

Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multi-centre randomized controlled trial

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*** Declaration of interest:** speaker's fees (of small amount) from Boehringer, Boston, Medtronic.

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on Behalf of the MORE-CARE Study Investigators

Sponsor: Medtronic Inc.

Clinical Registration: clinicaltrials.gov ID NCT00885677

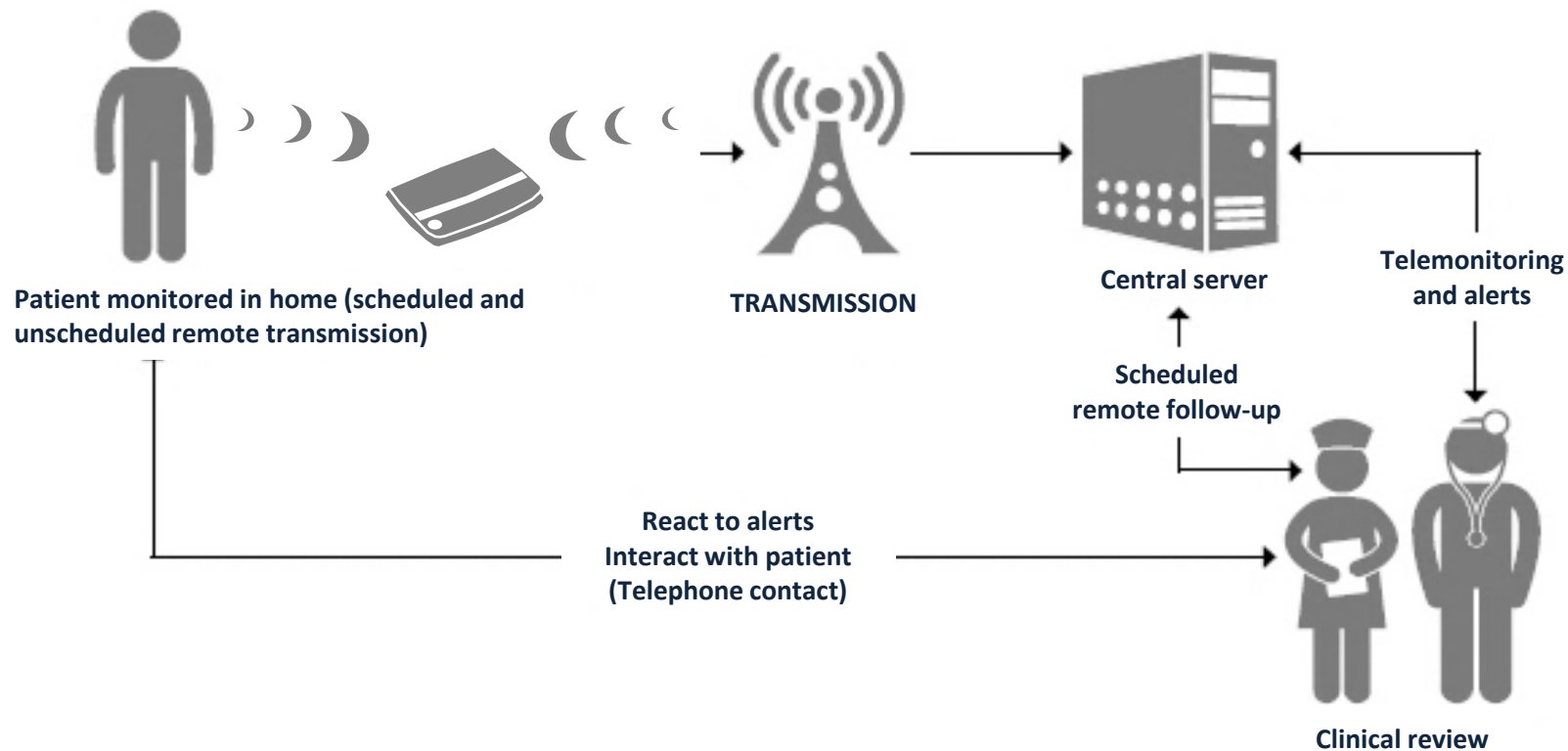


Background - Clinical Importance

- **Heart failure (HF)** is a frequent disease in developed countries and is associated with **increased mortality and morbidity, quality of life impairment, and heavy healthcare and economic burden.**
- **Cardiac resynchronization therapy (CRT)** is a device therapy based on biventricular pacing and has been shown to reduce mortality and re-hospitalization in selected HF patients, but the risk of hospitalization remains high.
- **Remote monitoring (RM)** of implantable cardiac devices facilitates device follow-up and prompt preventive actions aimed to improve HF outcomes. It is still not clear if RM can improve clinical outcomes and lead to a favourable economic profile.



