Inventory (STAI-Y1)***

  The State-Trait Anxiety Inventory Y1 form (Spielberger et al, 1983(17); Italian version by Pedribassi & Santinello 1989(97)) is a self-assessment questionnaire composed by 20 items on a Likert scale ranging from 1 (not all) to 4 (much). The questionnaire evaluates the level of state anxiety, which is how one feels in a specific moment. The internal consistency for state scale vary from .91 to .95. Total score ranges between 20 to 80 points, with a predictive threshold value of

anxious symptomatology set at 40 points. According to a scalar criterion it is possible to define the severity level of anxiety: from 40 to 50 mild form, from 51 to 60 moderate, over 60 serious.

- ***Amsterdam Preoperative Anxiety and Information Scale (APAIS)***

  It is designed to identify the level of preoperative anxiety and the need of more technical information about operation before surgery. The Italian version(106) maintains all psychometric characteristic of the original scale. It consists of 6 items on 6 point Likert scale from 1 (not at all) to 6 (very much). The scale is bi-factorial: items 1, 2, 4, 5 evaluate the anxious status of patient, while items 3 and 6 regard needs to receive more information. Internal coherency was calculated using Cronbach's alpha coefficient and the scale is considered reliable when this coefficient is 0.7. The cut-off to define an anxious patient from a non-anxious one is set at a score of 14.

- ***Perceived self-efficacy***

  We measured the perception of self-efficacy using the following question, which is specially designed for the study: "*We kindly ask you to indicate on a scale from 1 to 10 how much you perceive to be able to manage anxiety before surgery*". The score is on an analogue scale ranging from 1 (not at all able) to 10 (completely capable).

  In patients with rheumatoid arthritis, the minimal clinically significant change has been estimated as 1.1 points on an 10-point scale (107).

  We assumed that the treatment could be considered effective if the score increases by at least 1.1 point by comparing the score before and after the psychological intervention in the experimental group, in line with Wolfe et al. stated in their work (2007) (107).

T2 after psychological intervention

- ***Perceived self-efficacy***

For all patients of experimental group, we measured the perception of self-efficacy using the following question, which is specially designed for the study: "*We kindly ask you to indicate on a scale from 1 to 10 how much you perceive to be able to manage anxiety before surgery*". The score is on an analogue scale ranging from 1 (not at all able) to 10 (completely capable).

- ***State and Trait Anxiety Inventory (STAI-Y1)***

  The State-Trait Anxiety Inventory Y1 form (Spielberger et al, 1983(17); Italian version by Pedribassi & Santinello 1989(97)) is a self-assessment questionnaire composed by 20 items on a Likert scale ranging from 1 (not all) to 4 (much). The questionnaire evaluates the level of state anxiety, which is how one feels in a specific moment. The internal consistency for state scale vary from .91 to .95. Total score ranges between 20 to 80 points, with a predictive threshold value of anxious symptomatology set at 40 points. According to a scalar criterion it is possible to define the severity level of anxiety: from 40 to 50 mild form, from 51 to 60 moderate, over 60 serious.

Only for a subgroup of experimental patients who satisfied inclusion criteria (absence of jaundice, feverish states, pancreatic pain with analgesic therapy, recent neo-adjuvant therapy, psychotropic therapy or cardio-vascular problems) psychophysiological parameters were collected together with the following scales and measurements:

- ***Working Alliance Inventory Therapist version (WAI-T)(108, 109)***

  WAI-T is a 36-item Likert scale on 7 points. There is no cut-off. Higher values indicate a better working alliance.

- ***Working Alliance Inventory Client version (WAI-C) (108, 109)***

  WAI-C is a 36-item Likert scale on 7 points. There is no cut-off. Higher values indicate a better working alliance.

Patient's psychophysiological reaction during the psychological intervention was also assessed by collecting Skin Conductance Level (SCL) and hearth rate (ECG). SCL is

measured in microsiemens (μS), using the Biopac MP150 system, connected to a Windows 7 operated computer running Acknowledge 4.1 data acquisition program and Observer XT 10.0 (Noldus). ECG signals are recorded by means of ECG100C Electrocardiogram Amplifier from BIOPAC MP150 system, with a sampling rate of 500 Hz. BIOPAC is connected to a Windows 7 operated computer running Acknowledge 4.1 data acquisition program and Observer XT 10.0 (Noldus). This parameter is collected during the psychological intervention only in the patient. Based on ECG signals, Heart Rate Variability (HRV), considering beat-to-beat variation of heart rate over time, is also calculated.

SCL was collected also in the therapist. Concordance in SCL between physician and patient is considered as an index of therapeutic relationship(110-113). A good quality of the relationship is strongly related to better outcomes(114, 115).

T3 post-operative period

- ***Brief Pain Inventory (BPI-I)***

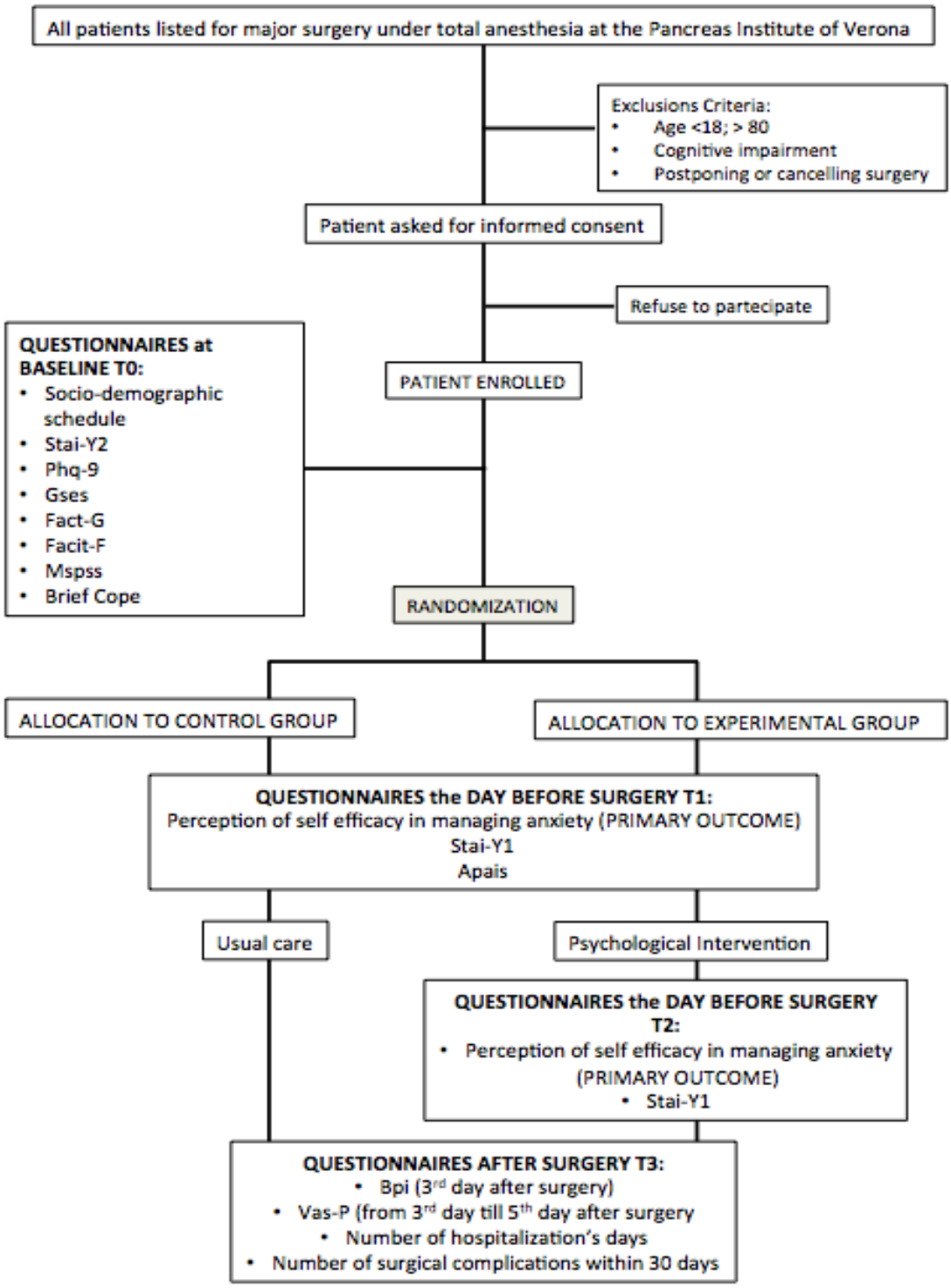
  BPI-I(116) administered on 3rd day after surgery. It is a brief questionnaire which evaluates the intensity of perceived pain during the last 24 hours. The scale has no cut-off: lower values indicate a greater state of wellbeing. The patient indicates on a human figure where is located the pain and its intensity on an analogue scale (range 1-10), then the patient responds to seven questions asking how this pain interferes with general activities, work, mood, ability to walk, quality of slumber and social relationships.

- ***Visual Analogue Scale for Pain (VAS-P)***

  VAS(117) is administered from the 3rd day until the 7th day after surgery. It is a visual analogue scale where number 0 represents “absence of pain” and number 10 indicates “the worse pain ever tried”. To measure perceived postoperative pain, patients respond to the following question: "We kindly ask you to indicate on a scale from 0 to 10 the intensity of your pain". The scale has no standardized scores or cut-off. Each patient applies his or her own "yardstick" in answering questions. Lower values are considered a better outcome.

We also considered the description of the number and type of p*ost-operative complications* within 30 days after surgical intervention. Fewer days correspond to a better outcome. The exact number of hospitalization days for each patient, from the date of hospital admission until the date of discharge or the date of death from any cause, whichever came first, assessed up to 6 months, was calculated. A lower number of hospital admission corresponds to a better outcome.

Figure 1. Flow chart of the study procedure



All the questionnaires used are shown in the Appendix 2. Some questionnaires were already owned by the research unit that conducted the study, who bought them by specific organizations (see Table 2). Others scales are in the public domain and do not need formal permission.

Table 2: Required permissions for questionnaires

Questionnaire	Owned	Public Domain
Stai –Y1-Y2	X	
PHQ-9	X	
GSES		X
MSPSS	X	
FACIT-F	X	
FACT-G	X	
Brief COPE	X	
APAIS		X
Self-efficacy scale	X	
BPI		X
VAS-P	X	
WAI-T E WAI-P		X

3.6 Sample size and allocation

Although the study on social support of Elizur & Hirsh(58) and the study of the importance of pre-surgery psychological intervention of Powell *et al*.(74) are pivotal references to the present study, none of them studied the variation in the perception of self-efficacy in managing anxiety of patients undergoing pancreatic surgery. Therefore, in the lack of literature on which to base our sample size calculation, we considered to conduct a feasibility study, collecting data for at least one year, to have a good picture of the surgical population. The clinical register of the Pancreas Institute reported that in 2016, 366 surgical interventions were performed. Since the number of interventions was increasing, we decided to set a sample size of 400 subjects, 200 per group (control vs. experimental).

