Explaining the mixed findings of a randomised trial of telehealth with centralised remote support for heart failure: qualitative evaluation

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Research

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Abstract

Background

Centralised specialist remote support, in which a clinician responds promptly to biomarker changes, could potentially improve outcomes in heart failure. The SUPPORT-HF2 trial compared telehealth technology alone with the same technology combined with centralised remote support. The intervention was implemented differently in different sites; no significant impact was found overall. We sought to explain these findings in a qualitative evaluation.

Methods

51 people (25 patients, 3 carers, 18 clinicians and 4 additional research staff) were interviewed and observed in 7 SUPPORT-HF sites across UK between 2016 and 2018. We also collected 110 pages of documents. Analysis was informed by sociotechnical theory.

Results

Patients' experiences of the technology were largely positive; staff engaged with the intervention to a variable degree. Existing services, staffing levels, technical capacity and previous experience with telehealth all influenced how the complex intervention of 'telehealth technology plus centralised specialist remote support' was interpreted and the extent to which it was adopted and used to its full potential. In some settings, the intervention was quickly mobilised to fill significant gaps in service provision. In others, it was seen as usefully extending the existing care model for selected patients. However, in some settings, the new care model was actively resisted and the technology little used. In one setting, centralised provision of specialist advice aligned awkwardly with an existing community-based heart failure support service.

Conclusions

The introduction of a telehealth programme rests not only on the technological intervention but also on the individuals involved and numerous subtle aspects of local service design. An iterative approach that attends to patients' illness experiences, clinicians' professional values, work practices and care pathways could lead to more effective telehealth support for patients with heart failure.

Contribution To The Literature On Implementation Science

- Explores the different ways in which a complex telehealth intervention was implemented in 7 participating UK sites in a randomised controlled trial
- Implementation was affected by local path-dependencies (existing service arrangements which had emerged historically) and current pressues
- 'Co-design' of a technology-based complex intervention must go beyond the material features of the user interface to involve local teams in embedding the technology in existing service models

Introduction

Background

As the number of patients with heart failure grows and services are increasingly overstretched, telehealth is often depicted as a partial solution [1, 2]. A key determinant of outcome in heart failure is the proportion of patients on maximum tolerated therapy [3], but most heart failure patients are sub-optimal doses of medication [4, 5]. The efficacy of

telehealth solutions for heart failure has been widely studied in randomised controlled trials (RCTs), some but not all of which have shown a small benefit over usual care, as measured (for example) by reduced hospital admissions [1, 2]. Where benefit has been demonstrated, it has generally been attributed to more timely and detailed provision of biomarker data (e.g. blood pressure, weight, oxygen saturation), which allows prompt adjustment of medication in response to indicators of decompensation [2]. A new generation of trials has focused on exploring and optimising the human component of the telehealth intervention [6, 7].

The SUPPORT-HF2 trial

SUPPORT-HF2 was a RCT in 7 UK sites, which aimed to improve use of recommended medical therapy in heart failure as defined by evidence-based guidelines [7, 8]. Participants were randomised to 'supported medical management' (intervention) or 'enhanced self-management' (control). Those in both arms submitted daily symptom reports and measurements of weight, blood pressure and heart rate, alongside free text comments. In the intervention arm, home monitoring was combined with a clinical decision support system that provided risk rankings and tailored alerts. These were processed by the central clinical management (CCM) team – a cardiologist and heart failure specialist nurses (HFSNs) – who provided treatment recommendations (where relevant) to patients and their health professionals.

In the control arm, patients' measurements were recorded in raw format only, without any processing by the clinical decision support system or the CCM team. Feedback messages were generated automatically as soon as patients entered their data. If readings fell outside pre-defined ranges, automated messages encouraged patients to contact their usual health professional.

We describe the hypothesis, inclusion criteria, blinding and outcome measures for the SUPPORT-HF2 trial in the appendix. More details can be found in previous publications, which describe the trial design and baseline participant characteristics [8] and the quantitative findings [7]. Despite being adequately powered, the trial showed no significant difference between treatment arms in the primary outcome measure (proportion of patients on optimum medical treatment as measured by a 'mean opportunity score') or in various secondary outcome measures including disease-related quality of life [7]. This paper is describes a qualitative study into how the complex intervention of remote support was interpreted by patients and staff, and how and why it played out differently in different sites.

The technology and linked service model

The patient-facing component of the technology consisted of a tablet personal computer, blood pressure and heart rate monitor, and weighing scales. The tablet portal listed current medication, health data entered by the patient, educational modules on heart failure, and a messaging link to SUPPORT-HF2 clinicians. Patients were asked to complete a daily symptom checker (e.g. questions on activity and breathlessness). They then measured their blood pressure and weight and entered the data, which were transmitted from the peripheral devices to the SUPPORT-HF app on the tablet via Bluetooth (subject to WiFi connection). Patients could view their data in graphical form along with an indication of normal range.