Remote monitoring system



Study Aim and Design

Aim: to evaluate if RM provides higher clinical and/or economic value when compared to standard follow-up strategies in the management of systolic HF patients implanted with a CRT-D.

Multicentre (64 centers), international, randomised study with 2 arms enrolling 917 patients with:

- CRT-ICD indication according to guidelines ESC 2009

LVEF $\leq 35\%$

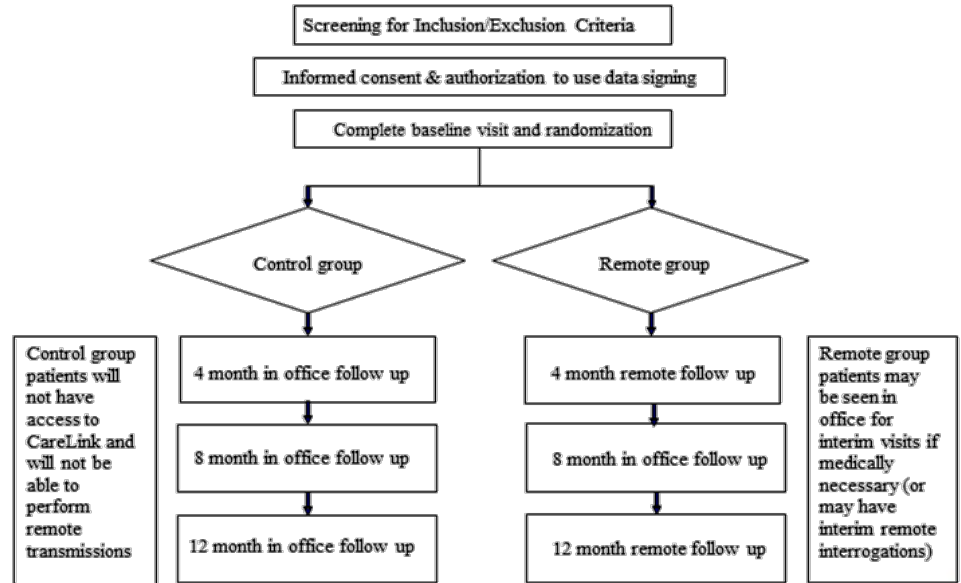
NYHA functional class III-IV,

QRS ≥ 120 ms

Optimized medical treatment

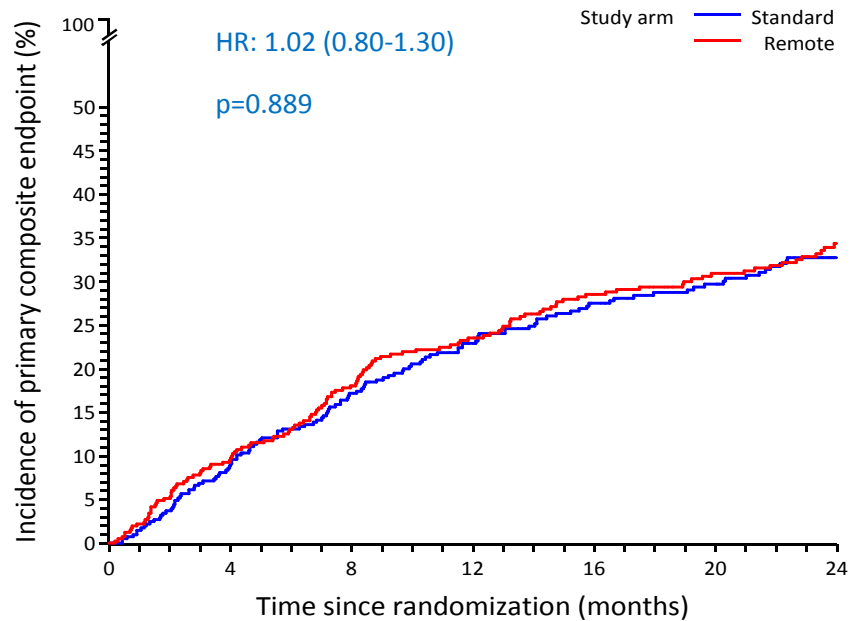
- No permanent AT/AF
- First implant of CRT-D

