



Supporting Information

Supplementary methods and results

This appendix was part of the submitted manuscript and has been peer reviewed.
It is posted as supplied by the authors.

Appendix to: Stewart S, Patel SK, Lancefield TF, et al. Promoting resilience to weather-related and seasonal provocations to health in people with multimorbid heart disease: a prospective pragmatic, randomised trial. *Med J Aust* 2025; doi: 10.5694/mja2.52699.

Supplementary methods

1. REsilience to Seasonal ILlness and Increased Emergency admissionNs CarE: The RESILIENCE Trial. Statistical Analysis Plan, version 2.3: 1 September 2024



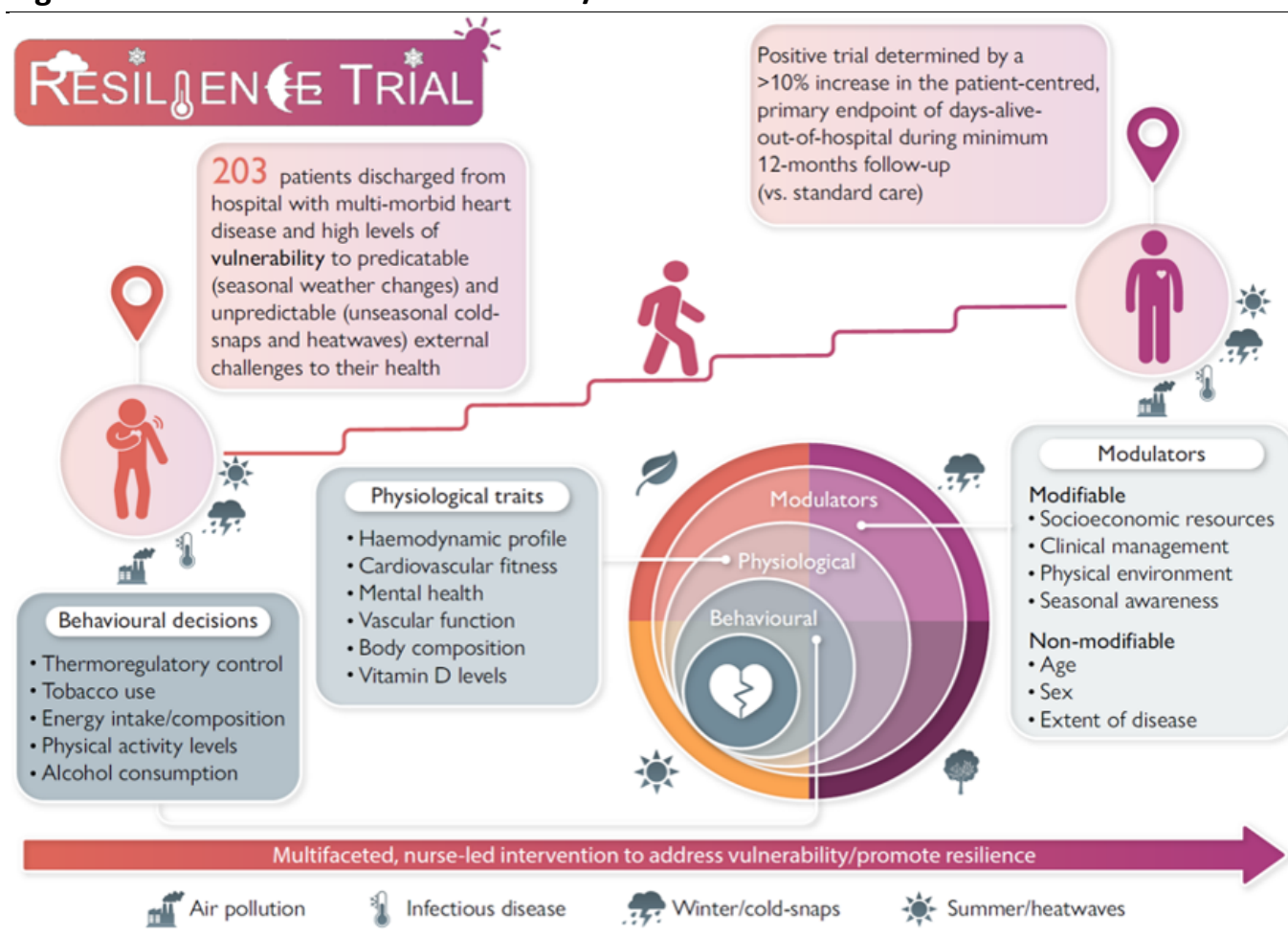
REsilience to Seasonal ILlness and Increased Emergency admissioNs CarE: The RESILIENCE Trial

Statistical Analysis Plan

Version 2.3: 1st September 2024

Brief Introduction. Despite a range of evidence-based programs to identify high-risk patients and apply strategies to keep them out of hospital, a growing number of cases are "resistant" to such programs. These "seasonal frequent flyers" routinely overwhelm hospital services. Numerous surveillance studies have revealed "peaks" and "troughs" in cardiovascular event rates worldwide.¹ Concerningly, the threat of a combination of currently predictable (i.e. the onset of winter¹ or even Christmas²) and unpredictable (i.e. extreme heat waves³) provocations to cardiovascular health will grow as climate change generates more weather extremes and makes many traditional adaptations to the climate redundant.⁴ Those most vulnerable to this complex phenomenon (with peak event rates rising by 10-20%) include older women and those living with multimorbid heart disease. From this research, the investigators have identified vulnerability to provocation of seasonal and acute weather changes ("seasonality") as a major driver of preventable/costly hospitalisations in typically older patients with heart disease and multimorbidity subject to gold-standard care. They have developed the **REsilience to Seasonal Illness and Increased Emergency admissionNs CarE (RESILIENCE) Trial** that is tailored to each person and designed to assist the participants to become more "resilient" to changes in the weather (**Figure 1**).

Figure 1: RESILIENCE Trial Rationale/Theoretical Framework



Study Hypothesis. The RESILIENCE Trial is testing the hypothesis that - a specifically tailored, multifaceted intervention designed to build resilience to external provocations to health is superior to standard management alone and would significantly increase (**>10% relative difference**) in the patient-centred primary endpoint of (all-cause) **days-alive-and out-of-hospital (DAOH)** relative to standard management alone, during minimum follow up of 12 months* among individuals discharged from acute hospital care (point-of-follow-up) with multimorbid heart disease.

NB. The original hypothesis/study power was predicated on an analysis of outcomes at minimum 12-month follow-up (with completion of participant profiling – as per Case Report Forms [CRFs]). However, as Version date: 1st September 2024

subsequently reported (see reference below describing the study rationale, design and cohort characteristics), due to the profound impact of the COVID-19 pandemic, the original hypothesis was retained, but with the intention of analysing outcome data for the entirety of study follow-up (up to and including the extended study census date). **Appendix I** summarises the main changes to the study protocol in the context of the major disruptions of the COVID-19 pandemic.

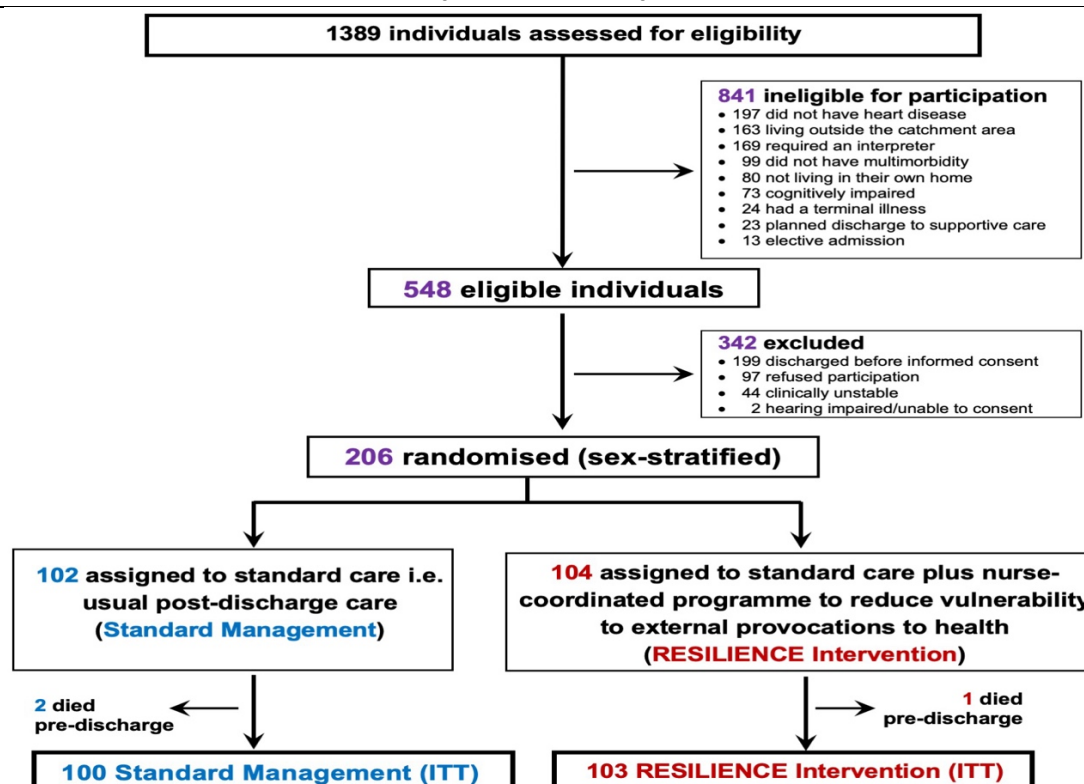
Study Design & Methods. RESILIENCE is a single-centre, prospective, open, pragmatic randomised trial with blinded endpoint acquisition and adjudication (PROBE design) trial. The study adheres to CONSORT guidelines for a pragmatic trial with adjustment of clinical management and follow-up where appropriate. While the nature of the study intervention precluded participant and health service provider blinding to its application, wherever possible data collection and analyses were obtained and adjudicated on a blinded basis. A detailed description of the rationale and study design of RESILIENCE, including study power calculations to adequately test the pre-specified hypotheses, are described in the peer-reviewed publication:

Stewart S, Patel SK, Lancefield TF, Rodrigues TS, Doumstis N, Jess A, Vaughan-Fowler ER, Chan YK, Ramchard J, Yates PA, Kwong JC, McDonald CF, Burrell LM. Vulnerability to environmental and climatic health provocations among women and men hospitalised with chronic heart disease: Insights from the RESILIENCE TRIAL cohort. *European Journal of Cardiovascular Nursing*. 2023; 23(3) 278-186.

The trial was approved by Human Research Ethics Committee of Austin Health and registered with the **ClinicalTrials.gov (NCT04614428)**. It is funded by the Medical Research Future Fund of Australia (MRF1175865). The study sponsors had no role in the conduct, analysis, and interpretation of study data.

Study Cohort. As shown in **Figure 2**, individuals aged ≥ 18 years presenting as a medical emergency for any reason and admitted to the 671-bed Austin Hospital were eligible if they had a diagnosis of chronic heart disease and multimorbidity (two or more chronic conditions requiring active clinical management), were living independently in the community post-index hospitalisation (within a 10km radius) and provided informed consent. Exclusion criteria were unable to provide informed consent (e.g., due to language barriers), living in residential aged care or with a terminal illness requiring palliative management, or died during index admission.

FIGURE 2 TRIAL COHORT/FLOW-CHART (AUGUST 2023)



Legend: ITT = intention-to-treat cohort based on randomisation

TABLE 1 BASELINE CHARACTERISTICS – INDEX ADMISSION

	All (n = 203)	Women (n = 104)	Men (n = 99)
Demographic Profile			
Age, years	75.7 ± 10.2	77.4 ± 8.7	73.8 ± 11.3
Living alone, %	79 (38.9%)	50 (48.1%)	29 (29.3%)
≤12 years education, %	124 (61.4%)	80 (76.9%)	44 (44.4%)
Non-English-speaking/cultural background, %	41 (20.4%)	23 (22.1%)	18 (18.6%)
Clinical/Risk Profile			
Hypertension	146 (71.9%)	79 (76.0%)	67 (67.7%)
Diabetes mellitus, %	84 (41.4%)	36 (34.6%)	48 (48.5%)
Smoking status, %			
Current	18 (8.9%)	7 (6.7)	11 (11.1%)
Ex-smoker	93 (45.8%)	34 (32.7)	59 (59.6%)
Alcoholic beverages/week	45 (22.2%)	12 (11.7%)	33 (33.0%)
<2 times per week	30 (14.7%)	8 (7.7%)	22 (22.2%)
3+ times per week	18 (8.9%)	5 (4.8%)	13 (13.1%)
Exercise (recommended >2.5 hours/week), %	89 (43.8%)	39 (37.9%)	50 (50.0%)
Body Mass Index (BMI), kg/m ²	29.5 ± 7.3	30.4 ± 8.1	28.5 ± 6.2
HbA1c, %	6.39 ± 1.19	6.31 ± 1.11	6.48 ± 1.26
Vitamin D level, nmol/l (median/IQR)	63.0 (40.5, 86.5)	69.0 (54.0, 91.0)	53.5 (36.7, 78.7)
Rockwood Clinical Frailty Scale Category, (0-9)	3.64 ± 1.32	3.98 ± 1.19	3.27 ± 1.35
Montreal Cognitive Assessment Score, (0-30)	25.3 ± 3.7	25.0 ± 3.9	25.5 ± 3.5
eGFR, mL/min/1.73 m ²	61.5 ± 25.7	58.6 ± 23.9	64.5 ± 27.3
HADS anxiety score (median/IQR)	4.0 (2.0, 6.0)	4.5 (3.0, 7.0)	3.0 (1.0, 6.0)
HADS depression score (median/IQR)	5.0 (3.0, 7.0)	5.0 (3.0, 7.0)	4.0 (3.0, 7.0)
Cardiovascular Disease Profile			
Coronary artery disease	115 (56.7%)	54 (51.9%)	61 (61.6%)
Heart failure	103 (50.7%)	59 (56.7%)	44 (44.4%)
Atrial fibrillation	101 (49.8%)	54 (51.9%)	47 (47.5%)
Cerebrovascular disease/stroke	37 (18.2%)	16 (15.4%)	21 (21.2%)
Valvular heart disease	50 (24.6%)	31 (29.8%)	19 (19.2%)
Other Chronic Conditions			
Renal disease/dysfunction	85 (41.9%)	39 (37.5%)	46 (46.5%)
Chronic lung disease	71 (35.5%)	38 (36.5%)	34 (34.3%)
Depression	47 (23.2%)	28 (26.9%)	19 (19.2%)
Comorbidity Profile			
Combination of HF/AF/CAD	190 (93.6%)	96 (92.3%)	94 (94.9%)
ARISE-HF profile (number/10)	4.6 ± 1.6	4.8 ± 1.5	4.4 ± 1.7
Charlson index of co-morbidity score	6.5 ± 2.7	6.4 ± 2.1	6.6 ± 3.2
Pre-Admission Symptoms			
Multiple symptoms	134 (66.0%)	75 (72.1%)	59 (59.6%)
Breathlessness	93 (45.8%)	48 (46.2%)	45 (45.5%)
Chest Pain	68 (33.5%)	37 (35.6%)	31 (31.3%)
Index Admission			
Length of stay, days (median/IQR)	6.0 (4.0, 9.0)	6.0 (4.0, 9.7)	5.0 (3.0, 9.0)
Acute episode/rapid atrial fibrillation, %	39 (19.2%)	23 (22.1%)	16 (16.2%)
Decompensated heart failure, %	65 (32.0%)	38 (36.5%)	27 (27.3%)
Unstable angina/non-ST elevation myocardial infarction	54 (26.6%)	30 (28.8%)	24 (24.2%)
ST elevation myocardial infarction	14 (6.9%)	5 (4.8%)	9 (9.1%)
Respiratory illness, %	34 (16.7%)	18 (17.3%)	16 (16.2%)
Post-Discharge Management			

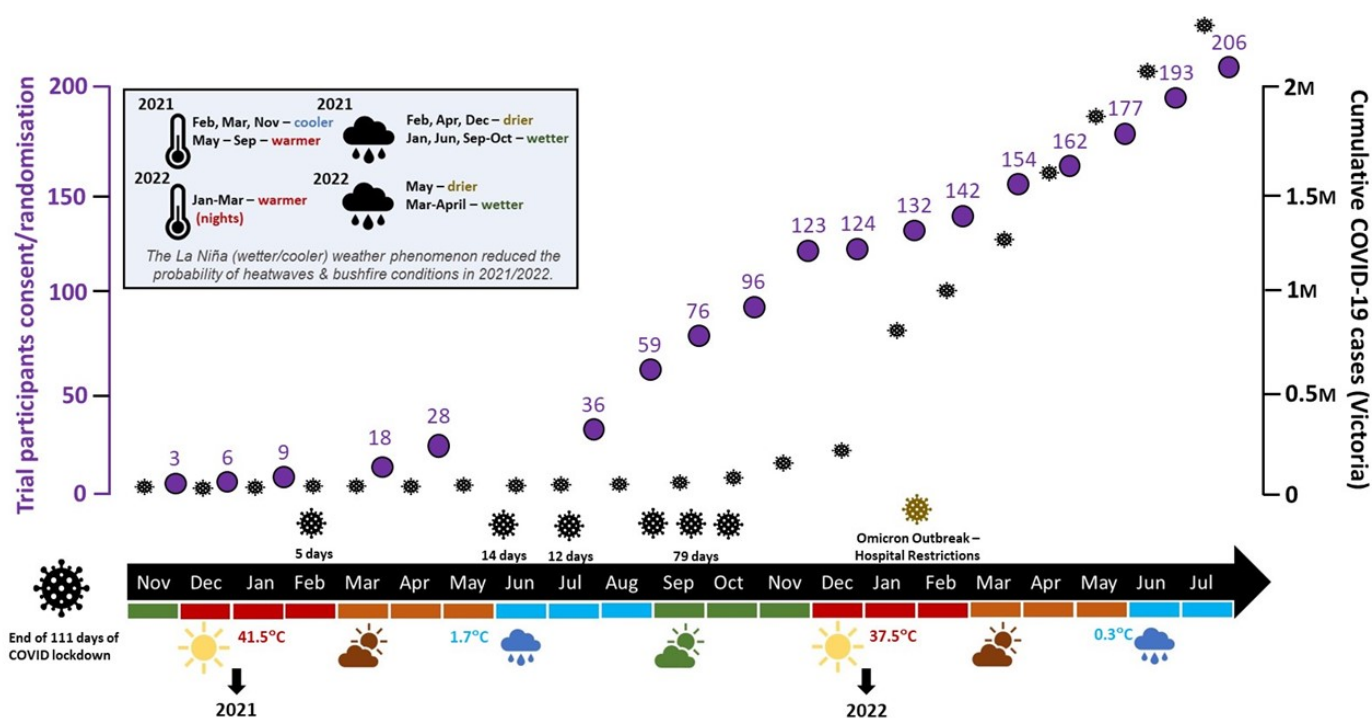
Standard care	100 (49.3%)	51 (49.0%)	49 (49.5%)
RESILIENCE Intervention Program	103 (50.7%)	53 (51.0%)	50 (50.5%)

Legend: Results are presented as mean $\pm$ SD, median (interquartile range (IQR)) or n (%). BP, blood pressure; BMI, body mass index; eGFR, estimated glomerular filtration rate; Vitamin D levels (201 cases), MoCA Score (150 cases), HbA1c (202 cases)

Table 1 (above) summarises the baseline characteristics of the finalised RESILIENCE cohort (n = 203 of the original target of 300 study participants) according to biological sex. Consistent with a representative, real-world cohort of hospitalised individuals with multimorbid heart disease, mean age was 76 ± 10 years (51% female), and more than half were reliant on public health system (56%). Clinical history was typically complex with a high proportion of participants with combination of coronary artery disease (CAD) heart failure (HF) and/or atrial fibrillation (AF).

