Testing the mediating effects of self-efficacy on physical and psychological outcomes following an Implantable Cardioverter Defibrillator (ICD)

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Abstract

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Purpose/Aims: Approximately 100,000 persons with heart failure or cardiac arrhythmias receive an implantable cardioverter defibrillator (ICD) each year in the U.S. Post-ICD implant recovery requires multiple lifestyle changes that can markedly influence the recovery trajectory. Few intervention programs have been based on social-cognitive theory, and none have included the patient's significant other in intervention programs. The purpose of this study was (I) to test the mediating effects of four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge assessment), and (II) to differentiate the mediating effects of eight content-specific elements of self-efficacy (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship) on the relationship between the P+P intervention conditions and patient physical function and psychological adjustment following completion of the P+P trial at 12 months. This research was also designed to (III) compare if ICD indication (primary vs. secondary prevention)

moderated the strength of the mediation pathways from the intervention through self-efficacy to the physical function and psychological adjustment at 12 months post ICD-implant.

Methods: This was a secondary analysis based on data from a randomized clinical trial that compared two interventions: Patient+Partner (P+P) vs. Patient-Only intervention (P-Only). Data used on this study was collected at hospital discharge, 3 and 12-months post-ICD implant. Structural equation modeling (SEM) with multiple indicators was used to test for the mediating effects of the dimensions of self-efficacy and content-specific elements of self-efficacy on physical function and psychological adjustment. ANOVA was used to compare study groups/ICD indication at baseline, 3 and 12-months and across time. Multiple group SEM was used to examine for differences in models for individuals receiving an ICD for primary vs. secondary prevention of sudden cardiac arrest.

Results: Participants (N = 301) were primarily male and white with a mean age of 64.14 (11.90). Mean ejection fraction was 34.08(14.33) with ICD implanted for primary (59.8%) and secondary prevention (40.2%). The models had satisfactory to good fit indices. There was an indirect effect of self-efficacy between the paths of interventions, physical function: $\beta = 0.035$ $p = 0.07$ and psychological adjustment $\beta = 0.023$, $p = 0.07$. The interventions also showed effects on physical function ($\beta = 0.056$ $p = 0.08$) and ($\beta = 0.028$ $p = 0.07$) psychological adjustment through outcome expectation. For the content specific elements of self-efficacy, a mediation effect

between intervention condition and both psychological adjustment and physical function were observed for SE-Physical changes ($\beta = 0.053$ $p = <0.05$; $\beta = 0.028$ $p = 0.07$, respectively). The indirect effect for the mediation of SE-Relationship between intervention condition and psychological adjustment was $\beta = 0.049$ $p = 0.08$. Comparing primary vs. secondary prevention, no statistically significant differences were shown for the dimensions of self-efficacy at baseline and three-months. The dimensions of self-efficacy improved for both groups across time (all $p<0.001$) independent of ICD indication. For physical function, bodily pain scores were higher for those with ICD implanted for secondary prevention. Similarly, psychological adjustment for depression, role emotional and social functioning had higher scores for those who had a secondary prevention ICD. Across time, physical functioning, role physical and depression had the greatest improvement in secondary prevention participants. Five separate models, one for each dimension of self-efficacy, and a full model were tested. ANOVA comparisons between models yielded no differences in the structural model groups for primary vs. secondary ICD indication: (I) Self-Efficacy Model. ANOVA $\chi^2_{diff} = 32.4$, $df_{diff} = 33$, $p = 0.50$); (II) Outcome Expectations Model. ANOVA $\chi^2_{diff} = 42.22$, $df_{diff} = 33$, $p = 0.13$; (III) Self-Management Behavior Model. ANOVA $\chi^2_{diff} = 40.79$, $df_{diff} = 33$, $p = 0.16$; (IV) ICD Knowledge Model. ANOVA $\chi^2_{diff} = 40.60$, $df_{diff} = 33$, $p = 0.17$; (V) Full Model (SE + OE + SMB + KSA). ANOVA $\chi^2_{diff} = 45.15$, $df_{diff} = 48$, $p = 0.59$.

Conclusion: For Aim 1, the effect of the P+P intervention vs. the P-only intervention on physical function and psychological adjustment was mediated by self-efficacy and by outcome expectations. For Aim 2, we observed that in the content-specific elements of self-efficacy analyses, the mediation pathways for psychological adjustment were with SE-physical changes and SE-relationship. For physical function, mediation was through SE-physical changes. For Aim 3, the hypothesized model describing the dimensions of self-efficacy mediation pathways between the interventions with physical function and psychological adjustment was similar for patients who received an ICD for either primary or secondary prevention of cardiac arrest. However, outcome trajectories differed by ICD indication, patients with an ICD implanted for secondary prevention had better physical (bodily pain) and psychological outcomes (depression, role emotional and social function). In addition, over 12-months period secondary prevention participants had sharpest improvement on physical functioning, role physical and depression.

Dedication

I dedicate my PhD dissertation to my mother (Elisabete C S Liberato), father (Jeronimo A Liberato) and my beloved husband (Alessandro Longhi).

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CHAPTER 1: INTRODUCTION

Background and Significance

Annually, more than 100,000 people in the United States receive an implantable cardioverter defibrillator (ICD). While the devices were initially developed for secondary prevention for survivors of sudden cardiac arrest (SCA) or individuals with recurrent unstable rhythms, science and technology advancements have led to increased numbers of patients receiving an ICD. The European and American guidelines assigned a class I recommendation to provide prophylactic ICD therapy for patients with heart failure and reduced ejection fraction.[1-3]

Most people who receive an ICD implant have difficulties with respect to physical and psychological adjustment to the device during the first year post-implant, including problems related to physical function and mental health (anxiety and depression).[4-6] Post-ICD implant recovery requires multiple lifestyle changes, including the acquisition of knowledge regarding living safely and successfully with the ICD, implementation, and self-monitoring of routine exercise, and learning to manage feelings of depression and anxiety that can markedly influence the recovery trajectory.[6,7,9]

Several intervention programs have been tested to improve physical and psychological health after ICD implant. Irvine and colleagues[8] developed a cognitive behavioral (CBT) intervention for first-time ICD patients to prevent anxiety and depression.[8] Significant reductions in anxiety and depression were found in participants randomized to the CBT group, with the effects of the intervention sustained over a 12-month follow-up. Crössmann and colleagues[9] created a psychosocial intervention focusing on anxiety management in first-time ICD recipients. Overall the effect of the intervention for anxiety was not statistically significant, but a subgroup of patients less than 65 years old reported reduced anxiety in contrast to those older than 65.[9] Kohn and colleagues[10] also developed an intervention based on CBT for reducing psychological distress (anxiety and depression) and lowering the incidence of arrhythmic events

that required ICD shocks in first-time recipients. CBT was associated with decreased depression and anxiety, and improved adjustment for illness for ICD recipients.[10]

In a separate line of research, Dougherty developed a psycho-educational intervention for first-time ICD patients following SCA based on social cognitive theory.[11,12] Self-efficacy, a core concept of Social Cognitive Theory, is the individual's belief in his or her capacity to execute behaviors necessary to produce a specific outcome.[13,14] Self-efficacy has been used as an effective framework for developing health behavior change interventions in cardiac patients.[15-17] Dougherty designed an intervention initially for the patient with ICD, which was tested in a randomized clinical trial.[18,19] The findings demonstrated that the ICD intervention, delivered by cardiovascular nurses, had a positive, statistically significant and sustained influence on physical and psychosocial outcomes.[18,19]

Recently, Dougherty[20] expanded the original ICD intervention, based on social cognitive theory, to assist both patients with ICDs and their partners in adjusting to the device, improving physical function, and enhancing psychological adjustment during the first year of recovery.[20,21] This study included two groups of ICD patients (n = 301 patient-partner pairs); in one group only the patient received an intervention (P-Only), in the other group both the patient and his/her partner received an intervention (P+P). Data were collected at baseline, 1, 3, 6 and 12-months post-ICD implantation. The intervention development was initially described by Dougherty et al. (2012).[20] Three foundational studies were described along with the rationale for testing the intervention on a larger scale with patients who received an ICD and their partners. In the first study, grounded theory methodology generated the domains of concern for patients and partners to guide the development of the P+P intervention. The second study[22] focused on intimate partners and described their mental and physical health. Most indicators of the psychological and physical health of partner were affected up to 3-months after hospital discharge. The third study[20] was a pilot test of the partner intervention, focused on partner concerns, physical, psychological health, and caregiving demands. The findings of this pilot study demonstrated feasibility,

acceptability, and potential efficacy of the intervention. Patients with ICDs reported reductions in symptoms and concerns at three-months, as well as reductions in anxiety and depression. Improvement was observed in patient self-efficacy expectations, outcomes expectations, and knowledge post-intervention.

While these intervention studies produced promising results, critical theoretical gaps exist, particularly with respect to understanding the mechanisms by which the interventions might influence physical and psychological outcomes. Thus, an initial step is to understand if self-efficacy serves as a mediator between the intervention and designated health outcomes. Understanding is needed regarding *which* intervention components play a pivotal role in promoting self-efficacy and outcome improvements, and if the reason the ICD was implanted serves to moderate responses to the intervention. Generating such knowledge will contribute to the tailoring of interventions for individuals, thereby reducing costs by increasing the precision of interventions and reducing patient burden associated with unnecessary intervention activities.

Social Cognitive Theory

In need of an intervention to improve physical and psychological outcomes for patients and intimate partners after ICD implantation, Dr. Dougherty developed the P-Only and P+P interventions based on domains of concern of patients[7] and partners[23] using elements of Social Cognitive theory (SCT).[15] SCT specifies a core set of determinants and the optimal ways of translating this knowledge into effective health behavior (Figure 1.1). The core determinants include *knowledge* of health risks and benefits of different health practices, *perceived self-efficacy* that one can exercise control over one's health habits, *outcome expectations* about the expected costs and benefits for different health habits, the health *goals* people set for themselves and the concrete plans and strategies for realizing them, and the *perceived facilitators* and social and structural *impediments* to the changes they seek.[13,14]

Self-efficacy is a central main concept of SCT. Self-efficacy is an individual's conviction in one's ability to perform a particular behavior that is required to achieve a certain outcome.[13-15] Self-efficacy is considered the foundation of human motivation and accomplishments, and it was demonstrated in studies the positive impact of self-efficacy on cardiovascular-related lifestyle changes.[24,25]

To change and maintain a behavior and achieve a designated outcome, SCT requires directed efficacy expectations, outcome expectations, and person characteristics.[13] *Self-efficacy expectations* are the person's belief in his or her self-confidence to carry out a specific behavior. *Outcome expectations* are the beliefs that carrying out a specific behavior will lead to a given outcome. Outcome expectations take three forms: 1) physical effects that accompany behavior such as pleasant sensory experiences or physical discomfort, 2) social reactions such as expressions of interest, social recognition, or social status, and 3) self-evaluative influences such as self-sanctions, self-satisfaction, and self-worth. The motivating influence of outcome expectations is directed in part by self-efficacy beliefs. The willingness of an individual to engage in a certain behavior is related to the positive benefits expected if the behavior is performed.[14] Outcome expectations are important to consider when changing behavior. However, efficacy expectations explain the majority of the variance and have greater predictive power on overall outcomes in behavior change.[13]

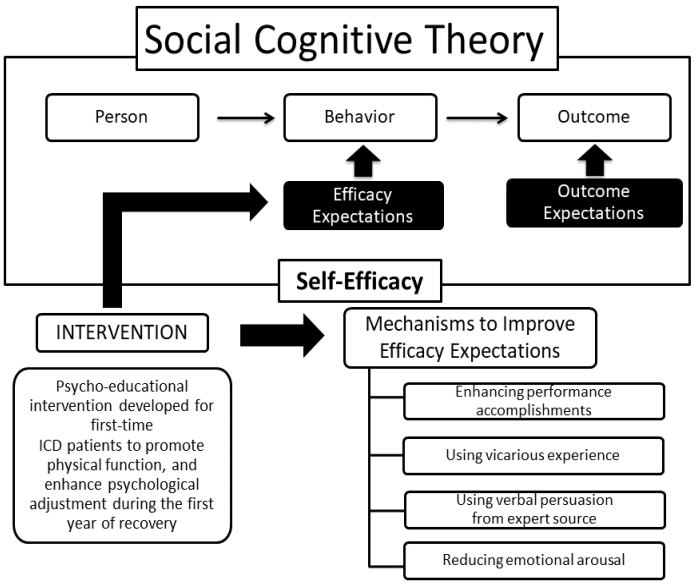

Figure 1.1 Self-Efficacy Theory and P+P Intervention

Bandura argues that, at the individual level, self-efficacy can be facilitated through four primary mechanisms: 1) *Enhancing performance accomplishments* - success develops based on one's ability to

perform an activity, 2) *Vicarious Experiences* - seeing others succeed enhances confidence that one can also succeed, 3) *Verbal persuasion* - experts convey confidence in your capability and 4) *Reducing (physical and emotional) arousal* – controlling the physical and emotional state in order to reduce stress, fatigue, and depression.[13,15] Taken together, these mechanisms help to curb anxiety, fear, and bodily stress reactions, and improve one's belief in the ability to produce desired results by their own actions..[14,15] Both the P-Only and P+P interventions incorporate four SCT mechanisms to promote self-efficacy (Figure 1.1). Thus, self-efficacy, facilitated by multiple strategies, was posited as the general mechanism by which the interventions would impact health outcomes.

Literature Review: ICD-related Interventions to Improve Physical Function and Psychological Adjustment

Between 1989 and the present, 20 psychological-educational interventions were developed and tested to improve outcomes for patients with an ICD (Appendix 1).[9,10,18,19,26-42] The majority of studies were randomized clinical trials (RCT), followed by cross-sectional and convenience studies. The sample size ranged from 12 to 289 participants. There is a range of interventions from support groups, phone counseling, cognitive behavior therapy (CBT), social cognitive theory booklets, self-management, relaxation technics, mindfulness, cognitive behavioral stress management, and most recently web-based programs. Interventions were applied in a single day, with a duration of 3, 6, 10, 12 weeks, with follow-ups for up to a year. The main outcomes of these studies were: anxiety, depression, quality of life, stress, anger, distress, post-traumatic stress disorder (PTSD) symptoms, ICD concerns, knowledge, ICD tolerance, ICD acceptance, health-care costs, missed work, symptoms, arrhythmia, hospitalization, ER visits, and ICD shocks. The purpose of each intervention study and the related results are described below.

In 1997, Sneed and colleagues[39] tested a multicomponent intervention completed by psychological nursing practitioners, including telephone calls and a support group on the outcomes of mood and psychosocial adjustment. The intervention included a pre-implantation evaluation, with follow-up telephone calls for eight weeks, and two support group sessions. There was no statistically significant difference between intervention and control groups on anxiety and mood at four-months.

In 2000, Kohn and colleagues[10] tested a CBT intervention in ICD patients (N = 49) receiving the device for secondary prevention. The intervention was composed of nine 60-minute sessions over five-months. At nine-months, depression, anxiety and sexual difficulty showed statistically significant improvement in the CBT group compared with the control group. The greatest effects of the intervention were in those who received an ICD shock.

Carlsson and colleagues [40] designed a pilot study intervention for patients (N = 20) one-month after receiving an ICD for secondary prevention. The intervention consisted of a preoperative visit by a registered nurse with a follow-up telephone call two-weeks following implant to check on the patient's health status and to deliver an educational intervention. Participants were randomly allocated in two groups (intervention x control). Sleep disturbances decreased by two-weeks in the intervention group. However, there were no between-group or within- group differences associated with the intervention on the Nottingham Health Profile or an author-derived health profile.

Fitchet and colleagues[26] targeted ICD patients (N = 16) 12 weeks after the implantation with a combined cardiac rehabilitation with a CBT intervention. This randomized control trial consisted of an aerobic exercise intervention combined with education, group support, and CBT self-help sessions performed two-hours per week for six-weeks. At 12 weeks, exercise time in the intervention group improved significantly, while anxiety and depression were reduced significantly. A study limitation was the high dropout rate, which resulted in only 16 patients participating in the intervention.

Frizelle and colleagues[27] initially tested the effects of 6 weekly two-hour CBT sessions with 21 participants with an ICD implanted for secondary prevention. Patients were randomized to immediate treatment or a wait list control group. The intervention significantly reduced anxiety, depression, ICD concerns, quality of life, and shuttle walk distance. The study was further expanded[31] to an ICD education plan, which included 2 booklets, a diary, a relaxation tape, and 4 CBT self-help telephone calls delivered before ICD implantation and at 1, 3, and 6 weeks post-implant. Results were evaluated at six-months with the intervention group, compared to usual care, showing significant improvements in physical health and physical limitations, more cost-effectiveness, and a lower hospitalization rate. The intervention did not significantly reduce anxiety, depression, or ICD shocks.

Dougherty and colleagues[18,19] tested in a randomized clinical trial (n = 168, 84 participants/group) an intervention based on the social cognitive theory in ICD recipients for secondary prevention. The intervention consisted of an 8-weeksof weekly nurse coaching and education calls, booklet, and a 24-hour pager for support. Compared to usual care, the intervention reduced concerns at 1 month and improved knowledge at three-months. There were no differences between groups regarding anxiety, depression, ICD shocks, or quality of life. At 12-months, there was a significant reduction in symptoms and anxiety and increased knowledge and self-efficacy in the intervention group. There was no significant impact on ICD shocks.

Chevalier and colleagues[28] compared six sessions of CBT delivered over 12 weeks. The CBT group (N = 35) compared to the no-treatment control group (n = 35) had higher heart rate variability, lower anxiety, and fewer ICD shocks. The results were sustained at 12-months for heart rate variability and anxiety. The intervention did not impact changes in depression or quality of life. The dropout rate was high (67%), with only 11 patients in each group contributing data at the 12-month follow-up.

Sears and colleagues [29] tested the for the effects of two stress management interventions in 30 participants after an ICD shock. The two interventions were: 1) CBT stress management intervention

delivered by psychologists over six-weeks in 90-minute sessions, for an average of nine-hours of intervention per participant, and 2) a one-day (four-hour) stress management workshop. There was no control group. Anxiety was significantly reduced in the CBT group. No significant differences were noted between the two interventions regarding depression, acceptance of the ICD, physical or mental health, salivary cortisol levels, or inflammation. Both interventions had a significant effect in reducing physiological and psychological markers of distress. However, the CBT intervention showed a greater reduction in anxiety.

Smeulders and colleagues[30] developed a pilot study for first-time ICD recipients (N = 10) to test a 6-week, nurse-delivered, group self-management intervention. This was a feasibility study using a single group pre-test/post-test design. Although no statistical significance was found after the intervention, anxiety, depression, and health-related quality of life outcomes trended toward improvement.

Dunbar and colleagues[32] targeted primary and secondary prevention patients (N = 246) to test a psychoeducational intervention, delivered either in four group or individual telephone counseling sessions, against usual care. The intervention consisted of one educational session delivered in the hospital, followed by post-hospitalization structured coping skills training and education using the two CBT formats, followed by an additional booster group/telephone call at four to five months. The intervention using the group format had lower anxiety and depression. No significant differences were observed between groups regarding physical functioning. Participants in the usual care group had higher probability of having depressive symptoms when compared to the intervention groups at 12-months. In addition, the usual care group reported more missed days from work at 12-months, and more telephone calls to their providers at one and six months than did the intervention groups.

Crossmann and colleagues[9] targeted patients (N = 119) who had received an ICD for secondary prevention in a randomized controlled trial with two study conditions, usual care (N = 63) and additional psychological treatment (N = 56). The intervention included a psychological component designed to

reduce anxiety, delivered via a booklet, and six months of individual phone counseling. Support calls were semi-structured and focused on living with an ICD, reducing avoidance behavior associated with the ICD, and increasing exercise, and self-efficacy. There were no significant intervention group effects on anxiety, depression, symptoms, quality of life, cardiac anxiety, or ICD attitudes. However, for those younger than 65 years of age, significant improvements were observed in anxiety, symptoms, and quality of life.

Irvine and colleagues[33] targeted hypertrophic cardiomyopathy patients (N = 193) with a first time ICD implantation, using a two-group (experimental vs. control) intervention design. The intervention included eight telephone session and a booklet with relaxation exercises. Significant reductions were observed in PTSD, avoidance symptoms, and improvements in depression and mental health, but no differences were observed between treatment conditions on ICD therapies during follow-up.

Berg and colleagues[43] developed the COPE study which included first-time ICD recipients (n = 196) three-months following implantation. The intervention had two components: 1) exercise training (aerobic and resistance) for 12 weeks for one-hour twice a week and 2) psychological, educational component once a month for six months and then two times a month through one year. There was an improvement in the SF-36 mental component scale and general health, in addition to the reduced number of ICD shocks and lower mortality in the intervention group over three-years.

Russell and colleagues[35] developed an intervention for participants (N = 83) who had had an ICD implant for at least three-months. The study compared the effects of the 10-week cognitive behavioral stress management to “Patient Education”. The stress management intervention compared to the active control, resulted in decreases in anxiety, anger, and perceived stress. However, the results were not sustained at the 6-months follow-up. There was no significant intervention effect on cardiac autonomic, hemodynamic responses, or cardiac arrhythmias or mental stress (anxiety, anger, and perceived stress).

Ford and colleagues[42] pilot tested in pre-post test study an intervention with 46 ICD patients who had elevated symptoms of PTSD. The psychosocial internet-based intervention was a single group study which included an evidence-based cognitive behavioral protocol for PTSD, which included four treatment modules of 30-60 minutes duration. The study purpose was to test the acceptability of the web-based intervention, and to examine for change in PTSD symptoms, general mental health, device acceptance and shock anxiety. PTSD symptoms were statistically reduced. The authors point to the need for future studies and noted that web-based intervention might be an effective supplemental therapy for this population.

In summary, four main intervention approaches have been tested with patients with an ICD: (I) Educational and Support, (II) CBT, (III) Stress Management and (IV) Internet-Based Interventions:

(I) *CBT* is the most common intervention approach used [10,26-29,31,32] and has been associated with improvement in anxiety, depression, ICD concerns, quality of life, and ICD shocks in patients with ICD. Several studies however, had high drop-out rates.

(II) *Education and support interventions*[9,18,19,30,34,39,40] for patients with ICD have shown stronger effects on anxiety than on depression, and were associated with improvements in self-efficacy and symptoms. More recently, the sample sizes of studies being conducted have increased, though no studies have had samples of more than 290 participants. *Support Group only intervention* was used in three studies.[37,38,41] These studies were conducted in the early 1990s, used non-randomized designs, small sample sizes, often lacking reported adherence and adequate intervention descriptions, thus precluding replication.

(III) *Stress management interventions*[33,35] yielded reductions in anxiety, depression, anger, and perceived stress, as well as increases in quality of life, producing the most robust results for decreases in psychological distress, improvement in the quality of life, and teaching skills for living successfully with an ICD.

(IV) *Internet-Based Intervention.* Two recent studies focused on web-based intervention delivery. First, Habibovic and colleagues[36] developed an the WEBCARE intervention, the first internet-based intervention developed for first-time ICD recipients. The randomized controlled trial had 249 participants comparing intervention to the control group. The intervention didn't have significant improvements in anxiety, depression, and quality of life when compared to controls. Second, Ford[42] and colleagues published a pilot study (N = 46) showing that internet-based intervention focusing on CBT for PTSD patients might help to reduce PTSD symptoms.

A broad range of interventions approaches have been used to achieve similar physical and psychological outcomes for patients receiving an ICD. It is necessary to understand which of these interventions strategies leads to achieving positive and sustained outcomes, in order to tailor and streamline interventions by including only those components with the greatest potential impact. Such modifications will be cost-effective and practical for clinical practice, promoting higher acceptability within healthcare systems, and effective integration into care protocols for patients with an ICD.

Dissertation Research Aims

The overall purpose of this study was to understand the mechanisms by which the P-Only and P+P interventions might affect physical and psychological outcomes in ICD patients through *dimensions of self-efficacy* and identified *content-specific elements of self-efficacy*. In addition, it is important to understand if outcomes and mediation pathways differ based on ICD indication (primary vs. secondary prevention). Thus, this dissertation was designed to address the following research aims:

- **AIM 1**. Test the mediating effects of four *dimensions of Self-Efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge) on the relationship between

the interventions (P+P and P-only) and patient physical function and psychological adjustment at 12-months.

- **AIM 2.** Differentiate the mediating effects of *content-specific elements of self-efficacy* (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship) on the relationship between the intervention and patient physical function and psychological adjustment at 12-months.
- **AIM 3**. Determine if different ICD indication (primary vs. secondary) would present difference intervention effects on *dimensions of self-efficacy* (self-efficacy, outcome expectations, self-management behavior, and ICD knowledge), patient physical functioning and/or psychological adjustment at 12-months.

In this dissertation, the research aims are presented as separate research papers. ***Chapter 2*** includes the abstract, introduction and methods used in testing the mediating effects of four dimensions of self-efficacy (**Aim1)**, and the content-specific elements of self-efficacy (**Aim 2**) on physical function and psychological adjustment. ***Chapter 3*** presents the results and discussion for Aim 1 (*dimensions of self-efficacy*), and ***Chapter 4*** reports on the findings and discussion related to Aim 2 (content specific elements of self-efficacy). ***Chapter 5*** details findings for Aim 3, an examination of the potential moderating effects of ICD indication (primary vs. secondary prevention) on the relationship between the *dimensions of self-efficacy* and *physical function* and psychological adjustment (**Aim 3**). ***Chapter 6***, the final chapter, summarizes the study findings for each aim, identifies directions for future research, and specifies implications for nursing science and practice.

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REFERENCES

1. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *European Heart Journal.* 2016.
2. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;62(16):e147-239.
3. Kolodziejczak M, Andreotti F, Kowalewski M, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy A Systematic Review and Meta-analysis. In. *Ann. Intern. Med.* Vol 1672017:103-111.
4. Sears SF, Todaro JF, Lewis TS, Sotile W, Conti JB. Examining the psychosocial impact of implantable cardioverter defibrillators: a literature review. *Clin Cardiol.* 1999;22.
5. Bainger EM, Fernsler JI. Perceived quality of life before and after implantation of an internal cardioverter defibrillator. *American journal of critical care : an official publication, American Association of Critical-Care Nurses.* 1995;4(1):36-43.
6. Dunbar SB. Psychosocial issues of patients with implantable cardioverter defibrillators. *Am J Crit Care.* 2005;14(4):294-303.
7. Dougherty CM, Benoliel JQ, Bellin C. Domains of nursing intervention after sudden cardiac arrest and automatic internal cardioverter defibrillator implantation. *Heart Lung.* 2000;29(2):79-86.
8. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosom Med.* 2011;73(3):226-233.
9. Crossmann A, Schulz SM, Kuhlkamp V, et al. A randomized controlled trial of secondary prevention of anxiety and distress in a German sample of patients with an implantable cardioverter defibrillator. *Psychosom Med.* 2010;72(5):434-441.
10. Kohn CS, Petrucci RJ, Baessler C, Soto DM, Movsowitz C. The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. *Pace.* 2000;23.
11. Dougherty CM, Pyper GP, Frasz HA. Description of a nursing intervention program after an implantable cardioverter defibrillator. *Heart Lung.* 2004;33(3):183-190.
12. Dougherty CM, Johnson-Crowley NR, Lewis FM, Thompson EA. Theoretical development of nursing interventions for sudden cardiac arrest survivors using social cognitive theory. *ANS Adv Nurs Sci.* 2001;24(1):78-86.
13. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977;84(2):191-215.
14. Bandura A. *Self-efficacy : the exercise of control.* New York: New York : W.H. Freeman; 1997.

15. Bandura A. *Social foundations of thought and action : a social cognitive theory.* Englewood Cliffs, N.J.: Englewood Cliffs, N.J. : Prentice-Hall; 1986.
16. Rajati F, Mostafavi F, Sharifirad G, et al. A theory-based exercise intervention in patients with heart failure: A protocol for randomized, controlled trial. *J Res Med Sci.* 2013;18(8):659-667.
17. Meland E, Maeland JG, Laerum E. The importance of self-efficacy in cardiovascular risk factor change. *Scand J Public Health.* 1999;27(1):11-17.
18. Dougherty CM, Thompson EA, Lewis FM. Long-term outcomes of a telephone intervention after an ICD. *Pacing Clin Electrophysiol.* 2005;28(11):1157-1167.
19. Dougherty CM, Lewis FM, Thompson EA, Baer JD, Kim W. Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. *Pacing Clin Electrophysiol.* 2004;27(12):1594-1602.
20. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and testing of an intervention to improve outcomes for partners following receipt of an implantable cardioverter defibrillator in the patient. *ANS Adv Nurs Sci.* 2012;35(4):359-377.
21. Dougherty C, Fairbanks A, Eaton L, Morrison M, Kim M, Thompson E. Comparison of patient and partner quality of life and health outcomes in the first year after an implantable cardioverter defibrillator (ICD). *Journal of Behavioral Medicine.* 2016;39(1):94-106.
22. Dougherty CM, Thompson EA. Intimate partner physical and mental health after sudden cardiac arrest and receipt of an implantable cardioverter defibrillator. *Research in nursing & health.* 2009;32(4):432-442.
23. Dougherty CM, Pyper GP, Benoliel JQ. Domains of concern of intimate partners of sudden cardiac arrest survivors after ICD implantation. *The Journal of cardiovascular nursing.* 2004;19(1):21-31.
24. Woodgate J, Brawley LR, Weston ZJ. Maintenance Cardiac Rehabilitation Exercise Adherence: Effects of Task and Self-Regulatory Self-Efficacy. *Journal of Applied Social Psychology.* 2005;35(1):183-222.
25. Taylor CB, Bandura A, Ewart CK, Miller NH, Debusk RF. Exercise testing to enhance wives' confidence in their husbands' cardiac capability soon after clinically uncomplicated acute myocardial infarction. *The American Journal of Cardiology.* 1985;55(6):635-638.
26. Fitchet A, Doherty PJ, Bundy C, Bell W, Fitzpatrick AP, Garratt CJ. Comprehensive cardiac rehabilitation programme for implantable cardioverter-defibrillator patients: a randomised controlled trial. *Heart.* 2003;89(2):155-160.
27. Frizelle DJ, Lewin RJ, Kaye G, et al. Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: a pilot study. *Br J Health Psychol.* 2004;9(3):381-392.

28. Chevalier P, Cottraux J, Mollard E, et al. Prevention of implantable defibrillator shocks by cognitive behavioral therapy: A pilot trial. *American Heart Journal.* 2006;151(1).
29. Sears SF, Sowell LD, Kuhl EA, et al. The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. *Pacing Clin Electrophysiol.* 2007;30(7):858-864.
30. Smeulders ESTF, van Haastregt JCM, Dijkman-Domanska BK, van Hoef EFM, van Eijk JT, Kempen GIJM. Nurse- and peer-led self-management programme for patients with an implantable cardioverter defibrillator; a feasibility study. *BMC Nursing.* 2007;6(1):6.
31. Lewin RJ, Coulton S, Frizelle DJ, Kaye G, Cox H. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. *Heart.* 2009;95(1):63-69.
32. Dunbar SB, Langberg JJ, Reilly CM, et al. Effect of a Psychoeducational Intervention on Depression, Anxiety, and Health Resource Use in Implantable Cardioverter Defibrillator Patients. *Pacing and Clinical Electrophysiology.* 2009;32(10):1259-1271.
33. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosomatic medicine.* 2011;73(3):226.
34. Berg SK, Pedersen PU, Zwisler AD, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology.* 2015;14(1):34-44.
35. Russell DC, Smith TL, Krahn DD, et al. Effects of Cognitive Behavioral Stress Management on Negative Mood and Cardiac Autonomic Activity in ICD Recipients. *Pacing Clin Electrophysiol.* 2015;38(8):951-965.
36. Habibovic M, Denollet J, Cuijpers P, et al. Web-based distress management for implantable cardioverter defibrillator patients: A randomized controlled trial. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2017;36(4):392-401.
37. Badger JM, Morris PL. Observations of a support group for automatic implantable cardioverter-defibrillator recipients and their spouses. *Heart & lung : the journal of critical care.* 1989;18(3):238.
38. Molchany CA, Peterson KA. The psychosocial effects of support group intervention on AICD recipients and their significant others. *Progress in cardiovascular nursing.* 1994;9(2):23.

39. Sneed NV, Finch NJ, Michel Y. The effect of psychosocial nursing intervention on the mood state of patients with implantable cardioverter defibrillators and their caregivers. *Progress in cardiovascular nursing.* 1997;12(2):4.
40. Carlsson E, Olsson SB, Hertervig E. The Role of the Nurse in Enhancing Quality of Life in Patients With an Implantable Cardioverter-Defibrillator: The Swedish Experience. *Progress in cardiovascular nursing.* 2002;17(1):18-25.
41. Dickerson SS, Wu Y, Kennedy MC. A CNS-facilitated ICD support group - A clinical project evaluation. *Clin Nurse Spec.* 2006;20(3):146-153.
42. Berg SK, Svendsen JH, Zwisler AD, et al. COPE-ICD: a randomised clinical trial studying the effects and meaning of a comprehensive rehabilitation programme for ICD recipients -design, intervention and population. *BMC Cardiovasc Disord.* 2011;11:33.
43. Berg SK, Pedersen PU, Zwisler A-D, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European Journal of Cardiovascular Nursing.* 2015;14(1):34-44.
44. Christensen AV, Zwisler AD, Svendsen JH, et al. Effect of cardiac rehabilitation in patients with ICD: are gender differences present? Results from the COPE-ICD trial. *Pacing Clin Electrophysiol.* 2015;38(1):18-27.
45. Berg SK, Støier L, Moons P, Zwisler AD, Winkel P, Ulrich Pedersen P. Emotions and health: findings from a randomized clinical trial on psychoeducational nursing to patients with implantable cardioverter defibrillator. *The Journal of cardiovascular nursing.* 2015;30(3):197-204.

