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Improving TRansitions ANd outcomeS for heart FailurE patients in home health CaRe (I-TRANSFER-HF): a type 1 hybrid effectiveness-implementation trial: study protocol

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Abstract

Background Some of the most promising strategies to reduce hospital readmissions in heart failure (HF) is through the timely receipt of home health care (HHC), delivered by Medicare-certified home health agencies (HHAs), and outpatient medical follow-up after hospital discharge. Yet national data show that only 12% of Medicare beneficiaries receive these evidence-based practices, representing an implementation gap. To advance the science and improve outcomes in HF, we will test the effectiveness and implementation of an intervention called Improving TRansitions ANd OutcomeS for Heart FailurE Patients in Home Health CaRe (I-TRANSFER-HF), comprised of early and intensive HHC nurse visits combined with an early outpatient medical visit post-discharge, among HF patients receiving HHC.

Methods This study will use a Hybrid Type 1, stepped wedge randomized trial design, to test the effectiveness and implementation of I-TRANSFER-HF in partnership with four geographically diverse dyads of hospitals and HHAs ("hospital-HHA" dyads) across the US. Aim 1 will test the effectiveness of I-TRANSFER-HF to reduce 30-day readmissions (primary outcome) and ED visits (secondary outcome), and increase days at home (secondary outcome) among HF patients who receive timely follow-up compared to usual care. Hospital-HHA dyads will be randomized to cross over from a baseline period of no intervention to the intervention in a randomized sequential order. Medicare claims data from each dyad and from comparison dyads selected within the national dataset will be used to ascertain outcomes. Hypotheses will be tested with generalized mixed models. Aim 2 will assess the determinants of I-TRANSFER-HF's implementation using a mixed-methods approach and is guided by the Consolidated Framework for Implementation Research 2.0 (CFIR 2.0). Qualitative interviews will be conducted with key stakeholders across the hospital-HHA dyads

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to assess acceptability, barriers, and facilitators of implementation; feasibility and process measures will be assessed with Medicare claims data.

Discussion As the first pragmatic trial of promoting timely HHC and outpatient follow-up in HF, this study has the potential to dramatically improve care and outcomes for HF patients and produce novel insights for the implementation of HHC nationally.

Trial registration This trial has been registered on ClinicalTrials.Gov (#NCT06118983). Registered on 10/31/2023, https://clinicaltrials.gov/study/NCT06118983?id=NCT06118983&rank=1.

Keywords Transitional care, Heart Failure, Implementation Science

Background

Heart failure (HF) affects over 6 million adults in the US and is associated with poor outcomes, including one million hospitalizations per year, costing over $30 billion annually [1]. Nearly 20–25% of Medicare beneficiaries hospitalized for HF are readmitted within 30 days, with 50–60% of these readmissions occurring within 15 days of discharge [2, 3]. Readmissions are associated with increased morbidity and mortality for patients, and are costly for the healthcare system [4]. Despite a decade of innovation, interventions, and financial policies aimed at reducing readmissions, including the Centers for Medicare and Medicaid Services' Hospital Readmissions Reduction Program [5], readmission rates remain persistently high, highlighting the need to focus on identifying and implementing evidence-based strategies into practice [6–11].

A promising strategy to reduce readmissions and adverse outcomes in HF is using home health care (HHC) to monitor patients after hospital discharge. HHC, which is provided by certified home health agencies (HHAs), provides skilled nursing care, physical and occupational therapy, social work, and aide services to patients in the post-acute period (~60 days), to promote recovery, regain or maintain function, and avoid readmission [12, 13]. Annually, 34% of Medicare beneficiaries hospitalized for HF are discharged home with HHC, a rate that has increased in recent years, exceeding most other chronic conditions [14, 15].

Despite its promise, the manner and timing of HHC delivery is critical for optimal outcomes [16]. Within HHC, receiving early and intensive nurse visits (defined as receiving two thirds of total HHC nurse visits within the first few weeks of HHC episode) is the HHC industry gold standard [17–24]. In addition to early HHC, early outpatient medical follow-up post-discharge is a key aspect of successful transitions of care for HF patients, as reflected in the American College of Cardiology's "See You in Seven" campaign [25]. Follow-up within seven days of discharge is associated with a lower 30-day readmission risk compared to none or later follow-up appointments (between 8 and 30 days after discharge) [17, 23, 25]. Notably, a prior observational comparative effectiveness study of 100,000 Medicare beneficiaries tested the effectiveness of these two evidence-based early visit patterns (1) early and intensive HHC nurse visits and 2) early outpatient medical follow-up within seven days) on outcomes, among HF patients receiving HHC after discharge [17]. The study found that while neither intervention individually reduced readmissions, the two combined were associated with an 8% absolute reduced readmission rate compared to those who received neither (40% relative reduction). Unfortunately, only 12.6% received both [17]. These findings suggest that the most promising strategy to reduce readmissions among HF patients receiving HHC is being delivered to the fewest patients, signaling an implementation gap.

