

SHORT MESSAGING SERVICE TO IMPROVE HEART FAILURE OUTCOMES (SMS-HF) : A Pilot RCT

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On behalf of SMS-HF team

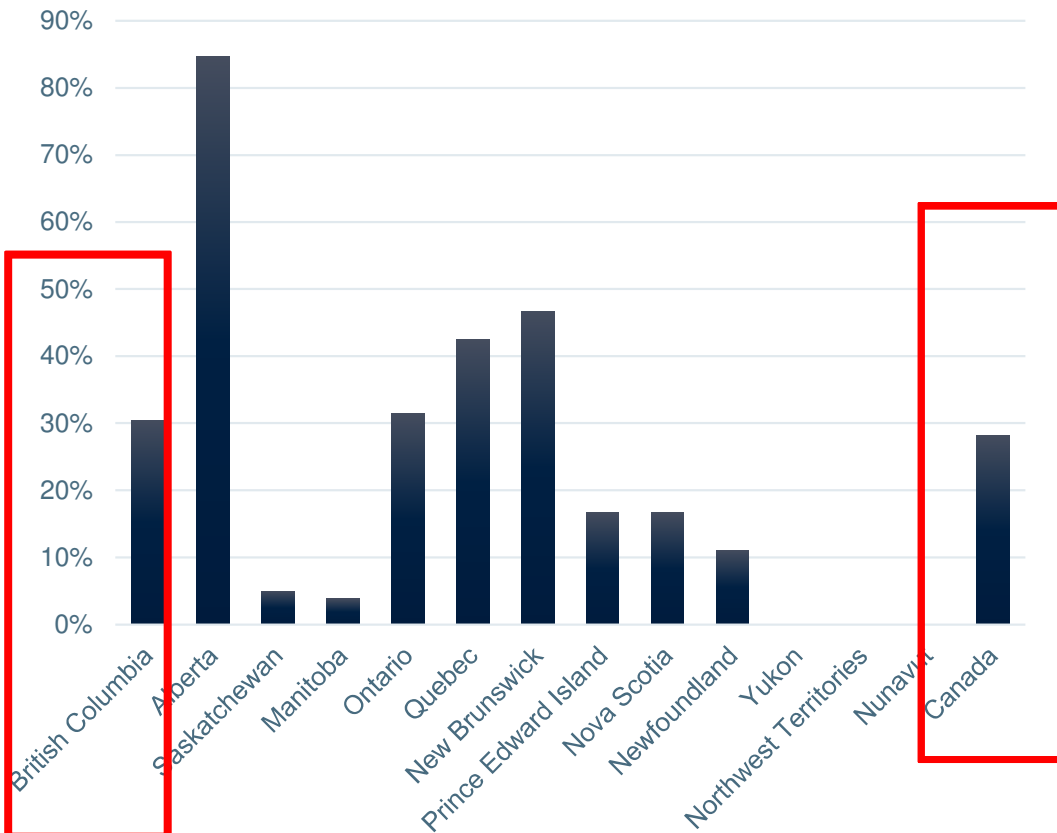


The Heart Failure Epidemic

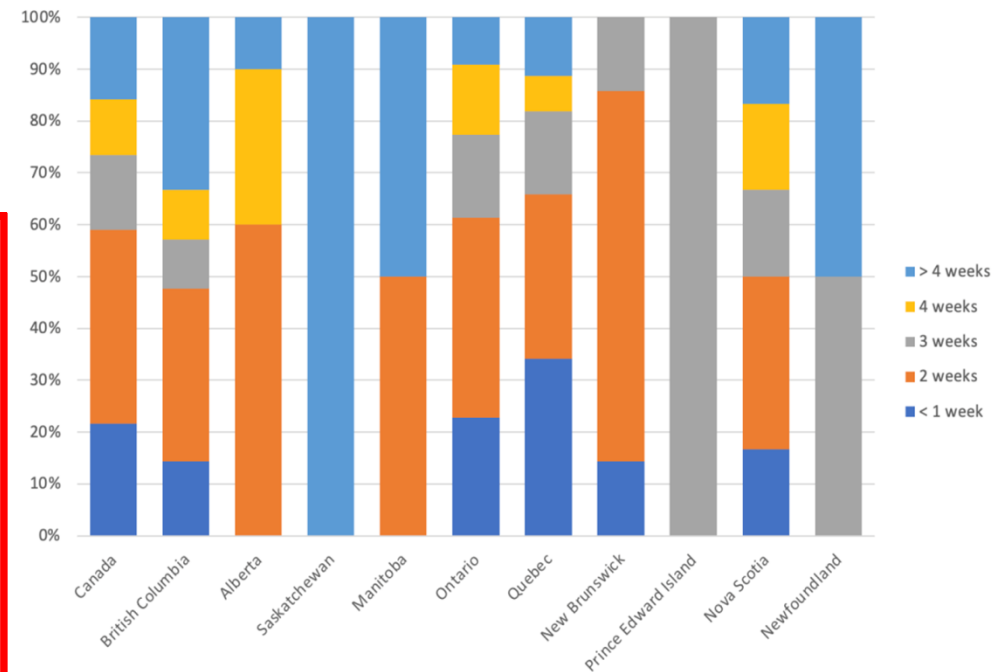
- HF affects more than 787,000 Canadians with over 111,000 new HF diagnoses annually.