The randomization with blocks of 10 subjects each has been created using the statistical software STATA 11(118). The list contains the patient's de-identification code and the

random assignment to the control or psychological intervention group. Patient's allocation was communicated to the psychotherapist the same day of patient's hospitalization, the day before surgery.

3.7 Data collection and methods

Data were entered daily on a database specifically created for the study, encrypted by using a dedicated password. Data entry was weekly supervised by the data manager. Monthly meetings were established for the assessment of data quality collection. The reasons for which participants, both of control and experimental group, discontinued from the study were reported in the database.

Scales and questionnaires adopted for the study are translated in Italian and are already validated, showing the same psychometric, reliability and validity properties of the ones in their original language.

3.8 Data Management and Monitoring

Data holders are the Pancreas Institute of AOUI and the Department of Clinical Psychology of the University of Verona.

Access to data is allowed only to authorized personnel directly involved in the study.

Research managers protect the privacy of the participants to the study by processing the data exclusively for statistical and scientific research purposes. They also undertake not to communicate or disseminate data except in anonymous form. The data are kept confidential and are processed in full compliance with Legislative Decree 196/03 (protection of persons and other subjects regarding the processing of personal data), in application of which all participants are asked to sign the informed consent.

The beginning and the progress of the study is supervised by the Ethics Committee of the Hospital Trust of Verona. The study has no economical sponsor, therefore there are no competing interests. It is a no profit study.

The researcher devoted to the enrolment of patients, questionnaires collection and dataset management will report all reasons related to discontinuity from the study to the

PI and on dataset.

If there might be impeding factors to continue the study the PI and the main collaborators will make the final decision to terminate the trial.

3.9 Statistical Methods

The characteristics of all patients have been synthesized using descriptive statistics.

The analysis of the efficacy related to the primary end-point has been carried out on the Per Protocol (PP) population, which includes the randomized subjects who completed T1and T2 phases.

In order to compare two independent groups, a preliminary analysis for checking the normal distribution of the variables was applied by using skewed-kurtosis test. Then Student's t-test and Levene test were performed respectively to compare mean values and standard deviations. For categorical variables, Pearson's Chi-sqaure and Fisher's exact test were applied where appropriate.

In more detail, for the analysis of the primary outcome, "Perception of perceived personal effectiveness on the management of anxiety", measured by a Likert scale from 1 to 10 points, the paired Student's t test has been used to compare the results before and after the psychological intervention in the experimental group. As confirmed by the preliminary analysis regarding the normal distribution of our data, Student' t test has been carried out to compare the same outcome between the control and experimental groups. For this comparison the data collected at T1 for the control group and the end point at T2 for the experimental group has been considered.

Statistical analysis related to secondary outcomes and outcomes followed the same strategies and tests adopted for the primary outcome analysis.

In this phase of the analysis we wanted to highlight, through the comparison between the control and experimental groups, if the management of anxiety had effects on post-operative outcomes (T3) in terms of a lower perception of pain by comparing the scores on VAS scales, perceived pain at BPI-I, the number of perioperative complications and the duration of admission. We used the repeated measures ANOVAs for secondary outcomes (pain perception).

The internal consistency, for each scale of the administered questionnaires, was evaluated by using Cronbach's alpha. It measures the inter-correlation among items within a scale, when the items are based on Likert scale. Alpha ranges from 0 to 1; when it is more than 0.80, the reliability is usually considered good.

Statistical significance level was set at 5%. All estimated parameters have been reported with the appropriate 95% confidence interval. As far as regards the primary end point, since there is no formal calculation of the sample size, the confidence interval serves as an indication of the power of the study.

In order to evidence that the randomization produced balanced groups, descriptive statistics and also two independent groups comparison were used for the baseline measures. As CONSORT guidelines state, these expected results are a chance of randomization (119, 120), and although not necessary, we reported them only for an easier interpretation.

The statistical software program STATA 11(118) has been used for the analyses.

4. RESULTS

Figure 2. Flow diagram of patients' recruitment.

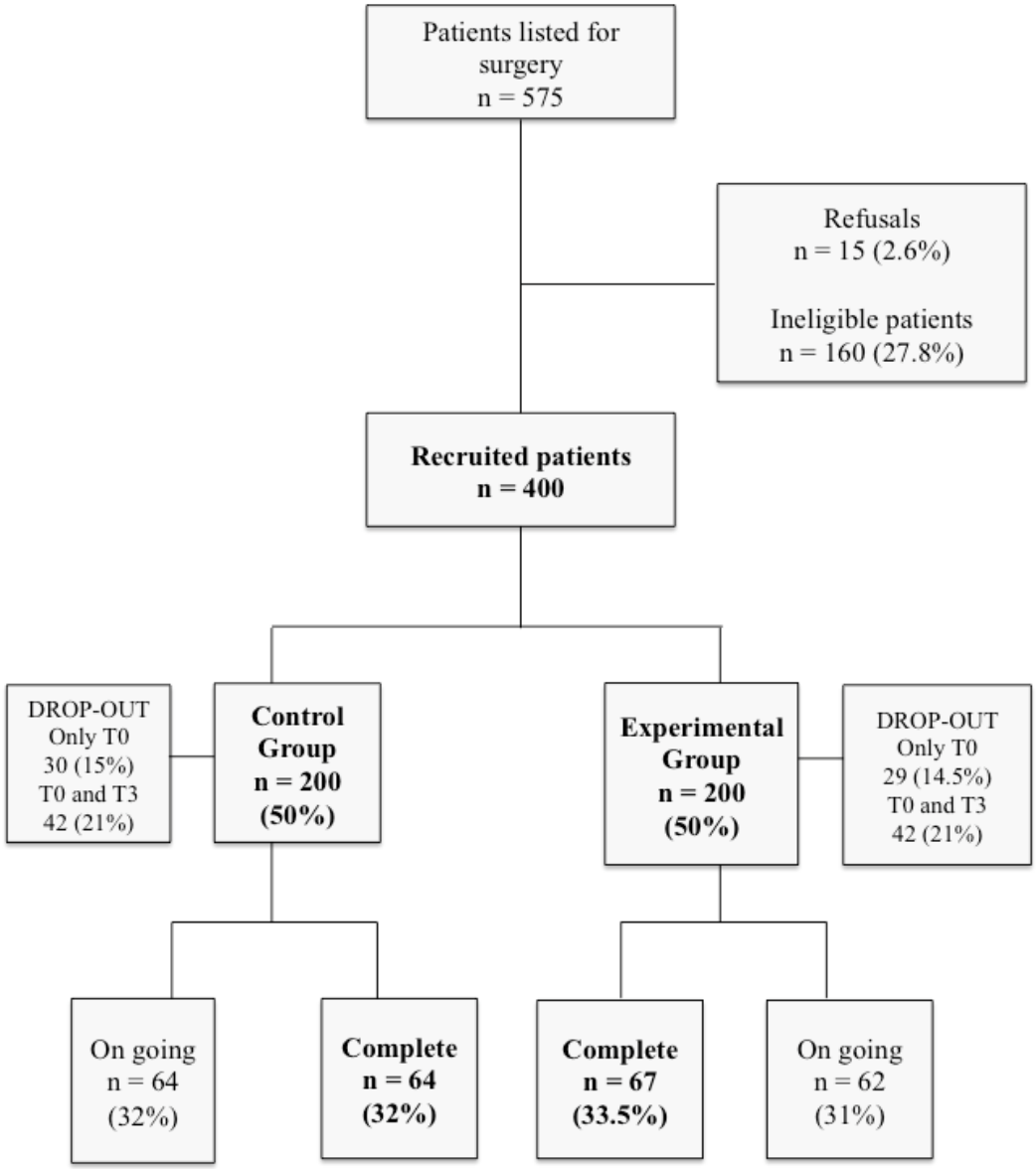


Figure 2 shows the flow diagram, as indicated by CONSORT guidelines, where the frequencies of participants were reported in the different phases of the study: enrolment, intervention allocation, follow-up, and data analysis. 575 patients were listed for

surgery: 15 (2.6%) patients refused to participate in the study due to anxiety for preoperative visits and no interest for psychological support, or impossibility to carry out the psychological visit due to further medical examinations. Furthermore 160 (27.8%) did not meet inclusion criteria to participate to the study as reported in table 3.

Table 3. Reasons for no-inclusion in the study (*n=160*)

Reason	N (%)
Other surgical procedures	54 (33.7%)
No surgery	21 (13.1%)
Lost	39 (24.4%)
Hospitalization on the same day	11 (6.9%)
Critical medical conditions	10 (6.2%)
Age over 80 years	23 (14.4%)
Spoken language	2 (1.3%)

Once included in the study, patients were randomized into control or experimental group. 32% of patients belonging to the control group and 31% of the experimental group did not conclude data collection. 59 (14.8%) patients were excluded for logistic problems or complicated hospitalizations and 84 patients (21%) did not complete all stages of the study.

The number of dropouts was very high, mainly because several patients were admitted during weekends or evening hours when the psychotherapist, expert in the psychological intervention, was absent from work (see table 4).

Table 4. Reasons for drop -out

Reason	N (%)
Evening hospitalization	51 (35,9%)
Festivity days	53 (37,3%)
Change of surgery	12 (8.5%)
psychologist not available for clinical reasons	20 (14.1%)
Other medical examination already appointed	3 (2.11%)
rejection	3 (2.11%)

4.1 Socio demographic characteristics of the recruited sample of patients

As reported in table 5, male patients were 202, sample mean age was 61.36 (63.75 $\pm$ 10.39 for male and 58.98 $\pm$ 13.12, for female). Most patients were married or engaged in a relationship (80,1%) with children (84.4%).

40% had at least 8 years of education, 45.7% were retired from work and 40.5% were workers. At T0 82.9% did not smoke and only 1% were alcohols users.

Table 6 shows the use of psychotropic drugs in the sample.

Table 5. Socio-demographic characteristics of the sample at T0 (n = 400).

Variables	N (%)
Gender	
Male	202 (50.8)
Education Level	
None	8 (2.0)
Primary school	66 (16.6)
Middle school	93 (23.4)
High school	146 (36.8)
Degree	84 (21.2)
Marital Status	
Married	303 (76.3)
Cohabitant	15 (3.8)
Divorced	22 (5.5)
Widower	28 (7.0)
Unmarried	29 (7.3)
Children	
No	62 (15.6)
Yes	335 (84.4)
Employment	
Student	6 (1.5)
Worker	161 (40.5)
Jobless	13 (3.3)
Housewife	36 (9.0)
Retired	182 (45.7)
Citizenship	
Italian	393 (98.7)
Other	5 (1.3)
Region of Origin	
Veneto	80 (20.1)
Other Italian regions	318 (79.9)
Smoking	
No	330 (82.9)
Yes	68 (17.0)
Alcoholic Beverages	
No	394 (99.0)
Yes	4 (1.0)

Table 6. Use of psychotropic drugs in the sample*

Type of drug	N (%)
Analgesics	
No	329 (82.7)
Yes	69 (17.3)
Hypnotics	
No	359 (90.2)
Yes	39 (9.8)
Anxiolytics	
No	365 (91.7)
Yes	33 (8.3)
Antidepressants	
No	382 (96)
Yes	16 (4)

***the sample is composed by 398 patients because, two of them refused to answer**

4.2 Clinical characteristics of the sample at baseline (T0)

As shown in table 7, the majority of patients had a malignant tumour (86.6%) and the surgery represented the first step of care in 66.3% of cases. The data refer to 329 patients because for 71 subjects the histological information was not yet clear.