Building on this observational evidence base, alongside a similar, and ongoing trial of timely HHC and outpatient visits for sepsis survivors, this study aims to test an intervention called "Improving TRansitions ANd OutcomeS for Heart FailurE Patients in Home Health CaRe" (I-TRANSFER-HF), comprised of an initial HHC nursing visit on the day of or day after hospital discharge with a total of three or more nursing visits within the first week, coupled with an outpatient visit within seven days of discharge [17, 24]. Herein, we describe the protocol for how we will test the effectiveness of I-TRANSFER-HF for reducing 30-day readmissions while gathering information on its implementation using a national, Type-1 Hybrid effectiveness-implementation stepped wedge cluster randomized trial occurring in partnership with four geographically diverse dyads of hospitals and HHAs ("hospital-agency dyad").

Methods/Design

Study aims

Aim 1: Effectiveness of I-TRANSFER-HF

Aim 1: To test the effectiveness of the I-TRANSFER-HF intervention to reduce 30-day all-cause readmissions (primary outcome) and all-cause ED visits (secondary outcome) and increase days at home (secondary outcome) among Medicare beneficiaries hospitalized for HF discharged home with HHC, compared to usual care.

Aim 2: I-TRANSFER-HF's implementation

Aim 2: To assess the roles of context, processes, strategies, and determinants in I-TRANSFER-HF's implementation. Specifically, our four primary implementation outcomes include: acceptability, feasibility, fidelity, and adaptation. In an exploratory fashion, given the rise of telemedicine during COVID-19, we will test the association between the type of outpatient visit (in-person vs. virtual), its timing, and its association with outcomes.

Conceptual frameworks

Aim 1

The Andersen Behavioral Model of Health Services Use will guide Aim 1 (Fig. 1) [26]. Using the Model; we will consider predisposing factors that influence HHC and outpatient medical care and outcomes (age, sex, self-reported race, informal support), as well as enabling factors (include facilitators of health care services use such as insurance, income), and need/illness level (i.e., health status, cognitive and physical functioning, symptoms, and recent hospitalizations). Beyond these, we will also consider health services system determinants, community, and market characteristics (i.e., supply of HHAs, physician visits), and organizational factors (i.e. HHA and hospital characteristics). We will consider these factors for risk adjustment in our main analyses and when forming our national control sample (see "Aim 1- Hypotheses and Corresponding Analyses" section).

Aim 2

The Consolidated Framework for Implementation Research 2.0 (CFIR 2.0) framework will guide Aim 2 [27, 28]. CFIR 2.0 is a conceptual framework used extensively in implementation research to identify and assess factors that might influence implementation systematically [28]. CFIR 2.0 is comprised of five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process [28]. The "Intervention Characteristics" domain focuses on the intervention's attributes, such as its relative advantage, trialability, adaptability, and complexity. The "outer setting" includes external factors that affect implementation, like policies, local conditions, and incentives, while the "inner setting" domain investigates aspects of the implementing organization including its culture and readiness for implementation. The "individuals" domain captures how characteristics of the people involved in the implementation, like their roles, motivations, and capabilities, influence outcomes. Lastly, the "process" domain provides a way to evaluate how the planning and execution of the implementation affect its success.

Guided by CFIR 2.0, we will conduct qualitative interviews with key stakeholders across the four hospital-HHA dyads prior to and after I-TRANSFER-HF's implementation to assess the roles of context, processes, strategies, and determinants that influence its implementation [28]. Specifically, we will assess the interventions' acceptability, feasibility, fidelity, and adaptation with interviews, surveys, and Medicare claims data. Implementation determinants (barriers and facilitators) from the CFIR 2.0 domains (see "Aim 2: I-TRANSFER-HF's Implementation" section) may be added to the analyses for Aim 1 as variables that may impact outcomes [28].

Study design

The study concept and design were informed by an ongoing trial in HHC with sepsis survivors led by a member of the investigative team (K.H.B.) [24]. That study uses a Type 1 Hybrid design [29]. Since the prior evidence base for that study and this one are based on national observational comparative effectiveness studies [17, 29–32], testing effectiveness with a clinical trial is the next necessary step. Our trial will use a stepped wedge cluster RCT design, which is being increasingly used in the evaluation