Study Recruitment & Randomisation. Recruitment for the RESILIENCE trial commenced on November 19, 2020, with the first randomised subject being recruited on the 26th of November 2020, discharged from their index admission two days later. The last subject was recruited into the study on July 28, 2022 (a 20-month recruitment window – interrupted by numerous COVID lockdowns – see **Figure 3**).

FIGURE 3 TRIAL RECRUITMENT



<https://covidlive.com.au/report/daily-cases/vic> / <http://www.bom.gov.au/climate/current/annual/vic/summary.shtml> (Accessed Dec 2022)

A total of 206 recruited individuals were subject to a blinded, computer-generated randomised protocol implemented by an independent data management team – however, as shown in **Figure 2**, 3 individuals died during their index admission and were excluded from follow-up/analyses. Thus, the pre-determined randomisation sequence with block groups and stratified for sex, randomised participants on a 1:1 basis to the Standard Management (n=100) or Standard Management plus the RESILIENCE-Intervention (n=103).

Baseline Profiling. Trained personnel used standardised **Case Report Forms (CRFs** - see Appendix II) adapted from previous (NHMRC-funded and resulting in publications in major cardiologic and medical journals) pragmatic trials, with additional content derived from published pilot data, to comprehensively profile all trial participants using a combination of clinical records, validated tools, and structured/unstructured questionnaires. Except for those newly developed items focussing on environmental and seasonal challenges to health, nearly all CRF items had been developed and applied in previous disease management trials undertaken by our group previously.

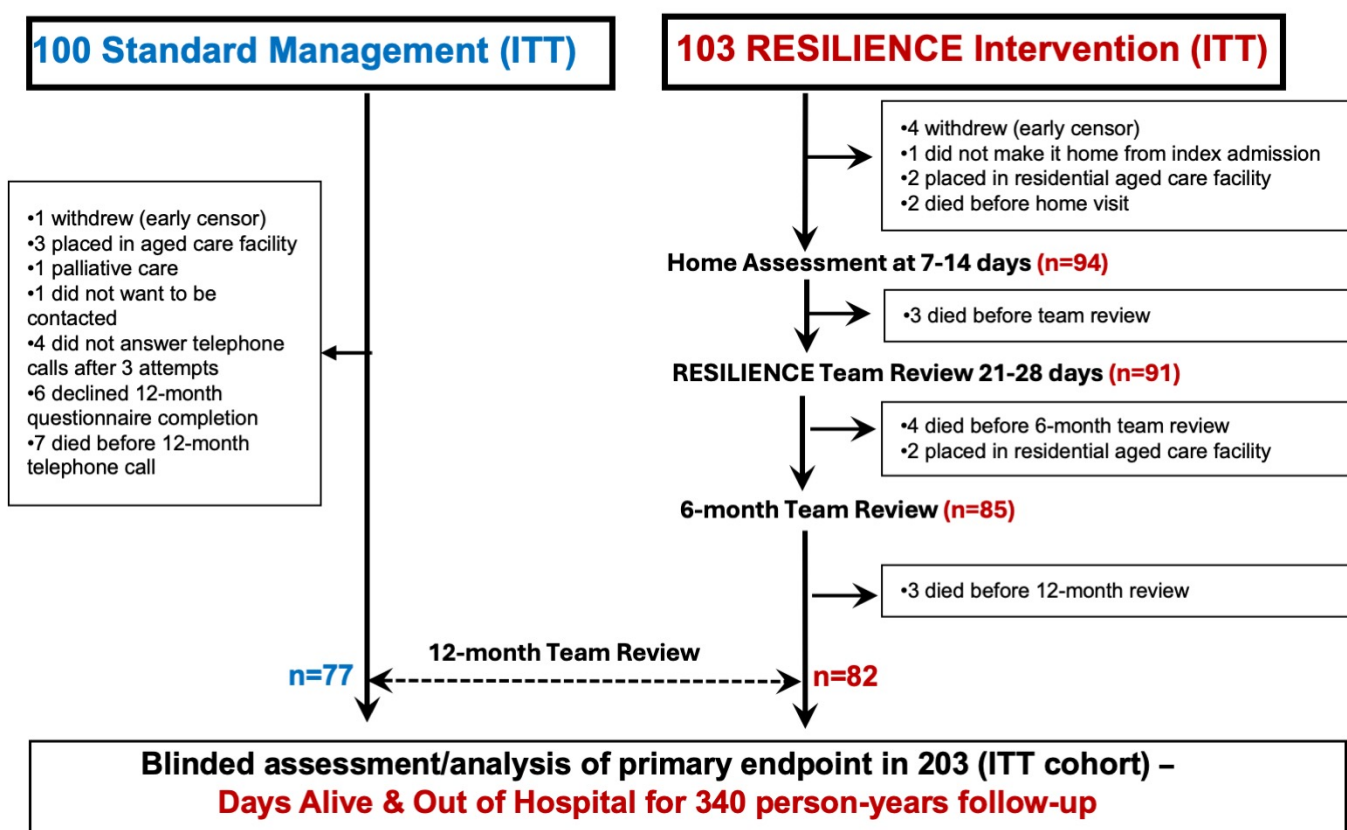
Follow-up. All surviving participants in the Intervention group were invited to a face to face formal assessment at **12 months following their index admission** to reassess their clinical status and quality of life, and a 12-month clinic appointment. The formal assessment was conducted using a combination of clinical records, validated tools, and structured/unstructured questionnaires administered by trained personnel. In Standard management, surviving patients were contacted by phone and information collected on clinical status and quality of life, including ARROL/HADS.

Figure 4 shows the original schedule of visits/assessments that were subsequently modified/truncated due to the COVID-19 pandemic (**Figure 5**). Prior to the COVID-19 epidemic the trial was powered to study a difference between groups in the primary endpoint during 12-month follow-up of 300 individuals. However, as noted in **Appendix I**, due to recruitment constraints, we revised the target of 200 trial participants with extended follow-up (Study Census 12 months following recruitment of the last participant). Accordingly, trial endpoints were collated during maximal follow-up of 626 (IQR 471 – 699) days, with actual follow-up (when considering deaths/early censor) of 606 (IQR 420 – 682) days follow-up.

Figure 4: Intended/Original Schedule of RESILIENCE Trial visits

Assessments	Timepoint	Screening/ Baseline	Home Assessment	RESILIENCE Team Review		
			7-14 days	21-28 days	6 months	12 months
Inclusion/exclusion criteria		X				
Informed Consent		X				
Randomisation		X				
Height, weight, BMI		X				R
Body temperature and blood pressure		X	R	R	R	R
Past and current medical history (including details of index admission at baseline, Charlson comorbidity index)		X				
Questionnaire (demographic profile, lifestyle factors)		X				X
Questionnaire on immunisation history and impact of COVID-19		X				X
Day before and day of admission weather information (temperature, rainfall, humidity, air quality)		X				
Cognitive Assessment (MOCA)		X				R
Questionnaire for quality of life (EQ-5D-5L), depression and anxiety (HADS, ARROL)		X				X
Pathology (HbA1c, haemoglobin, FBE, ferritin, vitamin D, serum Na and K, thyroid function, renal function, liver function)		X				R
Medications		X				X
Rockwood frailty score		X				
Handgrip strength test		X				R
Five-repetition sit to stand test		X				R
Accelerometer (GT9X-BT link bluetooth activity monitor)			R			
Home visit (self-care assessment and plan, disease awareness and education/resources, health assets index questionnaire), weather data (i.e. outdoor versus indoor temperature, humidity)			R			
RESILIENCE team review (medication management/adherence, vaccination, behavioral awareness and education, home environment support (e.g. energy subsidy referral, clothing support))				R	R	R

Key: R = RESILIENCE Intervention participants ONLY, X = both groups

Figure 5: Pattern of Follow-up at 12-months (as of August 2023)

Legend: ITT = intention-to-treat cohort based on randomisation

Study Data. All profiling and outcome data collected as part of the RESILIENCE Trial are described in a **Data Dictionary** (based on the CRFs – **Appendix II**) and collated by an independent **Data Management Team** and **Data Manager**. It will be their responsibility to prepare all outputs for trial reporting and blinded analyses by an independent **Trial Statistician**. The following components of data (including externally derived weather/climatic conditions during study follow-up), are essential to the primary and pre-specified secondary analyses of study data:

- **Clinical Profiling Data:** As per CRFs (**Appendix II**) based on well-validated instruments/profiling points used in previously published pragmatic trials.
- **Seasonal/Climatic Profiling:** As per the recently published Study Rationale/Design paper, with pre-specified areas of physiological and behavioural vulnerability derived from baseline profiling of ALL participants at their index hospitalisation - see **Figure 6** – noting that most areas of assessment were derived from well-validated instruments, with ‘poor thermoregulatory control’ based on a qualitative assessment of answers to structured questions (see CRFs) prior to group randomisation. More detailed profiling (based on home assessments where possible) were only conducted in the intervention group.

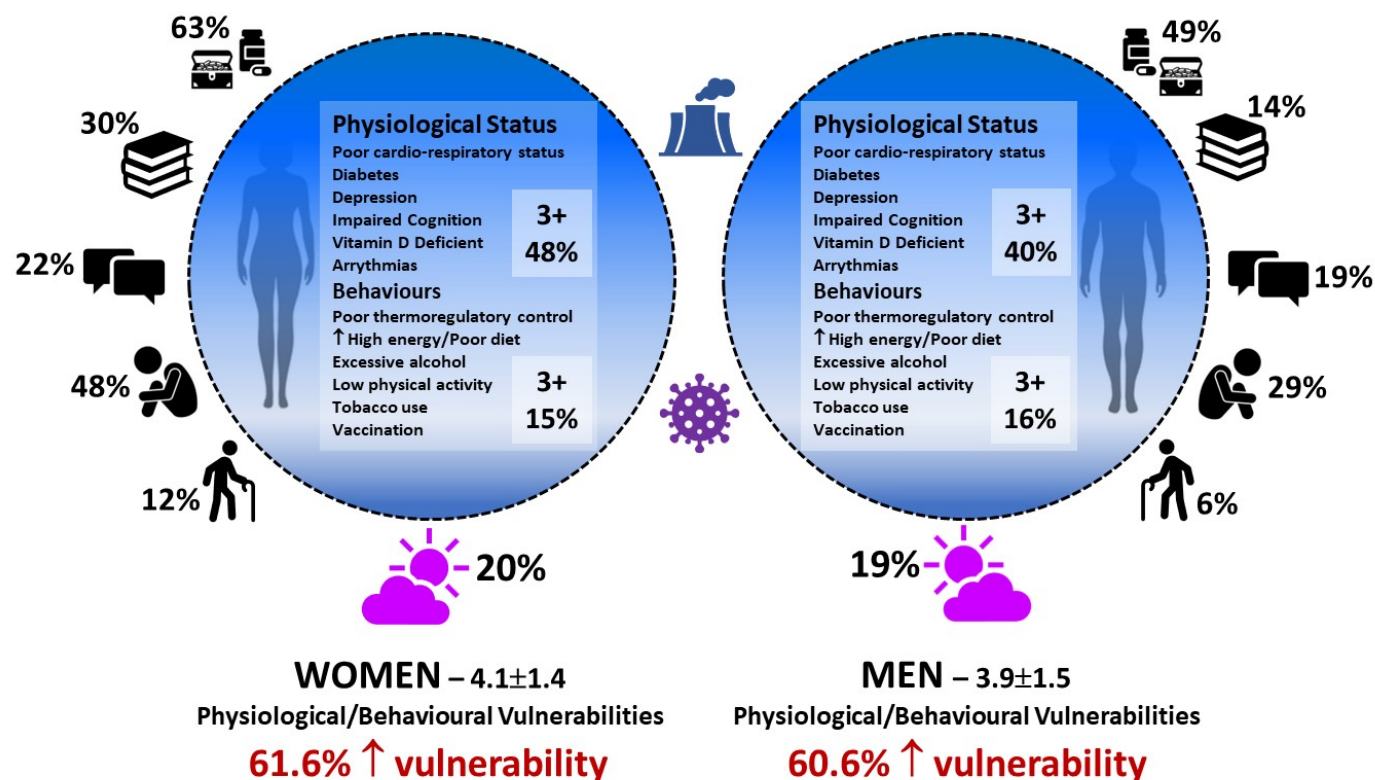


Figure 6: Pattern of Seasonal/Climatic Vulnerability at Baseline According to Sex⁶

- **Hospital Episodes/Stay:** For primary endpoint analyses (DAOH and its component parts), any hospital episode requiring an overnight hospital admission (i.e. not just an emergency presentation resulting in discharge to home) and spanning 2 calendar days for any reason, are discounted from maximal follow-up to calculate 'days out-of-hospital' (all-cause). Secondary analyses will focus on the Austin Hospital's listed cause(s) of hospital episodes during study follow-up (coded ICD-10 and diagnostic-related groupings). Days of hospital stay are calculated from the day of first admission to discharge.
- **Mortality:** For primary endpoint analyses (DAOH and its component parts), any death (all-cause) and the date it occurred post the index hospital admission will be discounted from maximal study follow-up to derive 'days alive'. Secondary analyses will focus on the listed cause(s) of death on the death certificate and whether it coincided with a readmission or otherwise (out-of-hospital).
- **Outpatient Episodes:** As part of a planned/nested health economic analysis, all outpatient visits to the Austin hospital (and where appropriate other tertiary referral hospitals) will be collated during study follow-up – *noting the severe disruptions of the pandemic truncated much of this expected healthcare activity and the investigators' ability to track/document remote contacts.*
- **Community Health Visits:** Also, as part of a planned/nested health economic analysis, all GP visits and other community-based health-related contacts (e.g. home-based pharmacy assessments and social-worker contacts) will be documented – *noting the severe disruptions of the pandemic truncated much of this expected healthcare activity and the investigators' ability to track/document remote contacts.*
- **Seasonal Climatic Transitions/Periods:** For all analyses based on the season in which study endpoints/health events of interest occurred (specifically death, hospital episode/readmission and days of readmission/hospital stay) the following definitions will apply:
 - o **Summer** – inclusive of the months of December, January and February
 - o **Autumn** – March, April and May
 - o **Winter** – June, July and August
 - o **Spring** – September, October and November

Data will also be collated on an individual monthly basis, with all comparisons (due to the varying number of days in each month and potentially different exposure days for each discrete period)

adjusting for the days in which an event/episode could occur. The periods of (contiguous) transition (Summer-Autumn, Autumn-Winter, Winter-Spring and Spring-Summer) will also be a point of focus.

- **Climatic Events:** Throughout the study period the following will be documented via the Australian Bureau of Meteorology reports/almanac data:
 - **Daily Temperatures** – with a specific focus on the conditions (minimum, maximum and temperature range) occurring within 24 hours of hospitalisation and out-of-hospital death.
 - **Humidity Levels**
 - **Air Quality Index**
 - **Significant Weather Events** – including the following:
 - **Thunderstorms**
 - **Rain**
 - **Dynamic change in temperatures (up or down by 20°C indicative of a heat or cold event) within a 24-hour to 72-hour period** – once again with a specific focus on those events occurring in proximity (within 72-hours) of a readmission or death.
 - **Presence of prevailing El Nino versus La Nina conditions**

Primary Endpoint. The primary endpoint is (all-cause) **days-alive-out-of-hospital** - defined as the proportion of maximal days follow-up where the study participant was not admitted to hospital and alive. DAOH data will be collected from hospital records by personnel blinded to group assignment. As noted above, only those hospitalisations resulting in an overnight stay in hospital (for any reason) will be counted. During minimum 12-month follow-up (fixed period extended due to COVID-19 impact of study recruitment – see **Appendix I**), the pre-specified threshold for a clinically significant effect in favour of the RESILIENCE intervention is a 10% increase in DOAH compared to standard management.

