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Original Article

Effectiveness of a self-regulation program using iPad-assisted communication in intubated patients with respiratory failure: A randomized controlled trial

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ABSTRACT

Background & Aim: Communication limitations in intubated patients with respiratory failure increase anxiety, compromise care quality, and may delay ventilator weaning. This study evaluated the effects of a self-regulation program using iPad-assisted communication on anxiety, perceived fulfillment of care needs, and weaning outcomes.
Methods & Materials: A randomized controlled trial was conducted from April to December 2024 and enrolled 60 mechanically ventilated patients with respiratory failure. Participants were randomly assigned to an experimental group (n= 30) and a control group (n = 30). Data were collected on demographics, health status, anxiety levels, perceived fulfillment of care needs, and ventilator weaning outcomes. Statistical analyses included descriptive statistics, chi-square or Fisher's exact tests, t-tests, and ANCOVA.
Results: Two hours after the intervention, the experimental group reported significantly lower anxiety levels and higher perceived fulfillment of care needs compared with baseline and the control group ($p< 0.001$). The experimental group also demonstrated a higher weaning success rate (83.33%) than the control group (66.67%) ($\chi^2= 6.76$, $p= 0.009$). Reintubation within 48 hours was significantly lower in the experimental group (16.67%) than in the control group (33.33%) ($\chi^2 = 4.85$, $p = 0.028$). The tracheostomy rate was lower in the experimental group (6.67% vs. 13.33%), but this difference was not statistically significant ($\chi^2 = 1.09$, $p = 0.296$).
Conclusion: The self-regulation program with iPad-assisted communication reduced anxiety, enhanced perceived care needs, and improved weaning outcomes. These results support its applicability as a patient-centered intervention to optimize respiratory care in intensive care settings.

Introduction

Respiratory failure (RF) is a critical condition that often necessitates endotracheal intubation and mechanical ventilation (MV) to maintain adequate oxygenation and ventilation (1). Although MV is a life-saving intervention, prolonged use is associated with several complications, including respiratory muscle weakness (2), pain (3), and communication barriers that contribute to elevated anxiety levels among patients (4). The anxiety experienced by mechanically ventilated patients is not solely a consequence of communication barriers; rather, it represents a complex interaction between preexisting psychological distress and the inability to effectively express needs, discomfort, and fears (5, 6). This interplay between anxiety and impaired communication undermines patients' sense of control, autonomy, and capacity for self-regulation during MV.

The process of ventilator weaning is a crucial phase in critical care management, as both premature extubation and unnecessary delays are associated with increased morbidity and mortality (7–10). Spontaneous breathing trials (SBTs) are commonly used to evaluate readiness for extubation, yet psychological readiness remains an often-overlooked component. Nurses play an essential role in this

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process by fostering communication, reducing anxiety, and providing emotional and informational support that enhances patient readiness for weaning (11).

Leventhal and Johnson's self-regulation theory (SRT) provides a valuable framework for understanding how structured information and cognitive guidance can help individuals interpret threatening situations, manage emotional responses, and engage in adaptive coping behaviors (12). Prior research has demonstrated that self-regulation interventions effectively reduce anxiety among patients undergoing bronchoscopy (13) and surgery (14) and among relatives of critically ill patients (15). Despite the documented benefits of various interventions, such as inspiratory muscle training (IMT) (16), qigong exercises (17), and psychological support programs (18, 19), there is limited evidence applying SRT specifically to intubated patients during the ventilator weaning process.

In addition to psychological interventions, augmenting patient communication is essential to supporting emotional stability and care participation. The use of iPad-assisted communication (IAC) tools has emerged as an effective method for enabling intubated patients, who are unable to speak, to convey their needs, emotions, and concerns to healthcare providers. This approach aligns with Davis's Technology Acceptance Model (TAM) (20), which posits that user adoption of technology depends on Perceived Usefulness (PU), the belief that technology improves performance, and Perceived Ease of Use (PEOU), the belief that it requires minimal effort. When technology is both useful and easy to operate, it enhances users' engagement and fosters positive behavioral intentions toward continued use.

Empirical studies have supported the practical value of IAC. Guttormson and McAndrew discovered that iPad-based communication applications were viable and well-received by both patients and nurses in critical care environments, enhancing emotional support and clarifying interactions (21). Santiago et al. similarly showed that tablet-based communication systems made intubated patients in the intensive care unit (ICU) happier and better able to express their needs (22). Nevertheless, no previous studies have integrated IAC within an SRT framework to address both the psychological and communicative challenges of ventilator weaning.

