



Effects of WEB-based distress management program for implantable CARdioverter defibrillator patients (WEBCARE) on reduction of anxiety and depression, and improvement of quality of life: 3-months follow-up of a randomized controlled trial

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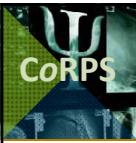



Project participants

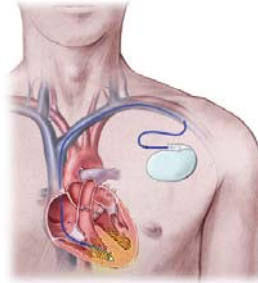
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Trial Registration: <http://www.ClinicalTrials.gov>. Identifier: NCT00895700.





Implantable Cardioverter Defibrillator (ICD)



- Used as primary and secondary prevention of sudden cardiac death
- ICD is superior to anti-arrhythmic drugs in saving lives
- The ICD can shock with up to 700-800 volts (appropriate or inappropriate)
- *"It's like getting kicked in the chest by a big horse!"*



ICD therapy: Benefits and side effects

- **Complications** (lead fractures, dislodgement, and infection)
- Significant **anxiety and depression** in 20-30% of patients
- Patient's **psychological reaction** to the device may increase the **risk of arrhythmias**

Risk that patients will refuse this potentially life-saving treatment

Tung et al. J Am Coll Cardiol 2008;52:1111-21

Pedersen et al. Pacing Clin Electrophysiol 2009;32:1006-11





Behavioral interventions

Table II.
Effect Sizes (Cohen's d) for Impact of Intervention versus Usual Care on Anxiety and Depression

Author	Follow-Up	Effect Size Intervention		Effect Size Controls		Measures	
		ANX	DEP	ANX	DEP	ANX	DEP
Badger and Morris ³⁶	2 months	–	–	–	–	–	–
Carlsson et al. ⁵⁰	1 month	–	–	–	–	–	–
Chevalier et al. ²⁷	12 months	0.72	–	–	–	HAM-A	BDI
Crössmann et al. ²²	6 months	0.13	–	–	–	HADS	HADS
		–0.39 [†]	–	–	–	–	–
Dougherty et al. ^{28,34}	12 months	0.38	–	–	–	STAI-S	CES-D
Dunbar et al. ²⁹	12 months	0.23/–0.13	–	–	–	STAI	BDI
Edelman et al. ³⁶	6 months	–	–	–	–	DASS	DASS
Fitchet et al. ²⁹	3 months	1.79	1.20	–	–	HADS	HADS
Frizelle et al. ³³	3 months	0.34	0.52	–	–	HADS	HADS
Irvine et al. ²⁴	12 months	–	–	–	–	HADS	HADS
Kohn et al. ³⁰	9 months	–	–	–	–	–	BDI
Kuhl et al. ²⁵	1 month	–	–	–	–	–	–
Lowin et al. ³¹	6 months	–	–	–	–	–	AS
Molchany and Peterson ³⁷	9 months	–	–	–	–	–	HADS
Sears et al. ³²	4 months	–	–	–	–	–	CES-D
Sneed et al. ⁵¹	4 months	–	–	–	–	–	POMS
Vazquez et al. ²⁶	1 month	–	–	–	–	–	–

Cohen's d/effect size: 0.20 = small; 0.50 = medium; 0.80 = large.
[†]Patients > 65.
[‡]Compared support group and telephone counseling to usual care.
[§]male/female.

ANX = anxiety; BDI = Back Depression Inventory; CES-D = Center for Epidemiologic Studies Depression Scale; DASS = Depression Anxiety Stress Scale; DEP = depression; FSAS = Florida Shock Anxiety Survey; HADS = Hospital Anxiety Depression Scale; HAM-A = Hamilton Anxiety Scale; POMS = Profile of Mood State; STAI(–S/T) = State-Trait Anxiety Inventory.

17 trials
Anxiety 0.10-1.79
Depression 0.23-1.20
N=12-193
High drop-out
(time constraints; travel burden)

Habibovic et al., 2013; PACE



WEBCARE-intervention

Components

- Psycho-education about the ICD
- Problem-solving skills
- Cognitive restructuring
- Relaxation training
- Personalized feedback by a therapist via the computer