- Nationally, 21% of patients admitted with HF are re-hospitalized within 30 days.
- Approximately 30% of early readmissions following HF hospitalization are related to suboptimal transitional care.



Access to HF Clinics



HF clinic wait times



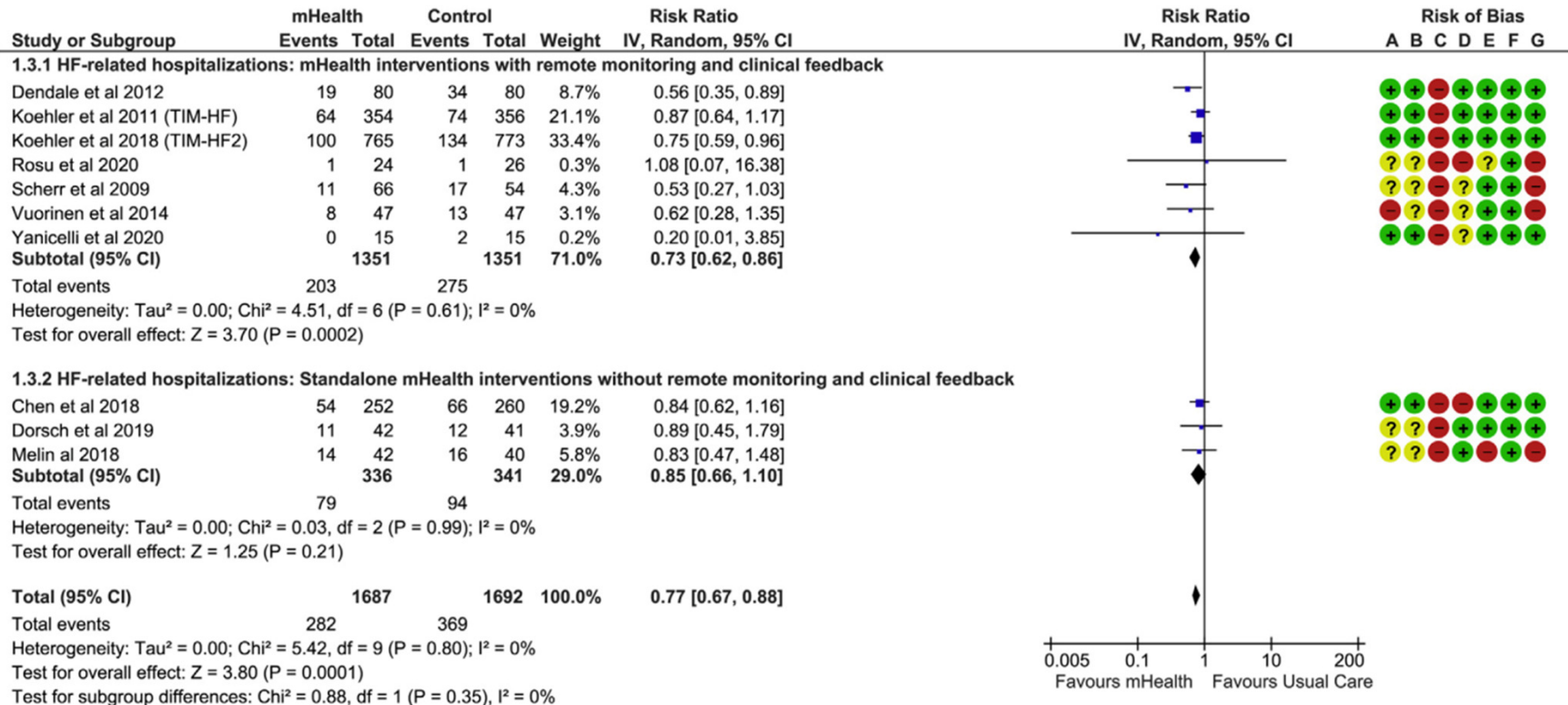
Moghaddam N, Hawkins NM, Virani S. Can J Cardiol. 2023 Oct;39(10):1469-1479.