Data entered onto the tablet were sent securely to the CCM team by mobile internet or Wi-Fi connection. Clinicians (including usual care teams) had access to patient data in raw format 'with no ranking or interpretation' via a secure login. For patients in the intervention arm, the CCM team was supported by a clinical decision support system which estimated risk of deterioration or deviation from globally defined parameters. The CCM team also drew on pre-established management plans, blood test results and other information from electronic records, and compared these with optimal therapy targets via a central dashboard [8].

When a patient's medication could be improved, the CCM team sent a letter to the patient's GP. The lead study nurse would confirm that the advice had been acted on, either by receiving a message from the patient or during 3-monthly scheduled reviews. Patients in the control arm received automated messages encouraging them to see their GP if their measurements fell outside pre-defined ranges, but no treatment or drug titration recommendations were provided. Patients in both arms were advised that SUPPORT-HF2 was an 'add-on' service that did not replace standard GP or hospital care.

The tablet device used for SUPPORT-HF2 had been co-designed with patient input [9] and tested in a usability study (without the central support component) in which patients suggested some minor adjustments [10, 11] before the trial began. In an early qualitative study, patients were visited at home to document the variable and emergent ways in which they appropriated the technology, made sense of it and embedded it in their routines [11].

Research questions

This qualitative study took place alongside the SUPPORT-HF2 trial. The evaluation questions, which were refined slightly as the study progressed, were:

1. How and why was the intervention (and the control intervention) implemented differently in different settings?
2. What was the patient experience of the remote monitoring technology and service as delivered in the intervention and control arms of the trial?
3. What was the staff experience of the technology and service as delivered in the intervention and control arms of the trial?
4. What were the material, technical and clinical challenges in delivering the technology and linked service model as defined for the trial?

Methods

Study design, governance and ethical approval

We conducted a multi-site qualitative evaluation with data collection from all 7 sites. The study was overseen by the SCALS (Studies in Co-creating Assisted Living Solutions) [12] steering group which had a lay chair and representation from NHS, social care, external academics and patients. Ethical approval was obtained in September 2015 from Oxfordshire South Central Research Ethics Committee (REC no. 15/SC/0553) and subsequent amendments.

Sampling and participants

Between May 2016 and September 2018, we interviewed and observed 51 people and collected various documents (summarised in Table 1).

Patient participants included people living with heart failure who were taking part in the SUPPORT-HF2 trial (both arms), plus, where relevant, their family members or carers. They were initially approached by heart failure nurses and trial managers. We sampled to obtain variety in clinical background and different experiences using the technology. Interviews were semi-structured and lasted 30-90 minutes; most were conducted in patients' homes. One patient discussion group (comprising 6 patients with heart failure and one carer) took place in a side room off a cardiology ward and lasted 90 minutes. Topic prompts included living with heart failure; experience of using the remote monitoring technology; and experience of clinical and research encounters.

Staff participants included consultant cardiologists, heart failure specialist nurses (HFSNs), general practitioners (GPs), and SUPPORT-HF2 trial staff (those managing the study from the central hub site and those recruiting and supporting patients in the 6 other sites). Discussions covered clinicians' experiences of managing patients with heart failure; the role of technology in supporting patients' self-management and communication with health professionals; and their experiences of being part of the SUPPORT-HF2 trial. We took contemporaneous field notes.

Documents included national and international guidelines for acute and chronic heart failure management, the annual output from the National Heart Failure Audit, heart failure nurse operational procedures and standard clinical information collection templates for patients outside the SUPPORT-HF2 trial.

Data management and analysis

42 of the 51 interviews were audio-recorded with consent and transcribed; the remainder were recorded as contemporaneous notes. Anonymised transcripts and other data sources were imported into NVivo 12. We analysed qualitative data thematically and produced summary narratives that we progressively refined over time, adding each new data item to an increasingly nuanced account of the overall patient, carer and staff experience [13]. We discussed ongoing data collection and emerging findings in regular team meetings that helped us shape interim analysis and further data collection.

