Interim analysis of the HF-TRACK multicenter crossover RCT in heart failure

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Background

The HF-TRACK trial (NCT06334822) is a multicenter, randomised, controlled crossover study assessing the effectiveness of an artificial intelligence (AI)-driven remote monitoring device for detecting peripheral edema[1] and its impact on Heart Failure (HF)-related hospitalizations. This interim analysis presents safety and efficacy data from the first six months of the study.

Methods

A total of 78 patients were recruited from family doctors, pharmacies, and hospitals. Participants were assigned to alternating periods of standard care and AI-assisted monitoring within a crossover design. The primary endpoints included HF-related hospitalization rates, mortality, and device-related adverse events. Secondary measures comprised all-cause hospitalizations and data availability comparisons between AI monitoring and conventional weighing scales.

Figure 1

Participants Baseline

Baseline information		All participants	Participants with HF events* (3)	Participants with any events* (10)
Age		77.3 (IQR 70.8-86.1)	78.7 (IQR 74.4-83.1)	76.9 (IQR 71.2-86.7)
Female		45%	67%	70%
Site of recruitment	GP	72%	67%	70%
	Pharmacy	26%	33%	30%
	Hospital	2%	0%	0%
Index of deprivation	Low (1-3)	47%	33%	50%
	Med (4-7)	28%	33%	30%
	High (8-10)	12%	0%	0%
	Prefer not to share this information for analysis	11%	33%	20%
	N/A	1%	0%	0%

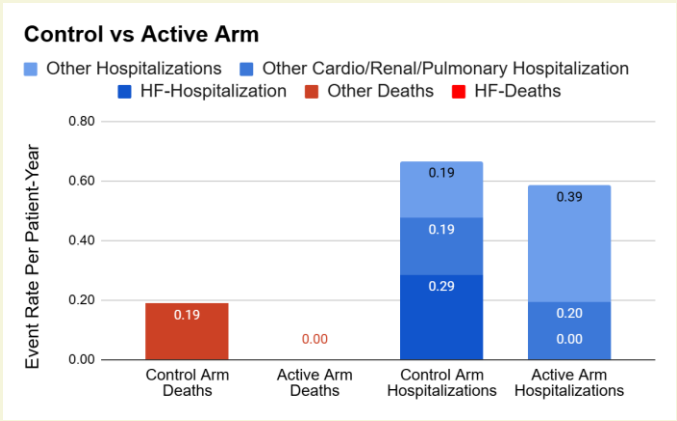
*events in this context are Hospitalizations and Deaths

Results

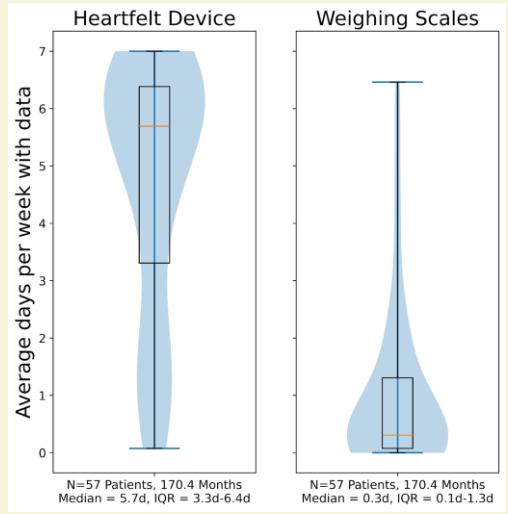
In the control arm, three HF-related hospitalizations were recorded (0.29 per patient-year), whereas no such events occurred in the AI-monitoring arm. All-cause hospitalizations were seven in the control arm (0.67 per patient-year) and six in the AI-monitoring arm (0.59 per patient-year). Two deaths were reported in the control group, though neither was HF-related. No device-related complications were observed in either study arm. The AI-based system demonstrated a markedly higher data availability rate, with a median of 5.7 monitoring days per week, compared to 0.3 days per week for standard weighing scales.

Figure 2

Event rate per patient-year during the first six months of the HF-TRACK trial, based on pre-specified analysis.



Violin plots illustrating the differences in data availability between the Heartfelt device and Bluetooth-connected weighing scales.



Conclusion

This interim analysis indicates that AI-enabled remote monitoring is safe and does not raise efficacy concerns. The significant improvement in data availability addresses a key limitation of conventional self-monitoring strategies[2]. More data is needed to clarify the potential of AI-driven monitoring to improve clinical outcomes and optimise healthcare resource utilisation.

References: 1- Chausiaux O et al. 2021, 2- Cowie, M. R et al.