Table 7. Type of tumour and preoperative treatment

Preoperative Treatment	**Type of Tumour**	
	Malignant (n=285)	**Benign (n=44)**
Adjuvant/neoadjuvant chemotherapy	96 (33.7%)	2 (4.5%)
Up-front	189(66.3%)	42(93.3%)

Table 8 reports the mean values in psychological screening tests at T0.

The average values of STAI-Y2 were 10 points below the cut-off (*M*=32.5 ± 9.5). Also PHQ-9 mean scores were below the clinical cut-off (*M*=5.3 ±4.7).

Patients showed good personal resources in terms of self-efficacy (*M*=34.9, sd ±5.0) and most enjoyed good social support (*M*= 65.9, sd ±9.3). On scales that measured fatigue, patients showed to have a good quality of life (FACIT-F: *M*=42.12 ±11.1;

FACT-G: *M*=55.23 ±9.13). Similarly, they showed good coping skills at the COPE scale (*M*=67.2, sd ±9.06).

Table 8. Clinical variables of the sample at T0

Variable	Mean (sd)	Min	Max
STAI-Y2	32.54 (9.48)	20	76
PHQ-9	5.26 (4.66)	0	21
GSES	34.97 (5.07)	14	40
MSPSS	65.92 (9.30)	19	72
Special Person	23.05 (2.97)		
Relatives	22.80 (3.09)		
Friend	20.07 (6.24)		
FACIT-F	42.13 (11.11)	6	52
FACT-G	55.23 (9.13)	16	96
Physic	3.47 (4.28)		
Family	22.66 (5.07)		
Affective	8.2 (4.1)		
Functioning	21.45 (7.02)		
Brief COPE	67.23 (9.06)	39	92
Socio-emotional	13.48 (4.19)		
Avoidance	25.44 (9.06)		
Acceptance	12.68 (3.31)		
Activities	10.59 (2.52)		

4.3 Reliability of questionnaires at T0 and T1

A reliability analysis was conducted for all scales at T0 and T1. All the questionnaires and their subscales showed to be reliable for the study.

Table 9. reliability of questionnaires

Questionnaire T0	**Alpha cronbach**
Stai-Y2	0.87
Phq-9	0.74
Gses	0.87
Mspss_TOT	0.88
Mspss_PP	0.89
Mspss_F	0.92
Mspss_A	0.96
Facit_F	0.92
Fact_G_TOT	0.87
Fact_G_	0.75
Fact_G_	0.75
Fact_G_	0.75
Fact_G_	0.79
Brief COPE_TOT	0.70
Brief COPE_Socio-emotional support	0.77
Brief COPE_avoidance	0.48
Brief COPE_acceptance	0.57
Brief COPE_active coping	0.75
Questionnaire at T1	**Alpha cronbach**
Stai_Y1	0.75
Apais_TOT	0.75
Apais_Anxiety	0.55
Apais_More info	

4.4 Comparison between Control and Experimental group at baseline (T0).

In order to check whether the randomization produced balanced groups, regarding both socio-demo and clinical characteristics, a set of two-sample tests for differences were performed using Pearson χ^2 test, Fisher exact test, and Student's t test. Comparisons, showed that the control and the experimental group were comparable for all socio-demographic variables (table 10). Regarding the use of psychotropic drugs, the two groups were comparable (table 11). Test comparisons showed that the control and the experimental group were comparable also for psychological variables (table 12), except for trait anxiety level. However, this difference had no clinical significance: the mean

scores are 33.6 and 31.5, respectively for control and experimental group, indicating low levels of trait anxiety (cut-off 40 for clinical anxiety).

As far as regards the type of cancer, the two groups did not differ for the type of treatment (table 13).

Table 10. Socio-demographic characteristics of control and experimental group.

Variables	Control N = 200	Experimental N = 200	t-test of χ^2	P value
Gender				
Male	100	102	0.04	.84
Age	61.71 (±12.24)	62.08 (±11.68)	0.47	.76 [a]
Education Level				
None	4	4	1.53_4	.82
Primary school	33	33		
Middle school	48	45		
High school	76	70		
Degree	37	47		
Marital Status				
Married	143	160	6.40_4	.17
Cohabitant	10	5		
Divorced	12	10		
Widower	19	9		
Unmarried	14	15		
Children				
No	32	30	0.09	.43[a]
Yes	166	169		
Employment				
Student	3	3	3.02_4	.55
Worker	77	84		
Jobless	4	9		
Housewife	18	18		
Retired	97	85		
Citizenship				
Italian	196	197	0.20	.65[b]
Other	3	2		
Region of Origin				
Veneto	48	32	4.00	.06[b]
Other Italian regions	151	167		
Smoking				

No	164	166	0.07	.80
Yes	35	33		
Alcoholic Beverages				
No	195	199	4.04	.12[b]
Yes	4	0		

using [a]: t-test for mean comparison Fisher exact test

Table 11. Use of psychotropic drugs in the control and the experimental group at baseline.

Type of drug	Control (N=200)	Experimental (N=200)	χ^2 or Fisher's test	p-value
Analgesic				
No	158	171	2.96	.09
Yes	41	28		
Hypnotics				
No	179	180	0.03	.87
Yes	20	19		
Anxiolytics				
No	180	185	0.83	.36
Yes	19	14		
Antidepressant				
No	191	191	0.00	1.00
Yes	8	8		

Table 12. Psychological variables of control (n=64) and experimental group (n=67) at baseline

Variable	Control Mean (sd)	Experimental Mean (sd)	t-test (P value)	IC 95%
STAI-Y2	33.56 (±10.48)	31.53 (±8.27)	2.15 (.03*)	-.74,5.80
PHQ-9	5.43 (±4.81)	5.10 (±4.51)	0.70 (.48)	-1.05,1.83
GSES	35.06 (±4.98)	34.88 (±5.18)	0.35 (.73)	-2.79,0.92
MSPSS	65.74 (±9.49)	66.10 (±9.13)	0.38 (.70)	-2.58,3.02
Special Person	23.06 (±2.80)	23.03 (±3.13)	0.10 (.91)	-0.19,1.88
Relatives	22.53 (±3.55)	23.08 (±2.53)	1.75 (.08)	-0.87,0.40
Friend	20.15 (±6.23)	19.99 (±6.26)	0.24 (.80)	-2.32,1.54
FACIT-F	41.44 (±11.63)	42.83 (±10.56)	1.21 (.22)	-5.12,2.49
FACT-G	55.52 (±8.40)	54.92 (±9.82)	0.63 (.52)	-1.91,4.19
Physic	3.65 (±4.57)	3.29 (±3.98)	0.81 (.42)	-1.49,1.38
Family	22.64 (±5.43)	22.68 (±4.70)	0.08 (.94)	-0.98,2.33
Affective	8.29 (±3.96)	8.10 (±4.24)	0.47 (.64)	0.94,1.67
Functioning	21.30 (±6.35)	21.60 (±7.64)	0.41 (.68)	-2.96,2.25
Brief COPE	67.19 (±9.15)	67.27 (±9.00)	0.09 (.92)	-3.35,3.01
Socio-emotional	13.32 (±4.18)	13.64 (±4.21)	0.74 (.45)	-1.86,0.95
Avoidance	24.64 (±9.21)	26.24 (±8.86)	1.77 (.07)	-5.01,1.11
Acceptance	12.84 (±3.32)	12.52 (±3.31)	0.97 (.33)	-0.86,1.25
Activities	10.51 (±2.56)	10.67 (±2.48)	0.80 (.54)	-0.73,0.98

Table 13. Clinical conditions of the control and experimental group at baseline

Preoperative Treatment	Control Group	Experimental Group	P value χ^2
Adjuvant/neoadjuvant chemotherapy	39 (60%)	57 (85%)	.20

4.5 Comparison between Control and Experimental group of on-going patients at baseline (T0).

Pearson χ^2 test comparisons showed that the control and the experimental group were comparable for gender and all socio- demographic variables (table 14). Regarding the use of psychotropic drugs, the two groups were comparable (table 15). T test comparisons showed that the control and the experimental group were comparable also for psychological variables (table 14), type of cancer and for the type of treatment (table 16).

Table 14. Socio-demographic characteristics of control and experimental group of on-going patients

Variables	Control N = 62	Experimental N = 64	t-test or χ^2	P value
Gender				
Male	35	38	0.11	.74
Age	61.23 (±12.37)	62.13 (±12.62)	.40	.70
Education Level				
None	2	1	2.32	.68
Primary school	14	13		
Middle school	16	15		
High school	20	19		
Degree	9	16		
Marital Status				
Married	44	52	2.26	.69
Cohabitant	2	2		
Divorced	2	1		
Widower	8	4		
Unmarried	5	5		
Children				
No	10	11	0.01	.91
Yes	51	53		
Employment				
Student	2	1	5.03	.28
Worker	20	24		
Jobless	-	4		
Housewife	3	3		
Retired	37	32		
Citizenship				
Italian	61	64	1.04	.31
Other	1	-		
Region of Origin				
Veneto	19	12	2.40	.12
Other Italian regions	43	52		
Smoking				
No	50	51	0.02	.89
Yes	12	13		
Alcoholic Beverages				
No	60	64	2.09	.15
Yes	2	-		

Table 15. Use of psychotropic drugs in the control and the experimental group of on-going patients at baseline.