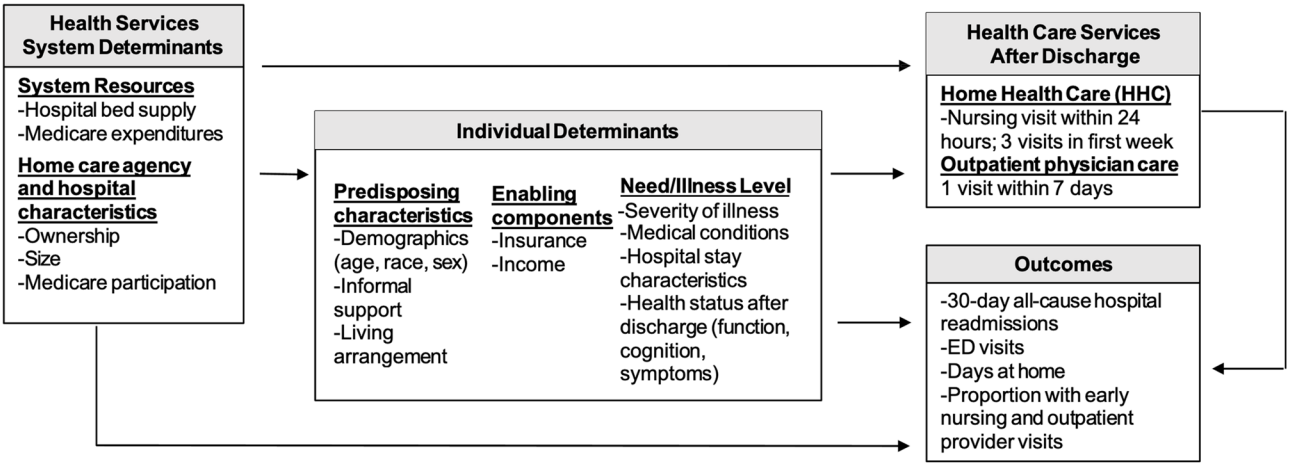

Fig. 1 Andersen Behavioral Model of Health Services Use Adapted to I-TRANSFER-HF

of service delivery interventions, especially when health systems are heterogeneous and traditional randomization of individuals is not possible, or where the risk of contamination is high [33]. The design involves an initial period where no entities (hospital-HHA dyads, or steps) are exposed to the I-TRANSFER-HF intervention followed by subsequent crossover of the entities from control to intervention in a randomly chosen sequence. This design was seen as more acceptable to participating sites (i.e., over a traditional cluster RCT) because dyads did not want to be randomized to the control group [30]. Unique to this RCT, our primary and secondary outcomes among HF patients within our hospital-agency dyads will be ascertained with Medicare claims data. In addition, data from matched controls (not at our study sites) will comprise an external control sample.

In line with Hybrid Type 1 effectiveness implementation studies, Aim 2 will assess the determinants and context for I-TRANSFER-HF's implementation using an observational, multi-method approach through qualitative interviews, surveys, and Medicare claims data [29, 30, 34]. Informed by CFIR 2.0, we will conduct qualitative interviews with key stakeholders across the hospital-HHA dyads before and after intervention implementation to identify barriers and facilitators that influence I-TRANSFER-HF's implementation and uptake [28]. We will assess the interventions' acceptability, feasibility, fidelity, and adaptation with qualitative interviews, surveys using validated measures, and process outcomes using Medicare claims data.

The I-TRANSFER-HF intervention

This intervention and its components are derived from the prior comparative effectiveness study [17]. The I-TRANSFER-HF intervention consists of two main components: (1) Early and intensive HHC nurse visits, with an initial HHC nurse visit within two days of hospital discharge, followed by two more nurse visits during the first week of discharge; and (2) an outpatient medical follow-up visit within the first week of discharge. The outpatient visit can be with a clinical provider (physician, nurse practitioner, physician assistant) from one of several medical specialties (e.g., cardiology, primary care, geriatric medicine). We adapted the intervention in two ways from the prior study. First, in accordance with feedback from HHAs regarding staffing challenges post-COVID-19, and alongside the emergence of telemedicine, we will allow HHAs to conduct subsequent HHC nurse visits to be in-person or virtual, with the initial HHC nurse visit being in-person [35]. The subsequent two HHC nurse visits may be conducted by a similarly trained HHC clinician (i.e. physical therapist) if the scope of care is similar to the nurse at the local site. We will also allow the outpatient follow-up visit to be completed either in-person or virtually.

Study period

As shown in Fig. 2, and in line with the stepped wedge RCT design, the study involves four hospital-HHA dyads (each considered a cluster, or "step"). Each will have a baseline period of usual care (UC) with no intervention, followed by a six-month onboarding (O) period when our research team works with the site to prepare for the trial (i.e. assemble the stakeholder team, conduct initial qualitative interviews, begin implementation mapping), a year-long intervention (I) period when the site team implements I-TRANSFER-HF with the research teams' support, followed by a six-month maintenance (M) period when the research team will assesses whether the intervention continues without the research teams' monitoring and feedback (Fig. 2). Each dyad will be randomized to an order using a random number generator software package in 'R' [36]. Data from the UC, O, I, and M periods for each dyad will be ascertained via Medicare claims. We will form control comparison groups from outside (matching) our partner sites using national Medicare claims data.