CHAPTER 2: AIMS 1 & 2 BACKGROUND & METHODS: TESTING THE MEDIATING EFFECTS OF DIMENSIONS OF SELF-EFFICACY AND CONTENT-SPECIFIC ELEMENTS OF SELF EFFICACY ON PATIENT PHYSICAL AND PSYCHOLOGICAL OUTCOMES FOLLOWING RECEIPT OF AN ICD

ABSTRACT

Purpose/Aims: Approximately 100,000 persons with heart failure or cardiac arrhythmias receive an implantable cardioverter defibrillator (ICD) each year in the U.S. Post-ICD implant recovery requires multiple lifestyle changes that can markedly influence the recovery trajectory. Few intervention programs have been based on social-cognitive theory, and none have included the patient's significant other in intervention programs. The purpose of this study was (I) to test the mediating effects of four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge assessment), and (II) to differentiate the mediating effects of eight content-specific elements of self-efficacy (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship) on the relationship between the P+P intervention conditions and patient physical function and psychological adjustment following completion of the P+P trial at 12 months.

Methods: This was a secondary analysis based on data from a randomized clinical trial that compared two interventions: Patient+Partner (P+P) vs. Patient-Only intervention (P-Only). Data used on this study were collected at hospital discharge, 3 and 12-months post-ICD implant. Structural equation modeling (SEM) with multiple indicators was used to test for the mediating effects of the *dimensions of self-efficacy* and content-specific elements of self-efficacy on physical and psychological outcomes.

Results: Participants (N = 301) were primarily male and white with a mean age of 64.14 (11.90). Mean ejection fraction was 34.08(14.33) with ICD implanted for primary (59.8%) and secondary prevention (40.2%). The models had satisfactory to good fit indices. There was an indirect of self-efficacy between the paths of interventions, physical function : $\beta = 0.035$ $p = 0.07$ and psychological adjustment $\beta = 0.023$, $p = 0.07$. The interventions also showed effects on physical ($\beta = 0.056$ $p = 0.08$) and ($\beta = 0.028$ $p = 0.07$) psychological outcomes through outcome expectation. For content specific elements of self-efficacy, there was a mediation effect between interventions and psychological adjustment by SE-Physical changes (: $\beta = 0.053$ $p = <0.05$), on physical function ($\beta = 0.028$ $p = 0.07$). The mediation paths between the interventions and psychological adjustment through SE-Relationship showed an indirect effect: $\beta = 0.049$ $p = 0.08$.

Conclusion: For Aim 1, the effects of P+P vs. the P-only intervention were mediated by self-efficacy and outcome expectations on physical function and psychological adjustment. For Aim 2, we observed for content specific self-efficacy that the intervention mediation paths on psychological adjustment were SE-physical changes and SE-relationship. For physical function, mediation was through SE-physical changes.

INTRODUCTION

Background

Annually, more than 100,000 people in the United States receive an implantable cardioverter defibrillator (ICD). The ICD was developed for those who are survivors of sudden cardiac arrest (SCA), have recurrent unstable rhythms, or as prophylactic therapy for patients with heart failure and reduced ejection fraction.[1,2,44]An ICD reduces all-cause mortality by 50% in SCA compared to patients receiving optimal medical treatment without an ICD implant. ICDs are effective in prolonging the lifespan of patients with life-threatening cardiac conditions.[45-50]

Many people who receive an ICD implant experience a period of adjustment with respect to their physical and psychological health during the first year post-implant (anxiety and depression).[4-6] It is common for patients with an ICD have physical symptoms after the implantation; the most common symptoms are palpitations, chest pain, dyspnea, sleep disturbances, loss of libido, and fatigue.[51,52] It is expected that symptoms will be alleviated over-time.[51] The most common psychological issues are increased anxiety and depression before ICD implantation, at three months after implantation, and some persistent symptoms over time, including the development of posttraumatic disorders.[4,53,54] Other research also demonstrates that anxiety impacts 13% to 45% of this population, [48,53,55-58] and that depression incidence of 10% to 46%.[48,53,58-60] These problems seem to be associated with the process of accommodating to an ICD implant. Studies show patients might take 3.6 months to become accustomed to an implanted ICD, with anxiety and depression higher during the first six months after implant.[4,54]

After an ICD implant, patients and their family members need to understand the new knowledge about their health condition, deal with the experience of arrhythmia treatment and device-related shocks, understand the physical, emotional and relationship changes.[45,53,61,62] Furthermore, post-ICD implant recovery requires multiple lifestyle changes, including the acquisition of knowledge regarding living safely and successfully with the ICD, implementation, and self-monitoring of routine exercise, and learning to manage feelings of depression and anxiety that can markedly influence the recovery trajectory.[6,7,9]

Patient Plus Partner Trial, the P+P Study

Dougherty et al. developed a psycho-educational intervention for first-time ICD patients following SCA based on Social Cognitive Theory (SCT).[11,12] A core concept of SCT is self-efficacy.[13,14] Self-efficacy has been used as an effective framework for developing health behavior change interventions.[15-17] In a randomized clinical trial, Dougherty demonstrated that the ICD intervention, delivered by cardiovascular nurses, had a significant and sustained influence on physical and psychosocial outcomes.[18,19]

Recently, Dougherty[20,63] expanded the original ICD intervention to assist both patients and their intimate partners in adjusting to the ICD, improving physical function, and enhancing psychological adjustment during the first year of recovery.[20,21,63] The patient P+P intervention was based on domains of concern of both patients[7] and partners[23] using elements of SCT.[15] The intervention goals were to assist patients to 1) manage physical symptoms and changes, 2) return to performance of activities of daily living and safe activity, 3) exercise safely with an ICD, 4) control anxiety and depression, 5) manage ICD shocks, 6) perform preventive ICD care, 7) obtain information related to ICD care, and 8) learn when to activate the emergency medical system.[63] P+P goals also included engaging the intimate partners in the recovery process to enhance patient outcomes.

The recent P+P study, a two-group randomized longitudinal design, compared the effects of a patient-only versus a patient + partner intervention from baseline (hospital discharge) to three-months. After baseline data were collected, subjects were randomized to either intervention condition stratified by baseline ICD indication.[22] A computerized program generated balanced randomization taking into account the reason for receiving an ICD, age, gender, and the Charlson co-morbidity index. The randomization algorithm used a modification of the minimization method described by Pocock.[64] Participants received intervention materials after they have completed the baseline questionnaires. For all patients, the *Nurse Telephone Support (NTS)* began the first week after hospital discharge and concluded with a final phone call at 12 weeks. Subjects reviewed *video segments* in association with the NTS calls. The *nurse pager* was available 24 hours/day for 1-year for questions or concerns that arose in between the planned phone calls. Partners participating in the *Partner Telephone Group (PTG) intervention* began the telephone group the same week as the NTS protocol that concluded at 12 weeks. All participants completed a battery of measurements at the same time periods, which included baseline (hospital discharge), 1, 3, 6, and 12-months. All subjects received usual care from their providers and interim telephone calls every three months to collect health care utilization data and update health information.

The P-Only intervention included the following components: *Structural Informational (SI) booklet, Nurse Telephone Support (NTS)* protocol, and the 24 hours/day *nurse pager*. The combined P+P intervention included everything in the patient-only intervention plus the *integration of the intimate partner into all aspects of the patient intervention* and the addition of the *Partner Telephone Group.* This intervention included a new partner version of the SI booklet, integrated partners in the NTS telephone calls with partner assignments, provided partners with access to the nurse pager and the video segments, and developed a partner only PTG. The partner was asked to participate fully in the NTS protocol with the ICD patient (20 minutes, once a week) and participated in weekly PTG (1 hour, once a week). More detailed information about interventions can be found elsewhere.[63]

Theoretical Model for the Present Study

Self-efficacy can be defined as the individual's belief in their ability to perform a particular behavior that is required to achieve a certain outcome (Figure 2.1).[13-15,24,25,65-69] To change and maintain behavior, SCT relies on the efficacy expectations, outcome expectations, and personal characteristics.[13] *Self-efficacy expectations* are the person's belief in his or her self-confidence to carry out a specific behavior. *Outcome expectations* are the beliefs that carrying out a specific behavior will lead to a given outcome. Outcome expectations take three forms: 1) physical effects that accompany behavior such as pleasant sensory experiences or physical discomfort, 2) social reactions such as expressions of interest, social recognition, or social status, and 3) self-evaluative influences such as self-sanctions, self-satisfaction, and self-worth. The motivating influence of outcome expectations is partly directed by self-efficacy beliefs. The willingness of an individual to engage in a certain behavior is related to the positive benefits expected if that behavior is performed.[14] Outcome expectations are important to consider when changing behavior. However, efficacy expectations explaining the majority of the variance and have greater predictive power on overall outcomes in behavior change.[13]

Behavioral change is both population and situation specific.[14,70] Content-specific measures to the target population in intervention studies are required to evaluate specific components of self-efficacy that can be improved on the specific population. Self-efficacy in dealing with an ICD implanted is not simply a matter of knowing and acquiring skills in how to handle the device therapies; it requires a capability to organize and integrate cognitive, social, and behavioral skills to meet a variety of realistic purposes and outcomes according to their specific population characteristics.[14,70] Individuals tend to avoid tasks and situations that they believe exceed their capabilities but readily undertake activities they judge themselves capable of performing. Knowing which content specific element of self-efficacy that ICD patients are having difficulties might help to focus on care and patient efforts in how to overcome obstacles present on chronic disease trajectories.

Bandura argues that at the individual level it is possible to improve self-efficacy by targeting four components (Figure 2.1): (1) *Enhancing performance accomplishments* - success develops based on one's ability to perform an activity, (2) *Vicarious Experiences* - seeing others succeed enhances confidence that one can also succeed, (3) *Verbal persuasion* - experts convey confidence in your capability and (4) *Reducing (physical and emotional) arousal* – controlling the physical and emotional state in order to reduce stress, fatigue, and depression.[13,15] Enhancing these four components helps to eliminate anxiety, fear, and bodily stress reactions, also, to improve their belief in their ability to produce desired results.[14,15] The P+P intervention was developed with the strategy of targeting each of these four components of SCT to increase self-efficacy. It was postulated that the mechanism by which the P+P intervention would impact outcomes would be through enhanced self-efficacy.

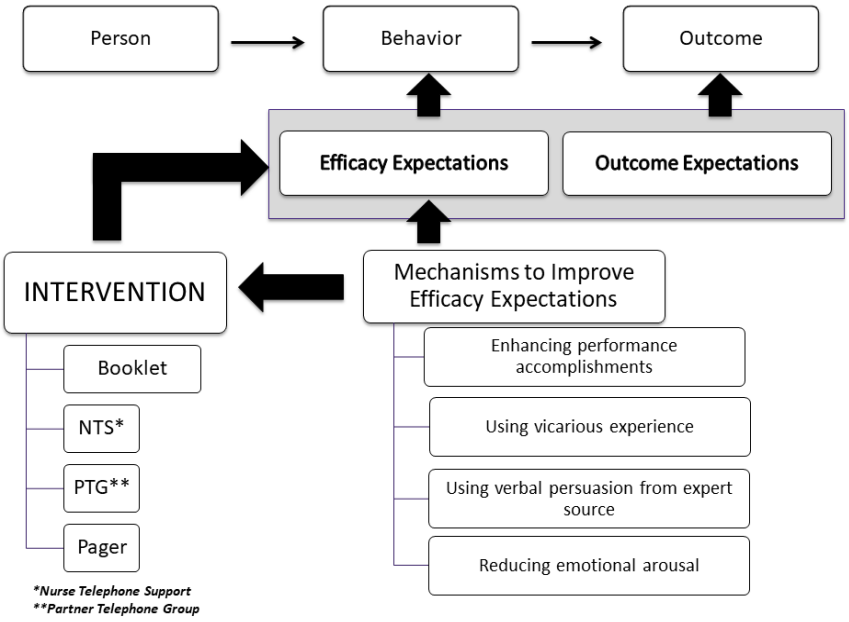


Figure 2.1. Self-Efficacy Theory and P+P Intervention Components. *NTS (Nurse Telephone Support), **PTG (Partner Telephone Group)

While these intervention studies produced promising results, critical theoretical gaps exist, particularly concerning understanding the mechanisms by which the interventions might influence physical and psychological outcomes. One initial step is to understand if enhanced self-efficacy serves as a mediator in affecting physical and psychological health outcomes. Also needed is an understanding of *which* intervention components play a pivotal role in promoting self-efficacy and outcome improvements. Such knowledge will contribute to the tailoring of interventions for individuals, thereby reducing costs and patient burden associated with unnecessary intervention activities.

Using data drawn from the recent clinical trial by Dougherty[63], this study tested the mediating effects of four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge) (Figure 2.2) and *content-specific elements of self-efficacy* (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship) (Figure 2.3) on the relationship between the interventions and patient physical function and psychological adjustments following completion of the P+P intervention at 12-months. Specifically, we examined whether the: (1) the theoretical models fit the data well; (2) four *dimensions of self-efficacy* mediated the association between the intervention and physical function and psychological adjustment outcomes; (3) eight *content-specific elements of self-efficacy* mediated the association between the intervention and physical function and psychological adjustment outcomes. We hypothesized that the effect of the intervention on *Physical function* and *Psychological Adjustment* at 12-months would be

mediated by changes on four *Dimensions of self-efficacy* (Figure 2.2) and eight *content-specific elements of self-efficacy* (Figure 2.3) measured at three-months.

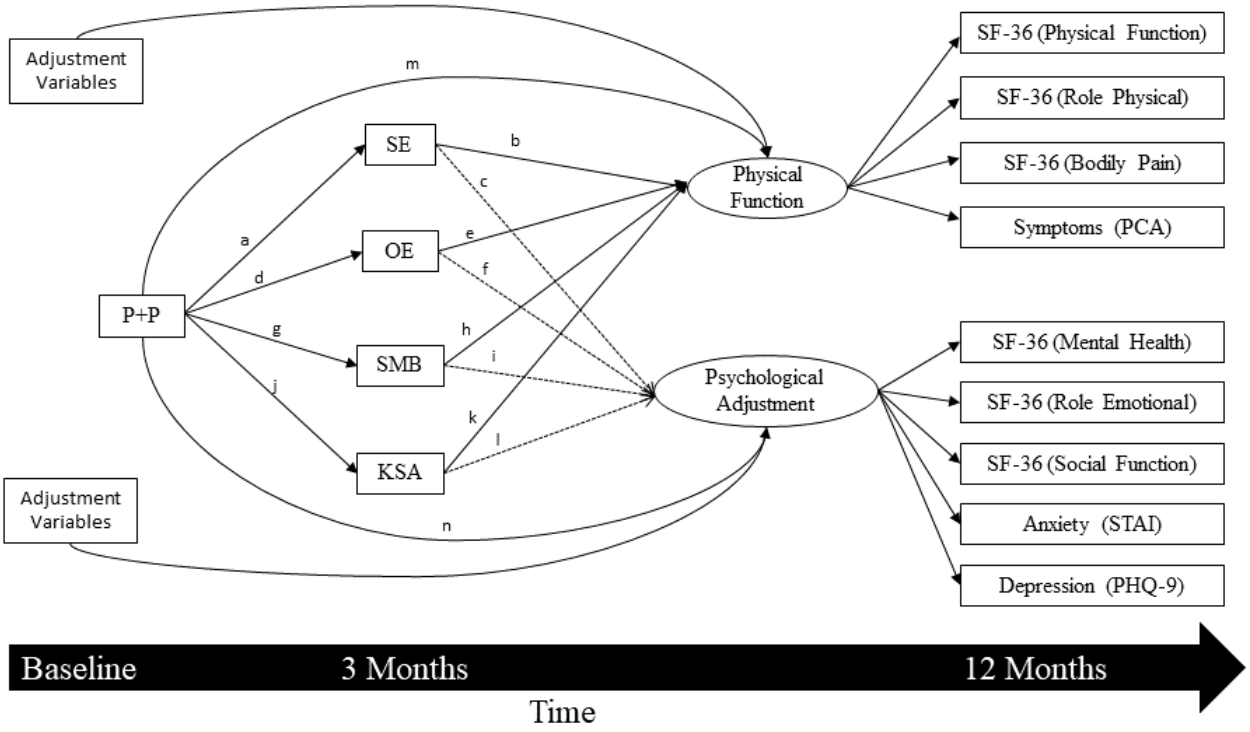


Figure 2.2. Proposed structural model with hypothesized intervention (P+P) mediating effects of Dimensions of Self-Efficacy on Physical Function and Psychological Adjustment. Circles represent latent variables; Boxes represent observed variables. Dashed lines are paths among dimensions of Self-Efficacy and Physiological Adjustment. Adjustment variables tested were age, gender, ethnicity, ICD indication, Ejection Fraction (EF), cardiac arrest, and Charlson Comorbidity Index all measured at baseline. Dimensions of self-efficacy at three-months were adjusted for baseline values.

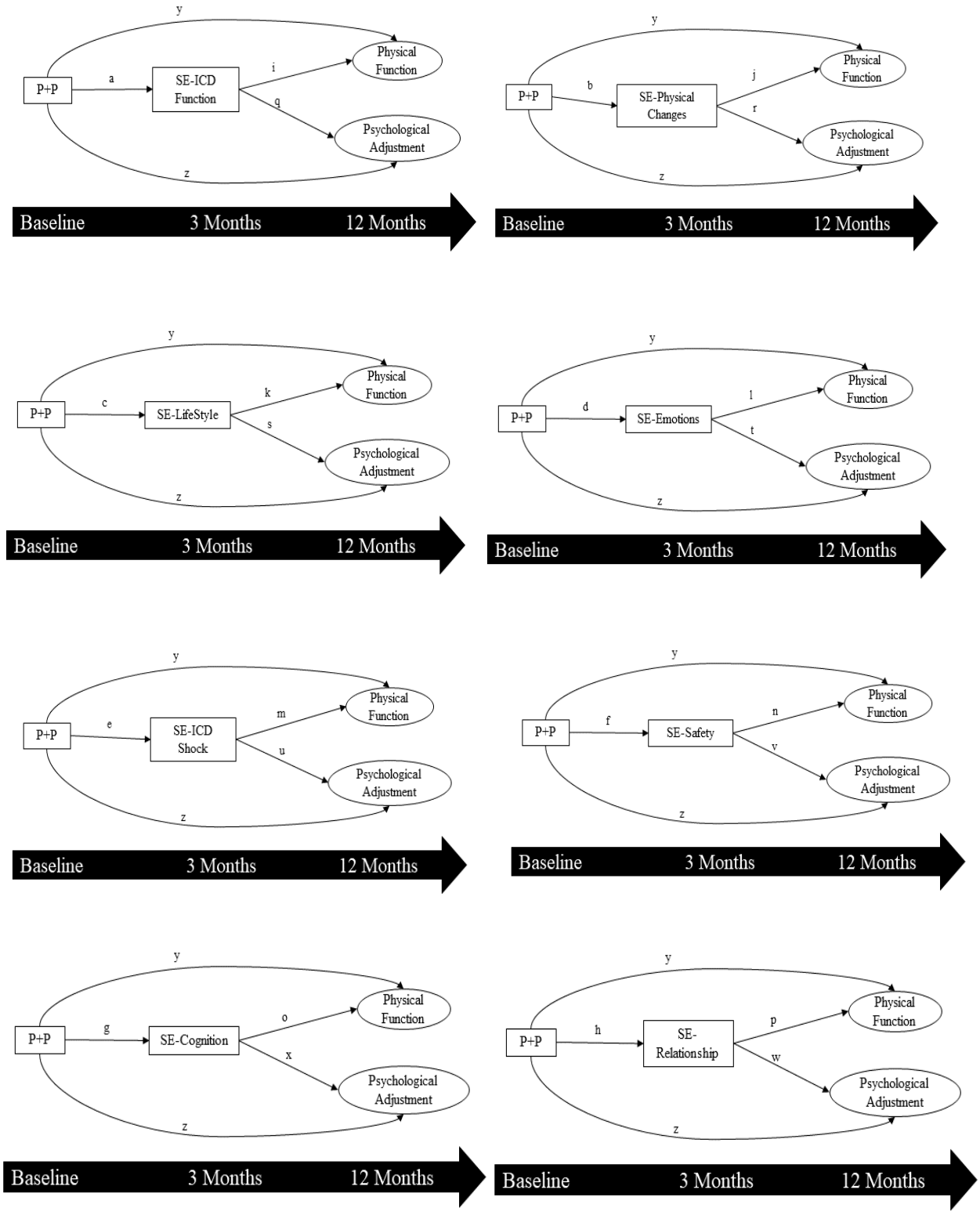


Figure 2.3. Proposed structural models with hypothesized intervention (P+P) mediating effects of Content Specific elements of self-efficacy on Physical Function and Psychological Adjustment. Circles represent latent variables; Boxes represent observed variables. Adjustment variables tested were age, gender, ethnicity, ICD indication, Ejection Fraction (EF), cardiac arrest, and Charlson Comorbidity Index all measured at baseline. Content Specific elements of self-efficacy at three-months were adjusted for baseline values. Circles represent latent variables; Boxes represent observed variables. Latent variables physical function and psychological adjustments were measured with the same indicators demonstrated in Figure 2.2.

METHODS

The data gathered for this secondary analysis were generated in a randomized clinical trial that tested the efficacy of two nursing interventions (P-only and P+P) for patients receiving an initial ICD.[21,63] In one condition, only patients (P-Only) received the intervention. In the other condition, the patient received the same intervention, which included a component to engage the patient's partner (P+P) in the recovery process. The intervention was delivered in the first three-months after ICD implantation. Outcome data were collected 5 times across 12-months. The data used in the present study included data collected at baseline, at 3-months at the end of the intervention, and at the 12-months from P-Only and P+P conditions. The intervention was designed and implemented using Social Cognitive Theory,[13,14] in which *dimensions of self-efficacy* and *content specific elements of self-efficacy* were defined as mediators.

Participants

The parent study included 301 patient-intimate partner pairs (150/group) identified from acute care institutions. Entry into the study was based on the index patient who received an ICD using the following ***inclusion criteria***: first ICD implantation due to primary or secondary prevention of SCA, intimate partner living at the same residence and willing to participate, able to read, speak and write English, and access to telephone for one year after ICD implantation. ***Exclusion criteria*** clinical comorbidities that severely impaired physical functioning at telephone screening, short BLESSED score > 6, age less than 21 years, AUDIT-C score $\geq$ 4 for alcohol use, ASSIST 2.0 score $\geq$4 for daily nonmedical use of opiates or hallucinogens. Data from partners were not included in this analysis.

Measures

The major outcomes, Physical Function and Psychological Adjustment, were measured using multiple indicators described below. Self-efficacy, the hypothesized mediating construct, was composed of four *dimensions of self-efficacy,* and there were eight *content-specific elements of self-efficacy*. The measures, including adjustment variables are described below.

Physical Function*:* was modeled as a latent variable with four indicators, described below and illustrated in Figure 2.2. Three indicators were derived from the SF-36, and the fourth, the physical symptom count (items 1-28), was from the Patient Concerns Assessment (PCA).*[71]* The Short Form Health Survey (SF-36)[72,73] includes 36 questions and eight subscales: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems and perceived mental health. Response options are based on a Likert-type scale — some with five or six points and others with two or three points. Subscale scores range from 0-100, in which higher the score better the health on that specific subscale. In this study, SF-36 presented internal consistency reliability (Cronbach alpha) of 0.83.

To measure physical function in this study (Figure 2.2), the following, non-overlapping SF-36 subscales were used:

1. Physical Functioning: 10 items are representing levels and types of physical limitations, including daily life activities, accounting for the severity of each limitation.[73]
2. Role Physical: four items are defining role limitations regarding daily physical function.[73]
3. Bodily Pain. two items measuring the frequency of bodily pain or discomfort and interference of pain on normal activities.[73]

In addition, *physical symptoms* were measured with the *Patient Concerns Assessment* (PCA)

4. PCA: This symptom checklist measures physical symptoms and fears common in the first few months after ICD implantation.[71,74] The PCA, developed by Jenkins (1996) is a disease-specific instrument for ICD quality of life, symptoms, and distress and has 58 items as a checklist. The score ranges from 0 to 58, with lower scores reflect fewer symptoms. It is a validated questionnaire for patients with ICD, and the reliability of this study was ($\alpha = 0.92$). In this study the physical symptom count (items 1-28) was used for physical symptoms.

Psychological Adjustment was represented with five indicators derived from separate sources (Figure 2.2), three SF-36 sub-scales (mental health, role emotional, social functioning), anxiety, the State-Trait Anxiety Inventory (STAI), and a measure of depression, the Patient Health Questionnaire (PHQ-9).

Overall mental health was assessed using three non-overlapping subscales from the SF-36, described below.

1. Mental Health: five items are measuring four major mental health concerns (anxiety, depression, loss of behavioral or emotional control, and psychological well-being).[73]
2. Role Emotional: three items are assessing role limitations associated with daily mental health.[73]
3. Social Functioning: two items are assessing health-related effects on social activities.[73]

In addition, Anxiety and Depression were measured with*:*

4. Anxiety was measured using the State-Trait Anxiety Inventory (STAI), state scale. The scale has 20 items, rated on a 4-point scale, total scores ranging from 20 to 80, with higher scores indicating greater anxiety.[75] A cut-off score ≥ 30 indicates moderate anxiety; a score ≥ 40 signals clinically significant anxiety. The scale internal consistency reliability (Cronbach alpha) for the present study was 0.95.
5. Depression was measured using The Physician Health Questionnaire-9 (PHQ-9), a multi-purpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression.[76] It includes 10 items rated in three to four-point Likert-type response. The score ranges from 0 to 24, with a higher score indicating greater depression. PHQ-9 scores of 5, 10, 15, and 20 represent

mild, moderate, moderately severe and severe depression, respectively.[76] Internal consistency for PHQ-9 in this study was 0.82.

Dimensions of Self-Efficacy: Four *dimensions of self-efficacy*, derived from Social Cognitive Theory,[15] were included as potential mediators between the interventions and hypothesized outcomes, as illustrated in Figure 2.2.

1. *Self-Efficacy Expectations (SE)* The Self-Efficacy Expectations after ICD Implantation Scale (SE-ICD) was used to measure beliefs in one's self-confidence to carry out a specific behavior. This 44-item scale focuses on expectations about one's ability to manage common problems encountered after receiving an ICD. The index has eight content-specific sub-scales measuring self-efficacy to manage tasks/functions after receiving an ICD (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship). Responses are based on a scale ranging from 0-10, where higher score greater patient confidence. The index is scored by summing the numerical ratings for each response and dividing by the number of items. Internal consistency (Cronbach alpha) for the present study was 0.98.
2. *Outcome expectations (OE)* was measured with a nine-item scale[70] that focuses on the perceived consequences of engaging in self-management behaviors after receiving an ICD. Study participants rate agreement with statements using a scale 0-10 ranging, where 0 = definitely false to 10 = definitely true. The index is scored by summing the numerical ratings for each response and dividing by the number of items. Internal consistency (Cronbach alpha) for the present study was 0.80.
3. *Self-Management Behavior (SMB)* was measured using a 38-item index in which patients report the total time they spent during the past week engaged in specific activities. Response options range from 0 to 4 in the first 6 questions, where 0 = none, 1 = less than 30 minutes per week, 2 = 30-60 minutes per week, 3 = 1-3 hours per week, and 4 = more than 3 hours per week. For the remaining items (7 to 38), responses are recorded using in a five-point Likert-type scale, where 0 = never and 5 = always. Internal consistency (Cronbach alpha) does not apply to this tool.
4. *Knowledge Self-Assessment (KSA)* was developed to measure patient knowledge regarding cardiac health. This index is based on 25 true-false items. Knowledge is reflected by the proportion of correct responses. Internal consistency (Cronbach alpha) for the present study was 0.83.

Content-specific elements of self-efficacy: These measures are a content specific to ICD patient's evaluation of self-efficacy early described, derived from the Self-Efficacy Expectations after ICD Implantation Scale. In the present study, each component of self-efficacy was included as potential

intervention mediators, as illustrated in Figure 2.3. These eight *Content-specific elements of self-efficacy* were addressed in the phone calls performed by a trained nurse. The *content specific self-efficacy* scales that were identical to intervention components were created specifically for the study. Questions were answered based on how confident the participant was with a prompt about the topic discussed on that week. Answers were in a Likert type scale with 0 to 10 points, in which 0 indicates – participant was "not at all confident", 5 – "Somewhat confident" and 10 – "Very confident". A total Score for each *content-specific element of self-efficacy* was calculated by the mean of all items of the scale.

There was a total of 10 intervention calls with focusing around eight *content-specific elements of self-efficacy*:

1. *ICD function.* Focused on patient's knowledge about ICD function and confidence in the operation of their ICD. There was a total of six questions. An example question was: "I can comprehend the functioning of my ICD".
2. *Physical Changes.* Focused on participant confidence in being able to manage physical symptoms related to receipt of the ICD. There was a total of seven questions. An example question was, "I feel I can manage my daily life schedule independently since receiving my ICD."
3. *Lifestyle*. Focused on participants confidence in managing lifestyle and physical activities since the ICD. There was a total of five questions. An example question was, "I have the self-reliance to cope with required changes in my lifestyle brought on by my ICD".
4. *Emotions.* Focused on participants confidence in being able to manage anxiety and depression. There was a total of seven questions. An example question was, "I can manage my own emotions related to my ICD".
5. *ICD shock.* Focused on participants confidence in being able to manage ICD shocks. There was a total of six questions. An example question was "I can create a plan for dealing with ICD shocks if they occur".
6. *Safety*. Focus on participants confidence in being able to life safely with the ICD. There was a total of three questions. An example question is "I can avoid environmental hazards that may cause my ICD to malfunction".
7. *Cognition*. Focuses on participant confidence in being able to manage thoughts related to their ICD and the future. There was a total of five questions. An example question was, "I am able to stop constantly thinking about my ICD".
8. *Relationship*. Focuses on the participant being able to adapt to the changes in the significant other relationship since the ICD. There was a total of five questions. An example question was, "I can manage intimate discussions with my partner about my ICD".

Intervention Condition: was represented as a binary variable, a value of *zero* represented patients in P-Only condition, and *one* represented patient's in the P+P condition.

Adjustment Variables

The variables included in the *dimensions of self-efficacy* models to adjust statistically for potential effects on physical function and/or psychological adjustment were age, ICD indication and the Charlson Comorbidity Index (CCI). In the *content-specific elements of self-efficacy* model, the adjustment variables included were age, gender, CCI, EF, cardiac arrest, and ICD indication. Adjustment variables used in the models were those which showed a statistically significant influence on the dependent variables for one or more of the tested paths.

Age was measured in years and considered as a continuous variable. CCI measures the presence of chronic diseases and is used to assess the prognostic influence of multiple chronic illnesses.[77] The index has 32 questions with yes/no response options. The scale score is weighted in 0, 1, 3 or 6; the higher the score greater the probability of complications due to multiple chronic diseases.[77] EF was measured in percentage and was considered a continuous variable. Gender was computed as a binary variable for 0 female and 1 male. Cardiac arrest was a binary variable for 0 no cardiac arrest and 1 for cardiac arrest. ICD indication was considered a binary variable with 0 for participants with ICD implanted for secondary indications and 1 for participants with ICD implanted for primary prevention. The influence of ICD shocks during recovery (binary variable, shock/no shock) was tested to evaluate if the experience of shock had a substantial impact on the study outcomes. The *dimension of self-efficacy* and *content-specific elements of self-efficacy* at three-months were adjusted for their baseline values to capture change in the specific dimension of self-efficacy.

Data Analysis

First, preliminary analyses were conducted to describe the main study variables and to provide descriptive data. Second, SEM analysis was completed by (1) establishing the measurement model and (2) estimating the structural model to evaluate the direct and indirect effects of the interventions on physical function and psychological adjustment at 12-months post-ICD implant.

Preliminary Analyses

Descriptive statistics and histogram displays (mean, SD) were used to examine properties of the quantitative and sociodemographic variables, for the full sample as well as by intervention group. The distributional properties of the variables were examined for outlier cases, and missing data were characterized. No imputation of missing data were used for SEM analyses since less than 5% of the self-report measures were missing. Pearson correlation coefficients were calculated to evaluate associations among all key variables (four *dimensions of self-efficacy,* eight *content-specific elements of self-efficacy,*

and multiple indicators of physical function and psychological adjustment). Associations between key variables and potential confounding variables including age, gender, ethnicity, ICD indication, ejection fraction (EF), cardiac arrest, and the CCI were examined adding each of these variables as adjustment to physical function and psychological adjustment on the SEM model. Variables that were correlated with the study outcomes ($p \leq 0.05$) were included in the SEM modeling.

SEM Analyses

Structural Equation Modeling (SEM) analyses were performed in R (version 3.4.2)[78] using RStudio (version 1.1.3.83) with lavaan, an R SEM statistical package.[79] Diagonally weighted least squares (DWLS) parameter estimation was used to produce more accurate parameter estimates, robust corrections to standard errors, and chi-square test statistics for ordinal data were used in this SEM modeling. The fit of the data to the measurement model and structural model were evaluated based on several fit indices,[80] including the model chi-square, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR). The following values, based on SEM reporting guidelines were used to define good fit: CFI $\geq$0.95, TLI $\geq$ 0.95, RMSEA <0.05, and SRMR $\leq$0.08.[80,81]

The *measurement models* were established by defining the observed variables included as indicators for physical function and psychological adjustment, based on the theoretic definition of the latent variables and the available measures. Selection of indicators for these two dimensions was also based on reducing the degree to which the physical and psychological indicators overlapped. An incremental approach was used to build the model, testing each latent variables separately, then together, and then adding the measures for the four *dimensions of self-efficacy* to the model. A similar incremental approach was used to evaluate adjustement variables included in the models. With all measures in the measurement model, modification indices (MI) were used to assess for correlated error among indicators, examining modification indices > 4.0. Six correlated errors, described in the Results, were included for indicator pairs, primarily within and across measures of physical function and psychological adjustment. Inclusion was based on both the theoretical rationale and measurement considerations (e.g., the similarity of wording, same scale items). The same approach was used to assess the measurement model for the *content-specific elements of self-efficacy.* In the latter model, four modification indices were identified, and added to the model.

Structural model for dimensions of self-efficacy. The first hypothesized mediation model (Figure 2.2) includes the measure of the interventions for study condition (P-Only vs. P+P), the four *dimensions of self-efficacy* measured at three-months and modeled as single indicator variables, and the 12-month outcomes of physical function and psychological adjustment, measured as multiple indicator latent variables. To test for the mediation effect of each *dimension of self-efficacy*, the four mediating variables

were assesed systematically, one mediator variable at a time along with the adjustment variables, and then the full model with four dimensions was tested. The *dimensions of self-efficacy* measured at three-months were controlled for their baseline values, to capture change in the self-efficacy.