www.leefmetjehart.com

12-weeks

6 lessons



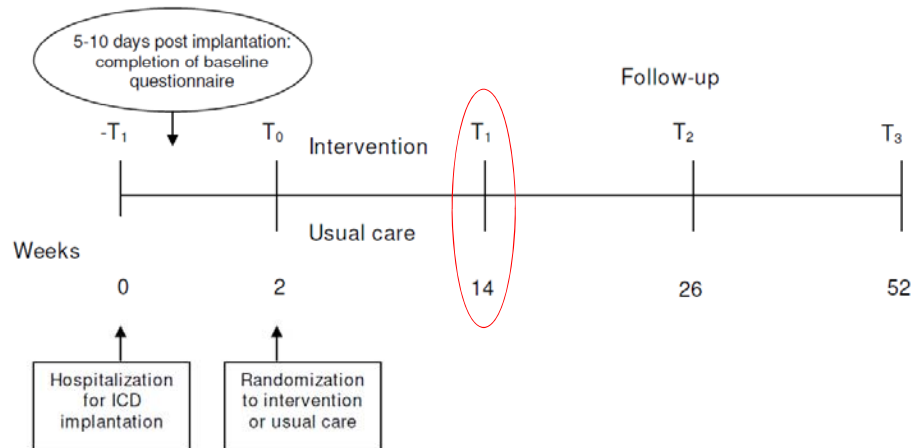
Topics dealt with

- Emotional reactions to ICD therapy
- Which aspects of ICD therapy may lead to distress
- How to deal with shocks
- Disease-specific issues and fears
- How to prevent the avoidance of activities
- Interpretation of bodily symptoms
- How to cope with uncertainty
- Help-seeking behaviour
- How to cope with stress





WEBCARE-design



Patient characteristics

	Total (N=289)	WEBCARE (N=146)	Usual Care (N=143)
Age	58.52±9.89	58.23±9.87	58.81±9.90
Gender (male)	235 (81.3)	120 (82.2)	115 (80.4)
Education (high)	208 (73)	107 (73.3)	102 (72.9)
Anxiety	4.30±4.54	4.57±5.02	4.03±3.98
Depression	4.57±5.02	5.93±5.11	5.37±4.53
PCS	40.57±10.44	40.19±10.55	40.96±10.35
MCS	44.29±11.08	43.83±11.28	44.76±10.89

No significant differences at baseline between groups

Cut-off Anxiety ≥10
Cut-off Depression ≥10

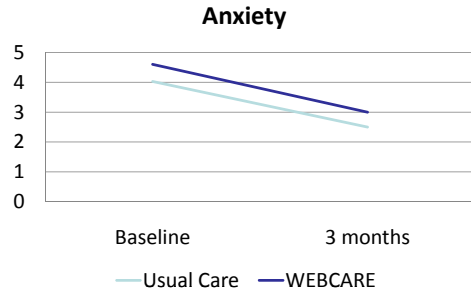




Results (1) - Anxiety

N=289

p=.455



Subgroup analysis

Baseline anxiety: *ns*

Age: *ns*

Working status: *ns*

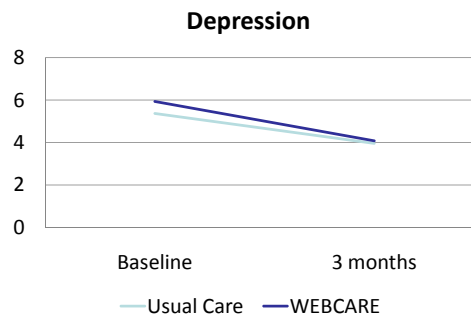
Completers vs non-completers → *ns*



Results (2) - Depression

N=289

p=.876



Subgroup analysis

Baseline depression: *ns*

Age: *ns*

Working status: *ns*

Completers vs non-completers → *ns*



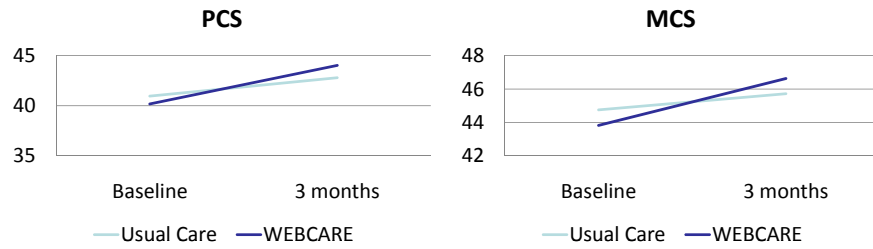


Results (3) – Quality of life

N=289

p=.287

p=.390



Subgroup analysis

Baseline QoL: ns

Age: ns

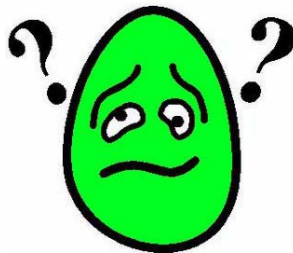
Gender: ns

Working status: ns

Completers vs non-completers → ns



WHY DIDN'T WEBCARE WORK???





CoRPS

Now....

- All patients were included regardless of their distress level at baseline (what were their needs??)
- Higher drop-out in WC vs UC group → too demending??
- Selection bias towards healthy, more motivated?, higher educated patients
- Exclusion due to lack of internet
- 23% completed the online course



CoRPS

Future....

- More patient tailored treatment
- Better understanding of patients needs
- Appropriate timing of the intervention
- Examine reasons for drop-out
- Stepped care approach?



Thank you

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