Study sites

We chose to select four sites as this number would allow us diversity in organization type while balancing feasibility. The four sites (hospital-HHA dyads) were selected for diversity across (1) geography and location (2) hospital and HHA relationship (e.g., hospital and HHA refers to a free-standing HHA vs. integrated hospital/HHA system) (3) HHA characteristics (small, medium, large, chain), (4) presence of existing collaborations, and (5) commitment

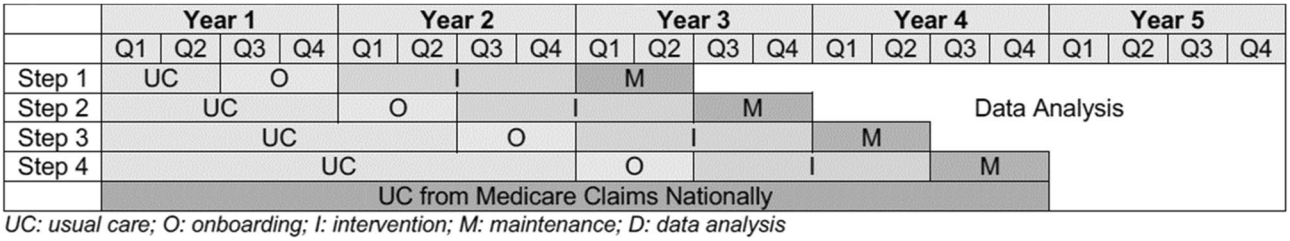

Fig. 2 Stepped wedge cluster randomized trial design and timeline

Table 1 Hospital and Home Health Care (HHC) Agency Dyads and HF admissions per year

Site	Geography	Hospital and Agency Characteristics	Estimated Patients per Dyad in the Study Period
Site 1	- Mid-Atlantic - Suburban	- Two large academic medical centers - Integrated home health agency (within hospital)	705
Site 2	- Mountain-West - Suburban	- Medium sized academic medical center - Small, local home health agency	245
Site 3	- Northeast - Urban	- Two large academic medical centers - Large, free-standing home health agency	3,010
Site 4	- West Coast - Suburban	- One medium academic medical center - Large, free-standing, chain home health agency	417

to implementation science. As shown in Table 1, the sites include six academic centers and four HHAs.

Study sample

Aim 1

This study will include Medicare beneficiaries hospitalized for HF who receive HHC at the partner HHA during the study period. Inclusion criteria include having Medicare (Traditional Medicare [TM] or Medicare Advantage [MA]), being hospitalized for HF (primary or secondary diagnosis of HF using ICD-10-CM codes) and being referred for HHC services to a partner HHA. Exclusion criteria include being discharged home without HHC, or to an inpatient rehabilitation facility, skilled nursing facility, or hospice, as well as having end stage renal disease on dialysis or a left ventricular device [24].

The intervention is being implemented at the dyad level, rather than the patient level. As such, there is no individual patient recruitment or prospective assignment at the individual level, or primary data collection from patients. Rather, the target of the intervention is the hospital-HHA site team (i.e., stakeholders) who will implement it. The number of subjects (patients) in each step (Fig. 2) will be dictated by the size of the population cared for at each site who meet inclusion criteria. The analysis will be completed on existing datasets. Our analytic sample will also include a control sample of hospital-HHA dyads matched on selected site characteristics; Medicare beneficiaries hospitalized for HF and discharged to HHC during the study period, but not at our study sites.

Based on our prior work, we expect approximately 630,000 Medicare beneficiaries nationally with HF hospitalization and received HHC to comprise the overall universe from which we will draw our implementation and potential control samples; they are likely to have a mean age of 79 years, be 60% female, 14.6% Black, a high prevalence of chronic cardiovascular conditions, and 80% will have two or more limitations in activities of daily living [14, 17, 37, 38].

Aim 2

Each hospital-HHA dyad selected as an intervention site will be headed by a site lead, with expertise in either internal medicine, geriatric medicine, cardiology, HHC, and/or implementation science. The site lead will work with the research team and PI (M.R.S.) to assemble a site team of roughly 10–15 key stakeholders from the hospital and ambulatory setting and HHA, that would be key to implementing I-TRANSFER-HF. While roles, titles, and individuals will differ by sites, team members may include: a social worker to identify HF patients discharged to HHC; nursing operations leaders; inpatient care coordinators to make outpatient appointments; hospitalists; HF and primary care doctors; and ambulatory care managers to determine appointment workflow. At the HHA, teams will likely include a hospital based HHC agency liaison to facilitate HHC referrals and transfer patient information to the HHA; an HHC intake nurse and HHC nurse who know the workflow for planning visits and working with patients; an intake director; and chief nursing officers who oversee operations. Stakeholders will participate in interviews as described below (see "Aim 2- Consolidated Framework for Implementation Research 2.0 (CFIR 2.0) Interviews" section). We estimate 60 stakeholders (15 per dyad) will be eligible and recruited. Participants will provide written consent.

Main outcomes

Main outcomes and measures, by Aim, are shown in Table 2. For Aim 1, the primary outcome is all-cause 30-day readmission, at the patient level. Secondary outcomes include all-cause 30-day ED visits and days at home (at the patient level), all ascertained via Medicare claims.