Type of drug	Control (N=62)	Experimental (N=64)	χ^2 or Fisher test	P value
Analgesic				
No	50	58	2.56	.11
Yes	12	6		
Hypnotics				
No	53	55	0.00	.94
Yes	9	9		
Anxiolytics				
No	54	61	2.67	.10
Yes	8	3		
Antidepressant				
No	57	62	1.46	.25
Yes	5	2		

Table 16. Psychological variables of control and experimental group of on-going patients at baseline

Variable	Control Mean (sd)	Experimental Mean (sd)	t-test (P value)	IC 95%
STAI-Y2	34.42 (±12.74)	30.06 (±7.28)	2.04 (.04*)	0.12;7.41
PHQ-9	5.64 (±5.04)	5.16 (±4.58)	0.56 (.58)	-1.22;2.19
GSES	35.47 (±4.92)	35.31 (±4.53)	0.18 (.86)	-1.59;1.90
MSPSS	63.37 (±11.82)	65.46 (±9.44)	1.08 (.284)	-5.94;1.76
Special Person	22.17 (±4.24)	23.30 (±2.73)	1.74 (.08)	-2.41;0.16
Relatives	22.53 (±3.55)	23.08 (±2.53)	1.81 (.07)	-2.16;0.10
Friend	19.08 (±6.74)	19.02 (±7.03)	0.05 (.96)	-2.41;2.55
FACIT-F	40.38 (±11.85)	43.29 (±10.70)	1.36 (.18)	-7.15;1.33
FACT-G	54.45 (±8.95)	54.27 (±8.54)	0.10 (.91)	-3,10;3.46
Physic	4.59 (±4.78)	2.96 (±3.55)	2.03 (.04*)	0.05;3.20
Family	21.20 (±6.13)	22.89 (±4.91)	1.62 (.11)	-3.78;0.39
Affective	8.23 (±3.95)	7.55 (±3.82)	0.92 (.36)	-0.78;2.14
Functioning	20.43 (±6.90)	21.63 (±6.48)	0.95 (.35)	-3.71;1.31
Brief COPE	67.05 (±9.12)	67.79 (±8.66)	0.45 (.65)	-3.95;2.48
Socio-emotional	14.02 (±3.83)	13.36 (±4.27)	0.90 (.37)	-0.80;2.11
Avoidance	26.57 (±8.72)	28.30 (±9.03)	1.08 (.28)	-4.90;1.43
Acceptance	12.68 (±2.77)	12.20 (±3.73)	0.80 (.42)	-0.70;1.66
Activities	10.58 (±2.19)	10.45 (±2.70)	0.29 (.77)	-0.75;1.01

4.6 Primary outcome, self-efficacy perception in managing anxiety the day before surgery

The randomization produced two balanced groups of patients regarding self-efficacy perception in managing anxiety: measured at T1: 7.0(±2.06) vs 6.90(±1.65), for control and experiments groups (t= 0.32; *p = .75);* Using t-test for independent samples, we compared average scores of self-efficacy perception, before and after psychological treatment in order to check the effect of psychological intervention table 17.

The comparison between the experimental and the control group is based on the assumption that at T1 no specific psychological treatment was given for both groups and that the control group did not carry out further treatments, thus with no modification in self-efficacy level. This allows us to make a comparison between T1 of the controls and T2 of the experimental.

Table 17. Comparison of self-efficacy perception between control and experimental group

Clinical Variable	Control Group (n=64)	Experimental Group (n=67)	T-test (P value)	IC 95%
Self-Efficacy	7.00 (±2.05)	8.29 (±1.29)	4.28 (<.001*)	-1.90,-0.70

The results showed an increase of confidence in managing preoperative anxiety with a raise of 1.29 points (p<.001). We used Fisher exact test, which confirmed the is statically significant (*p-value* =.006), in order to better evidence where the scores differ.

It can be noticed from table 18 that the control group with a score ranging between 0 to 5 represents 25% of the sample, while the experimental group has only one subject in this range of scores. In the range between 8 and 10 the control group has less subjects than the experimental group (45% vs 74%).

Table 18. Comparison between T1 (control group) and T2 (experimental group)

	Control (n=64)	Experimental (n=67)	Total (n=132)
Self-efficacy			
2	2	0	2
3	1	0	1
4	5	0	5
5	8	1	9
6	8	6	13
7	11	10	22
8	12	20	32
9	10	13	23
10	7	17	24

As expected, the same trend was observable by analysing the average scores in the experimental group before and after the intervention, by using paired t-test. There was an increase of self-efficacy perception, with a raise of 1.44 points.

Table 19. Comparison of self-efficacy perception within experimental group

Clinical Variable	T1	T2	T test (P value)	IC 95%
Self-Efficacy	6.88 (±1.64)	8.32 (±1.30)	11.25 (<.001*)	13.26,18.23

4.6 Secondary outcomes, anxiety levels the day before surgery.

The day before surgery, using t-test for independent samples, patients showed the same levels of anxiety. Regarding preoperative anxiety, measured using APAIS, we divided the total score in need of more information and general anxiety for surgery. Patients of both groups, appeared more anxious about surgical outcomes (Control Group M=11.51, sd=±5.06; Experimental group M=11.63, sd=±5.12) than about the lack of information received.

As far as regards state anxiety, patients were comparable (p= .64) and showed average scores just above the threshold (Control Group M=42.70±12.85; Experimental group M=43.79±13.63).

Table 20. comparison of anxiety level between two groups at T1 and T2.

Clinical Variable	Control Group (n=64)	Experimental Group (n=67)	T-test (P value)	IC 95%
APAIS tot	15.21(±6.79)	15.09 (±5.88)	0.11 (.91)	-2.09,2.32
APAIS anxiety	11.51(±5.06)	11.63 (±5.12)	0.13 (.89)	-1.89,1.65
APAIS more info	3.70 (±2.69)	3.46 (±1.77)	0.60 (.55)	-0.56,1.02
STAI-Y1	42.70 (±12.85)	43.79 (±13.63)	.64	-5.69,3.52

Using t-test for independent samples we compared average scores of anxiety levels, before and after psychological treatment.

The results showed an important decrease of anxiety level, with a reduction of 14 points (p<.001).

Table 21. Comparison of anxiety level the day before surgery at T1 time

Clinical Variable	Control Group (n=64)	Experimental Group (n=67)	t-test (P value)	IC 95%
Stai-Y1	42.70 (±12.85)	28.30 (±7.56)	7.82 (<.001*)	10.75,18.05

The same trend was observable by analysing the average scores in the experimental group. There was a decrease of state anxiety levels with a reduction of 15.74 points.

Table 22. comparison of anxiety level within experimental group (n=67)

Clinical Variable	T1	T2	t-test (P value)	IC 95%
Stai-Y1	44.03 (±13.59)	28.29 (±7.61)	12.45 (≤.001*)	13.21,18.26

In our study trait anxiety did not show to have an impact on state anxiety level, the day before surgery. This because the average levels of trait anxiety, for both groups, were clinically irrelevant and subjects showing significant anxiety were equally distributed in the two groups (see table 23). Also depressive symptoms did not influence the general mood of patients. Only 16 patients, belonging equally to both groups, showed high levels of depressive symptoms. So we did not consider this as a covariate.

Table 23. Relevant anxious and depressive symptoms for experimental and control group

Clinical Variable	Control Group (n=17)	Experimental Group (n=10)	t-test (P value)
STAY-Y2	47.47 (±8.34)	47.50 (±6.53)	.85
	Control Group (n=9)	**Experimental Group (n=7)**	
PHQ-9	12.44 (±2.0)	13.86 (±1.8)	.17

4.8 Other secondary outcomes after surgery at T3

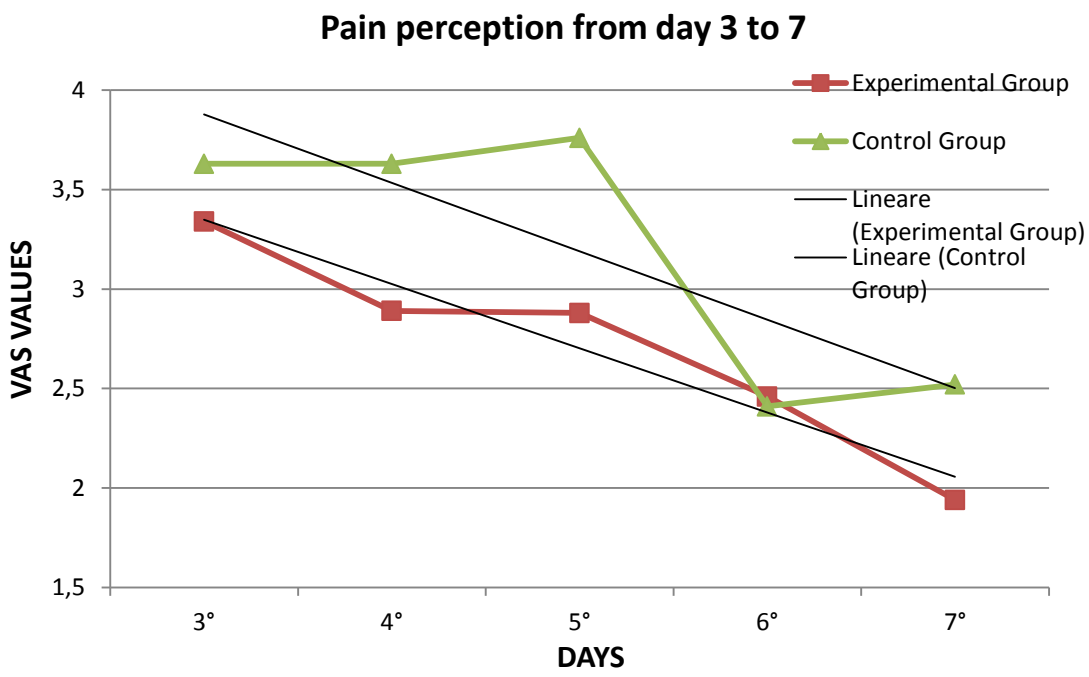
Three days after surgery data regarding the perception of pain were collected and compared by using T-test for independent samples. The experimental group showed a reduction in the mean values in the BPI compared to the control group; and a significant reduction in areas related to the emotional (p=.05) and operational interference (p=.04) of pain. (table 24).

Table 24. Perception of pain 3 days after surgery

Clinical Variable	Control Group (n=31)	Experimental Group (n=31)	P value
BPI_Pain	4.56 (±2.44)	4.28 (±1.55)	.60
BPI_Emotional	3.65(±2.52)	2.58 (±1.78)	.05*
BPI_Operative	6.22 (±2.63)	4.34 (±2.37)	.04*

We also analysed pain, using VAS (Visual Analogue Scale ranging 0 to 10) from day 3 to day 7. Repeated measures ANOVAs were used to determine VAS pain levels across time and between groups (see figure 3). The experimental group showed a tendency to lower average values compared to the control group. This trend, although not statistically significant, appeared more marked starting from the sixth to the seventh survey of the VAS.

Figure 3. VAS of pain from day 3 to day 7 after surery



5. DISCUSSION

Psychological interventions have been typically administered after cancer treatment. However, the perioperative period is particularly distressing for cancer patients (96), and growing evidence indicates that interventions delivered before surgery may have an impact on postoperative recovery (96).

This feasibility randomized controlled study examined the effectiveness of a short-term intervention using the "four elements protocol" (94) aiming to increase self-efficacy perception for patients one day prior to pancreatic surgery.

To our knowledge this study is the first conducted in Italy on patients with pancreatic cancer disease.

At the baseline the two groups of patients were comparable. Most patients did not show clinically significant anxiety or depressive symptoms. This was probably related to the presence of a very strong family support. Furthermore, the first evaluations took place at

a decisive moment for the patient, in which it was decided, on the basis of a series of clinical parameters, whether the surgical intervention would take place or not. Moreover, considering the type of pathology, the expectation and the desire to undergo surgery, mood states might have been positively influenced.

The primary goal of the intervention was to increase preoperative self-efficacy in managing anxiety.

The group of patients who received the psychological intervention reported a significant increase of self-efficacy perception. The difference with the control group, higher than 1.1 point, may not be considered the result of "a placebo effect" [105].