Secondary Endpoints. The individual components of DAOH, all-cause mortality and hospital stay will be examined together (as a single event-free survival outcome) and individually, along with the rate (per month of follow-up) of all-cause hospitalisation during follow-up. Additional endpoints will include change in quality of life among survivors at 12-months post index hospitalisation (EQ-5D) and the pattern of mortality, hospitalisations and events combined according to month/season and relationship to weather events. We will also examine the potential relationships/ interactions between seasonal/environmental vulnerabilities and specific intervention to address them and the subsequent pattern/timing of hospitalisation and mortality relative to climatic/weather conditions overall and within the RESILIENCE group.

Endpoint Analyses. The list below, outlines the priority of reporting trial outcomes (given the immediate availability of hospital episodes and deaths), followed by more complex analyses based on causality and climatic conditions during study follow-up:

- Days alive-out-hospital (all-cause) – *continuous variable*
- Days alive (all-cause) – *continuous variable*
- Days in hospital (all-cause) – *continuous variable*
- Event-free survival from death or hospitalisation – *time-dependent dichotomous variable (death/admission whichever comes first OR censored alive)*
- All-cause mortality – *time-dependent dichotomous variable (death OR censored alive)*
- Rate of hospitalisation/per month of follow-up – *continuous variable*
- Rate of hospital stay/per month of follow-up – *continuous variable*.
- Δ in HRQoL based on responses to the validated EQ-5D - *continuous variable prepared and analysed according to recommended methods*
- Distribution of monthly/seasonal/weather-linked events (hospitalisations and death).

If appropriate, the original timeframe of 12-months post-discharge from the index hospitalisation will be analysed, otherwise these will be analysed and reported according to the extended timeframe of follow-up (see **Appendix II**).

REPORTING STRATEGY

Two hierarchical analyses based on randomisation and then exposure to the intervention will be undertaken (in order of reporting and interpretation) in respect to the above:

1. Intention-to-Treat (ITT) based on the randomisation to Standard Management OR the RESILIENCE Intervention
2. Per-Protocol Analysis based on whether an individual was randomised to the RESILIENCE Intervention and received, at minimum, a combination of the **comprehensive home assessment plus the multidisciplinary intervention clinic** in the early phases of their post-discharge period versus those who were randomised to the RESILIENCE Intervention who did not receive/be exposed to the intervention plus those randomised to Standard Management.

The per-Protocol analysis reflects the difficulty in applying the study intervention in a timely manner during pandemic conditions.

Three additional analyses will take into consideration, including relevant strength/veracity of findings, the following (these have already reported in our index report published in the *European Journal of Cardiovascular Nursing*)

1. Outcomes according to extent of co-morbidity (as determined by the Charlson Index of Comorbidity and adapted ARISE-HF tools) and frailty (as determined by hand-grip strength and Rockwood Frailty Score).
2. Level of seasonal/environmental vulnerability according to our pre-specific model of bio-behavioural resilience and its relationship to outcomes.
3. Outcomes within the main diagnostic groups comprising the RESILIENCE cohort (>65 cases in each group)– a) CAD, b) HF, c) Renal dysfunction, d) Depression and e) Chronic pulmonary/lung disease with comparison to those without these conditions.

Additional information around each hospital episode and death will be further collated and reported. This will be based on standardised data collection (including clinical notes and hospital discharge summary), blinded adjudication will further classify hospital episodes as follows:

- Cardiovascular-related versus non-cardiovascular related hospitalisation

If an overnight hospitalisation is cardiovascular-related, each episode will be classified (via blinded adjudication) as follows:

- Heart failure-related (as per contemporary Australian guidelines)
- Acute coronary syndrome-related (specifically acute myocardial infarction [ST-segment and non-ST elevated AMI] according to ESC guidelines)
- Stroke-related (ischaemic versus haemorrhagic) according to ESC guidelines
- Falls-related (including collapse)

All recorded hospital events will be further coded using the Medical Dictionary for Regulatory Activities (MedDRA; Version 12.0).

Cause of death will be obtained from Births, Deaths and Marriages and reported according to ICD-10 categories – applying the same structure of reporting in relation to hospital episodes.

As described above, meteorological data/trends or Melbourne during the entire trial will be obtained from the Bureau of Meteorology records with weather events preceding (up to 3 days before) and occurring (within 24 hours) of any recorded event documented and used for any correlational analyses.

Original & Revised Study power. Based on our published pilot data⁵ derived from a similar cohort of individuals discharged to home following an admission for multimorbid chronic heart disease, we predicted 100 individuals randomised to Standard Care/Management would accumulate 1,500 days of hospital stay and 3,600 days of life lost (due to 20 all-cause deaths) during minimum 12-month follow-up; combined rate of 0.860 ± 0.035 days alive and out-of-hospital. Assuming a two-sided alpha of 0.05, initially, a target of 150 participants in each group provided 85% power to detect a >10% change in this outcome over 12-months follow-up (maximal 150 person-years event-free survival per group). As reported in our index report

(*European Journal of Cardiovascular Nursing*), given the unavoidable reduction in study participants (revised target of 200), we extended follow-up to a minimum of 12-month follow-up with study census (28th July 2023) established at 12 months following the last participant recruitment (28th July 2022). While this did not fully restore original study power, it does provide for maximal 170 person-years event-free survival per group. Given the lost potential of additional deaths and readmissions occurring both at the individual level (with the natural constraint of only 1 death per person) and within 12-months of initial admission, a decision was made not to recalculate study power, but to accept the revised cohort as it stood.

Statistical analyses. All study analyses will be blinded to study allocation by a **Study Statistician** who was not involved in conducting the study, acquiring data, or preparing study data for analyses/interpretation. The **Data Manager** (also independent of all other study processes) will prepare a locked, de-identified database (**Master Database** based on individual outcomes and pattern of health outcomes) for endpoint analyses based on this **Statistical Analysis Plan**. As per previous trials conducted by our group, no inferential statistics will be applied to the ITT cohort based on randomisation. Standard statistical methods for describing variables, including proportions, median (interquartile range - IQR) and means (standard deviations - $\pm$) will be applied. Between group (univariate) comparisons will be assessed by Student's t-tests (for normally distributed continuous variables), Mann Whitney U test (for non-normally distributed continuous data) and Chi-squared test (for discrete variables with calculation of odds ratios [OR] and 95% confidence intervals [CIs]) where appropriate. Consistent with previously published reports from our group, hospital data (number of events and days) will be converted to event rates (per person per month of follow-up) and, given skewed distributions, assessed using generalised linear models (e.g. a log gamma model may well provide best fit). Data will undergo transformations where appropriate, including but not limited to manipulation, normalization, attribute construction, generalization, and smoothing. Effect sizes will be reported. Cox proportional hazard models using baseline data (all participants) will be constructed to examine the independent correlates (including forced entry of age, sex and group allocation if appropriate) and the various interactions between risk factors and treatment mode as well as other potential correlates of major cardiovascular events, event-free survival and all-cause mortality during study follow-up with calculation of hazard ratios (HRs) and 95% CIs. Data will be included in the model if the univariate *P* value is <0.1 and retained (on a step-wise, backward basis) if the adjusted *P* value is <0.1 with assumption of proportional hazards confirmed. Multiple logistic regressions will be used to determine independent correlates of clinical events at fixed time-points. Consistent with focus of the RESILIENCE Trial (beyond 'if' an event occurs, but 'when' it specifically occurs), multinomial logistic regressions will be used to examine potential correlations and group differences (ITT) according to the season, month and specific weather events occurring in the 24-72 hours previously (see page 8) and the pattern/occurrence of hospital readmissions, associated length of hospital stay, and death. Likelihood ratio test and deviance goodness-of-fit test will be used to evaluate each model generated. Odd ratios and their 95% CIs will be extracted based on the significance of the *p*-values. Where appropriate, significance will be accepted at the level of $p<0.05$ (two-tailed).

Nested Health economic analyses. Depending on study outcomes (including consideration of outcomes derived from Per-Protocol and sub-group analyses), a cost-effectiveness analysis will be conducted by the *Trial Health Economist*. They will calculate the incremental costs per quality-adjusted life year (QALY) gained as well as other natural outcomes (e.g. hospitalisation averted). Prospectively collated health care costs for each group will be summed and divided to calculate cost per patient-month (and patient-year). QALY will be calculated from the utility weights based on the EQ-5D-5L. Each dimension in the EQ-5D-5L has five response levels: no problems (Level 1); slight; moderate; severe; and extreme problems (Level 5). There are 3,125 possible health states defined by combining one level from each dimension, ranging from 11111 (full health) to 55555 (worst health). EQ-5D-5L health states are converted into a single index 'utility' score using a scoring algorithm based on public preferences. In this study, the UK value set and scoring algorithm were used to calculate utility scores as an Australian scoring algorithm is not yet available for the 5L. The UK algorithm was estimated using a hybrid model of preference data collected using a time-trade off (TTO) and discrete choice experiment (DCE) and potential values from this algorithm ranged from

-0.281 to 1, where values lower than 0 represent states considered to be worse than death. The instrument also includes a visual analogue scale (EQ-VAS) which provides a single global rating of self-perceived health and is scored on a 0 to 100 mm scale representing “the worst...” and “the best health you can imagine”, respectively. The evaluation will adhere to the recommendations of the Washington Panel on Cost-Effectiveness in Health and Medicine.

Conclusions – To our knowledge, the RESILIENCE Trial is testing the impact of a unique intervention focussed on determining who is most vulnerable to external challenges to their health and then promoting bio-behavioural “resilience” to both expected (seasonal changes in the climate) and unpredictable (sudden heatwaves or cold-snaps) provocations. Success (in establishing greater resilience) will be measured in two ways – 1) more days alive and out of hospital overall (a traditional way of totalling all events) and 2) a potential shift in the pattern of events when exposed to provocative times of the year – it is this component of “when and why” events occur that differentiate RESILIENCE from many other disease management trials. Our aim is to provide definitive evidence that our innovative, individually tailored, interventional health care program designed to address the debilitating, costly and deadly phenomenon of seasonal vulnerability in a growing number of individuals admitted to hospital with multimorbid chronic heart disease is cost-effective. Given the circumstances (a once in a generation pandemic that impacted study recruitment and therefore study power) it is possible that further studies will be required.

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APPENDIX I – SUMMARY OF PROTOCOL AMENDMENTS DUE TO COVID-19

Original Protocol. The original RESILIENCE Trial protocol was finalised on the 18th of July 2019 (prior to the onset of the subsequent COVID-19 pandemic). It was co-authored by Professors Louise Burrell and Simon Stewart (Co-Principal Investigators), the study coordinator (Dr Sheila Patel) and with expert input from Professor Christine McDonald (respiratory medicine), Dr Jason Kwong (infectious diseases), Dr Paul Yates (aged care) and Dr Jay Ramchand (cardiology). Relevant to the subsequent conduct and reporting of its primary outcomes, the following represents the key components of this prospectively planned and conducted study that were most impacted by the disruptions imposed by the pandemic (noting additional changes in the pattern of profiling post the index hospitalisation and how community-based health care pivoted towards a ‘telehealth/remote’ approach):

1. **Study Recruitment Window:** ‘Eligible participants will be recruited (from the Austin Hospital) during a 15-month study period (ideally incorporating 2 winter periods seasons of hospital activity).’
2. **RESILIENCE Intervention:** ‘A formal home environment assessment including presence/type of heating and/or cooling equipment, air quality (e.g. passive smoke) and any other factors that might contribute to seasonal instability (e.g. lack of home insulation, large garden requiring upkeep, caring for young children). Indoor versus outdoor temperature and humidity will also be measured.’ AND ‘All participants and their significant others/carers will be invited to attend (participants with the capacity for videoconferencing will be offered “virtual/remote” attendance or a standard outpatient clinic appointment) a clinic review around 14-days post-discharge by the RESILIENCE physician and nurse to review the team’s findings and individual recommendations.’
3. **Primary Endpoint:** The original primary endpoint was based on minimum 12-month follow-up of 300 patients, with comparisons made at the all-important 12-month timeframe, as follows – ‘The primary endpoint (all-cause DAOH) for this study is being increasingly used in clinical trials (including our own) because it truly reflects the *patient journey*, adjusts for potential differences in survival/follow-up and requires fewer participants (i.e. trial efficiency) to validate a healthcare intervention. With no adjudication required, this endpoint is easily calculated from the maximal number of event-free days follow-up versus the actual number achieved by each participant [Example: 20 days of hospitalisation and died on day 100 of 365 days follow-up equates to 80/365 (0.219) DAOH].’
4. **Study Power (based on the original Primary Endpoint):** The original assumptions were based on published pilot data

Loader J, Chan YK, Hawley J, Moholdt T, McDonald CF, Jhund P, Petrie MC, McMurray JJ, Scuffham PA, Ramchand J, Burrell LM, Stewart S. Prevalence and profile of “seasonal frequent flyers” with chronic heart disease: Analysis of 1598 patients and 4588 patient-years follow-up. *International Journal of Cardiology*: 2019. 20(6):906-920.

As described in the original study protocol and summarised in this *Statistical Analysis Plan* - ‘Based on a “best-case” scenario (i.e. exposure to high-level care) per 100 SC (*standard care*) patients, subject to 12-month follow-up, a total of 300 all-cause readmissions (pilot study rate 6.6 ± 3.4 /patient) associated with 1,500 days of hospital stay (pilot study rate 40.3 ± 34.7 days) and 20 all-cause deaths associated with 3,600 days (180 days per fatality) will occur; combined DAOH (days-alive and out-of-hospital) rate of 0.860 ± 0.035 .’ AND the following power calculations – ‘To conservatively adjust for a wider variance of DAOH (SD 0.040) in the trial, as shown on left, 300 patients (150 in each group) will provide >85% study power (2-sided alpha) to detect a >10% change in DAOH; the selection of high-risk/-cost patients making this an efficient trial. If the variance in DAOH resembles that of the pilot study >260 patients will provide >90% study power to detect a >10% change in DAOH. Sensitivity analyses of the operational characteristics of study power (80% to 90%) relative to the minimum expected interventional effect on, and *variance* in DAOH, show that the target of 300 patients is most likely to adequately address the study hypothesis, even if non-parametric analyses need to be applied.’

COVID-19 Adapted Protocol. As explicitly described in the following publication (describing the key features of the study protocol and intended impact of the RESILIENCE Intervention) –

Stewart S, Patel SK, Lancefield TF, Rodrigues TS, Doumstis N, Jess A, et al. (Burrell L). Vulnerability to environmental and climatic health provocations among women and men hospitalised with chronic heart disease: Insights from the RESILIENCE TRIAL cohort. *European Journal of Cardiovascular Nursing*. 2023. 10.1093/eurjcn/zvad076

the COVID-19 pandemic severely disrupted the study in the following ways, relative to the key aspects of the original study protocol, highlighted above:

- 1. Study Recruitment Window:** Actual recruitment occurred in five non-contiguous phases with the ‘ideal’ season for recruitment (winter) under-represented and capacity to recruit even when it was possible to so (noting that hospital restrictions differed from those impose at the community level), severely disrupted.

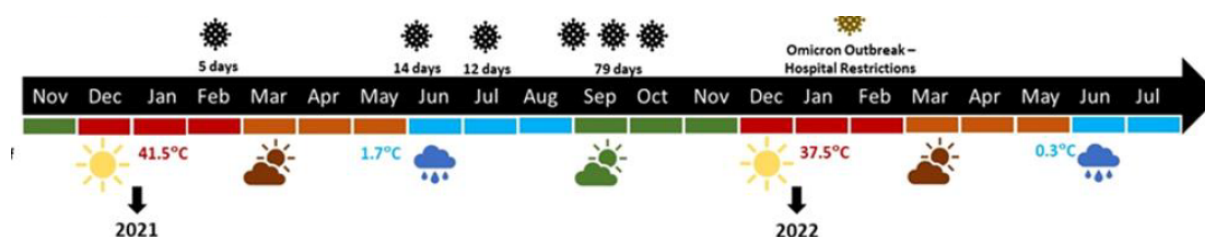


Figure 1. Pattern of COVID-19 lockdowns/restrictions on study recruitment

Consequences: Within the funding and timing framework, it was impossible to recruit the pre-specified target of 300 eligible participants. This severely impacted study power and the possibility of observing group differences given that days lost to death represents a major component of DAOH and the first 12-months following the index hospitalisation are when most events occur. Thus, increasing the follow-up time beyond 12 months, in 100 fewer patients could not restore study power and we refrained from recalculating this. Moreover, participants were recruited in non-contiguous seasons/climatic conditions, with the increased possibility of group differences given that ‘clusters’ of group randomisation at certain times of the year would skew the characteristics of those randomised into a particular group. This subsequently impacted on the exposure of study participants to subsequent seasons/climatic conditions.

- 2. RESILIENCE Intervention:** Most patients (73/103) allocated to the Intervention group received a face to face home visit (a critical component for improving health outcomes in people hospitalised with chronic forms of heart disease – see reference below), and 21/103 had a virtual home visit if the RESILIENCE Nurse was unable to enter the patient’s home and apply the full intended protocol of assessment and individualised support due to Victorian Government COVID-19 restrictions. Moreover, the capacity to organise and deliver follow-up community-based health care support was also limited by COVID-19 restrictions (the population of Melbourne being one of the most severely restricted peoples in the world in this regard).

Stewart S, Wiley JF, Ball J, Chan YK, Ahamed Y, Thompson DR, Carrington MJ. Impact of Nurse-Led, Multidisciplinary Home-Based Intervention on Event-Free Survival Across the Spectrum of Chronic Heart Disease: Composite Analysis of Health Outcomes in 1226 Patients From 3 Randomized Trials. *Circulation*. 2016;133(19):1867-77.

Consequences: Ongoing COVID-19 as well as hospital imposed restrictions effectively meant that the expected proportion of ‘face-to-face’ versus ‘remote’ clinic interventions/ discussions was reversed – with more non face-to-face consultations occurring. These changes were likely to have ‘degraded’ the potential impact of the study intervention given the loss of personalised care based on a full assessment of each participant’s personal circumstances and expressed needs – both within the first few months of the index admission and the critical time-period (12 months) of the pre-specified management period to mitigate any vulnerability to climatic conditions.