Structural model for content-specific elements of self-efficacy. The second hypothesized mediation models (Figure 2.3) include study condition (P-Only vs. P+P), the eight *content-specific elements of self-efficacy* measured at 3-months and modeled as single indicator variables, and the 12-month outcomes of physical function and psychological adjustment measured as multiple indicator latent variables. To test for the mediation effect of each *content-specific elements of self-efficacy,* each of the eight mediating variables were added systematically, one variable at a time, to the model along with the adjustment variables. We report the comparing the effects of the interventions on physical function and psychological adjustment through one *content-specific element of self-efficacy* at a time, and a model in which included only the *content-specific elements of self-efficacy* that were found to have statistically significant effects in the one-mediator models. The content-specific elements of self-efficacy at three-months were controlled for their baseline values.

In sum, the results are summarized in for different types of structural models: (1) four one-mediator models testing one *dimension of self-efficacy* at a time, (2) one model with all four *dimensions of self-efficacy* tested in the same model, (3) eight one-mediator models testing one *content-specific element* at a time, and (4) one model including only *content-specific elements of self-efficacy* found to have statistically significant effects in the one-mediator models. For all structural models, standardized and unstandardized parameter estimates (and their standardized errors) were examined in terms of their 1) *direct effects*, the unmediated effects of the interventions on the *self-efficacy* measures and the outcome variables of physical function, and psychological adjustment; 2) *indirect effects* of the intervention on physical function and psychological adjustment *mediated through* the *self-efficacy* measures, and 3) total effects, the sum of direct and indirect effects.[82,83]

Level of significance adopted on this study was 5%. For SEM analysis it was also considered tests with significance level of 10% given the exploratory nature of this research.

Human Subjects

This study was a secondary analysis of the P+P Intervention study (Dougherty, PI R01 HL086580, NCT01252615), conducted under the auspices of the University of Washington Internal Review Board. The present study analyses required the use of only de-identified data, and no new data were collected.

AIMS 1 AND 2 DESCRIPTIVE RESULTS

Descriptive results for Aims 1 and 2 are reported on the following paragraphs. The SEM results for each of these aims are reported in their own chapters (Aim 1 results on Chapter 3 and Aim 2 Chapter 4) to

facilitate distinguishing between results in which it was tested the mediation by dimensions of self-efficacy (Aim 1: Chapter 3) and content specific elements of self-efficacy (Aim 2: Chapter 4).

Demographic and Clinical Characteristics

Study participants were primarily white and male with a mean age of 64.14 (11.90) years. Sample clinical characteristics included mean EF of 34.08 (14.33), half of the participants had ICD implanted for primary prevention (60%), CCI mean was 2.29 (1.49), and 267 (88.7%) participants had no ICD shocks during the 12-months of the study period. No significant differences between the P+P and P-Only groups were observed for any of the baseline clinical and sociodemographic variables (Table 2.1). More detailed information regarding the parent study primary outcomes and patient characteristics has been reported.[63]

Table 2.1. Baseline sociodemographic and clinical characteristics for P-Only, P+P and Total Sample

Variable	Patients only (n = 151)	Patients part of P+P (n = 150)	Total Sample (n = 301)	Group Differences P-Only vs. P+P t-test	
				F	P-value
Age (years), mean (SD)	65.01(11.26)	63.26(12.50)	64.14(11.90)	1.68	0.20
Gender (male), n (%)	106 (70.2%)	116 (77.3%)	222(73.8%)	7.95	0.16
Race (white), n (%)	136 (90.1%)	138 (92.0%)	274(91%)	0.02	0.99
Ejection Fraction (%), mean(SD)	33.79(13.49)	34.38(15.17)	34.08(14.33)	3.93	0.72
ICD indication (primary), n(%)	91 (60.3%)	89 (59.3%)	180(59.8%)	0.11	0.87
Charlson Comorbidity Index, mean(SD)	2.26(1.44)	2.32(1.53)	2.29(1.49)	0.82	0.72
ICD shock (no shocks) n(%)	131(86.8%)	136(90.7%)	267(88.7%)	5.913	0.29
ICD shock (Number of shocks), mean(SD)	0.30(1.35)	0.14(0.505)	0.22(1.03)	4.644	0.29

Note. ICD indication was designated as (1) primary prevention or (0) secondary prevention of cardiac arrest. For the Charlson Comorbidity Index 0 = no comorbidities.

Correlations among observed variables. Correlations (Table 2.2) were moderate to large *within* the two indicator sets for Physical function (r = -0.522 to 0.706) and Psychological adjustment (r = -0.441 to 0.782). In contrast, correlations were small to moderate *between* the indicators of physical function and psychological adjustment and the four *dimensions of self-efficacy* (SE, OE, SMB, and KSA). More specifically, SE had low to moderate correlations (r = 0.212 to 0.482) with all indicators of *Physical Function* and Psychological adjustment. OE generally had small correlations (r = 0.116 to 0.240) with

indicators of physical function and psychological adjustment. SMB correlations were generally low (r = -0.069 to 0.228), the stronger correlations were with PCA and SF-36 Role Emotional (r = 0.206 and -0.228, respectively). For KSA, correlations ranged from -0.064 to 0.253, with stronger correlations between two indicators of *Physical Function,* SF-36 Physical Functioning and SF-36 Role Physical, (r = 0.228 and 0.241, respectively) and one indicator of Psychological adjustment (SF-36 Role Emotional, r = 0. 253). In sum, these patterns suggested that sets of outcome measures would serve as consistent indicators of the latent variables *Physical Function* and Psychological Adjustment as defined in this study.

For the *content specific elements of self-efficacy*, correlations with the outcome varied considerably with the largest correlations being with psychological ajustment variables. SE- ICD function had a moderate correlation with depression (r = 0.47), SE-Physical changes with anxiety (r = 0.367), Se-. Lifestyle with depression (r = 0.474, and SE Emotions with anxiety (r = 0.457). SE-ICD shock was correlated with anxiety (r = 0.331), SE- Safety with anxiety (r = 0.339), and Knowledge with anxiety (r = 0.435) and SE-relationship with anxiety(r = 0.433).

Results for the structural equation modeling, for dimensions of self-efficacy are reported in Chapter 3, and the content-specific elements of self-efficacy, on Chapter 4.

Table 2.2. Pearson correlation coefficients for measures of the Mediators: *Dimensions of Self-Efficacy* and *Content-Specific elements of Self-Efficacy* at three months and Outcome indicators of *Physical Function* and *Psychological Adjustment* at 12-months

Variable/Indicator	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Outcome: Physical Function																					
1. SF-36 Physical function	1	.71**	.58**	-.35**	.42**	.47**	.59**	-.25**	-.45**	.30**	.19**	-.07	.23**	.34**	.23**	.40**	.23**	.23**	.18**	.19**	.18**
2. SF-36 Role physical	.71**	1	.56**	-.33**	.43**	.53**	.61**	-.33**	-.46**	.28**	.19**	-.13*	.24**	.30**	.24**	.35**	.23**	.21**	.19**	.19**	.15*
3. SF-36 Bodily Pain	.58**	.56**	1	-.35**	.45**	.42**	.54**	-.29**	-.42**	.21**	.13*	-.11	.06	.26**	.15*	.23**	.19**	.13*	.10	.14*	.15*
4. Symptoms (PCA)	-.35**	-.33**	-.35**	1	-.28**	-.20**	-.38**	.26**	.38**	-.17**	-.06	-.04	-.04	-.17**	-.09	-.24**	-.16**	-.07	-.13*	-.13*	-.14*
Outcome: Psychological Adjustment																					
5. SF-36 Mental Health	.42**	.43**	.45**	-.28**	1	.54**	.62**	-.64**	-.69**	.44**	.24**	-.11	.1	.44**	.31**	.43**	.41**	.31**	.26**	.37**	.37**
6. SF-36 Role Emotional	.47**	.53**	.42**	-.20**	.54**	1	.57**	-.44**	-.59**	.30**	.12	-.23**	.25**	.31**	.27**	.34**	.27**	.17**	.16**	.21**	.25**
7. SF-36 Social Function	.59**	.61**	.54**	-.38**	.62**	.57**	1	-.49**	-.63**	.36**	.13*	-.07	.09	.40**	.25**	.39**	.34**	.20**	.22**	.28**	.33**
8. Anxiety (STAI)	-.25**	-.33**	-.29**	.26**	-.64**	-.44**	-.49**	1	.70**	-.48**	-.21**	.13*	-.09	-.44**	-.37**	-.41**	-.46**	-.33**	-.34**	-.43**	-.43**
9. Depression (PHQ-9)	-.45**	-.46**	-.42**	.38**	-.69**	-.59**	-.63**	.70**	1	-.47**	-.16**	.13*	-.10	-.47**	-.33**	-.47**	-.44**	-.28**	-.29**	-.39**	-.42**
Mediators: Dimensions of Self-Efficacy																					
10. Self-efficacy	.30**	.28**	.21**	-.17**	.44**	.30**	.36**	-.48**	-.47**	1	.43**	-.08	.09	.89**	.82**	.82**	.90**	.85**	.69**	.83**	.79**
11. Outcome Expectations	.19**	.19**	.13*	-.06	.24**	.12	.13*	-.21**	-.16**	.43**	1	.19**	.11	.37**	.33**	.28**	.35**	.39**	.43**	.43**	.35**
12. Self-Management Behaviors	-.07	-.13*	-.11	-.04	-.11	-.23**	-.07	.13*	.13*	-.08	.19**	1	-.06	-.11	-.08	-.10	-.13*	.01	-.03	-.07	.02
13. Knowledge Assessment	.23**	.24**	.06	-.04	.1	.25**	.09	-.09	-.10	.09	.11	-.06	1	.11	.12*	.04	.07	.081	.15*	.02	.07
Mediators: Content-Specific elements of Self-Efficacy																					
14. ICD function	.34**	.30**	.26**	-.17**	.44**	.31**	.40**	-.44**	-.47**	.89**	.37**	-.11	.11	1	.72**	.73**	.77**	.69**	.64**	.66**	.67**
15. Physical Changes	.23**	.24**	.15*	-.09	.31**	.27**	.25**	-.37**	-.33**	.82**	.33**	-.08	.12*	.72**	1	.63**	.67**	.69**	.51**	.62**	.54**
16. Lifestyle	.40**	.35**	.23**	-.24**	.43**	.34**	.39**	-.41**	-.47**	.82**	.28**	-.10	.04	.73**	.63**	1	.72**	.60**	.47**	.60**	.59**
17. Emotions	.23**	.23**	.19**	-.16**	.41**	.27**	.34**	-.46**	-.44**	.90**	.35**	-.13*	.07	.77**	.67**	.72**	1	.68**	.53**	.78**	.71**
18. ICD shock	.23**	.21**	.13*	-.07	.31**	.17**	.20**	-.33**	-.28**	.85**	.39**	.01	.08	.69**	.69**	.60**	.67**	1	.61**	.69**	.58**
19. Safety	.18**	.19**	.10	-.13*	.26**	.16**	.22**	-.34**	-.29**	.69**	.43**	-.03	.15*	.63**	.51**	.47**	.53**	.61**	1	.59**	.50**
20. Cognition	.19**	.19**	.14*	-.13*	.37**	.21**	.28**	-.43**	-.39**	.83**	.43**	-.07	.02	.66**	.62**	.60**	.78**	.69**	.59**	1	.58**
21. Relationship	.18**	.15*	.15*	-.14*	.37**	.25**	.33**	-.43**	-.42**	.79**	.35**	.02	.07	.67**	.54**	.59**	.71**	.58**	.50**	.58**	1

*p<0.05; **p<0.001;

REFERENCES

1. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *European Heart Journal.* 2016.
2. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;62(16):e147-239.
3. Kolodziejczak M, Andreotti F, Kowalewski M, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy A Systematic Review and Meta-analysis. In. *Ann. Intern. Med.* Vol 1672017:103-111.
4. Sears SF, Todaro JF, Lewis TS, Sotile W, Conti JB. Examining the psychosocial impact of implantable cardioverter defibrillators: a literature review. *Clin Cardiol.* 1999;22.
5. Bainger EM, Fernsler JI. Perceived quality of life before and after implantation of an internal cardioverter defibrillator. *American journal of critical care : an official publication, American Association of Critical-Care Nurses.* 1995;4(1):36-43.
6. Dunbar SB. Psychosocial issues of patients with implantable cardioverter defibrillators. *Am J Crit Care.* 2005;14(4):294-303.
7. Dougherty CM, Benoliel JQ, Bellin C. Domains of nursing intervention after sudden cardiac arrest and automatic internal cardioverter defibrillator implantation. *Heart Lung.* 2000;29(2):79-86.
8. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosom Med.* 2011;73(3):226-233.
9. Crossmann A, Schulz SM, Kuhlkamp V, et al. A randomized controlled trial of secondary prevention of anxiety and distress in a German sample of patients with an implantable cardioverter defibrillator. *Psychosom Med.* 2010;72(5):434-441.
10. Kohn CS, Petrucci RJ, Baessler C, Soto DM, Movsowitz C. The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. *Pace.* 2000;23.
11. Dougherty CM, Pyper GP, Frasz HA. Description of a nursing intervention program after an implantable cardioverter defibrillator. *Heart Lung.* 2004;33(3):183-190.
12. Dougherty CM, Johnson-Crowley NR, Lewis FM, Thompson EA. Theoretical development of nursing interventions for sudden cardiac arrest survivors using social cognitive theory. *ANS Adv Nurs Sci.* 2001;24(1):78-86.
13. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977;84(2):191-215.
14. Bandura A. *Self-efficacy : the exercise of control.* New York: New York : W.H. Freeman; 1997.

15. Bandura A. *Social foundations of thought and action : a social cognitive theory*. Englewood Cliffs, N.J.: Englewood Cliffs, N.J. : Prentice-Hall; 1986.
16. Rajati F, Mostafavi F, Sharifirad G, et al. A theory-based exercise intervention in patients with heart failure: A protocol for randomized, controlled trial. *J Res Med Sci.* 2013;18(8):659-667.
17. Meland E, Maeland JG, Laerum E. The importance of self-efficacy in cardiovascular risk factor change. *Scand J Public Health.* 1999;27(1):11-17.
18. Dougherty CM, Thompson EA, Lewis FM. Long-term outcomes of a telephone intervention after an ICD. *Pacing Clin Electrophysiol.* 2005;28(11):1157-1167.
19. Dougherty CM, Lewis FM, Thompson EA, Baer JD, Kim W. Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. *Pacing Clin Electrophysiol.* 2004;27(12):1594-1602.
20. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and testing of an intervention to improve outcomes for partners following receipt of an implantable cardioverter defibrillator in the patient. *ANS Adv Nurs Sci.* 2012;35(4):359-377.
21. Dougherty C, Fairbanks A, Eaton L, Morrison M, Kim M, Thompson E. Comparison of patient and partner quality of life and health outcomes in the first year after an implantable cardioverter defibrillator (ICD). *Journal of Behavioral Medicine.* 2016;39(1):94-106.
22. Dougherty CM, Thompson EA. Intimate partner physical and mental health after sudden cardiac arrest and receipt of an implantable cardioverter defibrillator. *Research in nursing & health.* 2009;32(4):432-442.
23. Dougherty CM, Pyper GP, Benoliel JQ. Domains of concern of intimate partners of sudden cardiac arrest survivors after ICD implantation. *The Journal of cardiovascular nursing.* 2004;19(1):21-31.
24. Woodgate J, Brawley LR, Weston ZJ. Maintenance Cardiac Rehabilitation Exercise Adherence: Effects of Task and Self-Regulatory Self-Efficacy. *Journal of Applied Social Psychology.* 2005;35(1):183-222.
25. Taylor CB, Bandura A, Ewart CK, Miller NH, Debusk RF. Exercise testing to enhance wives' confidence in their husbands' cardiac capability soon after clinically uncomplicated acute myocardial infarction. *The American Journal of Cardiology.* 1985;55(6):635-638.
26. Fitchet A, Doherty PJ, Bundy C, Bell W, Fitzpatrick AP, Garratt CJ. Comprehensive cardiac rehabilitation programme for implantable cardioverter-defibrillator patients: a randomised controlled trial. *Heart.* 2003;89(2):155-160.
27. Frizelle DJ, Lewin RJ, Kaye G, et al. Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: a pilot study. *Br J Health Psychol.* 2004;9(3):381-392.

28. Chevalier P, Cottraux J, Mollard E, et al. Prevention of implantable defibrillator shocks by cognitive behavioral therapy: A pilot trial. *American Heart Journal.* 2006;151(1).
29. Sears SF, Sowell LD, Kuhl EA, et al. The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. *Pacing Clin Electrophysiol.* 2007;30(7):858-864.
30. Smeulders ESTF, van Haastregt JCM, Dijkman-Domanska BK, van Hoef EFM, van Eijk JT, Kempen GIJM. Nurse- and peer-led self-management programme for patients with an implantable cardioverter defibrillator; a feasibility study. *BMC Nursing.* 2007;6(1):6.
31. Lewin RJ, Coulton S, Frizelle DJ, Kaye G, Cox H. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. *Heart.* 2009;95(1):63-69.
32. Dunbar SB, Langberg JJ, Reilly CM, et al. Effect of a Psychoeducational Intervention on Depression, Anxiety, and Health Resource Use in Implantable Cardioverter Defibrillator Patients. *Pacing and Clinical Electrophysiology.* 2009;32(10):1259-1271.
33. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosomatic medicine.* 2011;73(3):226.
34. Berg SK, Pedersen PU, Zwisler AD, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology.* 2015;14(1):34-44.
35. Russell DC, Smith TL, Krahn DD, et al. Effects of Cognitive Behavioral Stress Management on Negative Mood and Cardiac Autonomic Activity in ICD Recipients. *Pacing Clin Electrophysiol.* 2015;38(8):951-965.
36. Habibovic M, Denollet J, Cuijpers P, et al. Web-based distress management for implantable cardioverter defibrillator patients: A randomized controlled trial. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2017;36(4):392-401.
37. Badger JM, Morris PL. Observations of a support group for automatic implantable cardioverter-defibrillator recipients and their spouses. *Heart & lung : the journal of critical care.* 1989;18(3):238.
38. Molchany CA, Peterson KA. The psychosocial effects of support group intervention on AICD recipients and their significant others. *Progress in cardiovascular nursing.* 1994;9(2):23.

39. Sneed NV, Finch NJ, Michel Y. The effect of psychosocial nursing intervention on the mood state of patients with implantable cardioverter defibrillators and their caregivers. *Progress in cardiovascular nursing.* 1997;12(2):4.
40. Carlsson E, Olsson SB, Hertervig E. The Role of the Nurse in Enhancing Quality of Life in Patients With an Implantable Cardioverter-Defibrillator: The Swedish Experience. *Progress in cardiovascular nursing.* 2002;17(1):18-25.
41. Dickerson SS, Wu Y, Kennedy MC. A CNS-facilitated ICD support group - A clinical project evaluation. *Clin Nurse Spec.* 2006;20(3):146-153.
42. Berg SK, Svendsen JH, Zwisler AD, et al. COPE-ICD: a randomised clinical trial studying the effects and meaning of a comprehensive rehabilitation programme for ICD recipients -design, intervention and population. *BMC Cardiovasc Disord.* 2011;11:33.
43. Kolodziejczak M, Andreotti F, Kowalewski M, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy A Systematic Review and Meta-analysis. *Annals of internal medicine.* 2017;167(2):103-111.
44. Gonzalez-Enriquez S, Rodriguez-Entem F, Exposito V, et al. Single-chamber ICD, single-zone therapy in primary and secondary prevention patients: the simpler the better? *Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing.* 2012;35(3):343-349.
45. Zarraga IG, Dougherty CM, MacMurdy KS, Raitt MH. The effect of spironolactone on ventricular tachyarrhythmias in patients with implantable cardioverter-defibrillators. *Circulation Arrhythmia and electrophysiology.* 2012;5(4):739-747.
46. Ezekowitz JA, Armstrong PW, McAlister FA. Implantable cardioverter defibrillators in primary and secondary prevention: a systematic review of randomized, controlled trials. *Ann Intern Med.* 2003;138(6):445-452.
47. Habibović M, Denollet J, Pedersen SS. Posttraumatic stress and anxiety in patients with an implantable cardioverter defibrillator: Trajectories and vulnerability factors. *Pacing and clinical electrophysiology: PACE.* 2017;40(7):817-823.
48. Hlatky MA, Sanders GD, Owens DK. Evidence-based medicine and policy: the case of the implantable cardioverter defibrillator. *Health Aff (Millwood).* 2005;24(1):42-51.
49. Ooi SL, He HG, Dong Y, Wang W. Perceptions and experiences of patients living with implantable cardioverter defibrillators: a systematic review and meta-synthesis. *Health Qual Life Outcomes.* 2016;14(1):160.
50. Palacios-Cena D, Losa-Iglesias ME, Alvarez-Lopez C, et al. Patients, intimate partners and family experiences of implantable cardioverter defibrillators: qualitative systematic review. *J Adv Nurs.* 2011;67(12):2537-2550.

51. Colquitt JL, Mendes D, Clegg AJ, et al. Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure: Systematic review and economic evaluation. *Health Technology Assessment.* 2014;18(56):1-559.
52. Dunbar SB, Dougherty CM, Sears SF, et al. Educational and Psychological Interventions to Improve Outcomes for Recipients of Implantable Cardioverter Defibrillators and Their Families: A Scientific Statement From the American Heart Association. *Circulation.* 2012;126(17):2146-2172.
53. Hamner M, Hunt N, Gee J, Garrell R, Monroe R. PTSD and Automatic Implantable Cardioverter Defibrillators. In. Vol 401999:82-85.
54. Morken IM, Norekvål TM, Bru E, Larsen AI, Karlsen B. Perceptions of healthcare professionals' support, shock anxiety and device acceptance among implantable cardioverter defibrillator recipients. *Journal of Advanced Nursing.* 2014;70(9):2061-2071.
55. Sears SF, Conti JB. Quality of life and psychological functioning of icd patients. *Heart.* 2002;87.
56. Burke J, Hallas C, Clark-Carter D, White D, Connelly D. The psychosocial impact of the implantable cardioverter defibrillator: A meta-analytic review. *Br J Health Psychol.* 2003;8:165-178.
57. Redhead AP, Turkington D, Rao S, Tynan MM, Bourke JP. Psychopathology in postinfarction patients implanted with cardioverter-defibrillators for secondary prevention. A cross-sectional, case-controlled study. *J Psychosom Res.* 2010;69(6):555-563.
58. Bilge AK, Ozben B, Demircan S, Cinar M, Yilmaz E, Adalet K. Depression and Anxiety Status of Patients with Implantable Cardioverter Defibrillator and Precipitating Factors. *Pacing and Clinical Electrophysiology.* 2006;29(6):619-626.
59. Kapa S, Rotondi-Trevisan D, Mariano Z, et al. Psychopathology in patients with ICDs over time: results of a prospective study. *Pacing Clin Electrophysiol.* 2010;33(2):198-208.
60. Peacock J, Whang W. Psychological distress and arrhythmia: risk prediction and potential modifiers. *Progress in cardiovascular diseases.* 2013;55(6):582-589.
61. Sears SF, Matchett M, Conti JB. Effective management of ICD patient psychosocial issues and patient critical events. *Journal of cardiovascular electrophysiology.* 2009;20(11):1297-1304.
62. Dougherty CM, Thompson EA, Kudenchuk PJ. Patient plus partner trial: A randomized controlled trial of 2 interventions to improve outcomes after an initial implantable cardioverter-defibrillator. *Heart rhythm : the official journal of the Heart Rhythm Society.* 2018.
63. Pocock SJ. *Clinical trials : a practical approach.* Chichester [West Sussex] ; New York: Chichester West Sussex ; New York : Wiley; 1983.
64. Furber S, Butler L, Phongsavan P, Mark A, Bauman A. Randomised controlled trial of a pedometer-based telephone intervention to increase physical activity among cardiac patients not attending cardiac rehabilitation. *Patient Education and Counseling.* 2010;80(2):212-218.

65. Moore SM, Charvat JM. Using the CHANGE intervention to enhance long-term exercise. *Nursing Clinics of North America.* 2002;37(2):273-283.
66. Padula CA, Yeaw E, Mistry S. A home-based nurse-coached inspiratory muscle training intervention in heart failure. *Applied Nursing Research.* 2009;22(1):18-25.
67. Pinto BM, Dunsiger SI. Mediators of exercise maintenance after cardiac rehabilitation. *Journal of cardiopulmonary rehabilitation and prevention.* 2015;35(1):13-20.
68. Shao JH, Chang AM, Edwards H, Shyu YIL, Chen SH. A randomized controlled trial of self-management programme improves health-related outcomes of older people with heart failure. *Journal of Advanced Nursing.* 2013;69(11):2458-2469.
69. Dougherty CM, Johnston SK, Thompson EA. Reliability and Validity of the Self Efficacy Expectations and Outcome Expectations After ICD Implantation Scales. *Applied nursing research : ANR.* 2007;20(3):116-124.
70. Ware J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care.* 1996;34(3):220-233.
71. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.
72. Jenkins LS, Dunbar SB, Hawthorne MH. Patient concerns before and the first 9-months after ICD implantation. *Circulation.* 1997;96(8):745-745.
73. Brooks MM, Jenkins LS, Schron EB, Steinberg JS, Cross JA, Paeth DS. Quality of Life at Baseline: Is Assessment after Randomization Valid? *Medical Care.* 1998;36(10):1515-1519.
74. Speilberger C, Gorsuch R, Lushene R. *Manual for the state-trait anxiety inventory.* Palo Alto, CA: Consulting Psychologists Press; 1970.
75. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *Journal of General Internal Medicine.* 2001;16(9):606-613.
76. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
77. Team RC. *R: A language and environment for statistical computing.* Vienna, Austria. 2018.
78. Rosseel Y. lavaan: An R Package for Structural Equation Modeling. *Journal of Statistical Software.* 2012;48(2):1-36. http://www.jstatsoft.org/v48/i02/.
79. Schreiber JB. Core reporting practices in structural equation modeling. *Research in Social and Administrative Pharmacy.* 2008;4(2):83-97.
80. Schreiber JB. Update to core reporting practices in structural equation modeling. *Research in Social and Administrative Pharmacy.* 2017;13(3):634-643.

81. Kline RB. *Principles and practice of structural equation modeling.* 2nd ed. ed. New York: New York : Guilford Press; 2005.
82. Finch WH, Brian FF. *Latent Variable Modeling with R.* Taylor and Francis; 2015.
83. Zhu SJ, Nahm E, Resnick B, et al. The Moderated Mediating Effect of Self-Efficacy on Exercise Among Older Adults in an Online Bone Health Intervention Study: A Parallel Process Latent Growth Curve Model. *J Aging Phys Act.* 2017;25(3):378-386.
84. Cameron JE, Voth J, Jaglal SB, Guilcher SJT, Hawker G, Salbach NM. "In this together": Social identification predicts health outcomes (via self-efficacy) in a chronic disease self-management program. *Social science & medicine (1982).* 2018;208:172-179.
85. Brecht ML, Dracup K, Moser DK, Riegel B. The relationship of marital quality and psychosocial adjustment to heart disease. *The Journal of cardiovascular nursing.* 1994;9(1):74.
86. Grewal R, Cote J, Baumgartner H. Multicollinearity and Measurement Error in Structural Equation Models: Implications for Theory Testing. *Marketing Science.* 2004;23(4):519-529.
87. Ladwig KH, Baumert J, Marten-Mittag B, Kolb C, Zrenner B, Schmitt C. Posttraumatic stress symptoms and predicted mortality in patients with implantable cardioverter-defibrillators: results from the prospective living with an implanted cardioverter-defibrillator study. *Archives of general psychiatry.* 2008;65(11):1324-1330.
88. Buck HG, Dickson VV, Fida R, et al. Predictors of hospitalization and quality of life in heart failure: A model of comorbidity, self-efficacy and self-care. *Int J Nurs Stud.* 2015;52(11):1714-1722.
89. Barra S, Providência R, Paiva L, Heck P, Agarwal S. Implantable cardioverter-defibrillators in the elderly: rationale and specific age-related considerations. *EP Europace.* 2015;17(2):174-186.
90. Hamilton GA, Carroll DL. The effects of age on quality of life in implantable cardioverter defibrillator recipients. *J Clin Nurs.* 2004;13(2):194-200.
91. Cerin E, MacKinnon DP. A commentary on current practice in mediating variable analyses in behavioural nutrition and physical activity. *Public Health Nutr.* 2009;12(8):1182-1188.
92. Rogers LQ, Courneya KS, Anton PM, et al. Social Cognitive Constructs Did Not Mediate the BEAT Cancer Intervention Effects on Objective Physical Activity Behavior Based on Multivariable Path Analysis. *Annals of Behavioral Medicine.* 2017;51(2):321-326.
93. Young MD, Plotnikoff RC, Collins CE, Callister R, Morgan PJ. Social cognitive theory and physical activity: a systematic review and meta-analysis. *Obesity Reviews.* 2014;15(12):983-995.
94. Berg SK, Pedersen PU, Zwisler A-D, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European Journal of Cardiovascular Nursing.* 2015;14(1):34-44.

95. Christensen AV, Zwisler AD, Svendsen JH, et al. Effect of cardiac rehabilitation in patients with ICD: are gender differences present? Results from the COPE-ICD trial. *Pacing Clin Electrophysiol.* 2015;38(1):18-27.
96. Berg SK, Støier L, Moons P, Zwisler AD, Winkel P, Ulrich Pedersen P. Emotions and health: findings from a randomized clinical trial on psychoeducational nursing to patients with implantable cardioverter defibrillator. *The Journal of cardiovascular nursing.* 2015;30(3):197-204.

CHAPTER 3. AIM 1 RESULTS & DISCUSSION: MEDIATING EFFECTS OF DIMENSIONS OF SELF-EFFICACY ON PATIENT PHYSICAL AND PSYCHOLOGICAL OUTCOMES

AIM 1 STRUCTURAL EQUATION MODELING RESULTS

Measurement Model

Dimensions of Self-Efficacy. The fit between the data and the hypothesized measurement model (unadjusted) was satisfactory (chi-square: 2,345.85, p = 0.0001; CFI: 0.896, TLI: 0.850, RMSEA: 0.077 and SRMR: 0.052). Table 3.1 summarizes the indicator loadings based on the confirmatory factor analysis (CFA). For *Physical Function*, the indicator loadings were consistently strong, ranging from λ = 0.463 to 0.834. The strongest indicator was Role Physical, one of the subscales of the SF-36. For psychological adjustment, indicator loadings were similarly strong and ranged from λ = 0.641 to 0.850. Social Function, a subscale from the SF-36, was the strongest indicator of psychological adjustment. All loadings were statistically significant. For the four *dimensions of self-efficacy* loadings were fixed to 1.0, as they were based on a single indicator and considered to be measured without error.

Table 3.1. Measurement Model for *dimensions of self-efficacy at 12-months*. Confirmatory factor analysis indicator loadings for physical function, psychological adjustment, and four *dimensions of self-efficacy*

Source	Indicators	Latent Variables	
		Physical Function (std λ)	**Psychological Adjustment (std λ)**
SF-36 subscales	**Physical Functioning**	0.796	–
	Role Physical	0.834	–
	Bodily Pain	0.699	–
PCA	**Symptoms**	-0.463	–
SF-36 subscales	**Mental Health**	–	0.774
	Role Emotional	–	0.714
	Social Functioning	–	0.850
STAI	**Anxiety**	–	-0.641
PHQ-9	**Depression**	–	-0.818

All p< 0.0001. Note. Values represent standardized indicator loadings for physical function and psychological adjustment. The four *dimensions of self-efficacy* were modeled as single indicator variables, thus fixed at 1.0, assuming no measurement error. Standardized λ between physical function and psychological adjustment was 0.759 (p = 0.0001).

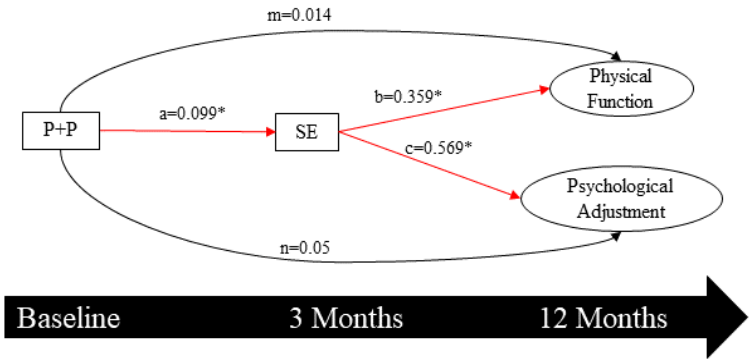
Structural Model: Testing Self-efficacy Mediating Effects

Aim 1 results are presented using two sets of models. The first set (Figure 3.1) contains one model for each of the four *dimensions of self-efficacy*, each tested as a single mediator at a time. The second (Figures 2.2 and 3.2) is a full model in which all *dimensions of self-efficacy* were tested together in the same model.

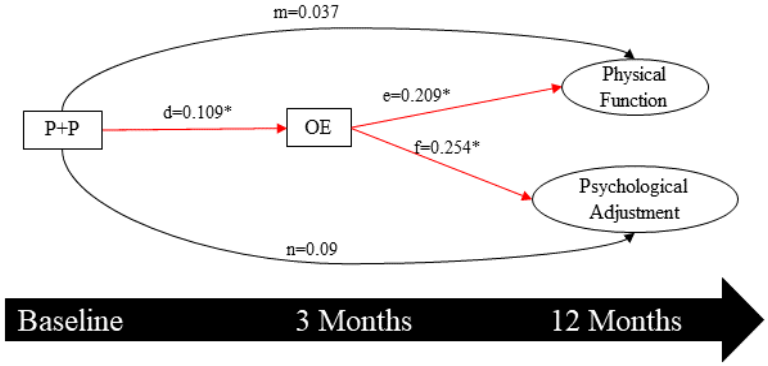
Separate Models for Dimensions of Self-efficacy

Four models, with one *dimension of self-efficacy* tested in each separately, were based on diagonally weighted least squares (DWLS) estimation and had 45 degrees of freedom. Model fit was satisfactory as observed in Figure 3.1 (**SE**: chi-square: 1523.38, p = 0.0001; CFI: 0.874, TLI: 0.919, RMSEA: 0.06 and SRMR: 0.06; **OE**: chi-square: 87.204, p = 0.0001; CFI: 0.903, TLI: 0.938, RMSEA: 0.057 and SRMR: 0.051; **SMB**: chi-square: 65.553, p = 0.0001; CFI: 0.962, TLI: 0.975, RMSEA: 0.038 and SRMR: 0.038 and **KSA**: chi-square: 1776.207, p = 0.0001; CFI: 0.936, TLI: 0.959, RMSEA: 0.048 and SRMR: 0.040).

