A Nursing Intervention to Enhance Acceptance of Implantable Cardioverter Defibrillators: A Randomized Pilot Study

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Abstract

***Background**: Patients may experience anxiety and reduced quality of life after implantable cardioverter defibrillator (ICD) device implantation.*

***Objective**: To assess the feasibility, acceptability, and preliminary efficacy of the Approach Caring and Cognitive Behavioural (PRO-CARE) intervention, aimed at improving ICD device acceptance and psycho-functional outcomes one month after implantation.*

***Methods**: The pilot study involved 30 patients randomized to the intervention (IG) or control (CG) groups. The three encounters of the PRO-CARE intervention addressed patient-specific ICD concerns by focusing on beliefs leading to lower device acceptance and psycho-functional outcomes.*

***Results**: Thirteen (87%) of the 15 IG patients received all three encounters. The intervention was both feasible and acceptable. Although not statistically significant, mean scores on ICD device acceptance, shock, and general anxiety favoured the IG.*

***Conclusions**: Further research is needed to replicate results from this pilot study, but our observations suggest that nurses need to assess ICD patient anxiety and to tailor their interventions accordingly.*

Trial registration: www.controlled-trials.com; ISRCTN95996799

Key words: implantable cardioverter defibrillator, pilot study, nursing intervention, device acceptance, anxiety

Cossette, S., Charchalis, M., Frasure-Smith, N., Mailhot, T., Guerra, P.G., Fontaine, G. & Guertin, M.-C. (2017). A Nursing Intervention to Enhance Acceptance of Implantable Cardioverter Defibrillators: A Randomized Pilot Study. *Canadian Journal of Cardiovascular Nursing*, *27*(1), 14–21.

Media Advisory Highlights

- The purpose of this pilot study was to assess the feasibility and acceptability of an individualized nursing intervention aimed at improving device acceptance in first-time recipients of implantable cardioverter defibrillators (ICD).
- The intervention was both feasible and acceptable as a means of potentially reducing ICD-related anxiety.

Implantable cardioverter defibrillators (ICD) can be used as primary prevention for those at risk of sudden cardiac arrest (SCA) or as secondary prevention in SCA survivors (Priori et al., 2015). Previous studies have proposed specific domains of concerns in SCA survivors including preventive care, activities of daily living (ADL), physical changes, emotional challenges, and possible ICD shocks (Dougherty, Benoliel, & Bellin, 2000; Wong, Sit, & Wong, 2012). These concerns may result in lower psycho-functional recovery including avoidance of ADL (Habibovic, Burg, & Pedersen, 2013). Therefore, improving patients' psychological health may improve their acceptance and adaptation to the ICD device.

Device acceptance is defined as "the psychological accommodation and understanding of the advantages and disadvantages of the ICD device, the recommendation of the device to others, and the derivation of benefit in terms of biomedical, psychological and social functioning," (Burns, Serber, Keim, & Sears, 2005, p. 385). Device acceptance has been associated with increased quality of life in ICD patients; therefore, developing strategies to increase device acceptance is important.

A review of interventions aiming to improve outcomes such as device acceptance in ICD patients, revealed some gaps limiting the transfer of research results to clinical practice (Dunbar et al., 2012; Habibovic et al., 2013). The majority of studies tested cognitive behavioural therapy (CBT) interventions provided by psychologists or mental health specialists, and many were part of comprehensive rehabilitation programs. Among the studies evaluating educational and CBT-based interventions provided by general practice nurses, Dougherty, Lewis, Thompson, Baer, and Kim (2004a) assessed an eight-week intervention with weekly 15- to 20-minute telephone calls. They found no effect of the intervention on anxiety, depressive symptoms, or quality of life at three months after ICD implantation, whereas a trend toward a decrease in anxiety, and improvement in knowledge and self-efficacy was observed at 12 months (Dougherty, Pyper, & Frasz, 2004b; Dougherty, Thompson, & Lewis, 2005).