- 3. Study Endpoints:** As noted above, the original plan was to recruit a minimum of 300 patients in whom 12 months follow-up was completed for the analysis of the primary endpoint (DAOH) and key secondary endpoints including the pattern of recurrent hospitalisation and stay (with a major focus on the timing of events according to climatic conditions). This equated to **300 person-years/~110,000 days maximal follow-up**. However, given the actual recruitment of two-thirds of the original recruitment target, a decision was made to extend the months of follow-up of study participants in which endpoint events

(deaths and hospital events/stay) beyond 12 months (the original timeframe for endpoint analyses) to the study census date, whereby the last patient recruited completed minimum 12-month follow-up.

Consequences: The overall time-frame in which post-index hospitalisation events (recurrent hospitalisation/stay) and/or deaths could occur was more than restored (from ~110,000 days to ~125,000 days). However, this was based on deaths occurring beyond 12 months in a smaller subset of patients and concurrently, the potential for more readmissions in those patients who survived beyond 12 months and recruited earlier in the study (the same patients in whom COVID-19 restrictions were at their greatest and most likely to influence the implementation of the study intervention). Overall, exposure to the critical period of 12-months following the index admission was reduced to **200 person-years**.

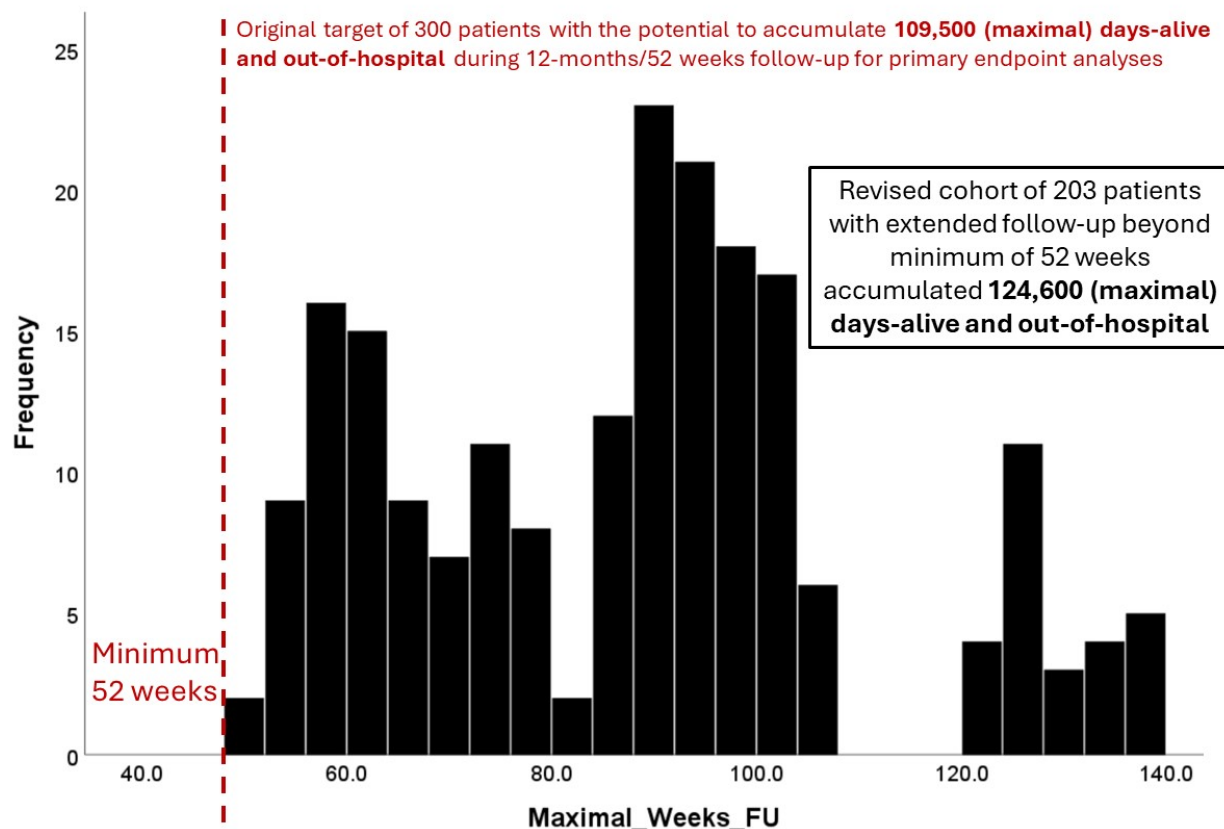


Figure 2. Pattern of maximal follow-up of the RESILIENCE cohort based on extended timeframe for primary and secondary endpoints.

- 4. Study Power:** As noted above, in extending the timeframe in which endpoints could occur (from a fixed time-point of 12 months to minimum 12-months to the study census date) some study power was restored - noting no formal re-calculations were made in this respect given the additional complications of differential timing of recruitment and exposures to climatic conditions during extended follow-up. This 'correction' was documented as follows on clinical.trial.gov (

Due to the impact of the COVID epidemic (with extensive lockdowns in Melbourne, Victoria and clinical restrictions at the Austin Hospital), a reduced study cohort was recruited (203 of planned 300 eligible and randomised participants) with follow-up extended beyond 12 months to (partially) restore study power to examine the potential impact of the study intervention on the same health outcomes.
<https://clinicaltrials.gov/study/NCT04614428>

Consequences: Despite the restoration of study follow-up and therefore partial restoration of study power, it was impossible for the extended follow-up of 203 patients (with the potential for 40 deaths if a mortality rate of 20% occurred) to fully adjust for the original target of 300 patients with complete 12-month follow-up, in whom there was potential for 54 deaths and a greater proportion of time lost to 'days alive' if a lesser mortality rate of 18% occurred.

APPENDIX II – CASE REPORT FORMS



CASE REPORT FORMS

NB: Using black or blue ball point pen, legibly print written responses using capital letters on the CRF forms.



Form 1 Baseline Eligibility



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Must meet ALL the following pre-selection criteria:

1. Age ≥ 18 years
2. Able to converse in English
3. Able to give consent
4. Be living at a private residence (*i.e. not residential care/SRS*) with plan for discharge back to pre-admission accommodation (*within a 10km radius of the hospital*)
5. Not in a terminal phase of illness
6. Presenting as a medical emergency for any reason (not necessarily for heart disease)

AND

A Have **chronic heart disease**

PLUS

B Have **multimorbidity** defined as **two** or more chronic conditions requiring active management

ELIGIBILITY CRITERIA		Yes	No
A	1. Coronary Artery Disease (<i>angina; ACS/AMI; CABG; coronary artery stent</i>)	1 ☐	0 ☐
	2. Heart failure	1 ☐	0 ☐
	3. Atrial fibrillation or atrial flutter	1 ☐	0 ☐
	4. Other arrhythmia	1 ☐	0 ☐
	5. Valvular disease (<i>including valve replacement or TAVI</i>)	1 ☐	0 ☐
	6. Cerebrovascular disease (<i>stroke, TIA, carotid endarterectomy etc</i>)	1 ☐	0 ☐
	7. Arterial disease (<i>peripheral vascular disease, aneurysm</i>)	1 ☐	0 ☐
	8. Hypertension	1 ☐	0 ☐
	9. Diabetes (<i>not including gestational</i>)	1 ☐	0 ☐
	10. Kidney disease	1 ☐	0 ☐
B	11. Chronic respiratory disease (<i>COPD, asthma, bronchiectasis etc</i>)	1 ☐	0 ☐
	12. Thyroid disease	1 ☐	0 ☐
	13. Obstructive sleep apnoea	1 ☐	0 ☐
	14. Depression or anxiety	1 ☐	0 ☐
	15. Musculoskeletal disease (<i>rheumatoid arthritis, osteoporosis etc</i>)	1 ☐	0 ☐
	16. Other serious chronic conditions	1 ☐	0 ☐
Please specify _____			

Form 1 Baseline Eligibility



Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Eligibility Comments

Is the patient eligible against the criteria :

1 ☐ Yes

0 ☐ No

Does the patient want to participate in the study:

1 ☐ Yes

0 ☐ No

Consent form completed

1 ☐ Yes

0 ☐ No

Consent form date enrolled

 / /

Telehealth questions

1. Are you experienced with telehealth?

1 ☐ Yes

0 ☐ No

2. Do you have technology available for telehealth appointments?

1 ☐ Yes

0 ☐ No

If 'yes' tick all that apply

a. Smart Phone

1 ☐ Yes

0 ☐ No

b. Tablet

1 ☐ Yes

0 ☐ No

c. Laptop

1 ☐ Yes

0 ☐ No

d. Computer

1 ☐ Yes

0 ☐ No

3. Have you downloaded the COVID Safe App?

1 ☐ Yes

0 ☐ No

4. Do you have any other apps related to information on COVID-19

1 ☐ Yes

0 ☐ No

5. If No, Why?



Form 2 Baseline Participant Details Form



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

UR #

Date / /

Date of admission / /

Time of admission (24h)

Group Randomisation

- 1 ☐ Standard Care
2 ☐ Resilience Intervention

CONTACT DETAILS

Title 1 ☐ Mr 2 ☐ Mrs 3 ☐ Ms 4 ☐ Other _____

First name Middle initial

Surname

Preferred name

DOB / / Age Sex 0 ☐ Male 1 ☐ Female

Street Address

Suburb

State Postcode

Home ph no ()

Mobile ph no

Email address
Please print clearly _____

NEXT OF KIN

First name

Surname

Relationship to participant
(e.g. daughter, husband)

Home ph no ()

Mobile ph no

Subject #

--	--	--	--	--

 Subject Initials

--	--	--

HEALTH CARE TEAM

[illegible]

1 ☐ Yes 0 ☐ No

Please complete Additional GP Form

First name																													
Surname																													
Specialisation	1 ☐ General Physician 2 ☐ Cardiologist 3 ☐ Aged Care Physician 4 ☐ Other (please specify) _____																												
Practice																													
Street Address																													
Suburb																													
State				Postcode																									
Phone no	()														Fax no	()													

Form 2 Baseline



Previous Medical History & Index Hospitalisation

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

IMMUNISATION HISTORY

Influenza

1 ☐ Yes

0 ☐ No

Date MM/YYYY

 /

Pneumovax

1 ☐ Yes

0 ☐ No

Date MM/YYYY

 /

Shingles

1 ☐ Yes

0 ☐ No

Date MM/YYYY

 /

COVID 19

1 ☐ Yes

0 ☐ No

2 ☐ N/A

Date MM/YYYY

 /

(Date of most recent dose)

CHARLSON INDEX OF COMORBIDITY

	No	Yes		No	Yes
Myocardial Infarct	0 ☐	1 ☐	Hemiplegia	0 ☐	1 ☐
Congestive Heart Failure	0 ☐	1 ☐	Moderate / Severe Renal Disease	0 ☐	1 ☐
Peripheral Vascular Disease	0 ☐	1 ☐	Diabetes with End Organ Damage	0 ☐	1 ☐
Cerebrovascular Disease	0 ☐	1 ☐	Any Tumour	0 ☐	1 ☐
Dementia	0 ☐	1 ☐	Leukemia	0 ☐	1 ☐
Chronic Pulmonary Disease	0 ☐	1 ☐	Lymphoma	0 ☐	1 ☐
Connective Tissue Disease	0 ☐	1 ☐	Moderate / Severe Liver Disease	0 ☐	1 ☐
Ulcer Disease	0 ☐	1 ☐	Metastatic Tumour	0 ☐	1 ☐
Mild Liver Disease	0 ☐	1 ☐	AIDS	0 ☐	1 ☐
Diabetes	0 ☐	1 ☐			

CLINICAL PROFILE

Date

 / /

Blood pressure:

 / mmHg

Heart rate:

 bpm

 / mmHg

Heart rate:

 bpm

 / mmHg

Heart rate:

 bpm

Body Temperature

 . °C

Form 2 Baseline



Previous Medical History & Index Hospitalisation

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

IMPACT OF CORONAVIRUS PANDEMIC

1. Did you ever develop symptoms of Covid-19?

¹ ☐ Yes

⁰ ☐ No

A) Did you seek medical advice for this?

¹ ☐ Yes

⁰ ☐ No

B) Did you find it easy to obtain medical advice for this?

¹ ☐ Yes

⁰ ☐ No

2. Have you ever been tested for Covid-19?

¹ ☐ Yes

⁰ ☐ No

A) If yes, what was the test result

¹ ☐ Positive

⁰ ☐ Negative

B) Did you present to an emergency department due to Covid-19 symptoms?

¹ ☐ Yes

⁰ ☐ No

C) Did you require a hospital admission for the treatment of Covid-19 symptoms

¹ ☐ Yes

⁰ ☐ No



Which hospital? _____

3. Have you ever been diagnosed or had close contact with someone diagnosed with COVID-19, and been required to self-isolate?

¹ ☐ Yes

⁰ ☐ No

If yes, date

 / /

A) If yes, who?

Myself

¹ ☐

Spouse/partner

² ☐

Other family member (same household)

³ ☐

Other family member (different household)

⁴ ☐

Carer

⁵ ☐

Colleague

⁶ ☐

Friend

⁷ ☐

Neighbour

⁸ ☐

Other

⁹ ☐

4. Did you need any extra help during 'lockdown' e.g. with groceries, medical supplies etc.?

¹ ☐ Yes

⁰ ☐ No

A) If yes, who helped you?

Friends

¹ ☐

Pre-existing support eg carers

⁴ ☐

Family

² ☐

New support (started in lockdown)

⁵ ☐

Neighbours

³ ☐

Other

⁶ ☐

5. If you needed to be quarantined or isolated at home for two weeks due to Covid-19, would you need additional help on top of what you already have? (eg from family, friends, healthcare providers).

¹ ☐ Yes

⁰ ☐ No

Form 2 Baseline



Previous Medical History & Index Hospitalisation

Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

PREVIOUS EVIDENCE OF SEASONALITY

A. Is this the first time the participant has been admitted primarily for cardiac disease? 1 ☐ Yes 0 ☐ No

B. When was the participant first diagnosed with cardiac disease? MM/YYYY /

Time since diagnosis: years months

C. Dates of admissions:

Date of discharge:

Discharge Unit

Season

Previous 12 months only

/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		
/ /	/ /		

D. If 3 or more admissions in the past 12 months,
>45% hospital stay in one season?

0 ☐ No

1 ☐ Yes

1 ☐ Summer

(December, January, February)

3 ☐ Winter

(June, July, August)

2 ☐ Spring

(September, October, November)

4 ☐ Autumn

(March, April, May)

Office use only

Subject # Subject Initials

PREVIOUS EVIDENCE OF SEASONALITY

Questions for participant:

1. Do you remember the weather in the days leading up to this hospital admission? 1 ☐ Yes 0 ☐ No
2. What do you remember about the weather on those days? _____

3. What did you do the day before and day of admission (eg gardening, visiting friends)? _____

4. Do you feel the weather affects your health? If so, how? _____

SEASONALITY INFORMATION

Day before admission

Minimum Temperature . °C Maximum Temperature . °C

Rainfall mm Relative humidity 9am % 3pm %

Average Air Quality Index } (b)

} (a)

Day of admission (unless admission time before 0900)

Minimum Temperature . °C Maximum Temperature . °C

Rainfall mm Relative humidity 9am % 3pm %

Average Air Quality Index } (b)

} (a)

(a) <http://www.bom.gov.au/climate/data/index.shtml>(b) <https://aqicn.org/city/australia/melbourne/melbourne-cbd/>

Form 2 Baseline

Previous Medical History & Index Hospitalisation



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

PRE-ADMISSION PROFILE

Please ask the participant if they experienced the following symptoms prior to admission. If yes, please check box and document duration of symptoms in days.