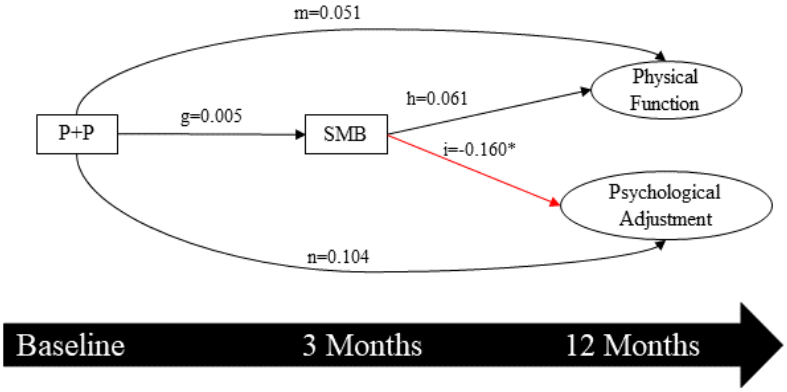
Direct effects (Figure 3.1). For all 4 individual models, the direct effect of the interventions on physical function (shown as path m in all figures) showed m, $\beta = 0.014$ to 0.054, p = 0.12 to 0.80 and on psychological adjustment path n, $\beta = 0.04$ to 0.11, p = 0.06 to 0.54. The direct effects of the interventions on *dimensions of self-efficacy* for SE was small however significant (path a, $\beta = 0.099$, p = 0.05). The effect of P+P intervention over P-only on OE dimension of self-efficacy was statistically significant (path d, $\beta = 0.109$, p = 0.03). SMB and KSA at three-months were small and non-significant, SMB (path g, $\beta = 0.005$, p = 0.92) and KSA (path j, $\beta = -0.011$, p = 0.84). The model for KSA was p = 0.06, shown as a dashed red line in Figure 3.1. The other values were small and non-significant for all individual SEM analysis.



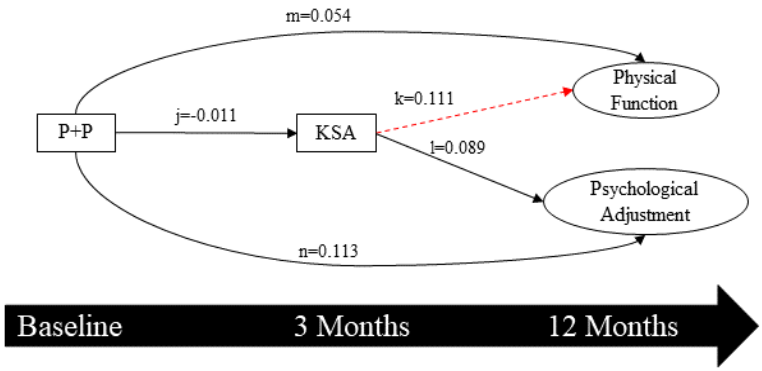
Model Fit Indices	
χ2 (p-value)	523.38(<0.001)
CFI	0.874
TLI	0.919
RMSEA	0.060
SRMR	0.060



Model Fit Indices	
χ2 (p-value)	65.553 (<0.001)
CFI	0.962
TLI	0.975
RMSEA	0.038
SRMR	0.038



Model Fit Indices	
χ2 (p-value)	1776.21 (<0.001)
CFI	0.936
TLI	0.959
RMSEA	0.048
SRMR	0.040



Model Fit Indices	
χ2 (p-value)	87.204 (<0.001)
CFI	0.903
TLI	0.938
RMSEA	0.057
SRMR	0.051

Figure 3.1. Separate Models for 4 *Dimension of self-efficacy*. * and red arrows represent p <0.05. Dashed red line between KSA→Physical Function represents p = 0.06. Values are standardized coefficients. The four dimensions of self-efficacy measured at three-months (SE, OE, SMB and KSA) were adjusted to their baseline values.

With respect to the mediator variables (*dimensions of self-efficacy, Figure 3.1*), the direct effects of SE at three-months on physical function (path b, β = 0.35, p = 0.0001) and psychological adjustment (path c, β = 0.569, p = 0.0001) were statistically significant. The mediating effects were significant through OE at three-months for physical function (path e, β = 0.209, p = 0.01) and psychological adjustment (path f, β = 0.254, p = 0.003). The influence of SMB at three-months on physical function (path h, β = -0.061, p = 0.309) was not statistically significant, but was for psychological adjustment (path i, β = -0.160, p = 0.02). The influence of KSA at three-months on physical function (path k, β = 0.111, p = 0.06) approached significance, but was not significant for psychological adjustment (path l, β = 0.089, p = 0.19).

Table 3.2. Separate Models for Four *Dimension of Self-efficacy*, Indirect and Total effects and R^2.

		Indirect Effects				**Total Effects**			**R^2**
Latent Variable	**Mediator Variable**	**Path ‡**	**B (SE)**	β	**p-value**	**B (SE)**	β	**p-value**	
Physical Function	**SE**	a*b	0.129 (0.07)	0.035	**0.08**	0.182 (0.22)	0.106	0.41	0.31
	OE	d*e	0.085 (0.05)	0.023	**0.08**	0.224 (0.23)	0.06	0.32	0.24
	SMB	g*h	-0.001 (0.01)	-0.0001	0.92	0.196 (0.24)	0.051	0.41	0.20
	KSA	j*k	-0.005 (0.02)	-0.001	0.84	0.203 (0.23)	0.05	0.39	0.21
Psychological Adjustment	**SE**	a*c	0.142 (0.08)	0.056	**0.07**	0.268 (0.14)	0.106	**0.05**	0.50
	OE	d*f	0.069 (0.04)	0.028	**0.08**	0.304 (0.15)	0.122	**0.04**	0.25
	SMB	g*i	-0.002 (0.02)	-0.0001	0.92	0.264 (0.15)	0.104	**0.08**	0.21
	KSA	j*l	-0.003 (0.01)	-0.001	0.84	0.284(0.16)	0.112	**0.07**	0.19

‡The indirect Path letters correspond to the path labels in Figure 3.1. Total effects are adding the direct paths m and n to the indirect effect of their respective outcome variable (ex: total effect P+P→SE→physical function is calculated by m+(a*b). B = unstandardized coefficient; β = standardized coefficient. Highlighted paths in this table were statistically significant ($p<0.05$) or neared statistical significance ($p < 0.10$).

Indirect Effects. The indirect effects, reported in Table 3.2, reflect the influence of the interventions *through* the hypothesized mediators, that is, the four *dimensions of self-efficacy*. The indirect effect of the intervention through SE for physical function (path a*b) was β = 0.035, p = 0.081, and for psychological adjustment (path a*c) was β = 0.056, p = 0.071), both weakly positive. The indirect effect of OE approached significance for physical function (path d*e) β = 0.023, p = 0.082 and psychological adjustment (path d*f) β = 0.028, p = 0.082. The indirect effects through SMB (paths g*h

and g*i) and KSA (paths j*k and j*l) were non-significant for both outcomes. The indirect effects indicated that SE and OE served to mediate the intervention effect on physical function and psychological adjustment.

Total Effects. Estimates (Table 3.2) represents the direct effect of the interventions on physical function (m) and psychological adjustments (n) in addition to the indirect effect of interventions through the *dimensions of self-efficacy*. Total effects consider any modeled effect of the intervention on physical and psychological outcomes. For example, took into consideration the indirect effect of the P+P intervention compared to P-Only through self-efficacy (a*b) on physical function as well as the direct effect from the intervention on physical function (m). Total standardized effects ranged between 0.05 and 0.122 and were statistically significant between P+P → SE → Psychological Adjustment (path n+(a*c)) and P+P → OE → Psychological Adjustment (path n+(d*f)). This suggested an effect of P+P over P-only on the psychological adjustment outcome through self-efficacy and outcome expectations, but also considered the direct effect of P+P compared to P-only on psychological adjustment. Of note, the significance for the total effects for P+P → SMB → Psychological Adjustment (path n+(g*i)) and P+P → KSA → Psychological Adjustment (path n+(j*l)) were p = 0.08 and 0.07, respectively, with weak coefficients of 0.10 and 0.11. This revealed a weak relationship between when comparing the influence of the two interventions on psychological adjustment through self-management behavior and ICD knowledge, taking into account their direct effects (n) and indirect effects (g*i and j*l).

The full model of Dimension of Self-Efficacy

Following tests for mediation effects of the four *dimensions of self-efficacy* in separate models, the four *dimensions of self-efficacy* were tested simultaneously in the same model. Results from this model are in Table 3.3 and Figure 3.2. This model, based on DWLS estimation and 78 degrees of freedom, fit the data satisfactorily, with a chi-square of 192.44, p = 0.0001, CFI = 0.867, TLI = 0.927,

RMSEA = 0.046 and SRMR = 0.055. The R^2 for physical function was 0.314 and for psychological adjustment was 0.484 (Table 3.3).

Direct effects. The direct effects of the P+P intervention compared to P-only on physical function (path m, β = 0.011, p = 0.86) and psychological adjustment (path n, β = 0.05, p = 0.37) were small and non-significant. The direct effects of the P+P intervention on Dimensions of self-efficacy for SE was small (path a, β = 0.085, p = 0.078) indicating that P+P intervention over P-only had an effect on improving self-efficacy. The effect of P+P intervention on OE dimension of self-efficacy was statistically significant (path d, β = 0.115, p = 0.02) indicating that the P+P intervention over P-only had an impact on improving outcome expectations. SMB and KSA at three-months were small and non-significant, SMB (path g, β = 0.016, p = 0.75) and KSA (path j, β = -0.009, p = 0.88).

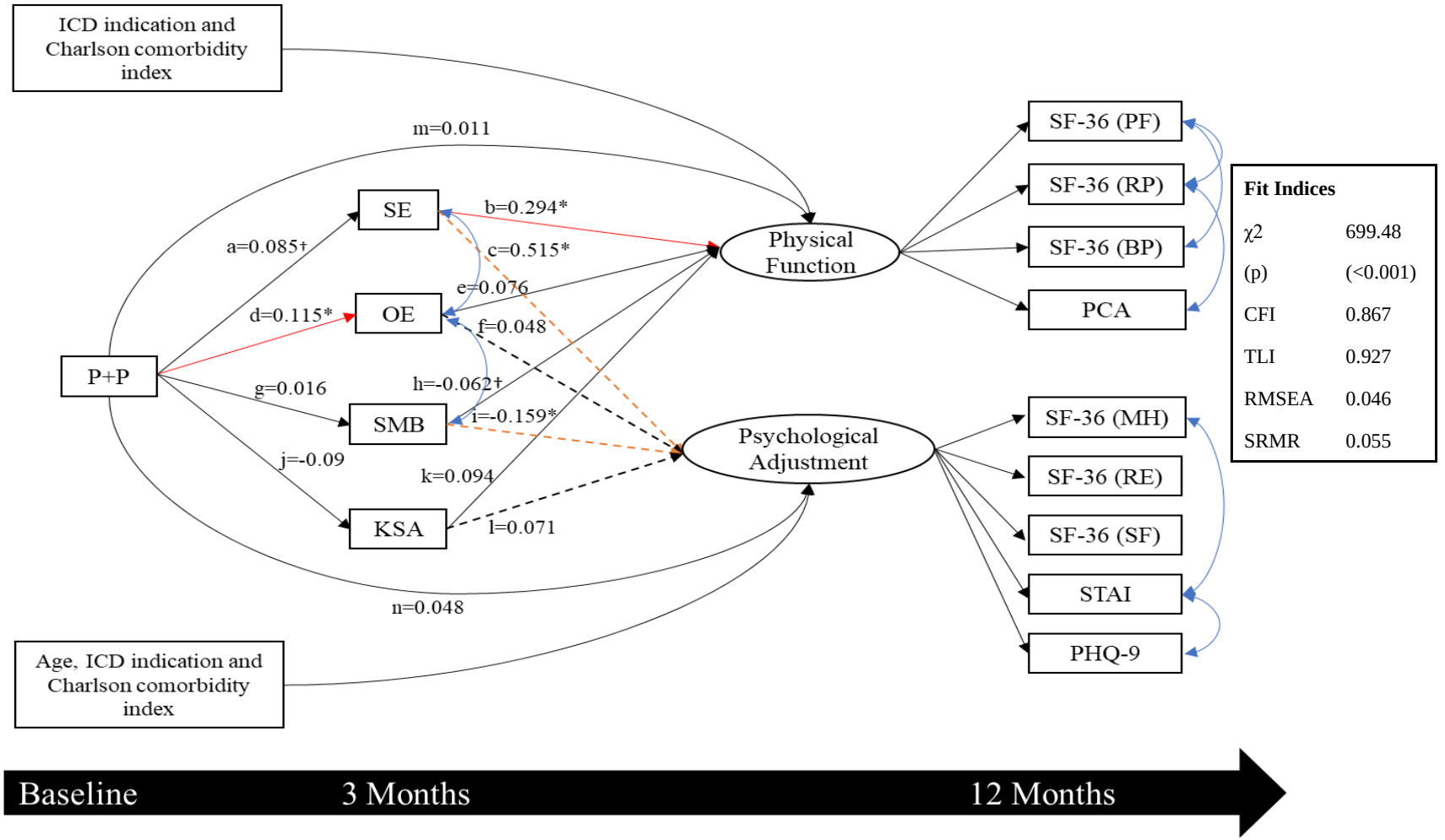


Figure 3.2. Structural Model. Standardized parameter estimates and fit indices for test of mediating effects of self-efficacy on *physical function* and *psychological adjustment*. The red arrows and * represents a statistically significant path ($p < 0.05$). †$p = 0.08$. Dashed lines are used to distinguish paths between the dimensions of self-efficacy and psychological adjustment. In this model, physical function was adjusted for ICD indication (primary, secondary) and baseline CCI. Psychological adjustment was adjusted for age as well as ICD indication and baseline CCI; Four *dimensions of self-efficacy* at three-months (SE, OE, SMB and KSA) were adjusted to their baseline values; Blue arrows are correlated errors; SF-36 subscales: MH (Mental Health), RE (Role Emotional), SF (Social Functioning), PF (Physical Functioning), RP (Role Physical), BP (Bodily Pain); STAI (anxiety , PHQ-9 (depression) and PCA (symptoms).

With respect to the mediator variables, the direct effects of SE at three-months on physical function (path b, β = 0.294, p = 0.001) and psychological adjustment (path c, β = 0.515, p = 0.0001) were statistically significant or approaching significance, as were the direct effects of 3-month SMB on physical function (path h, β = - 0.062, p = 0.07) and psychological adjustment (path i, β = - 0.159, p = 0.01). The direct effects of outcome expectations (OE) and knowledge (KSA) on physical function and psychological adjustment were not significant.

Table 3.3. Full model indirect, total effects and r^2.

		Indirect Effects				**Total Effects**			**R^2**
Latent Variable	**Mediator Variable**	**Path‡**	**B (SE)**	β	**p-value**	**B (SE)**	β	**p-value**	
Physical Function	**SE**	a*b	0.09 (0.06)	0.025	0.12	0.129 (0.22)	0.036	0.55	0.48
	OE	d*e	0.031 (0.04)	0.009	0.39	0.071 (0.22)	0.02	0.74	
	SMB	g*h	-0.004 (0.012)	-0.001	0.77	0.036 (0.22)	0.01	0.87	
	KSA	j*k	-0.003 (0.02)	-0.001	0.88	0.036 (0.22)	0.01	0.87	
Psychological Adjustment	**SE**	a*c	0.109 (0.06)	0.044	0.10	0.227 (0.14)	0.092	0.10	0.31
	OE	d*f	0.014 (0.03)	0.005	0.61	0.132 (0.13)	0.053	0.32	
	SMB	g*i	-0.006 (0.02)	-0.003	0.76	0.112 (0.13)	0.045	0.40	
	KSA	j*l	-0.002 (0.01)	-0.001	0.88	0.117 (0.13)	0.047	0.38	

‡The indirect Path letters correspond to the path labels in Figures 2.2 and 3.2. Total effects are adding the direct paths m and n to the indirect effect of their respective outcome variable (ex: total effect P+P→SE→Physical function is calculated by m+(a*b). B = unstandardized coefficient; β = standardized coefficient.

Indirect Effects. The indirect effect of the intervention through SE on physical function (path a*b) was β = 0.025, p = 0.123, and for psychological adjustment (path a*c) was β = 0.044, p = 0.097), both non-significant. The indirect effects through SMB (paths g*h and g*i) were likewise non-significant for both outcomes. This indicated that, although the direct effect of three-months SE and SMB on the outcomes were significant, the effects of the interventions were not mediated by SE or SMB.

Total Effects ranged between 0.01 and 0.092 and were not statistically significant (Table 3.3).

Effects of baseline values of dimensions of SE at three-months. Baseline values of *dimensions of self-efficacy* presented statistically significant effect on three-months measures with all p<0.0001.

$SE_{baseline} \rightarrow SE_{3Months}$ had a standardized coefficient of 0.467, $OE_{baseline} \rightarrow OE_{3Months}$ was 0.457, $SMB_{baseline} \rightarrow SMB_{3Months}$ was 0.02, and $KSA_{baseline} \rightarrow KSA_{3Months}$ was 0.036.

Adjustment variables for Dimension of Self-Efficacy Models

On the structural models testing one or all *dimensions of self-efficacy* at a time, the latent variables physical function and psychological adjustment were adjusted for at least one of the following in the final model: age, CCI, and ICD indication. In the model testing one *dimension of self-efficacy* at a time, the adjustment variables in the final model were: for Physical function, the effects of both the CCI (range of β = -0.385 to -0.351, p <0.001) and ICD indication (range of β = -0.157 to -0.144, p< 0.03) were statistically significant. Indicating that those with more comorbidities, higher CCI scores, had worst physical function in the present model. Similarly, those with ICD indication implanted for secondary prevention had significantly higher physical function. For Psychological adjustment, older participants presented better psychological adjustment indicated by age (range of β = 0.261 to 319, p = <0.001), the higher number of comorbidities also influenced on lower psychological scores tested by CCI (range of β = -0.377 to -0.203), p < 0.001) and those with ICD indication implanted for secondary prevention had significantly higher psychological adjustment (range of β = -0.168 to -0.190, p < 0.008).

In the model testing all four *dimensions of self-efficacy* at the same time, for Physical function, the adjustment variables in the final model were: the effects of both CCI (β = -0.379, p <0.001) and ICD indication (β = -0.174, p = 0.009) were statistically significant. This indicates that those with more comorbidities, with higher CCI scores, had worst physical function in the present model. Similarly, those with ICD indication implanted for secondary prevention had significantly higher physical function. For Psychological adjustment, age higher the age better psychological adjustment results (β = 0.312, p = <0.001). Those with more comorbidities had worst psychological outcomes demonstrated by CCI (β = -0.259, p < 0.001) and ICD indication for secondary prevention showed better psychological adjustment outcomes when compared to primary prevention (β = -0.181, p = 0.004).

Table 3.4. Summary of mediation effects found in tested models

Model	Indirect Effects: Mediation Pathway (p-value)
Independent Models for Four Dimensions of Self-efficacy	1. P+P → SE → physical function (0.08) 2. P+P → SE → psychological adjustment (0.07) 3. P+P → OE → physical function (0.08) 4. P+P → OE → psychological adjustment (0.08)
Full Model with Four Dimensions of Self-Efficacy	No mediation

Note: Paths presented in this table neared statistical significance ($p < 0.10$) for indirect effects.

DISCUSSION

The purpose of dissertation Aim 1 was to evaluate the mediating effects of four *dimensions of self-efficacy* (self-efficacy, outcome expectation, self-management behavior, and ICD knowledge) between the interventions and physical function and psychological adjustment in recipients of an initial ICD. The models compared the P+P versus the P-Only intervention; that is, we examined the effects of adding a partner to the ICD nursing intervention.

Four Dimensions of Self-efficacy as Mediators

Models testing one *dimension of self-efficacy* at a time showed mediation with intervention effects on physical function and psychological adjustment through Self-Efficacy and Outcome Expectations. There was no evidence of significant mediation for Self-Management Behaviors or ICD Knowledge. Thus, having a partner included in the intervention has an important effect on the patient's self-efficacy and outcome expectations, on the other hand adding a partner did not influence patient's self-management behavior or ICD knowledge. Self-management behavior determined the extent to which the interventions had influenced behavioral change. In this intervention study, participants were asked to incorporate behaviors to manage symptoms, begin to exercise, use stress management techniques to mitigate anxiety and depression, create an ICD shock plan, take a CPR class, and discuss future implications of the ICD on their significant relationship. It might be the case that adding a partner on the

intervention did not assist participants in changing the performance of these activities sufficiently in comparison to the P-Only intervention. To improve ICD knowledge, participants received booklets and watched videos to increase their understanding about the device, in a similar way, participant ICD knowledge did not improve with the inclusion of a significant other in the intervention. These results suggest that while the self-efficacy and outcome expectation elements of SCT were supported in the interventions, P+P patients' behavior and knowledge compared to P-Only did not improve significantly with partner involved in the intervention.

When testing the model with all four *dimensions of self-efficacy* simultaneously, mediation of the intervention through the *dimensions of self-efficacy* was not found for either physical function or psychological adjustment. Self-efficacy had indirect effects close to statistical significance for psychological adjustment. Evident on the left side of the model in Figure 3.2 is a direct effect for P+P vs. P-Only for Outcome Expectations, but not for the other *dimensions of self-efficacy* on *physical function or psychological adjustment*. There were statistically significant effects of self-efficacy and self-management behavior on physical function and psychological adjustment. However, no mediation effects of outcome expectations or ICD knowledge were found for the study outcomes. Thus, in brief, no statistically mediation effects were found in the full model.

Previous interventions developed for patients with cardiovascular disease using social cognitive theory have not shown significant intervention effects on self-efficacy. Pinto and colleagues[68] tested a telephone-based maintenance intervention to improve exercise participation in post-cardiac rehabilitation. The intervention improved exercise participation at 12-months compared to controls. A multiple mediation analyses showed that the intervention significantly increased social support from friends at six-months, but not measure of self-efficacy—behavioral processes of change, decisional balance index, or enjoyment of exercise.[68] Zhu et al.[84] tested a self-efficacy based exercise intervention among adults between 50-64 vs. those 65 years old or older. The intervention did not affect change in self-efficacy

when the whole sample was considered. However, for those 50 - 64 years, an intervention mediation effect through self-efficacy was found for the exercise outcome.[84] With respect to the current study, possible reasons the interventions did not show mediation in the full model could be multicollinearity between self-efficacy and outcome expectations, a study design testing the effect of two interventions without a control groups leading to small intervention effects on *dimensions of self-efficacy*, in addition to the sample size being on the lower side of acceptability for SEM analysis and the lack of further validation of some ICD specific scales used on this study.

Self-Efficacy models and multicollinearity

In the individual *dimensions of self-efficacy* models the intervention indirect effects intervention on physical function and psychological adjustment through self-efficacy and outcome expectations were close statistical significance, that is, with p values between 0.07 and 0.08. This suggests the potential for mediation. On the other hand, these statistically significant paths were not observed in the model that included all four *dimensions of self-efficacy* simultaneously. To better understand the relationship between these two variables, we verified the Pearson correlation coefficient between SE and OE, r = 0.43, reflecting a moderate sized correlation between these two variables.

It is possible that multicollinearity between the self-efficacy and outcome expectations accounted for the lack of mediation. One strategy to manage multicollinearity is to adjust for measurement error between measures. These adjustments were considered in the full model, and this approach is also known to attenuate correlations among the exogenous variables. The presence of measurement error is likely to mask the correlations among constructs.[85] This might be the reason why the full model of *dimensions of self-efficacy* did not show mediation among all self-efficacy concepts.

ICD Indication, Charlson Comorbidity Index and Age

Possible moderators of the relationship between *self-efficacy* and physical function and psychological adjustment noted a statistically significant effect of ICD indication, Charlson comorbidity

index and age on physical function and on psychological adjustment. For physical function and psychological adjustment, patients with primary ICD indication had the worst outcomes. This may have occurred because patients who receive an ICD for primary prevention have different characteristics when compared to those who receive the ICD for secondary prevention. Those who had a secondary indication for ICD implantation have a reference from which to understand the impact of potential recurrence of SCA or ventricular arrhythmia. On the other hand, patients receiving ICD for primary prevention have a more limited understanding of their survival and might have additional difficulties in placing the potential impact of the ICD into context.[53,86] In this setting, information about ICD and its benefits might be crucial to primary prevention patients to understand the potential lifesaving benefits of the ICD and maximize the perceived value of the device.[53] The chronic nature of the heart condition in primary care might not allow for an intervention aimed at improving health outcomes to have a big effect when physical health is poor. For example, simply by improving a person's confidence to deal with an ICD would not convey benefits to health.

Those patients with more comorbidities had the worst *physical function and psychological adjustment* at 12-months. Buck and colleagues found that the number of comorbidities may weaken the strength of the relationship between self-efficacy and self-care maintenance. They recommended tailoring interventions to improve self-efficacy considering different levels of comorbidity to impact outcomes.[87]

Age was an adjustment variable for psychological outcomes, such older patients compared to younger patients (< 60) showed better psychological outcomes. Prior studies have shown that older patients with ICDs tend to have decreased physical functioning, more comorbidities, and worse symptoms impacting their quality of life, while younger patients are more likely to experience increased psychological distress, anxiety and depression.[88,89]

Non-statistically significant paths

The P+P intervention study is one of a few randomized controlled trials with cardiac patients that has tested for theoretically based mediation of intervention effects on physical function and psychological adjustment comparing two interventions in ICD patients. To our knowledge, this is the first analysis using structural equation modeling to evaluate the mediation effect of social cognitive theory in patients who have received a first-time ICD. It is possible for the effects pf mediation to be suppressed when some social cognitive theory constructs improve while others worsen.[90,91] This may have been the case for the negative effect of self-management behaviors on psychological adjustment. Contrary to what we hypothesized, there was a negative influence of self-management behavior on psychological adjustment. However, the path between self-management behavior and psychological outcomes is negative, indicating that self-management is worsening psychological adjustment. This might be the case if patients have increased distress related to performing certain behaviors. Another possible reason of failure in finding significant effects of the intervention on Knowledge can be related to a "ceiling effect" of this construct, given that the scores for all subjects are relatively high. This might have influenced detecting changes on this construct.

Moreover, mediation pathways may not be sufficiently strong for detection with the sample size of 300, given that significant indirect effects by social cognitive theory constructs are not frequently reported. Larger sample sizes may be required for detecting small mediation effect sizes.[90,92] It is also important to highlight that in this study, we are evaluating the impact on patient outcomes both with and without the partner. This impact might be small. Also, a lack of psychometrically tested scales for the self-efficacy and self-management behavior *dimension of self-efficacy* may be causing measurement error, making it difficult to understand the mediation process for this specific construct.

Strengths

The strengths of this study were the use of the theoretical model for intervention development and testing, measures of mediators administered in a temporal sequence to test for mediation at three-months and outcomes at 12-months, and the use of an advanced and robust statistical method to understand the mechanism which the interventions impact outcomes. Moreover, since ICD indication, Charlson comorbidity index and age were important outcome moderators, evaluating multi-group SEM would allow the understanding of the intervention mediators based on these characteristics. It is also important to understand the effect of the intervention on partners self-efficacy, physical and psychological health to fully comprehend which components are critical in the intervention for both patients and partners. Further research is needed to understand better the role of *content specific self-efficacy* constructs for partners and moderators within multivariate models in patients with an ICD participating in an intervention.

Limitations

There are four main limitations to this study: (I) a limited ethnic or racial diversity in the study sample. The results are limited to a sample of well-educated, predominantly white male patients, even though this might be a characteristic of patients who receive an ICD in the United States. (II) There was no patient control group; patients from both groups in this study received an intervention. The model is showing the difference between having a partner or not on the intervention. This might be affecting the paths showing small effects. Having a third study arm with controls that didn't receive an intervention would allow further understanding of the intervention and mediation effects. (III) Third, the tool used to measure self-management behavior and self-efficacy were developed specifically for this study and were not yet been tested for reliability and validity. (IV) Finally, in this analysis partners response to the intervention was not considered. There is a possibility that partners self-efficacy, physical and psychological health might influence patient physical function and psychological adjustment.

Recommendations for future studies would be to consider a later follow-up of the P+P subjects (three to four years after the intervention) to allow the evaluation of longer-term benefits of the intervention. Other outcomes such as mortality rates, complications, physical and psychological outcomes evaluation when compared to usual care, would provide benefits of the intervention on these outcomes.

CONCLUSION

The addition of a partner in an intervention based on Social Cognitive Theory improved physical function and psychological adjustment mediated in part by self-efficacy and outcome expectations among patients with initial ICDs. Self-Management Behavior and ICD Knowledge were not mediators but contributed to physical and psychological health outcomes.

REFERENCES

1. Pinto BM, Dunsiger SI. Mediators of exercise maintenance after cardiac rehabilitation. *Journal of cardiopulmonary rehabilitation and prevention.* 2015;35(1):13-20.
2. Zhu SJ, Nahm E, Resnick B, et al. The Moderated Mediating Effect of Self-Efficacy on Exercise Among Older Adults in an Online Bone Health Intervention Study: A Parallel Process Latent Growth Curve Model. *J Aging Phys Act.* 2017;25(3):378-386.
3. Grewal R, Cote J, Baumgartner H. Multicollinearity and Measurement Error in Structural Equation Models: Implications for Theory Testing. *Marketing Science.* 2004;23(4):519-529.
4. Dunbar SB, Dougherty CM, Sears SF, et al. Educational and psychological interventions to improve outcomes for recipients of implantable cardioverter defibrillators and their families: a scientific statement from the American Heart Association. *Circulation.* 2012;126(17):2146-2172.
5. Ladwig KH, Baumert J, Marten-Mittag B, Kolb C, Zrenner B, Schmitt C. Posttraumatic stress symptoms and predicted mortality in patients with implantable cardioverter-defibrillators: results from the prospective living with an implanted cardioverter-defibrillator study. *Archives of general psychiatry.* 2008;65(11):1324-1330.
6. Buck HG, Dickson VV, Fida R, et al. Predictors of hospitalization and quality of life in heart failure: A model of comorbidity, self-efficacy and self-care. *Int J Nurs Stud.* 2015;52(11):1714-1722.
7. Barra S, Providência R, Paiva L, Heck P, Agarwal S. Implantable cardioverter-defibrillators in the elderly: rationale and specific age-related considerations. *EP Europace.* 2015;17(2):174-186.
8. Hamilton GA, Carroll DL. The effects of age on quality of life in implantable cardioverter defibrillator recipients. *J Clin Nurs.* 2004;13(2):194-200.
9. Cerin E, MacKinnon DP. A commentary on current practice in mediating variable analyses in behavioural nutrition and physical activity. *Public Health Nutr.* 2009;12(8):1182-1188.
10. Rogers LQ, Courneya KS, Anton PM, et al. Social Cognitive Constructs Did Not Mediate the BEAT Cancer Intervention Effects on Objective Physical Activity Behavior Based on Multivariable Path Analysis. *Annals of Behavioral Medicine.* 2017;51(2):321-326.
11. Young MD, Plotnikoff RC, Collins CE, Callister R, Morgan PJ. Social cognitive theory and physical activity: a systematic review and meta-analysis. *Obesity Reviews.* 2014;15(12):983-995.

CHAPTER 4: AIM 2 RESULTS & DISCUSSION: MEDIATING EFFECTS OF CONTENT-SPECIFIC ELEMENTS OF SELF EFFICACY ON PATIENT PHYSICAL AND PSYCHOLOGICAL OUTCOMES

Chapter 4 focuses on Aim 2, presenting the results and discussion about testing the mediation processes, between the intervention and physical function and psychological adjustments, based on the eight content-specific elements of self-efficacy.

AIM 2 STRUCTURAL EQUATION MODELING RESULTS

Measurement Model

Content-specific elements of self-efficacy. The fit between the data and the hypothesized measurement model using eight content specific elements of self-efficacy unadjusted were satisfactory (chi-square: 142.449, p = 0.0001; CFI = 0.979, TLI = 0.963, RMSEA = 0.055 and SRMR = 0.046). Table 4.1 summarizes the multiple indicator loadings for this CFA. For Physical function, the indicator loadings were consistently strong, ranging from $\lambda_1 = 0.437$ to 0.830. The strongest indicator was Role Physical, followed by Physical functioning subscales from the SF-36. For psychological adjustment, indicator loadings were similarly strong and ranged from $\lambda_2 = 0.653$ to 0.897. Social Function, subscale from SF-36, was the strongest indicator of psychological adjustment. All loadings were statistically significant. The eight *content-specific elements of self-efficacy* loadings were based on single indicators and fixed at 1.0.

Table 4.1. Measurement Model for 8 Content Specific Self-Efficacy. Confirmatory factor analysis indicator loadings for physical function, psychological adjustment.

Source	Indicators	Latent Variables	
		Physical Function (λ_1)	**Psychological Adjustment (λ_2)**
SF-36 subscales	**Physical Functioning**	0.828	–
	Role physical	0.830	–
	Bodily Pain	0.686	–
PCA	**Symptoms**	-0.437	–
SF-36 subscales	**Mental Health**	–	0.794
	Role Emotional	–	0.653
	Social Functioning	–	0.897
STAI	**Anxiety**	–	-0.782
PHQ-9	**Depression**	–	-0.878

All $p < 0.0001$. Note. Values represent standardized indicator loadings for physical function and psychological adjustment. The eight *content-specific elements of self-efficacy* are not represented in this table.

