

Official title: A Randomised Controlled Study to Evaluate the Effectiveness of the Combined Psychological Resilience and Self-efficacy Intervention for Oesophageal Cancer Surgery Patients

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Study Protocol

Session 1	1-3 days before surgery	
Theme	Know Each Other Well	
Target	<ol style="list-style-type: none"> 1. Inform patients of the intervention plan and the purpose and process of this study; 2. Establish trusting relationships with patients; 3. To understand patients' baseline information. 	
Content	Self-introduction	Self-introduction and introduce the purpose and process of the intervention of this study to patients.
	Strengthen disease-related knowledge guidance and health education	Strengthen the health promotion of preoperative knowledge related to oesophageal cancer: Watch the video of oesophageal cancer promotion, help patients to have better self-knowledge, correct and guide the wrong cognition of the disease in time, give the patients confidence in recovery, so that the patients can have the correct cognition and behaviours in the fight against the disease. Communicate with patients, listen to their inner feelings after diagnosis, care about their emotional feelings, and help them relieve their bad emotions as much as possible. About 30min.
	Direct mastery experiences	Patients relieve past experiences of facing significant life changes such as diseases or adversity.
	Vicarious experiences	Help patients get to know each other and discuss with patients with similar conditions. About 5min.
	Verbal persuasion	During communications with patients, use more encouraging language to promote positive expression and learning.
	Arousal states: Family support	Family members should accompany and encourage patients and strengthen communication with the patient.
	T0 evaluation	Instruct patients to fill in the relevant scales (General Situation Questionnaire, CD-RISC, GSES, HADS) and answer questions.
	Homework	Record mindfulness logs (number of times encouraged by the researcher and relatives, insights from experiences shared by peers, etc.).

Session 2	3-4 days after surgery	
Theme	Selective Awareness	
Target	<ol style="list-style-type: none"> 1. To guide patients to establish a correct way of thinking about the disease; 2. To strengthen patients' knowledge of postoperative diseases; 3. Initially understand and grasp the theory and content of mindfulness; 4. To understand patients' feelings and recovery after surgery. 	
Content	Strengthen disease-related knowledge guidance and health education	<p>Describe the content of this theme. Distribute health education brochures on oesophageal cancer, explaining the prevention and treatment of postoperative complications, the types, nature and amount of postoperative diet to choose, avoiding the phenomena of fear, anxiety and depression brought about by the lack of knowledge or previous wrong perceptions, and rebuilding the patients' correct cognition of oesophageal cancer.</p> <p>Communicate with patients, listen to their inner feelings after diagnosis, care about their emotional feelings, and help them relieve their bad emotions as much as possible. About 10min.</p>
	Direct mastery experiences	Patients gain experiences from the diagnosis of the disease to the completion of the operation.
	Vicarious experiences	Discussions are held between patients with similar conditions. About 5min.
	Verbal persuasion	During communications with patients, use more encouraging language to promote positive expression and learning.
	Arousal states: Mindfulness interventions + Family support	<p>Explain the theory related to positive thinking and watch the guided video of mindfulness meditation, so that patients can initially understand the knowledge related to mindfulness meditation and be guided to accept the reality of oesophageal cancer. Perform body scanning according to the audio prompts of mindfulness, starting from the toes and going up to the top of the head, objectively experiencing every part of the body, and guiding the patient to use this technique to relieve discomfort when pain or</p>