For Aim 2, data on the four implementation outcomes (acceptability, feasibility, fidelity, and adaptation) will be assessed through qualitative interviews, surveys, and claims data (Table 2). Data collection and analysis will be guided by an implementation science expert (J.N.T.). Acceptability, the perception among stakeholders that I-TRANSFER-HF is agreeable, or satisfactory, will be assessed through qualitative interviews (Table 2) and a validated, Acceptability of Intervention Measure (AIM), before and after the implementation period [39]. Similarly, feasibility will be assessed through qualitative interviews and the validated Feasibility of Intervention Measure (FIM) [39], before and after implementation, and claims data including: (a) number of HF patients

Table 2 Selected Interview Questions for Hospital-Home Health Agency Dyad Site Teams, informed by domains and constructs of the CFIR 2.0 Framework

CFIR 2.0 Domain	Constructs[a]	Selected Interview Questions with Site Team Members
Intervention Characteristics (Innovation)	• Adaptability • Trialability • Complexity • Relative Advantage	1. In your own words, what is the I-TRANSFER-HF intervention? 2. How does the I-TRANSFER intervention compare to other workflow practices aimed at reducing readmission for HF patients?
Outer Setting	• Local Conditions • Financing • Policies and Laws • Partnerships and Connections	1. How do you foresee the larger community (your local area) or system factors (your health system or other home health agencies) impacting the upcoming implementation? 2. What external factors (e.g., policies, regulations, external relationships) do you anticipate could influence the implementation process?
Inner Setting	• Culture • Tension for Change • Relative Priority • Compatibility	1. How do you perceive the organizational culture/beliefs/attitudes of your Hospital/HHA might influence implementation efforts? 2. How do you perceive the readiness and commitment level among staff members to implement this intervention?
Individuals	• Opinion Leaders • Implementation Leads • Intervention Deliverers	1. Based on what you know about the intervention, do we have the necessary institutional figures involved for successful implementation? If not, who are we missing? 2. Are there any specific training or capacity-building efforts planned to support implementation? What else might make a difference?
Implementation Process	• Teaming • Assessing Needs • Planning • Tailoring Strategies • Adapting	1. What do you anticipate may need to be modified or adapted to ensure that the intervention can be implemented? 2. As we go through implementing this intervention, what will be your benchmarks for evaluating success?

[a]Not all constructs are listed

eligible to receive the intervention; (b) number who received both components, one, or none; (c) type of outpatient follow-up (in-person vs. virtual) and timeliness of visits. Finally, we will assess whether additional staff were needed to implement the intervention [39]. Fidelity will be assessed with: (1) checklists that measure the timing of and adherence to intervention components as well as claims data (receipt vs. not); (2) automated reports to assess delivery of intervention components, and (3) qualitative interviews. Adaptation(s) (locally, at sites) will be assessed with qualitative interviews.

Data sources and collection

Aim 1- Medicare claims data

We will use a national sample of Medicare administrative, home health, Outcome and Assessment Information Set (OASIS) and claims data for Medicare beneficiaries who had a HHC episode during the study period. These data sources will allow us to obtain information about the index hospitalization, subsequent HHC and outpatient visits, and outcomes [24]. The OASIS is a comprehensive assessment tool collection of nearly 100 items related to home health recipients' functional and clinical status, and service needs during an HHC episode [24]. Additional details of the OASIS are described elsewhere [24]. The Medicare claims, administrative and OASIS data will be requested from the CMS Chronic Condition Warehouse (CCW) sequentially for each calendar year of interest. Based on our prior experience, we expect a 15-18-month lag time between the close of each calendar year of interest and receiving access to the data, which is built into our study timeline. Additional source files will include: (1) the CMS Provider of Services file (which contain hospital, HHC, and other provider characteristics); (2) the Area Health Resources file, a national, county-level record of the supply of health care services; and (3) Census data that include ZIP code level socio-economic measures.

The PI (M.R.S.) will provide oversight along with input from co-investigators with expertise in claims and HHC data analysis (M.R., Y.B., S.B., M.R., J.B.R, L.M.K. K.H.B.)

Aim 2- Consolidated Framework for Implementation Research 2.0 (CFIR 2.0) Interviews

Qualitative interviews will be led by the PI (M.R.S.) and research coordinators and manager (C.E, D.S., M.S.), all trained in qualitative research methods, with content input from K.H.B, M.M, (expertise in HHC), J.N.T (implementation science), clinical trial design (M.M.S.) ambulatory care use patterns (L.M.K.), and HF care (P.G.). Interviews will begin during the O-period and will be guided by the CFIR 2.0 framework. After informed consent, participants will complete a short baseline survey which includes the 12-item validated Organizational Readiness for Implementing Change scale (ORIC). The ORIC assesses organizational members' shared beliefs in their collective capability and readiness to change [40]. Each question uses a 5-point Likert scale; a summative score is calculated with lower scores representing less readiness for implementing change. In addition to the

ORIC, demographic, employment, and organizational information will be collected [40].