Dunbar et al. (2009) compared two different interventions with usual care. Each intervention began with a face-to-face encounter at the day of hospital discharge and a brief phone call at one week, followed either by four group meetings or four telephone follow-ups initiated one or two months after the ICD implantation. Dunbar et al. observed a decrease in anxiety and depressive symptoms at three months, a result that was not maintained at one year. While the studies assessed a wide range of interventions, in order to facilitate their use in clinical practice, we sought to test an intervention that could be administered within a short timeframe by regular staff nurses.

Aim and Methods

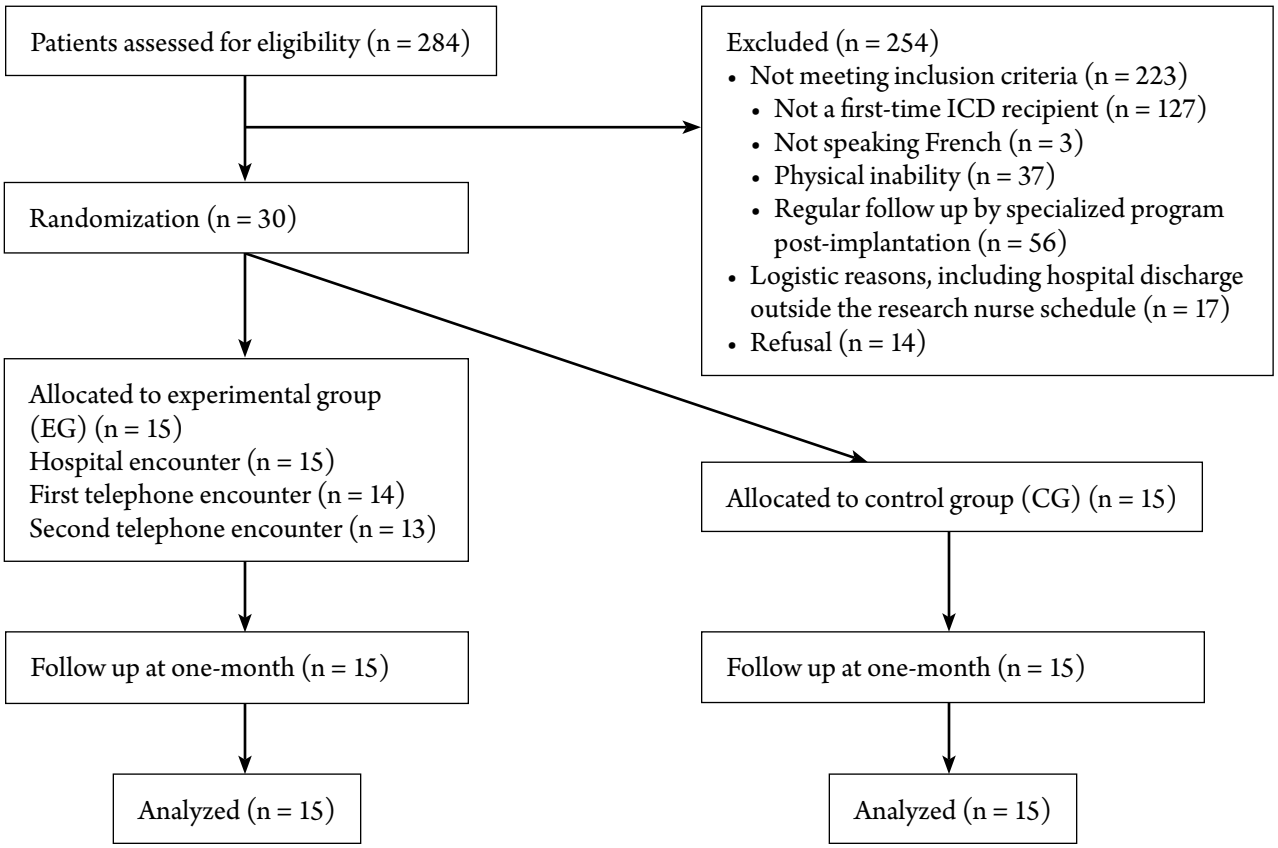
The purpose of this randomized pilot study was to evaluate the feasibility, acceptability, and preliminary efficacy of the Nursing Approach Caring and Cognitive Behavioural (PRO-CARE) intervention, a caring and cognitive behavioural nursing approach aimed at improving psycho-functional outcomes one month after first ICD implantation. We hypothesized that compared to the control group, the intervention group would demonstrate greater device acceptance (Hypothesis; H1); lower shock anxiety (H2); lower general anxiety (H3); and higher ADL functioning (H4) one month post-ICD implantation.