Enrollment and Follow-up Schedule



Primary Outcome (All-Cause Death, CV or device related hospitalizations)

No differences
between study arms
were found in the
primary endpoint and
in its components



2-years event occurrence Primary composite endpoint, n (%)	Remote (n = 437)	Standard (n = 428)	Hazard Ratio (95% CI)	p-value
Death or first CV or device-related hospitalization (≥48-hours stay)	130 (29.7)	123 (28.7)	1.02 (0.80-1.30)	0.889



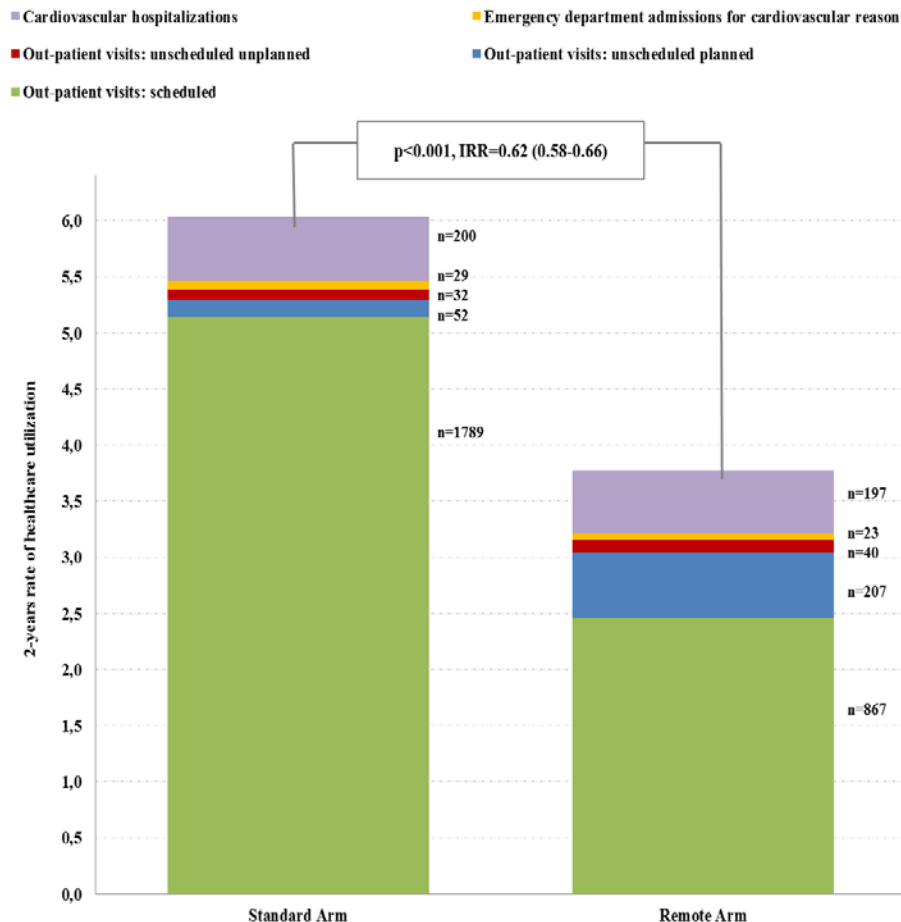
Healthcare Resources

HCU type	Events (Patients with HCU)		2-year event rate per 100 patients (95%CI)		Adjusted IRR (95%CI) Remote vs. Standard F-up	p-value
	Remote arm N=437	Standard arm N=428	Remote arm N=437 (707 FU years)	Standard arm N=428 (696 FU years)		
	a – Hospitalizations					
Hospitalizations for any reason	337 (165)	312 (151)	96 (86 - 106)	90 (80 - 100)	1.02 (0.83 - 1.26)	0.833
Cardiovascular hospitalizations	197 (111)	200 (112)	56 (48 - 64)	58 (50 - 66)	0.91 (0.72 - 1.15)	0.418
HF related hospitalizations	111 (63)	103 (60)	32 (26 - 38)	30 (24 - 36)	0.97 (0.74 - 1.29)	0.846
Device related hospitalizations	24 (20)	22 (21)	6.8 (4.6 - 10.2)	6.2 (4.2 - 9.6)	1.16 (0.82 - 1.65)	0.399
b – Emergency Department (ED) admissions not leading to hospitalization						
ED for any reason	40 (27)	56 (41)	11.4 (8.4 – 15.4)	16.0 (12.4 - 20.0)	0.72 (0.53 - 0.98)	0.037
Cardiovascular ED	23 (15)	29 (24)	6.6 (4.4 – 9.8)	8.4 (5.8 - 12.0)	0.78 (0.55 - 1.09)	0.142
HF related ED	14 (8)	17 (14)	4.0 (2.4 – 6.6)	4.8 (3.0 - 7.8)	0.78 (0.54 - 1.12)	0.180
Device related ED	7 (7)	2 (2)	2.0 (1.0 – 4.2)	0.6 (0.2 - 2.2)	3.53 (2.19 - 5.68)	<0.001
c – Out-patient visits						
All visits	1114 (315)	1873 (538)	316 (297-334)	538 (515-563)	0.59 (0.56-0.62)	<0.001
Scheduled visits	867 (367)	1789 (393)	246 (230-262)	514 (490-538)	0.48 (0.46 - 0.50)	<0.001
Unscheduled visits	247 (140)	84 (61)	70 (62-80)	24 (19-30)	2.80 (2.16 - 3.63)	<0.001



Healthcare Resources for CV reasons

The burden of healthcare resources utilization for CV reason was 38% lower in the Remote than in the Standard arm with 2-year rates of 3.7 (95%CI 3.5-3.9) and 6.0 (95%CI 5.7-6.2) per 100 patients, respectively.



Costs for CV and Device Related Events (1)

The National healthcare system perspective

HCU type	Unit Cost (€)	2-year cost * 100 patients (95%CI)		2-year cost saving * 100 patients (€)
		Remote arm	Standard arm	
Cardiovascular and device related hospitalizations				
