



## Intervention for Patients Intubated and Conscious to decrease Peritraumatic Distress (IPIC-PTD) – Acceptability and feasibility

## Intervention pour les patients intubés et conscient visant à diminuer la détresse péritraumatique (IPIC-PTD) – Acceptabilité et faisabilité

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Résumé de l'article

Introduction. Il a été démontré que maintenir les patients intubés conscients aux soins intensifs améliore la santé physique, mais peut potentiellement entraîner l'apparition de détresse péritraumatique et de stress post-traumatique. Les facteurs de risque pouvant causer des conséquences psychologiques dans cette population comprennent les symptômes inconfortables suivants : l'anxiété, le délirium, la douleur et la perturbation du sommeil. Objectif. L'objectif de cette étude était de décrire l'acceptabilité et la faisabilité d'une intervention infirmière visant à diminuer les symptômes inconfortables chez les patients intubés et conscients aux soins intensifs afin de prévenir l'apparition de la détresse péritraumatique et d'un état de stress post-traumatique dans cette population. Méthodes. Une étude descriptive a permis de documenter les perspectives des patients (n=9) exposés à l'intervention d'une part, et celles des intervenants (n=4) qui l'ont appliquée, d'autre part. Les données sur l'acceptabilité et la faisabilité ont été collectées à l'aide d'un questionnaire auto-administré complété par les participants et des notes de terrain des chercheurs. Résultats. L'intervention a été jugée acceptable et faisable par les patients et les intervenants dans un environnement de soins intensifs. La fidélité de l'administration de l'intervention a été maintenue par les intervenants dédiés dans le cadre de cette étude pilote. Discussion et conclusion. Des études utilisant des devis mixtes devraient être menées pour mieux documenter les obstacles et les facilitateurs de l'implantation de l'intervention dans un contexte clinique d'unité de soins intensifs et afin de décrire les mécanismes sous-jacents à l'efficacité d'une telle intervention.

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## **Intervention for Patients Intubated and Conscious to decrease Peritraumatic Distress (IPIC-PTD) – Acceptability and feasibility**

### **Intervention pour les patients intubés et conscient visant à diminuer la détresse péritraumatique (IPIC-PTD) – Acceptabilité et faisabilité**

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## Keywords

acceptability;  
feasibility;  
intensive care  
unit;  
peritraumatic  
distress; post-  
traumatic stress  
disorder

## Abstract

**Introduction:** Keeping patients conscious while mechanically ventilated in intensive care has been shown to improve physical health but also to potentially cause peritraumatic distress and posttraumatic stress disorder. Risk factors for onset of psychological consequences in this population include bothersome symptoms, such as anxiety, delirium, pain, and sleep alteration.

**Objective:** The objective of this study was to describe the acceptability and feasibility of a nursing intervention to prevent onset of peritraumatic distress and post-traumatic stress disorder in conscious intubated patients in intensive care unit by decreasing their bothersome symptoms.

**Methods:** A descriptive design was used to document the perspective of patients (n=9) exposed to the intervention and of the interventionists (n=4) who delivered it. Data on acceptability and feasibility were collected through a self-administered questionnaire completed by participants and from researchers' field notes. **Results:** The intervention was deemed acceptable and feasible by patients and interventionists in the intensive care unit environment. Intervention delivery fidelity was maintained by the dedicated interventionists participating in this pilot study.

**Discussion and conclusion:** Mixed-design studies should be undertaken to further document the barriers to and facilitators of intervention implementation in a clinical intensive care unit context and to describe the mechanisms underlying intervention efficacy.

## Résumé

**Introduction :** Il a été démontré que maintenir les patients intubés conscients aux soins intensifs améliore la santé physique, mais peut potentiellement entraîner l'apparition de détresse péri-traumatique et de stress post-traumatique. Les facteurs de risque pouvant causer des conséquences psychologiques dans cette population comprennent les symptômes incommodes suivants : l'anxiété, le délirium, la douleur et la perturbation du sommeil. **Objectif :** L'objectif de cette étude était de décrire l'acceptabilité et la faisabilité d'une intervention infirmière visant à diminuer les symptômes incommodes chez les patients intubés et conscients aux soins intensifs afin de prévenir l'apparition de la détresse péri-traumatique et d'un état de stress post-traumatique dans cette population. **Méthodes :** Une étude descriptive a permis de documenter les perspectives des patients (n=9) exposés à l'intervention d'une part, et celles des intervenants (n=4) qui l'ont appliquée, d'autre part. Les données sur l'acceptabilité et la faisabilité ont été collectées à l'aide d'un questionnaire auto-administré complété par les participants et des notes de terrain des chercheurs. **Résultats :** L'intervention a été jugée acceptable et faisable par les patients et les intervenants dans un environnement de soins intensifs. La fidélité de l'administration de l'intervention a été maintenue par les intervenants dédiés dans le cadre de cette étude pilote. **Discussion et conclusion :** Des études utilisant des devis mixtes devraient être menées pour mieux documenter les obstacles et les facilitateurs de l'implantation de l'intervention dans un contexte clinique d'unité de soins intensifs et afin de décrire les mécanismes sous-jacents à l'efficacité d'une telle intervention.