The pilot study was registered at Controlled Trials (#ISRCTN95996799) and approved by the Scientific and Ethics Committee of the Montréal Heart Institute Research Centre (Reference number: 2011-1294). The investigation conforms with the principles outlined in the Declaration of Helsinki (Rickham, 1964). Each participant signed a written consent form after receiving explanations on study procedures in an individual encounter with the project nurse. Participants were informed they could withdraw from the study at any time without consequences. An identification number was assigned to each participant to ensure confidentiality. Reporting of the study sequence was guided by the SPIRIT guidelines as suggested by the CONSORT group (Chan et al., 2013; Zwarenstein et al., 2008) (see Figure 1).

Study Setting and Sample

The study was conducted with adult patients who were hospitalized for a first ICD implantation at a tertiary cardiac hospital in Montreal, Canada. This pilot study involved two randomized parallel groups (1:1 ratio), counting in total 30 patients. To be included, patients had to be aged 18 years or older; a first-time ICD recipient; able to speak, read, and understand French; hospitalized for a maximum of two weeks after ICD implantation; and discharged home. In order to avoid multiple interveners, patients were excluded if they had specialized follow-up in an outpatient clinic.

Figure 1. CONSORT Flow Diagram for the PRO-CARE Pilot Randomized Study



When patients were stabilized after ICD implantation, the project nurse approached them to explain the study and obtain informed consent. A self-report questionnaire was then administered to collect baseline data, and clinical data were obtained from the hospital files. The project nurse also enquired if a family member would be interested in participating, because of their possible supportive role in ICD acceptance; however, their presence was not mandatory.

Study Procedures

Usual care. All participants in the IG and the CG received usual care during their hospital stay and after discharge. This included educational and discharge planning interventions and usual follow-up, including device testing and adjustment, as needed, by a cardiac electrophysiology technician.

The PRO-CARE intervention. The aim of the PRO-CARE intervention was to facilitate ICD device acceptance by addressing specific concerns expressed by patients. It combined an adaptation of both caring-based (Watson, 2009) and Cognitive Behavioural Therapy (CBT)-based (Bandura, 1977; Dougherty et al., 2000) interventions and was designed to be transferable into regular practice with post-ICD patients. The caring-based interventions aimed to foster a trusting and helping relationship with patients in order to create an optimal environment for ICD device acceptance. The nursing intervention included identifying patient-specific ICD concerns, with a focus on their interpretation of the events.

CBT-based interventions are based on the principle that a person's emotions are more the result of his/her beliefs rather than of only the events. For example, an ICD recipient receiving a shock while walking might develop a belief that this physical activity generates shocks, which could result in anxiety and avoidance of walking. CBT-based techniques would then focus on reinterpretation of the event with the aim to reduce anxiety and avoidance. Studies have also shown that CBT has a beneficial impact on anxiety (Dunbar et al., 2012). CBT-based nursing interventions have been previously adapted for nursing practice in several studies (Dougherty et al., 2004a; Dunbar et al., 2009).

Intervention content and structure. The nurse who provided the intervention received two days of training in CBT-based nursing interventions through a continuing education program by the provincial order of nurses. This training was provided by a clinical nurse specialist in mental health and the interventions are within the scope of practice of registered nurses. PRO-CARE included three encounters: one in-hospital after consent and randomization but before discharge, and two by telephone at 7 ± 2 and 14 ± 2 days after discharge (see Table 1). The telephone encounters targeted a time when patients usually resume their ADL, which can trigger anxiety and concerns for them and their families.