Further, the day before surgery, the intervention group demonstrated a more pronounced reduction in state anxiety immediately after psychological intervention than the control group, although pre-operation anxiety levels, measured at T1 time, were comparable.

The challenge of our study was to build an effective psychological intervention applicable in a single session before surgery. The attempt to offer a brief psychological intervention was determined by the origin of the patients (mostly extra-region) and by the time of hospitalization usually envisaged by the ward. Literature provides little information on patients' experiences and anxiety in this setting (88).

Compared to the analysis of pain detected on the third day post-operative, using the BPI shows that the three factors identified are each expression of equally important aspects of the same phenomenon. This means that the intensity of pain and its interference in emotional life and daily activities contribute equally to define different aspects of pain. They are, therefore, factors that must be considered simultaneously in the approach to a patient who must undergo a surgical intervention.

The results of this study suggest that, during hospitalization, participants in the experimental group experienced better pain control than control group participants for the first 7 days after surgery. This finding is consistent with the results of previous studies, which show that preoperative interventions have a positive effect on pain management after surgery (121, 122).

Despite the interesting results, the most important limit of our study is related to the high number of drop-outs (especially for the secondary post-operative outcomes) due to the complexity of the pathology per se and the type of intervention required. Several

patients were hospitalized in urgency, during the evening or on weekends, during which the psychotherapist expert in the manualized intervention could not be present. The comparison of the group of subjects who dropped out with those who participated to the study showed that they did not differ. Thus we can conclude that the randomization was effective. In our case, we did not have previous studies on which to base sample size calculation, therefore the more reliable measure to start our feasibility study was to consider the total number of patients that underwent surgery in one year.

To implement a real RCT, randomization needs to be applied on patients who enter for surgery just the day before, allowing strategies to implement the presence of a specialized psychotherapist in day moments different from usual working times (8 am - 5 pm).

We have also to consider that, given the severity of the pathology under consideration, the probability of a high number of drop-outs is still present due to important comorbidities that require further assessments and specialist visits.

A strength of our study is that it differs from previous investigations with regard to the short time frame between the psychological intervention and the surgery. Patients had to adapt to the upcoming surgery very quickly and the intervention had to show to be effective at the first stage, which indeed occurred as hypnotized. The reason may be found in the easiness of the psychological intervention proposed (easy to remember, being based on the image of four natural elements) and its foundation in body experience (breath, salivation) and positive memories (recording of a secure place). Moreover, the intervention was proposed in a crucial moment of patient experience (the day before surgery) when any suggestion to better recover and manage anxiety might be considered significant by the patient herself. The cue of the coloured bracelet helped patients to remember the intervention. Most of them reported to apply the technique at least one or even several times before and after surgery to manage anxiety. And last, but not least, the open attitude of the psychotherapist at the beginning of the intervention, which allowed patients to express their concerns and worries related to surgery, permitted to put them at ease and to find a caring health provider that offered support and empathy all along their hospitalization experience.

6. CONCLUSIONS

The findings from this study show an important need to focus on a holistic approach to patients waiting for surgery (96).

More high-quality research is needed to elucidate whether preoperative interventions can effectively improve patients' postoperative outcomes. Surgery departments have to identify the psychosocial needs of the patients. Although the idea of better preparing patients for cancer surgery with psychological interventions seems intuitive, instituting an intervention is expensive, and testing the efficacy is difficult. This may account for the current paucity of studies in this area. Future studies should be better powered to detect differences in traditional postoperative outcomes to demonstrate cost effectiveness.

Preoperative anxiety is an unpleasant emotion that affects many patients awaiting surgery. Multiple tools have been developed to screen surgical patients for anxiety and various treatments, both non pharmacological and pharmacological, have been shown to be effective in reducing patient anxiety. Screening and treating patients for preoperative anxiety will result in both improved patient satisfaction and outcomes and need to become a standard of care in preparing patients for surgery.

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APPENDIX

1. **Approval of Ethical Committee**
2. **Psychological intervention for experimental group: the "Four Element Protocol"**
3. **Questionnaires**

AZIENDA OSPEDALIERA UNIVERSITARIA INTEGRATA
VERONA
(D.Lgs. n. 517/1999 - Art. 3 L.R.Veneto n. 18/2009)
DIPARTIMENTO DIREZIONE MEDICA OSPEDALIERA

COMITATO ETICO PER LA SPERIMENTAZIONE CLINICA DELLE PROVINCE DI VERONA E ROVIGO

UFFICIO DI SEGRETERIA TECNICO-SCIENTIFICA DEL COMITATO ETICO
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Prot. n. 2900 *del* 13/06/2017

Sperimentatore: Dr.ssa Lidia Del Piccolo - Psicologia Clinica Br (USD) - Azienda Ospedaliera Universitaria Integrata - Verona

NRC: A.O. UNIVERSITARIA INTEGRATA DI VERONA

Oggetto: Presa d'atto della Segreteria Scientifica del CESC relativa allo Studio Clinico: "PREPARE: VALUTAZIONE DI UN INTERVENTO PSICOLOGICO PRE-OPERATORIO IN PAZIENTI CHE SARANNO SOTTOPOSTI A CHIRURGIA DEL PANCREAS. - Codice Protocollo: PREPARE – PREoPerative Anxiety REduction – Prog. 1288CESC

Il Comitato Etico per la Sperimentazione clinica delle Province di Verona e Rovigo (CESC) nella seduta del **10/05/2017** ha approvato a condizione lo studio in oggetto.

A seguito di tale decisione, il promotore ha inoltrato all'Ufficio di Segreteria Scientifica del CESC la seguente documentazione modificata:
- Foglio informativo e modulo di Consenso informato (versione 2 del 15/05/2017)

Si prende atto di tale documentazione, che soddisfa le richieste del CESC. Lo studio si considera pertanto approvato.

Si ricorda che:
- Per l'attivazione della sperimentazione è necessario attendere, ove previsto, la ricezione dell'autorizzazione della propria Amministrazione.
- Lo Sperimentatore è tenuto a segnalare al Comitato Etico l'arruolamento del primo paziente.
- Al termine dello Studio, lo Sperimentatore dovrà inviare al Comitato Etico la relazione finale.

Cordialmente.

Il Responsabile dell'Ufficio di Segreteria del CESC
Dr.ssa Anna Fratucello

Sperimentazione Prog. **1288CESC**

STUDIO PREPARE – T2 GRUPPO SPERIMENTALE
ESERCIZIO DEI QUATTRO ELEMENTI PER LA GESTIONE DELLO STRESS

PROTOCOLLO OPERATIVO

- **Introduzione informativa all'intervento e spiegazione dell'esercizio dei 4 elementi**
- **Consegna Bollino Rosso (da attaccare al braccialetto)**

T: "*Mi potrebbe descrivere come si sente rispetto all'attesa dell'anestesia e dell'intervento chirurgico*?"
……
……
……
……

T: "*Mi potrebbe descrive che cosa la preoccupa in particolare?"*
……
……
……
……

T: "Bene. Ora faremo un esercizio che la aiuterà a gestire lo stress di questo momento. Lo scopo di questo esercizio è quello di aiutarla a gestire l'ansia o l'agitazione che in questo momento prova, rimanendo all'interno di quella che indicheremo come la Sua "*finestra di tolleranza*" dello stress. Questo esercizio si chiama "Esercizio dei quattro elementi" e dovrebbe aiutarla a gestire per alcune ore o tutto il giorno un aumento per accumulo del Suo livello di stress, favorendo la sua capacità di gestire la situazione.

Prendiamo subito nota del Suo livello di stress/ansia in questo momento con l'aiuto di una scala. Il valore 0 corrisponde all'assenza totale di stress/ansia o a una situazione di indifferenza mentre il valore 10 corrisponde al massimo livello di stress/ansia che riesce ad immaginare.

Quanto di sente stressato/a o in ansia in questo momento?
0 1 2 3 4 5 6 7 8 9 10

L'esercizio consiste in quattro brevi attività che, senza interventi di altri, le daranno tranquillità e faciliteranno il Suo senso di autocontrollo. La sequenza dei "quattro elementi" – Terra, Aria, Acqua e Fuoco – è concepita per seguire la scansione corporea che farà risalendo dai piedi, allo stomaco, attraverso il torace e la gola, fino alla bocca e poi ancora più su fino alla testa, in modo che poi le da solo/a possa ripercorrerli e ridurre l'eventuale senso di agitazione/stress che può provare nell'attesa dell'intervento.

Cominciamo.

1. **Il primo elemento è la TERRA**.

La TERRA rappresenta l'idea di radicarsi nel presente e di renderci consapevoli che nel presente possiamo sentirci sicuri. L'idea di Terra rappresenta il nostro radicamento nell'ambiente, la possibilità di sentirci stabili.

Metta entrambi i piedi a contatto con il terreno, cerchi di sentire il sostegno che le dà la seggiola, percependo il proprio peso ancorato su di essa. Si concentri bene sulla sensazione dei suoi piedi appoggiati e del suo

corpo che poggia sulla sedia. Si concentri bene su questa sensazione interna, quindi diriga la sua attenzione verso l'esterno.

Guardi attorno a sé e prenda nota di tre cose sulle quali cade il Suo sguardo.

……

Mi dica cosa sente.

…….....

Mi dica quali odori percepisce.

……

2. Il secondo elemento è l' ARIA.

Continui a sentire la SICUREZZA del QUI e ORA che le danno i piedi ben piantati a TERRA e faccia tre o quattro respiri più profondi, più lenti, dallo stomaco al torace, assicurandosi di espirare completamente in modo da far posto ad aria nuova che le dà energia.

Noti ora come - mentre inspira – l'aria è più fredda di quando – espirando – la "butta fuori", diventando più calda. Si concentri su queste sensazioni. Inspiri ed espiri almeno tre-quattro volte e mentre procede nell'inspirare-espirare, immagini anche di liberarsi di parte dello stress, come se lo stesse soffiando via. Mentre fa questo concentri la sua attenzione all'interno, verso il diaframma e i polmoni che si chiudono e si espandono man mano che inspira ed espira.

L'Aria rappresenta l'equilibrio e la capacità di concentrarsi in contrapposizione agli stati ansiosi caratterizzati da assenza di ossigeno.

3. Il terzo elemento è l' ACQUA.

Per mezzo dell'elemento ACQUA, possiamo andare verso una risposta di relax e diventare tranquilli e controllati.

Presti attenzione se ha saliva in bocca.

Si è accorto che quando è ansioso o stressato, la bocca spesso si secca perché la risposta di emergenza allo stress comporta l'interruzione del funzionamento del sistema digestivo? E' un automatismo, legato all'attività del nostro Sistema Nervoso Simpatico.

Se ricomincia a produrre saliva, riattiverà automaticamente il sistema digestivo, favorendo una risposta di relax. Per aiutarla a produrre volontariamente saliva, provi a pensare al gusto del limone o qualsiasi altra cosa che lei sa le fa aumentare la salvazione. L'elemento ACQUA rappresenta la chiave del cambiamento verso una risposta di maggiore relax. Se riuscirà a produrre saliva, riuscirà anche a controllare in modo ottimale pensieri e corpo.