Why Mobile Technology in HF?

- Mobile technology platforms focused on health (**mHealth**) create opportunities for personalized, scalable health interventions to improve health outcomes.
- The ubiquity of mHealth has substantial potential to reduce inequalities in marginalized, underserved, and remote populations.
- mHealth combined with artificial intelligence (AI) approaches, including natural language processing (NLP) and machine learning (ML), has created new opportunities for delivering multifaceted interventions in chronic disease management, including HF.



Evidence for mHealth in HF



- **Complex technology, low uptake and poor adherence**
- **Inconsistent integration into the provider workflow**
- **Intervention focusing narrowly on symptoms, signs, education, or medication adherence**

SMS-HF Proposal

- **Two-year pilot RCT** of the **WeiTel mHealth platform**, using Short-Messaging Service to Improve Outcomes in Heart Failure (SMS-HF), to support **transitions of care in patients discharged after acute HF hospitalization**.
- This pilot will assess **feasibility** of conducting a larger subsequent trial by evaluating 1) recruitment and retention (recruitment, withdrawal, loss to follow-up, 2) implementation (randomization, adherence, patient and provider acceptability), and 3) potential primary and secondary outcome measure characteristics and collection.



WelTel mHealth

- WelTel mHealth is a Vancouver-based non-profit social enterprise dedicated to improve health outcomes by designing patient-centered, equitable solutions. WelTel uses open, two-way text-messaging (SMS) with AI interpretation
- WelTel mHealth, used across diverse clinical settings:
 - In Kenya (HIV, maternal care)
 - Rwanda (COVID-19)
 - Vancouver (TB and HIV clinics),
 - BC Children's Hospital (Solid organ transplant)
 - Haida Gwaii (chronic disease management)



SMS-HF Hypothesis

- Among patients discharged from hospital after an acute HF episode, a pilot trial of WeTel mHealth text-messaging is feasible in terms of: 1) recruitment, 2) withdrawal of consent, 3) loss to follow-up, 4) adherence, 5) provider acceptability, 6) outcome measurement.