		Days			Days
1	☐ Abdominal pain		11	☐ Haematemesis, melaena	
2	☐ Back pain		12	☐ Headache	
3	☐ Breathless		13	☐ Limb pain/swelling	
4	☐ Chest pain		14	☐ Palpitations	
5	☐ Confusion/delirium/behaviour disturbance		15	☐ Rash	
6	☐ Cough		16	☐ Nausea and vomiting	
7	☐ Diarrhoea		17	☐ Weakness/paralysis	
8	☐ Falls		18	☐ Urinary symptoms	
9	☐ Fever		19	☐ Joint pain/swelling	
10	☐ Fit/seizure		20	☐ Dizzy, collapse, blackout, faint, syncope	

Any other symptoms not listed? 1 ☐ Yes 0 ☐ No

If yes please list and give duration of symptoms in days:

1. _____	
2. _____	
3. _____	
4. _____	

Form 2 Baseline



Previous Medical History & Index Hospitalisation

Office use only

Subject # Subject Initials

PRECIPITATING FACTORS

- | | | |
|---|--------------------------------|-------------------------------|
| 1 Previous pattern of seasonality? | 1 ☐ Yes | 0 ☐ No |
| 2 Adverse/extreme weather conditions in days leading to admission? | 1 ☐ Yes | 0 ☐ No |
| 3 Sudden change in weather conditions in days leading to admission? | 1 ☐ Yes | 0 ☐ No |
| 4 Any evidence of adaptation of activities based on weather? | 1 ☐ Yes | 0 ☐ No |
| 5 Reliable support network in case of adverse weather impacting activities? | 1 ☐ Yes | 0 ☐ No |

DIAGNOSES ON DISCHARGE

- | | |
|--|--|
| 1 ☐ Atrial fibrillation/flutter | 16 ☐ Hyponatraemia |
| 2 ☐ Exacerbation of heart failure | 17 ☐ Hypoglycaemia |
| 3 ☐ Unstable angina/non-ST elevation MI | 18 ☐ Hyperglycaemia |
| 4 ☐ ST elevation MI | 19 ☐ Anaemia |
| 5 ☐ Exacerbation of COPD | 20 ☐ Deep vein thrombosis |
| 6 ☐ Pneumonia | 21 ☐ Mental health problem |
| 7 ☐ Respiratory viral infection | 22 ☐ Injury |
| 8 ☐ Pulmonary embolism | 23 ☐ Epilepsy |
| 9 ☐ Gastroenteritis | 24 ☐ Fracture |
| 10 ☐ Urinary tract infection | |
| 11 ☐ Skin/soft tissue infection | Any other diagnosis not listed? 1 ☐ Yes 0 ☐ No |
| 12 ☐ Gastrointestinal bleeding | <i>If yes please list:</i> |
| 13 ☐ Constipation | 1. _____ |
| 14 ☐ Delirium | 2. _____ |
| 15 ☐ Acute Kidney Injury | 3. _____ |
| | 4. _____ |

Form 2 Baseline

Previous Medical History & Index Hospitalisation



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

INVESTIGATIONS

- 1 **Cultures**

Blood ₀ ☐ No ₁ ☐ Yes → Copy of results ₁ ☐ Yes

DATE / /

Urine ₀ ☐ No ₁ ☐ Yes → Copy of results ₁ ☐ Yes

DATE / /

- 2 **Chest X-ray**

DATE / /

₀ ☐ No ₁ ☐ Yes → Copy of report ₁ ☐ Yes

↓

If yes, pulmonary oedema ₀ ☐ No ₁ ☐ Yes

- 3 **12-lead ECG**

DATE / /

₀ ☐ No ₁ ☐ Yes → Copy of ECG ₁ ☐ Yes

- 4 **Echocardiogram**

DATE / /

₀ ☐ No ₁ ☐ Yes → Copy of report ₁ ☐ Yes

- 5 **CT Scan**

☐ Chest/ abdomen / pelvis ₀ ☐ No ₁ ☐ Yes → Copy of report ₁ ☐ Yes

DATE / /

☐ Brain ₀ ☐ No ₁ ☐ Yes → Copy of report ₁ ☐ Yes

DATE / /

- 6 **Inpatient Pulmonary Function Tests**

₀ ☐ No ₁ ☐ Yes → Copy of report ₁ ☐ Yes

DATE / /

Other (please specify): _____

Comments:

Anthropometric and Pathology Details

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
DISCHARGE ANTHROPOMETRIC MEASUREMENTS
 1. Height m BMI Kg/m²
 2. Weight kg
DISCHARGE PATHOLOGY DETAILS

- Please use last recorded results prior to discharge and print a copy of the results.
- If the required pathology is not performed - collect blood from patient in the correct tubes and send to pathology.

 PATHOLOGY DATE CHECKED / /

Hb	g/L	Iron	μmol/L
MCV	fL	Ferritin	μg/L
WCC	x10 ⁹ /L	Transferrin	g/L
PLT	x10 ⁹ /L	HbA1c	mmol/mol
Na ⁺	mmol/L		%
K ⁺	mmol/L	TSH	mU/L
Urea	mmol/L	FT3	pmol/L
Creatinine	μmol/L	FT4	pmol/L
ALT	U/L	Vitamin D	nmol/L
Bilirubin	μmol/L		
Albumin	g/L		

Are extra bloods required for pathology?

☐ Yes ☐ No

Form 2 Baseline

Functional/ physiological Details



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

ADMISSION AND DISCHARGE DETAILS

Date of Admission / / Date of Discharge / /

Admitting Unit _____

Discharging Unit _____

Days in general ward

Days in cardiac ward

Days in ICU

Total length of stay

HAND GRIP STRENGTH

Dominant hand Left ¹ ☐ Right ² ☐

First kg

Second kg

Third kg

Average kg

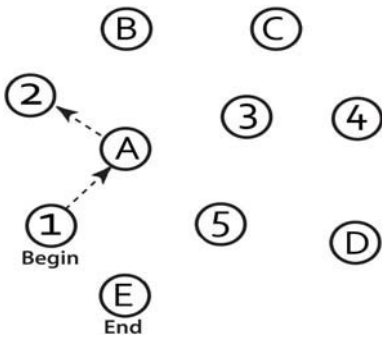
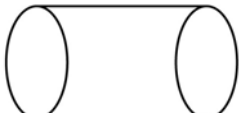
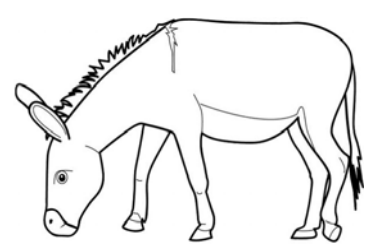
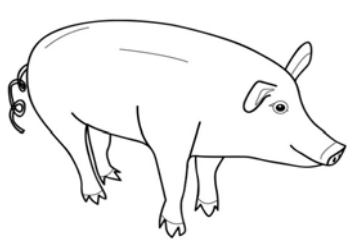
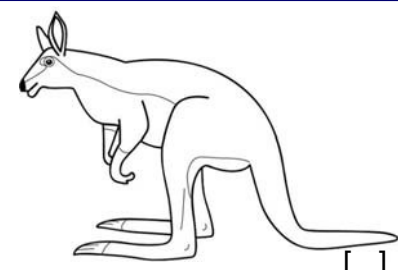
FIVE-REPETITION SIT-TO-STAND TEST (5STS)

Sit-Stand Test Performed ¹ ☐ Yes ⁰ ☐ No

Time at standing position on 5th repetition

.
Min Sec

Office use only
 Subject # Subject Initials
COGNITIVE ASSESSMENT

VISUOSPATIAL / EXECUTIVE		POINTS																				
 Copy cylinder  Draw CLOCK (ten past nine) [] [] [] Contour Numbers Hands ___ /5																						
NAMING		POINTS																				
 []	 []	 []	___ /3																			
MEMORY	Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	<table border="1"> <tr> <td></td> <td>TRAIN</td> <td>EGG</td> <td>HAT</td> <td>CHAIR</td> <td>BLUE</td> </tr> <tr> <td>1st trial</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2nd trial</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		TRAIN	EGG	HAT	CHAIR	BLUE	1st trial						2nd trial						No Points	
	TRAIN	EGG	HAT	CHAIR	BLUE																	
1st trial																						
2nd trial																						
ATTENTION	Read list of digits (1 digit/sec.). Subject has to repeat them in the forward order [] 5 4 1 8 7 Subject has to repeat them in the backward order [] 1 7 4	___ /2																				
Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2	[] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B	___ /1																				
Serial 7 subtraction starting at 80	[] 73 [] 66 [] 59 [] 52 [] 45 4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt	___ /3																				
Repeat:	She heard his lawyer was the one to sue after the accident. [] The little girls who were given too much candy got stomach aches. []	___ /2																				
Fluency / Name maximum number of words in one minute that begin with the letter B	[] _____ (N ≥ 11 words)	___ /1																				
ABSTRACTION	Similarity between e.g., banana - orange = fruit [] eye - ear [] trumpet - piano	___ /2																				
DELAYED RECALL	<table border="1"> <tr> <td>Has to recall words</td> <td>TRAIN</td> <td>EGG</td> <td>HAT</td> <td>CHAIR</td> <td>BLUE</td> <td rowspan="3">Points for UNCUEd</td> </tr> <tr> <td>Category cue</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Multiple choice cue</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	Has to recall words	TRAIN	EGG	HAT	CHAIR	BLUE	Points for UNCUEd	Category cue						Multiple choice cue						___ /5	
Has to recall words	TRAIN	EGG	HAT	CHAIR	BLUE	Points for UNCUEd																
Category cue																						
Multiple choice cue																						
ORIENTATION	[] Date [] Month [] Year [] Day [] Place [] City	___ /6																				
Normal ≥ 26 / 30		TOTAL /30																				

Comments

Medications



Office use only

Subject #

Subject Initials

Prescribed Medications At Discharge			
	Medication name	Dose	Total daily dose
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
DEMOGRAPHIC INFORMATION

- What is your marital status? 1 ☐ Married/Living with partner 3 ☐ Widowed
2 ☐ Separated/Divorced 4 ☐ Never married
- Do you live alone? 1 ☐ Yes 0 ☐ No
→ How many people live with you? 1 ☐ One 2 ☐ Two 3 ☐ Three+
- Do you live in a: 1 ☐ House 2 ☐ Flat/Apartment 3 ☐ Other _____
- How many bedrooms does your home have? 1 ☐ One 2 ☐ Two 3 ☐ Three 4 ☐ Four+
- What is your ethnicity? 1 ☐ European/Caucasian (e.g. Australian) 5 ☐ Pacific Islander
2 ☐ Aboriginal/Torres Strait Islander 6 ☐ Middle Eastern
3 ☐ Asian (including the Indian sub-continent) 7 ☐ Latin American
4 ☐ Black African 8 ☐ Other (please specify) _____
- What is your highest level of education? 1 ☐ Primary School 4 ☐ Degree, Diploma or Grad Certificate
2 ☐ Secondary School 5 ☐ Postgraduate Studies
3 ☐ TAFE/Trade School 6 ☐ Other (please specify) _____
- Are you retired? 1 ☐ Yes 0 ☐ No
- What is or was your main occupation? _____
- Did you speak English before you were five years of age? 1 ☐ Yes 0 ☐ No
- Is English the main language you speak at home? 1 ☐ Yes 0 ☐ No
- Do you have private health insurance? 1 ☐ Yes 0 ☐ No
→ If yes 1 ☐ Hospital Cover 2 ☐ Extras Cover 3 ☐ Hospital +Extras Cover

LIFESTYLE FACTORS**A. Smoking**

- Are you a smoker? 1 ☐ Yes 2 ☐ Not anymore 3 ☐ Never
- Did you smoke in the last 12 months? 1 ☐ Yes 0 ☐ No

B. Alcohol

How often do you drink beer, wine, spirits, liquor or any other alcoholic beverages?

- 1 ☐ Never 3 ☐ <1/week 5 ☐ 3-4 times/week 7 ☐ Everyday
2 ☐ Rarely 4 ☐ 1-2 times/week 6 ☐ 5-6 times/week

 How many alcoholic drinks do you consume on each occasion?
C. Exercise

On average, do you do at least 2.5 hours of physical activity per week (e.g. 30 mins a day on 5 or more days a week)?

- 1 ☐ Yes 0 ☐ No

D. Sleep Quality

How well do you sleep?

- 1 ☐ Very poor 2 ☐ Poor 3 ☐ Average 4 ☐ Well 5 ☐ Very well

 How much sleep do you usually get a night? Hours Minutes

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
QUALITY OF LIFE
 A. Under each heading, please **tick the ONE box** that best describes your health TODAY.

1. Mobility

- 1 ☐ I have no problems in walking about
- 2 ☐ I have slight problems in walking about
- 3 ☐ I have moderate problems in walking about
- 4 ☐ I have severe problems in walking about
- 5 ☐ I am unable to walk about

2. Self-care

- 1 ☐ I have no problems washing or dressing myself
- 2 ☐ I have slight problems washing or dressing myself
- 3 ☐ I have moderate problems washing or dressing myself
- 4 ☐ I have severe problems washing or dressing myself
- 5 ☐ I am unable to wash or dress myself

3. Usual activities

- 1 ☐ I have no problems doing my usual activities
- 2 ☐ I have slight problems doing my usual activities
- 3 ☐ I have moderate problems doing my usual activities
- 4 ☐ I have severe problems doing my usual activities
- 5 ☐ I am unable to do my usual activities

4. Pain/discomfort

- 1 ☐ I have no pain or discomfort
- 2 ☐ I have slight pain or discomfort
- 3 ☐ I have moderate pain or discomfort
- 4 ☐ I have severe pain or discomfort
- 5 ☐ I have extreme pain or discomfort

5. Anxiety/depression

- 1 ☐ I am not anxious or depressed
- 2 ☐ I am slightly anxious or depressed
- 3 ☐ I am moderately anxious or depressed
- 4 ☐ I am severely anxious or depressed
- 5 ☐ I am extremely anxious or depressed

B. We would like to know how good or bad your health is **TODAY**

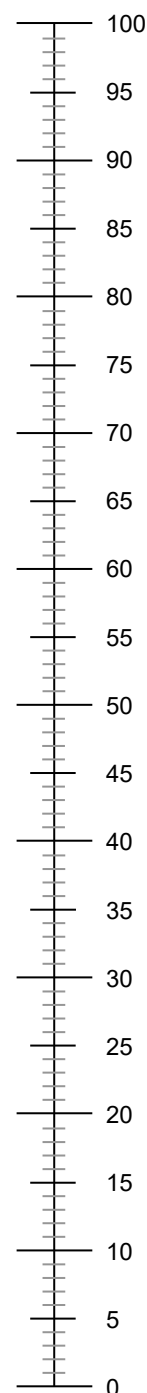
This scale is numbered from 0 to 100.

 100 means the best health you can imagine.

 0 means the worst health you can imagine.

 Mark an **X** on the scale on the right to indicate how the patient's health is TODAY.

PATIENT'S HEALTH STATE TODAY =

SCALE
 The best health
you can imagine

 The worst health
you can imagine

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
ARROL

- A. During the past month have you often been bothered by feeling down, depressed or hopeless?
- 1 ☐ Yes
0 ☐ No
- B. During the past month have you often been bothered by little interest or pleasure in doing things?
- 1 ☐ Yes
0 ☐ No

HOSPITAL ANXIETY AND DEPRESSION SCALES (HADS)

- 1 (A). I feel tense or 'wound up':**
- 3 ☐ Most of the time
2 ☐ A lot of the time
1 ☐ From time to time, occasionally
0 ☐ Not at all
- 2 (D). I still enjoy the things I used to enjoy:**
- 0 ☐ Definitely as much
1 ☐ Not quite so much
2 ☐ Only a little
3 ☐ Hardly at all
- 3 (A). I get a sort of frightened feeling as if something awful is about to happen:**
- 3 ☐ Very definitely and quite badly
2 ☐ Yes, but not too badly
1 ☐ A little, but it doesn't worry me
0 ☐ Not at all
- 4 (D). I can laugh and see the funny side of things:**
- 0 ☐ As much as I always could
1 ☐ Not quite so much now
2 ☐ Definitely not so much now
3 ☐ Not at all
- 5 (A). Worrying thoughts go through my mind:**
- 3 ☐ A great deal of the time
2 ☐ A lot of the time
1 ☐ From time to time, but not too often
0 ☐ Only occasionally
- 6 (D). I feel cheerful:**
- 3 ☐ Not at all
2 ☐ Not often
1 ☐ Sometimes
0 ☐ Most of the time
- 7 (A). I can sit at ease and feel relaxed:**
- 0 ☐ Definitely
1 ☐ Usually
2 ☐ Not Often
3 ☐ Not at all
- 8 (D). I feel as if I am slowed down:**
- 3 ☐ Nearly all the time
2 ☐ Very often
1 ☐ Sometimes
0 ☐ Not at all
- 9 (A). I get a sort of frightened feeling like 'butterflies' in the stomach:**
- 0 ☐ Not at all
1 ☐ Occasionally
2 ☐ Quite Often
3 ☐ Very Often
- 10 (D). I have lost interest in my appearance:**
- 3 ☐ Definitely
2 ☐ I don't take as much care as I should
1 ☐ I may not take quite as much care
0 ☐ I take just as much care as ever
- 11 (A). I feel restless as I have to be on the move:**
- 3 ☐ Very much indeed
2 ☐ Quite a lot
1 ☐ Not very much
0 ☐ Not at all
- 12 (D). I look forward with enjoyment to things:**
- 0 ☐ As much as I ever did
1 ☐ Rather less than I used to
2 ☐ Definitely less than I used to
3 ☐ Hardly at all
- 13 (A). I get sudden feelings of panic:**
- 3 ☐ Very often indeed
2 ☐ Quite often
1 ☐ Not very often
0 ☐ Not at all
- 14 (D). I can enjoy a good book or radio or TV program:**
- 0 ☐ Often
1 ☐ Sometimes
2 ☐ Not often
3 ☐ Very seldom

Anxiety Score Depression Score

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
ROCKWOOD FRAILTY SCORE**Clinical Frailty Scale***

1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2 Well – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



3 Managing Well – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



4 Vulnerable – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being "slowed up", and/or being tired during the day.



5 Mildly Frail – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6 Moderately Frail – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7 Severely Frail – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. Terminally Ill - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

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 Score:
ARISE-HEART DISEASE & MULTIMORBIDITY PROFILING (ALL PATIENTS)

	Yes	No
1. Anaemia (sex-specific, based on current Hb level or Hb levels in the last 3 months or iron deficiency)	1 ☐	0 ☐
2. Musculoskeletal Disease (Diagnosis/weak handgrip (age-sex adjusted))	1 ☐	0 ☐
3. Depression (Diagnosis/HADS Score > 10)	1 ☐	0 ☐
4. Sleep Disorder (Diagnosis)	1 ☐	0 ☐
5. Metabolic Disease (Diabetes, HbA1c > 7%, Vitamin D deficiency, Obese)	1 ☐	0 ☐
6. Cardiac Arrhythmia (other than AF, diagnosis ECG)	1 ☐	0 ☐
7. Renal Disease or Impairment (eGFR < 60 ml/min/1.73m ²)	1 ☐	0 ☐
8. Respiratory Disease (Diagnosis/ low FEV1 [age-sex adjusted])	1 ☐	0 ☐
9. Thyroid Disease (Thyroxine Levels)	1 ☐	0 ☐
10. Cognitive Impairment (MoCA Score < 26)	1 ☐	0 ☐

 Patient's total score =

Form 4 Post-Discharge Intervention Planning



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

PRE-DISCHARGE SEASONAL RESILIENCE PLANNING (RESILIENCE GROUP ONLY)

A. Previous Pattern of Seasonal Admissions?

₁ ☐ Yes

₀ ☐ No

B. Discussion with participant as to potential reasons?

₁ ☐ Yes

₀ ☐ No

C. Pre-Home Visit Intervention Required?

₁ ☐ Yes

₀ ☐ No

D. Nature of Intervention

E. Actigraph/Monitor Fitted?

₁ ☐ Yes → Date of fitting

/ /

₀ ☐ No

F. First Post-Discharge Home Visit Organised

₁ ☐ Yes → If yes, please record planned date and time

/ / Date

₀ ☐ No

: Time

G. First RESILIENCE Clinic Visit Organised

₁ ☐ Yes → If yes, please record planned date and time

/ / Date

₀ ☐ No

: Time

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Date of review

 / /

In addition to the patient, who is present?