Stakeholders will be interviewed at two time points (O period, and post-I period). Interviews will be conducted virtually (Zoom) in a one-on-one fashion, or in small groups, at the stakeholders' preference. Data collected from interviews during the O period will be analyzed formally using thematic analysis and the findings will be presented back to the site team to plan the implementation (I) as described below [41–44]. During the I-period, regular check-in meetings will occur at least monthly per site. These discussions will be recorded for analysis in Dedoose [46].

Implementation mapping

Following formal interviews, and during the I-phase, our research team will work with the site team to conduct the implementation mapping process. This systematic, iterative process is comprised of five steps for developing strategies to implement evidence-based interventions, like I-TRANSFER-HF, in the real world [47–50]. First is the needs assessment (qualitative interviews) to identify barriers and opportunities. This will inform each site of the key players and decision makers, and resources available. Second, our research and site team will generate implementation outcomes and performance objectives and create matrices of change, which are used to help sites identify *what* must change to make something happen, *who* will do what, and *how* success will be measured. For example, the hospital care coordinators may need to determine the workflow and strategies for making follow-up outpatient appointments before the site team can implement processes. Third, researchers and site members will select implementation strategies for each of I-TRANSFER-HF's four components. While the exact strategies will depend on the findings, it is likely that they will consist of multifaceted approaches to implementation including staff education, changes to organizational workflow, information technology, and audit and feedback to clinicians and staff. Fourth, we will produce implementation protocols. Lastly, we will monitor progress and fidelity [50]. While maintaining the core I-TRANSFER-HF components, in line with a pragmatic design, we will allow variation in the workflow for site preferences while providing monitoring and feedback of the implementation. As such, we will document the implementation strategies and workflows suggested, adopted, modified, or discarded by study sites [24].

Analysis

Aim 1- Construction of analytical files and key variables

Data analyses will be performed by experienced analysts (J.R., M.R.) with oversight from HHC claims experts (M.B.R.) and statisticians (Y.B, S.B). We will request CCW data on all Medicare beneficiaries with a claim for a HHC service provided one year prior to the start of the study to six months after the end of the last intervention phase (Fig. 2). Using the inpatient file, we will identify HF index stays as having a HF discharge diagnosis in the primary or secondary diagnosis field using ICD-10 codes (ICD-10-CM codes I50.1 to I50.9, I11.0, I13.0, and I13.2). Among them we will identify those discharged to HHC using the home health claims file. Each hospital discharge of a HF patient to HHC will represent a unique record. Some Medicare beneficiaries will have more than one index hospitalization during the study period. Data available will give us the flexibility to define an "index" hospitalization in several ways. Our main approach will be to analyze all eligible hospitalizations followed by HHC (allowing multiple events per beneficiary) and to adjust for the potential effect of clustering at the patient and provider level [24]. We will conduct a sensitivity analysis using only the first eligible hospitalization followed by HHC for each beneficiary.

Aim 1- Power analysis

The sample size for the RCT will be comprised of patients from the hospital-HHA dyads who receive the intervention, alongside before-intervention matched (UC) controls from these sites, and a national matched Medicare sample not at these sites. We estimated the minimum number of patients at the sites required to detect an 8% reduction (from prior study) in 30-day readmission rate using a national average 30-day readmission rate of 23% for HF patients in HHC. Our estimated minimum sample size requirement is an average of 450 patients per step or dyad with a total $N=1800$ with >80% power at an alpha of 5% [51]. Current estimates from the sites give us a total of 4,376 patients across the 4 dyads with an average of 1,094 per dyad (Table 2), which exceeds the minimum required. The power calculations included a range of intra-class coefficient (0.01–0.10), a range of average sample size per dyad (400, 450) and a range of effect sizes (7.5-8.5% reduction) [52, 53]. To account for heterogeneous sample sizes across the 4 dyads (Table 2), power was estimated from 1000 Monte Carlo simulations that randomly generated hospital-HHC agency dyads (minimum of 200, mean of target size i.e., 400 or 450, SD=150) from a truncated Gaussian distribution [54].

Aim 1- Hypotheses and corresponding analyses

We hypothesize that compared to usual care, HF patients who receive I-TRANSFER-HF will have significantly fewer all-cause 30-day readmissions and ED visits and greater days at home.

In our stepped wedge RCT design, each hospital-HHA dyad will serve as its own control. In addition to patients belonging to the control untreated dyads (before

implementation), additional matched patients will be used to provide a much larger sample of control observations. These observations will be drawn from the population of Medicare beneficiaries with HF who receive HHC not cared for by any of the participating sites, as Co-I's have done before [24]. The primary outcome, all-cause 30-day readmission will be modeled with hierarchical logistic regression; each cluster (dyad) will be accounted for as a random effect [55]. In addition to an intent-to-treat indicator, the regression will include covariates specified by the Andersen Behavioral Model as well as site-specific factors identified from qualitative analyses. The secondary outcome of all-cause 30-day ED visit utilization will be modeled with similar hierarchical logistic regression [24, 26]. The secondary outcome of days at home (during HHC episode) will be modeled with similar hierarchical linear or Poisson regression as distributionally appropriate.