The PRO-CARE nurse began by asking "What concerns you the most about your ICD?" This aimed to assess patients' concerns based on Dougherty et al.'s (2000) seven domains of post-ICD implantation concerns. These include 1) physical changes and symptoms, 2) activities, 3) emotional reactions, 4) shocks from the ICD, 5) partner relationships, 6) safety and prevention, and 7) health care providers. In response to each concern expressed by patients, the nurses used caring-based interventions based on previous work by the team (Cossette, Cote, Pepin, Ricard, & D'Aoust, 2006) and CBT-based nursing interventions based on the literature (e.g., Dougherty et al., 2004a).

The nurse used a checklist to ensure *per protocol* delivery of the experimental interventions, but tailored the interventions to address each patient's particular concerns. This checklist included 25 possible interventions divided into eight categories: 1) explore the concerns towards the ICD; 2) offer tailored counselling regarding ICD concerns; 3) assess ICD-specific consequences; 4) acknowledge and support patient's belief system and hope; 5) assess strategies

Table 1: Study Sequence

	In-hospital			***After hospitalization***		
	$-t_1$	t_0	t_1	t_2	t_3	t_4
Participants timeline	Enrolment and baseline measures	Randomization	Pre-hospital discharge	7th day	14th day	One-month measures
Control group	√	√	Usual care			√
Intervention group	**√**	**√**	**PRO-CARE**	**PRO-CARE**	**PRO-CARE**	**√**
Preliminary efficacy measures	Time of data collection					
H1 – device acceptance with the FPAS	√					√
H2 – shock anxiety with the FSAS	√					√
H3 – general anxiety with the HAD	√					√
H4- functioning with the FPI-SF	√					√

Note. Template adapted from the SPIRIT guideline (Chan et al., 2013); FPAS: Florida Patient Acceptance Survey; FSAS: Florida Shock Anxiety Survey; HAD: Hospital Anxiety and Depression scale; FPI-SF: Functional Performance Inventory Short Form.

regarding ICD concerns; 6) encourage new behaviours and autonomy; 7) go over the progress made; and 8) set a precise, realistic goal for the next encounter. The checklist was validated before the study by 16 new ICD recipients, four spouses, seven nurses, and one volunteer responsible for an ICD recipient support group (Charchalis & Cossette, 2010; Charchalis et al., 2011).

Measures

Feasibility and acceptability. While feasibility refers to the possibility of providing the intervention as planned, acceptability refers to the appropriateness of the intervention for participants and intervention providers (Feeley & Cossette, 2015; Feeley et al., 2009).

Feasibility of the experimental intervention was assessed using predetermined indicators for intervention structure and content as suggested by Feeley and Cossette (2015). Structure was documented using a research log including information on intervention sequence and duration. Content was documented using the nursing intervention checklist and the domains of patient ICD concerns list completed by the nurse after each encounter.

Acceptability of the experimental intervention was assessed with the Treatment Acceptability and Preference (TAP) measure (Sidani, Epstein, Bootzin, Moritz, & Miranda, 2009). The TAP includes four items assessing whether the intervention was perceived as appropriate, acceptable, and effective in supporting ICD device acceptance, and whether patients would be willing to participate if a similar study would be offered to them. Answers on a 5-point Likert scale ranged from "not at all" (0) to "extremely" (4). An overall question about satisfaction was added. The TAP and other scales were translated into French using the back-translation method and verified by the research team. The alpha coefficients reported by Sidani et al. (2009) ranged from 0.80 to 0.87.

Preliminary efficacy. The preliminary efficacy of the intervention was assessed by collecting outcome data at one month after discharge using a telephone questionnaire administered by a research assistant who was blinded to the study group assignment.