Therefore, this study aimed to examine the effectiveness of a self-regulation program incorporating IAC on anxiety, perceived fulfillment of care needs (PFCN), and ventilator weaning success among intubated patients with RF. Specifically, this research sought to determine whether such a program could reduce anxiety, enhance PFCN, and improve ventilator weaning outcomes compared with standard ICU care.

Methods

Study design

This study employed a randomized controlled trial (RCT) with a two-group pretest–posttest design to evaluate the effectiveness of a self-regulation program incorporating iPad-assisted communication (IAC) among mechanically ventilated patients undergoing weaning. The research project was registered in the Thai Clinical Trials Registry (TCTR) under the code TCTR20251119002 (https://www.thaiclinicaltrials.org/show/TCTR20251119002)

Participants

Participants were adult patients undergoing ventilator weaning using a T-piece at the intensive care units (ICUs) of a secondary-level hospital in a province near Bangkok, Thailand. Inclusion criteria were: 1) age ≥18 years; 2) diagnosis of respiratory failure requiring intubation; 3) use of mechanical ventilation for at least 24 hours but not exceeding 7 days; 4) physician-assessed readiness to begin T-piece weaning; 5) no prior experience with ventilator weaning; 6) conscious and oriented; 7) stable vital signs: heart rate (HR) 50–120 bpm, respiratory rate (RR) <30 bpm, systolic blood pressure (SBP) 90–180 mmHg, diastolic blood pressure (DBP) 60–110 mmHg, and oxygen saturation ≥90% or PaO_2 >60 mmHg (23); 8) no vasodilator use or only low-dose administration; 9) not receiving continuous intravenous sedation (e.g., fentanyl, midazolam, or cisatracurium besylate); 10) motor power score ≥4, literate in Thai; 11) no visual or auditory impairments; and 12) ability to nod and read text (Angsana New, 20-point font) from a distance of 1–2 feet.

Exclusion criteria included: 1) active COVID-19 or tuberculosis during the contagious phase; 2) diagnosis of Parkinson's disease, circulatory disorders, or schizophrenia. Participants were withdrawn from the study if they 1) became clinically unstable (e.g., SBP <90/60 mmHg or SpO_2 <90%), 2) experienced accidental/self-extubation, or 3) opted to discontinue participation.

The sample size was calculated using Cohen's formula (24), based on a previous study (18) with a power of 0.80, a significance level of 0.05, and an expected effect size of 0.80. The required sample size was 50 participants (25 per group). To account for potential attrition, an additional 20% was added (25), yielding a total sample size of 60 (30 in each group) (Figure 1).