## Mots-clés

acceptabilité;  
faisabilité; unité  
de soins  
intensifs;  
détresse  
péri-traumatique;  
état de stress  
post-  
traumatique

## INTRODUCTION

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Patients are hospitalized in the intensive care unit (ICU) when in critical condition. Mechanical ventilation through a tube inserted into the trachea is a life-saving intervention often used in this context (Urden, Stacy, & Lough, 2017). Sedation has long been the gold-standard approach for intubated patients, but recent evidence has suggested that keeping mechanically ventilated ICU patients conscious could significantly improve physical health indicators (Barr et al., 2013; Devlin et al., 2018). This is the therapeutic approach now being promoted. Studies have shown that it does not influence the occurrence of psychological consequences, such as peritraumatic distress (PTD) or post-traumatic stress disorder (PTSD) following hospitalization in the ICU (Rock, 2014; Samuelson, Lundberg, & Fridlund, 2008). However, the depth of sedation can have an impact on the patient's perception of this period. Findings from qualitative studies have revealed that patients experienced a loss of self-control, felt at the mercy of strangers, and found themselves in a scary care environment (Egerod et al., 2015; Karlsson, Bergbom, & Forsberg, 2012). Also, several conscious intubated patients who experienced an episode of delirium in the ICU reported feeling close to death (Instenes et al., 2018). The combination of life-threatening illness and invasive life-saving interventions, such as mechanical ventilation, increases the risk of developing PTSD (McGiffin, Galatzer-Levy, & Bonanno, 2016). Indeed, the prevalence of PTSD symptoms is estimated at 14% to 51% in all mechanically ventilated ICU patients (Bienvenu et al., 2015; Girard et al., 2007; Huang et al., 2016; Kress et al., 2003) and is significantly higher in this group than in the general population, where it ranges from 1.1% to 3.5% (Karam et al., 2014; Kessler, Chiu, Demler, Merikangas, & Walters, 2005; Van Ameringen, Mancini, Patterson, & Boyle, 2008). Three systematic reviews (Parker et al., 2015; Ratzer, Romano, & Elklit, 2014; Wade, Hardy, Howell, & Mythen, 2013) have identified potentially modifiable risk factors for PTD and PTSD in conscious intubated patients. These include the presence of bothersome symptoms

such as anxiety, delirium, pain, and sleep alteration. This suggests that interventions could be implemented to prevent these psychological complications in this vulnerable population (McKinley, Fien, Elliott, & Elliott, 2016).

Several guidelines and theories recommend various measures to prevent PTD and PTSD in mechanically ventilated patients. These include the systematic evaluation of bothersome symptoms and the implementation of nursing interventions such as soothing the patient with music, keeping an ICU diary, and providing verbal information to re-orient the patient (Balas et al., 2012; Barr et al., 2013; Devlin et al., 2018; Long, Kross, Davydow, & Curtis, 2014). The impact of each of all these measures separately have been shown in empirical studies to have positive results for ICU patients but have not been specifically tested with conscious intubated patients, which constitute a relatively new population (Andrews, Silva, Kaplan, & Zimbardo, 2015; Cho, Song, Piao, Jin, & Lee, 2015; Georgiou, Hadjibalassi, Lambrinou, Andreou, & Papatthanassoglou, 2015; Hu et al., 2015; Munro et al., 2017; Najafi Ghezeljeh, Mohades Ardebili, Rafii, & Haghani, 2016; Teece & Baker, 2017).

In an effort to address this shortcoming, we drew on the framework proposed by Sidani and Braden (2011) to develop an intervention aimed at reducing anxiety, delirium, pain and sleep alteration in conscious intubated patients and, ultimately, preventing onset of PTD and PTSD in this population. The Intervention for Patients Intubated and Conscious to decrease Peri-Traumatic Distress (IPIC-PTD) entails: a) systematically assessing the patient's symptoms every four hours, b) exposing the patient to two 30-minute music sessions per day, c) a trained interventionist and the patient's family keeping a diary on a daily basis, and d) briefing the patient on what was entered recorded in the diary. Following a literature review, the components of the intervention were selected on the basis of three criteria: 1) doable by a nurse, 2) feasible in a research context, and 3) sufficiently documented with respect to intubated ICU patients. The preliminary effects of the IPIC-PTD were previously measured in a quasi-experimental pilot study (Gosselin, Lavoie, G elinas, & Bourgault, 2018). However, as this new combination of interventions

had not been tested specifically in conscious mechanically ventilated ICU patients, it was essential also to describe its acceptability and feasibility in this population (Bowen et al., 2009; Feeley et al., 2009).

## OBJECTIVE

The objective of this study was to describe the acceptability and feasibility of the IPIC-PTD from the perspective of conscious intubated ICU patients and interventionists.

## METHODS

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### DESIGN

A descriptive design was used in this quasi-experimental pilot study to describe acceptability and feasibility from the viewpoint of patients exposed to the intervention and of four dedicated nurse interventionists.