Hypothesis testing. Hypothesis 1 on device acceptance was assessed by the Florida Patient Acceptance Scale (FPAS) (Burns et al., 2005), which is a specific scale for this population (Dunbar et al., 2012). The FPAS includes 15 items that make the four sub-scores including return to functioning, positive appraisal, device-related distress, and body image concerns. Respondents answer on a 5-point agreement scale ranging from "strongly disagree" (1) to "strongly agree" (5). A higher score indicates higher patient acceptance of the device. Burns et al. (2005) reported an alpha coefficient of 0.83.

Hypothesis 2 on shock anxiety was assessed using the Florida Shock and Anxiety Scale (FSAS) (Kuhl, Dixit, Walker, Conti, & Sears, 2006). The FSAS includes 10 items providing a total score of shock-specific anxiety. Respondents' feelings in relation to possible ICD shocks were assessed on a 5-point Likert scale ranging from "not at all" (1) to "all the time" (5), with higher scores indicating higher anxiety. The alpha coefficient reported by Kuhl et al. (2006) was 0.91.

Hypothesis 3 on general anxiety was assessed by the seven-item anxiety sub-scale of the Hospital Anxiety and Depression (HAD) scale (Zigmond & Snaith, 1983). Response scores vary from 1 to 4 with qualifiers depending on the statement. A higher score reflects higher general anxiety. The alpha coefficient reported by Savard, Laberge, Gauthier, Ivers, and Bergeron (1998) for the anxiety subscale was 0.89.

Hypothesis 4 on functioning in ADL was assessed with the Functional Performance Inventory Short Form (FPI-SF) (Leidy, 1999; Leidy & Knebel, 2010). This questionnaire includes 32 items assessing six domains of functioning: body care, maintaining the household, physical exercise, recreation, spiritual activities, and social interactions. Respondents indicated the difficulty level of each activity: "not performed because of health difficulties (0)," "no difficulty (1)," "some difficulty (2)," "much difficulty (3)," or not applicable (NA). A score was calculated if at least 80 percent of the items in a subscale were rated on the difficulty levels. A higher score reflects higher difficulty in functioning. The alpha coefficient reported by Leidy and Knebel (2010) was 0.93.

Baseline data obtained from medical charts included gender, age, days in hospital, diagnosis, NYHA heart failure class, antecedents, comorbidities, ICD indications, type of ICD, and ejection fraction. Self-reported baseline data included marital and employment status, and education.

Sample Size and Randomization

A sample size of 15 per group (N = 30) was planned. No specific cut-off was predetermined to decide on feasibility, but we hoped to deliver all three encounters to at least 50% of the intervention group sample (Charchalis, 2012). For the hypotheses, the pilot study was not designed to attain an adequate statistical power, but to observe the direction and amplitude of the differences between the two groups in order to assess the preliminary efficacy of the intervention. Randomization occurred after informed consent, and assignment was then revealed. The randomization scheme was automatically generated by an independent statistician and was carried out using sealed opaque envelopes.

Data Analysis

Sociodemographic and clinical variables were summarized as mean and standard deviation (SD) for continuous variables and as count and percentage for categorical variables. Alpha coefficients were calculated at baseline and at one-month for the scales and the subscales. The hypotheses were tested using analysis-of-covariance (ANCOVA) models including the baseline score as a covariate. We examined the direction and amplitude of the differences between groups, as well as *p* values. *P* values ≤.05 were considered statistically significant.

Results

Reliability of the Measures

For the FPAS subscores, alphas at baseline and at one month were respectively 0.48 and 0.70 for return to functioning, 0.78 and 0.54 for device-related distress, 0.82 and 0.84 for positive appraisal, 0.88 and 0.82 for body image concerns, and 0.81 and 0.84 for the total score. At baseline and one month, alphas were respectively 0.85 and 0.86 for the total score of the FSAS, and 0.72 and 0.65 for the HAD. For the FPI-SF alphas were 0.69 and 0.46 for body care, 0.83 and 0.80 for household maintenance, 0.76 and 0.59 for physical exercise, 0.72 and 0.55 for recreation, 0.76 and 0.59 for spiritual activities, and 0.89 and 0.84 for social interactions.