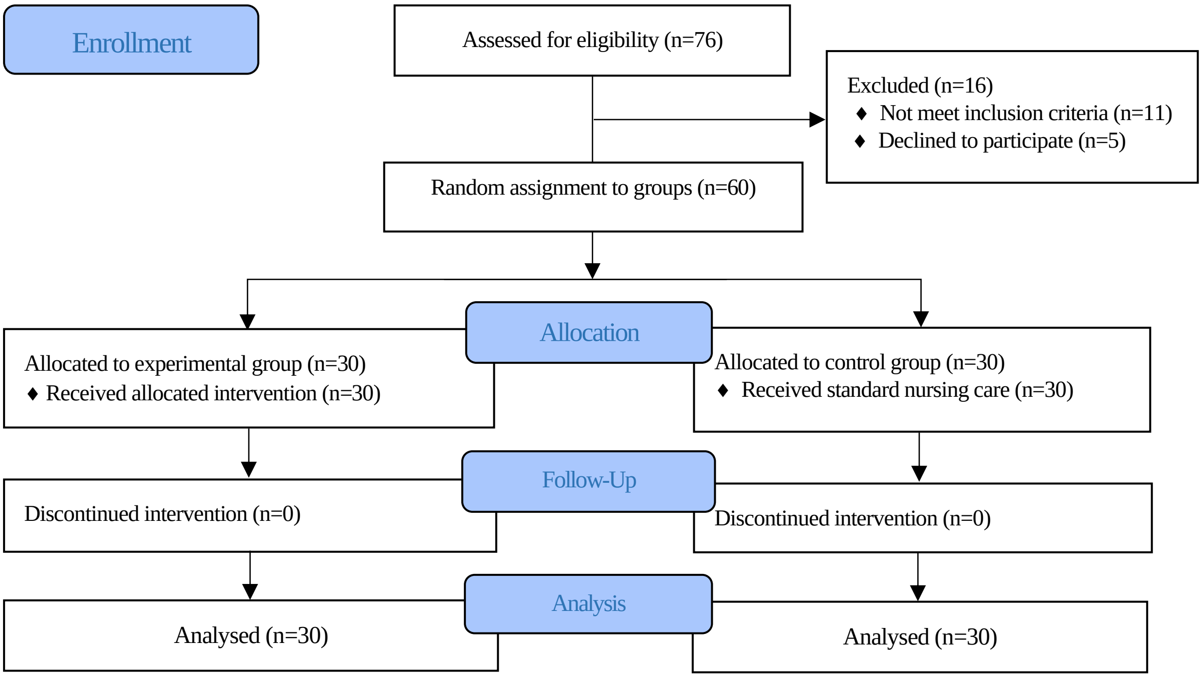

Figure 1. Flow diagram of the study

Randomization

This randomized controlled trial (RCT) assigned participants to either the experimental or control group using a randomization procedure. Participants who met the inclusion criteria were randomly allocated using a permuted block randomization method to ensure balance between groups throughout the enrollment process. Fifteen blocks were created, each containing four participants, with allocation sequences randomly chosen from six potential permutations. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes (SNOSE) to prevent selection bias.

Because the intervention was visible, neither the participants nor the principal investigator (PI) could be blinded. However, outcome assessors were blinded to group assignments to minimize bias. Data collection related to the main outcomes, anxiety, perceived fulfillment of care needs (PFCN), and weaning success, was conducted by nursing staff who were not involved in the intervention and were unaware of participants' group allocation. Additionally, all data were coded using identification numbers instead of group labels before statistical analysis. This procedure ensured that assessors and data analysts evaluated outcomes independently and without knowledge of group assignments.

Procedure

Experimental group

Participants in the intervention group received the Self-Regulation with iPad Use

Program (SRIUP), which was developed by the principal investigator (PI) based on Leventhal and Johnson's self-regulation theory (12) and integrated with the three phases of the American Association of Critical-Care Nurses (AACN) ventilator weaning process. The program consisted of:

Phase 1: Pre-weaning (70 minutes), Participants received preparatory information through video media on ventilator weaning, self-regulation techniques, and iPad use for communication. This phase included six structured activities focused on physical and emotional readiness.

Phase 2: Weaning (2 hours), During a T-piece trial, participants used iPads to express needs, feelings, and symptoms. The PI monitored progress every 30 minutes (5 minutes per session), encouraged skill use (e.g., diaphragmatic breathing, relaxation, coughing), and provided positive reinforcement.

Phase 3: Post-extubation (30 minutes+48-hour follow-up), The PI evaluated weaning outcomes, anxiety levels, and PFCN. Patients were followed up 48 hours post-extubation to confirm the absence of re-intubation.

A custom iPad application was developed for this study, featuring 30 pre-recorded voice messages addressing urgent concerns during the weaning process (e.g., "I feel tired," "I have chest pain"). Messages were transmitted to a nurse station computer when selected, allowing a prompt nurse response. Content was validated by expert reviewers and pilot-tested for usability. Details of implementations of the SRIUP are shown in the Appendix, Table 1. The PI personally delivered the program at all stages, strictly following a detailed activity manual. Each session was conducted consistently according to the prescribed procedures. The PI observed and recorded participants' use of the iPad during the intervention to ensure that the program was delivered with fidelity and maintained standardized implementation across all participants.

Control group

The control group received standard nursing care during ventilator weaning. This included airway management through suctioning, administration of bronchodilator nebulization, and elevation of the head of the bed to facilitate optimal lung expansion. However, participants in this group did not receive the SRIUP, which incorporates self-regulation strategies, nor did they have access to iPad-assisted communication to express their needs. Alternative communication methods, such as writing or gestural signals, were used as appropriate to convey information to healthcare providers.

Research instruments

1. Patient characteristics and medical history form

This PI-developed tool collected demographic and clinical data, including age, sex, education, diagnosis, history of intubation, MV duration before weaning, and medications affecting consciousness.