		discomfort arises. Family members should accompany and encourage patients and strengthen communication with the patient. About 15min.
	Homework	Review mindfulness interventions videos and record mindfulness logs (number of times encouraged by the researcher and relatives, insights from experiences shared by peers, mindfulness frequency and duration, whether relatives accompanied them etc.).
Session 3	7 days after surgery (day of discharge)	
Theme	Cognitive Reconstruction + Environmental Changes	
Target	<ol style="list-style-type: none"> To help patients develop a correct knowledge of the disease; To enhance patients' knowledge of the disease after discharge; Become proficient in positive thinking interventions; To obtain peer and family support. 	
Content	Pre-session reflection	Review the last homework assignment, emphasise the correct way of thinking and recall positive mental experiences. Summarise the content of the last topic and explain the content of the current topic.
	Strengthen disease-related knowledge	Strengthening patients' post-discharge rehabilitation knowledge, the type, nature, and number of dietary choices, to avoid fear, anxiety, and depression brought about by a lack of knowledge or previous misperceptions.
	guidance and health education	Communicate with patients, listen to their inner feelings after diagnosis, care about their emotional feelings, and help patients alleviate their bad emotions as much as possible. About 10min.
	Direct mastery experiences	Patients gain experiences from completing the surgery to their current recovery.
	Vicarious experiences	Invite patients who have recovered well to make video recordings and pass on their recovery experience. Patient exchange meetings are held to discuss among patients with similar conditions. About 10min.
	Verbal persuasion	During communications with patients, use more encouraging words to promote positive expression and learning.

	Arousal states: Mindfulness interventions + Family support	<p>Let patients meditate in a quiet environment, observe the thoughts, ideas and impulses that appear in their mind at this moment, and observe these thoughts, emotions and psychological experiences in their mind intentionally and without avoiding them, without criticising or rejecting them, accepting them objectively, improving the patients' abilities to perceive their own physiological states, so as to enhance the patients' sense of self-control, and guiding them to be able to objectively perceive and reasonably react to the negative emotions. Family members should accompany and encourage patients and strengthen communication with the patient. About 15min.</p>
	T1 evaluation	Instruct patients to complete relevant scales (CD-RISC, GSES, HADS) and answer questions.
	Homework	<ol style="list-style-type: none"> 1. Review the method of mindfulness interventions and record mindfulness logs (number of times encouraged by the researcher and relatives, insights from experiences shared by peers, mindfulness frequency and duration, whether relatives accompanied them etc.); 2. Patients share and exchange positive experiences with each other and form a WeChat group; 3. Patients dictate a specific event or moving moment of family support during the illness.
Session 4	14 days after surgery (1 week after discharge)	
Theme	Active Response	
Target	<ol style="list-style-type: none"> 1. Practice mindfulness interventions diligently; 2. Share positive experiences with other patients and gain peer and family support. 	
Content	Pre-session reflection	<p>Review the last homework assignment, emphasising the correct perception of illness and recalling the methods of mindfulness interventions.</p> <p>Summarise the content of the last topic and explain the content of the current topic.</p>

	Direct mastery experiences	Patients gain experiences from the time they were discharged from hospital to their current recovery at home.
	Vicarious experiences	Discussions are held between patients with similar conditions. About 5min.
	Verbal persuasion	Encourage patients by using positive languages and emotions frequently within the WeChat group.
	Arousal states: Mindfulness interventions + Family support	Record mindfulness practices on videos when patients are at home after discharge. Family members accompany and encourage patients more, and strengthen communication with patients. About 15min once.
	Homework	<ol style="list-style-type: none"> 1. Clock complete mindfulness videos and record mindfulness logs within the WeChat group (number of times encouraged by the researcher and relatives, insights from experiences shared by peers, mindfulness frequency and duration, whether relatives accompanied them etc.); 2. Share new positive experiences and communicate with patients with each other within the WeChat group; 3. Post a sentence describing a specific event or moving moment of family support within the WeChat group.
Session 5	3-4 weeks after surgery (2-3 weeks after discharge)	
Theme	Behavioural Reinforcement	
Target	<ol style="list-style-type: none"> 1. Practice and continually reinforce methods of mindfulness interventions; 2. Enhance access to peer and family support. 	
Content	Pre-session reflection	Review the last homework assignment and reward patients who completed it well. Summarise the content of the last topic and explain the content of the current topic.
	Direct mastery experiences	Patients gain experiences from their last home recovery to their current home recovery.