### POPULATION AND SAMPLING

The study population consisted of conscious patients intubated and mechanical ventilated in one of three ICUs at a suburban university hospital in Quebec, Canada. The nurse-patient ratio in the ICUs was one to one or one to two. Sedation and analgesia were adjusted by bedside nurses following standardized protocols, including daily interruption. Physical restraints were commonly used. The inclusion criteria were to aim for a score of 3 to 5 on the Sedation Assessment Scale (SAS) during mechanical ventilation, be over 18 years old, and speak French. The exclusion criteria were delirium at recruitment, history of dementia, trauma or PTSD, mechanical ventilation by tracheostomy, elective surgery, and expected extubation before receiving the intervention once. These exclusion criteria were used to obtain a homogeneous sample in terms of lived experience in the ICU. Based on pilot study guidelines, a sample of 10 to 15 participants was expected to be recruited through convenience sampling (Billingham, Whitehead, & Julious, 2013; Hertzog, 2008).

Moreover, four dedicated nurse interventionists were hired to deliver the IPIC-PTD. Each had at least five years of ICU work experience.

### INTERVENTION

Each participant received the IPIC-PTD at least once. The intervention was delivered twice a day by trained, dedicated interventionists for up to five days. Moreover, systematic symptoms assessments were completed every four hours. Each session began with symptom assessment, the results of which were conveyed to the bedside nurse. Then, the technical set up for the music component was performed, including having the participant select the music and volume level. While the participant listened to music, the interventionist noted any significant events in the diary. After the participant had listened to music for 30 minutes, the interventionist briefed them on what was recorded in the diary in order to reorient the patient before reassessing symptoms. The morning session was administered between 9 and 11 a.m., and the evening session between 8 and 10 p.m. An intervention guide was developed to optimize intervention delivery fidelity. It presented an overview of the intervention, the resources required to deliver it, and a detailed description of each component and procedure. Overall, the acceptability and feasibility of the original version of the IPIC-PTD were considered good by expert panels (Gosselin, Bourgault, Lavoie, & Gélinas, 2018).

### INDICATORS

**Acceptability.** Acceptability was defined as the perceptions and preferences of patients and caregivers, as proposed by Sidani and Braden (2011).

Recruitment and dropout rates were calculated using a flow chart and researchers' field notes to document uptake and adherence (Sidani & Braden, 2011). Participants completed the French-language version of the Treatment Acceptability and Preference (TAP) questionnaire 24 hours after extubation, as did the interventionists before and after data collection. The four items of this self-report questionnaire, respectively, address the four attributes of

acceptability, namely, effectiveness, suitability, appropriateness, and willingness to adhere to the intervention. The items were rated on a five-point descriptive scale for each component of the IPIC-PTD (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009). The original English-language version of the instrument has been shown to have good internal consistency, obtaining Cronbach's alphas ranging from .80 to .87. The original questionnaire was translated into French by two independent translators using the forward-backward method and a final version was arrived at by consensus at a meeting of the two (Sousa & Rojjanasrirat, 2011).

**Feasibility.** Feasibility referred to the practical and logistical aspects of the intervention. Researchers' and interventionists' field notes, as well as a detailed budget, were used to describe availability, quality and training of interventionists, intervention implementation fidelity, and physical and social context/resources (Becker, Darius, & Schaumberg, 2007; Sidani & Braden, 2011). After each delivery of the IPIC-PTD, interventionists were asked to rate fidelity to the intervention guide on a scale of 0 (poor) to 10 (perfect).

#### DATA ANALYSIS

Non-parametric statistics such as medians and ranges were calculated (Field, 2017). To document acceptability and feasibility indicators, researchers' field notes were condensed into summary tables (Corbière & Larivière, 2014; Miles, Huberman, & Saldana, 2014). Categories were created based on indicators of acceptability and feasibility suggested by Sidani and Braden (2011).

#### ETHICAL CONSIDERATIONS

The study was approved by the local research ethics committee. The study complied with the Helsinki declaration. Conscious intubated patients initially granted their free and informed consent at the beginning of the study by nodding their head in front of a witness. They later signed a written consent form as soon as possible. Participation in the study was voluntary, and participants could withdraw from the study at any time. Participants were assigned a code to ensure anonymity and data confidentiality.

## RESULTS

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#### SAMPLE

Six of the nine participants who received the IPIC-PTD were men (66.7%), six had surgery (66.7%), and three (33.3%) were admitted for medical reasons. They were hospitalized in three different ICUs: medical (n=4, 44.4%), mixed (n=4, 44.4%), and surgical (n=1, 11.1%). The sample had a median age of 64 years (range of 20–74), was mechanically ventilated for a median of 104 hours (range of 34–160), and had a median of five antecedents (range of 1–12).

A total of 28 intervention sessions were documented, for a median of three intervention sessions per participant. About half were administered in the evening (n=15, 53.6%) and half in the morning (n=13, 46.4%).