Ora, continui a sentire la SICUREZZA del QUI e ORA che le danno i piedi piantati a TERRA, si senta CENTRATO quando INSPIRA ed ESPIRA e si concentri sulla produzione di SALIVA". Dare del tempo

4. Il quarto elemento è il FUOCO.

Il FUOCO è il quarto elemento dell'esercizio, utile per aprire la porta all'immaginazione. Ora, vorrei che pensasse a un posto, in cui sia stato o in cui abbia immaginato di essere, che le dia una sensazione di grande sicurezza o tranquillità. Può essere un luogo in cui si è realmente trovato o un luogo della sua immaginazione o una situazione specifica che ha vissuto. L'importante è che le dia una sensazione di calma e sicurezza. Qual è questo luogo? Me lo descriva nel dettaglio. Com'è fatto? ……

Che cosa nota? Che colori vede? Che odori sente? Che sensazioni fisiche prova?

Si concentri totalmente sul suo posto sicuro, su ciò che vede, sui suoni, sugli odori e sulle sensazioni corporee. Mi dica tutto quello che può su ciò che osserva.

……..

Resti nel suo posto al sicuro. Lei sta sentendo la SICUREZZA del QUI ed ORA che le danno i piedi ben piantati nell'Elemento Terra, si sente CENTRATO con l'Elemento Aria perché INSPIRA ed ESPIRA e si sente TRANQUILLO e CAPACE di AUTOCONTROLLO perché produce sempre più saliva (l'Elemento Acqua). In quale parte del corpo sente maggiormente la sensazione di calma e sicurezza? Si concentri su questa.

……

Se sente delle tensioni in qualche parte del corpo provi a cambiare postura e immagini che vi passi l'aria del respiro in modo da appianarle.

Torni alla sensazione di calma e sicurezza che le dà il posto sicuro

Si concentri sulla sensazione positiva che percepisce sul corpo.

Istallazione con "*abbracci alla farfalla*".

Adesso, lei sta continuando a sentire la SICUREZZA del QUI ed ORA che le danno i piedi piantati a TERRA; si sente centrato perché INSPIRA ed ESPIRA; si sente TRANQUILLO e CAPACE di AUTOCONTROLLO perché produce sempre più SALIVA; ora è arrivato il momento di fare sì che il FUOCO FACCIA LUCE e apra la strada all'IMMAGINAZIONE per poter evocare l'IMMAGINE del suo posto SICURO.

Ora tocchi il suo braccialetto e cominci a pensare alla terra – i piedi e il suo corpo ben appoggiati, poi all'aria – il suo respiro, poi all'acqua – la saliva e infine al fuoco – il suo posto sicuro.

Provi a rifare l'esercizio della farfalla finché riesce ad evocare tutto questo insieme o in successione.

……

Benissimo. Nelle prossime ore e per i prossimi giorni potrà utilizzare questa modalità per installare o per connettere il braccialetto agli elementi della terra, dell'aria, dell'acqua e del fuoco.

Come è andata?

Facciamo una lettura aggiornata del livello di stress o ansia che prova, con 0 che corrisponde all’assenza totale di stress/ansia o alla sensazione di indifferenza e con 10 che è massimo livello di stress/ansia che riesca immaginare.

Quanto si sente stressato/a o in ansia in questo momento?

0 1 2 3 4 5 6 7 8 9 10

Poi si fanno tutte le scale di valutazione.

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37134, Verona, Italia

PREPARE

PREoPerative Anxiety REduction

ID _____

DATA _____

OPERATORE _____

ID

Data

Questionario Socio-Demografico

Data di nascita.....

Titolo di studio

- ☐ Nessuno
- ☐ Licenza elementare
- ☐ Licenza media inferiore
- ☐ Diploma
- ☐ Laurea

Stato civile

- ☐ Coniugato/a
- ☐ Convivente
- ☐ Separato/a
- ☐ Vedovo/a
- ☐ Celibe/Nubile

Ha figli?

- ☐ Sì
- ☐ No

Cittadinanza

- ☐ Italiana
- ☐ Altro .....

Regione di provenienza

- ☐ Veneto
- ☐ Altro .....

Quale descrizione corrisponde meglio alla sua situazione attuale?

- ☐ Studente
- ☐ Ho un lavoro retribuito
- ☐ Disoccupato/a alla ricerca di un lavoro
- ☐ Disabile
- ☐ Casalinga
- ☐ Pensionato/a

Quali farmaci assume?

- ☐ Antidolorifici
- ☐ Ipnoinducenti

- [ ] Ansiolitici
- [ ] Antidepressivi

Consumo di sigarette

- [ ] Sì
- [ ] No

Consumo di bevande alcoliche

- [ ] Sì
- [ ] No

ID

Data

Questionario S.T.A.I – FORM Y-2

(State-Trait Anxiety Inventory – Form Y2; Spielberger, 1989)

Istruzioni: Sono qui di seguito riportate alcune frasi che le persone spesso usano per descriversi. Legga ciascuna frase e poi contrassegni con una crocetta il numero che indica come lei *abitualmente* si sente. Non ci sono risposte giuste o sbagliate. Non impieghi troppo tempo per rispondere alle domande e dia la risposta che le sembra descrivere meglio **COME LEI SI SENTE ABITUALMENTE**.

1 = QUASI MAI	2 = QUALCHE VOLTA	3 = SPESSO	4 = QUASI SEMPRE

1.	Mi sento bene	1	2	3	4
2.	Mi sento teso/a ed irrequieto/a	1	2	3	4
3.	Sono soddisfatto/a di me stesso/a	1	2	3	4
4	Vorrei poter essere felice come sembrano gli altri	1	2	3	4
5.	Mi sento un/a fallito/a	1	2	3	4
6.	Mi sento riposato/a	1	2	3	4
7.	Io sono calmo/a, tranquillo/a e padrone di me	1	2	3	4
8.	Sento che le difficoltà si accumulano tanto da non poterle superare	1	2	3	4
9.	Mi preoccupo troppo di cose che in realtà non hanno importanza	1	2	3	4
10.	Sono felice	1	2	3	4
11.	Mi vengono pensieri negativi	1	2	3	4
12.	Manco di fiducia in me stesso/a	1	2	3	4
13.	Mi sento sicuro/a	1	2	3	4
14.	Prendo decisioni facilmente	1	2	3	4
15.	Mi sento inadeguato/a	1	2	3	4
16.	Sono contento/a	1	2	3	4
17.	Pensieri di scarsa importanza mi passano per la mente e mi infastidiscono	1	2	3	4
18.	Vivo le delusioni con tanta partecipazione da non poter togliermele dalla testa	1	2	3	4
19.	Sono una persona costante	1	2	3	4
20.	Divento tesa e turbata quando penso alle mie attuali preoccupazioni	1	2	3	4

ID

Data

PHQ-9

(Patient Health Questionnaire; Spitzer et al. 1999)

Istruzioni: di seguito troverà un elenco di affermazioni che possono essere usate per descrivere il proprio stato emotivo. Le chiediamo cortesemente di indicare, utilizzando la scala di valutazione da 0 (mai) a 3 (quasi tutti i giorni), la frequenza con cui ha sperimentato tali stati. Le chiediamo di rispondere con la massima precisione possibile.

	Durante le ultime due settimane con quale frequenza è stato disturbato da qualcuno dei seguenti problemi?	*Mai*	*Molti giorni*	*Più della metà dei giorni*	*Quasi tutti i giorni*
1.	Scarso interesse o piacere nel fare le cose	0	1	2	3
2.	Sentirsi giù, depresso o disperato	0	1	2	3
3.	Difficoltà ad addormentarsi o mantenere il sonno, o dormire troppo	0	1	2	3
4.	Sentirsi stanco o avere poca energia	0	1	2	3
5.	Scarso appetito o mangiare troppo	0	1	2	3
6.	Sentirsi in colpa o di essere un fallito o di aver danneggiato sé stesso o la sua famiglia	0	1	2	3
7.	Difficoltà concentrarsi sulle cose, come leggere il giornale o guardare la televisione	0	1	2	3
8.	Muoversi o parlare così lentamente tanto che anche gli altri se ne accorgevano o, al contrario, essere così irrequieto o agitato da doversi muovere da ogni parte molto più del solito	0	1	2	3
9.	Pensare che sarebbe meglio essere morto o di farsi del male in qualche modo	0	1	2	3

Se ha riscontrato la presenza di qualcuno dei problemi indicati nel presente questionario, in che misura quei problemi Le hanno creato difficoltà nel suo lavoro, nel prendersi cura delle cose a casa o nello stare insieme agli altri?			
Nessuna difficoltà	**Qualche difficoltà**	**Notevole difficoltà**	**Estrema difficoltà**

ID

Data

GSES

(General Self-Efficacy Scale; Schwarzer& Jerusalem, 1995)

Istruzioni: Di seguito troverà una serie di frasi. Pensando a sé stesso, indichi quanto si riconosce nelle affermazioni che seguono, indicando da 1 a 4 il suo grado di accordo.

1 =	Fortemente in disaccordo
2 =	In disaccordo
3 =	D'accordo
4 =	Fortemente d'accordo

		Grado di accordo			
1.	Riesco sempre a risolvere i problemi se ci provo abbastanza seriamente	1	2	3	4
2.	Se qualcuno mi contesta, riesco comunque a trovare il modo o il sistema per ottenere ciò che voglio	1	2	3	4
3.	Per me è facile attenermi alle mie intenzioni per raggiungere i miei obiettivi	1	2	3	4
4.	Sono sicuro che potrei affrontare efficacemente eventi inattesi	1	2	3	4
5.	Grazie alle mie risorse so come gestire situazioni impreviste	1	2	3	4
6.	Posso risolvere la maggior parte dei problemi se ci metto l'impegno necessario	1	2	3	4
7.	Rimango calmo nell'affrontare le difficoltà perché posso fare conto sulle mie capacità di affrontarle	1	2	3	4
8.	Quando mi trovo di fronte ad un problema, di solito riesco a trovare parecchie soluzioni	1	2	3	4
9.	Quando mi piomba addosso qualcosa di nuovo, generalmente sono capace di affrontarlo	1	2	3	4
10.	Non importa quello che mi può capitare, di solito sono in grado di gestirlo	1	2	3	4

ID

Data

MSPSS

(*Scala Multidimensionane del Sostegno Sociale Percepito; Prezza & Principato, 2002*)

Istruzioni: di seguito troverà 12 affermazioni (riguardanti i suoi rapporti con amici e parenti) con le qual può essere d'accordo o non d'accordo. Indichi con segno il suo grado di accordo considerando la seguente griglia.