2. Ventilator weaning success assessment

Adapted from Mingburee (2011), this instrument assessed physiological stability at 120 minutes post-weaning. Four criteria were evaluated: 1) RR $\leq$30 breaths/min; 2) SpO_2 $\geq$90%; 3) HR $\leq$140 bpm or $\leq$20% increase from baseline; and 4) SBP between 90–180 mmHg. Each criterion met received one point (range: 0–4). A score of 4 and no re-intubation within 48 hours indicated successful weaning.

3. State anxiety during weaning questionnaire

Adapted from the State-Trait Anxiety Inventory (STAI) (6), this 20-item tool assessed anxiety during the weaning process. Ten items reflected positive anxiety and ten negative anxiety, rated on a 5-point Likert scale. Scores ranged from 20 to 100, with higher scores indicating greater anxiety. Content validity was confirmed by five experts (CVI = 0.82).

Cronbach's alpha was 0.86 in the pilot study and 0.88 in the main study.

4. Perceived fulfillment of care needs during weaning questionnaire

Developed by the PI using Petro-Yura's and Walsh's human needs framework, this 30-item questionnaire measured the degree to which patients' needs were met during weaning. Items were grouped into physical (16 items), psychological/spiritual (7 items), and emergency needs (7 items), rated on a 5-point Likert scale. Total scores ranged from 30 to 150, with higher scores indicating greater perceived support. Expert validation yielded a CVI of 0.86. Cronbach's alpha was 0.84 (pilot) and 0.86 (main study).

Data collection

The study was conducted between April and December 2024. Following IRB approval, the PI coordinated with ICU staff, explained the study, and obtained signed informed consent from participants and their caregivers. Three trained ICU nurses served as research assistants. They were blinded to group assignments and trained in data collection protocols and ethics, with emphasis on neutrality.

Baseline data, including demographics and clinical history, were collected prior to the intervention. Questionnaires assessing anxiety and PFCN were administered before and two hours after the SRIUP by research assistants, who read the questions aloud while patients pointed to responses on a board. The PI implemented the SRIUP with the experimental group. For the control group, the PI made two visits: one for informed consent and baseline data collection, and another after two hours. If control group participants could not be weaned at that time, they subsequently received the SRIUP.

Data analysis

Descriptive statistics, including frequencies and percentages, were used to summarize demographic and clinical data. The Shapiro–Wilk test confirmed normal distribution of continuous variables ($p > 0.05$). Paired t-tests were used to compare pre- and post-intervention scores of anxiety and PFCN within each group. For between-group comparisons, independent t-tests were first used to compare post-intervention anxiety and PFCN scores between the experimental and control groups. To control for baseline differences, an analysis of covariance (ANCOVA) was subsequently conducted using pretest scores as covariates, allowing for a more accurate estimation of the intervention's effect. Categorical data, such as ventilator weaning success rates, were analyzed using the chi-square test or Fisher's exact test when expected cell counts were less than five. Weaning success rates were presented as percentages. Statistical significance was set at $p < 0.05$ for all analyses.

Ethical considerations

Ethical approval for this study was obtained from the Institutional Review Board of the Faculty of Nursing, Rattana Bundit University, Thailand (IRB No. RBAC-EC-NUS-1-003/67), with the approval date of March 19, 2024. Participants were informed of their right to withdraw from the study at any time without any consequences. Informed consent was obtained from both patients and their caregivers. All data were anonymized and reported in aggregate form to ensure confidentiality and protect participants' privacy.

Results

A total of 60 participants were enrolled in this study, with 30 assigned to the experimental group (EG) and 30 to the control group (CG). The majority of participants were male, with a mean age of 60.32 years. Most had completed only elementary school. Pneumonia was the most common primary diagnosis, and most participants had no prior experience with endotracheal intubation. The majority began weaning from MV 1–2 days after intubation, and most were not receiving medications that affected their level of consciousness. There were no statistically significant differences between the experimental and control groups in demographic or clinical characteristics at baseline (Table 1).