Participant Flow

Recruitment started in June 2011 and ended in April 2012, including a one-month follow-up (Figure 1). Among the 284 potential participants, 223 did not meet inclusion criteria, most because they were not first-time ICD recipients (e.g., ICD box change), 17 were excluded because of logistical issues (e.g., discharge hours), and 14 refused to participate, resulting in 30 patients randomized in the experimental and control groups.

Characteristics of the Sample

As shown in Table 2, some differences were found for the sociodemographic and clinical variables. The control group included four women, while the intervention group did not include any women. The control group also had a longer length of hospital stay, a higher rate of NYHA class III (vs II), less type 2 diabetes, less previous myocardial infarction, more ICDs implanted as secondary prophylaxis, and higher ejection fraction.

Table 2: Socio-Demographic and Clinical Characteristics

	IG (N = 15) n (%) or mean (SD)	**CG** (N = 15) n (%) or mean (SD)
Sex, male	15 (100)	11 (73)
Age (yr)	60.17 (11.88)	60.42 (15.36)
Married	8 (53)	10 (67)
Not working	7 (47)	9 (60)
Education > high school	10 (67)	11 (73)
Number of days of hospitalization	2.45 (2.60)	5.26 (7.10)
Number of days of hospital stay between ICD implantation and hospital discharge	1.74 (1.10)	2.18 (1.94)
Diagnosis		
Congestive heart failure	13 (87)	12 (80)
Arrhythmia and/or sudden cardiac arrest	2 (13)	3 (20)
NYHA functional classification		
I	1 (7)	5 (33)
II	10 (67)	5 (33)
III	3 (20)	8 (50)
Not available	1 (7)	2 (13)
Antecedents-comorbidities		
Diabetes (type 2)	5 (33)	2 (13)
Previous myocardial infarction	8 (53)	4 (27)
Hypertension	7 (47)	8 (53)
Valve (stenosis, insufficiency)	8 (53)	6 (40)
Chronic renal insufficiency	2 (13)	2 (13)
ICD indications		
Primary prophylaxis	13 (87)	11 (73)
Secondary prophylaxis	2 (13)	4 (27)
Types of ICD		
Single chamber	6 (40)	6 (40)
Double chamber	2 (13)	4 (27)
Biventricular	7 (47)	5 (33)
Percent left ventricular ejection fraction	24.33 (7.57)	34.21 (14.83) [a]

Note. IG: intervention group; CG: control group; ICD: implantable cardioverter defibrillator; NYHA: New York Heart Association.
[a] n = 14.

Feasibility Results

Intervention structure. The first aspect of feasibility was assessed through the success of delivering the intervention structure as planned. The first encounter during hospitalization (mean duration of 20 minutes) was completed with all 15 experimental patients. For the post-discharge telephone calls, 14 patients were reached for the first telephone call (mean duration 22 minutes) and 13 patients were reached for the second (mean duration 19 minutes). A spouse or family member was present in eight of the 15 in-hospital encounters.

Intervention content. The second aspect of feasibility was the intervention content documented with the nursing intervention checklist and the domains of patient concerns list. Two patients told the nurse they had "no" concerns about the ICD during the first encounter, and another one had no concerns at the second telephone call. The duration of the encounters was very short for patients without any concerns (e.g., less than 10 minutes). The most prevalent concern at the in-hospital encounter was regarding ADL, such as the types of ADL to perform or to avoid, issues during the first days after returning home, and how to adapt to changes. Concerns related to physical issues (care for the scar, discomfort at the ICD site, sleeping difficulties), ICD shock, and ICD functioning were also reported by almost half of the IG patients in at least one of the three encounters. Relationships with health professionals (scheduling visits, who to call if needed) were also reported in the second and third encounters while patients were home.