1=	moltissimo in disaccordo
2=	molto in disaccordo
3=	un po' in disaccordo
4=	un po' d'accordo
5=	molto d'accordo
6=	moltissimo d'accordo

		Grado accordo					
1.	C'è una persona particolare che mi è vicina quando ne ho bisogno	1	2	3	4	5	6
2.	C'è una persona particolare con cui posso condividere le mie gioie e i miei dispiaceri	1	2	3	4	5	6
3.	La mia famiglia cerca veramente di aiutarmi	1	2	3	4	5	6
4.	Ricevo dalla mia famiglia l'aiuto morale e il sostegno di cui ho bisogno	1	2	3	4	5	6
5.	Ho una persona particolare che è un'autentica fonte di supporto per me	1	2	3	4	5	6
6.	I miei amici cercano veramente di aiutarmi	1	2	3	4	5	6
7.	Posso contare sui miei amici quando le cose vanno male	1	2	3	4	5	6
8.	Posso parlare dei miei problemi nella mia famiglia	1	2	3	4	5	6
9.	Ho amici con i quali posso condividere le mie gioie e i miei dispiaceri	1	2	3	4	5	6
10.	C'è una persona particolare nella mia vita che si interessa dei miei sentimenti	1	2	3	4	5	6
11.	La mia famiglia è disponibile ad aiutarmi quando devo prendere decisioni	1	2	3	4	5	6
12.	Posso parlare dei miei problemi con i miei amici	1	2	3	4	5	6

ID

Data

FACIT-F

(Functional Assessment of Chronic Illness Therapy-Fatigue; Cella, 1997)

Istruzioni: La preghiamo di indicare in quale misura queste affermazioni riflettono la sua esperienza degli ultimi 7 giorni

	ULTERIORI PROBLEMI	*Niente*	*Un po'*	*Qualche cosa*	*Abbastanza*	*Molto*
HI7.	Mi sento affaticato/a	0	1	2	3	4
HI12.	Mi sento indebolito/a	0	1	2	3	4
An1.	Mi sento svogliato/a	0	1	2	3	4
An2.	Mi sento stanco/a	0	1	2	3	4
An3.	Sono così stanco/a che ho difficoltà ad iniziare qualunque cosa	0	1	2	3	4
An4.	Sono così stanco/a che ho difficoltà a finire qualsiasi cosa	0	1	2	3	4
An5.	Ho energia	0	1	2	3	4
An7.	Sono in grado di svolgere le mie attività quotidiane (lavorare, andare a scuola, fare la spesa, svolgere attività durante il tempo libero, ecc.)	0	1	2	3	4
An8.	Ho bisogno di dormire durante il giorno	0	1	2	3	4
An12.	Mi sento troppo stanco/a per mangiare	0	1	2	3	4
An14.	Ho bisogno di aiuto per svolgere le mie attività quotidiane (lavorare, andare a scuola, svolgere attività durante il tempo libero, ecc.)	0	1	2	3	4
An15.	Mi deprime essere troppo stanco/a per fare le cose che desidero fare	0	1	2	3	4
An16.	Devo limitare la mia vita sociale perché sono stanco/a	0	1	2	3	4

ID _____

Data _____

FACT-G

(Functional Assessment of Cancer Therapy – General; Cella et al., 1993)

Istruzioni: Si prega di apporre un segno su un numero della scala per indicare la Sua risposta per quanto attiene agli ultimi 7 giorni. Se non ritiene opportuno rispondere a qualche domanda può tralasciarla.

	BENESSERE FISICO	*Niente*	*Un po'*	*Qualche cosa*	*Abbastanza, un po'*	*Molto*
GP1.	Ho una mancanza di energia	0	1	2	3	4
GP2.	Ho la nausea	0	1	2	3	4
GP3.	A causa della mia condizione fisica, ho difficoltà a soddisfare le esigenze della mia famiglia	0	1	2	3	4
GP4.	Ho dolore	0	1	2	3	4
GP5.	Soffro di effetti collaterali al trattamento	0	1	2	3	4
GP6.	Mi sento male	0	1	2	3	4
GP7.	Sono costretto a trascorrere del tempo a letto	0	1	2	3	4

	BENESSERE SOCIALE - FAMIGLIA	*Niente*	*Un po'*	*Qualche cosa*	*Abbastanza, un po'*	*Molto*
GS1.	Mi sento vicino ai miei amici	0	1	2	3	4
GS2.	Ricevo sostegno emotivo dalla mia famiglia	0	1	2	3	4
GS3.	Posso ottenere assistenza dai miei amici	0	1	2	3	4
GS4.	La mia famiglia ha accettato la mia malattia	0	1	2	3	4
GS5.	Sono soddisfatto della comunicazione familiare della mia malattia	0	1	2	3	4
GS6.	Mi sento vicino al mio partner (o la persona che è il mio supporto principale)	0	1	2	3	4
Q1.	*Indipendentemente dal suo attuale livello di attività sessuale, si prega di rispondere alla seguente domanda. Qualora non si volesse rispondere alla domanda, si prega di contrassegnare questa casella e andare alla sezione seguente.*					

GS7.	Sono soddisfatto della mia vita sessuale	0	1	2	3	4

	BENESSERE EMOTIVO	*Niente*	*Un po'*	*Qualche cosa*	*Abbastanza, un po'*	*Molto*
GE1.	Mi sento triste	0	1	2	3	4
GE2.	Sono soddisfatto di come sto affrontando la mia malattia	0	1	2	3	4
GE3.	Sto perdendo la speranza nella lotta contro la mia malattia	0	1	2	3	4
GE4.	Mi sento nervoso	0	1	2	3	4
GE5.	Mi preoccupo di morire	0	1	2	3	4
GE6.	Temo la mia condizione peggiorerà	0	1	2	3	4

	BENESSERE FUNZIONALE	*Niente*	*Un po'*	*Qualche cosa*	*Abbastanza, un po'*	*Molto*
GF1.	Sono in grado di lavorare (includere il lavoro a casa)	0	1	2	3	4
GF2.	Sto adempiendo il mio lavoro (includere il lavoro a casa)	0	1	2	3	4
GF3.	Sono in grado di godermi la vita	0	1	2	3	4
GF4.	Ho accettato la mia malattia	0	1	2	3	4
GF5.	Io dormo bene	0	1	2	3	4
GF6.	Mi sto godendo le cose che di solito si fanno per divertimento	0	1	2	3	4
GF7.	Io sono contento della qualità della mia vita in questo momento	0	1	2	3	4

ID

Data

Brief-COPE

(Coping Orientation to Problems Experienced - Brief version; Carver, 1997)

Istruzioni: Alle persone, capita che nel corso della loro vita, debbano confrontarsi con difficoltà e con eventi stressanti. Numerosi sono i modi con cui si cerca di far fronte allo stress: il presente questionario Le chiede di indicare che cosa Lei generalmente fa e prova di fronte ad eventi stressanti. Ovviamente eventi differenti richiedono risposte in qualche modo diverse, cerchi tuttavia di pensare a ciò che di solito fa quando si trova sotto uno stress notevole. Cerchi di rispondere a ciascuna domanda come se questa, nella sua mente fosse separata da tutte le altre. Scelga attentamente la sua risposta in modo che essa sia la più vera possibile per Lei.
Risponda a ciascuna domanda facendo un cerchietto attorno al numero che, in base alla tabella sottostante, indica la sua risposta.

1 =	Abitualmente non faccio assolutamente questo
2 =	Abitualmente faccio questo poche volte
3 =	Abitualmente faccio questo frequentemente
4 =	Abitualmente faccio proprio così

1.	Mi applico al lavoro o ad altre attività sostitutive per distogliere la mia mente dagli eventi	1	2	3	4
2.	Concentro i miei sforzi nel fare qualcosa per la situazione in cui mi trovo	1	2	3	4
3.	Mi dico " questo non è reale"	1	2	3	4
4.	Faccio uso di alcool o di stupefacenti per sentirmi meglio	1	2	3	4
5.	Cerco di ottenere un supporto emotivo dagli altri	1	2	3	4
6.	Rinuncio a cercare di occuparmene	1	2	3	4
7.	Metto in atto azioni per cercare di migliorare la situazione	1	2	3	4
8.	Rifiuto di credere che sia accaduto	1	2	3	4
9.	Dico cose che lasciano venir fuori i miei sentimenti spiacevoli	1	2	3	4
10.	Cerco aiuto e consigli da parte degli altri	1	2	3	4
11.	Faccio uso di alcol e droghe per aiutarmi a superare questo	1	2	3	4

12.	Cerco di vedere la cosa in una luce diversa per farla apparire più positiva	1	2	3	4
13.	Sono autocritico	1	2	3	4
14.	Cerco di trovare una strategia per ciò che si deve fare	1	2	3	4
15.	Cerco conforto e comprensione dagli altri	1	2	3	4
16.	Rinuncio a tentare di affrontare la situazione	1	2	3	4
17.	Cerco di trovare qualcosa di buono in ciò che è accaduto	1	2	3	4
18.	Ci scherzo sopra	1	2	3	4
19.	Faccio qualcosa per pensare di meno a questo, come andare al cinema, guardare la televisione, leggere, sognare ad occhi aperti, dormire, fare spese	1	2	3	4
20.	Accetto la realtà del fatto che ciò è accaduto	1	2	3	4
21.	Esprimo le mie sensazioni negative	1	2	3	4
22.	Cerco di trovare conforto nella mia religione o nelle mie convinzioni spirituali	1	2	3	4
23.	Cerco di ottenere dagli altri consigli o aiuti su ciò che è necessario fare	1	2	3	4
24.	Imparo a conviverci	1	2	3	4
25.	Penso seriamente a quali mosse fare	1	2	3	4
26.	Rimprovero me stesso per quanto è accaduto	1	2	3	4
27.	Prego e medito	1	2	3	4
28.	Metto in ridicolo la situazione	1	2	3	4

ID

Data

Grado di informazione e gradimento supporto psicologico

1. Ha cercato informazioni riguardo il suo stato di salute?
   - ☐ No nessuna
   - ☐ Sì da internet o libri
   - ☐ Sì, parlando con altri medici
   - ☐ Sì, confrontandomi con parenti e/o amici
   - ☐ Altro_____

2. Se nella precedente domanda ha risposto affermativamente, può descrivere quali informazioni possiede riguardo la sua malattia?

3. Pensa che potrebbe esserle di aiuto effettuare un colloquio psicologico prima dell'intervento chirurgico?

SI	NO

ID _____

Data _____

Questionario Clinico

1. Patologia benigna
   - ☐ Sì
   - ☐ No

2. Tipologia intervento chirurgico
   - ☐ Up front
   - ☐ Dopo chemioterapia/radioterapia neoaudivante

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PREPARE

PREoPerative Anxiety REduction

T1

ID _____

DATA _____

OPERATORE _____

ID _____

Data _____

APAIS

(Amsterdam Preoperative Anxiety and Information Scale; Pasquale Buonanno et al., 2017)

Istruzioni: di seguito troverà un elenco di affermazioni che possono essere usate per descrivere il proprio stato emotivo in vista dell'intervento chirurgico. Le chiediamo cortesemente di indicare, utilizzando la scala di valutazione da 1 (poco) a 6 (moltissimo), l'intensità del suo stato attuale.