Aim 1- Sensitivity and exploratory analyses

We will conduct sensitivity and exploratory analyses. These will include checks of robustness of findings with and without HF patients who are readmitted shortly after discharge (within seven days) and those with very short (one day) or very long hospital stays (>30 days), as we have done previously [18]. Exploratory analyses will be stratified by sex, geographic region, type of HHC clinician, and type of follow-up visit (in-person vs. video), and these results will be displayed using a forest plot.

Aim 2- Analysis of mixed methods-data

Aim 2 will use a mixed-methods approach, including qualitative interviews and surveys with site teams and quantitative analysis of Medicare claims data to assess the feasibility of I-TRANSFER-HF (e.g., the number of HF patients who received the intervention components) and process measures (e.g., type and timing of outpatient visit [in-person vs. video]). These qualitative and quantitative data sources will be analyzed using a mixed methods approach.

Aim 2- Implementation outcomes

For qualitative data, we will use the same approach described above. For survey data, we will summarize implementation outcomes with descriptive statistics. We will test our process hypotheses using claims data with generalized mixed models. For example, we will test whether compared to usual care, HF patients who receive I-TRANSFER-HF will have a higher proportion of timely first week HHC nursing visits and outpatient visits compared to usual care. In an exploratory fashion, we will also test the association between the type of outpatient visit (in-person vs. virtual), and its association with outcomes.

Aim 2- Analysis of qualitative data

Interviews will be transcribed, and transcripts will be uploaded into qualitative software Dedoose to facilitate data organization and analysis. The analysis will be guided by the PI, who has expertise in qualitative research, alongside trained study staff and team members, we will use a thematic analysis, which is appropriate since an established conceptual model (CFIR 2.0) will inform the topic guide and coding process [42–45]. The team members will use the CFIR 2.0 and independently read and code the first three interviews. Content identified by the research team members in this initial reading will be compared to each other, reconciled, and a provisional structure of the coding scheme, partially deduced from the CFIR 2.0 domains, will be developed [24]. The trained team will code the remaining data and meet regularly to review findings and confirm the agreement of codes. Ambiguities, differences, and commonalities will be discussed and resolved. Alternative approaches in workflow, barriers, facilitators, and differences in acceptability observed between the study sites will be noted, compared, contrasted, and reported as study results so agencies with similar barriers can see suggested solutions to increase generalizability of the findings. Dedoose software can accommodate ongoing changes and additions to the labels describing the implementation determinants within each domain of the CFIR 2.0 framework [24, 28, 46]. Through constant comparative analysis, results will be refined for conceptual flow and consistency [50]. Strategies to increase and ensure the trustworthiness and scientific adequacy of the study include *credibility* (iteratively member checking the findings with the site implementation teams) and *transferability* (developing a thick description, notes and diagrams taken during the interviews and implementation mapping), which will permit comparisons with other contexts to which I-TRANSFER-HF might be contemplated. Following the analysis, the findings will contain a full description of contextual factors, determinants, process, and strategies which can offer insights to study sites, but also non-study sites who may want to improve HHC delivery for HF patients in the future *Confirmability* of findings will be assessed using audit, feedback, and fidelity checks [24]. ORIC survey data will be analyzed with descriptive statistics.

Aim 2- Data analysis for the maintenance phase

At the end of the twelve month I-period (by dyad), the study team will stop communicating and monitoring fidelity with sites. Visit patterns will be compared during the "maintenance" period to the I-period, evaluating for stability or decline in the proportion of HF patients receiving the early visit protocol compared to the I-period [24]. Hierarchical regressions, as described for Aim 1, will be used and we will assign separate treatment

indicators for the intervention and maintenance periods. Regressions will test equality of coefficients on the treatment indicators on the two periods. Equality of coefficients will imply maintenance of effects after the team exits.

National advisory board and dissemination

An interdisciplinary group of leaders in HHC, HF and cardiovascular disease, nursing, gerontology, and policy will advise the team annually and will assist by identifying key opportunities for dissemination of research findings, and review information that is tailored to those specific audiences. The members of the Board will provide guidance on industry trends and best practices, the current policy landscape, and input on I-TRANSFER-HF and its implementation. They will have a key role in facilitating dissemination of the findings to national stakeholder groups. Findings will be disseminated to the public and healthcare professionals in related fields, in peer-reviewed journals, professional conferences and community forums.