Structural Model: Testing self-efficacy mediating effects

In answering Aim 2, results will be presented using two set of models. The first (Figures 2.3 and 4.1) set of models tested each of the eight *content-specific elements of self-efficacy one at a time.* The second model (Figure 4.2) tested only those *content-specific elements of self-efficacy* that presented significant, or close to significant paths between interventions and *content-specific elements of self-efficacy.*

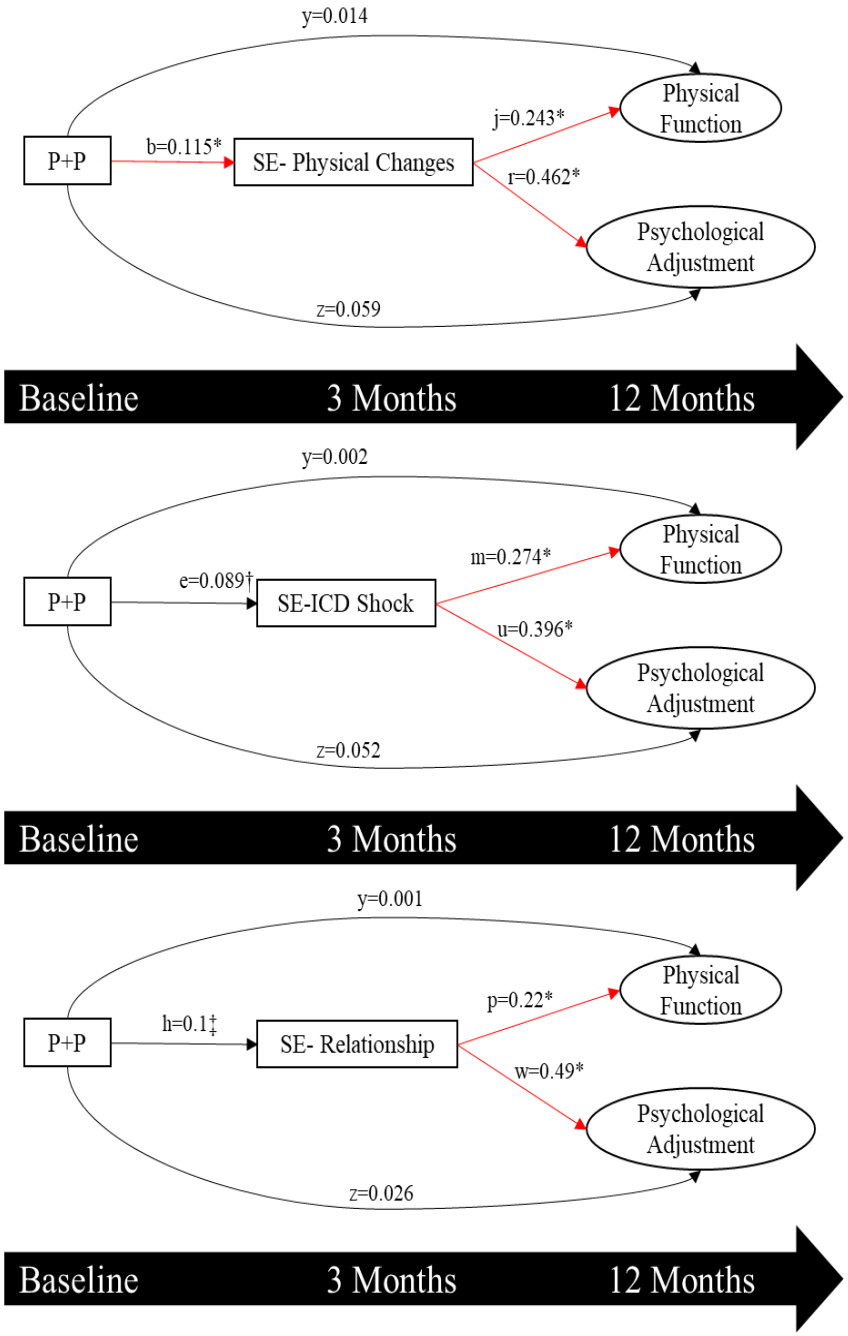
Eight individual Models for Content Specific elements of self-efficacy

SEM was used to test the effect of the interventions on Physical function and psychological adjustment with one *Content Specific element of self-efficacy* at a time in eight models. Results can be found in Figure 4.1 and Table 4.2.

Direct effects. The direct effects of the interventions on physical function ranged on path y, β = 0.001 to 0.015, and on psychological adjustment on path z, β = 0.026 to 0.078, none of these paths were statistically significant. The direct effects of the intervention on each *Content Specific element of self-*

efficacy were small and non-significant: ICD function (path a, β = 0.076, p = 0.17), Life Style (path c, β = 0.068, p = 0.202), Emotions (path d, β = 0.094, p = 0.138), ICD shock (path e, β = 0.089, p = 0.118), Safety (path f, β = 0.076, p = 0.181), Cognition (path g, β = 0.04, p = 0.478). For the paths to physical changes (path b, β = 0.115, p = 0.036) and relationship (path h, β = 0.100, p = 0.057) were small and statistically significant or close to be significant.

With respect to the mediator variables (*Content Specific elements of self-efficacy*), the direct effects of all mediators on physical function (paths i, j, k, l, m, n, o and p (Figure 2.3) had β between 0.220 and 0.431 and psychological adjustment (paths q, r, s, t, u, v, x and w (Figure 2.3) had β between 0.358 and 0.580 and were all statistically significant.



Model Fit Indices	
χ2 (p-value)	111.46 (<0.001)
CFI	0.88
TLI	0.94
RMSEA	0.056
SRMR	0.062

Model Fit Indices	
χ2 (p-value)	129.57(<0.001)
CFI	0.87
TLI	0.94
RMSEA	0.05
SRMR	0.07

Model Fit Indices	
χ2 (p-value)	106.91 (<0.001)
CFI	0.90
TLI	0.95
RMSEA	0.05
SRMR	0.07

Figure 4.1. Structural Models. Standardized parameter estimates and fit indices for test of mediating effects *content specific elements of self-efficacy* on *physical function* and *psychological adjustment*. The red arrows* represent a statistically significant path ($p < 0.05$). †p-value 0.12 and ‡p of 0.06. In these models, *Physical Function* was adjusted for gender, baseline CCI, cardiac arrest and EF. *Psychological Adjustment* was adjusted for age, gender as well as ICD indication and baseline CCI; *content specific elements of self-efficacy* at three-months were adjusted to baseline values.

Table 4.2. Eight individual Models for *Content Specific elements of self-efficacy*. Models indirect, total effects and r^2.

		Indirect Effects				Total Effects			
Latent Variable	**Mediator Variable**	**Path‡**	**B (SE)**	β	**p-value**	**B (SE)**	β	**p-value**	**R^2**
Physical Function	**ICD function**	a*i	0.097 (0.075)	0.026	0.19	0.096 (0.219)	0.026	0.66	0.32
	Physical Changes	b*j	0.106 (0.060)	0.028	**0.07**	0.158 (0.224)	0.042	0.48	0.24
	Lifestyle	c*k	0.115 (0.092)	0.030	0.21	0.175 (0.218)	0.045	0.42	0.41
	Emotions	d*l	0.116 (0.090)	0.030	0.20	0.130 (0.225)	0.034	0.56	0.31
	ICD shock	e*m	0.093 (0.064)	0.024	0.15	0.102 (0.224)	0.027	0.65	0.28
	Safety	f*n	0.069 (0.058)	0.018	0.23	0.116 (0.232)	0.029	0.62	0.29
	Cognition	g*o	0.041 (0.062)	0.011	0.50	0.097 (0.228)	0.025	0.67	0.27
	Relationship	h*p	0.089 (0.058)	0.022	0.13	0.093 (0.237)	0.023	0.69	0.28
Psychological Adjustment	**ICD function**	a*q	0.113 (0.088)	0.044	0.20	0.096 (0.219)	0.026	0.11	0.50
	Physical Changes	b*r	0.138 (0.069)	0.053	**0.05**	0.291 (0.146)	0.112	**0.05**	0.38
	Lifestyle	c*s	0.094 (0.076)	0.037	0.22	0.285 (0.145)	0.111	**0.05**	0.44
	Emotions	d*t	0.139 (0.101)	0.054	0.17	0.264 (0.144)	0.102	**0.07**	0.49
	ICD shock	e*u	0.092 (0.062)	0.035	0.14	0.228 (0.152)	0.087	0.13	0.32
	Safety	f*v	0.072 (0.058)	0.027	0.21	0.277 (0.154)	0.105	**0.07**	0.32
	Cognition	g*x	0.046 (0.067)	0.018	0.49	0.219 (0.151)	0.084	0.14	0.36
	Relationship	h*w	0.128 (0.074)	0.049	**0.08**	0.195 (0.148)	0.075	0.19	0.41

*p<0.05; †p ≤ 0.07. ††p ≤0.08 ‡The indirect Path letters correspond to the path labels in Figures 2.3 and 4.1. Total effects are adding the direct paths y and z to the indirect effect of their respective outcome variable (ex: total effect P+P→ ICD shock → Physical function is calculated by y+(e*m).

Indirect Effects. The indirect effects reflect the influence of the interventions *through* hypothesized mediators that is, the eight *Content Specific elements of self-efficacy* (Table 4.2) . The indirect effect of the intervention through Physical Changes on psychological adjustment (path b*r: β = p 0.046) was statistically significant. This indicated that P+P compared to the P-only intervention improved confidence in managing physical symptoms and changes after the ICD. Self-efficacy for physical changes

on physical function (path b*j) had β = 0.028 and p 0.07 and relationship on psychological adjustment (path h*w) had β = 0.049 and p = 0.08. Both indicating near significance.

Total Effects. Estimates of total effects (Table 4.2) represent the direct effect of P+P intervention on latent variables physical function (path y) and psychological adjustment (path z), in addition to the indirect effect of P+P intervention on latent variables through the *Content Specific elements of self-efficacy*. Total effects ranged between 0.023 and 0.045 on physical function with none of the paths being statistically significant. Total effects on psychological adjustment ranged from 0.026 to 0.112, through SE-physical changes (path z+(b*r) β = 0.112 p = 0.05) and SE-lifestyle (path z+(c*s) β = 0.111 p = 0.04), were statistically significant and approaching significance on SE-emotions (path z+(d*t) β = 0.102 p = 0.07) and SE-safety (path z+(f*v) β = 0.105 p = 0.07).

Model with statistically significant Content Specific elements of self-efficacy

SEM was used to test the effect of the interventions on physical function and psychological adjustment with statistically significant c*ontent specific elements of self-efficacy* at the same model. Results can be found in Figure 4.2 and Table 4.3.

Direct effects. The direct effects of the intervention on physical function were small and non-significant for path y (β = -0.003, p = 0.96) and psychological adjustment (path z, β = 0.036, p = 0.51). The direct effects of the interventions on SE-physical changes (path b, β = 0.104, p = 0.05) and SE-relationship (path h, β = 0.107, p = 0.04) were small, however significant. The effect of interventions on SE-ICD shocks (path e, β = 0.110, p = 0.06) and was small and approaching significance.

With respect to the mediator variables (*Content Specific elements of self-efficacy*), the direct effects of SE-physical changes (path r, β = 0.269, p = 0.02) and SE-relationship (path w, β = 0.399, p = 0.001) at three-months on psychological adjustment at 12-months were statistically significant (Figure 4.2). Other paths were not statistically significant.

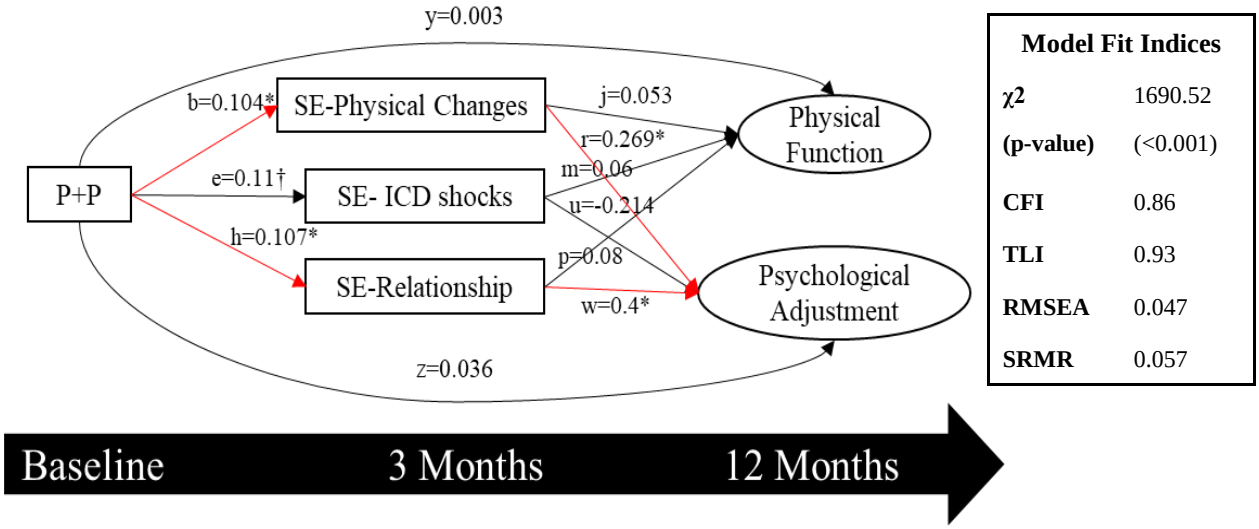


Figure 4.2. Structural Model. Standardized parameter estimates and fit indices for test of mediating effects *content specific elements of self-efficacy* on *physical function* and *psychological adjustment*.*p-value<0.05; †p = 0.06; Red arrows and * are pointing statistically significant paths. *Content specific elements of self-efficacy* were adjusted for baseline values. Physical functioning was adjusted for gender and CCI. Psychological adjustment was adjusted for age, EF and CCI.

Indirect Effects. The indirect effects are reported in Table 4.3**.** The indirect effect of the interventions through SE-physical changes (b*j), SE-ICD shocks (e*m) and SE-relationship (h*p) on physical function ranged from β = 0.005 to 0.009 and were not statistically significant. The effect of intervention through *content specific elements of self-efficacy* on psychological adjustment ranged from β = -0.023 to 0.043, with SE-relationship approaching significance (path h*w, β = 0.043, p = 0.087), which indicates an effect of P+P intervention over the P-only intervention on psychological adjustment through SE-relationship. The mediation effect was weak (β = 0.043) and with 8.7% chance that this effect occurred by chance.

Total Effects. Estimates of total effects (Table 4.3) ranged between β = 0.002 and 0.006 for *physical functioning* and between β = 0.013 and 0.079 for psychological adjustment and were not statistically significant.

Table 4.3. Model with statistically significant Content Specific elements of self-efficacy. Model indirect, total effects and r^2.

		Indirect Effects				Total Effects			R^2
Latent Variable	**Mediator Variable**	**Path‡**	**B (SE)**	β	**p-value**	**B (SE)**	β	**p-value**	
Physical Function	**Physical Changes**	b*j	0.021 (0.04)	0.005	0.61	0.009 (0.233)	0.002	0.97	0.20
	ICD shock	e*m	0.024 (0.049)	0.007	0.50	0.012 (0.232)	0.003	0.92	
	Relationship	h*p	0.034 (0.05)	0.009	0.21	0.022 (0.230)	0.006	0.83	
Psychological Adjustment	**Physical Changes**	b*r	0.07 (0.048)	0.028	0.62	0.160 (0.140)	0.064	0.95	0.38
	ICD shock	e*u	-0.059 (0.047)	-0.023	0.14	0.031 (0.147)	0.013	0.25	
	Relationship	h*w	0.106 (0.062)	0.043	**0.08**	0.197 (0.145)	0.079	0.17	

‡The indirect Path letters correspond to the path labels in Figure 4.2. †p = 0.087; Total effects are adding the direct paths y and z to the indirect effect of their respective outcome variable (ex: total effect P+P→ICD shock→physical function is calculated by y+(e*m).

Adjustment variables for Content-specific elements of Self-Efficacy Models

On the structural models testing one or all statistically significant *content-specific elements of self-efficacy* at a time, the latent variables physical function and psychological adjustment were adjusted for at least one of the following: age, gender, CCI, ICD indication, cardiac arrest and EF.

In the model testing each of eight *content-specific elements of self-efficacy* at a time, for physical function, the effects of CCI (range of β = -0.377 to -0.160), gender (range of β = -0.369 to -0.157), presence of cardiac arrest (range of β = 0.159 to 0.138) and EF (range of β = 0.114 to 0.095) were statistically significant. Indicating that on the content specific dimensions of self-efficacy models those with more comorbidity had worst physical function. Males also presented worst physical function when compared to females. Regarding to cardiac arrest and EF, those with cardiac arrest for secondary prevention for CF or VT had worst outcome and the higher EF, better was the physical function. For Psychological adjustment, age had a positive impact showing that those with higher age had better

psychological outcomes (range of β = 0.307 to 0.243). For gender, males presented worst psychological outcomes when compared to females (range of β = -0.117 to -0.096). For EF, higher their values better were the psychological adjustment (range of β = 0.196 to 0.142). The higher number of comorbidities leaded to a worst psychological adjustment measured by CCI (range of β = -0.232 to -0.166) and regarding ICD indication, those with ICD implanted for primary prevention had better psychological adjustment (effected only SE-physical change with β = 0.179) had significant effects.

In the model testing statistically significant *content-specific elements of self-efficacy*, for Physical function, the effects of both the CCI (β = -0.190) and gender (β = -0.173) were negative and statistically significant, meaning that physical function was worst on those with lower CCI scores and males. For psychological adjustment with older age (β = 0.268) and higher EF (β = 0.190) indicated better psychological adjustment, while lower scores of CCI (β = -0.190) indicated lower psychological adjustment.

Table 4.4. Summary of mediation effects found in tested models for content specific elements of self-efficacy

Model	Indirect effects (mediation)
Eight individual Models for Content Specific elements of self-efficacy	1. P+P→ SE-Physical Changes → psychological adjustment (p = 0.05) 2. P+P→ SE-Physical Changes → physical function (p = 0.07) 3. P+P→ Relationship → psychological adjustment (p = 0.08)
Model with statistically significant Content Specific elements of self-efficacy	1. P+P→ SE-Relationship → psychological adjustment (p = 0.08)

Note: paths presented on this table were statistically significant or close to statistically significant indirect effect on the tested models.

DISCUSSION

The purpose of the present study was to evaluate the mediating effects of *content specific elements of self-efficacy* (SE-ICD function, SE-physical changes, SE-lifestyle, SE-emotions, SE-ICD SE-shock, SE-safety, SE-cognition and SE-relationship) between the interventions and physical function and psychological adjustment outcomes in recipients of an initial ICD. The hypothesized models compared the P+P versus the P-Only intervention, to examine the effect of adding a partner to the intervention. The findings were an extension of Aim 1. In Aim 1, the mediation effects of general self-efficacy were revealed weak mediation for self-efficacy. To advance understanding self-efficacy as a mediator, we explored for the potential mediating effects of measures of *specific* and *targeted* intervention content. We tested for the differential (P+P vs. P-Only) influence content-related measures of the hypothesized intervention outcomes. That is, to examine and distinguish the impact of specific self-efficacy content, we focused on differences in the potential mediating effects of eight *content-specific* indicators of self-efficacy scale.

Content-specific Elements of Self-efficacy as Mediators

The mediation roles were tested on the eight *content-specific elements of self-efficacy* to evaluate the effect of the P+P vs. P-Only intervention on *physical function and psychological adjustment*. For psychological adjustment, the mediation path of SE-physical had a statistically significant indirect effect for the P+P compared to the P-Only intervention. Significant indirect effects were observed for P+P compared to P-Only for physical function mediated through SE-physical change ($p = 0.07$), and for psychological adjustment mediated through SE-relationship ($p = 0.08$).

For most models no statistically significant intervention effects were observed for the *content-specific elements of self-efficacy*. Only SE-physical change had a statistically significant mediation path, followed by SE-ICD shock and SE-relationship, which approached significance. All the *content-specific elements of self-efficacy*, however, had a statistically significant influence on the physical functioning and

psychological adjustment. This suggested that the eight content-specific elements of self-efficacy were important for promoting physical and psychological health but did not necessarily reflect a differential impact of the P+P vs. P-only intervention.

Considering the trends in significant effects (< 0.10) for the P+P vs. P-Only mediators, it was tested a model which included three *content-specific elements of self-efficacy* mediators (SE-physical change, SE-ICD shock and SE-relationship). This model showed fewer statistically significant mediation paths compared to the individual-mediator models. The path h*w showed significant P+P intervention effects on psychological adjustment through SE-relationship ($p = 0.08$). There were direct effects of P+P vs. P-Only intervention on SE-physical changes and SE-relationship, and direct effects of these two *content-specific elements of self-efficacy* on psychological adjustment. However, no indirect effect was found for those paths indicating no mediation.

The content-specific measurements reflect important self-efficacy content provided for ICD patients. Mediation paths were through SE-physical change on physical function and SE-physical change on psychological adjustment, and SE-relationship on psychological adjustment. This suggests that having a partner included in the intervention had an important additive effect on patient confidence to manage physical health following receipt of an ICD, and the ability adapt to ICD-related changes in relationships with their partners. On the other hand, adding a partner did not influence other *content-specific elements of self-efficacy* (SE-ICD function, SE-lifestyle, SE-emotions, SE-ICD shock, SE-safety and SE-cognition). Similarly, Cameron[93] found in chronic lung disease, heart disease, stroke and arthritis, that a group derived, efficacy-based self-management intervention model had a positive and statistically significant effect on self-efficacy, that benefitted both mental and physical health.

The findings show that promoting self-efficacy related to physical changes and relationship has important benefits for patient outcomes. This findings are supported by studies focusing on response to illness, which show that in chronic cardiac conditions, recovery is influenced by the family support.[23,94]

Having family support during the ICD implantation adjustment phase has improves self-efficacy, particularly in reducing patient physical and emotional arousal. Family support is one of the mechanisms indicated in SCT[13,14,95,96] that can improve patient's self-efficacy. People with high self-efficacy are more likely to persevere in the face of challenges because they believe they can change situations and behaviors to achieve more positive outcomes.[97]

Content-specific Elements of Self-Efficacy and Multicollinearity

Content-specific elements of self-efficacy were highly correlated, indicative of multicollinearity. This suggests the importance of evaluating these eight components as individual mediators, however such a strategy limits the model, as it does not account for influences in one another.

For the *content-specific elements of self-efficacy* models, the single-mediator models revealed one significant mediation pathway (P+P → SE-Physical Changes → psychological adjustment), and two trends toward mediation (P+P → SE Physical Changes → physical function and P+P → SE Relationship → psychological adjustment). A model tested with three content-specific elements of self-efficacy, showed only one significant trend toward mediation (P+P → SE Relationship → psychological adjustment). The inability to detect relationships reinforces the importance of evaluating single-mediator models due to possible multicollinearity.

Strengths and limitations

In addition to strengths identified in the discussion of for Aim 1 (Chapter 3), evaluating *content specific elements of self-efficacy* allowed greater understanding of the specific effects of the intervention content on patient outcomes. In addition to limitations reported on Aim1 (Chapter 3), Aim 2 related limitations are that the tool used to measure *content specific elements of self-efficacy* was developed specifically for this study, as recommended by Bandura, and does not been fully tested for validity and reliability.

CONCLUSION

Specifically, for P+P vs P-Only, self-efficacy related to physical changes and relationship influenced both physical function and psychological adjustment. The *content specific elements of self-efficacy* SE-ICD function, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety and SE-cognition did not mediate the effect of the P+P intervention vs. P-Only on outcomes, but nonetheless, showed significant direct influences on these outcomes.

REFERENCES

1. Cameron JE, Voth J, Jaglal SB, Guilcher SJT, Hawker G, Salbach NM. "In this together": Social identification predicts health outcomes (via self-efficacy) in a chronic disease self-management program. *Social science & medicine (1982).* 2018;208:172-179.
2. Brecht ML, Dracup K, Moser DK, Riegel B. The relationship of marital quality and psychosocial adjustment to heart disease. *The Journal of cardiovascular nursing.* 1994;9(1):74.
3. Dougherty CM, Pyper GP, Benoliel JQ. Domains of concern of intimate partners of sudden cardiac arrest survivors after ICD implantation. *The Journal of cardiovascular nursing.* 2004;19(1):21-31.
4. Bandura A. *Self-efficacy : the exercise of control.* New York: New York : W.H. Freeman; 1997.
5. Bandura A. Self-efficacy mechanism in human agency. *American Psychologist.* 1982;37(2):122-147.
6. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977;84(2):191-215.
7. Bandura A. Social cognitive theory of self- regulation. *Organizational Behavior and Human Decision Processes.* 1991;50(2):248-287.
8. Schieman S, Campbell JE. Age Variations in Personal Agency and Self-Esteem: The Context of Physical Disability. *Journal of Aging and Health.* 2001;13(2):155-185.

CHAPTER 5. AIM 3 BACKGROUND, METHOD, RESULTS & DISCUSSION: THE INFLUENCE OF ICD INDICATION ON PATIENT MEDIATION AND OUTCOME VARIABLES FOLLOWING ICD IMPLANT

ABSTRACT

Introduction. Sudden cardiac arrest is an emerging public health concern with a survival rate of less than 20%. The ICD is an implantable medical device used to treat cardiac arrhythmias with shocks to return the heart to sinus rhythm. Patients' understanding of the underlying disease and its prognosis are linked to their knowledge and attitudes about the ICD. This understanding may differ between patients receiving an ICD for primary vs. secondary prevention. Health-related symptoms and general health characteristics differentiate these two ICD indications. For dissertation Aim 3, taking into consideration both intervention conditions and patient ICD indication (primary vs. secondary), this study examined for differences in the mediating influence of the four *dimensions of self-efficacy* (self-efficacy, outcome expectations, self-management behavior, and ICD knowledge) on patient physical functioning and psychological adjustment post-intervention at 12-months.

Methods. This secondary analysis was based on data from a randomized clinical trial with 301 patients, which compared two interventions: Patient+Partner (P+P) vs. Patient-Only (P-Only). The analysis used data collected at hospital discharge and then at three- and 12-months post-ICD implantation. Repeated measures ANOVA was used to compare study groups at baseline, 3 and 12-months. Multiple group structural equation modeling (SEM) was used to examine for model differences for individuals receiving an ICD for primary vs. secondary prevention of sudden cardiac arrest.

Results: Participants (N = 301) were primarily male and white with a mean age of 64.14 (11.90). Mean ejection fraction was 34.08(14.33) with ICD implanted for primary (59.8%) and secondary prevention (40.2%). Comparing primary vs. secondary prevention by study condition, there were no statistically significant differences on dimensions of self-efficacy at baseline and three-months. All group dimensions of self-efficacy improved over time (all $p<0.001$) independent of ICD indication. For physical function, bodily pain scores were higher for those with ICD implanted for secondary prevention. Similarly, psychological adjustment for depression, role emotional and social functioning had higher scores for those who had a secondary prevention ICD. Across time, physical functioning, role physical and depression had the greatest improvement in secondary prevention participants. Five models, one for each dimension of self-efficacy and a full model were tested. ANOVA comparisons between models yielded no differences in the structural model groups for primary vs. secondary ICD indication: (1) Self-Efficacy Model. ANOVA $\chi^2_{diff} = 32.4$, $df_{diff} = 33$, $p = 0.50$); (2) Outcome Expectations Model. ANOVA $\chi^2_{diff} = 42.22$, $df_{diff} = 33$, $p = 0.13$; (3) Self-Management Behavior Model. ANOVA $\chi^2_{diff} = 40.79$, $df_{diff} = 33$, $p =$

0.16; (4) ICD Knowledge Model. ANOVA $\chi^2_{diff} = 40.60$, $df_{diff} = 33$, $p = 0.17$; (5) Full Model (SE + OE + SMB + KSA). ANOVA $\chi^2_{diff} = 45.15$, $df_{diff} = 48$, $p = 0.59$.

Conclusion. For Aim 3, the hypothesized model describing the self-efficacy mediation pathways between the interventions with physical function and psychological adjustment were similar for patients who received an ICD for either primary or secondary prevention of cardiac arrest. However, outcome trajectories differed depending on the ICD indication. Those with an ICD implanted for secondary prevention had better physical (bodily pain) and psychological outcomes (depression, role emotional and social function). In addition, over the 12-month period they had sharpest improvement in physical functioning, role physical and depression. Participants with ICD implanted for secondary prevention who are part of P+P intervention are adjusting to ICD faster and in our model, there was no difference on the mediation process between participants receiving ICD for primary or secondary prevention of cardiac arrest.

INTRODUCTION

Sudden cardiac arrest (SCA) is an emerging public health concern with global implications as there is less than a 20 percent survival, and most of the cases result in unanticipated deaths.[50,98] Ventricular tachycardia is the main cause of sudden cardiac arrest deaths, accounting for six million deaths annually worldwide.[50,98] The ICD is a device that treats life-threatening arrhythmias with timely cardiac shocks, bringing the heart to sinus rhythm and protecting the individual from sudden cardiac death.[99-101]

The use of the ICD for primary prevention of sudden cardiac arrest was first described in 1984. I 2002, clinical practice guidelines[102] were updated to include ICD implantation for those patients with drug-resistant ventricular tachycardia or prolonged QT syndrome and secondary prevention of Torsades de Pointes ventricular tachycardia. Further along, indications included primary prevention for patients with ischemic cardiomyopathy, individuals with congestive failure, and left ventricular ejection fraction ≤30%.[103,104] An ICD reduces all-cause mortality by 50% in SCA compared to patients receiving optimal medical treatment without an ICD.[45-50] However, physical and psychological difficulties create major challenges for ICD patients post-implant. Half of this population report behavioral changes including changes in function and lifestyle.[53] After an ICD implant, patients and their family members need to comprehend new knowledge about their health condition, manage the experience of arrhythmia treatment and device-related shocks, incorporate lifestyle changes, understand physical and emotional changes, and manage potential changes in their relationships with partners.[45,53,61,62]

The patient's understanding of the underlying disease and its prognosis has a crucial link with their understanding and attitudes about ICDs. This might differ between patients who receive an ICD for primary vs. secondary prevention. ICD indication for individuals with *increased risks* of having the first life-threatening arrhythmia, such as ventricular fibrillation, sustained ventricular tachycardia, or SCA is classified as *primary prevention*.[99,105,106] On the other hand, the indication for those who are survivors of SCA or who have recurrent unstable rhythms, usually ventricular fibrillation or ventricular tachycardia

with a hemodynamic compromise, who need protection against a recurrent life-threatening arrhythmia are classified as *secondary prevention*.[99,105,106]

Patients who receive an ICD for primary prevention vs. secondary prevention can have different disease characteristics, which may impact their physical and psychological health. Regarding physical outcomes, those who have an ICD for primary prevention have a higher number of comorbidities,[107] perform less physical activities,[107] have lower chances of presenting with ventricular tachycardia[108] and appropriate ICD therapy,[108-112] and receive the first appropriate ICD shock a longer period of time after the ICD implantation when compare to those receiving and ICD for secondary prevention.[111] Similarities in these two groups are in mortality rates,[109,111,112] number of inappropriate ICD shocks,[113,114] and cardiopulmonary symptoms.[113,114] These physical differences might result in differences in response to the intervention and thus to physical and psychologic outcomes as well as expectations of the ICD benefits.

Regarding psychological outcomes, a systematic review by Pedersen et al. in 2009[113] showed that ICD indication does not impact patient-centered outcomes such as quality of life,[109,115,116] anxiety,[59,114,117,118] depression,[59,117] feelings of disability[118] and ICD concerns[118]. More specifically, for physical and mental health quality of life improvement over 12-months, results indicate that both primary and secondary prevention groups experience similar improvement.[109] There is one study in the Japanese population that indicated those with primary prevention had higher quality of life, anxiety, and worry.[119]

It is expected that individuals who receive an ICD for secondary prevention have a reference point from which to understand the potential impact of SCA or ventricular arrhythmia recurrence. Conversely, those who receive an ICD for primary prevention may overestimate the contribution of SCA to potential mortality as they have a more limited understanding of survival and might have additional difficulties in placing the potential impact of the ICD in the context of their experience.[53,86] In the primary prevention context, information about ICD and its benefits might be crucial to understand the potential lifesaving benefits of the ICD and to maximize the perceived value of the device.[53]

A broad range of interventions has been used to achieve similar physical function and psychological adjustment for patients with an ICD. However, it is unknown if participants would present different intervention mechanism according to ICD indication. It is necessary to understand which intervention components achieve the most positive and sustained outcomes, are most appropriate for specific subgroups within this population, with the goal of tailoring interventions to include only those components producing the greatest impact on physical function and psychological adjustment.

Using data drawn from a recent clinical trial by Dougherty,[63] we explored if the *dimensions of self-efficacy* (self-efficacy, outcome expectations, self-management behavior, and ICD knowledge) were differentially influenced by the intervention, and the dimensions differentially influenced the patient outcomes of physical function and psychological adjustment at 12-months post-intervention. We previously used SEM with multiple indicators to test for the mediating effects of the *dimensions of self-efficacy*—self-efficacy expectations, outcome expectations, self-management behavior, and ICD knowledge)—on physical function and psychological adjustment. Results from those analyses are reported at Aim 1 for this dissertation.

The purpose of this analysis was to compare the major pathways of mediation of four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge – Figure 5.1) on the relationship between the interventions and patient physical function and psychological adjustment at 12-months *by* primary vs. secondary ICD indication groups. Specifically, we tested if ICD indication (primary vs. secondary prevention) was associated with differences in parameter estimates for the overall measurement model, and mediation pathway models for (1) self-efficacy expectations, (2) outcome expectations, (3) self-management behaviors, and (4) ICD knowledge, as well as (5) all four *dimensions of self-efficacy* estimated simultaneously. We hypothesized that the mediation models would differ depending on patient ICD indication.