1. Sono preoccupato per l'anestesia

Per niente					Moltissimo
1	2	3	4	5	6

2. Penso continuamente all'anestesia

Per niente					Moltissimo
1	2	3	4	5	6

3. Vorrei sapere il più possibile sull'anestesia

Per niente					Moltissimo
1	2	3	4	5	6

4. Sono preoccupato per l'intervento

Per niente					Moltissimo
1	2	3	4	5	6

5. Penso continuamente all'intervento

Per niente					Moltissimo
1	2	3	4	5	6

6. Vorrei sapere il più possibile sull'intervento

Per niente					Moltissimo
1	2	3	4	5	6

ID

Data

STAI Y-1

(State-Trait Anxiety Inventory – Form Y1; Spielberger, 1989)

Istruzioni: Sono qui di seguito riportate alcune frasi che le persone spesso usano per descriversi. Legga ciascuna frase e poi contrassegni con una crocetta il numero che indica come lei si **SENTE ADESSO, CIOÈ IN QUESTO MOMENTO**. Non ci sono risposte giuste o sbagliate. Non impieghi troppo tempo per rispondere alle domande e dia la risposta che le sembra descrivere meglio i suoi *attuali* stati d'animo.

1 = PER NULLA	2 = UN PO'	3 = ABBASTANZA	4 = MOLTISSIMO

1.	Mi sento calmo/a	1	2	3	4
2.	Mi sento sicuro/a	1	2	3	4
3.	Sono teso/a	1	2	3	4
4	Mi sento sotto pressione	1	2	3	4
5.	Mi sento tranquillo/a	1	2	3	4
6.	Mi sento turbato/a	1	2	3	4
7.	Sono attualmente preoccupato/a per possibili disgrazie	1	2	3	4
8.	Mi sento soddisfatto/a	1	2	3	4
9.	Mi sento intimorito/a	1	2	3	4
10.	Mi sento a mio agio	1	2	3	4
11.	Mi sento sicuro/a di me	1	2	3	4
12.	Mi sento nervoso/a	1	2	3	4
13.	Sono agitato/a	1	2	3	4
14.	Mi sento indeciso/a	1	2	3	4
15.	Sono rilassato/a	1	2	3	4
16.	Mi sento contento/a	1	2	3	4
17.	Sono preoccupato/a	1	2	3	4
18.	Mi sento confuso/a	1	2	3	4
19.	Mi sento disteso/a	1	2	3	4
20.	Mi sento bene	1	2	3	4

ID

Data

Percezione gestione dell'ansia

Le chiediamo cortesemente di indicare su una scala da 1 a 10 quanto si percepisce in grado di gestire l'ansia prima dell'intervento chirurgico.

Per nulla in grado									Totalmente in grado
1	2	3	4	5	6	7	8	9	10

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PREPARE

PREoPerative Anxiety REduction

T2

ID _____

DATA _____

OPERATORE _____

ID

Data

STAI Y-1

(State-Trait Anxiety Inventory – Form Y1; Spielberger, 1989)

Istruzioni: sono qui di seguito riportate alcune frasi che le persone spesso usano per descriversi. Legga ciascuna frase e poi contrassegni con una crocetta il numero che indica come lei *si sente adesso, cioè in questo momento*. Non ci sono risposte giuste o sbagliate. Non impieghi troppo tempo per rispondere alle domande e dia la risposta che le sembra descrivere meglio i suoi ATTUALI stati d'animo.

1 = PER NULLA	2 = UN PO'	3 = ABBASTANZA	4 = MOLTISSIMO

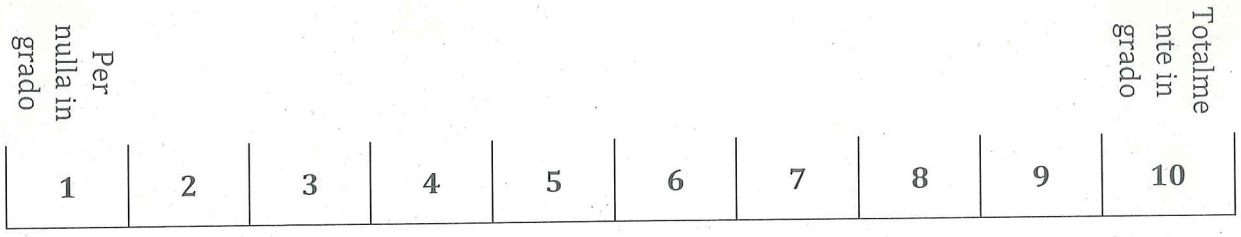
1.	Mi sento calmo/a	1	2	3	4
2.	Mi sento sicuro/a	1	2	3	4
3.	Sono teso/a	1	2	3	4
4	Mi sento sotto pressione	1	2	3	4
5.	Mi sento tranquillo/a	1	2	3	4
6.	Mi sento turbato/a	1	2	3	4
7.	Sono attualmente preoccupato/a per possibili disgrazie	1	2	3	4
8.	Mi sento soddisfatto/a	1	2	3	4
9.	Mi sento intimorito/a	1	2	3	4
10.	Mi sento a mio agio	1	2	3	4
11.	Mi sento sicuro/a di me	1	2	3	4
12.	Mi sento nervoso/a	1	2	3	4
13.	Sono agitato/a	1	2	3	4
14.	Mi sento indeciso/a	1	2	3	4
15.	Sono rilassato/a	1	2	3	4
16.	Mi sento contento/a	1	2	3	4
17.	Sono preoccupato/a	1	2	3	4
18.	Mi sento confuso/a	1	2	3	4
19.	Mi sento disteso/a	1	2	3	4
20.	Mi sento bene	1	2	3	4

ID

Data

Percezione gestione dell'ansia

Le chiediamo cortesemente di indicare su una scala da 1 a 10 quanto si percepisce in grado di gestire l'ansia prima dell'intervento chirurgico.



AOUI - Azienda Ospedaliera Universitaria Integrata di Verona

UOC di Chirurgia Generale B – Istituto del Pancreas

USD di Psicologia Clinica BR

Ospedale Policlinico G.B. Rossi, Piazzale L.A. Scuro 10

37134, Verona, Italia

PREPARE

PREoPerative Anxiety REduction

T3

ID _____

DATA _____

OPERATORE _____

ID

Data

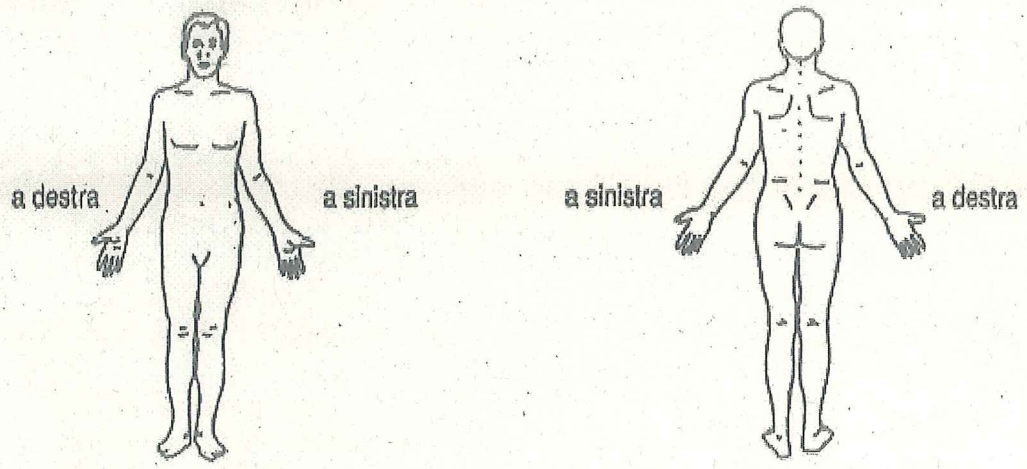
BPI-I

(Questionario Breve per la Valutazione del Dolore; Caraceni &Grassi, 1996)

1. Nel corso della vita, la maggior parte di noi ha avuto di tanto in tanto qualche dolore (come mal di testa, uno strappo muscolare, mal di denti).
   Oggi ha avuto un dolore diverso da questi dolori di tutti i giorni?

   1. SI 2. NO

2. Tratteggi nel disegno le parti dove sente dolore, metta una X sulla parte che fa più male



3. Valuti il suo dolore facendo un cerchio intorno al numero che meglio descrive l'intensità del suo peggiore dolore nelle ultime 24 ore

Nessun dolore	0	1	2	3	4	5	6	7	8	9	10	Il dolore più forte che si possa immaginare

4. Valuti il suo dolore facendo un cerchio intorno al numero che meglio descrive l'intensità del suo dolore più lieve nelle ultime 24 ore

Nessun dolore	0	1	2	3	4	5	6	7	8	9	10	Il dolore più forte che si possa immaginare

5. Valuti il suo dolore facendo un cerchio intorno al numero che meglio descrive l'intensità del suo dolore in media nelle ultime 24 ore

Nessun dolore	0	1	2	3	4	5	6	7	8	9	10	Il dolore più forte che si possa immaginare

6. Valuti il suo dolore facendo un cerchio intorno al numero che meglio descrive l'intensità del suo dolore in questo momento

Nessun dolore	0	1	2	3	4	5	6	7	8	9	10	Il dolore più forte che si possa immaginare

7. Che terapie mediche sta ricevendo per il suo dolore?

_____

_____

8. Nelle ultime 24 ore, quanto sollievo ha ricevuto dalle terapie o medicine? Faccia un cerchio intorno alla percentuale che meglio descrive quanto sollievo ha ottenuto.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

9. Faccia un cerchio intorno al numero che meglio descrive quanto nelle ultime 24 ore il dolore ha interferito con:

   a. la sua attività in generale

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

   b. il suo umore

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

   c. la sua capacità di camminare

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

   d. la sua normale capacità lavorativa

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

e. le sue relazioni con le altre persone

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

f. il sonno

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

g. il suo gusto di vivere

Non interferisce	0	1	2	3	4	5	6	7	8	9	10	Interferisce completamente

ID _____

Data _____

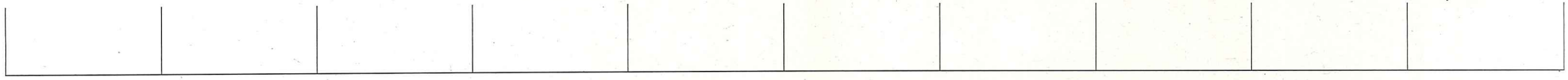
VAS-P

(Visual Analogue Scale – Pain)

Le chiediamo cortesemente di indicare, con una crocetta, su una scala da 0 a 10 l'intensità del suo dolore.

Nessun dolore — *Peggior dolore possibile*

Nessun dolore — *Peggior dolore possibile*



Nessun dolore — *Peggior dolore possibile*

ID _____

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Le chiediamo cortesemente di indicare, con una crocetta, su una scala da 0 a 10 l'intensità del suo dolore.

Nessun dolore — *Peggior dolore possibile*

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