Table 1. Baseline clinical characteristics of the participant

Characteristics	n (%) Total (n=60)	Experimental group (n= 30)	Control group (n= 30)	Statistic value	p-value
Sex					
- Male	44 (73.33)	21 (70.00)	23 (76.67)	0.763^C	0.374
- Female	16 (26.67)	9 (30.00)	7 (23.33)		
Age (years): Mean (SD)	60.32 (10.56)	59.83 (11.85)	60.28 (10.04)		
- 18-40	6 (10.00)	4 (13.33)	2 (6.67)	0.246^t	0.768
- 41-60	23 (38.33)	11 (36.67)	12 (40.00)		
- > 60	31 (51.67)	15 (50.00)	16 (53.33)		
Education level					
- Uneducated	17 (28.33)	8 (26.67)	9 (30.00)	1.869^C	0.826
- Elementary school	30 (50.00)	16 (53.33)	14 (46.67)		
- Secondary education	13 (21.67)	6 (20.00)	7 (23.33)		
Diagnosis:					
Respiratory problem					
- Chronic obstructive pulmonary disease	6 (10.00)	2 (6.67)	4 (13.33)		
- Pulmonary embolism	2 (3.33)	1 (3.33)	1 (3.33)		
- Acute respiratory distress syndrome	3 (5.00)	2 (6.67)	1 (3.33)		
- Pulmonary edema	3 (5.00)	2 (6.67)	1 (3.33)		
Cardiovascular problem					
- Congestive heart failure	5 (8.33)	3 (10.00)	2 (6.67)		
- ST-elevation myocardial infarction	3 (5.00)	2 (6.67)	1 (3.33)	1.876^F	0.932
- Non-ST-elevation myocardial infarction	4 (6.67)	2 (6.67)	2 (6.67)		
- Cardiogenic shock	2 (3.33)	1 (3.33)	1 (3.33)		
Infectious problem					
- Pneumonia	22 (36.68)	10 (33.33)	12 (40.00)		
- Septic shock	5 (8.33)	2 (6.67)	3 (10.00)		
Renal problem					
- End-stage renal disease	3 (5.00)	2 (6.67)	1 (3.33)		
Metabolic problem					
- Diabetic ketoacidosis	2 (3.33)	1 (3.33)	1 (3.33)		
Intubation experience					
- Never received	33 (55.00)	18 (60.00)	15 (50.00)	0.635^C	0.716
- Has been 1-2 times	16 (26.67)	7 (23.33)	9 (30.00)		
- Has been 3-4 times	11 (18.33)	5 (16.67)	6 (20.00)		
Time of use of a ventilator before preparation for weaning from a ventilator					
- 24-48 hours (1- 2 days)	25 (41.67)	12 (40.00)	13 (43.33)	3.234^C	0.869
- 49-96 hours (3-4 days)	19 (31.67)	10 (33.33)	9 (30.00)		
- 97-168 hours (5-7 days)	16 (26.66)	8 (26.67)	8 (26.67)		
Medications that affect the patient's consciousness					
- None	30 (50.00)	14 (46.67)	16 (53.33)	0.658^C	0.378
- Ativan 0.5 mg oral	21 (35.00)	11 (36.67)	10 (33.33)		
- Ativan 1 mg oral	9 (15.00)	5 (16.66)	4 (13.34)		

^{t} = *t*-test, ^{C} = Chi-square test, ^{F} = Fisher' exact test

Anxiety and perceived fulfillment of care needs

This study examined the effects of a self-regulation program using iPad-assisted communication (IAC) on anxiety and PFCN during weaning in intubated patients. Prior to the intervention, no significant differences were observed between the experimental and control groups in either state-trait anxiety (Mean difference= 1.80, 95% CI: −3.67 to 7.27; *t*= −0.452, *p*= 0.658; Cohen's *d* = 0.18) or PFCN (Mean difference= −0.68, 95% CI: −5.41 to 4.05; *t*= −0.642, *p*= 0.524; Cohen's *d*= 0.08).

Following the 2-hour implementation of the program, the experimental group demonstrated a significant reduction in anxiety compared with the control group (Mean difference = −19.06, 95% CI: −24.19 to −13.93; *t*= −7.280, *p*< 0.001), with a very large effect size (Cohen's *d*= 1.92). Within-group analyses confirmed a statistically significant decrease in anxiety among participants in the experimental group (*t*= −8.765, *p*<0.001), whereas no significant change was observed in the control group (*t*= −0.652, *p* = 0.521).

Similarly, PFCN scores increased significantly in the experimental group after the intervention (Mean difference = 12.57, 95% CI: 10.00 to 15.14; t= −10.623, p < 0.001), with a very large effect size (Cohen's d = 2.53). Within-group comparisons confirmed a substantial improvement in the experimental group (t= −10.648, p< 0.001), whereas the control group did not show any significant change (t = −0.482, p = 0.635).