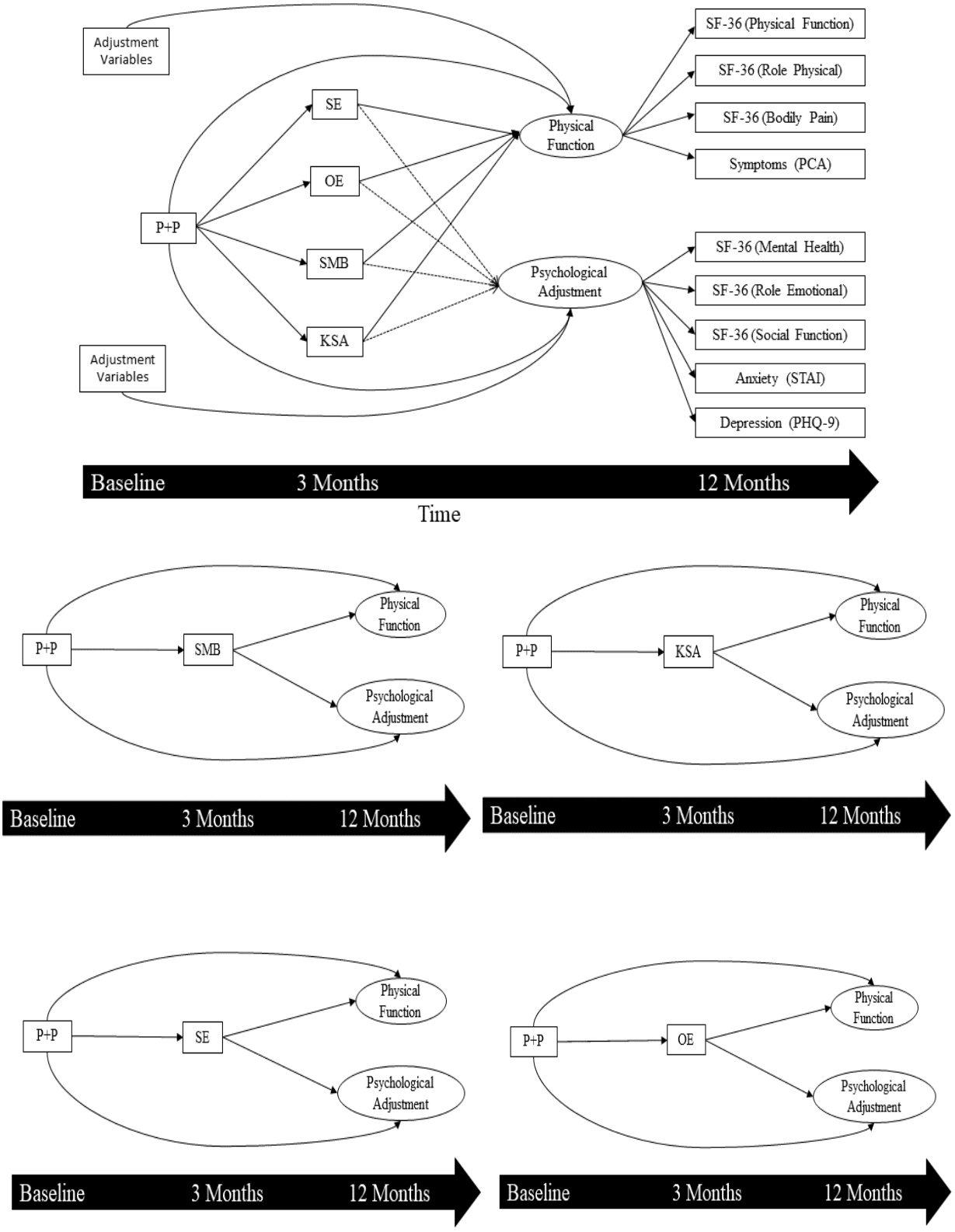


Figure 5.1. Models tested in the Multiple-Group Structural Equation Modeling (SEM) to evaluate difference in mediation pathways between ICD indication groups (Primary vs Secondary). Latent variables physical and psychological outcomes, represented as circles in the models, were measured with same indicators for all 5 models as demonstrated on the first model on top.

METHODS

Measures

Physical function was measured using four indicators, including the Patient Concerns Assessment (PCA) items 1-28, and and three SF-36 subscales (physical function, role physical-function, and bodily pain).

Psychological adjustment was assessed using five indicators, including the State-Trait Anxiety Inventory (STAI), Physician Health Questionnaire-9 (PHQ-9) and SF-36 subscales (mental-health, role-emotional, and social function) (Figure 5.1).

Dimensions of Self-Efficacy was measured by four *dimensions of self-efficacy* and included as potential mediators between the interventions and hypothesized outcomes, as illustrated in Figure 2.2. The four scales were: *Self-Efficacy Expectations (SE), Outcome expectations (OE), Self-Management Behavior (SMB)* and *Knowledge Self-Assessment (KSA).*

Intervention Condition was represented as a binary variable, a value of *zero* represented patients in P-Only condition, and *one* represented patient's in the P+P condition.

Adjustment Variables, each dimension of self-efficacy was controlled by their baseline values. Outcome variables, physical function and psychological adjustment were controlled for patients score on CCI and age. Age was measured in years and considered as a continuous variable. CCI measures the presence of chronic diseases and is used to assess the prognostic influence of multiple chronic illnesses.[77] The higher the score greater the probability of complications due to multiple chronic diseases.[77]

Analysis

Preliminary analysis. Descriptive statistics and histogram displays (mean, SD) were used to examine properties of sociodemographic variables for the full sample as well as by ICD indication (primary vs. secondary). We assessed the distributional properties of the variables, examined for outlier cases, and characterized missing data. No imputation of missing data were used as less than 5% of the

self-report measures were missing. Pearson correlation coefficients were calculated by ICD indication to evaluate associations among study variables (four *dimensions of self-efficacy* and multiple indicators of physical function and psychological adjustment). Associations between key variables and potential confounding variables, including age, gender, ethnicity, ejection fraction (EF), cardiac arrest, and the Charlson Comorbidity Index (CCI) were examined.

Comparisons of Study Groups. Analysis of Variance (ANOVA) was used (SPSS version 19.0, IBM, Chicago, Il, USA) to establish baseline differences and to examine for change in the *dimensions of self-efficacy* and the indicators of physical function and psychological adjustment. To conduct the analyses, a single variable called 'group' was created. The new four-category group variable classifies both (a) intervention group [2 categories] and (b) ICD indication group [2 categories]. Thus, the four groups are: 1) P-Only primary (n = 91), 2) P+P primary (n = 89), 3) P-Only secondary (n = 60) and 4) P+P secondary (n = 61) (see Table 5.2A for comparisons of indication/intervention groups). Data were collected at baseline, post-intervention at three-months and 12-months. Three ANOVA approaches were used:

1) One-way ANOVA was used to examine for differences among the 4 groups at baseline and at three months (Table 5.2A) for the four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behavior, and ICD knowledge). Oneway ANOVA was also used to test for differences among the four groups at each of 3 timepoints: baseline, 3 months and 12 months (Table 5.3A) for the measures of *physical functioning* (PCA, SF-36 subscales: physical function, role physical-function, and bodily pain) and psychological adjustment (STAI, PHQ-9, SF-36 subscales: mental-health, role-emotional, and social function).
2) ANOVA *controlling* for the respective baseline values was used to examine for differences among the four groups from baseline to 3 months (Table 5.2B). This analysis assessed

change in the *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors and ICD knowledge)

3) Repeated measures (RM) ANOVA (GLM) was used to compare patterns of change across time from baseline to 3 months to 12-months (Table 5.3B) for the five indicators of physical functioning and 4 indicators of psychological adjustment.

For all tests, significance was established at 0.05.

Multiple Group SEM. Multiple group comparisons were conducted using structural equation modeling (SEM) in R (version 3.4.2,[78] RStudio, version 1.1.3.83) with lavaan,[79] an R SEM statistical package. Diagonally weighted least squares (DWLS) parameter estimation was used to ensure accurate parameter estimates and robust corrections to standard errors and χ^2 test statistics given that the data were ordinal. The mediation model, derived from an earlier structural equation modeling (SEM) study (Dissertation Aim 1), examined if the effects of the P+P intervention compared to the P-Only intervention on patient outcomes was mediated through *four dimensions of self-efficacy* (self-efficacy, outcome expectations, self-management behavior, and ICD knowledge). This analysis extended that work by testing for model comparisons by ICD indication using multiple group SEM analysis. Analysis of covariance structures (ACS) was used to (1) test if the measurement models were equivalent for both groups (primary vs. secondary ICD indication); and (2) test if the hypothesize mediation paths differed

between patient primary vs. secondary ICD prevention groups. In brief, we tested both the hypothesized ***measurement model*** and ***structural mediation models*** for group differences using multiple groups SEM ACS. The five structural models of primary interest were presented in Figure 5.1.

For each of the five models above, two SEM analyses were conducted. The first analysis estimated separate SEM parameters (factor loadings, intercepts, residuals, latent variable variances/covariances) for primary vs. secondary groups, based on the assumption that the models were not equivalent. The second analysis "fixed" the values of the estimated parameters to be equal for the two ICD prevention groups (primary vs. secondary). The results from these two SEM analyses were compared using ANOVA with level of significance at 5%.[120,121] An ANOVA F test in SEM is used to identify significant differences between the primary vs. secondary prevention groups. The ANOVA compared the difference in χ^2 test statistics accounting for their degrees of freedom. In addition, the fit of each model was assessed for the difference in the Comparative Fit Index (CFI) with values $\geq$0.95.[80,81] See Figure 5.2.

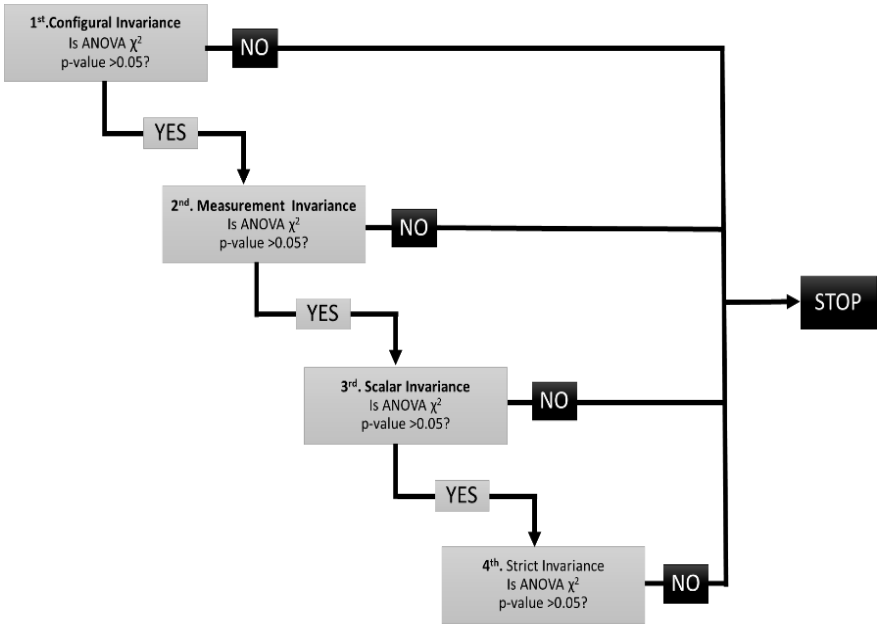


Figure 5.2. Procedures to evaluate model invariance and test structural difference in Multiple Group Structural Equation Modeling. For each step it is evaluated if there is a statistically significant difference in χ^2 between restricted and unrestricted models. *Configural invariance* tests to see if the basic factor structure is equivalent across groups. *Measurement Invariance*, tests if the latent variables are being measured in the same way across groups. *Scalar invariance* tests if the mean difference in the observed indicators across groups is due to difference in the mean of latent variables. *Strict*

Testing the difference between the two ICD groups followed a commonly used 4-step process[83,120,122,123] to test increasingly more restrictive hypotheses regarding model similarities for primary vs. secondary prevention groups. The analysis advanced from one step to the next step only if a significant difference between groups was observed in the current step. For example, as illustrated in Figure 5.2, testing for measurement invariance (step two) would be performed only if the test for configural invariance (step one) was statistically significant.

Adjustment variables. Control variables were included in the analyses based on observation of statistically significant differences between the groups. CCI and age were controlled for physical function and for psychological adjustment.

Human Subjects. This secondary analysis of the P+P Intervention study (Dougherty, PI R01 HL086580, NCT number NCT01252615.) was conducted under the auspices of and approved by the University of Washington Internal Review Board. The analyses required the use of only de-identified data, and no new data were collected.

RESULTS

Demographic and Clinical Characteristics

Study participants were primarily Caucasian and male with a mean age of 64.96 (12.68) years, the primary prevention group, and 62.92(10.58) for secondary prevention group (Table 5.1). Clinical characteristics included a mean ejection fraction of 28.84 (12.02) for primary indication, and 41.88 (13.97) for the secondary indication groups, and CCI means of 2.49(1.30) and 1.99(1.69), respectively. Regarding ICD shocks, most participants received no shocks (165, 91.7% and 102, 84.3%, respectively). Detailed information regarding patient characteristics and primary outcomes and has been published.[63] Participants who received an ICD for primary vs. secondary indication differed with respect to their presenting clinical indicators, such as EF and CCI. Those who had ICD implanted for primary prevention

in the P-Only and P+P groups presented with lower EF. Ejection fraction < 35% was a criterion for receiving an ICD for those with a primary prevention indication. In this sample, those with ICD implanted for primary prevention had a higher CCI score, reflecting more disease co-morbidities at the time of receipt of the ICD.

Table 5.1. Baseline sociodemographic and clinical characteristics for P-Only and P+P by ICD indication.

Variable	**Patient Only (n = 151)**			**P+P (n = 150)**		
ICD Indication	**Primary Prevention (n = 91)**	**Secondary Prevention (n = 60)**	**Group Difference† t (p-value)**	**Primary Prevention (n = 89)**	**Secondary Prevention (n = 61)**	**Group Difference† t (p-value)**
Age (years), mean (SD)	65.31 (12.16)	64.47 (9.82)	-0.39 (0.69)	64.61 (13.25)	61.30 (11.12)	-1.60 (0.11)
Gender (male), n (%)	59 (64.8)	47 (78.3)	1.78 (0.08)	69 (77.5)	47 (77.0)	-0.07 (0.96)
Race (white), n (%)	81 (89.0)	55 (91.7)	0.53 (0.60)	79 (88.8)	59 (96.7)	1.77 (0.08)
Ejection Fraction (%), mean (SD)	28.80 (10.88)	41.35 (13.63)	**6.27 (0.01)**	28.88 (13.15)	42.41 (14.40)	**5.95 (0.01)**
Charlson Comorbidity Index, mean (SD)	2.52 (1.32)	1.87 (1.55)	**-2.76 (0.01)**	2.46 (1.29)	2.11 (1.83)	-1.34 (0.18)
ICD shock (no shocks) n (%)	82 (93.3)	49 (81.7)	1.49 (0.14)	83 (93.3)	53 (86.9)	1.37 (0.19)
ICD shock (Number of shocks), mean (SD)	0.41 (2.49)	2.22 (9.77)	1.49 (0.14)	0.1 (0.40)	0.48 (1.65)	1.37 (0.19)

Note. ICD indication defined as primary prevention or secondary prevention of cardiac arrest. T-tests were used to asses differences between primary vs. secondary indication by intervention group. CCI has 32 questions with both yes/no response options. The scale score is weighted in 0, 1, 3 or 6; the higher the score greater the probability of complications due to multiple chronic diseases.[77] †Group difference is comparing secondary vs primary ICD indication by study arm (P+P vs P-only).

Group Comparisons: Self-Efficacy

Dimensions of Self-Efficacy. Table 5.2A reports the results of the one-way ANOVA, which is an omnibus test used to examine for the presence of *any* group differences among three or more groups.

Means for each *dimension of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors and ICD knowledge) are reported in Table 5.2A for the four ICD indication/intervention groups (standard deviation in parentheses). Post-hoc comparisons were also conducted to identify pairs of groups that differed. Means without a superscripted letter *do not differ* from another group means. Significant differences ($p < 0.05$) between group means are noted with the same/identical superscripted letter in Table 5.2A. At baseline and at three-months, there were no group differences in self-efficacy expectations, outcome expectations or self-management behavior. In contrast, study group differences were observed for ICD knowledge at baseline (identified by superscripted letter a: $F = 3.57$, $p = 0.001$) and at three-months (superscripted letter b: $F = 4.01$, $P = 0.008$).

At baseline, a significant difference existed between the primary prevention/P-Only group and secondary prevention/P+P group. The primary prevention/P-Only group had a lower knowledge score. The baseline mean difference between these two groups was 0.99. This value would not be considered clinically significant as it indicated that the secondary prevention/P+P participants had, on average, only one additional correct answer on the ICD knowledge questionnaire. At three-months, a statistically significant mean difference of 1.04 was found between the two primary and secondary P+P intervention groups. Similar to the baseline findings for ICD Knowledge, this indicated that secondary prevention P+P compared to the primary P+P had an average of one additional correct answer on the knowledge scale, not indicative of superior knowledge.

Table 5.2A. Group Comparisons of Self-Efficacy Dimensions at Baseline and at three-months: Primary vs. Secondary Prevention by Intervention Group (P-only and P+P).

	P-Only		**P+P**		**ANOVA Analysis**
Self-Efficacy Dimensions	**Primary Prevention (n = 91) Mean(SD)**	**Secondary Prevention (n = 60) Mean(SD)**	**Primary Prevention (n = 89) Mean(SD)**	**Secondary Prevention (n = 61) Mean(SD)**	**One-way ANOVA F (p-value)**
Self-efficacy Expectations					
Baseline	7.88(1.87)	7.92(1.52)	7.89(1.71)	7.89(1.56)	0.006(0.99)
3 Months	9.04 (1.07)	8.92 (1.27)	9.14(1.08)	9.18(0.99)	0.72(0.54)
Outcome Expectations					
Baseline	8.56(1.64)	8.46(1.93)	8.47(1.33)	8.45(1.38)	0.08(0.97)
3 Months	9.06(1.14)	8.87(1.72)	9.26(0.93)	9.04(1.20)	1.22(0.30)
Self-Management Behavior					
Baseline	18.02(6.62)	16.85(5.56)	17.90(6.86)	17.11(4.89)	0.73(0.53)
3 Months	20.52(8.32)	19.02(7.50)	18.98(8.86)	19.08(6.24)	0.71(0.55)
ICD Knowledge					
Baseline	20.71(2.42)[a]	21.43(1.81)	20.79(2.21)	21.70(2.11)[a]	**3.57(0.01)**
3 Months	21.96(2.17)	22.67(1.73)	21.84(2.35)[b]	22.88(2.22)[b]	**4.01(0.008)**

Note. Any two groups (ICD indication/intervention group) with the *same* superscripted letter are statistically *different* than one another.

Change in Self-Efficacy from Baseline to Three Months.

The one-way ANOVA presented in Table 5.2A described simple group differences at two separate time points (baseline and three-months). In contrast, Table 5.2B shows findings based on an examination of *change* in the *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behavior and ICD knowledge) from baseline to three months. That is, we adjusted for the baseline values of each dimension and examined for group differences in this change . The analyses revealed no statistically significant differences in 1-3 month change for the *dimensions of self-efficacy*. That is, no differences among the four ICD indication/intervention groups were observed for

any *dimension of self-efficacy*. Of note, the primary compared to secondary prevention group (in both P-Only and in P+P) had slightly lower knowledge scores.

Table 5.2B. Comparison of Change in Self Efficacy at 3 Months, controlling for baseline value of the variable: Primary vs. Secondary Prevention by Intervention Group

	P-Only (n = 151)		**P+P (n = 150)**		**ANOVA** SE at 3 Months, controlling for baseline values
Dimensions of Self-Efficacy	**Primary Prevention Mean(SD)**	**Secondary Prevention Mean(SD)**	**Primary Prevention Mean(SD)**	**Secondary Prevention Mean(SD)**	**Test of within Group (ICD Indication/ Intervention arm) Difference F (p-value)**
Self-efficacy Expectations					
Baseline	7.88(1.87)	7.92(1.52)	7.89(1.71)	7.89(1.56)	
3 Months	9.04 (1.07)	8.92 (1.27)	9.14(1.08)	9.18(0.99)	1.15 (0.32)
Outcome Expectations					
Baseline	8.56(1.64)	8.46(1.93)	8.47(1.33)	8.45(1.38)	
3 Months	9.06(1.14)	8.87(1.72)	9.26(0.93)	9.04(1.20)	1.86 (0.13)
Self-Management					
Baseline	18.02(6.62)	16.85(5.56)	17.90(6.86)	17.11(4.89)	
3 Months	20.52(8.32)	19.02(7.50)	18.98(8.86)	19.08(6.24)	1.70 (0.17)
ICD Knowledge					
Baseline	20.71(2.42)	21.43(1.81)	20.79(2.21)	21.70(2.11)	
3 Months	21.96(2.17)	22.67(1.73)	21.84(2.35)	22.88(2.22)	1.83 (0.14)

Note: To assess change in each dimension of self-efficacy at 3 months, the ANOVA procedure incorporated the baseline value of each dimension, thereby controlling for baseline values of the *dimensions of self-efficacy*.

Group Comparisons: Indicators of Physical Function and Psychological Adjustment

***Indicators of Physical Function*.** The one-way ANOVA presented in Table 5.3A, similar to the one-way ANOVA described on Table 5.2A, described simple group differences at each time point between the four ICD indication/intervention groups. This analysis reports group differences in physical function indicators (PCA, SF-36 subscales: physical function, role physical-function, and bodily pain) at three separate times: baseline, 3 and 12 months. Post-hoc comparisons were conducted to identify pairs of groups that differed. Significant differences ($p < 0.05$) between group means are noted by an identical superscripted letter in Table 5.3A. If two means differed, the difference is indicated by identical superscripted letters, such as $^{a, b}$ or ^{c}. Means *without* a superscripted letter *do not differ* from any other group. All pairs of means for each variable at baseline, 3 and 12 months were tested. No statistically significant ICD indication/intervention group differences were found at either baseline or three-months.

There were, however, significant differences between at least two of four groups (ICD indication/intervention groups) at 12-months for all four indicators of physical function: PCA ($F = 2.90$, $p = 0.03$), SF-36:physical functioning ($F = 6.93$, $p = <0.001$), SF-36:role physical ($F = 2.68$, $p = 0.05$), and SF-36:bodily pain ($F = 3.77$, $p = 0.01$).

Specifically, for physical symptoms (PCA), there were statistically significant differences between the ICD indication groups (Table 5.3A) at 12 months, where the 12-month value for the secondary indication/P+P group revealed the greatest decline (mean difference between baseline and 12 months was 20.46) in physical symptoms, and the primary/P-Only group showed the least decline. At baseline, physical functioning (SF-36) was lowest for the secondary prevention groups (Table 5.3A) and highest for secondary prevention groups at 3 months. A statistically significant difference between primary and secondary prevention groups was observed, with the P-Only primary prevention group showing significantly lower physical functioning at 12-months than either the primary or secondary groups in the P+P intervention. For role physical (SF-36) at 12-months, the overall difference between ICD indication/intervention groups was statistically significant, but the post-hoc comparisons revealed no statistically significant group differences. In the P+P intervention group, the difference between primary and secondary participants at 12-months showed a trend for statistical significance, with a $p = 0.078$. For bodily pain (SF-36) in the P-Only intervention, the secondary vs. primary prevention groups showed significantly less bodily pain at 12-months (Table 5.3A). The pattern was similar for the P+P intervention, although in the posthoc analysis the difference did not reach statistical significance ($p = 0.55$). Differences between primary preventions in P-Only and P+P approached significance with a $p = 0.078$ with those on P+P group showing less bodily pain.

Table 5.3A. Group Comparisons of physical function and psychological adjustment at baseline, 3- and 12- months: Primary vs. Secondary Prevention by Intervention Group. F statistic refers to difference between one of the 4 groups (ICD indication by intervention group) by timepoint.

Outcomes	Outcome Indicators	P-Only		P+P		ANOVA analysis
		Primary Prevention (n = 91) Mean(SD)	Secondary Prevention (n = 60) Mean(SD)	Primary Prevention (n = 89) Mean(SD)	Secondary Prevention (n = 61) Mean(SD)	One-way ANOVA F (p-value)
Physical Function	**Symptoms: PCA**					
	Baseline	57.95(43.08)	52.38(33.99)	54.79(41.15)	55.14(35.15)	0.26(0.86)
	3 Months	45.86(37.12)	41.57(38.06)	45.38(42.19)	36.75(32.44)	0.84(0.47)
	12 Months	52.08(43.41)[a]	37.47(39.46)	43.78(35.39)	34.68(31.27)[a]	**2.90(0.03)**
	SF-36: Physical Functioning					
	Baseline	52.73(23.72)	59.43(23.57)	56.57(25.57)	51.88(26.74)	1.33(0.27)
	3 Months	60.96(26.25)	72.08(26.65)	65.20(23.68)	68.36(27.27)	2.35(0.07)
	12 Months	57.93(25.58)[b,c]	74.94(23.83)[d]	63.37(27.04)[b,d]	73.45(25.01)[c]	**6.93(<0.001)**
	SF-36: Role Physical					
	Baseline	32.42(39.53)	25.42(36.39)	38.63(39.19)	23.50(33.90)	2.49(0.06)
	3 Months	51.17(42.94)	51.72(43.89)	48.27(42.25)	62.50(41.3)	1.42(0.24)
	12 Months	45.12(43.47)	61.16(42.35)	52.38(40.82)	62.93(41.16)	**2.68(0.05)**
	SF-36: Bodily Pain					
	Baseline	59.24(24.99)	62.48(26.67)	68.28(24.63)	62.75(24.76)	1.98(0.12)
	3 Months	68.46(25.44)	76.46(27.23)	72.64 26.03)	75.7(25.89)	1.42(0.24)
	12 Months	66.43(24.79)[e]	79.02(24.76)[e]	68.51(25.56)	76.33(27.15)	**3.77(0.01)**
Psychological Adjustment	**Anxiety: STAI**					
	Baseline	32.14(11.60)	30.85(9.84)	31.01(10.51)	30.82(10.73)	0.28(0.84)
	3 Months	28.44(9.94)	28.91(10.23)	28.54(10.25)	26.86(8.28)	0.53(0.66)
	12 Months	30.47(11.88)	28.86(11.03)	28.47(10.60)	28.76(9.05)	0.56(0.65)
	Depression: PHQ-9					
	Baseline	5.37(5.02)	5.09(4.17)	4.38(4.14)	5.46(4.51)	0.75(0.52)
	3 Months	4.09(4.37)	3.88(4.35)	4.16(4.40)	3.04(3.05)	1.03(0.38)
	12 Months	5.38(5.36)[f,g]	3.46(4.22)[f]	4.00(3.78)	3.01(3.52)[g]	**4.05(0.008)**
	SF-36: Mental Health					
	Baseline	73.61(20.27)	77.11(18.38)	76.55(20.31)	76.61(17.63)	0.56(0.64)
	3 Months	79.96(16.39)	83.74(16.07)	79.08(18.17)	83.05(14.2)	1.35(0.26)
	12 Months	76.01(18.06)[h]	82.21(15.61)	79.51(17.36)	84.1(15.64)[h]	**3.01(0.03)**
	SF-36: Role Emotional					
	Baseline	69.05(39.56)	71.11(38.06)	66.29(42.19)	71.31(38.02)	0.26(0.85)
	3 Months	71.37(38.88)	75.29(37.23)	73.95(38.85)	86.67(28.26)	2.25(0.08)
	12 Months	66.67(40.57)[i,j]	84.52(31.76)[i]	73.02(37.12)	86.21(29.97)[j]	**4.67(0.003)**
	SF-36: Social Functioning					
	Baseline	70.88(26.88)	70.00(26.36)	69.94(26.23)	69.47(27.44)	0.04(0.99)
	3 Months	79.26(23.11)	81.03(26.20)	79.89(24.44)	84.79(18.85)	0.75(0.52)
	12 Months	76.37(25.91)[k]	87.05(21.18)[k]	77.23(24.17)	85.34(19.33)	**3.74(0.01)**

Note. At baseline, 3 and 12 months, any pair of groups noted with the *same* superscripted letter were statistically *different* than one another. Thus, groups without a superscripted letter *do not differ* from one another.

Indicators of Psychological Adjustment.

Oneway ANOVA was used to test for simple group differences at each time point (baseline, 3 and 12 months) comparing the four ICD indication/intervention groups (Table 5.3A). The comparison was on five indicators of psychological adjustment (Anxiety-STAI, Depression-PHQ-9, SF-36 Mental health, SF-36 Role emotional and SF-36 Social Functioning). Similar to the physical function outcomes, no statistically significant group (ICD indication/intervention groups) differences were found for the indicators of psychological adjustment at either baseline or three-months. There were, however, significant between-group differences at 12-months for four of the five indicators, depression (PHQ-9) ($F = 4.05$, $p = 0.008$), SF-36: Mental health ($F = 3.01$ $p = 0.03$), SF-36: Role emotional ($F = 4.67$, $p = 0.003$) and SF-36 Social Functioning ($F = 3.74$, $p = 0.01$). Anxiety (STAI) showed no group differences at baseline, three- or 12-months. Generally, there were moderate, but non-significant decreases in anxiety for all ICD indication/ intervention groups.

For depression (PHQ-9) at 12 months, statistically significant group differences by ICD indication were observed for the P-Only group (superscripted letter f on Table 5.3A). Primary prevention patients in P-Only showed the highest level of depression at 12 months, and secondary prevention patients in P+P showed the lowest level of depression (superscripted letter g on Table 5.3A). Also, within the P-Only intervention, primary vs. secondary prevention patients had significantly higher levels of depression at 12 months.

For mental health status (SF-36) at 12 months, both the secondary prevention groups in P-Only and P+P interventions showed greater improvements in mental health. Participants in the secondary prevention group had higher levels of mental health at 3 and 12 months, though not always statistically significant. A significant group difference, however, was found only for the primary prevention/P-Only primary vs. secondary prevention/P+P groups (superscripted letter h on Table 5.3A).

The pattern of group differences for emotional role functioning (SF-36 Role Emotional) were similar to those found for depression. Primary prevention patients in P-Only showed the lowest level of emotional role functioning at 12-months, and secondary prevention patients in P+P showed the highest level of emotional role functioning. Statistically significant group differences were observed between ICD indication for emotional role functioning in the P-Only group (superscripted letter I on Table 5.3A). Primary compared to secondary prevention patients in P-Only reported a statistically lower level of emotional role functioning at 12-months (superscripted letter j on Table 5.3A). Secondary vs. primary prevention patients in both interventions demonstrated greater improvements in role emotional.

For social functioning (SF-36) at 12-months, only patients in the P-Only intervention group showed differences by ICD indication group. Secondary vs. primary patients in P-Only reported higher levels of social functioning (superscripted letter k on Table 5.3A). Generally, though not always statistically significant, secondary vs. primary prevention patients in both interventions showed higher levels of social functioning.

Change in Physical function and psychological adjustment from Baseline to 12-months.

We compared patterns of change by the four groups (ICD indication by intervention arm) across the 12-month period (Table 5.3B). Three (physical functioning, role physical and bodily pain) of the four physical function indicators showed significant group x time interaction effects, indicating that change across time was significantly associated with ICD indication and intervention. More specifically, individuals with an ICD for secondary prevention showed greater declines in physical symptoms ($F = 8.5$, $P = <0.001$) in both P-Only and P+P intervention groups and had the lowest levels of symptoms at 12 months (Figure 5.3). For role functioning ($F = 5.38$, $P = 0.001$) (SF-36 Role Physical), greater improvements were noted across time for secondary prevention in both study interventions (Table 5.3B and Figure 5.3). There was also a statistically significant quadratic effect ($F = 2.69$, $p = 0.046$) that reflected the u-shaped pattern of change for secondary prevention/P-Only and primary prevention/P+P.

With respect to bodily pain ($F = 5.07$, $P = 0.002$), for secondary vs. primary prevention, had the greatest improvements in bodily pain for both the P-Only and P+P interventions.

Table 5.3B. Change in physical function and psychological adjustment from baseline to 12 months: Primary vs. Secondary Prevention by Intervention Group

Outcome	Outcome Indicators	P-Only (n = 151)		P+P (n = 150)		ANOVA baseline, 3- and 12-months
		Primary Prevention Mean(SD) 1	Secondary Prevention Mean(SD) 3	Primary Prevention Mean(SD) 2	Secondary Prevention Mean(SD) 4	Test of within Group (ICD Indication/ Intervention arm by time) Difference F (p-value)
Physical Function	**Symptoms: PCA**					
	Baseline	57.95(43.08)	52.38(33.99)	54.79(41.15)	55.14(35.15)	
	3 Months	44.66(37.75)	40.38(38.35)	44.68(42.48)	37.02(32.79)	
	12 Months	52.17(43.51)	38.07(39.55)	43.78(35.39)	34.68(31.27)	2.28(0.079)
	SF-36: Physical Functioning					
	Baseline	51.76(23.16)	59.10(23.10)	58.15(24.89)	52.23(27.05)	
	3 Months	60.53(26.41)	74.73(24.23)	66.57(22.49)	68.99(26.73)	
	12 Months	58.17(25.66)	74.67(23.96)	63.37(27.04)	73.45(25.01)	**8.55(0.0001)**
	SF-36: Role physical					
	Baseline	29.43(39.58)	25.45(36.16)	40.66(39.38)	24.71(34.34)	
	3 Months	50.94(43.20)	54.09(43.77)	50.60(41.86)	64.22(40.85)	
	12 Months	44.62(43.79)	60.45(42.40)	53.01(40.65)	62.93(41.16)	**5.38(0.001)**†
	SF-36: Bodily Pain					
	Baseline	57.63(24.34)	63.65(27.01)	68.51(24.36)	61.76(24.73)	
	3 Months	67.80(25.47)	77.13(27.02)	73.52(25.99)	74.86(25.93)	
	12 Months	67.52(23.91)	78.64(24.83)	68.51(25.56)	76.33(27.15)	**5.07(0.002)**
Psychological Adjustment	**Anxiety: STAI**					
	Baseline	32.24(11.28)	30.49(9.66)	30.69(10.39)	30.76(10.76)	
	3 Months	28.81(10.17)	28.76 (10.44)	28.43(10.23)	26.92(8.36)	
	12 Months	30.48(11.96)	28.89(11.12)	28.47(10.60)	28.76(9.05)	0.052(0.98)
	Depression: PHQ-9					
	Baseline	5.33(4.86)	5.21(4.02)	4.21(4.02)	5.58(4.65)	
	3 Months	4.29(4.47)	3.60(4.05)	4.12(4.43)	3.07(3.07)	
	12 Months	5.35(5.40)	3.51(4.25)	4.00(3.78)	3.01(3.52)	**4.09(0.007)**
	SF-36: Mental Health					
	Baseline	72.86(20.38)	77.80(17.65)	76.20(20.72)	76.51(17.68)	
	3 Months	79.46(16.73)	83.36(16.38)	79.52(18.07)	82.74(14.27)	
	12 Months	76.21(18.13)	82.03(15.70)	79.51(17.36)	84.10(15.64)	0.79(0.50)
	SF-36: Role Emotional					
	Baseline	67.93(40.45)	69.69(38.63)	65.47(42.18)	70.98(38.31)	
	3 Months	72.15(39.74)	77.57(35.17)	74.21(38.50)	86.21(28.64)	
	12 Months	67.09(40.82)	84.24(31.98)	73.02(37.12)	86.21(29.97)	2.44(0.06)
	SF-36: Social Functioning					
	Baseline	69.77(27.05)	70.22(26.29)	70.68(26.50)	70.04(27.99)	
	3 Months	79.59(23.36)	83.18(24.68)	81.10(23.56)	85.99(17.38)	
	12 Months	76.74(26.31)	86.81(21.30)	77.23(24.17)	85.34(19.33)	2.49(0.06)

Note: Any two groups with the *same* superscripted letter are statistically *different* than one another. †Statistically significant quadratic effect F = 2.69 (p = 0.046), reflecting the U-shaped pattern of some group findings. Visual demonstration of this table is on Figures 5.3 and 5.4.

