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 oedema 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.

AIMS

To evaluate whether the Heartfelt device, an AI-enabled remote monitoring system, that passively detects peripheral oedema can improve the management of heart failure by (1) reducing unscheduled HF-related hospitalizations, (2) maintaining safety with respect to mortality and device-related adverse events, and (3) increasing the availability and reliability of patient-generated monitoring data compared with standard self-monitoring approaches.

METHOD

The data from the first 78 participants recruited onto the HF-TRACK trial from family doctors, pharmacies, and hospitals was analysed as part of the pre-specified preliminary analysis. 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. Additional information about participants such as their home set up, the reasons they may struggle with regular RPM etc was collected.

References: *1- Ponikowski P et al. 2016, 2- Chausiaux O et al. 2021, 3- Cowie, M. R et al.*

Baseline information		Participants: All	With no HF events	With one HF event	With two or more HF events
Age		75.0	75.0	76.5	68.0
Female		43%	44%	33%	57%
Number of Co-morbidities		3.9	3.8	5.6	5.3
Number of HF events during trial		0.38	0	1	6.88
Site of recruitment	GP	83	79	4	0
	Pharmacy	30	27	1	2
	Hospital	59	44	10	5
	Personal health record Platform	13	13	0	0
Index of Multiple Deprivation Decile	Low (1-3)	47%	44%	62%	83%
	Med (4-7)	37%	37%	38%	17%
	High (8-10)	17%	19%	0%	0%
	Participant number	172	153	13	6

Figure 1: Participant Baseline

RESULTS

Twenty HF-related hospitalisations were recorded in the control arm (0.54 per patient-year), and 11 in the AI-driven device arm (0.29 per patient-year). Three deaths occurred in the control group and two in the AI-driven device arm. Two of the deaths in the control arm were HF-related deaths. No device-related complications were recorded in either arm. The AI device demonstrated substantial superiority in data availability, with a median of 4.2 monitoring days per week compared to 0.3 days for conventional 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. More data is needed to clarify the potential of AI-driven monitoring to improve clinical outcomes and optimise healthcare resource utilisation.

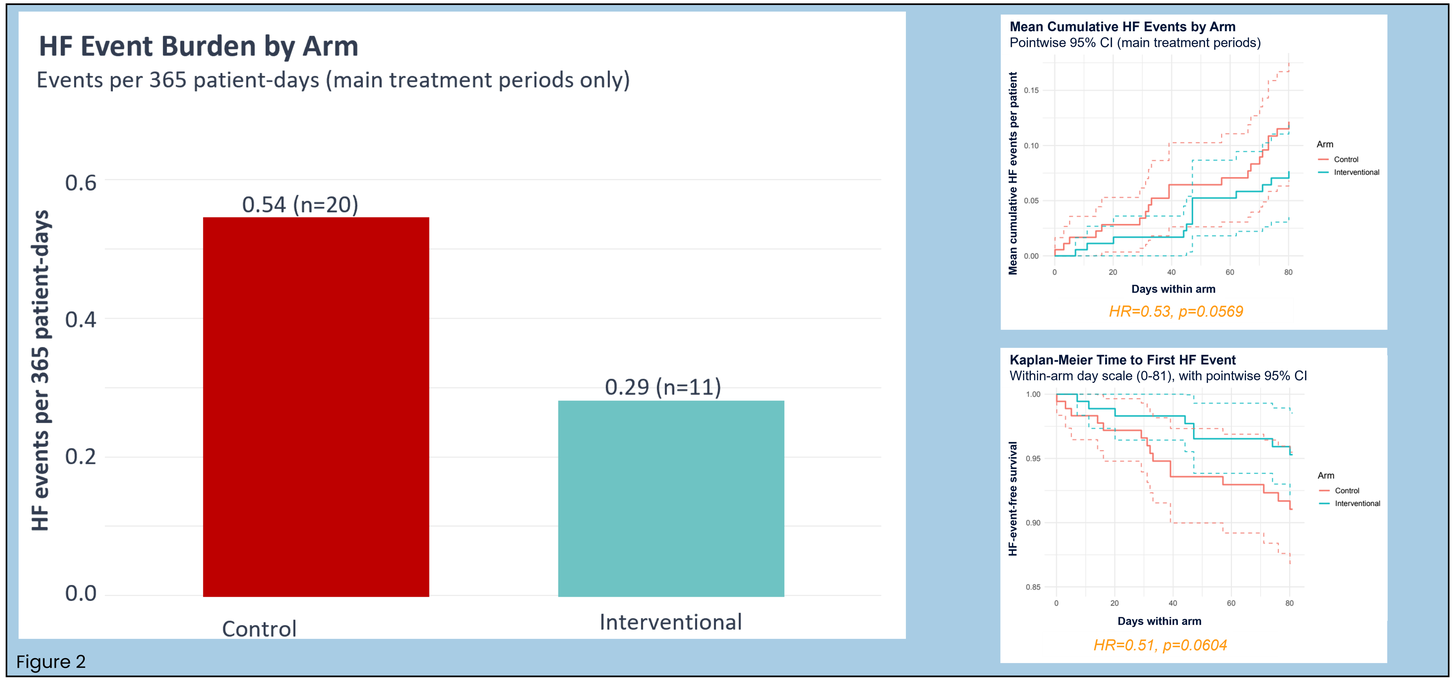

Figure 2

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