Theoretical framework

We drew on sociotechnical theory – of which there are many interpretations and versions [12, 14]. Broadly speaking, sociotechnical theories depict technologies as part of complex systems; they focus on how those technologies are perceived, interpreted and used by individuals and how the use (or non-use) of particular technologies affects and is affected by the wider system. A sociotechnical approach to technologies in the home considers how and to what extent they are 'domesticated', both technically (e.g. do they work; are they dependable?) and symbolically (e.g. are they reassuring or threatening?) [15]. A sociotechnical approach to technologies in the workplace considers how they influence work practices and routines and how their use either enhances or challenges professional standards of quality, safety and equity of care [14, 16]. An early and important contribution to socio-technical theory was Albert Cherns' work on the need for extensive reconfiguration of work practices to ensure that new technologies are smoothly embedded in processes and systems [16].

Results

The study generated a rich and heterogeneous qualitative dataset comprising several hundred pages of interviews, ethnographic field notes, email exchanges and extracts from documents. Below, we present how the trial was operationalised differently in each setting, leading to different impacts on the care pathway. We then describe the experiences of patients and health professionals and consider specific material, technical and clinical issues in the trial.

Differences in how the intervention was implemented across study sites

Study sites joined the trial with different existing service models, staffing levels, technical and clinical capabilities, and distribution of professional responsibilities. Different local demographics, histories, cultures and past experiences with telehealth and other technology projects (Table 2) led to variability in trial implementation.

In Site A (the main 'hub') some of the patients initially recruited by the CCM lead research nurse were also receiving support from a nurse-led community heart failure service. Due to professional tensions, the clinical teams eventually arrived at a policy of keeping trial participants separate from this community-based service and recruiting patients from areas with less intensive community-based services. Site D also had a nurse-led community heart failure service; these HFSNs who appeared less interested in the trial and made few referrals (in a few cases, they actively resisted cooperation). But the hospital-based team in site D actively recruited patients to SUPPORT-HF, partly because they saw remote monitoring as a solution to long geographical distances.

In Site B, neither community HFSNs nor GPs recruited patients or particiopated actively in the study (probably because of a negative experience with a previous telehealth trial); the hospital research nurse and principal site investigator (a consultant cardiologist) took on responsibility for recruitment and prescribing. In Site F, hospital-based HFSNs had a large number of complex or unstable patients which they deemed unsuitable for the trial (given lack of active management in the control arm) and decided to refer only the more straightforward patients whom they would normally have referred to community HFSNs. In this site, the trial served as an alternative rather than an add-on to the usual care pathway, which may also explain why recruitment stalled part-way through the trial.

In site C, there was no consultant involvement; the community HFSN team actively recruited patients whom they were about to discharge to their GPs for follow-up, because they saw the intervention as a useful supplement to existing care. Although some of these community HFSNs continued to see patients who were participants in the trial, no interprofessional conflicts were described with the CCM team (unlike in site A). In sites E and G, there was no specialist community nursing to augment GP management of heart failure; SUPPORT-HF2 was welcomed by local clinicians as it aligned well with pressing service needs. In Site E, the principal site investigator (consultant cardiologist) deliberately sought to recruit patients in localities with substantial pressures on hospital outpatient appointments and lack of community HFSNs. In Site G, the hospital outpatient clinic seized the opportunity to "hand patients over" to the trial due to lack of resources for specialist care post-discharge.

"It fits in really nicely with the existing infrastructure. We need a way of surveilling all those being up-titrated. And to monitor the sicker ones such as those receiving home IV diuretics. So we can use it for disease management but also to see progression, and see when they're falling off their perch." Consultant, PI, Site E [SUPPStaff11]

This is consistent with the SUPPORT-HF2 protocol, which hypothesised the value of digital health interventions to be higher "*in contexts where quality of care is (on average) suboptimal with substantial unwarranted variability at the provider-level*." [8, p.62]. The different experiences across sites, however, highlight the challenges of running an RCT alongside existing standard care that may be historically embedded and involve staff with varying degrees of buy-in to the research.

Impact of SUPPORT-HF2 on the care pathway

The rationale behind SUPPORT-HF2 includes the importance of a tight feedback loop in deteriorating patients. This was sometimes achieved successfully, with local input from site staff via the SUPPORT-HF2 dashboard and active intervention by staff at the central support unit (see Figure 1).

Sometimes, however, the feedback loop did not work as intended, mainly due to challenges in communicating recommendations to GPs, establishing whether these had been actioned (either by GPs or by patients themselves), and confirming timeframes for up-titration. The complexity of the wider system (for example, the unavoidable use of traditional 'snail mail' letters with GPs who at the time used neither email nor faxes) caused considerable delays.