SMS-HF Design

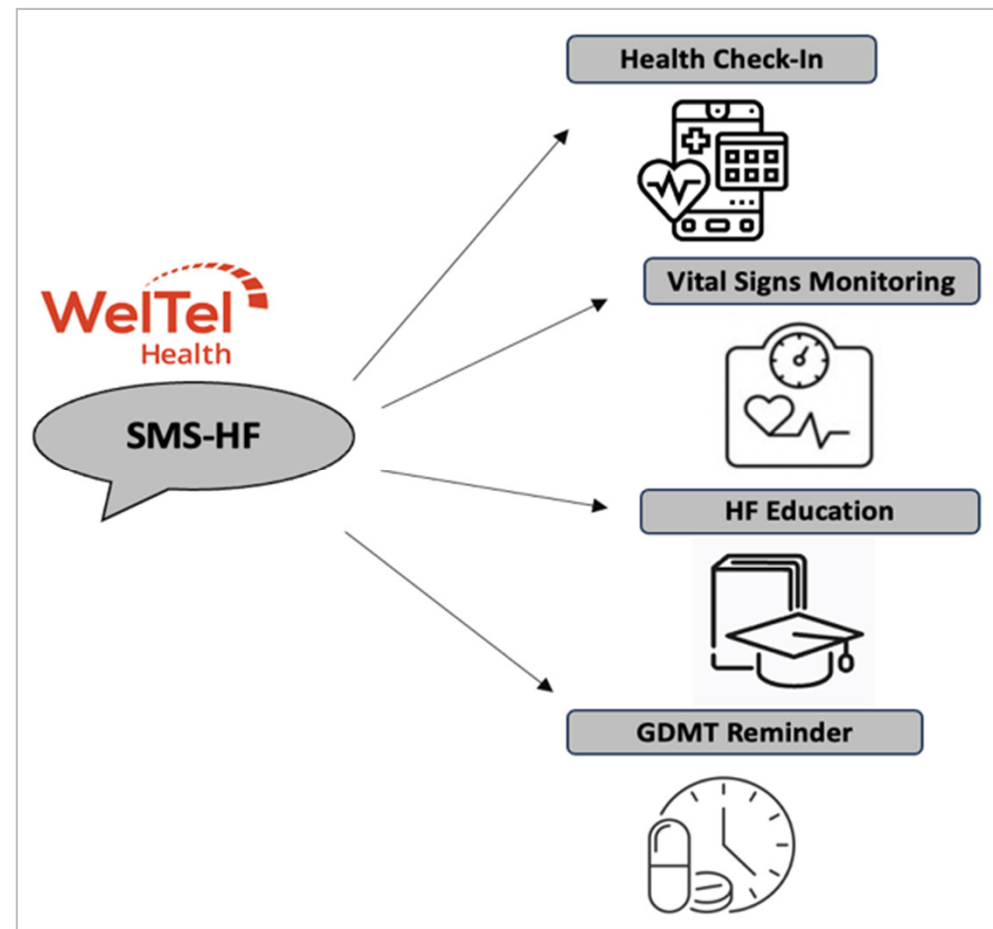
- **Analyses:** External pilot study
- **Randomization:** 1:1 unblinded to *WeiTel mHealth plus usual HF care VS usual care* at time of hospital discharge for AHF admission
- **Duration of follow up:** 180 days
- **Number of patients:** 96
- **Study sites:** 3
 - *Urban site:* Vancouver General Hospital/St. Paul's Hospital
 - *Community site:* Royal Inland Hospital
 - *Rural site:* Haida Gwaii Hospital & Health Center
- **Inclusion criteria:** 1) Age ≥ 18 years, 2) hospitalized or recently discharged (within 7 days) with decompensated HF, 3) symptoms and/or signs of HF, AND 4) structural or functional cardiac abnormality 5) either elevated natriuretic peptide levels (BNP ≥ 100 pg/mL or NT-proBNP ≥ 300 pg/mL) or objective evidence of cardiogenic pulmonary or systemic congestion by imaging or hemodynamic measurement.
- **Exclusion criteria:** : 1) Anticipated life expectancy of less than 6 months, 2) not being discharged to home, 3) inability to provide consent/comply with mHealth intervention.