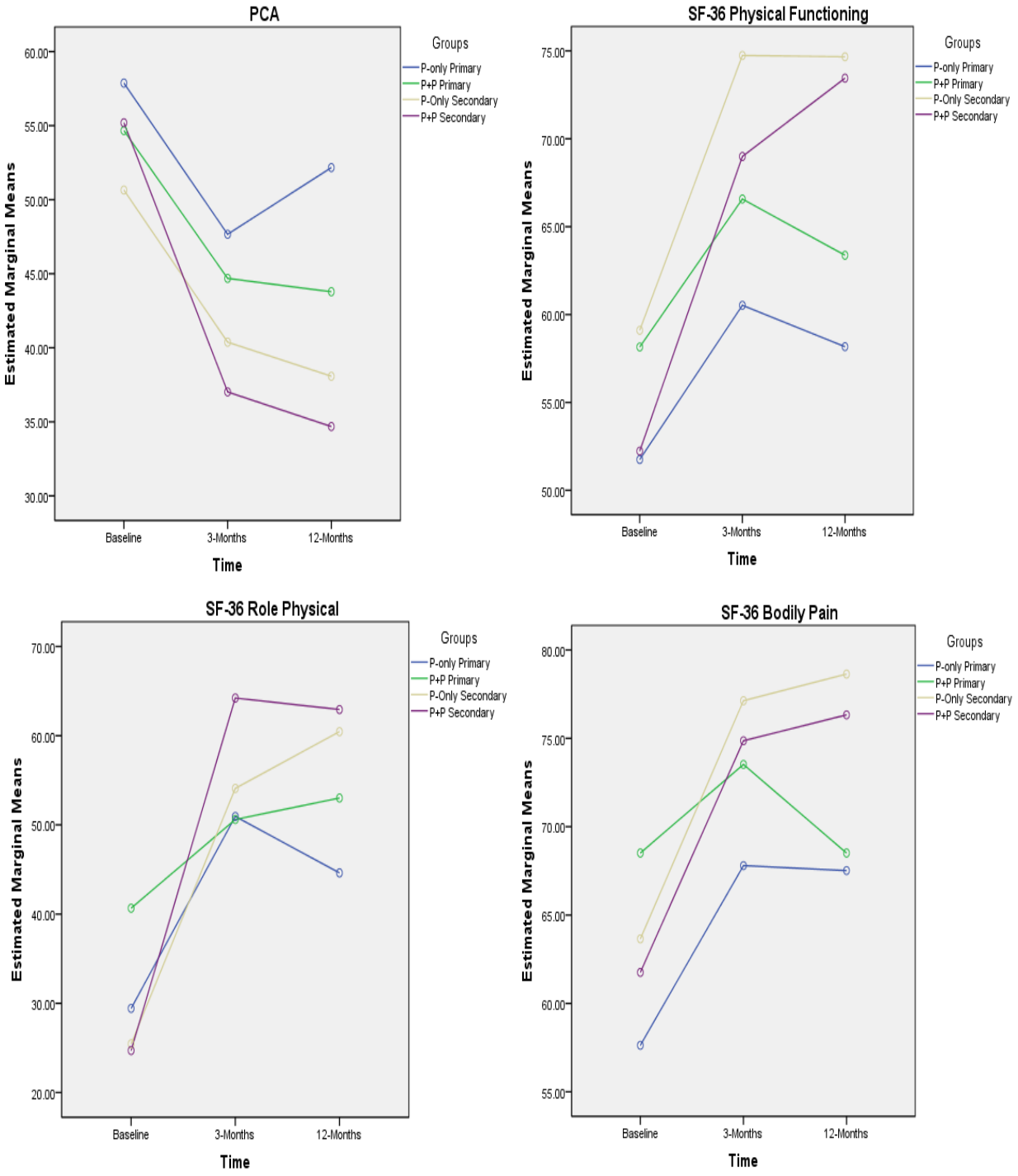


Figure 5.3. Trend analysis of change over time on physical function outcomes.

Note: statistically significant difference between groups was observed on PCA, SF-36 Physical functioning, SF-36 Role Physical and SF-36 Bodily pain.

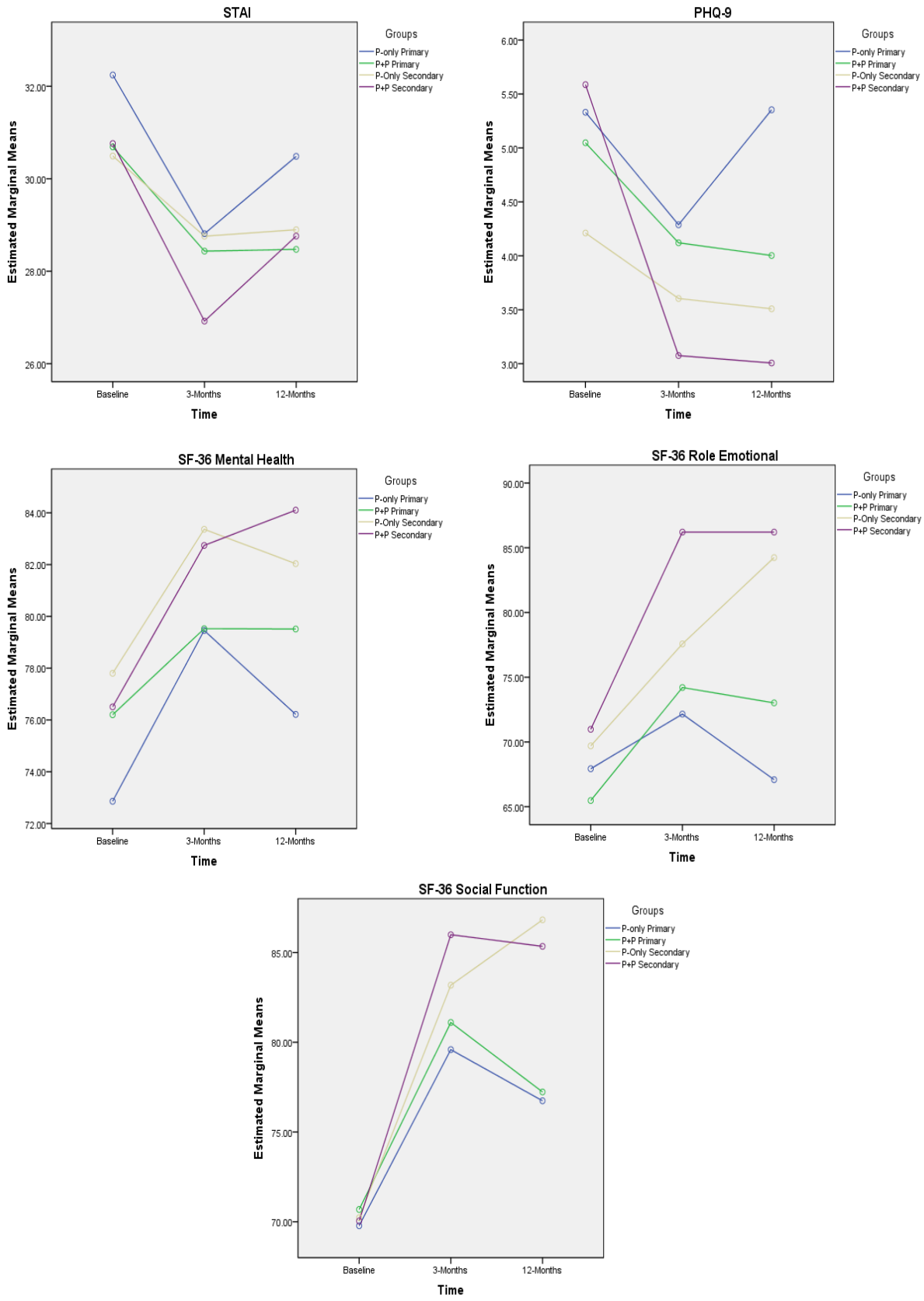


Figure 5.4. Trend analysis for psychological adjustment indicators. A statistically significant difference between groups was observed for PHQ-9 (Depression).

With respect to psychological adjustment across time, only one (depression) of the five psychological adjustment indicators showed significant group x time interaction effects, indicating differences in rates of change across time among the four ICD indication/intervention groups (Figure 5.4). Change in anxiety across time and groups was modest. For depression ($F = 4.09$ $P = 0.007$), the greatest improvement was seen in the secondary prevention /P+P group, where drops in depression were the steepest. Briefly, there were overall improvements in psychological adjustment in both intervention groups, independent of ICD indication. There was a tendency for secondary prevention patients to show more improvement across time in all indicators of psychological adjustment, except for anxiety.

In summary, at baseline and 3 months, there were few statistically significant ICD indications x intervention group differences for the four dimensions of self-efficacy. Those who received an ICD for secondary prevention compared to primary prevention had a higher rate of recovery based on the indicators of physical function and psychological adjustment, with modest continued improvement at 12 months.

Multiple-Group Comparisons using SEM

The following section describes multiple-group SEM analysis used to compare mediation models by ICD indication (primary vs secondary prevention). The mediation models were based on four the dimensions of self-efficacy. First, we compared measurement models for primary vs. secondary prevention groups, followed by comparisons of the group structural models. For the latter, the hypothesized mediation models compared the primary vs. secondary prevention groups. Four structural equation models were tested separately, one for each self-efficacy measure (self-efficacy expectations, outcome expectation, self-management behavior, ICD knowledge), and then a full structural model including all four self-efficacy dimensions as mediators was tested.

Measurement Model

Initially, we verified the measurement model for the primary vs. secondary groups, beginning with a model in which models' parameters were allowed to be freely estimated, and then moving to a fixed or fully constrained model, where the model parameters for both groups were fixed as equivalent. The chi-square difference values (χ^2_{diff}) between the *first analysis* (χ^2 = 77.228, df = 106, CFI: 0.91) and the *second analysis* (χ^2 = 166.392, df = 150, CFI: 0.96) was *not* statistically significant (ANOVA χ^2_{diff} = 47.28, df_{diff} = 44, p = 0.34), indicating that the measurement models are comparable once tested in a single sample and in two different samples (primary vs secondary).

For the measurement model with free parameters: in primary prevention, standardized indicator loadings for physical function ranged from 0.48 and 0.78; that was comparable for psychological adjustment ranging from 0.47 and 0.79. For secondary prevention, standardized loadings for physical function were between 0.64 and 0.85; for psychological adjustment values ranged between 0.64 and 0.83. All indicator loadings were statistically significant.

For the model with fixed parameters: for primary prevention, the standardized indicator loadings for physical function were between 0.47 and 0.79, and for psychological adjustment between 0.66 and 0.84. For secondary prevention, standardized loadings for physical function ranged from 0.47 and 0.79, and for psychological adjustment between 0.66 and 0.84. Thus, the measurement models for primary and secondary indication were considered comparable, and the analysis moved forward to comparing the structural models for primary vs. secondary ICD indication.

Structural Model

Given comparable measurement models, we moved forward to compare the hypothesized structural model for primary vs. secondary indication groups. We tested the mediating effects of the four *dimensions of self-efficacy*, one dimension at a time. In the final step, we tested the full model, including all *dimensions of self-efficacy* in the model (Figure 5.1). As presented in Table 5.4 and briefly

summarized below, no structural differences were observed in the five mediation models for the primary vs. secondary prevention groups, indicating no mediation in the models and no differences in either model by ICD indication.

Self-Efficacy Mediation Model.

The χ^2_{diff} between the model with free parameters (χ^2 = 100.69, df = 124) and fixed parameters (χ^2 = 150.64, df = 157) was *not* statistically significant (ANOVA χ^2_{diff} = 32.4, df $_{diff}$ = 33, p = 0.50). Thus, model parameters were equivalent in the primary and secondary ICD indication groups. That is, for self-efficacy, there was no difference in the structural model for primary vs. secondary ICD indication (Table 5.4).

For the free parameter model with the *primary prevention* group, the significant paths indicated moderate positive effects of self-efficacy on physical function (SE→Physical) and psychological adjustment (SE→Psychological) with path coefficients of 0.37 and 0.59, respectively, p<0.001. In analysis of the *secondary prevention* group, statistically significant paths also indicated moderate positive effects of self-efficacy on physical function (SE→Physical) and psychological adjustment (SE→Psychological) with standardized loadings of 0.34 and 0.52, respectively, p<0.001.

For the fixed parameters model, analysis of the *primary prevention group*, statistically significant paths were found for the effects of the intervention on self-efficacy (Intervention→SE), self-efficacy on physical function (SE→Physical) and psychological adjustment (SE→Psychological) with standardized loadings of 0.09, 0.38 and 0.59, respectively and p<0.05. For the *secondary prevention group*, statistically significant paths were found for the intervention effect on self-efficacy (Intervention→SE), self-efficacy on physical function (SE→Physical) and psychological adjustment (SE→Psychological) with standardized loadings of 0.105, 0.33 and 0.55, respectively and p<0.05.

Outcome Expectations Mediation Model.

The χ^2_{diff} between the free parameters model (χ^2 = 96.63, df = 124) and fixed parameters model (χ^2 = 180.61, df = 157) was *not* statistically significant (ANOVA χ^2_{diff} = 42.22, df_{diff} = 33, p = 0.13) (Table 5.4). Thus, for outcome expectations primary and secondary ICD indication groups had comparable structural models.

For the free parameter model in *primary prevention*, the significant paths indicated moderate positive effects of outcome expectation on physical function (OE→Physical) and psychological adjustment (OE→Psychological) with path coefficients of 0.25 and 0.24, respectively, p<0.001. In *secondary prevention*, the path outcome expectation on psychological adjustment (OE→Psychological) indicated moderate positive effect of with standardized loading of 0.28 and p<0.05.

For the fixed parameters model, analysis of the *primary prevention group*, statistically significant paths were found for the effects of the intervention on outcome expectations (Intervention→OE), and outcome expectation on physical function (OE→Physical) and psychological adjustment (OE→Psychological) with standardized loadings of 0.12, 0.22 and 0.24, respectively, p<0.02. In *secondary prevention*, statistically significant paths were found for the intervention effect on outcome expectations (Intervention→OE) and outcome expectation on physical function (OE→Physical) and psychological adjustment (OE→Psychological) with standardized loadings of 0.11, 0.23 and 0.26, respectively, p<0.02.

Table 5.4. ANOVA results comparing SEM mediating models for primary vs. secondary ICD indication

Model	χ^2	df	χ^2_{diff}	df_{diff}	p-value	CFI
Self-Efficacy (SE) as Mediator						
Free parameters	100.686	124	32.4	33	0.50	0.921
Fixed parameters	150.642	157				0.956
Outcome Expectations (OE) as Mediator						
Free parameters	96.628	124	42.221	33	0.13	0.943
Fixed parameters	180.608	157				0.931
Self-Management Behavior (SMB) as Mediator						
Free parameters	89.864	124	40.788	33	0.16	0.970
Fixed parameters	168.621	157				0.954
ICD Knowledge (KSA) as Mediator						
Free parameters	90.327	124	40.597	33	0.17	0.965
Fixed parameters	168.521	157				0.952
Full Model with SE, OE, SMB, KSA as Mediators						
Free parameters	258.76	264	45.151	48	0.59	0.892
Fixed parameters	324.918	312				0.925

Note. X^2 was computed using DWLS estimation. CFI represents the computed robust values.

Self-Management Behavior Mediation Model.

The χ^2_{diff} between free parameters model (χ^2 = 89.86, df = 124) and fixed parameters model (χ^2 = 168.62, df = 157) was *not* statistically significant (ANOVA χ^2_{diff} = 40.79, df_{diff} = 33, p = 0.16). That is, for Self-management behavior, there was no difference in the structural model for primary vs. secondary ICD indication (Table 5.4).

For the free parameter model in *primary prevention*, the significant paths indicated moderate negative effect of self-management behavior on physiological outcomes (SMB→Psychological) with standardized loadings of -0.21 and p = 0.04. In *secondary prevention*, none of the paths were statistically significant.

For the fixed parameters model, analysis of the *primary prevention group*, statistically significant paths were found for the effects of self-management behavior on physiological outcomes (SMB→Psychological) with standardized loadings of -0.17, $p<0.02$. In *secondary prevention*, statistically significant paths were also showing a negative effect of self-management behavior on physiological outcomes (SMB→Psychological) with standardized loadings of -0.14, $p<0.02$.

ICD Knowledge Model.

The χ^2_{diff} between free parameters model ($\chi^2 = 90.33$, df = 124) and fixed parameters model ($\chi^2 = 168.52$, df = 157) was *not* statistically significant (ANOVA $\chi^2_{diff} = 40.60$, $df_{diff} = 33$, $p = 0.17$). Thus, model parameters are the same across Primary and Secondary ICD Indication. (Table 5.4).

For free parameter models, in the analysis of the *primary prevention* and *secondary prevention* groups, none of the paths were statistically significant. For the fixed parameters, analysis of the *primary prevention group*, a trend for showing statistically significant paths were found for the effects of the intervention on psychological outcomes (Intervention→Psychological) and ICD knowledge effect on physical function (KSA→Physical) with standardized loadings of 0.11 and 0.10, respectively, $p = 0.07$. In *secondary prevention*, the same paths (Intervention→Psychological and KSA→Physical) showed a trend to significance with standardized loadings of 0.11 and 0.07, respectively, and $p = 0.07$.

Four Mediator Full Model (SE + OE + SMB + KSA).

The χ^2_{diff} between the free parameter model ($\chi^2 = 258.76$, df = 264) and fixed parameter model ($\chi^2 = 324.92$, df = 312) was *not* statistically significant (ANOVA $\chi^2_{diff} = 45.15$, $df_{diff} = 48$, $p = 0.59$). Thus, model parameters were considered equivalent for the primary vs. secondary prevention ICD indication groups. Testing the covariance structure, we found no differences due to primary vs. secondary ICD indication with no difference in the structural model (Table 5.4).

For the free parameter model with the *primary prevention* group, the significant paths indicated moderate positive effects of self-efficacy on physical function (SE→Physical) and psychological

adjustment (SE→Psychological) with path coefficients of 0.53 and 0.29, respectively, $p<0.001$. The significant paths of self-management behavior on psychological adjustment (SMB→Psychological) showed a trend of significance with the loading of -0.16, $p = 0.07$. In *secondary prevention*, statistically significant paths were between self-efficacy and physical function (SE→Physical) and psychological adjustment (SE→Psychological) with standardized loadings of 0.46 and 0.30, respectively, $p<0.01$.

For the fixed parameters model, analysis of the *primary prevention group*, statistically significant paths were found for the effects of the intervention effect on outcome expectation (Intervention→OE), self-efficacy on physical function (SE→Physical), psychological adjustment (SE→Psychological), and self-management behavior on psychological adjustment (SMB→Psychological) with standardized loadings of 0.13, 0.31, 0.53 and -0.17, respectively, $p<0.05$. In *secondary indication*, statistically significant paths were found for the intervention effect on self-efficacy (Intervention→SE), self-efficacy on physical function (SE→Physical) and psychological adjustments (SE→Psychological) with standardized loadings of 0.105, 0.33 and 0.55, respectively, $p<0.05$.

In brief, a comparison of four mediating models for primary vs. secondary prevention groups were structurally equivalent, indicating no differences in the hypothesized pathways by reason for receiving an ICD. Thus, the analysis was complete at this point; it was not necessary to move forward to test differences in specific pathways based on the two groups (Figure 5.1).

DISCUSSION

Comparing ICD indication group differences by intervention for *dimensions of self-efficacy*, the only difference found between groups was for ICD knowledge, with secondary prevention participants presenting a higher rate at three-months. However, this was a 1-point difference, which indicates that those participants got one extra question correct when compared to primary prevention, not being clinically meaningful.

When considering physical function outcomes between the primary and secondary prevention groups, irrespective of the intervention, differences between ICD indication on bodily pain, with primary participants presenting higher rates were noted. There was also a difference in physical functioning between primary indication participants in P-Only and P+P intervention groups, such that those in the P+P group had better physical functioning. This can indicate that having a partner participating in an intervention might be beneficial for primary prevention patients on quality of life-related to physical functioning. Participants might feel more capable of doing physical activities after having a partner support.

For psychological adjustment outcomes of depression, role emotional and social function, higher scores were noted in primary prevention participants in the P-Only group over the P+P group. This indicates that having a partner modifies depression outcomes. Those participants who received an ICD for secondary prevention started the intervention with higher levels of depression. Over 12-months they had a greater decrease and sharpest decline (rate of change) in depression compared to participants receiving a device for primary prevention. For quality of life related to role emotional and social function, participants receiving an ICD for secondary prevention showed the sharpest and sustained increase over 12 months, while the ICD primary prevention group had an increase on quality of life related to role emotional and social function, but this was not sustained at 12 months. In all these analysis patients with ICD for secondary prevention that were in the P+P intervention condition showed superior outcomes compare to those in P-Only. This suggests that it will be important to take account of ICD indication to improve outcomes for ICD patients, and that those with ICD for primary prevention might need to be assessed differently and/or followed closer. Overall, though, adding a partner to the intervention help patients to achieve and sustain lower levels of depression and better quality of life.

When considering physical function and psychological adjustment between the primary and secondary prevention groups, participants who receive an ICD for secondary prevention had higher

recovery rates on study outcomes than those with primary prevention. This might indicate the need for a longer or different intervention for those participants with primary prevention. This ICD indication group contains patients with a "class I" indication for the use of prophylactic ICD therapy with heart failure, NYHA class 2–3 symptoms, and ejection fraction (EF) ≤35%.[124] In addition, different disease characteristics might influence the recovery trajectory delaying intervention response. In a retrospective subgroup analysis from the PainFREE Rx II trial[109] that tested whether empirical ATP is a safe and effective treatment for fast ventricular tachycardia, a difference by ICD indication on quality of life over 12-months revealed that physical functioning was higher in those with a secondary prevention ICD, similar to our findings. However, for role physical, social functioning, and role emotional over 12 months, scores were similar between those receiving ICD for primary vs secondary prevention in the PAINFREE trial. Primary prevention sample. Bodily pain and mental health were similar between the ICD indication groups. Findings from PainFREE Rx II trial[109] were contrary to the findings from this study in which participants in P-Only and P+P intervention with secondary prevention had superior quality of life at 12-months when compared to the primary prevention group.

Using SEM, in the five tested models, there were no differences in mediation pathways between ICD indication in any of the tested models of self-efficacy, outcome expectations, self-management behavior, ICD knowledge and in a model considering all previously mentioned *dimensions of self-efficacy* in the same model. These findings were contrary to the initial hypothesis, in which it was expected that patients would have different mediation pathways depending on ICD indication. When considering patient-centered outcomes separately, Rahmawati and colleagues[119] found that there was no difference between ICD indication groups on general health-related quality of life, however those with an ICD implanted for primary prevention, were more prone to experience worries about their ICD, anxiety and poor quality of life, mainly thorough declines in vitality, which was more impaired for primary prevention vs. secondary prevention patients.[119] Bilge[59] did not find any differences in anxiety between ICD

indication groups. There are other factors that might influence the mediation pathways that were not accounted for in the hypothesized models that would provide better understanding of the differences between primary and secondary prevention patients, such as more time points (such as 6-months) and partner outcomes.

Strengths and Limitations

The strengths of this study are the robust statistical method used to compare mediating pathways and differences in patients receiving an ICD for primary or secondary prevention for sudden cardiac arrest. These findings allow us to understand further if adding a partner to an intervention focusing on adjustment after an ICD implantation would show a different impact on the patient's outcomes according to their ICD indication. An important finding from this study in patients with an ICD implanted for primary prevention is that they have slower recovery rates for physical function and psychological adjustment when compared to secondary prevention. This indicates the need for primary prevention to receive a longer or different intervention to achieve results similar to secondary prevention.

Limitations of this study are the small sample size by ICD indications (Primary n = 180 and Secondary n = 121). Some authors suggest sample sizes of 200 per group[121] while others mention 300.[123] Even though sample size might be a study limitation, there was acceptable model fit that would support these findings.

Summary/Implication for Practice

There is no difference between the mediation pathways for patients receiving an ICD as a primary or secondary indication. Regarding differences in *dimensions of self-efficacy*, all dimensions were similar for primary and secondary prevention ICD participants over three-months. For outcomes, there was a difference by ICD indication with secondary prevention in P-Only group showing better scores on bodily pain, depression, role emotional and social functioning. For P+P arm, there was a difference between ICD indication with secondary prevention presenting lower scores on depression and higher scores on quality

of life related to role emotional and social functioning. Over 12-months, secondary prevention participants presented higher recovery rates. The SEM models showed that independent of their ICD indication; patients had similar physical function and psychological adjustment at 12-months.

It appears that *dimensions of self-efficacy* do not differ based on the ICD indication at 3 months, however outcomes at 12 months showed differences. In designing future interventions, patients receiving an ICD for primary prevention may need a longer intervention with partners or significant others engaged in the intervention process to boost patient's improvement.

Future studies accounting on the model for time and partner outcomes are recommended for better understand of patterns of change over time and the influence of the partner on ICD patient outcomes.

REFERENCES

1. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *European Heart Journal.* 2016.
2. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;62(16):e147-239.
3. Kolodziejczak M, Andreotti F, Kowalewski M, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy A Systematic Review and Meta-analysis. In. *Ann. Intern. Med.* Vol 1672017:103-111.
4. Sears SF, Todaro JF, Lewis TS, Sotile W, Conti JB. Examining the psychosocial impact of implantable cardioverter defibrillators: a literature review. *Clin Cardiol.* 1999;22.
5. Bainger EM, Fernsler JI. Perceived quality of life before and after implantation of an internal cardioverter defibrillator. *American journal of critical care : an official publication, American Association of Critical-Care Nurses.* 1995;4(1):36-43.
6. Dunbar SB. Psychosocial issues of patients with implantable cardioverter defibrillators. *Am J Crit Care.* 2005;14(4):294-303.
7. Dougherty CM, Benoliel JQ, Bellin C. Domains of nursing intervention after sudden cardiac arrest and automatic internal cardioverter defibrillator implantation. *Heart Lung.* 2000;29(2):79-86.
8. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosom Med.* 2011;73(3):226-233.
9. Crossmann A, Schulz SM, Kuhlkamp V, et al. A randomized controlled trial of secondary prevention of anxiety and distress in a German sample of patients with an implantable cardioverter defibrillator. *Psychosom Med.* 2010;72(5):434-441.
10. Kohn CS, Petrucci RJ, Baessler C, Soto DM, Movsowitz C. The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. *Pace.* 2000;23.
11. Dougherty CM, Pyper GP, Frasz HA. Description of a nursing intervention program after an implantable cardioverter defibrillator. *Heart Lung.* 2004;33(3):183-190.
12. Dougherty CM, Johnson-Crowley NR, Lewis FM, Thompson EA. Theoretical development of nursing interventions for sudden cardiac arrest survivors using social cognitive theory. *ANS Adv Nurs Sci.* 2001;24(1):78-86.
13. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977;84(2):191-215.
14. Bandura A. *Self-efficacy : the exercise of control.* New York: New York : W.H. Freeman; 1997.

15. Bandura A. *Social foundations of thought and action : a social cognitive theory*. Englewood Cliffs, N.J.: Englewood Cliffs, N.J. : Prentice-Hall; 1986.
16. Rajati F, Mostafavi F, Sharifirad G, et al. A theory-based exercise intervention in patients with heart failure: A protocol for randomized, controlled trial. *J Res Med Sci.* 2013;18(8):659-667.
17. Meland E, Maeland JG, Laerum E. The importance of self-efficacy in cardiovascular risk factor change. *Scand J Public Health.* 1999;27(1):11-17.
18. Dougherty CM, Lewis FM, Thompson EA, Baer JD, Kim W. Short-term efficacy of a telephone intervention by expert nurses after an implantable cardioverter defibrillator. *Pacing Clin Electrophysiol.* 2004;27(12):1594-1602.
19. Dougherty CM, Thompson EA, Lewis FM. Long-term outcomes of a telephone intervention after an ICD. *Pacing Clin Electrophysiol.* 2005;28(11):1157-1167.
20. Dougherty CM, Thompson EA, Kudenchuk PJ. Development and testing of an intervention to improve outcomes for partners following receipt of an implantable cardioverter defibrillator in the patient. *ANS Adv Nurs Sci.* 2012;35(4):359-377.
21. Dougherty C, Fairbanks A, Eaton L, Morrison M, Kim M, Thompson E. Comparison of patient and partner quality of life and health outcomes in the first year after an implantable cardioverter defibrillator (ICD). *Journal of Behavioral Medicine.* 2016;39(1):94-106.
22. Dougherty CM, Thompson EA. Intimate partner physical and mental health after sudden cardiac arrest and receipt of an implantable cardioverter defibrillator. *Research in nursing & health.* 2009;32(4):432-442.
23. Dougherty CM, Pyper GP, Benoliel JQ. Domains of concern of intimate partners of sudden cardiac arrest survivors after ICD implantation. *The Journal of cardiovascular nursing.* 2004;19(1):21-31.
24. Woodgate J, Brawley LR, Weston ZJ. Maintenance Cardiac Rehabilitation Exercise Adherence: Effects of Task and Self‐Regulatory Self‐Efficacy. *Journal of Applied Social Psychology.* 2005;35(1):183-222.
25. Taylor CB, Bandura A, Ewart CK, Miller NH, Debusk RF. Exercise testing to enhance wives' confidence in their husbands' cardiac capability soon after clinically uncomplicated acute myocardial infarction. *The American Journal of Cardiology.* 1985;55(6):635-638.
26. Fitchet A, Doherty PJ, Bundy C, Bell W, Fitzpatrick AP, Garratt CJ. Comprehensive cardiac rehabilitation programme for implantable cardioverter-defibrillator patients: a randomised controlled trial. *Heart.* 2003;89(2):155-160.
27. Frizelle DJ, Lewin RJ, Kaye G, et al. Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: a pilot study. *Br J Health Psychol.* 2004;9(3):381-392.

28. Chevalier P, Cottraux J, Mollard E, et al. Prevention of implantable defibrillator shocks by cognitive behavioral therapy: A pilot trial. *American Heart Journal.* 2006;151(1).
29. Sears SF, Sowell LD, Kuhl EA, et al. The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. *Pacing Clin Electrophysiol.* 2007;30(7):858-864.
30. Smeulders ESTF, van Haastregt JCM, Dijkman-Domanska BK, van Hoef EFM, van Eijk JT, Kempen GIJM. Nurse- and peer-led self-management programme for patients with an implantable cardioverter defibrillator; a feasibility study. *BMC Nursing.* 2007;6(1):6.
31. Lewin RJ, Coulton S, Frizelle DJ, Kaye G, Cox H. A brief cognitive behavioural preimplantation and rehabilitation programme for patients receiving an implantable cardioverter-defibrillator improves physical health and reduces psychological morbidity and unplanned readmissions. *Heart.* 2009;95(1):63-69.
32. Dunbar SB, Langberg JJ, Reilly CM, et al. Effect of a Psychoeducational Intervention on Depression, Anxiety, and Health Resource Use in Implantable Cardioverter Defibrillator Patients. *Pacing and Clinical Electrophysiology.* 2009;32(10):1259-1271.
33. Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosomatic medicine.* 2011;73(3):226.
34. Berg SK, Pedersen PU, Zwisler AD, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology.* 2015;14(1):34-44.
35. Russell DC, Smith TL, Krahn DD, et al. Effects of Cognitive Behavioral Stress Management on Negative Mood and Cardiac Autonomic Activity in ICD Recipients. *Pacing Clin Electrophysiol.* 2015;38(8):951-965.
36. Habibovic M, Denollet J, Cuijpers P, et al. Web-based distress management for implantable cardioverter defibrillator patients: A randomized controlled trial. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2017;36(4):392-401.
37. Badger JM, Morris PL. Observations of a support group for automatic implantable cardioverter-defibrillator recipients and their spouses. *Heart & lung : the journal of critical care.* 1989;18(3):238.
38. Molchany CA, Peterson KA. The psychosocial effects of support group intervention on AICD recipients and their significant others. *Progress in cardiovascular nursing.* 1994;9(2):23.