The issue of professional responsibility for patients across the care pathway, especially in terms of nursing care, was a recurring finding. The SUPPORT-HF study team envisaged that the intervention would run alongside and complement usual care and not challenge the work of local heart failure teams, and the trial protocol assumed that data generated by the decision support dashboard and the advice given by the CCM would be uncontested and unproblematic. In reality, clinical disagreements sometimes led to conflicts between nurses from different teams and required time-consuming efforts to resolve differences and negotiate professional boundaries:

"What we have all found is that co-managing doesn't work. Because the numbers are saying one thing but we have visually seen the patients and we may have known those patients for a long time, know their complexities and when the SUPPORT-HF team give advice we sometimes disagree with some of the decisions. We've had to unpick that, it's very complex. It meant a lot of sitting in a back room making calls" Community HFSN, Site A [FACEHFSN3]

These conflicts appeared to stem from two things: an implicit knowledge hierarchy in which the technology's decision support system appeared to override their personal knowledge of the patient; and the fact that patients in the control arm were sent a generic alert but no specific support.

Principal investigators in the study sites (who were all cardiologists) did not perceive role conflicts with the central remote support team, with the one exception of the cardiologist in site B, who vetted recommendations from the central support team. He said he knew the patients personally and could take account of exceptions, and he felt the GPs (whose views on telehealth had been influenced by adverse past experiences) would have greater confidence in implementing recommendations from him than from the CCM.

Patient experiences of SUPPORT-HF

The patients we interviewed (sometimes together with family members) came from different socio-economic backgrounds, from rural and urban settings, had different experiences living with heart failure and other medical and life-related complexities, and had varied views on the technology. As trial participants, they were not necessarily representative of heart failure patients in general. With those caveats, our data suggest that many patients used the SUPPORT-HF2 tablet devices without too much difficulty and saw great value in monitoring their condition, especially in terms of gaining reassurance and legitimising help-seeking when they needed clinical care.

Patients generally valued the SUPPORT-HF tablet device and regretted having to hand it back at the end of the trial. But a few described it as "intrusive" and found it impossible to get into the routine of regular monitoring; a few were skeptical about the clinical value of the technology (*"they don't actually see the patient, they're just based on figures"*: interview 13, heart failure patient and wife, Site C). Some patients felt they could not rely on the machine and assumed a responsibility for confirming their data had been received by the central support team and their medicines were listed correctly.

The care model assumed that users would largely remain static in their homes where they would have good access to the devices on an everyday basis. More active patients (especially those who travelled away from home) found this too restrictive, and some withdrew from the study. Others saw the technology as a constant reminder of their ill health. For instance, one man with severe fluid retention awaiting a heart transplant could not bear the anxiety engendered by a data trend indicating weight increase.

A few patients, especially sicker ones, found regular monitoring physically burdensome; some were physically unable to use the weighing scales (one was an amputee; another had difficulty with balance). Many did not grasp that the main purpose of weighing was to monitor fluid overload rather than weight gain; they needed support from study staff to interpret the readings and adjust medications.

Staff gave examples of patients who (for various reasons including comorbidity, anxiety or wider life issues) declined to participate in the trial, withdrew after enrolment, or expressed relief when the trial ended. Such cases were relatively rare, though withdrawal rates varied across sites.

Staff experiences of SUPPORT-HF

Despite some challenges with implementing the intervention (see above), most staff expressed positive views on telehealth technology enabling remote support in heart failure care. HFSNs felt the technology was well-designed, easy to use, useful and fulfilling for patients, whom they felt had benefited from both the technology and the day-to-day input from the central support team.

There were, however, tensions in the way different professional groups made sense of the potential of the technology in heart failure care. For example, some consultants thought that the reluctance of HFSNs to engage with the technology stemmed from a belief that the technology would replace their jobs. The nurses themselves had a more nuanced view. They worried that if routine uptitration in relatively stable patients was carried out by a telehealth service, they would lose the valued reference point of the straightforward, treatment-responsive patient and be left with a case load of unrelentingly complex and unstable cases.

Another concern was that the structured and algorithmic element of the telehealth intervention would miss important aspects of quality care. Technology, HFSNs felt, provided narrow and decontextualized information and could not replace the nuanced and holistic assessments that experienced clinicians undertook on their patients – including, for example, home visits which gave them rich information about the patient's the environment and allowed them to observe how the patients approached activities of daily living and medication management. The Chief Investigator, however, rejected the nurses' characterization of the SUPPORT-HF2 intervention as crudely algorithmic. On the contrary, he argued, the intervention design recognised and accommodated the need for human input and judgement where necessary, while attempting to streamline redundancy and repetition.

Material and technical issues

Interviewees raised a number of practical issues with the technology. Some patients needed extra support to feel confident with it. When technical difficulties emerged (quite commonly with WiFi or Bluetooth connection, but also due to malfunctioning equipment) input from the trial team and local nurses was often crucial for addressing issues quickly, though patients sometimes found solutions themselves.