Cardiovascular hospitalization	€ 4,432	€ 248,192 (213K-284K)	€ 257,056 (222K-293K)	€ 8,864
Device related hospitalization	€ 4,432	€ 30,137 (20K-45K)	€ 27,478 (19K-43K)	-€ 2,659
Cardiovascular and device related Emergency Department (ED) admissions not leading to hospitalization				
Cardiovascular ED	€ 241	€ 1,591 (1,060-2,362)	€ 2,024 (1,398-2,892)	€ 433
Device related ED	€ 241	€ 482 (241-1012)	€ 145 (48-530)	-€ 337
Out-patient visits, in-office for cardiovascular or device related reasons				
Scheduled visit	€ 27.90	€ 6,863 (6,4K-7,3K)	€ 14,341(13,7K-15,0K)	€ 7,478
Unscheduled visit	€ 27.90	€ 1,953 (1,7K-2,2K)	€ 670 (0.5K-0.8K)	-€ 1,283
Remote device checks				
Scheduled remote device check	€0-13.95	€0 - €3,710	€ 0	€0 - €3,710
Unscheduled remote device check	€0-13.95	€0 - €5,887	€ 0	€0 - €5,887
Total				
Scenario1:	No reimbursement remote device check	€ 289,22	€ 301,71	€ 12,496
Scenario2:	Remote device check reimbursed as 1/2 in-office	€ 298,82	€ 301,71	€ 2,899



Costs for CV and Device Related Events (2)

The patient budget perspective

- **Information about patient and caregiver travel to and from hospital** showed an average distance between patient's home and hospital of 52 kilometers and the average time required for a one-way journey was 50 minutes.
- In 66% of visits, patients were accompanied by a relative, and in 5% by an acquaintance or nurse or a caregiver.
- The majority of journeys (77%) were made by car; other modes of transportation included local transport by bus (11%), taxi (6%) and train (3%).
- **The estimated 2-year expenses for the patient traveling** to the hospital were €373 in the Remote arm and as €518 in the Standard arm (i.e. a **cost saving of €145** resulting from RM).



Conclusions

- In HF patients implanted with a CRT-D, remote monitoring did not reduce mortality or risk of CV or device-related hospitalization.
- The use of remote monitoring had a positive impact on the use of healthcare resources through a 41% reduction of in-office visits, without compromising patient safety.
- The favorable profile in terms of costs savings of remote monitoring vs. standard follow-up emerged from the perspective of the health care system as well as from the perspective of the patient.

The full article of MORE-CARE trial available on-line today on *The European Journal of Heart Failure*.



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Received 5 July 2016; revised 27 July 2016; accepted 27 July 2016