#### ACCEPTABILITY

**Recruitment and dropout.** Ten of fifteen patients who met the eligibility criteria were approached to participate in the study, of which nine agreed (recruitment rate: 60%). The other five patients were not invited to participate in the study for a variety of reasons: lack of coordination with the ICU care team (n=2), already participating in another research project (n=1), refused to meet with research team (n=1), and research team not available (n=1). The patient who refused to participate after being approached gave fatigue as the reason (n=1).

All of the nine participants received the IPIC-PTD as long as they were intubated, for a maximum of five days. Data collection was planned 24 hours after extubation but was not completed for five patients for the following reasons: a) participant did not remember receiving the intervention (n=2), b) fatigue (n=2), and c) complications requiring re-intubation (n=1).

**Patients.** Four patients completed the TAP questionnaire. Table 1 gives the median of the patients' responses. According to them, the most acceptable component was music sessions, followed by information briefing, diary keeping and systematic symptoms evaluation. The median of their general opinion of the IPIC-PTD was high at

3.75/4. Regarding the four acceptability attributes, the highest median scores were for willingness to adhere and appropriateness, with effectiveness and suitability tied for third.

## FEASIBILITY

### Availability and quality of interventionists.

Two interventionists and the principal investigator administered the intervention five times (17.9%), one interventionist delivered it 13 times (46.4%),

**Tableau 1**

*Acceptability of IPIC-PTD – Patients (n=4)*

| Attributes <sup>1</sup> | Intervention's components                        |                                  |                                 |  |                                   | Total<br>Median (range) |
|-------------------------|--|----------------------------------|---------------------------------|--|-----------------------------------|-------------------------|
|                         | Systematic symptoms evaluation<br>Median (range) | Music sessions<br>Median (range) | Diary keeping<br>Median (range) | Information briefing<br>Median (range) | General opinion<br>Median (range) |                         |
| Effectiveness           | 2 (2–2)  | 3 (3–4)                          | 3 (3–4)                         | 3 (1–3)                                | 3 (3–4)                           | 3 (2.6–3)               |
| Suitability             | 2 (2–2)  | 3 (3–4)                          | 3 (3–4)                         | 3 (3–4)                                | 3.5 (3–4)                         | 3 (2.8–3)               |
| Appropriateness         | 2 (2–3)  | 3.5 (2–4)                        | 2.5 (2–3)                       | 3.5 (2–4)                              | 4 (3–4)                           | 3.2 (2.8–3.4)           |
| Willingness to adhere   | 2 (1–4)  | 3.5 (3–4)                        | 3 (2–4)                         | 3 (3–4)                                | 4 (3–4)                           | 3.2 (3.2–3.4)           |
| <b>Total</b>            | 2 (1.75–2.75)                                    | 3.5 (2.75–3.5)                   | 2.88 (2.5–3.75)                 | 3.13 (2.25–3.75)                       | 3.75 (3.25–4)                     |                         |

<sup>1</sup> Acceptability attributes rated from 0 (not at all) to 4 (very much)

**Interventionists.** All four interventionists completed the TAP questionnaire after two hours of training and at the end of data collection (Table 2). Prior to intervention delivery, the most acceptable components to them were systematic symptoms evaluation and information briefing (tied), followed by music sessions and diary keeping. The attribute with the highest median was willingness to adhere, followed by effectiveness, suitability, and appropriateness. The median for their general opinion of the intervention was high as well, reaching 3/4.

At the end of data collection, music sessions were the most acceptable component, followed by systematic symptoms evaluation, information briefing, and diary keeping. Suitability was the indicator with the highest median, followed by appropriateness, effectiveness, and willingness to adhere. Their general opinion of the IPIC-PTD was higher than at the beginning of the study, as evidenced by a median of 3.5/4.

and another provided the intervention three times with the help of another interventionist (10.7%). Only one potential patient could not be recruited because of lack of availability on the part of the research team. To ensure sufficient availability, the principal investigator, too, delivered the IPIC-PTD.

**Training of interventionists.** All the interventionists participated in a two-hour training session that included a lecture, exercises with clinical vignettes, and time to become familiar with the material and tools used. The training plan comprised an introduction (10 minutes), a summary of the research project (10 minutes), a detailed presentation of the overall IPIC-PTD and of each component (75 minutes) (Gosselin, Bourgault, Lavoie, & Gélinas, submitted), a description of the role of the interventionist and the forms to complete (15 minutes), and a conclusion (10 minutes). Each interventionist received the intervention guide. In addition to this training, the principal investigator supported the interventionists the first time they delivered the intervention, either by telephone or in person.