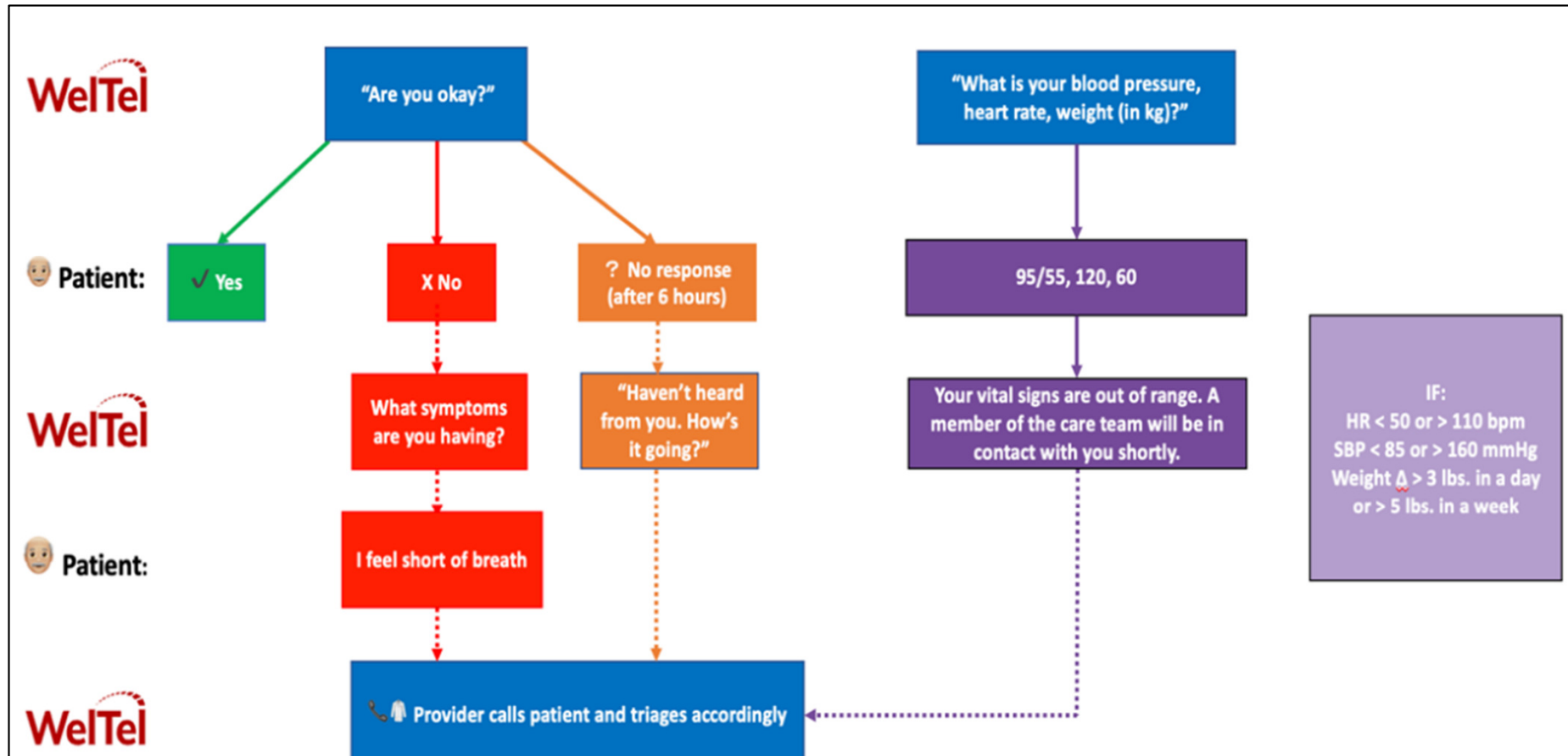
SMS-HF Intervention

The intervention comprises four types of periodic text messages in addition to usual care:

- 1) Health check-in
- 2) Vital sign reporting
- 3) HF education
- 4) Medication support