These findings indicate that the self-regulation program using IAC has a substantial and clinically meaningful effect in reducing anxiety and enhancing PFCN during weaning among intubated patients. However, the observed large effect sizes may have been influenced by the relatively small sample size and short duration of the intervention. Despite these limitations, the results provide strong preliminary evidence supporting the program's efficacy in facilitating successful weaning from mechanical ventilation (Table 2).

After adjusting for pretest scores using ANCOVA, a significant difference was found between the experimental and control groups in both anxiety and PFCN. For anxiety, the covariate (pre-test) was significantly related to post-test scores (F= 18.72, p < .001). After controlling for this effect, the between-group comparison revealed a significant difference in post-test anxiety scores (F= 211.69, p < .001). Likewise, for PFCN, the covariate (pre-test) had a significant effect on the post-test scores (F= 22.62, p< .001). After adjusting for pre-test scores, there remained a highly significant difference between the experimental and control groups (F = 270.83, p < .001). These results indicate that the SRIUP intervention effectively reduced anxiety and enhanced perceived fulfillment of care needs among intubated patients during ventilator weaning, even after controlling for baseline differences (Table 3).

Table 2. A comparison study of anxiety and perceived fulfillment of care needs between the experimental and control groups was conducted, both before and after the experiment

Variables	Time	Experimental Group (n= 30) Mean ±SD	Control Group (n= 30) Mean ± SD	Mean Difference (EC−CG) (95% CI)	t	P-value	Cohen's d
Anxiety	Before intervention	80.12 ± 10.63	78.32 ± 10.54	1.80 (−3.67, 7.27)	−0.452[b]	0.658	0.18
	2 hours post-intervention	60.76 ± 9.25	79.82 ± 10.56	−19.06 (−24.19, −13.93)	−7.280[b]	<0.001	1.92
	t (within-group)	−8.765[a]	−0.652[a]				
	P-value	0.001	0.521				
Perceived fulfillment of care needs	Before intervention	97.68 ± 9.64	98.36 ± 8.65	−0.68 (−5.41, 4.05)	−0.642[b]	0.524	0.08
	2 hours post-intervention	112.25 ± 4.56	99.68 ± 5.34	12.57 (10.00, 15.14)	−10.623[b]	<0.001	2.53
	t (within-group)	−10.648[a]	−0.482[a]				
	P-value	<0.001	0.635				

[a] = paired t-test, [b] = independent t-test

Table 3. Comparison of post-intervention anxiety and perceived fulfillment of care needs between the experimental and control groups after adjusting for pre-test scores using ANCOVA

Variables	Source	Sum of Squares	df	MS	F	p-value
Anxiety	Covariate (Pre-test)	912.54	1	912.54	18.72	< .001
	Between-group	10285.95	1	10285.95	211.69	< .001
	Error	2776.35	57	48.71		
	Total	13974.83	60			
Perceived fulfillment of care needs	Covariate (Pre-test)	724.28	1	724.28	22.62	< .001
	Between-group	8647.93	1	8647.93	270.83	< .001
	Error	1822.41	57	31.97		
	Total	11194.62	60			

Success of weaning from mechanical ventilation

After the intervention, the rate of successful weaning was significantly higher in the experimental group (83.33%) than in the control group (66.67%) (χ^2=6.76, p=0.009). Re-intubation within 48 hours occurred less frequently in the experimental group (16.67%) than in the control group (33.33%) (χ^2 = 4.85, p= 0.028). Although the tracheostomy rate was lower in the experimental group (6.67%) than in the control group (13.33%), the difference was not statistically significant (χ^2= 1.09, p = 0.296). These findings indicate that the SRIUP program improved ventilator weaning success and reduced early re-intubation among intubated patients, highlighting its clinical relevance for ICU care (Table 4).

Table 4. A comparison of the number and percentage of weaning outcomes between the experimental and control groups after the intervention

Variables	Experimental Group (n = 30) n (%)	Control Group (n = 30) n (%)	χ^2	p-value
Success in weaning				
Successful	25 (83.33%)	20 (66.67%)	6.76	0.009
Unsuccessful (re-intubation within 48 hours)	5 (16.67%)	10 (33.33%)	4.85	0.028
Tracheostomy rate	2 (6.67%)	4 (13.33%)	1.09	0.296

Discussion

According to Davis' (20) Technology Acceptance Model (TAM), an individual's acceptance of innovation and technology is influenced by two key perceptions: perceived usefulness (PU) and perceived ease of use (PEOU). The findings of this study support both elements and demonstrate how TAM can effectively explain patients' positive responses to the SRIUP.