**Tableau 2***Acceptability of IPIC-PTD – Interventionists, before and after (n=4)*

| Attributes                   | Intervention's components      |                            |                             |                            |                             |                            |                             |                            |                             |                            | Median for attribute        |                            |
|------------------------------|--------------------------------|----------------------------|-----------------------------|----------------------------|-----------------------------|----------------------------|-----------------------------|----------------------------|-----------------------------|----------------------------|-----------------------------|----------------------------|
|                              | Systematic symptoms evaluation |                            | Music sessions              |                            | Diary keeping               |                            | Information briefing        |                            | General opinion             |                            |                             |                            |
|                              | Before<br>Median<br>(range)    | After<br>Median<br>(range) | Before<br>Median<br>(range) | After<br>Median<br>(range) | Before<br>Median<br>(range) | After<br>Median<br>(range) | Before<br>Median<br>(range) | After<br>Median<br>(range) | Before<br>Median<br>(range) | After<br>Median<br>(range) | Before<br>Median<br>(range) | After<br>Median<br>(range) |
| <b>Effectiveness</b>         | 3<br>(3–3)                     | 3<br>(3–4)                 | 3<br>(2–3)                  | 3.5<br>(2–4)               | 2<br>(2–3)                  | 2<br>(2–3)                 | 3.5<br>(3–4)                | 3<br>(3–4)                 | 3<br>(2–3)                  | 3.5<br>(2–4)               | 2.9<br>(2.4–3.4)            | 3<br>(2.8–3.4)             |
| <b>Suitability</b>           | 3<br>(3–3)                     | 3.5<br>(3–4)               | 3<br>(2–4)                  | 4<br>(3–4)                 | 2<br>(2–3)                  | 2.5<br>(2–3)               | 3<br>(3–4)                  | 3<br>(3–4)                 | 3<br>(2–4)                  | 3.5<br>(3–4)               | 2.9<br>(2.4–3.4)            | 3.4<br>(3–3.4)             |
| <b>Appropriateness</b>       | 3<br>(3–4)                     | 3<br>(3–4)                 | 2.5<br>(2–3)                | 3.5<br>(2–4)               | 2<br>(2–2)                  | 2<br>(2–3)                 | 3<br>(3–4)                  | 3.5<br>(3–4)               | 3<br>(3–4)                  | 4<br>(3–4)                 | 2.8<br>(2.4–3)              | 3.1<br>(3–3.8)             |
| <b>Willingness to adhere</b> | 3.5<br>(3–4)                   | 3<br>(2–4)                 | 3<br>(3–3)                  | 3.5<br>(2–4)               | 3<br>(2–3)                  | 3<br>(3–4)                 | 3<br>(3–4)                  | 3<br>(3–4)                 | 3<br>(3–4)                  | 3<br>(2–4)                 | 3.2<br>(2.8–3.6)            | 2.9<br>(2.4–3.6)           |
| <b>Median for element</b>    | 3.13<br>(3–3.5)                | 3.38<br>(3–3.5)            | 2.87<br>(2.25–3.25)         | 3.6<br>(2.25–4)            | 2.25<br>(2–3)               | 2.13<br>(2–3)              | 3.13<br>(3–4)               | 3.13<br>(3–4)              | 3<br>(2.25–3.5)             | 3.5<br>(2.5–4)             |                             |                            |

<sup>2</sup>Acceptability attributes rated from 0 (not at all) to 4 (very much)



Following the training, one interventionist took the initiative to create a chronological summary checklist to further clarify the steps needed to fully complete the IPIC-PTD. This checklist was added to the intervention guide.

**Resources.** Table 3 details the costs involved in delivering the intervention, which totalled approximately CAN\$2,300. The overall cost of the material resources needed to deliver the IPIC-PTD to nine patients in three separate settings was less than CAN\$1,000. All of the scales used in the systematic symptoms evaluation were printed out, except for the pain thermometers, which were provided free of charge by a member of the research team. The music sessions were the most expensive component of the intervention at a cost of CAN\$639.31. Fourteen diaries were printed out for the interventionists and for study purposes, including 30 pages with a case for pictures and a hardcover, at the approximate cost of CAN\$10 per participant. The information briefings required no material resources. About CAN\$1,500 was needed to cover the interventionists' salaries.

**Context.** During the study the ICUs were busy critical care environments where the patients were frequently subjected to exams or procedures, thereby rendering them unavailable to receive the IPIC-PTD. This, of course, affected implementation fidelity. One intervention session was cancelled because the patient was away from his room to undergo a procedure. The ICUs were under isolation to prevent transmission of nosocomial diseases for the data collection of three patients. Moreover, another patient was under isolation after contracting a resistant bacteria. Additional infection control precautions needed to be taken in these situations to prevent material contamination. On another level, the fact that a research team was already on site recruiting, collecting data and promoting research on the units ensured that the ICU care team kept an open-minded attitude about research. However, this also led to the need to coordinate recruitment in order to avoid overstressing patients and to ensure the utmost efficiency in the screening process.