1 ☐ Spouse

2 ☐ Close relative

3 ☐ Significant other

0 ☐ No one

HOME ENVIRONMENT

Type of residence:

1 ☐ House

2 ☐ Flat/Apartment

3 ☐ Residential care

4 ☐ Other _____

Primary construction (cladding):

1 ☐ Full-brick

2 ☐ Brick-veneer

3 ☐ Timber/Weatherboard

4 ☐ Fibro

5 ☐ Other _____

Roof:

1 ☐ Tiled

3 ☐ Other _____

2 ☐ Colour-bond steel

How many bedrooms does your home

1 ☐ One

2 ☐ Two

3 ☐ Three

4 ☐ Four+

Number of people living with you?

 persons

Heating thermo-regulatory control:

1 ☐ Gas heater

2 ☐ Electric heater

3 ☐ Open fire

4 ☐ Portable heater

5 ☐ Ducted heating

6 ☐ Oil heater

Whole house heated?

1 ☐ Yes 0 ☐ No

→ If No, number of rooms covered

 rooms

Cooling thermo-regulatory control:

1 ☐ Ceiling fan

2 ☐ Portable fan

3 ☐ Evaporative cooling

4 ☐ In-room air-conditioning

5 ☐ Ducted air-conditioning

6 ☐ Portable air-conditioner

Whole house cooled?

1 ☐ Yes 0 ☐ No

→ If No, number of rooms covered

 rooms

Evidence of damp inside the house: 1 ☐ Yes 0 ☐ No

Specific modification to improve insulation:

1 ☐ Yes 0 ☐ No

Anyone smoking inside the house?

1 ☐ Yes 0 ☐ No

Garden?

0 ☐ No

1 ☐ Yes

If Yes, garden size

Comments:

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.**HEATH ASSETS INDEX**

1. At approximately what age did you start school? Age: _____
2. At approximately what age did you finish school? Age: _____
3. What is your primary language? Language: _____
4. Do you have a carer or someone you can rely on to help with day to day activities? 0 ☐ No 1 ☐ Yes
5. Do you have a support person who is positive towards discharge or maintaining residence in the community? 0 ☐ No 1 ☐ Yes
6. Do you live alone or with others? 0 ☐ Alone 1 ☐ With others
7. Do you have a regular GP? 0 ☐ No 1 ☐ Yes
8. Do you have private health insurance or other form of health services cover such as Department of Veterans' Affairs Gold Card? 0 ☐ No 1 ☐ Yes
9. Do you own your own home? 0 ☐ No 1 ☐ Yes, mortgage 2 ☐ Yes
10. How do you manage on the income you have available? 0 ☐ Difficult, mostly 1 ☐ Difficult, sometimes 2 ☐ Always manageable
11. How many children do you have? 0 ☐ Zero 1 ☐ One to two 2 ☐ Three or more
12. Can you count on anyone to provide you with emotional support, for example, talking over a problem, or helping with a decision? 0 ☐ No 1 ☐ Yes
13. How many times a week do you see or talk to a family member or friend who does not live with you? 0 ☐ Never 1 ☐ Less than once per week 2 ☐ Once per week or more
14. In the 3 days prior to the onset of the illness precipitating admission number of days went out of the house or building in which he or she resides (no matter how short the period). 0 ☐ Never 1 ☐ Did not go out in last 3 days but usually goes out over a 3 day period 2 ☐ 1-2 days 3 ☐ 3 days
15. Do you have control over the important things in life? 0 ☐ Never 1 ☐ Sometimes 2 ☐ Mostly
16. Overall how would you rate your quality of life? 0 ☐ Mostly bad 1 ☐ Sometimes good/bad 2 ☐ Mostly good
17. In general would you say your health is: 0 ☐ Poor or fair 1 ☐ Good or excellent

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
CLINICAL PROFILE
 Physiological monitors recovered: ₁ ☐ Yes ₀ ☐ No

 Days of monitoring post-discharge: days

 Blood pressure: / mmHg

 Heart rate: bpm

 / mmHg

 Heart rate: bpm

 / mmHg

 Heart rate: bpm

 Body Temperature . °C

Any clinical deterioration, please comment:

HOME WEATHER INFORMATION
 Time of measurement

 Internal Temperature . °C

 External Temperature . °C

 Internal Humidity %

 External Humidity %

 Internal CO₂ ppm

 Internal Air pressure mbar

 Outdoor versus indoor climate °Celsius

 % Humidity

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
SEASONAL BEHAVIOURS
Instructions: After discussing the participant's habits in response to seasonal changes, provide a rating from 1 (minimal adaptation) to 10 (maximal adaptation) in relation to:
SPRING/SUMMER IE WHEN THE WEATHER IS WARMER1. What habits would the participant change with regard to **clothing** ?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
2. What habits would the participant change with regard to **physical activity**?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
3. What **dietary** habits would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
4. What habits related to **home heating/cooling** would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
5. What habits related to **avoiding infections** would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
AUTUMN/WINTER IE WHEN THE WEATHER IS COOLER1. What habits would the participant change with regard to **clothing** ?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
2. What habits would the participant change with regard to **physical activity**?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
3. What **dietary** habits would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
4. What habits related to **home heating/cooling** would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation
5. What habits related to **avoiding infections** would the participant change?
 Minimal adaptation 1 2 3 4 5 6 7 8 9 10 Maximal adaptation

Comments:

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.**SEASONAL AWARENESS**

1. How important does the participant think changes in the weather are on their heart and general health?

None

0

☐

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Very important

2. If the participant was warned there was particularly cold and wet weather arriving the next day, how likely would they be to change their plans to venture outside to go shopping, visit a friend or go for a doctor's appointment?

None

0

☐

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Very important

3. If the participant was warned there was a heat wave arriving the next day, how likely would they be to change their plans to venture outside to go shopping, visit a friend or go for a doctor's appointment?

None

0

☐

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Very important

Comments:

SEASONAL RESOURCES1. What resources does the participant have to maintain a comfortable home environment in respect to **clothing**?

Very little

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Everything they need

2. What resources does the participant have to maintain a comfortable home environment in respect to **heating**?

Very little

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Everything they need

3. What resources does the participant have to maintain a comfortable home environment in respect to **cooling**?

Very little

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Everything they need

4. What resources does the participant have to avoid being exposed to extremely cold or hot weather?

Very little

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Everything they need

5. How much does the cost of heating or cooling their home, affect the participant's decision to use thermoregulatory

Very little

1

☐

2

☐

3

☐

4

☐

5

☐

6

☐

7

☐

8

☐

9

☐

10

☐

Very concerned

Comments:

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
RESILIENCE INTERVENTION

1. Identified areas of Seasonal Vulnerability:

- | | |
|--|--|
| 0 ☐ None | 3 ☐ Seasonal Behaviours |
| 1 ☐ Clinical Stability Management | 4 ☐ Seasonal Awareness |
| 2 ☐ Home Environment | 5 ☐ Seasonal Resources |

2. Immediate Actions:

- 0 ☐ None
- 1 ☐ Immediate referral for medical assessment
☐ GP ☐ ambulance ☐ Other, please specify _____
- 2 ☐ Informal review of home environment with participant/family or recommendation for formal review*
- 3 ☐ Plan for individualised seasonal reminders to prepare for winter/summer and acute weather events approaching with agreed behavioural changes
- 4 ☐ Participant/family/carer education and plan for seasonal alerts (participant and/or family/carers)
- 5 ☐ Referral to social worker or financial subsidy program**

3. Need for repeat home visit (within 1 month) following 1st **RESILIENCE CLINIC** review (21 post-discharge clinic):

- 0 ☐ No
- 1 ☐ Yes → if yes, please indicate date: / / date (dd/mm/yyyy)

Comments:

***Heating and Cooling:**
<http://yourhome.gov.au/sites/prod.yourhome.gov.au/files/pdf/YOURHOME-Energy-HeatingAndCooling.pdf>
****Need for support:**
<https://www.dss.gov.au/about-the-department/benefits-payments/energy-supplement>

Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Date of clinic review / /

Type of Clinic ☐ Face to Face ☐ ~~Virtual~~

Name of doctor conducting appointment _____

Other staff present? ☐ Trial Nurse
☐ If other, who? _____

In addition to the participant, who is present?

1 ☐ Spouse	3 ☐ Significant other
2 ☐ Close relative	0 ☐ No one

Please list other relevant Specialists the patient is seeing:

1. _____
2. _____
3. _____
4. _____
5. _____

Blood pressure: / mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

Body Temperature . °C

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

CLINICAL MANAGEMENT		YES	NO
1. Previous pattern of seasonality		1 ☐	0 ☐
2. Clinical Instability detected at home visit		1 ☐	0 ☐
3. Physiological risk of seasonality detected (ie ARISE score)		1 ☐	0 ☐
4. Recommended adjustment of pharmacological therapy required		1 ☐	0 ☐
If yes, please indicate:		Yes	No
Vaccination	1 ☐ 0 ☐	Required vaccinations: _____	
Vitamin D Supplements	1 ☐ 0 ☐	_____	
Asthma/COPD Plan	1 ☐ 0 ☐		
Flexible Diuretic Plan	1 ☐ 0 ☐		
Describe recommended adjustments to GP in letter, copying in any specialists the participant is seeing.			
5. Adjustment of non-pharmacological therapy required		1 ☐	0 ☐
If yes, please describe:			

RESILIENCE CASE-MANAGEMENT		YES	NO
1. Environment			
Recommended changes to home environment?		1 ☐	0 ☐
Referral to Energy subsidy?		1 ☐	0 ☐
Clothing support?		1 ☐	0 ☐

Comments:

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
RESILIENCE CASE-MANAGEMENT CONTINUED**2. Behaviours/Awareness**
 Personal Hygiene Education? 1 ☐ 0 ☐

 Personalised Weather Alerts via SMS? 1 ☐ 0 ☐

Other: _____

Comments:

3. Referrals
 Social Worker 1 ☐ 0 ☐

 Pharmacist 1 ☐ 0 ☐

 GP 1 ☐ 0 ☐

 Occupational Therapy 1 ☐ 0 ☐

Other: _____

Comments:

 Issues with virtual clinic?: 1 ☐ Yes 0 ☐ No

If Yes, please provide details.

Risk of readmission:

LOW-RISK
INTERMEDIATE-RISK
HIGH-RISK

 1 ☐

 2 ☐

 3 ☐

List of participant priorities

1. _____
2. _____
3. _____
4. _____
5. _____

Form 7 Resilience Clinic 2 (6 month review)



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Date of clinic review / /

Type of Clinic ☐ Face to Face ☐ Virtual

Name of doctor conducting appointment _____

Other staff present?

☐ Trial Nurse

☐ If other, who? _____

In addition to the participant, who is present?

₁ ☐ Spouse

₃ ☐ Significant other

₂ ☐ Close relative

₀ ☐ No one

Please list other relevant Specialists the patient is seeing:

1. _____
2. _____
3. _____
4. _____
5. _____

Blood pressure: / mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

Body Temperature . °C

Form 7 Resilience Clinic 2 (6 month review)



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

CLINICAL MANAGEMENT		YES	NO
1. Previous pattern of seasonality		1 ☐	0 ☐
2. Clinical Instability detected at home visit		1 ☐	0 ☐
3. Physiological risk of seasonality detected (ie ARISE score)		1 ☐	0 ☐
4. Recommended adjustment of pharmacological therapy required		1 ☐	0 ☐
If yes, please indicate:		Yes	No
Vaccination	1 ☐ 0 ☐	Required vaccinations: _____	
Vitamin D Supplements	1 ☐ 0 ☐	_____	
Asthma/COPD Plan	1 ☐ 0 ☐		
Flexible Diuretic Plan	1 ☐ 0 ☐		
Describe recommended adjustments to GP in letter, copying in any specialists the participant is seeing.			
5. Adjustment of non-pharmacological therapy required		1 ☐	0 ☐
If yes, please describe:			

RESILIENCE CASE-MANAGEMENT		YES	NO
1. Environment			
Recommended changes to home environment?		1 ☐	0 ☐
Referral to Energy subsidy?		1 ☐	0 ☐
Clothing support?		1 ☐	0 ☐

Comments:

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
RESILIENCE CASE-MANAGEMENT CONTINUED**2. Behaviours/Awareness**
 Personal Hygiene Education? 1 ☐ 0 ☐

 Personalised Weather Alerts via SMS? 1 ☐ 0 ☐

Other: _____

Comments:

3. Referrals
 Social Worker 1 ☐ 0 ☐

 Pharmacist 1 ☐ 0 ☐

 GP 1 ☐ 0 ☐

 Occupational Therapy 1 ☐ 0 ☐

Other: _____

Comments:

 Issues with virtual clinic?: 1 ☐ Yes 0 ☐ No

If Yes, please provide details.

Risk of readmission:

LOW-RISK
INTERMEDIATE-RISK
HIGH-RISK

 1 ☐

 2 ☐

 3 ☐

List of participant priorities

1. _____
2. _____
3. _____
4. _____
5. _____

Form 8 Resilience Clinic 3 (12 month review)



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Date of clinic review / /

Type of Clinic ☐ Face to Face ☐ Virtual

Name of doctor conducting appointment _____

Other staff present? ☐ Trial Nurse
☐ If other, who? _____

In addition to the participant, who is present?

1 ☐ Spouse	3 ☐ Significant other
2 ☐ Close relative	0 ☐ No one

Please list other relevant Specialists the patient is seeing:

1. _____
2. _____
3. _____
4. _____
5. _____

Blood pressure: / mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

/ mmHg

Heart rate: bpm

Body Temperature . °C

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

CLINICAL MANAGEMENT		YES	NO
1. Previous pattern of seasonality		1 ☐	0 ☐
2. Clinical Instability detected at home visit		1 ☐	0 ☐
3. Physiological risk of seasonality detected (ie ARISE score)		1 ☐	0 ☐
4. Recommended adjustment of pharmacological therapy required		1 ☐	0 ☐
If yes, please indicate:		Yes	No
Vaccination	1 ☐	0 ☐	Required vaccinations: _____
Vitamin D Supplements	1 ☐	0 ☐	_____
Asthma/COPD Plan	1 ☐	0 ☐	
Flexible Diuretic Plan	1 ☐	0 ☐	
Describe recommended adjustments to GP in letter, copying in any specialists the participant is seeing.			
5. Adjustment of non-pharmacological therapy required		1 ☐	0 ☐
If yes, please describe:			

RESILIENCE CASE-MANAGEMENT		YES	NO
1. Environment			
Recommended changes to home environment?		1 ☐	0 ☐
Referral to Energy subsidy?		1 ☐	0 ☐
Clothing support?		1 ☐	0 ☐

Comments:

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
RESILIENCE CASE-MANAGEMENT CONTINUED**2. Behaviours/Awareness**
 Personal Hygiene Education? 1 ☐ 0 ☐

 Personalised Weather Alerts via SMS? 1 ☐ 0 ☐

Other: _____

Comments:

3. Referrals
 Social Worker 1 ☐ 0 ☐

 Pharmacist 1 ☐ 0 ☐

 GP 1 ☐ 0 ☐

 Occupational Therapy 1 ☐ 0 ☐

Other: _____

Comments:

 Issues with virtual clinic?: 1 ☐ Yes 0 ☐ No

If Yes, please provide details.

Risk of readmission:

LOW-RISK
INTERMEDIATE-RISK
HIGH-RISK

 1 ☐

 2 ☐

 3 ☐

List of participant priorities

1. _____
2. _____
3. _____
4. _____
5. _____

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☐ Print text in block style completely within boxes.
ANTHROPOMETRIC MEASUREMENTS

1. Height . m BMI Kg/m²

2. Weight . kg

HAND GRIP STRENGTH
 Dominant hand Left 1 Right 2

First kg Second kg Third kg

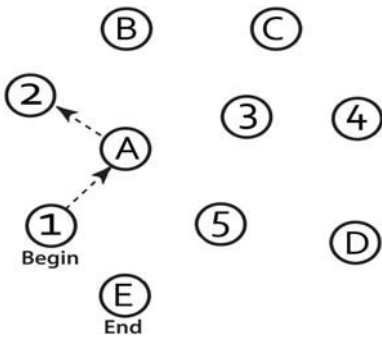
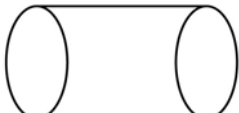
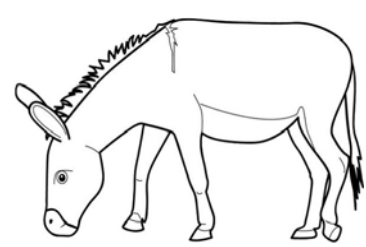
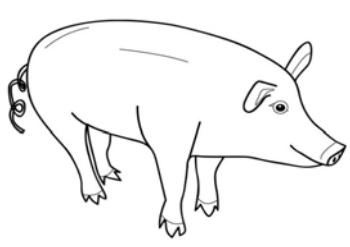
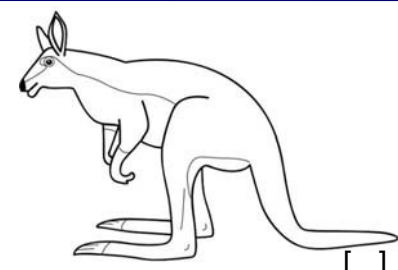
Average kg

FIVE-REPETITION SIT-TO-STAND TEST (5STS)
 Sit-Stand Test Performed 1 ☐ Yes 0 ☐ No

Time at standing position on 5th repetition

 .
 Min Sec

Office use only
 Subject # Subject Initials
COGNITIVE ASSESSMENT

COGNITIVE ASSESSMENT									
VISUOSPATIAL / EXECUTIVE		 Copy cylinder  Draw CLOCK (ten past nine) [] Contour [] Numbers [] Hands					POINTS ___ /5		
NAMING		  					___ /3		
MEMORY		Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.					No Points		
		TRAIN	EGG	HAT	CHAIR	BLUE			
		1st trial							
		2nd trial							
ATTENTION		Read list of digits (1 digit/sec.). Subject has to repeat them in the forward order [] 5 4 1 8 7 Subject has to repeat them in the backward order [] 1 7 4					___ /2		
		Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 [] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B					___ /1		
		Serial 7 subtraction starting at 80 [] 73 [] 66 [] 59 [] 52 [] 45 4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt					___ /3		
REPEAT		Repeat: She heard his lawyer was the one to sue after the accident. [] The little girls who were given too much candy got stomach aches. []					___ /2		
		Fluency / Name maximum number of words in one minute that begin with the letter B [] _____ (N ≥ 11 words)					___ /1		
ABSTRACTION		Similarity between e.g., banana - orange = fruit [] eye - ear [] trumpet - piano					___ /2		
DELAYED RECALL		Has to recall words TRAIN EGG HAT CHAIR BLUE					Points for UNCUEDED ___ /5		
Optional		Category cue							
		Multiple choice cue							
ORIENTATION		[] Date	[] Month	[] Year	[] Day	[] Place	[] City	___ /6	
Normal ≥ 26 / 30						TOTAL ___ /30			
Comments									

Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.**QUALITY OF LIFE**A. Under each heading, please **tick the ONE box** that best describes your health TODAY.