This study revealed that after receiving the SRIUP intervention for two hours during the weaning process from MV, patients demonstrated improved clinical outcomes, including a higher rate of weaning success, reduced anxiety, and greater PFCN. The effectiveness of SRIUP can be attributed to its foundation in Leventhal and Johnson's (12) self-regulation theory, which posits that individuals facing health threats develop cognitive representations of their situation and engage in self-directed behaviors to manage their emotional and physiological responses.

The SRIUP intervention provided patients with accurate and relevant information about the purpose and process of ventilator weaning. It also introduced self-regulation strategies, including breathing control, relaxation through deep breathing, and airway clearance via coughing. These techniques enabled patients to participate actively in the weaning process, fostering greater confidence and physiological readiness. From the perspective of TAM, the findings suggest that patients recognized the benefits of the SRIUP program, as it facilitated effective self-management and communication. This aligns with previous research indicating that patient education and behavioral regulation improve extubation outcomes. Consequently, the program's congruence with self-regulation theory substantiates TAM's assertion that individuals are predisposed to embrace technologies they believe will improve performance and results.

During ventilator weaning, it is especially important for patients and nurses to talk to each other clearly. A distinctive feature of this study—differentiating it from previous research—was the use of an iPad-based communication device (compatible with both Android and iOS systems) specifically designed for intubated patients. The device enabled multimodal communication through text, audio, and images, allowing patients to express their physical, emotional, or urgent care needs. This finding is consistent with prior evidence highlighting the advantages of iPads in ICU settings due to their portability, intuitive interface, and capacity to support diverse communication modes (21, 27). Moreover, improved communication has been shown to directly reduce anxiety by enhancing patients' sense of control and autonomy in their interactions with healthcare providers (28).

From the TAM perspective, these findings further support perceived ease of use. Despite physical limitations, patients were able to access and navigate the communication interface with minimal difficulty. Features such as a large, responsive touchscreen and an audible alert system, linked directly to the nursing station, provided immediate feedback, promoting a sense of control and reducing anxiety. These usability features likely mitigated technological barriers and facilitated user acceptance, consistent with TAM's assertion that ease of use fosters adoption.

The integration of self-regulation theory and TAM within the SRIUP framework is particularly impactful. By offering both meaningful information and practical tools for behavioral management, SRIUP not only improved physiological outcomes but also enhanced patient engagement with the technology. Patients perceived the system as both beneficial and easy to use, two critical factors that promote sustained user acceptance (29).

Participants' improved cognitive understanding of the situation further explains the significant reduction in anxiety they observed. Patients were able to construct mental representations of their condition, thereby reducing fear and uncertainty, thanks to accurate information and self-regulation training (30). This finding aligns with previous studies demonstrating that cognitive framing and meaningful information contribute to anxiety reduction during critical care experiences (29, 30).

SRIUP is generally effective and well-liked by users, but there are some areas that need work. Feedback from both patients (post-extubation) and nurses suggested the inclusion of an "emergency needs" category within the communication interface. This feature would let patients express urgent concerns more quickly and clearly during the weaning process, which would make the system easier to use and safer for patients.

In summary, the SRIUP program exemplifies a successful integration of self-regulation theory and the Technology Acceptance Model. The combined influence of perceived usefulness, reflected in improved clinical outcomes and patient empowerment, and perceived ease of use, achieved through an intuitive and responsive communication interface, contributed to strong patient engagement and acceptance. These findings highlight the significance of creating theoretically grounded and user-centered healthcare innovations to maximize adoption and improve patient outcomes.

Conclusion

This RCT investigated the effects of a self-regulation intervention integrated with iPad-assisted communication (IAC) during ventilator weaning. The findings demonstrate that this combined approach significantly reduced patient anxiety, particularly anxiety arising from communication barriers, and enhanced PFCN. Consequently, patients in the intervention group achieved higher rates of successful weaning from mechanical ventilation compared to the control group. These outcomes demonstrate the potential for technology-supported self-regulation programs to improve both psychological well-being and clinical recovery among critically ill patients during the weaning process.

Limitation

This study has several limitations that should be considered when interpreting the findings. First, the sample size was relatively small, with only 60 participants, which may reduce the statistical power and limit the generalizability of the results. Second, the intervention duration was short, lasting approximately two hours, and the follow-up period was limited to 48 hours after extubation, which restricts the ability to evaluate the long-term sustainability of the observed effects. Third, the study was conducted in a single center, which may limit the applicability of the findings to other settings or populations. Finally, potential biases may exist due to the non-blinded design of the study, as participants and personnel were aware of the intervention allocation. Future research with larger, multi-center samples, longer intervention periods, extended follow-up, and more rigorous blinding procedures is recommended to enhance the reliability, generalizability, and robustness of the findings.

