

Appendix A.

Detailed information regarding the Danish TeleCare North Heart Failure Trial[25]. ACE: angiotensin-converting enzyme, HF: Heart failure, NYHA: New York Heart Association.

Trial characteristics	
Study characteristics	<p>A multi-center, two-arm parallel group, unblinded, superiority study comparing a telehealthcare intervention to the usual practice in a Danish setting (the North Denmark Region). The study was executed in the period Jan 2016 to March 2018 with a follow-up of approximately 12 months; actual follow-up differed between participants due to continuous enrollment.</p> <p>The predetermined sample size was 316 participants under an expected loss to follow-up of 10 %, giving 284 participants. The estimate was based on an expected change equal to 5 for the SF-36 physical component summary score (effect measure applied in the effectiveness evaluation) indicating statistical significance with a two-sided p-value of <0.05, a power of 80%, equal-sized groups, and a standard deviation of 15%.</p> <p>Two hundred ninety-nine participants were enrolled; 35% were lost in follow-up (23 participants withdrew their consent, 15 died, and 67 did not respond).</p>
Eligibility criteria	<p>All patients were considered eligible who had a diagnosis of HF[7], a NYHA classification of II-IV, and who were expected to benefit from telehealthcare. In addition, patients should exhibit motivation for participating in the study and the use of telehealthcare, as evaluated by healthcare professionals. Furthermore, patients should have permanent residence, have a landline or mobile phone, and be able to speak Danish or live with a relative speaking Danish. Comorbidity was not considered a reason for</p>

	exclusion. Clinical staff were responsible for identifying potential participants, and patient participation was voluntary.
Control group	
Usual care	Participants in the control group received usual care as provided in real-life practice to HF patients in the North Denmark Region, including monitoring, care, and, if necessary, treatment. As part of usual care, in the North Denmark Region, HF patients are offered rehabilitation consisting of screening for risk factors and dietary advice (if necessary) amongst other potential lifestyle changes that may be beneficial in relation to their disease, training, and medication review in response to patients' health (e.g. evaluation of prescriptions of ACE inhibitors, beta-blockers, spironolactone, etc.). The rehabilitation period usually lasts three to six months. Usual care is managed by general practitioners or outpatient clinics.
Intervention group	
Healthcare provision intervention	<p>Before the start-up of the trial, several meetings were held to inform different staff groups of the trial and to provide general competency development on the management of HF. The trial administration office behind the TeleCare North HF was in charge of the meetings and educational seminars:</p> <ul style="list-style-type: none"> - Project managers, key persons, and health care professionals expected to be involved in the implementation of the trial participated in kick-off information meetings - General practitioners received information on the trial and telehealthcare solution in after-work meetings

- Regional and municipality nurses participated in an educational seminar and received initial and follow-up education on the use of the Telekit and the associated monitoring system (Open Tele)
- Regional nurses participated in an educational seminar on rehabilitation
- Specialist nursing professionals who worked with telemedicine from municipalities and HF outpatient clinics participated in educational seminars on palliation
- Meetings were held, providing municipality nurses and health care assistants with general competency development on the management of HF, specifically on the monitoring responsibility in relation to the trial.

The responsibility for the monitoring was shared between educated municipality nurses in the participants' residing municipality. The responsible parties were to incorporate the monitoring into their normal job duties. The monitoring included assessment and evaluation of measurements and was performed asynchronously on a weekly or biweekly basis. After the assessment, an acknowledgment of assessment was transmitted to the patient. If physical measurements were outside predefined thresholds (systolic blood pressure 100-170 mmHg, diastolic blood pressure 90-50 mmHg, pulse 80-55 beats per minute, and weight ± 2 kg compared to baseline), the nurses had the option to 1) contact the patient to ensure the accuracy of the measurement or have the measurement replicated, if necessary, 2) contact the patient to assess his/her condition, 3) start a self-treatment plan for the patient, 4) ask the patient to contact his/her own general practitioner if considered suitable, and 5)

	<p>establish rapport with the patient's general practitioner directly. Measurements were classified as being within or outside the normal ranges.</p>
Patient-level intervention	<p>After randomization, participants in the intervention group were contacted by phone by a nurse from their residing municipality, and an appointment was made on whether the patient would like to receive the Telekit in their home or a municipality health center. If the patient wanted to receive the Telekit at home, a 45-min appointment was made at which time an educated municipality nurse would demonstrate the use of the tablet and how to make the physical measurements using the associated equipment. If the participants wanted to participate in a group session of 3-4 persons at the municipality center to be introduced to the use of the equipment, the session would be 75 min long. Participants were asked to use the blood pressure monitor and scale daily in the two first weeks of the trial. 2-4 weeks after the first appointment, a follow-up appointment of 45 min was made with participants to ensure that they used the Telekit correctly. Instructions on the use of the Telekit were handled by municipality nurses.</p>
Device characteristics; Telekit	<p>In the trial, the Telekit consisted of a tablet (Samsung Galaxy Tab 2, incl. a target stylus) and associated equipment. The equipment consisted of a digital blood pressure monitor (UA-767 Plus BT-C, A&D Medical, Tokyo, Japan) and a scale with automatic Bluetooth connection to the tablet (UC-321 PBT-C, A&D Medical, Tokyo, Japan). The tablet automatically reminded the patients to take measurements and transmitted the information to enable asynchronous monitoring by healthcare professionals. In addition, the participants received an information package including a welcome letter, a user manual, and various patient information leaflets.</p>

	Delivery and replacement of faulty equipment were performed by the supplier (Atea Denmark, Aalborg, Denmark), and support and maintenance were managed by a specialized support center.
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