Nursing interventions included exploration about the significance of and difficulties dealing with the ICD, provision of information, encouragement to discuss their feelings, reinforcement of strengths, and pointing out positive experiences.

Acceptability Results

The acceptability of the intervention, according to the TAP measure, was very strong with 12 of 15 patients in the IG indicating it was "extremely" appropriate and acceptable. The perceived efficacy of the intervention in helping patients accept the device was low for three patients who responded "not at all" and "a little". Thirteen of the 15 patients responded that they would agree to receive the intervention again. The 15 IG patients were extremely satisfied (n = 13) or very satisfied (n = 2) with the intervention.

Preliminary Efficacy of the Intervention

As presented in Table 3, although differences were minimal, most favoured the IG. In the IG, the total ICD device acceptance mean score (H1) was higher, and the shock anxiety (H2), as well as the general anxiety (H3) mean scores were lower. The general functioning in ADL mean score was lower in the IG, and this reflects lower difficulties in ADL. Not surprisingly in a pilot study, none of the differences analyzed with the ANCOVAs were statistically significant.

Discussion

This pilot study aimed to assess the feasibility and acceptability of a nursing intervention to improve ICD device acceptance, shock anxiety, general anxiety, and ADL functioning among post-ICD implantation patients. The PRO-CARE intervention was considered feasible, as more than 50% of participants received the three encounters. All 15 IG patients received the in-hospital encounter, and 14 and 13 received the first and second telephone follow-ups. The content was relevant given that 12 of the 15 IG patients reported at least one primary concern before hospital discharge; only three patients had no concerns before hospital discharge. Responses to the TAP measure indicated acceptability of the intervention.

In the ICD population, intervention duration ranged from two weeks to six months (Dunbar et al., 2012), making it challenging to choose an appropriate duration for our study intervention. To facilitate the possible use of the PRO-CARE intervention in clinical practice, we selected a dosage and duration of three interviews lasting a mean of 20 minutes each. Since providing educational and discharge planning interventions require time in usual practice, delivering these interventions in a different manner without adding time may be an interesting avenue to explore in practice. Adjusting educational and discharge intervention content to focus on patient-specific ICD concerns, similar to PRO-CARE, could result in more tailored intervention, rather than standardized discharge planning package. However, it is possible that some of the content of the PRO-CARE intervention was initiated too early for some patients, especially regarding possible ICD shock. The topic of ICD shock could be generally introduced to patients and their families during hospitalization; for instance, providing general information about what to expect and what to do in case of ICD shock. In a future study, patient-specific discussion about this topic could be offered after their return home or after a registered ICD shock in order to be tailored to the patient's concerns.

Table 3: Hypothesis Testing Results at One-Month (results of the ANCOVA analyses)

	IG (n = 15)	CG (n = 15)	*p*	95% CI
	Mean (SD)			
H1: ICD device acceptance [a]	64.77 (6.31)	61.99 (10.70)	0.715	-6.65 ; 4.63
H1a: Return to functioning	17.0 (3.16)	15.64 (4.03)	0.615	-3.48 ; 2.10
H1b: Positive appraisal	18.0 (2.72)	16.6 (3.79)	0.478	-1.23 ; 2.55
H1c: Device-related distress	21.21 (2.86)	20.64 (4.03)	0.840	-2.99 ; 2.45
H1d: Body image concerns	8.50 (2.41)	9.07 (2.02)	0.718	-1.36 ; 1.94
H2: Shock anxiety [b]	14.89 (6.31)	15.46 (7.52)	0.389	-2.87 ; 7.06
H3: General anxiety	1.87 (1.64)	3.53 (3.02)	0.103	-3.39 ; 0.33
H4: Functioning in ADL	61.80 (19.26)	62.86 (11.04)	0.803	-10.29; 13.18
H4a: Body care	13.80 (1.74)	13.47 (1.88)	0.703	-1.17 ; 1.63
H4b: Home maintenance	15.27 (7.28)	14.67 (4.85)	0.841	-3.88 ; 4.73
H4c: Physical exercise	8.80 (3.70)	9.60 (2.89)	0.462	-3.23 ; 1.51
H4d: Entertainment	9.73 (4.22)	11.33 (3.04)	0.196	-4.50 ; 0.97
H4e: Spiritual activities	3.87 (5.04)	5.33 (4.65)	0.317	-4.40 ; 1.48
H4f: Social activities	5.13 (1.51)	4.27 (2.15)	0.237	-0.59 ; 2.26