1. Mobility

- 1 ☐ I have no problems in walking about
 2 ☐ I have slight problems in walking about
 3 ☐ I have moderate problems in walking about
 4 ☐ I have severe problems in walking about
 5 ☐ I am unable to walk about

2. Self-care

- 1 ☐ I have no problems washing or dressing myself
 2 ☐ I have slight problems washing or dressing myself
 3 ☐ I have moderate problems washing or dressing myself
 4 ☐ I have severe problems washing or dressing myself
 5 ☐ I am unable to wash or dress myself

3. Usual activities

- 1 ☐ I have no problems doing my usual activities
 2 ☐ I have slight problems doing my usual activities
 3 ☐ I have moderate problems doing my usual activities
 4 ☐ I have severe problems doing my usual activities
 5 ☐ I am unable to do my usual activities

4. Pain/discomfort

- 1 ☐ I have no pain or discomfort
 2 ☐ I have slight pain or discomfort
 3 ☐ I have moderate pain or discomfort
 4 ☐ I have severe pain or discomfort
 5 ☐ I have extreme pain or discomfort

5. Anxiety/depression

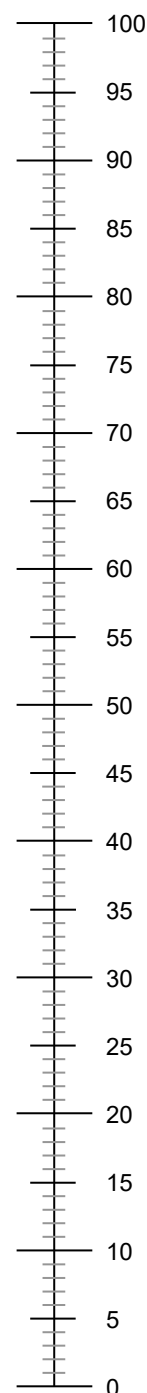
- 1 ☐ I am not anxious or depressed
 2 ☐ I am slightly anxious or depressed
 3 ☐ I am moderately anxious or depressed
 4 ☐ I am severely anxious or depressed
 5 ☐ I am extremely anxious or depressed

B. We would like to know how good or bad your health is **TODAY**

This scale is numbered from 0 to 100.

100 means the best health you can imagine.0 means the worst health you can imagine.Mark an **X** on the scale on the right to indicate how the patient's health is TODAY.

PATIENT'S HEALTH STATE TODAY =

SCALEThe best health
you can imagineThe worst health
you can imagine

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
ARROL

A. During the past month have you often been bothered by feeling down, depressed or hopeless?

 1 ☐ Yes

 0 ☐ No

B. During the past month have you often been bothered by little interest or pleasure in doing things?

 1 ☐ Yes

 0 ☐ No

Please check you have answered all the questions

HOSPITAL ANXIETY AND DEPRESSION SCALES (HADS)
1 (A). I feel tense or 'wound up':

 3 ☐ Most of the time

 2 ☐ A lot of the time

 1 ☐ From time to time, occasionally

 0 ☐ Not at all

2 (D). I still enjoy the things I used to enjoy:

 0 ☐ Definitely as much

 1 ☐ Not quite so much

 2 ☐ Only a little

 3 ☐ Hardly at all

3 (A). I get a sort of frightened feeling as if something awful is about to happen:

 3 ☐ Very definitely and quite badly

 2 ☐ Yes, but not too badly

 1 ☐ A little, but it doesn't worry me

 0 ☐ Not at all

4 (D). I can laugh and see the funny side of things:

 0 ☐ As much as I always could

 1 ☐ Not quite so much now

 2 ☐ Definitely not so much now

 3 ☐ Not at all

5 (A). Worrying thoughts go through my mind:

 3 ☐ A great deal of the time

 2 ☐ A lot of the time

 1 ☐ From time to time, but not too often

 0 ☐ Only occasionally

6 (D). I feel cheerful:

 3 ☐ Not at all

 2 ☐ Not often

 1 ☐ Sometimes

 0 ☐ Most of the time

7 (A). I can sit at ease and feel relaxed:

 0 ☐ Definitely

 1 ☐ Usually

 2 ☐ Not Often

 3 ☐ Not at all

8 (D). I feel as if I am slowed down:

 3 ☐ Nearly all the time

 2 ☐ Very often

 1 ☐ Sometimes

 0 ☐ Not at all

9 (A). I get a sort of frightened feeling like 'butterflies' in the stomach:

 0 ☐ Not at all

 1 ☐ Occasionally

 2 ☐ Quite Often

 3 ☐ Very Often

10 (D). I have lost interest in my appearance:

 3 ☐ Definitely

 2 ☐ I don't take as much care as I should

 1 ☐ I may not take quite as much care

 0 ☐ I take just as much care as ever

11 (A). I feel restless as I have to be on the move:

 3 ☐ Very much indeed

 2 ☐ Quite a lot

 1 ☐ Not very much

 0 ☐ Not at all

12 (D). I look forward with enjoyment to things:

 0 ☐ As much as I ever did

 1 ☐ Rather less than I used to

 2 ☐ Definitely less than I used to

 3 ☐ Hardly at all

13 (A). I get sudden feelings of panic:

 3 ☐ Very often indeed

 2 ☐ Quite often

 1 ☐ Not very often

 0 ☐ Not at all

14 (D). I can enjoy a good book or radio or TV program:

 0 ☐ Often

 1 ☐ Sometimes

 2 ☐ Not often

 3 ☐ Very seldom
Anxiety Score Depression Score

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
PATHOLOGY DETAILS

PATHOLOGY DATE CHECKED

 / /

Hb

 g/L

Iron

 μmol/L

MCV

 fL

Ferritin

 μg/L

WCC

 . x10⁹/L

Transferrin

 . g/L

PLT

 x10⁹/L

HbA1c

 . mmol/mol
Na⁺
 mmol/L

 . %
K⁺
 . mmol/L

TSH

 . mU/L

Urea

 . mmol/L

FT3

 . pmol/L

Creatinine

 μmol/L

FT4

 . pmol/L

ALT

 U/L

Vitamin D

 nmol/L

Bilirubin

 μmol/L

Albumin

 g/L

Are extra bloods required for pathology?

☐ Yes ☐ No



Office use only

Subject #						Subject Initials			
-----------	----------------------	----------------------	----------------------	----------------------	----------------------	------------------	----------------------	----------------------	----------------------

PRESCRIBED MEDICATIONS AT 12-months

	Medication name	Dose	Total daily dose
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

Form 15: Demographic/Lifestyle (12 month review)



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

DEMOGRAPHIC INFORMATION

What is your marital status? 1 ☐ Married/Living with partner 3 ☐ Widowed
2 ☐ Separated/Divorced 4 ☐ Never married

Do you live alone? 1 ☐ Yes 0 ☐ No
→ How many people live with you? 1 ☐ One 2 ☐ Two 3 ☐ Three+

Do you live in a: 1 ☐ House 2 ☐ Flat/Apartment 3 ☐ Other _____

How many bedrooms does your home have? 1 ☐ One 2 ☐ Two 3 ☐ Three 4 ☐ Four+

What is your ethnicity? 1 ☐ European/Caucasian (e.g. Australian) 5 ☐ Pacific Islander
2 ☐ Aboriginal/Torres Strait Islander 6 ☐ Middle Eastern
3 ☐ Asian (including the Indian sub-continent) 7 ☐ Latin American
4 ☐ Black African 8 ☐ Other (please specify) _____

What is your highest level of education? 1 ☐ Primary School 4 ☐ Degree, Diploma or Grad Certificate
2 ☐ Secondary School 5 ☐ Postgraduate Studies
3 ☐ TAFE/Trade School 6 ☐ Other (please specify) _____

Are you retired? 1 ☐ Yes 0 ☐ No

What is or was your main occupation? _____

Did you speak English before you were five years of age? 1 ☐ Yes 0 ☐ No

Is English the main language you speak at home? 1 ☐ Yes 0 ☐ No

Do you have private health insurance? 1 ☐ Yes 0 ☐ No
→ If yes 1 ☐ Hospital Cover 2 ☐ Extras Cover 3 ☐ Hospital +Extras Cover

LIFESTYLE FACTORS

A. Smoking

Are you a smoker? 1 ☐ Yes 2 ☐ Not anymore 3 ☐ Never
Did you smoke in the last 12 months? 1 ☐ Yes 0 ☐ No

B. Alcohol

How often do you drink beer, wine, spirits, liquor or any other alcoholic beverages?
1 ☐ Never 3 ☐ <1/week 5 ☐ 3-4 times/week 7 ☐ Everyday
2 ☐ Rarely 4 ☐ 1-2 times/week 6 ☐ 5-6 times/week
How many alcoholic drinks do you consume on each occasion?

C. Exercise

On average, do you do at least 2.5 hours of physical activity per week (e.g. 30 mins a day on 5 or more days a week)?
1 ☐ Yes 0 ☐ No

D. Sleep Quality

How well do you sleep?
1 ☐ Very poor 2 ☐ Poor 3 ☐ Average 4 ☐ Well 5 ☐ Very well
How much sleep do you usually get a night? Hours Minutes



CASE REPORT FORMS

Standard Care - 12 month follow-up

NB: Using black or blue ball point pen, legibly print written responses using capital letters on the CRF forms.



Form 1: SC - Medical History (12 month)



Office use only

Subject # Subject Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

IMMUNISATION HISTORY

Influenza

¹ ☐ Yes ⁰ ☐ No

Date MM/YYYY

 /

Pneumovax

¹ ☐ Yes ⁰ ☐ No

Date MM/YYYY

 /

Shingles

(age 70 or 71-79 until end 2021)

¹ ☐ Yes ⁰ ☐ No

Date MM/YYYY

 /

COVID 19

¹ ☐ Yes ⁰ ☐ No
² ☐ N/A

Dose 1

Date MM/YYYY

 /

Dose 2

Date MM/YYYY

 /

Booster

Date MM/YYYY

 /

Which Vaccine (dose 1/2)?

Which Booster Vaccine ?

Form 1: SC - Medical History (12 month)



Office use only

Subject #

Subject
Initials

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

IMPACT OF CORONAVIRUS PANDEMIC

1. Did you ever develop symptoms of Covid-19?

¹ ☐ Yes

⁰ ☐ No

A) Did you seek medical advice for this?

¹ ☐ Yes

⁰ ☐ No

B) Did you find it easy to obtain medical advice for this?

¹ ☐ Yes

⁰ ☐ No

2. Have you ever been tested for Covid-19?

¹ ☐ Yes

⁰ ☐ No

A) If yes, what was the test result

¹ ☐ Positive

⁰ ☐ Negative

B) Did you present to an emergency department due to Covid-19 symptoms?

¹ ☐ Yes

⁰ ☐ No

C) Did you require a hospital admission for the treatment of Covid-19 symptoms

¹ ☐ Yes

⁰ ☐ No



Which hospital?

3. Have you ever been diagnosed or had closed contact with someone diagnosed with COVID-19, and been required to self-isolate?

¹ ☐ Yes

⁰ ☐ No

If yes, date

 / /

A) If yes, who?

Spouse/partner

¹ ☐

Colleague

⁵ ☐

Other family member (same household)

² ☐

Friend

⁶ ☐

Other family member (different household)

³ ☐

Neighbour

⁷ ☐

Carer

⁴ ☐

Other

⁸ ☐

4. Did you need any extra help during 'lockdown' e.g. with groceries, medical supplies etc.?

¹ ☐ Yes

⁰ ☐ No

A) If yes, who helped you?

Friends

¹ ☐

Pre-existing support eg carers

⁴ ☐

Family

² ☐

New support (started in lockdown)

⁵ ☐

Neighbours

³ ☐

Other

⁶ ☐

5. If you needed to be quarantined or isolated at home for two weeks due to Covid-19, would you need additional help on top of what you already have? (eg from family, friends, healthcare providers).

¹ ☐ Yes

⁰ ☐ No



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Subject #

Subject Initials

PRESCRIBED MEDICATIONS AT 12-months

	Medication name	Dose	Total daily dose
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
DEMOGRAPHIC INFORMATION

- What is your marital status? 1 ☐ Married/Living with partner 3 ☐ Widowed
2 ☐ Separated/Divorced 4 ☐ Never married
- Do you live alone? 1 ☐ Yes 0 ☐ No
→ How many people live with you? 1 ☐ One 2 ☐ Two 3 ☐ Three+
- Do you live in a: 1 ☐ House 2 ☐ Flat/Apartment 3 ☐ Other _____
- How many bedrooms does your home have? 1 ☐ One 2 ☐ Two 3 ☐ Three 4 ☐ Four+
- What is your ethnicity? 1 ☐ European/Caucasian (e.g. Australian) 5 ☐ Pacific Islander
2 ☐ Aboriginal/Torres Strait Islander 6 ☐ Middle Eastern
3 ☐ Asian (including the Indian sub-continent) 7 ☐ Latin American
4 ☐ Black African 8 ☐ Other (please specify) _____
- What is your highest level of education? 1 ☐ Primary School 4 ☐ Degree, Diploma or Grad Certificate
2 ☐ Secondary School 5 ☐ Postgraduate Studies
3 ☐ TAFE/Trade School 6 ☐ Other (please specify) _____
- Are you retired? 1 ☐ Yes 0 ☐ No
- What is or was your main occupation? _____
- Did you speak English before you were five years of age? 1 ☐ Yes 0 ☐ No
- Is English the main language you speak at home? 1 ☐ Yes 0 ☐ No
- Do you have private health insurance? 1 ☐ Yes 0 ☐ No
→ If yes 1 ☐ Hospital Cover 2 ☐ Extras Cover 3 ☐ Hospital +Extras Cover

LIFESTYLE FACTORS**A. Smoking**

- Are you a smoker? 1 ☐ Yes 2 ☐ Not anymore 3 ☐ Never
Did you smoke in the last 12 months? 1 ☐ Yes 0 ☐ No

B. Alcohol

How often do you drink beer, wine, spirits, liquor or any other alcoholic beverages?

- 1 ☐ Never 3 ☐ <1/week 5 ☐ 3-4 times/week 7 ☐ Everyday
2 ☐ Rarely 4 ☐ 1-2 times/week 6 ☐ 5-6 times/week

How many alcoholic drinks do you consume on each occasion?

C. Exercise

On average, do you do at least 2.5 hours of physical activity per week (e.g. 30 mins a day on 5 or more days a week)?

- 1 ☐ Yes 0 ☐ No

D. Sleep Quality

How well do you sleep?

- 1 ☐ Very poor 2 ☐ Poor 3 ☐ Average 4 ☐ Well 5 ☐ Very well

How much sleep do you usually get a night?

 Hours

 Minutes

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 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
QUALITY OF LIFE
 A. Under each heading, please **tick the ONE box** that best describes your health TODAY.

1. Mobility

- 1 ☐ I have no problems in walking about
- 2 ☐ I have slight problems in walking about
- 3 ☐ I have moderate problems in walking about
- 4 ☐ I have severe problems in walking about
- 5 ☐ I am unable to walk about

2. Self-care

- 1 ☐ I have no problems washing or dressing myself
- 2 ☐ I have slight problems washing or dressing myself
- 3 ☐ I have moderate problems washing or dressing myself
- 4 ☐ I have severe problems washing or dressing myself
- 5 ☐ I am unable to wash or dress myself

3. Usual activities

- 1 ☐ I have no problems doing my usual activities
- 2 ☐ I have slight problems doing my usual activities
- 3 ☐ I have moderate problems doing my usual activities
- 4 ☐ I have severe problems doing my usual activities
- 5 ☐ I am unable to do my usual activities

4. Pain/discomfort

- 1 ☐ I have no pain or discomfort
- 2 ☐ I have slight pain or discomfort
- 3 ☐ I have moderate pain or discomfort
- 4 ☐ I have severe pain or discomfort
- 5 ☐ I have extreme pain or discomfort

5. Anxiety/depression

- 1 ☐ I am not anxious or depressed
- 2 ☐ I am slightly anxious or depressed
- 3 ☐ I am moderately anxious or depressed
- 4 ☐ I am severely anxious or depressed
- 5 ☐ I am extremely anxious or depressed

B. We would like to know how good or bad your health is **TODAY**

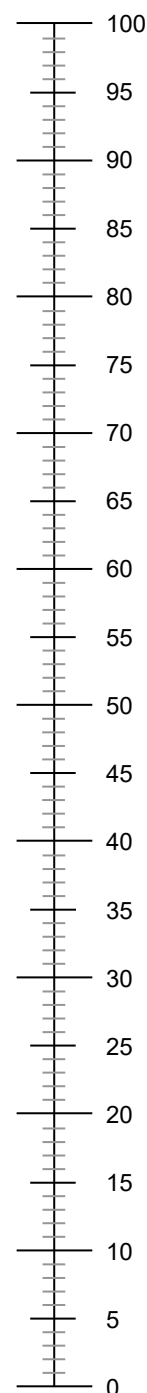
This scale is numbered from 0 to 100.