It was necessary to visit every participant at home, usually on two occasions, to set up the equipment and show the patient how to use it. This was a time-consuming process (typically two hours for the first visit and one for the second), though it is not clear how much of this time was spent setting up the equipment and how much on requirements specific to the clinical trial.

In one site (B), half of all potentially eligible patients could not be randomised due to lack of broadband coverage in the area where they lived. This was not a problem in other sites, though sometimes synchronisation of readings via Bluetooth between the monitor and the tablet was slow because of fluctuation in signal, leading to problems with data transmission; this usually resolved if a Wi-Fi connection could be established. These transmission issues sometimes led to patient confusion as they could see that the data had not been 'sent'.

Research nurses used a workaround to help manage these synchronization issues. They gave participants a separate phone number to use if the messaging facility of the tablet was not working, and if they had not received any data or

messages from a participant for a day or two, they would phone them to check that all was well. In most cases, such problems were due to patients not connecting properly to their own Wi-Fi. Occasionally the CCM nurse was contacted to help troubleshoot.

"Another person had somehow changed the setting so it was now in a foreign language. And we couldn't read it to correct it. Had to get [CCM research nurse] involved and she talked us through screen by screen." Research administrator, Site E [SUPPStaff15]

The trial allowed for some iterative changes in the technology. Most of these were made to facilitate data collection for research, though the bioengineer's input was occasionally sought to make adjustments, aiming to improve the clinical care of participants. As software changes were resource-intensive and costly, this seems to have constrained the number of co-designed modifications.

Clinical safety issues

One of the SUPPORT-HF2 trial's secondary objectives was investigating the clinical safety of technology-supported medicines management as captured by significant event reporting and the trial's stated secondary objective of a composite clinical safety endpoint [8]. Our interviewees described some safety issues. In the case of one patient, the system did not flag up a clinically important weight increase because it did not occur rapidly enough (i.e. over a 3-day period - the conventional assessment time frame). The central support team worked with IT colleagues to adjust the system to change the alert in this case, but such changes were labour-intensive and hence expensive and unscalable. The CCM Lead Nurse commented that further refinement of the dashboard, enabling safety alert flags to be easily individualised, could improve the safety of the technology.

It was occasionally possible to personalise clinical management without modifying the technology. For example, one patient had profound and symptomatic Parkinson's Disease-related postural hypotension. At the GP's request, the CCM nurse asked the patient to follow each seated BP with a standing BP; from the paired readings, it was possible for her to discern the standing BP and base her up-titration directions on that value. In this example, it was the GP's knowledge of patient, and the GP's initiative in contacting CCM nurse that led to this safety-critical workaround. The CCM nurse, who was an expert in heart failure not Parkinson's disease, was unaware of the level of clinical concern. Notably, the patient did not disclose their Parkinson's Disease to the research team.

As anticipated (and as stated in the SUPPORT-HF2 protocol), critically unstable or end-stage heart failure patients were generally deemed unsuitable for management through the telehealth technology. HFSNs described needing to actively look after these patients, including co-ordination with a complex set of additional services, depending on the case. As the patients themselves observed, being severely unwell with the complications of heart failure reduced their ability to carry out the necessary tasks. In most sites, clinical staff excluded such patients from the study:

Site E, however, in the absence of community structures to support heart failure patients, deemed SUPPORT-HF2 as filling a gap in service provision, and deliberately included "*patients who needed closer attention*" (PI, Site E [SUPPStaff11]). Variations in the definition of instability and difficulties identifying when patients are 'end-stage' combined with perceived deficiencies in usual care may have prompted creative interpretation of this exclusion criterion.

In relation to safety, our results illustrate, on the one hand, the potential for the SUPPORT-HF2 intervention to 'tighten the feedback loop' and detect clinically important deterioration promptly. On the other hand, our findings also illustrate how the physical effects of heart failure (or its comorbidities) can create a safety challenge when patients are simply not well enough to self-monitor or engage effectively with the system. Staff in the different sites balanced practical and logistical issues to achieve the safest use of SUPPORT-HF2 in the circumstances.

Discussion

Summary of main findings

This qualitative study of the SUPPORT-HF2 trial produced a number of key findings. First, heart failure patients and clinical staff saw potential in a technology that supports regular data monitoring, but also identified challenges in mainstreaming its use. Trial participants experienced the technology as usable and useful; they were (mostly but not invariably) reassured by the monitoring and support, and found that the data informed and legitimised their help-seeking behaviour. However, some found regular monitoring burdensome, described feelings of alienation and saw the technology as a constant reminder of their ill health. Few patients found the 'generic' educational materials helpful. Clinical staff valued the technology but they also identified challenges in reconciling what they saw as an algorithmically driven intervention with holistic, personalised care based on long knowledge of the patient. Co-management of patients by both the central support team and community HFSNs produced tensions of professional responsibility and judgement.