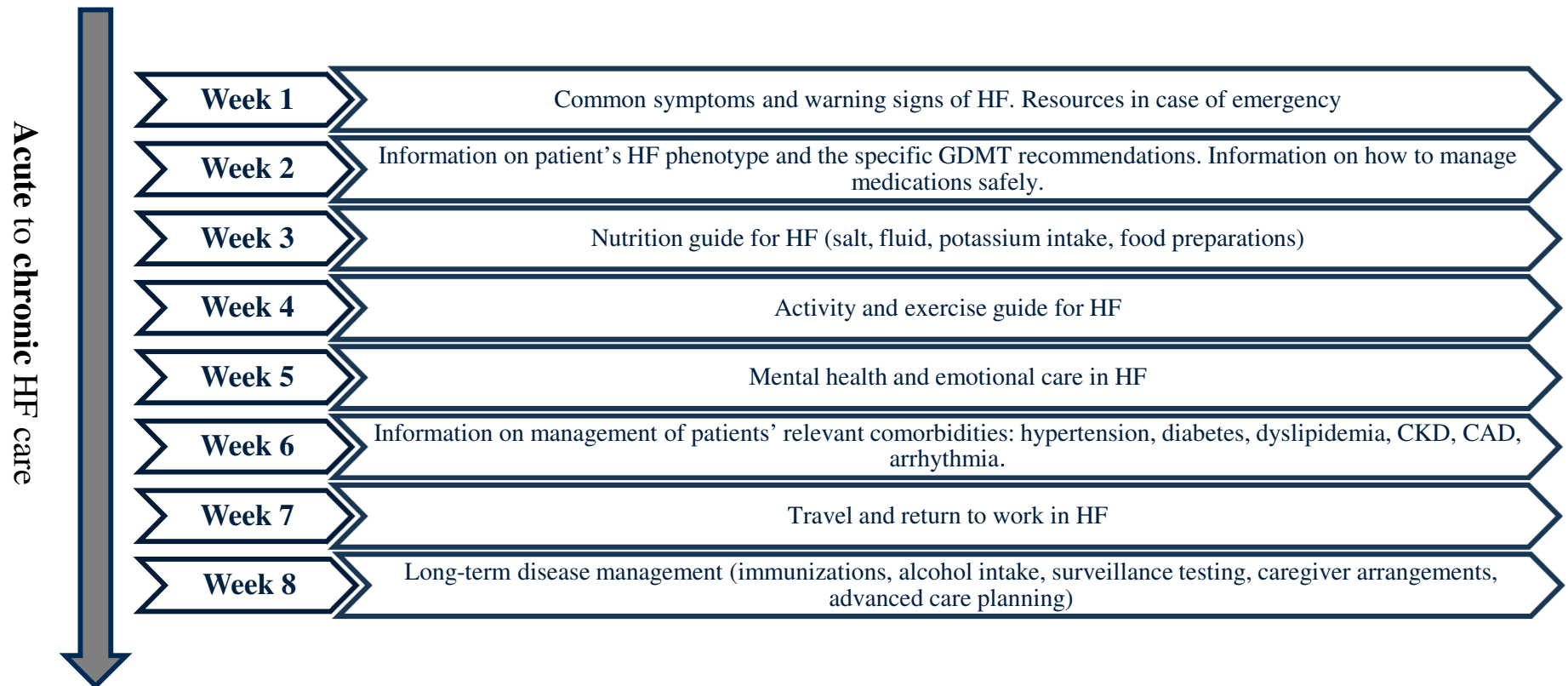
Health Check-in and Vital Signs Reporting



- ConVIScope, an AI program focused health conversation analytics and visualization tool will be tested. This will use NLP to examine patient-provider text message conversations, can train the underlying ML models to learn from previous patient responses, enabling effective conversation streamlining and triaging.

HF Education

- Weekly targeted educational resources sent as a link to a PDF file
- Earlier post discharge content will focus on common symptoms, warning signs, and the 'Heart Failure zones' to reduce readmission risk
- Later messages will introduce chronic disease management including understanding and living with HF, diet, exercise, mental health, and comorbidities



Text message frequency



A) very low and low risk patients (EFFECT score ≤ 90)

	Month 1				Month 2	Month 3	Month 4	Month 5	Month 6
	Week 1	Week 2	Week 3	Week 4					
Health check in	Daily	Weekly	Weekly	Weekly	Biweekly	Biweekly	Biweekly	Biweekly	Biweekly
Vital sign monitoring	Daily	Weekly	Weekly	Weekly	Biweekly	Biweekly	Biweekly	Biweekly	Biweekly
HF education	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly			
GDMT reminder	Monthly				Monthly	Monthly	Monthly	Monthly	Monthly