Practical recommendations

The findings of this study suggest that the Self-Regulation with SRIUP can be effectively applied in ICU settings to support intubated patients during ventilator weaning. Nurses should facilitate patient use of the program to enhance communication, reduce anxiety, and address patient needs. Incorporating an "emergency needs" function within the iPad interface may further improve responsiveness and safety. Tailoring the program to individual patient abilities and preferences, along with staff training and ongoing outcome monitoring, is recommended to maximize its clinical effectiveness.

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Conflict of interest

The authors have no conflicts of interest to declare.

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Author contributions

Provided research idea, Nuttapol Chaihan, Pattarin Pirompanich, Anucha Wimoonchart, Wauranittha Timklay; Collected data and analyzed, Nuttapol Chaihan; Supervised data collection, and analysis, Nuttapol Chaihan, Pattarin Pirompanich, Anucha Wimoonchart, Wauranittha Timklay; Prepared the draft original writing and edited the manuscript, Nuttapol Chaihan, Pattarin Pirompanich. The authors have read and agree to publish this manuscript.

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Appendix

Table 1. The procedure for implementing the self-regulation with iPad use program

Session/ time	Objectives	Program activities	Media
1. Pre-weaning phase			
(20 minutes)	Introduction and baseline measurement	*Activity 1* Assess readiness for weaning off a ventilator. The PI asked the participants to complete the Demographic Characteristics and Health Status Questionnaire, the State Anxiety During Weaning Questionnaire, and the Perceived Fulfillment of Care Needs assessment by reading the questions to the patients and having them indicate their responses on the answer board.	-
(10 minutes)	To determine whether the participants were ready for weaning from the ventilator	*Activity 2* The PI coordinates with the doctor to determine whether the cause of the patient's respiratory failure has been resolved. The doctor offered his opinion and provided a treatment plan to wean him from the ventilator with a T-piece.	-
(5 minutes)	To make patients understand the importance of weaning ourselves from ventilators	*Activity 3* Inform the patient of the importance and necessity of weaning from the ventilator.	The video presentation: The content will be animated with audio commentary for presentations
(5 minutes)	To allow the patient to visualize the situation that will occur and be able to face that situation	*Activity 4* Provide patient information about procedures and methods for weaning off the ventilator	The video presentation
(10 minutes)	To make patients understand how to behave while weaning themselves from a ventilator	*Activity 5* Provide information to the patient on how to behave while weaning off the ventilator	The video presentation
(20 minutes)	So that patients can control themselves by using the correct techniques when weaning themselves from ventilators	*Activity 6* Practice self-regulation skills while weaning off a ventilator, namely the skill of breathing correctly, deep-breathing relaxation skills, and coughing skills to expel phlegm	The video presentation
2. Weaning phase			
(2 hours)	To allow patients to practice self-regulation to be able to wean off the ventilator	*Activity 1* Patients receive training in weaning from a ventilator by using a T-piece for 2 hours.	-
Monitored every 30 minutes (5 minutes each time)	To ensure patient safety while weaning off the ventilator	*Activity 2* Monitoring and assessing changes while weaning from the ventilator	-
(Monitored every 30 minutes, 5 minutes each time)	To give patients confidence and have the courage to control themselves, and to be able to wean off the ventilator	*Activity 3* The PI monitors, encourages, and provides positive reinforcement to encourage the patient to control himself by using breathing skills correctly, deep breathing and relaxation skills, as well as skills for coughing and expelling phlegm while weaning off the ventilator every 30 minutes.	-
3. Weaning outcome on extubation			
(30 minutes)	To evaluate results from the program	The PI evaluates the success in weaning from the Mechanical Ventilators Assessment Tool, the State Anxiety During Weaning Questionnaire, and the Perceived Fulfillment of Care Needs assessment. He then asks the participants about any problems or obstacles they experienced while receiving the program, and he invites suggestions for improving it in the future.	-
(48 hours after removing the endotracheal tube)	To assess the success of weaning from ventilators	The PI had to follow up with the patient again 48 hours after the patient was extubated. He did so to make certain that they didn't end up re-intubated.	-