The second key finding was that significant human effort was required to embed the intervention and make it 'work'. It was often necessary for patients or staff to resolve issues with network or device connectivity to ensure that data were collected and transmitted reliably. Patients felt responsible for confirming that their data had been transmitted and providing context for them. Clinical staff had to engage in significant co-ordination work to communicate recommendations to other health professionals and/or to patients, establish whether these recommendations had been acted on, and confirm steps and timeframes for medication changes. In contrast to the assumptions in the protocol, these were not neutral information exchange tasks but required professional negotiations and careful management of boundaries and expertise between clinicians.

The third key finding was a high degree of variability in acceptance of the technology and implementation of the complex intervention. Existing service models, staffing levels and distribution of responsibilities, capacity at each site, and previous experience with telehealth all had a strong influence on the extent to which the intervention was accepted and implemented. In some settings, technology-supported remote specialist input was seen as potentially useful in supplementing existing care and readily mobilized to fill specific gaps in service provision (including, in one site, using it as a safety-net for sicker patients). Sites with relatively comprehensive existing services accommodated the SUPPORT-HF2 intervention mainly by targeting it to patients considered stable enough not to need local HFSN input. In some sites, the SUPPORT-HF2 model of care was actively resisted for historical reasons. Recruitment and implementation were also influenced by concerns that patient care should not be compromised if they were allocated to the control arm.

Strengths and limitations

This qualitative study drew on a large volume of data to understand the role of central remote specialist support in telehealth for heart failure. A multidisciplinary team was involved in the analysis of the data, combining an understanding of clinical aspects and current service models in heart failure, with expertise on qualitative evaluation of digital health solutions and the social study of technology. Whilst we sought to draw on a maximum variation sample and interview participants with different experiences with the technology, those who had negative views may be under-represented. We were unable to identify patients who had declined to participate in the trial (although we did interview patients who withdrew). Community HFSNs who had refused to refer patients to the trial were also unavailable for interview by our team. The slow recruitment of participants in the trial was due partly to non-engagement of front-line nurses, but the reasons for their resistance could only be explored indirectly.

Comparison with other studies

The use of telehealth in heart failure management remains controversial, with some clinicians and policymakers strongly enthusiastic [17-20] and others unconvinced or opposed [21-23]. In a recent review carried out by our team, we found that telehealth showed more benefits when “usual” heart failure care was sub-optimal and when it targeted high-risk patients – its success improved with the number of variables monitored, the frequency of monitoring and the timeliness of human remote support [1]. However, the literature on telehealth in heart failure (especially trials) appeared to suffer from publication bias, and poor recruitment was a common challenge [1, 24].

Factors shown to account for poor uptake of telehealth by heart failure patients include preference for face-to-face encounters, lack of perceived relative advantage of the technology over existing care, physical or mental impairments, and lack of confidence that limit patients’ ability to use the technology [1]. Consistent with our findings on the implementation of SUPPORT-HF2, several studies have also identified clinician non-acceptance as a major factor in low uptake of telehealth [25-29]. It has been proposed that champions in telehealth service development could support acceptance as they work to enthusiastically cultivate relationships and promote and legitimate telehealth [30]. Technical factors identified in this study, such as challenges with bandwidth availability (esp. in rural areas) and connectivity, and lack of interoperability with electronic patient records, have also been identified elsewhere [1].

Previous research has consisted of either outcome-focused RCTs or (less commonly) qualitative studies in a non-RCT setting. This study has extended the knowledge base by producing ‘behind-the-scenes’ qualitative insights into the socio-technical challenges of running a multi-site RCT of a highly complex care intervention. We have shown that however committed trial teams are to delivering a standardized intervention across multiple sites, in reality the intervention will be shaped and constrained by historical path-dependencies and local realities.

Clinical and practice considerations

In chronic heart failure, episodes of acute deterioration are common and if not promptly treated may lead to rapid decompensation. An assumption underlying SUPPORT-HF2 is that earlier detection of deterioration using the remote monitoring equipment (blood pressure, body weight, particular symptoms) could trigger rapid intervention that would prevent decompensation. But heart failure is a very complex condition with heterogeneous aetiology and frequent co-morbidities, which means that many patients will be ‘exceptions’ to the standard algorithm and a high degree of personalisation of care is often required. For this reason, it will be hard to demonstrate in a trial that a standardised intervention significantly impacts on outcomes such as hospital admission rates or contacts with the health service.