**Tableau 3**  
*Intervention costs*

| Components                             | Resources  | Cost <sup>3</sup> | Total             |
|--|--|-------------------|-------------------|
| Systematic symptoms evaluation         | Scales   | Free              | \$0               |
| Music sessions                         | iPod   | \$409.89          | \$639.31          |
|  | Noise-cancelling headsets                                  | \$138.52          |                   |
|  | Playlists  | \$90.90           |                   |
| Diary keeping                          | 14 diaries printed   | \$11.19/diary     | \$156.66          |
| Information briefing                   | None   | Free              | \$0               |
| <b>Subtotal for material resources</b> |  |                   | <b>\$795.97</b>   |
| <b>Human resources</b>                 | Four dedicated interventionists – 28 intervention sessions | \$55/session      | \$1,540.00        |
| <b>Subtotal for human resources</b>    |  |                   | <b>\$1,540.00</b> |
| <b>Total</b>                           |  |                   | <b>\$2,335.97</b> |

<sup>3</sup> All expenses expressed in CAN\$

Finally, the patients' family members played a major role in the social environment in which the intervention took place. They participated in the IPIC-PTD by helping with the choice of music, bringing music in from home, filling out the diary, and relaying information to the patient.

**Intervention fidelity.** According to the intervention guide, every participant should have received the IPIC-PTD twice a day for the duration of mechanical ventilation, up to a maximum of five days. One intervention session was not administered because the participant was out for a procedure. Another participant had to be sedated again for medical reasons and, therefore, did not receive the IPIC-PTD for five days. Yet another participant was extubated without receiving all the intervention sessions as a result of miscommunication with the ICU care team.

interventionists from delivering intervention sessions on three occasions across two participants. Table 4 summarizes the indicators of time and intervention fidelity. Overall, the median time to completely administer the four components of an intervention session was 35 minutes. However, the range was wide (15–86 minutes). The median time ranged from 30 to 42 minutes for the four dedicated interventionists (range of 15 to 86 minutes) and was 55 minutes for the principal investigator (range of 27 to 82 minutes) (data not shown). The interventionists gave their implementation fidelity nearly perfect ratings. The range was narrow for music sessions, diary keeping and information briefing, but much wider for systematic symptoms evaluation. However, further analysis of the database revealed that this was due to an outlier.

**Tableau 4**  
*Summary of indicators of IPIC-PTD time and fidelity*

| Component                      | Time <sup>4</sup> | Interventions sessions | Fidelity <sup>5</sup> | Interventions sessions |
|--------------------------------|-------------------|------------------------|-----------------------|------------------------|
|                                | Median (range)    | Number of sessions     | Median (range)        | Number of sessions     |
| Systematic symptoms evaluation | 5 (2–16)          | 24                     | 10 (3–10)             | 23                     |
| Music sessions <sup>6</sup>    | 30 (10–60)        | 21                     | 10 (8–10)             | 20                     |
| Diary keeping                  | 20 (5–75)         | 27                     | 10 (8–10)             | 26                     |
| Information briefing           | 4 (2–50)          | 24                     | 10 (8–10)             | 23                     |
| <b>Total</b>                   | 35 (15–86)        | 22                     | 39 (34–40)            | 19                     |

<sup>4</sup> Time in minute

<sup>5</sup> Fidelity to the intervention guide rated from 0 (poor) to 10 (perfect)

<sup>6</sup> Music sessions: classical (n=1); country (n=7); French (n=3); hard rock (n=1); jazz (n=0); nature (n=1); relaxation (n=2); '50s and '60s rock 'n' roll (n=2); radio (n=2)

Seven intervention sessions were not completely delivered at the predetermined time. Music sessions did not take place on six occasions across four participants on account of impending extubation, family presence, sleep, confusion or agitation. Three of the four participants with incomplete intervention sessions asked to keep the music material for personal use. Participant discomfort, fatigue or confusion prevented the

## DISCUSSION

This study described the acceptability and feasibility of the IPIC-PTD, a nursing intervention intended to reduce bothersome symptoms in order to prevent onset of PTD and PTSD in conscious, mechanically ventilated ICU patients.

Acceptability was quantitatively evaluated by participants who received the intervention and by interventionists who delivered it. Feasibility was described through detailed field notes from researchers. Both acceptability and feasibility of the IPIC-PTD appeared satisfactory for the implementation of the intervention in a future study.

#### ACCEPTABILITY

**Recruitment and dropout.** The recruitment rate was 60% and the dropout rate for the intervention was 0%. Two other studies regarding music therapy for mechanically ventilated patients had similar recruitment rates, 58% in one case (Beaulieu-Boire et al., 2013) and 66% in the other (Hunter et al., 2010). A recruitment rate of 96% was obtained in a study using the ICU diary (Garrouste-Orgeas et al., 2012). The reasons given for refusing to participate in these studies included the following: not interested in music or did not believe music would help, not interested in research, deafness, family did not consent, presence of delirium, and prior participation in another study (Beaulieu-Boire et al., 2013; Garrouste-Orgeas et al., 2012; Hunter et al., 2010). Dropout rates in these studies ranged from 11% (Beaulieu-Boire et al., 2013) to 26% (Hunter et al., 2010). The reasons for patient exclusion or dropout included the following: hard of hearing, increased delirium, feeling overwhelmed, and missed music sessions or data collection times (Beaulieu-Boire et al., 2013; Hunter et al., 2010). Our eligibility criteria limited the study's accessible population to specific patients who could benefit from the intervention, which probably explains our low refusal and dropout rates. Moreover, no patients were excluded from the study for having missed sessions given that intervention feasibility was a matter of interest in the study. Lastly, the fact that the intervention comprised four different components might have contributed to the retention rate, as this might have given it a wider appeal.