B) intermediate and high risk patients (EFFECT score > 90)

	Month 1*				Month 2	Month 3	Month 4	Month 5	Month 6
	Week 1	Week 2	Week 3	Week 4					
Health check in	Daily	Daily	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly
Vital sign monitoring	Daily	Daily	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly
HF education	Weekly	Weekly	Weekly	Weekly	Weekly	Weekly			
GDMT reminder	Monthly				Monthly	Monthly	Monthly	Monthly	Monthly

Other Features

- Proxy and multi-enrolment
- Multi-language support
- Closed loop provider response



Primary Outcomes

- Feasibility outcomes



	Measurement	Target	Threshold
Recruitment	Patients per month per site(s)	>4.0	>2.8 (70%)
Withdrawal of consent	Percent of patients recruited, categorized as withdrawal of consent to 1) intervention, 2) follow-up, 3) any follow-up including via medical/death records ³⁷	<5%	<10%
Loss to follow-up	Categorized as loss to follow-up for 1) primary end point, or 2) vital status only ³⁶	<5%	<10%
Adherence	Percent of patients with at least 70% response rate to text messages (i.e., per patient not per message definition) ¹³	>90%	>80%
Provider/Patient acceptability	Focus groups and qualitative interviews with patients and providers including evaluation of clinical workflows	n/a	n/a

Secondary Outcomes

- **KCCQ-DAOH:** Health status adjusted days alive and out of hospital (DAOH) at 180 days following discharge from hospital. DAOH will be weighted by a HF disease specific health status instrument, the Kansas City Cardiomyopathy Questionnaire (KCCQ).
- **DAOH and percent DAOH**
- **Generic and disease specific health-related quality of life**
- **Self-care**



Domain	Questionnaire	Minutes to complete
Generic health status	<u>Euroqol 5D (EQ-5D)</u> ⁴¹	3 minutes
Disease specific health status	Kansas City Cardiomyopathy Questionnaire	4-6 minutes
Self-care management	Self-Care Heart Failure Index (SCHFI) ⁴²	3 minutes
HF Knowledge	Dutch HF knowledge scale ⁴³	3-5 minutes

- **Medication Adherence:** Assessed at 90- and 180-days post-discharge using Pharmanet outpatient dispensing records, quantified as proportion of days covered (PDC; total days of medication supplied divided by follow-up duration), and medication possession ratio (MPR; total days of medication supplied divided by the total number of days between the first and last prescription refill during this period)

Team members

- **Dr. Nima Moghaddam** (nominated principal applicant)
- **Dr. Nathaniel Hawkins** (Co-principal applicant)
- **Dr. Kathryn Armstrong** (led WelTel implementation in BCCH transplant clinic)
- **Marc Bains** (founder of the HeartLife foundation) and Co-Principal Investigator of the Canadian Heart Function Alliance.
- **Dr. Justin Ezekowitz** (University of Alberta)
- **Dr. Kendall Ho** (Director of UBC Digital Emergency Medicine)
- **Dr. Richard Lester** (co-founder of WelTel Incorporated)
- **Dr. Jean Rouleau** (Co-PI of the Canadian Heart Function Alliance).
- **Dr. Tara Sedlak**
- **Dr. Gabrielle Serafini** (CEO of WelTel Health).
- **Dr. Abhinav Sharma** (McGill University)
- **Dr. Nicholas Schnee**
- **Dr. Penny Tam** (co-investigator of the WelTel H2Home trial).
- **Dr. Sean Virani**



Anticipated Results and Future Plans

- To demonstrate feasible recruitment, test and refine all major components of a future main trial, gather sufficient data to estimate sample size, and plan analyses
- Progression to future larger trial
- Scaling WelTel for HF
- Impact on patient care
- Integration into existing clinical workflows
- Collaboration between Canadian HF community
- Pragmatic equity design
- Equity, Diversity and Inclusion (EDI)



Thank you

- **Dr. Nat Hawkins**
- **Andrea Chee**
- **Constance Bos**





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QUESTIONS?