	Vicarious experiences	Patients share the positive emotional experiences gained during the intervention with each other within the WeChat group.
	Verbal persuasion	During outpatient review and communication with patients, use more encouraging language to promote positive expression and learning. When patients are at home, use positive languages and emoticons more often in the WeChat group to encourage patients.
	Arousal states: Mindfulness interventions + Family support	Instruct and supervise the patient in mindfulness practices during the patient's clinic review. Let patients meditate in a quiet environment, observe the thoughts, ideas and impulses that appear in their minds at this moment, observe these thoughts, emotions and psychological experiences that appear in their minds intentionally and without avoiding them, without criticising or rejecting them, accept them objectively, improve the patients' ability to perceive the reality of their physiological state, thus enhancing their sense of self-control, and guiding the patients to be able to objectively perceive the negative emotions and to make reasonable reaction. Family members accompany and encourage patients more, and strengthen communication with patients. About 15min.
	T2 evaluation	During outpatient review, instruct patients to fill in relevant scales (CD-RISC, GSES, HADS) and answer their questions.
	Homework	<ol style="list-style-type: none"> 1. Review the intensive mindfulness intervention methodology, where patients clock complete mindfulness videos and record mindfulness logs within the WeChat group while at home (number of times encouraged by the researcher and relatives, insights from experiences shared by peers, mindfulness frequency and duration, whether relatives accompanied them etc.); 2. Share new positive experiences with other patients within the WeChat group; 3. Post a one-sentence description of a specific event or moving moment of family support within the WeChat group.

Session 6	5 weeks after surgery (4 weeks after discharge)	
Theme	Review and Conclusion	
Target	<ol style="list-style-type: none"> Review the entire intervention, summarise the shortcomings of the intervention and improve them; Diligent practices and continuous internalisation of the mindfulness interventions; Stable access to peer and family support. 	
Content	Pre-session reflection	Review the last homework assignment, develop patients' abilities to internalise thoughts in their daily life and reward better completion. Summarise the content of the last topic and explain the content of the current topic.
	Direct mastery experiences	Patients gain experiences from their last home recovery to their current home recovery.
	Vicarious experiences	Patients share the positive emotional experiences gained during the intervention with each other within the WeChat group.
	Verbal persuasion	Encourage patients by using positive languages and emotions frequently within the WeChat group.
	Arousal states: Mindfulness interventions + Family support	Record mindfulness practices on videos when patients are at home after discharge and clock in on the WeChat group. Family members accompany and encourage patients and strengthen communication with patients. About 15min once.
	Mindfulness logs summary	Retrieve each patient's mindfulness log to collate the length of intervention, number of times, format, whether accompanied or not, etc., and to summarise advantages and limitations.
	Homework	None.

Note. The text in red refers to the content of mindfulness intervention in the single intervention group.

Statistical Analysis Plan

EpiData 3.1 software will be used for data entry and SPSS 25.0 software for statistical analysis, with $P<0.05$ indicating a statistically significant difference. Quantitative data such as demographic information will be described using frequency and component ratios, and qualitative data such as psychological resilience, self-efficacy, and anxiety and depression will be described using means and standard deviations. Comparison of quantitative data between the combined intervention group, single intervention group and control group will be performed by chi-square test if it meets normal distribution, and vice versa by rank-sum test; and comparison of qualitative data between the three groups will be performed by ANOVA. Comparisons between the three groups at pre-intervention, mid-intervention and post-intervention will be analysed by ANOVA; differences between the three groups at different time points will be analysed by repeated measures ANOVA. Effectiveness will be evaluated using both conformity to protocol set analysis (Per-protocol, PP) and intention-to-treat (ITT) because of the removal or dropout of patients from the trial. Per-protocol analysis is an analysis of subjects who comply with the trial protocol and complete the entire trial, also known as "active cases" or "evaluable subjects", which are a subset of the total number of subjects. The principle of intentionality analysis is that, in addition to the need to include all subjects with valid test results in the analysis of results at the endpoint of the trial, it is also necessary to include randomly assigned subjects who discontinued after a period of time in the trial, and missing values are treated by carrying over the most recent observation to the endpoint, so that the number of subjects in each group at the endpoint is the same as at the beginning of the trial, an analytical method that ensures the principle of randomisation. PP analyses can overestimate the efficacy of a trial, whereas ITT analyses often underestimate the efficacy of a trial, and it is generally considered appropriate to apply both methods of statistical analyses in validation trials, which increases the credibility of the findings when the conclusions analysed by the two methods are essentially the same.