Discussion

This paper describes the protocol for the I-TRANSFER-HF trial, which will evaluate the effectiveness and implementation of the I-TRANSFER-HF intervention among Medicare beneficiaries hospitalized for HF who receive HHC after discharge. The study uses a Type 1 hybrid effectiveness/implementation design; to assess effectiveness by utilizing a stepped wedge cluster RCT design, and to examine implementation by utilizing the CFIR 2.0 framework. The study will be conducted across four geographically diverse hospital-HHA dyads across the US. As the first pragmatic trial of HHC in HF, this study will examine whether an HCC-based intervention can improve care and outcomes for the highly vulnerable HF population and produce novel insights for the implementation of HHC nationally.

Limitations

Our study design is not without limitations. First, contamination is possible in that dyads may begin to implement parts of the protocol prior to or during the on-boarding period. However, we believe the I-TRANSFER-HF components will be hard to achieve in full and effectively without collaborative efforts across hospitals and HHAs. Additionally, fidelity monitoring of all dyads will allow us assess implementation. For assurance, additional specification checks will include treatment indicators in the retrospective control data and onboarding period to determine whether such activities were taking place [24]. Second, the sample of HF patients receiving HHC from non-participating dyads (Medicare Claims) is a useful external comparison group only if their characteristics match with those of the participating dyads. However, by using the entire population of Medicare beneficiaries who receive home care during the study period, and through matching techniques, we are likely to assemble a well-matched cohort. Third, our four sites may use different strategies to implement the protocol, but we may not be able to compare these by site (i.e. which strategies is superior to others), which would require a separate follow-on study.

Impact

This proposed study is innovative and likely to have an impact on clinical care for HF patients, HHC, and policy. It focuses on an understudied process (transition to and care in HHC and outpatient settings) among a vulnerable and high-risk patient population (HF) by tackling a large, costly, and common challenge: preventing readmission to the hospital and keeping patients at home. It can transform practice at the patient level through the implementation of an early visit intervention among HF patients, a high-risk patient population that utilizes HHC more than any other condition, but one that has defied improvement with outcomes in the post-discharge period.

It can also inform standardization of practice at the health system and HHC agency levels. Currently there is substantial variation in how health systems and HHC work together. This variation not only contributes to poor patient outcomes but also leads to poor communication and coordination of healthcare across settings.

Finally, it is designed to inform national discussions about how to improve quality in the context of new payment models for home care. CMS has recently proposed major changes to the way HHC is reimbursed, by shifting from fee-for-service models to value-based purchasing [56]. Under this model, HHC agencies are being financially rewarded or penalized if they cannot effectively manage unplanned hospitalizations (among other quality measures) for patients. Rigorous well-designed studies like this can generate robust evidence for how HHC agencies can improve quality of care for some of the most vulnerable patients experiencing one of the costliest conditions, HF.

In conclusion, to our knowledge, this will be the first pragmatic clinical trial of HHC in HF targeting the creation of hospital-HHA collaboration and frontloading of visits with potential to transform the paradigm for healthcare delivery for this high risk, vulnerable population, and the rapidly growing home health industry. This study will produce new knowledge about both the real-world effectiveness and implementation determinants of the I-TRANSFER-HF intervention. The findings can inform clinical care, HHC practice and policy, and large-scale implementation and scale up of the intervention

among hospitals and HHC agencies in the US in a subsequent Type 2 or 3 Hybrid trial.

Abbreviations

AIM	Acceptability of Intervention Measure
CFIR	Consolidated Framework for Implementation Research
CMS	Centers for Medicare & Medicaid Services
CCW	Chronic Condition Warehouse
ED	Emergency Department
FIM	Feasibility of Intervention Measure
HHA	Home Health Agency
HHC	Home Health Care
HF	Heart Failure
ICD	International Classification of Diseases
I	TRANSFER–HF–Improving TRansitions ANd OutcomeS for Heart FailurE Patients in Home Health CaRe
MD	Medical Doctor
NP	Nurse Practitioner
OASIS	Outcome and Assessment Information Set
ORIC	Organizational Readiness for Implementing Change
PA	Physician Assistant
PI	Principal Investigator
RCT	Randomized Controlled Trial

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Authors' contributions
MRS, KHB, JNT, MMS, LMK, SB, MBR, and YB contributed to the concept and design of the research study. MRS, CGE, DS, KHB, and MS contributed to the drafting of the manuscript. MRS, CGE, DS, MS, MVM, MBR, YB, JNT, LMK, MMS, SB, PG, JBR, MR, AIA, CDJ, JAD, CC, and KHB contributed to the critical review of the manuscript for important intellectual content. MBR, JBR, MR, SB, and YB contributed to the statistical analysis of the paper. MRS and KHB contributed to obtaining funding for this research study. MS contributed to the administrative, technical, and material support of this manuscript. MRS and KHB supervised the conduct of this research study. All authors read and approved the final manuscript.

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Availability of data and materials
Not applicable.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This protocol was approved by the institutional review board of VNS Health (VNS IRB #E23-03) and Weill Cornell Medicine (WCM IRB #23-06026204). Informed consent was obtained for all participants prior to their inclusion in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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