Secondary care heart failure nurses emphasised safety concerns for the often very complex and unstable patients attending their clinics. Most took a strongly precautionary stance (possibly beyond that intended and expressed in the protocol’s exclusion criteria) that patients should not be recruited if there was a potential for harm. Such a restrictive recruitment strategy, while understandable from a professional perspective, not only slowed recruitment but may also have diluted the effect of the intervention (since patients likely to benefit from prompt efficient medication optimization and enhanced monitoring rarely entered the trial at all). This conundrum is relevant to the design of any future trial of telehealth supported care in heart failure.

Policy and research considerations

This study has raised but not answered the question of how telehealth-linked central remote support for heart failure can be usefully embedded in health systems and how best to evaluate its contribution to patient outcomes and healthcare

improvement. Remote monitoring technologies create new forms of knowledge and new possibilities for care which require fundamental changes to clinical roles and service models and place (sometimes hidden) burdens on patients, carers and staff [1]. Aspirations to introduce technology-supported care often clash with the immediate needs of pressured NHS services, as institutional and system capacity is critical to successfully and sustainably embedding emerging technologies in pre-existing infrastructures [31].

Complex, multi-level change requires ecological and social practice perspectives to supplement mechanical efforts in introducing and mainstreaming interventions [32]. Iterative co-development of the technology-supported service (rather than just co-designing the patient-facing technological components) becomes important, including negotiating the underpinning values and standards that will be built into this new model of care, as well as engaging staff and patients in shaping the pathways and routines in which it will be embedded or depend on [1]. One unresolved, contested aspect of change in SUPPORT-HF2 related to managing the trade-off between algorithmic risk indications and provision of patient care centered on unique individual circumstances and histories. Although these two approaches may not necessarily work in competition, processes for reconciling the conflicts between (on the one hand) algorithmic, guideline-derived knowledge and (on the other hand) the experience and judgement of front-line clinicians currently appear both underdeveloped and under-researched. Further qualitative studies may usefully illuminate how such conflicts can be overcome and/or productively harnessed.

Conclusions

This paper has attempted to contextualize some of the SUPPORT-HF2 trial findings and explain the apparent lack of efficacy of a complex intervention involving both technology and human input. To summarise, in sites with insufficient specialist input to heart failure management in primary care, SUPPORT-HF2 was seen as a potentially useful component to patient care. At sites where care pathways in the community were relatively comprehensive, patient recruitment was highly selective and focused on patients who had had less to gain from the intervention. Our findings suggest, therefore, that the trial has not demonstrated definitively that the intervention is 'ineffective'. Indeed, it is possible that further iteration of both the technology and the care practices and pathways in which it is used *could* produce bespoke local care models that lead to safer and more effective care of patients with heart failure.

Abbreviations

CCM Central clinical management [team]

CI Chief investigator

GP General practitioner

HFSN Heart failure specialist nurse

PI [site-based] Principal investigator

RCT Randomised controlled trial

SCALS Studies in Co-creating Assisted Living Technologies

SUPPORT-HF Seamless User-centred Proactive Provision Of Risk-stratified Treatment for Heart Failure) [trial]

Declarations

Ethics approval and consent to participate

Ethical approval was obtained in September 2015 from the Oxfordshire South Central Research Ethics Committee (REC no. 15/SC/0553) and subsequent amendments. Interviews were audio-recorded with participant consent.

Consent for publication

All participants quoted in this study have given written informed consent for publication.

Availability of supporting data

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The study was conceptualized by TG in liaison with the Chief Investigator of the SUPPORT-HF trial. All authors were involved in data collection and analysis. CP and CAC wrote a first draft of the internal evaluation report; all other authors contributed to its refinement. TG wrote the paper based on the evaluation report. All authors have seen and approved the final manuscript.

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CP is a social scientist specializing in the implementation of health and care technologies. CAC is a GP and (at the time of the study) was also cardiology lead for her locality. SS is a social scientist. JW has a psychology and human-computer interaction background. TG is medically qualified and a social science researcher.