Note: IG: intervention group; CG: control group; Ns lower than 30 are due to non-response to some items precluding calculation of a total score for a particular scale.
[a] n = 28; [b] n = 27

Regarding hypothesis testing, the ANCOVAs showed no statistically significant between-group differences at the end of the study. The small sample size might explain this, but future studies should consider screening anxious patients who express concerns about the ICD to determine study eligibility in order to address more specific concerns raised in that population.

The choice of outcome measures is crucial in clinical trials. Basing our choice on the literature, we selected specific measures for ICD patients: device acceptance and shock anxiety (Burns et al., 2005, Kuhl et al., 2006). However, device acceptance levels, which were already high at baseline, may have resulted in a ceiling effect, leaving little room for improvement. Regarding shock anxiety, previous studies included patients who had already experienced an ICD shock and, therefore, may have benefited more from the intervention than in our sample patients who did not experience any shocks during the study duration.

Implications for Practice

Although pilot studies only inform on the preliminary efficacy of interventions, observations from the present study are relevant to clinical nursing practice. First, nurses could readily assess the anxiety level and beliefs of ICD recipients in order to quickly identify patients who could benefit from an intervention aimed at ICD acceptance. Assessing anxiety as part of a therapeutic relationship could be performed using open-ended questions, taking into account each patient's particular concerns and family support system, as described in the guidelines published by the Registered Nurses Association of Ontario (2006). Furthermore, by assessing logistical needs after ICD implantation (e.g., resources at home, medical follow-up, etc.), we may better target patient-specific needs. Our results also suggest that a "one-size-fits-all approach" to interventions is far from being the ideal way to address patient-specific ICD concerns (Habibovic et al., 2013). Instead, nurses could address these concerns by using a PRO-CARE-based intervention in their clinical nursing practice. Finally, because we observed that some patients were anxious while others were not, assessing specific concerns and anxiety levels in ICD recipients could be helpful in tailoring nursing interventions.

Study Limitations and Strengths

Our study had several limitations. An important limitation was the small sample size. Although adequate for a pilot study, the small sample was not representative of the general ICD population and did not allow for sufficient power for statistical testing. The baseline differences between the two groups might also be attributed to small sample size. The study did, however, have methodological strengths, including design and documentation of the intervention as recommended by CONSORT (Zwarenstein et al., 2008). We measured specific ICD outcomes as recommended for this population (Dunbar et al., 2012). Moreover, since some ICD recipients reported avoidance behaviour in the literature, we decided to assess ADL functioning—something that, to our knowledge, has not previously been done. The time required to assess baseline measures and outcomes was realistic, and participants reacted positively to the questionnaire format.

Conclusion

The PRO-CARE nursing intervention was found to be both feasible and acceptable, as a possible means of improving device acceptance and reducing anxiety in ICD recipients. Based on our findings, ICD interventions should focus on anxious patients. In addition, the optimal timing for delivery should be explored. Delivery later after discharge could possibly help patients deal with the concerns they experience once they return home. Future study interventions should be more tailored, to better deal with the specific concerns of every patient. ♥

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Acknowledgements and Funding

The authors would like to acknowledge the financial support from the Quebec Nursing Intervention Research Network, the Fonds de Recherche en Santé du Québec (FRQS), the Ministry of Higher Education of Quebec, the Faculty of Nursing of Université de Montréal, as well as from the Montréal Heart Institute Foundation and Research Centre. Finally, we would like to thank Kate Johnson for her careful manuscript editing.

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