**Patients and interventionists.** All the median scores on the acceptability questionnaires completed by participants and interventionists suggested good acceptability. Moreover, they increased at the end of the study for interventionists, both for total components and

acceptability attributes. These were also all higher than the one obtained for experts in the development phase, which came in at 2.75/5 (Gosselin et al., submitted). This difference might be explained by two main elements.

First, interventionists received two hours of training on the IPIC-PTD and provided with detailed information while the IPIC-PTD was only briefly presented to experts in five minutes. It has been acknowledged that justifying the relevance of intervention components from a credible theoretical standpoint and establishing a logical link with objectives fosters greater interventionist engagement (Forbes, 2009; Sidani & Braden, 2011).

Second, the expert committee examined acceptability as if the IPIC-PTD was to be implemented by ICU nursing staff, whereas the participants and interventionists in our study rated acceptability when the intervention was implemented by dedicated human resources. Acceptability would have likely been rated lower if the intervention translated into an increase in workload for nurses. Several implementation studies have pointed out this barrier to intervention implementation in ICU (Beaulieu-Boire et al., 2013; Cho et al., 2015; Egerod, Schwartz-Nielsen, Hansen, & Laerkner, 2007). This could impede future implementation of the IPIC-PTD in the clinical context, namely other challenges with acceptability that could not be documented in this pilot study.

The systematic symptoms evaluation was one of the most acceptable components for the interventionists, as it was for the experts in the development phase, but it was less so for the patients (Gosselin et al., submitted). These results are not surprising given that the component was already among the regular nurses' duties, according to the provincial nurses' association, and should already be implemented in healthcare settings (Ordre des infirmières et infirmiers du Québec, 2018). However, patients might not have seen the relevance of these systematic assessments, experiencing them more as an inconvenience and failing to perceive the benefits (Sidani & Braden, 2011).

At the end of the study, the component with the highest acceptability score was the music

sessions, for both the patients and the interventionists, whereas at the start of the study, it was not the favourite of the interventionists or the experts (Gosselin et al., submitted). This change might be explained by the fact that patients and interventionists could observe the short-term effects of the music on bothersome symptoms (Sidani & Braden, 2011). Prior to data collection, both the experts and the interventionists expressed concern about the feasibility of the music sessions in the ICU, which likely diminished their perception of the component's acceptability.

Diary keeping is the component that received the lowest acceptability score from the patients, the interventionists, and the experts (Gosselin et al., submitted). Several hypotheses might explain this finding. First, the effects of the diary are observable only in the longer term. Since its benefits are not directly observable by interventionists or patients during mechanical ventilation, the logical link with the objective of the IPIC-PTD is unclear for this specific component, and this might decrease their engagement (Sidani & Braden, 2011). This barrier to implementation was underlined in other implementation studies conducted in ICU (Cho et al., 2015; Egerod et al., 2007; Faraklas et al., 2013). Moreover, patients completed the acceptability questionnaire only 24 hours after being extubated, which means they might not have had used the diary yet.

The information briefing was judged equally acceptable by the patients and the interventionists. This component facilitated communication between the two parties by providing an occasion for direct feedback. As is the case with the music sessions, the benefits of imparting information are instantly observable, and this might have rendered the component more acceptable, as proposed in the literature (Sidani & Braden, 2011).

## FEASIBILITY

### **Availability and quality of interventionists.**

The number of interventionists seemed to be sufficient considering that only one potential participant could not be approached owing to a lack of availability on the part of the interventionists. Having a sufficient amount of human resources in the ICU has been highlighted

as a necessary condition for success in several ICU studies (Carrothers et al., 2013; Cho et al., 2015; Egerod et al., 2007; Yoder et al., 2014). The fact that the principal investigator delivered the intervention five times might have increased the fidelity scores.

**Training of interventionists.** A training session, an intervention guide and supervision were offered to all interventionists by the principal investigator. Lack of knowledge or training is frequently cited as a barrier to intervention fidelity (Carrothers et al., 2013; Chen, Shao, Hsiao, & Lee, 2013; Yoder et al., 2014). Training and an intervention guide make it easier to understand the key ingredients of an intervention and provide an opportunity for experts to develop the skills required to deliver it (Murphy & Gutman, 2012; Sidani & Braden, 2011; Yoder et al., 2014). The use of experiential teaching strategies, such as simulation scenarios and video clips, makes it possible to integrate knowledge (Egerod et al., 2007; Gélinas et al., 2014; Sidani & Braden, 2011). Providing clinical support and feedback has also proven an effective strategy for standardizing interventionist practices (Bosak, Pozehl, & Yates, 2012; Gearing et al., 2011). However, it might not be realistic to expect healthcare professionals to be freed off unit work for a two-hour training session to implement a multi-faceted intervention.