39. Sneed NV, Finch NJ, Michel Y. The effect of psychosocial nursing intervention on the mood state of patients with implantable cardioverter defibrillators and their caregivers. *Progress in cardiovascular nursing.* 1997;12(2):4.
40. Carlsson E, Olsson SB, Hertervig E. The Role of the Nurse in Enhancing Quality of Life in Patients With an Implantable Cardioverter‐Defibrillator: The Swedish Experience. *Progress in cardiovascular nursing.* 2002;17(1):18-25.
41. Dickerson SS, Wu Y, Kennedy MC. A CNS-facilitated ICD support group - A clinical project evaluation. *Clin Nurse Spec.* 2006;20(3):146-153.
42. Ford J, Littleton H, Lutes L, et al. Evaluation of an Internet-based intervention for ICD patients with elevated symptoms of posttraumatic stress disorder. *Pacing and clinical electrophysiology : PACE.* 2019;42(5).
43. Berg SK, Svendsen JH, Zwisler AD, et al. COPE-ICD: a randomised clinical trial studying the effects and meaning of a comprehensive rehabilitation programme for ICD recipients -design, intervention and population. *BMC Cardiovasc Disord.* 2011;11:33.
44. Kolodziejczak M, Andreotti F, Kowalewski M, et al. Implantable Cardioverter-Defibrillators for Primary Prevention in Patients With Ischemic or Nonischemic Cardiomyopathy A Systematic Review and Meta-analysis. *Annals of internal medicine.* 2017;167(2):103-111.
45. Gonzalez-Enriquez S, Rodriguez-Entem F, Exposito V, et al. Single-chamber ICD, single-zone therapy in primary and secondary prevention patients: the simpler the better? *Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing.* 2012;35(3):343-349.
46. Zarraga IG, Dougherty CM, MacMurdy KS, Raitt MH. The effect of spironolactone on ventricular tachyarrhythmias in patients with implantable cardioverter-defibrillators. *Circulation Arrhythmia and electrophysiology.* 2012;5(4):739-747.
47. Ezekowitz JA, Armstrong PW, McAlister FA. Implantable cardioverter defibrillators in primary and secondary prevention: a systematic review of randomized, controlled trials. *Ann Intern Med.* 2003;138(6):445-452.
48. Habibović M, Denollet J, Pedersen SS. Posttraumatic stress and anxiety in patients with an implantable cardioverter defibrillator: Trajectories and vulnerability factors. *Pacing and clinical electrophysiology: PACE.* 2017;40(7):817-823.
49. Hlatky MA, Sanders GD, Owens DK. Evidence-based medicine and policy: the case of the implantable cardioverter defibrillator. *Health Aff (Millwood).* 2005;24(1):42-51.
50. Ooi SL, He HG, Dong Y, Wang W. Perceptions and experiences of patients living with implantable cardioverter defibrillators: a systematic review and meta-synthesis. *Health Qual Life Outcomes.* 2016;14(1):160.

51. Palacios-Cena D, Losa-Iglesias ME, Alvarez-Lopez C, et al. Patients, intimate partners and family experiences of implantable cardioverter defibrillators: qualitative systematic review. *J Adv Nurs.* 2011;67(12):2537-2550.
52. Colquitt JL, Mendes D, Clegg AJ, et al. Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure: Systematic review and economic evaluation. *Health Technology Assessment.* 2014;18(56):1-559.
53. Dunbar SB, Dougherty CM, Sears SF, et al. Educational and Psychological Interventions to Improve Outcomes for Recipients of Implantable Cardioverter Defibrillators and Their Families: A Scientific Statement From the American Heart Association. *Circulation.* 2012;126(17):2146-2172.
54. Hamner M, Hunt N, Gee J, Garrell R, Monroe R. PTSD and Automatic Implantable Cardioverter Defibrillators. In. Vol 401999:82-85.
55. Morken IM, Norekvål TM, Bru E, Larsen AI, Karlsen B. Perceptions of healthcare professionals' support, shock anxiety and device acceptance among implantable cardioverter defibrillator recipients. *Journal of Advanced Nursing.* 2014;70(9):2061-2071.
56. Sears SF, Conti JB. Quality of life and psychological functioning of icd patients. *Heart.* 2002;87.
57. Burke J, Hallas C, Clark-Carter D, White D, Connelly D. The psychosocial impact of the implantable cardioverter defibrillator: A meta-analytic review. *Br J Health Psychol.* 2003;8:165-178.
58. Redhead AP, Turkington D, Rao S, Tynan MM, Bourke JP. Psychopathology in postinfarction patients implanted with cardioverter-defibrillators for secondary prevention. A cross-sectional, case-controlled study. *J Psychosom Res.* 2010;69(6):555-563.
59. Bilge AK, Ozben B, Demircan S, Cinar M, Yilmaz E, Adalet K. Depression and Anxiety Status of Patients with Implantable Cardioverter Defibrillator and Precipitating Factors. *Pacing and Clinical Electrophysiology.* 2006;29(6):619-626.
60. Kapa S, Rotondi-Trevisan D, Mariano Z, et al. Psychopathology in patients with ICDs over time: results of a prospective study. *Pacing Clin Electrophysiol.* 2010;33(2):198-208.
61. Peacock J, Whang W. Psychological distress and arrhythmia: risk prediction and potential modifiers. *Progress in cardiovascular diseases.* 2013;55(6):582-589.
62. Sears SF, Matchett M, Conti JB. Effective management of ICD patient psychosocial issues and patient critical events. *Journal of cardiovascular electrophysiology.* 2009;20(11):1297-1304.
63. Dougherty CM, Thompson EA, Kudenchuk PJ. Patient plus partner trial: A randomized controlled trial of 2 interventions to improve outcomes after an initial implantable cardioverter-defibrillator. *Heart rhythm : the official journal of the Heart Rhythm Society.* 2018.
64. Pocock SJ. *Clinical trials : a practical approach.* Chichester [West Sussex] ; New York: Chichester West Sussex ; New York : Wiley; 1983.

65. Furber S, Butler L, Phongsavan P, Mark A, Bauman A. Randomised controlled trial of a pedometer-based telephone intervention to increase physical activity among cardiac patients not attending cardiac rehabilitation. *Patient Education and Counseling.* 2010;80(2):212-218.
66. Moore SM, Charvat JM. Using the CHANGE intervention to enhance long-term exercise. *Nursing Clinics of North America.* 2002;37(2):273-283.
67. Padula CA, Yeaw E, Mistry S. A home-based nurse-coached inspiratory muscle training intervention in heart failure. *Applied Nursing Research.* 2009;22(1):18-25.
68. Pinto BM, Dunsiger SI. Mediators of exercise maintenance after cardiac rehabilitation. *Journal of cardiopulmonary rehabilitation and prevention.* 2015;35(1):13-20.
69. Shao JH, Chang AM, Edwards H, Shyu YIL, Chen SH. A randomized controlled trial of self‐management programme improves health‐related outcomes of older people with heart failure. *Journal of Advanced Nursing.* 2013;69(11):2458-2469.
70. Dougherty CM, Johnston SK, Thompson EA. Reliability and Validity of the Self Efficacy Expectations and Outcome Expectations After ICD Implantation Scales. *Applied nursing research : ANR.* 2007;20(3):116-124.
71. Jenkins LS, Dunbar SB, Hawthorne MH. Patient concerns before and the first 9-months after ICD implantation. *Circulation.* 1997;96(8):745-745.
72. Ware J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care.* 1996;34(3):220-233.
73. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care.* 1992;30(6):473-483.
74. Brooks MM, Jenkins LS, Schron EB, Steinberg JS, Cross JA, Paeth DS. Quality of Life at Baseline: Is Assessment after Randomization Valid? *Medical Care.* 1998;36(10):1515-1519.
75. Speilberger C, Gorsuch R, Lushene R. *Manual for the state-trait anxiety inventory.* Palo Alto, CA: Consulting Psychologists Press; 1970.
76. Kroenke K, Spitzer RL, Williams JBW. The PHQ‐9. *Journal of General Internal Medicine.* 2001;16(9):606-613.
77. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
78. Team RC. *R: A language and environment for statistical computing.* Vienna, Austria. 2018.
79. Rosseel Y. lavaan: An R Package for Structural Equation Modeling. *Journal of Statistical Software.* 2012;48(2):1-36. http://www.jstatsoft.org/v48/i02/.
80. Schreiber JB. Core reporting practices in structural equation modeling. *Research in Social and Administrative Pharmacy.* 2008;4(2):83-97.

81. Schreiber JB. Update to core reporting practices in structural equation modeling. *Research in Social and Administrative Pharmacy.* 2017;13(3):634-643.
82. Kline RB. *Principles and practice of structural equation modeling.* 2nd ed. ed. New York: New York : Guilford Press; 2005.
83. Finch WH, Brian FF. *Latent Variable Modeling with R.* Taylor and Francis; 2015.
84. Zhu SJ, Nahm E, Resnick B, et al. The Moderated Mediating Effect of Self-Efficacy on Exercise Among Older Adults in an Online Bone Health Intervention Study: A Parallel Process Latent Growth Curve Model. *J Aging Phys Act.* 2017;25(3):378-386.
85. Grewal R, Cote J, Baumgartner H. Multicollinearity and Measurement Error in Structural Equation Models: Implications for Theory Testing. *Marketing Science.* 2004;23(4):519-529.
86. Ladwig KH, Baumert J, Marten-Mittag B, Kolb C, Zrenner B, Schmitt C. Posttraumatic stress symptoms and predicted mortality in patients with implantable cardioverter-defibrillators: results from the prospective living with an implanted cardioverter-defibrillator study. *Archives of general psychiatry.* 2008;65(11):1324-1330.
87. Buck HG, Dickson VV, Fida R, et al. Predictors of hospitalization and quality of life in heart failure: A model of comorbidity, self-efficacy and self-care. *Int J Nurs Stud.* 2015;52(11):1714-1722.
88. Barra S, Providência R, Paiva L, Heck P, Agarwal S. Implantable cardioverter-defibrillators in the elderly: rationale and specific age-related considerations. *EP Europace.* 2015;17(2):174-186.
89. Hamilton GA, Carroll DL. The effects of age on quality of life in implantable cardioverter defibrillator recipients. *J Clin Nurs.* 2004;13(2):194-200.
90. Cerin E, MacKinnon DP. A commentary on current practice in mediating variable analyses in behavioural nutrition and physical activity. *Public Health Nutr.* 2009;12(8):1182-1188.
91. Rogers LQ, Courneya KS, Anton PM, et al. Social Cognitive Constructs Did Not Mediate the BEAT Cancer Intervention Effects on Objective Physical Activity Behavior Based on Multivariable Path Analysis. *Annals of Behavioral Medicine.* 2017;51(2):321-326.
92. Young MD, Plotnikoff RC, Collins CE, Callister R, Morgan PJ. Social cognitive theory and physical activity: a systematic review and meta‐analysis. *Obesity Reviews.* 2014;15(12):983-995.
93. Cameron JE, Voth J, Jaglal SB, Guilcher SJT, Hawker G, Salbach NM. "In this together": Social identification predicts health outcomes (via self-efficacy) in a chronic disease self-management program. *Social science & medicine (1982).* 2018;208:172-179.
94. Brecht ML, Dracup K, Moser DK, Riegel B. The relationship of marital quality and psychosocial adjustment to heart disease. *The Journal of cardiovascular nursing.* 1994;9(1):74.
95. Bandura A. Self-efficacy mechanism in human agency. *American Psychologist.* 1982;37(2):122-147.

96. Bandura A. Social cognitive theory of self- regulation. *Organizational Behavior and Human Decision Processes.* 1991;50(2):248-287.
97. Schieman S, Campbell JE. Age Variations in Personal Agency and Self-Esteem: The Context of Physical Disability. *Journal of Aging and Health.* 2001;13(2):155-185.
98. Mehra R. Global public health problem of sudden cardiac death. *Journal of electrocardiology.* 2007;40(6 Suppl):S118-122.
99. Magnusson P, Morner S, Gadler F, Karlsson J. Health-related quality of life in hypertrophic cardiomyopathy patients with implantable defibrillators. *Health Qual Life Outcomes.* 2016;14:62.
100. Schinkel AF, Vriesendorp PA, Sijbrands EJ, Jordaens LJ, ten Cate FJ, Michels M. Outcome and complications after implantable cardioverter defibrillator therapy in hypertrophic cardiomyopathy: systematic review and meta-analysis. *Circulation Heart failure.* 2012;5(5):552-559.
101. Brouwer TF, Yilmaz D, Lindeboom R, et al. Long-Term Clinical Outcomes of Subcutaneous Versus Transvenous Implantable Defibrillator Therapy. *J Am Coll Cardiol.* 2016;68(19):2047-2055.
102. Gregoratos G, Abrams J, Epstein AE, et al. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). *Circulation.* 2002;106(16):2145.
103. Pires LA, Lehmann MH, Steinman RT, Baga JJ, Schuger CD. Sudden death in implantable cardioverter-defibrillator recipients: Clinical context, arrhythmic events and device responses. *Journal of the American College of Cardiology.* 1999;33(1):24-32.
104. Dickerson SS, Kennedy M, Wu Y-WB, Underhill M, Othman A. Factors related to quality-of-life pattern changes in recipients of implantable defibrillators. *Heart & Lung - The Journal of Acute and Critical Care.* 2010;39(6):466-476.
105. Russo AM, Stainback RF, Bailey SR, et al. ACCF/ HRS/ AHA/ ASE/ HFSA/ SCAI/ SCCT/ SCMR 2013 appropriate use criteria for implantable cardioverter- defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. *Journal of the American College of Cardiology.* 2013;61(12):1318.
106. Maron BJ. Contemporary considerations for risk stratification, sudden death and prevention in hypertrophic cardiomyopathy.(Editorial). *Heart.* 2003;89(9):977.

107. Berg SK, Moons P, Christensen AV, Zwisler AD, Pedersen BD, Pedersen PU. Clinical Effects and Implications of Cardiac Rehabilitation for Implantable Cardioverter Defibrillator Patients: A Mixed-Methods Approach Embedding Data From the Copenhagen Outpatient ProgrammE-Implantable Cardioverter Defibrillator Randomized Clinical Trial With Qualitative Data. *The Journal of cardiovascular nursing.* 2015;30(5):420-427.
108. Manuchehry A, Agusala K, Montevecchi M, Kadish A, Passman R. Ventricular Tachyarrhythmias in Patients Receiving an Implantable Cardioverter-Defibrillator for Primary versus Secondary Prophylaxis Indications. *PACE-Pacing Clin Electrophysiol.* 2011;34(5):571-576.
109. Sweeney MO, Wathen MS, Volosin K, et al. Appropriate and inappropriate ventricular therapies, quality of life, and mortality among primary and secondary prevention implantable cardioverter defibrillator patients: results from the Pacing Fast VT REduces Shock ThErapies (PainFREE Rx II) trial. *Circulation.* 2005;111(22):2898-2905.
110. Boulé S, Sémichon M, Guédon-Moreau L, et al. Long-term outcome of implantable cardioverter-defibrillator implantation in secondary prevention of sudden cardiac death. *Archives of cardiovascular diseases.* 2016;109(10):517-526.
111. Konstantino Y, Shafat T, Novack V, Novack L, Amit G. Incidence of Implantable Cardioverter Defibrillator Therapy and Mortality in Primary and Secondary Prevention of Sudden Cardiac Death. *The Israel Medical Association journal : IMAJ.* 2015;17(12):760-763.
112. van Welsenes GH, van Rees JB, Borleffs CJW, et al. Long-term follow-up of primary and secondary prevention implantable cardioverter defibrillator patients. *Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology.* 2011;13(3):389-394.
113. Pedersen SS, Sears SF, Burg MM, Van Den Broek KC. Does ICD indication affect quality of life and levels of distress? *Pacing Clin Electrophysiol.* 2009;32(2):153-156.
114. van den Broek KC, Nyklicek I, van der Voort PH, Alings M, Meijer A, Denollet J. Risk of ventricular arrhythmia after implantable defibrillator treatment in anxious type D patients. *J Am Coll Cardiol.* 2009;54(6):531-537.
115. Groeneveld PW, Matta MA, Suh JJ, Yang F, Shea JA. Quality of Life Among Implantable Cardioverter‐Defibrillator Recipients in the Primary Prevention Therapeutic Era. *Pacing and Clinical Electrophysiology.* 2007;30(4):463-471.
116. Pedersen SS, van den Broek KC, Sears SF, Jr. Psychological intervention following implantation of an implantable defibrillator: a review and future recommendations. *Pacing Clin Electrophysiol.* 2007;30(12):1546-1554.

117. Pedersen SS, Spindler H, Johansen JB, Mortensen PT, Sears SF. Correlates of patient acceptance of the cardioverter defibrillator: cross-validation of the Florida Patient Acceptance Survey in Danish patients. *Pacing Clin Electrophysiol.* 2008;31(9):1168-1177.
118. van Den Broek K, Nyklícek I, Denollet J. Anxiety Predicts Poor Perceived Health in Patients With an Implantable Defibrillator. *Psychosomatics.* 2009;50(5):483-492.
119. Rahmawati A, Chishaki A, Ohkusa T, et al. Influence of primary and secondary prevention indications on anxiety about the implantable cardioverter-defibrillator. *Journal of arrhythmia.* 2016;32(2):102-107.
120. Byrne BM. *Structural equation modeling with Mplus : basic concepts, applications, and programming.* Hoboken, NJ: Hoboken, NJ : Taylor & Francis; 2011.
121. Byrne B. *Structural equation modeling with AMOS: Basic concepts, applications, and programming.*: Lawrence Erlbaum Associates, Inc.; 2001.
122. Byrne BM. Testing for Multigroup Invariance Using AMOS Graphics: A Road Less Traveled. *Structural Equation Modeling: A Multidisciplinary Journal.* 2004;11(2):272-300.
123. Kline RB. *Principles and practice of structural equation modeling.* Fourth edition. ed. New York: New York : The Guilford Press; 2015.
124. Epstein AE, Dimarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (Book review). In. Vol 512008:e1-e62.
125. Berg SK, Pedersen PU, Zwisler A-D, et al. Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial. *European Journal of Cardiovascular Nursing.* 2015;14(1):34-44.
126. Christensen AV, Zwisler AD, Svendsen JH, et al. Effect of cardiac rehabilitation in patients with ICD: are gender differences present? Results from the COPE-ICD trial. *Pacing Clin Electrophysiol.* 2015;38(1):18-27.
127. Berg SK, Støier L, Moons P, Zwisler AD, Winkel P, Ulrich Pedersen P. Emotions and health: findings from a randomized clinical trial on psychoeducational nursing to patients with implantable cardioverter defibrillator. *The Journal of cardiovascular nursing.* 2015;30(3):197-204.

CHAPTER 6: SUMMARY, RECOMMENDATIONS & CONCLUSIONS

MAJOR FINDINGS FROM EACH DISSERTATION AIM

Major findings for Aim 1 and Aim 2 are in table 6.1.

Table 6.1. Summary of main findings for aims 1 and 2

Model	Indirect effects (mediation)	Direct effects intervention on self-efficacy	Direct effects Self-efficacy on outcomes
Separate models for four Dimension of self-efficacy	1. P+P→ SE → *physical* (p = 0.08) 2. P+P→ SE → *psychological* (p = 0.07) 3. P+P→ OE → *physical* (p = 0.08) 4. P+P→ OE → *psychological* (p = 0.08)	1. P+P→SE (p<0.05) 2. P+P→OE (p<0.05)	1. SE→Physical (p<0.05) 2. SE→ Psychological (p<0.05) 3. OE → Physical (p<0.05) 4. OE → Psychological (p<0.05) 5. SMB →Psychological (p<0.05) 6. KSA → Physical (p 0.06)
Full model with four Dimensions of Self-Efficacy	No mediation	1. P+P→SE (p = 0.08) 2. P+P→OE (p<0.05)	1. SE→Physical (p<0.05) 2. SE→ Psychological (p<0.05) 3. SMB →Physical (p = 0.08) 4. SMB →Psychological (p<0.05)
Separate models for eight content-specific elements of self-efficacy	1. P+P→SE-Physical Changes →*psychological* (p<0.05) 2. P+P→ SE-Physical Changes → *physical* (p = 0.07) 3. P+P→ Relationship → *psychological* (p = 0.08)	1. P+P →SE-Physical changes (p<0.05) 2. P+P → SE-ICD shocks (p = 0.12) 3. P+P → SE-Relationship (p = 0.06)	All
Model including statistically significant content-specific elements of self-efficacy	1. P+P→ SE-Relationship → *psychological* (p = 0.08)	7. P+P →SE-Physical changes (p<0.05) 8. P+P → SE-ICD shocks (p = 0.06) 9. P+P → SE-Relationship (p<0.05)	1. SE-Physical change → Psychological (p<0.05) 2. SE-Relationship → Psychological (p<0.05)

Note: paths presented on this table were statistically significant or close to statistically significant. No direct effects from Intervention on Outcomes were found.

AIM 1.

Test the mediating effects of four *dimensions of self-efficacy* (self-efficacy expectations, outcome expectations, self-management behaviors, and knowledge) on the relationship between the intervention and patient physical function and psychological adjustment at 12-months.

Findings:

1. P+P vs. P-Only intervention effects for physical function and psychological adjustment through self-efficacy expectations and outcome expectations.
2. For P+P compared to P-Only, self-management behavior and ICD knowledge did not mediate the relationships between intervention and outcomes.
3. Adding a partner to the P+P intervention, based on social cognitive theory, helps improvement in self-efficacy expectations and outcomes expectations leading to improved patient outcomes.
4. Multicollinearity may be a concern in models that incorporate more than one measure of self-efficacy at a time.

Implications for Nursing Science: Once considering a nursing intervention for ICD patients based on social cognitive theory, it is important to include partners on the activities related to improving self-efficacy and outcome expectations. This will help patients achieve better physical function and psychological adjustment.

AIM 2.

Differentiating the mediating effects of *content-specific elements of self-efficacy* (SE-ICD function, SE-physical changes, SE- lifestyle, SE-emotions, SE-ICD shock, SE-safety, SE-cognition, SE-relationship) on the relationship between the interventions and patient physical function and psychological adjustment demonstrated:

1. A mediation effect between the P+P vs. P-Only intervention and psychological outcome through SE-physical changes.
2. Indirect effects between the intervention and physical functioning through SE-physical changes and psychological adjustment through SE-relationship.
3. Possible multicollinearity concerns might have occurred with more than one self-efficacy measure at the same model.

Implications for Nursing Science: This study showed that two main components of the P+P intervention, SE-physical changes and SE-relationship, mediated the impact of the P+P intervention compared to P-Only for patient physical function and psychological adjustment. This finding promotes understanding how to tailor the intervention and raise the issue as to whether or not partners should be engaged in those components that were mediators.

AIM 3.

To determine if patients with different ICD indication (primary vs. secondary) would present different effects on *dimensions of self-efficacy* (self-efficacy, outcome expectations, self-management behavior, and ICD knowledge), patient physical functioning and/or psychological adjustment at 12-months, the study demonstrated:

- The measurement model to evaluate physical function and psychological adjustment in patients with ICD part of P+P intervention does not differ between ICD indication groups (primary vs secondary).
- There is no difference between ICD indication groups on the mediation process from intervention to physical function and psychological adjustment by *dimensions of self-efficacy*.
- Comparing primary vs. secondary prevention by study arm, there was no statistically significant difference on *dimensions of self-efficacy* at baseline and three-months. All groups *dimensions of self-efficacy* improved over time (all $p<0.001$) independent of ICD indication.

- For physical function outcomes, bodily pain showed better results for those with ICD implanted for secondary prevention.
- For psychological adjustment, better scores in depression, role emotional and social functioning were found with those for secondary prevention.
- Across time, the fastest rates of improvement for secondary prevention participants were for physical functioning, role physical and depression. This suggests that participants who receive an ICD for secondary prevention have a faster recover rate than those with primary prevention over 12-months period.

Implications to nursing Science: Patients who receive ICD for secondary prevention might have experienced a faster recovery on physical function and psychological adjustment than those with ICD implanted for primary prevention. Patients with ICD for primary prevention might benefit from a closer follow up in order to facilitate adjustment to the device.

RECOMMENDATION FOR FUTURE STUDIES

The design and execution of future studies should consider:

1. Testing models in which the partner's response to the intervention is assessed and incorporated into the analyses. Determining qualities of effective partners or other significant others.
2. Evaluating the psychometric properties of the self-management behavior scales and content-specific elements of self-efficacy for patients with an ICD.
3. Using growth curve modeling to account for differences in time intervals (e.g., baseline to 3 months to 12-months, not accounted for in RM ANOVA) or adding 6 months measures to ensure equal intervals of change.
4. Applying grow mixture modeling to identify variation in patterns of change during recovery, to improve longer term patient outcomes.

IMPLICATIONS FOR NURSING SCIENCE

Nurses play a pivotal role in delivering care to patients after an ICD, not only in managing complex technology, but also addressing patient uncertainty about related physical and psychosocial adjustment. Implementation of a behavioral intervention by nurses after receipt of an ICD is likely to assist patients with improved adjustment, increase patients' life activities and improve overall quality of life. In addition, translating these research results into practice would be a major contribution for nurses who are responsible for the crucial tasks of evaluating patients and their partners – based on specific clinical and psychological characteristics – and who would benefit most in receiving an intervention. It would offer providers a focused guideline to ICD recovery care incorporating the key intervention features needed to achieve better physical and/or psychological outcomes for ICD patients.

This study provides methodological guidelines for nursing researchers interested in evaluating theory-based interventions with the use of robust statistical methods such as SEM-path analysis. In addition, the study promotes understanding of the application of social cognitive theory in psychoeducational interventions focused on enhancing self-efficacy. Taken together, these contributions will advance the overall state of nursing science and the impact of these interventions for patients with an implantable cardioverter defibrillator.

APPENDIX

Appendix 1

#	***Author/Year*** ***Design*** ***N = Sample size***	***Sample***	***Intervention***	***Outcomes***
1	Badger et al, 1989[37] Convenience N = 12	Secondary prevention I = 6 C = no intervention Age = I = 62 C = 58	8-week support group	1.SF-12 Role Function and Psych Adaptation 2.ICD shocks
2	Molchany & Peterson, 1994[38] Cross-sectional comparison N = 16	I: 11 attending support group C: 5 who did not attend support group Age: I = 61-79 years C = 51-75 years	I = Monthly support group over 9 months C = those who could not attend support group	1.STAI 2.SF-12 3.Anxiety VAS
3	Sneed et al, 1997[39] Convenience N = 34	SCA Survivors I: Mean age 65 years C: Mean age 61 years	(I): Pre-op evaluation -Telephone x 8 weeks -2 ICD support groups (C): no intervention	1.POMS 2.PAIS-SR 4
4	Kohn et al, 2000[10] RCT N = 36	Secondary prevention Age 66$\pm$10	I: CBT x 9 sessions (30-60 min each) x 5 months C: no intervention	1.BDI 2.STAI 3.PAIR-SR 4.ICD shocks

5	Carlsson et al, 2002[40] RCT N = 20	ICD for 2nd prevention I: n = 10 C: n = 10 Age 63	I: RN visit at pre and post ICD -1 phone call at 2 weeks C: Pre-ICD education	1.Nottingham Health Profile at 1 month (NHP) 2. Author derived health profile
6	Fitchet et al, 2003[26] RCT cross over N = 16	ICD for 2nd prevention I: n = 8 C: n = 8 Age: 58	I = Cardiac Rehab x 2hrs/week x 6 Exercise training 12 weeks Education, group, CBT, self-help sessions C = wait list control	1. Exercise time 12 weeks 2. HADS at 12 weeks
7	Frizelle et al, 2004[27] RCT N = 21	ICD for 2nd prevention I: n = 11 C: wait list; n = 11 Age: I = 60+10.1 C = 62.6+4.7	I = CBT 2 hours/week x 6 C = wait list control 12 weeks	1. HADS at 3 months 2. ICD total concerns 3. QLMI 4. EuroQual 5. Shuttle test
8	Dougherty et al, 2004[18], 2005[19] RCT N = 168	SCA survivors I: n = 84 Age = 63 C: n = 84 Age = 65	I: 8-week telephone, pager, self-efficacy booklets C: usual care	1. PCA at 1 & 3 months 2. SF12 PCS 3. SF12 MCS 4. ICD shocks 5. STAI 6. CES-D 7. Knowledge 8. Hospitalizations 9. ER visits 10. Outpatient visits
9	Chevalier et al, 2006[28] RCT N = 70	ICD patients I: n = 35 C: n = 35 Age 59+10	I = CBT every 2 weeks x 12 weeks in group format C = usual care	1. HRV 3 and 12 months 2. HAMA-French 3. BDI 4. author derived QOL 5. ICD tolerance author derived
10	Sears et al, 2007[29] RCT N = 20	ICD patients with at least 1 shock = 10 C = 10 Age 59.77+12.6	I = CBT 90 min x 6 weeks stress management C = 4 hours stress mgt workshop x1	2 months (after I) and 4 months 1. STAI 2. CES-D

				3. Florida Acceptance tool 4. SF12 5. Cortisol 6. TNF-alpha
12	Dickerson et al, 2006[41] Cross sectional comparison N = 112	Total N = 112 I: Mean age = 61.8 yrs C: Mean age = 63yrs.	I: Monthly CNS led support group. 2 hours/month, C: those not attending;	Quality of Life -Cardiac Version
13	Smeulders et al, 2007[30] Single group N = 10	ICD patients living near Dutch medical center Age 65.5+7.9	I: nurse led self-management x 6 weekly sessions, 2.5 hours each	Pre-post intervention 1. HADS 2. SF-36
14	Lewin et al, 2009[31] RCT-centers randomized to I or C N = 148	Primary and 2nd prevention patients I: n = 53, age = 58.7 C: n = 95, age = 63.4	I: ICD plan: 2 booklets, diary, relaxation tape, CBT self-help x 4 phone calls(pre, 1,3,6, weeks) C: usual care	1. HADS at 6 months 2. SF-12 3. Seattle Angina Questionnaire (SAQ) 4. ICD shocks 5. Health care costs
15	Dunbar et al, 2009[32] RCT – patients randomized to control, I by group or me by phone N-246	N = 246 Primary and Secondary prevention I = 58.5±10.7 I = group = 85 or telephone = 83 C = 58.5±11.1, n = 78	Intervention delivered 2 days: group or telephone vs. usual care. Delivered in hospital and then 3 months after ICD I: education, stress management (hospital), CBT for coping skills + booster month 4.5(4 sessions at 2 hours each).	1. Anxiety (STAI); means/% with anxiety (32.5; 41% at BL) 2. Depression BDI-II; mean and % with depressive symptoms (21.2-26% at BL) 3. Hospitalizations 4. ER visits 5. Calls to provider 6. Missed work
16	Crossmann et al. 2010[9] RCT N = 119	I: n = 56 C: n = 63 (I) :mean age 60.6 years (C): mean age 61.1 years Initial ICD Primary and 2nd prevention	I = written information on medical and psychological consequences of ICD, 6 months individual semi-structured phone counseling C = usual care	1. HADS-A HADS-D Cardiac Anxiety Questionnaire (CAQ) 2. SCL K9 symptoms 3. SF-36 4. ICD Attitude scale
17	Irvine, et al, 2011[33] RCT I = 83	N = 193 HCM for primary or secondary prevention after 1st ICD implant.	(I) CBT x 8 telephone plus psychoeducational booklet, mindfulness and progressive relaxation	1. HADS-A and D 2. Phobic anxiety-Crown-Crisp

	C = 77	(I): mean age = 65.6 yrs (C): mean age 63.2	(C): usual care	3. PTSD-Impact of Events Scale-R 4. SF-36v2 5. ICD shocks and ATP events
18	Berg et al., (2015a)[125] Christensen et al., (2015)[126] Berg et al., (2015b)[127] prospective RCT n = 196	1st time ICD implantation, exercise started 3 months after implantation -VF arrest prior to ICD 20% each group LVEF% <35% 32.2% both groups **Gender** n (% male): Male: Ex: 79 (80%) C: 76 (78%) **Age** (mean ± SD) EX: 57.6 ± 12.9 C: 56.7 ±13.5	**EX** (n = 99): **aerobic and resistance training** (aerobic exercise + resistance + psych-educational: 1h x 2x week with 50-80% of estimated heart rate x 12 weeks **psych-educational** 1x month x 6 months and them every 2 months x 1-year, Total sessions = 9 (N = 99) **C** (n = 97): 2h group session on the ICD x 1	1. PeakVO2 (ml/kg/min) 2. SF-36 – General health (GH) 3. SF-36 – Mental Component Score (MCS) 4. PeakVO2 (mg/kg/min) 5. Exercise time (min) 6. Gender difference 7. Time to first admission (days) 8. Time to first after heart admission (days) 9. ATP 10. ICD Shock 11. Mortality 12. Cost Hospitalization (US$) 13. Cost Outpatient Treatment (U$) 14. Total Cost (U$)
19	Russell, 2015[35] RCT N = 103	83 patients continued to either CBSM (n = 44) Patient Education (n = 39)	10-week programs of CBSM	1. Anxiety - Spielberger State-Trait Anxiety Inventory (STAI) 2. Depression 3. Anger - Spielberger State-Trait Anger Expression Inventory (STAXI) 4. Stress - Profile of Moods State (POMS), the Perceived Stress Score (PSS), 5. SF-36 for physical and emotional well-being and functioning 6. Mental stress 7. arrhythmia

19	Habibovic, 2017[36] RCT N = 289	The WEB-based distress management program for ICD patients (WEBCARE) ICD patients from 6 referral hospitals in the Netherlands were randomized to either the WEBCARE I: (*n* = 146) C: (*n* = 143) group.		1. Anxiety - General Anxiety Disorder (GAD-7) Scale 2. Depression - PHQ-9 3. Health-related quality of life - The Dutch version of the Short-Form Health Survey 12 (SF-12) 4. Type D (distressed) personality assessed using 14-item DS14 Scale 5. ICD Patient Concerns (ICDC) Questionnaire 6. Shock anxiety: Florida Shock Anxiety Survey (FSAS) 7. Device acceptance: The Florida Patient Acceptance Survey (FPAS)
20	Ford et al., 2019 Pilot study N = 46	ICD patients with elevated PTSD symptoms.	Web-based Cognitive based intervention with 4 modules (1 module a week) with duration of 30-60 min each module.	1. Acceptability of the web-based intervention 2. PTSD symptoms (PTSQ check list) 3. General mental health (Four-dimensional questionnaire anxiety scale – FDAS & Center for epidemiological studies depression scale-CES-D) 4. Device acceptance: Florida Patient 5. Acceptance Scale (FPAS) 6. Shock anxiety (Florida shock anxiety scale-FSAS)

Note. I: Intervention group; C: Control group.