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Tables

TABLE 1: Summary of data sources								
	SITE A	**SITE B**	**SITE C**	**SITE D**	**SITE E**	**SITE F**	**SITE G**	**TOTAL**
SUPPORT-HF2 staff interviews	11: consultant cardiologist/CI, trial manager, lead research nurse, 6 community HFSNs, bio-engineer, GP	3: consultant cardiologist/PI, 2 research nurses	4: Research nurse, 3 HFSNs (1 hospital, 2 community)	1: Research practitioner	2: consultant cardiologist/PI, research administrator	1: hospital HFSN	1: consultant cardiologist/CI	23
SUPPORT-HF2 patient interviews	4 (incl. 1 spouse)		5 (incl. 1 spouse)	4	3	0	5	21
SUPPORT-HF2 patient discussion group		7 (6 patients, 1 spouse)						7
Documents	SUPPORT-HF2 study protocol Minutes of 5 meetings during study set up phase Minutes of a significant event review meeting (exploring relationship between SUPPORT-HF2 driven drug up-titration and subsequent hospital admission) Approximately 50 email exchanges between site staff and researchers Approximately 10 emails between lead study nurse and researchers							approx. 110 pages
TOTAL	Directly involved in the trial: 25 patients; 3 spouses; 4 consultant cardiologists who were also local principal investigators; 10 heart failure specialist nurses, 4 research nurses, 1 trial manager, 1 bioengineer, 1 research practitioner, 1 research administrator							51 people

TABLE 2: Cross-site comparison – contexts and implementation							
	SITE A Large city South East England	**SITE B** Major city Northern Ireland	**SITE C** Major city East Midlands	**SITE D** Rural South West England	**SITE E** Major city North West England	**SITE F** Urban area South East England	**SITE G** Major town South England
Existing service prior to SUPPORT-HF2 trial	Consultant-led clinics and inpatient management Standard primary care diagnosis and ongoing management						
	Hospital HFSN team. Community HFSN teams serving HFrEF only.	Hospital and community HFSN teams.	Hospital and community HFSN teams	Hospital and community HFSN teams	Community HFSN team in one part of CCG only.	Hospital and community HFSN teams	No community HFSN team.
Staff involved in SUPPORT-HF2 trial	Chief investigator, secondary care HF nurses, SUPPORT HF trial team	Local PI, 2 research nurses	Local PI, secondary care based lead HFSN and 2 community	Local PI, secondary care HFSNs, 2 research practitioners	Local PI, research administrator	Local PI, secondary care-based HFSN	Local PI
Setting for recruitment	Study Lead nurse recruited from wards or clinics. Community HF nurses in early phase only.	Research nurse recruited from CCU and other wards or by letters sent out post-discharge	Recruited by lead HFSN then later by research nurse and community HFSNs from clinic	2 Research practitioners, secondary care HFSNs and local PI recruited from wards and hospital clinics	By local PI in hospital clinic.	By secondary care nurse in hospital clinic.	By local PI in hospital clinic.
Clinical profile of participants in this site	As per protocol, no specific distinction described	As per protocol, no specific distinction described	Patients were recruited only when ready for discharge from hospital clinic or HFSN service	As per protocol, no specific distinction described	Patients were targeted if they were particularly unwell and deemed in need of monitoring between 6 monthly clinic visits	In time, with appreciation of RCT design, staff avoided recruitment of any patients deemed too unstable for the control arm	As per protocol, no specific distinction described
How technology use by patients was supported during the trial	By CCM team	By local research nurse, supported by CCM team	By local research nurse, supported by CCM team	By local research nurse, supported by CCM team	By CCM team	By CCM team	By CCM team
Extent to which the model was integrated into clinical pathways	Initially integrated, later separated due to role overlap.	Limited: resistance from both hospital and community	Partial: intention was for participants to be looked after by the CCM team, but sometimes the	Partial: Integrated with secondary care only as community	Not integrated: following recruitment participants were looked after by CCM team.	Not integrated: following recruitment participants were looked after by CCM team.	Not integrated: following recruitment participants were looked

		HFSNs and GPs.	hospital HFSN accessed patient data.	HFSN service was resistant.			after by CCM team.

Figures

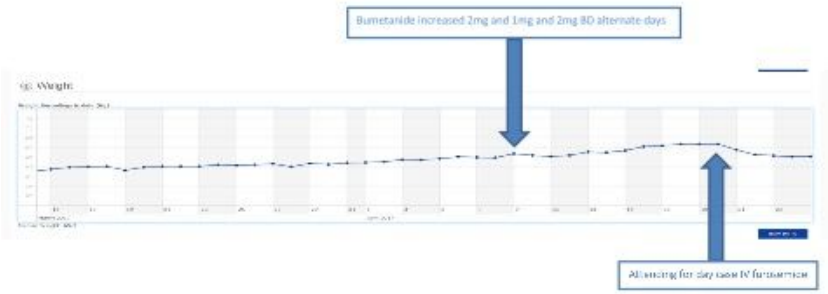

Figure 1

Longitudinal weight readings entered by patient and active interventions recommended by central support staff based on the SUPPORT-HF algorithm