**Material resources.** The expenses related to the IPIC-PTD were covered by operating funding. The music sessions were the most expensive component, but the material was reusable. Printing the diaries was affordable. The development of a low-cost and low-resource intervention was shown to be a facilitating factor that improved intervention feasibility in other ICU settings (Aghaie et al., 2014; Gélinas et al., 2014; Lee, Chung, Chan, & Chan, 2005).

**Context.** A small number of intervention sessions were not delivered because infection control measures were in effect on the ICU and because the patient's condition did not allow it. For instance, music sessions were under-utilized or stopped on account of onset of delirium in one case in the present study, as this barrier was underlined in other studies. Moreover, as witnessed in other studies (Beaulieu-Boire et al., 2013; Han et al., 2010), ICU patients frequently

undergo exams and procedures and are in great need of rest, which limits their availability to receive other less pressing interventions. This was the case for one patient in our study who did not receive the intervention at all.

The presence of family members at the patient's bedside increased dose, by helping deliver components in some cases. Integrating families in the development and application of interventions was identified as a facilitating factor that boosted feasibility in the case of past interventions tested in ICU settings (Delaney, 2014; Garrouste-Orgeas et al., 2012; Lee et al., 2005). Moreover, it has been recommended that social support be provided immediately following a traumatic event in order to prevent onset of PTSD (Joseph & Linley, 2008).

**Intervention fidelity.** A quarter of the intervention sessions were deemed incomplete mostly owing to the patient's condition. Three patients received unlimited music sessions at their request, and one brought his personal music from home. Patients and their families expressed different preferences and beliefs regarding the interventions and treatments they received, especially when it came to selecting the music, as it was the case in other studies (Aghaie et al., 2014; Saadatmand et al., 2013).

It took about 35 minutes on average to deliver all four components of the IPIC-PTD. Considering the heavy workload of ICU staff and the critical condition of ICU patients, the time available to carry out an intervention on a regular basis is limited. If the intervention session is too long, interventionists are tempted to resort to shortcuts (Beaulieu-Boire et al., 2013; Cho et al., 2015; Han et al., 2010). However, an intervention could lessen the workload for nurses the rest of their shift if it succeeded in relieving the patient's bothersome symptoms. The principal investigator took longer than other interventionists to deliver the intervention. This might be explained by the fact that, in her capacity of principal investigator, she also answered staff and family questions about the study while doing so.

Interventionists rated fidelity high in their self-evaluations, which suggests that it is possible to reproduce the key components of the IPIC-PTD. The self-evaluation of fidelity based on field notes

encouraged the interventionists to deliver the intervention according to the intervention guide, a phenomenon observed elsewhere (Bosak et al., 2012; Gearing et al., 2011; Sidani & Braden, 2011). Given the individual differences across interventionists and patients, it is difficult to administer a complex intervention in a standardized manner (Beck et al., 2010; Bell et al., 2007). A balance must be struck between the rigorous application of an intervention and its feasibility (Morrison et al., 2009; Sidani & Braden, 2011). Allowing the interventionists the flexibility to adapt the intervention sessions to the circumstances and the patient while maintaining the key components to achieve the intended effects proved a facilitating strategy in our study as it did in others (Beck et al., 2010; Gearing et al., 2011).

#### LIMITATIONS

Our use of convenience sampling may have introduced a participant selection bias. Given that the participants came from a single hospital and the sample size was small, the generalizability of the results is very limited. The decision to go with dedicated interventionists may have increased intervention acceptability and feasibility. It is essential to further document these indicators in a clinical implementation context. Moreover, only quantitative data were analyzed to document acceptability, and the same questionnaire was completed by both the patients and the interventionists. It would be useful to use qualitative research methods to identify barriers and facilitators in order to arrive at a deeper understanding of the acceptability and feasibility of the IPIC-PTD.

#### APPLICATIONS

Ultimately, it is hoped that implementation of the IPIC-PTD will improve quality of care and reduce psychological distress among consequences for conscious intubated ICU patients. It would be interesting in future studies to document the IPIC-PTD's acceptability in a clinical implementation context, given that the dedicated nurses used in our pilot study may have skewed matters in this regard. The next step in this

project will be to undertake a study using a mixed-methods design to develop a theory to explain the effectiveness of the IPIC-PTD. However, several elements must be taken into consideration before implementing the intervention in routine care. These include training, time required to deliver the intervention, long-term monitoring of intervention fidelity, and a deeper understanding of the mechanisms underlying the intervention's effects. To enhance fidelity in the clinical context, it would be worthwhile to integrate key elements of it in nurses' routine care documentation. Lastly, it would be interesting to involve families in a standard way to increase IPIC-PTD feasibility in future studies.

## CONCLUSION

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In summary, the IPIC-PTD was deemed acceptable and feasible by patients and interventionists in the ICU environment. Moreover, maintaining fidelity of delivery appeared possible within the context of a pilot study with dedicated interventionists. Future mixed-design studies are needed to further document the barriers to and facilitators of implementing the IPIC-PTD in a clinical ICU context and to describe the mechanisms underlying its effectiveness. This pilot study represents a first step toward decreasing bothersome symptoms in order to prevent PTSD and PTSD in conscious intubated ICU patients.

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