 100 means the best health you can imagine.

 0 means the worst health you can imagine.

 Mark an **X** on the scale on the right to indicate how the patient's health is TODAY.

PATIENT'S HEALTH STATE TODAY =

SCALE
 The best health
you can imagine

 The worst health
you can imagine

Office use only
 Subject # Subject Initials
Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.
ARROL

- A. During the past month have you often been bothered by feeling down, depressed or hopeless?
- 1 ☐ Yes
0 ☐ No
- B. During the past month have you often been bothered by little interest or pleasure in doing things?
- 1 ☐ Yes
0 ☐ No

HOSPITAL ANXIETY AND DEPRESSION SCALES (HADS)

- 1 (A). I feel tense or 'wound up':**
- 3 ☐ Most of the time
2 ☐ A lot of the time
1 ☐ From time to time, occasionally
0 ☐ Not at all
- 2 (D). I still enjoy the things I used to enjoy:**
- 0 ☐ Definitely as much
1 ☐ Not quite so much
2 ☐ Only a little
3 ☐ Hardly at all
- 3 (A). I get a sort of frightened feeling as if something awful is about to happen:**
- 3 ☐ Very definitely and quite badly
2 ☐ Yes, but not too badly
1 ☐ A little, but it doesn't worry me
0 ☐ Not at all
- 4 (D). I can laugh and see the funny side of things:**
- 0 ☐ As much as I always could
1 ☐ Not quite so much now
2 ☐ Definitely not so much now
3 ☐ Not at all
- 5 (A). Worrying thoughts go through my mind:**
- 3 ☐ A great deal of the time
2 ☐ A lot of the time
1 ☐ From time to time, but not too often
0 ☐ Only occasionally
- 6 (D). I feel cheerful:**
- 3 ☐ Not at all
2 ☐ Not often
1 ☐ Sometimes
0 ☐ Most of the time
- 7 (A). I can sit at ease and feel relaxed:**
- 0 ☐ Definitely
1 ☐ Usually
2 ☐ Not Often
3 ☐ Not at all
- 8 (D). I feel as if I am slowed down:**
- 3 ☐ Nearly all the time
2 ☐ Very often
1 ☐ Sometimes
0 ☐ Not at all
- 9 (A). I get a sort of frightened feeling like 'butterflies' in the stomach:**
- 0 ☐ Not at all
1 ☐ Occasionally
2 ☐ Quite Often
3 ☐ Very Often
- 10 I have lost interest in my appearance:**
- 3 ☐ Definitely
2 ☐ I don't take as much care as I should
1 ☐ I may not take quite as much care
0 ☐ I take just as much care as ever
- 11 I feel restless as I have to be on the move:**
- 3 ☐ Very much indeed
2 ☐ Quite a lot
1 ☐ Not very much
0 ☐ Not at all
- 12 (D). I look forward with enjoyment to things:**
- 0 ☐ As much as I ever did
1 ☐ Rather less than I used to
2 ☐ Definitely less than I used to
3 ☐ Hardly at all
- 13 I get sudden feelings of panic:**
- 3 ☐ Very often indeed
2 ☐ Quite often
1 ☐ Not very often
0 ☐ Not at all
- 14 I can enjoy a good book or radio or TV program:**
- 0 ☐ Often
1 ☐ Sometimes
2 ☐ Not often
3 ☐ Very seldom

Anxiety Score Depression Score

Form 6: SC - Hospital admissions (12 month)

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Subject #

--	--	--	--	--

Subject Initials

--	--	--

Instructions: Mark option boxes like this: ☒ Print text in block style completely within boxes.

Details/ dates of any hospital admissions during the 12 months and reasons:

- 1.
- 2.
- 3.
- 4.
- 5.

Supplementary results

2. REsilience to Seasonal ILlness and Increased Emergency admissioNs CarE (RESILIENCE) intervention case study

‘This is much better than the last time I left hospital and had no follow up. You feel like you’re just left to your own devices when you’re not even properly back on your feet again. This seems like a fantastic idea, and I feel like I hit the jackpot being included in the intervention group.’

Participant Profile: Ms. R, aged 76 years, was recruited into the trial during the transitional period of late winter/early spring with average temperatures in Melbourne hovering around 10°C, with temperatures near freezing on the day of her admission. Like two-thirds of the RESILIENCE cohort, this was not Ms R’s first cardiac admission, having been admitted twice already in the past few winter months. Consistent with the target patient population (multimorbid heart disease), Ms R. was recently diagnosed with heart failure with preserved ejection fraction, following a long history hypertension and type 2 diabetes. She was admitted for acute heart failure precipitated by rapid atrial fibrillation. Overall, she spent 6 days in hospital before being discharged to her own home.

RESILIENCE Profiling: Regardless of group assignment, all trial participants were subject to additional profiling to better understand their extent of multimorbidity (applying a tool¹ developed by the Co-Principal Investigators) and, based on an interdisciplinary model² supported by pilot data³, and any pre-existing vulnerabilities to climatic conditions/seasonal transitions in the weather. This more intensive profiling revealed significant issues among participants randomised to both groups, that required intervention before hospital discharge. In Ms R’s case, this included iron-deficiency anaemia and vitamin D deficiency – both of which were treated in-hospital. Typical of other women recruited into the trial (2-fold more likely than men) she also had a debilitating musculoskeletal condition that would hinder plans to improve her cardio-respiratory fitness. However, unlike 36% of other participants, she had no evidence of respiratory disease. Alternatively, as found in 20% of participants overall, it was noted Ms. R had a pre-existing pattern of ‘winter-based’ hospital admissions, and she reported ‘*venturing out into a very cold morning to do her shopping*’ before becoming ill, without indicating this may have contributed to her hospital admission. Beyond a poor history of vaccinations, Ms R demonstrated mild cognitive impairment during the index admission, had a high body mass index indicative of obesity and poorly controlled diabetes based on her glycated haemoglobin levels. Overall, a preliminary assessment indicated both physiological (3+ factors) and behavioural (3+ factors) indicative of seasonal/climatic vulnerability, complicated by her living alone.

Post-Discharge Home Visit: As per the interventional protocol, Ms. R was visited in her home 10 days following her hospital discharge by the RESILIENCE Nurse (who only contacted/managed those assigned to the intervention group – delivered in 94/103 participants). This occurred after COVID-19 restrictions, but it still required infection control measures (mask and distancing). Consistent with one in five home assessments, Ms. R demonstrated a combination of – **a**) poor awareness of potential weather-related provocations to her health, **b**) a paucity of warm clothes (combined with a blunted awareness of cold temperatures), **c**) a poorly insulated home, and **d**) ‘fuel poverty’ with an inability to pay for heating when she did feel cold. Whilst Ms. R appeared to be reasonably clinically stable, her temperature was in the low range (36°C) combined with a high heart rate (102 bpm) and blood pressure (150/92 mmHg) with evidence that she struggled to adhere to her pharmacological regimen. As with all participants in this group (but not Standard Care), the RESILIENCE Nurse, sat down (socially distanced) with Ms. R and made a list of priorities (immediate and for discussion at the RESILIENCE clinic) for case-management.

RESILIENCE Clinic: As part of the next phase of the interventional protocol, Ms. R attended a “virtual” phone clinic appointment with the RESILIENCE Nurse and Physician 7 days later where with Ms. R, the team reviewed the entirety of information and priorities collated thus far. Prior to this clinic visit, the RESILIENCE Nurse had already sourced warm clothing, door seals (for better insulation) and secured a home heating/cooling subsidy (also secured for 46% of intervention participants). At the clinic, it was recognised that Ms R. needed more general education and goal setting to avoid climatic provocations to her health and automated weather alerts (via her phone) were set up. A pharmacist medicines home review was arranged, with a dosette likely needed. As with many other patients, the RESILIENCE physician up-titrated Ms R’s pharmacological regimen to achieve

improved blood pressure and diabetes control, arranged pneumococcal and varicella vaccinations and scheduled a COVID-19 vaccination booster. A report was then sent to her general practitioner.

12-Month Follow-up: Along with one third of other people within the intervention group, Ms. R was categorised as highly vulnerable to climatic provocations to her health. Thus, the RESILIENCE Nurse maintained regular contact with Ms. R and conducted one further home visit to ensure initial plans were being implemented and no further intervention was applied. At 6-months (summer months) and 12-months (winter months) Ms. R remained free from hospitalisation, although she was readmitted (briefly for 3 days) with rapid atrial fibrillation during a spring cold-spell shortly thereafter.

References

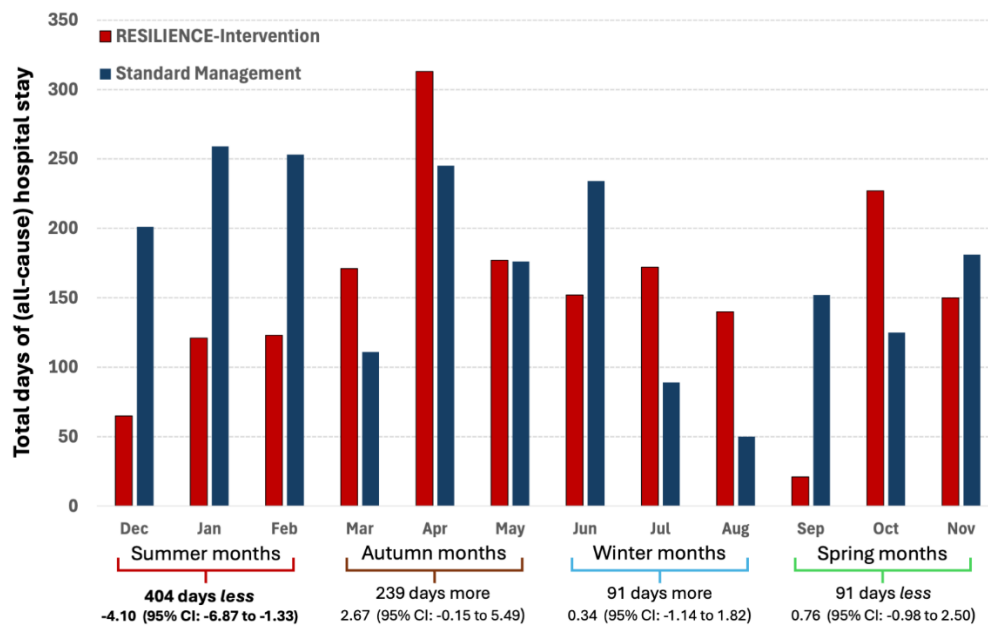
1. Stewart S, Riegel B, Boyd C, et al. Establishing a pragmatic framework to optimise health outcomes in heart failure and multimorbidity (ARISE-HF): A multidisciplinary position statement. *Int J Cardiol* 2016; **212**: 1-10.
2. Loader J, Chan YK, Hawley JA, et al. Prevalence and profile of "seasonal frequent flyers" with chronic heart disease: Analysis of 1598 patients and 4588 patient-years follow-up. *Int J Cardiol* 2019; **279**: 126-32.
3. Stewart S, Keates AK, Redfern A, McMurray JJV. Seasonal variations in cardiovascular disease. *Nat Rev Cardiol* 2017; **14**(11): 654-64

Table 1. Hospital re-admission or death during follow-up of participants in the RESILIENCE trial: Cox proportional hazards analysis*

		Status during follow-up		Cox Proportional Hazards Model
	Participants included	Event-free	Re-admission/death	Adjusted HRs (95% CIs)
Management group				
Standard management	100	28 (28%)	72 (72%)	0.96 (0.68–1.35)
RESILIENCE intervention	103	31 (31%)	72 (70%)	1
Demographic Profile				
Age (years), mean (SD)	203	71.9 (11.7)	77.2 (9.1)	1.01 (0.99–1.03)
Men	99	70 (71%)	29 (29%)	0.78 (0.54–1.10)
Women	104	74 (71%)	30 (29%)	1
Live alone	79	15 (19%)	64 (81%)	1.59 (1.12–2.26)
Live with someone	124	44 (35%)	80 (64%)	1
Behaviours				
3+ seasonal risk behaviours	30	7 (23%)	23 (77%)	1.54 (0.95–2.10)
<3 risk behaviours	173	52 (70%)	121 (70%)	1
Clinical Diagnoses (chronic heart disease)				
Coronary artery disease	113	32 (28%)	81 (72%)	1.46 (1.01–2.20)
Not diagnosed with coronary artery disease	90	27 (30%)	63 (70%)	1
Heart failure	92	18 (20%)	74 (80%)	1.67 (1.14–2.44)
Not diagnosed with heart failure	111	41 (37%)	70 (63%)	1
Comorbidity				
Diabetes	84	17 (20%)	67 (80%)	1.60 (1.11–2.31)
Not diagnosed with diabetes	119	42 (35%)	77 (65%)	1
Depressive symptoms on admission	87	23 (26%)	64 (74%)	1.53 (1.07–2.20)
No depressive symptoms on admission	116	36 (31%)	80 (69%)	1
Clinical Status				
eGFR (ml/min/1.73m ²), mean (SD)	203	72.6 (24.0)	57.0 (25.1)	0.99 (0.98–1.00)
Vitamin D level (nmol/L), mean (SD)	203	63.0 (34.1)	68.2 (31.7)	1.01 (1.00–1.01)
Clinical Management				
Pneumovax vaccination	84	17 (20%)	67 (80%)	1.64 (1.14–2.35)
Not vaccinated	119	42 (35%)	77 (65%)	1
Index Admission				
Length of stay (days), mean (SD)	203	5.3 (3.1)	9.1 (6.4)	1.02 (1.00–1.05)

CI = confidence interval; HR = hazard ratio; SD = standard deviation. * Proportional hazards confirmed by visual inspection. The model included the variables listed in Box 2 in the main article, with stepwise backward conditional removal of variables with $P > 0.1$ in univariate analyses; forced retention of intention-to-treat randomisation group, age, and sex, each statistically non-significant.

Figure 1. Pattern of all-cause hospital stay per month and season of readmission



CI = confidence interval.

Table 2. Adjusted difference (with 95% CI) between the intervention and standard management groups in hospital stay days per person per month during follow-up

Months	Absolute group difference (days of all-cause hospital stay)	Adjusted days per person (95% CI)
Summer		
Dec	136 days less	-3.38 (-6.06, -0.71)
Jan	138 days less	-4.26 (-6.84, -1.68)
Feb	130 days less	-6.10 (-8.91, -3.29)
Autumn		
Mar	60 days more	-1.29 (-2.99, 0.41)
Apr	68 days more	1.38 (-1.68, 4.44)
May	1 days more	0.79 (-0.63, 2.21)
Winter		
June	82 days less	-2.59 (-5.74, 0.56)
July	83 days more	4.11 (-0.08, 8.30)
Aug	90 days more	2.68 (-3.31, 8.67)
Spring		
Sept	131 days less	-1.44 (-5.33, 2.45)
Oct	102 days more	2.88 (-0.18, 5.94)
Nov	31 days less	-0.72 (-2.40, 0.96)

CI = confidence interval.

The TIDieR (Template for Intervention Description and Replication) Checklist*

Note: The page and section numbers in this checklist refer to the submitted manuscript, not to the published article or its Supporting Information file.

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Abstract/p2	Supplementary Statistical Analysis Plan (SAP)
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Introduction/p4	Index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076) & supplementary SAP
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Methods/p5-6 & Results/p8	Supplementary case report forms (CRF)s, SAP, Case Study & Index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Methods/p4-7 & Results/p8	Supplementary CRFs, SAP, Case Study & Index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Methods/p5-6 & Results/p8	Supplementary CRFs, SAP, Case Study & index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Methods p6 Results/p8	Supplementary Case Study
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Methods/p5-6 & Results/p8	Supplementary CRFs, SAP, Case-Study & index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Figure 1, p19 Results/p9	Supplementary Case Study, supplementary SAP
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Methods/p5-6 & Results/p9	Supplementary Case Study & Index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)
	MODIFICATIONS		
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Methods/p5-7	Supplementary SAP: Appendix I + Index paper (REF 13, https://doi.org/10.1093/eurjcn/zvad076)
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Methods/p5-6	Supplementary SAP & Case Study
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Figure 1, p19	Supplementary SAP & Case Study

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Note The page and section numbers in this checklist refer to the submitted manuscript, not to the published article or its Supporting Information file.

Section/Topic	Item No	Checklist item	Reported on page No**
Title and abstract	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5 + Statistical Analysis Plan (SAP)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5 + supplementary SAP + Index Paper (REF 13)
Participants	4a	Eligibility criteria for participants	5 + supplementary SAP
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6, 9, 19 + supplementary Case Study + Index Paper (REF 13)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7 + supplementary SAP
	6b	Any changes to trial outcomes after the trial commenced, with reasons	5 + supplementary SAP + Appendix1
Sample size	7a	How sample size was determined	6-7 + supplementary SAP
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment		describing any steps taken to conceal the sequence until interventions were assigned	N/A

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Supplementary SAP
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Supplementary SAP
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6-7 + Supplementary SAP
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6-7 + Supplementary SAP
Results Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	19, Figure 1 (flow-chart)
	13b	For each group, losses and exclusions after randomisation, together with reasons	19, Figure 1 (flow-chart, page 19)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7, 19 Figure 1 (flow-chart)
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17-18, Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9, 10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9-10
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10-13
Discussion Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13 + Supplementary SAP
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-13
Other information Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page