ESC Congress
2023 Amsterdam

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European Society of Cardiology

Heart failure trials

Gassan Moady

Galilee Medical Center, Nahariya

Disclosures

None

Selected trials

STEP HFPEF

HEART FID

STRONG HF

MESSAGE HF

Semaglutide in patients with heart failure with preserved ejection fraction and obesity

Mikhail N. Kosiborod[1]; Steen Z. Abildstrøm[2]; Barry A. Borlaug[3]; Javed Butler[4]; Søren Rasmussen[2]; Melanie Davies[5]; G. Kees Hovingh[2]; Dalane W. Kitzman[6]; Marie L. Lindegaard[2]; Daniél Vega Møller[2]; Sanjiv J. Shah[7]; Marianne Bach Treppendahl[2]; Subodh Verma[8]; Walter Abhayaratna[9]; Fozia Z. Ahmed[10]; Vijay Chopra[11]; Justin Ezekowitz[12]; Michael Fu[13]; Hiroshi Ito[14]; Małgorzata Lelonek[15]; Vojtěch Melenovský[16]; Béla Merkely[17]; Julio Núñez[18]; Eduardo Perna[19]; Morten Schou[20]; Michele Senni[21]; Kavita Sharma[22]; Peter van der Meer[23]; Dirk Von Lewinski[24]; Dennis Wolf[25]; and Mark C. Petrie[26] for the STEP-HFpEF Trial Committees and Investigators

[1]Department of Cardiovascular Disease, Saint Luke's Mid America Heart Institute, University of Missouri-Kansas City School of Medicine, Kansas City, MO, USA; [2]Novo Nordisk A/S, Søborg, Denmark; [3]Department of Cardiovascular Medicine, Mayo Clinic, Rochester, MN, USA; [4]Baylor Scott and White Research Institute, Dallas, TX, USA, and Department of Medicine, University of Mississippi, Jackson, MS, USA; [5]Diabetes Research Centre, University of Leicester, Leicester, UK, and NIHR Leicester Biomedical Research Centre, Leicester, UK; [6]Department of Cardiovascular Medicine and Section on Geriatrics and Gerontology, Wake Forest School of Medicine, Winston-Salem, NC, USA; [7]Division of Cardiology, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [8]Division of Cardiac Surgery, Li Ka Shing Knowledge Institute of St Michael's Hospital, Unity Health Toronto, University of Toronto, Toronto, ON, Canada; [9]College of Health and Medicine, The Australian National University, Canberra, Australia; [10]Division of Cardiovascular Sciences, Faculty of Biology, Medicine and Health, University of Manchester, UK; [11]Max Super Specialty Hospital, Saket, New Delhi, India; [12]University of Alberta, Edmonton, Canada; [13]Section of Cardiology, Department of Medicine, Sahlgrenska University Hospital-Ostra, Gothenburg, Sweden; [14]Department of General Internal Medicine 3, Kawasaki Medical School, Okayama, Japan; [15]Department of Noninvasive Cardiology, Medical University of Lodz, Lodz, Poland; [16]Institute for Clinical and Experimental Medicine – IKEM, Prague, Czech Republic; [17]Heart and Vascular Centre, Semmelweis University, Budapest, Hungary; [18]Hospital Clínico Universitario de Valencia, INCLIVA, Universidad de Valencia, and CIBER Cardiovascular, Valencia, Spain; [19]Instituto de Cardiologia J. F. Cabral, Corrientes, Argentina; [20]Department of Cardiology, Herlev-Gentofte Hospital, University of Copenhagen, Herlev, Denmark; [21]ASST Papa Giovanni XXIII, Bergamo, Italy; [22]John Hopkins Hospital, Baltimore, MD, USA; [23]Department of Cardiology, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands; [24]Medical University of Graz, Graz, Austria; [25]Cardiology and Angiology, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany; [26]School of Cardiovascular and Metabolic Health, University of Glasgow, Glasgow, UK.

This trial was sponsored by Novo Nordisk and is registered with ClinicalTrials.gov (NCT04788511). Administrative support and development of figures and tables was provided by Casey McKeown, RVN, and Lucy Ambrose, DPhil, CMPP, FdSc, of Apollo, OPEN Health Communications, and funded by Novo Nordisk A/S, in accordance with Good Publication Practice guidelines.

Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

Background

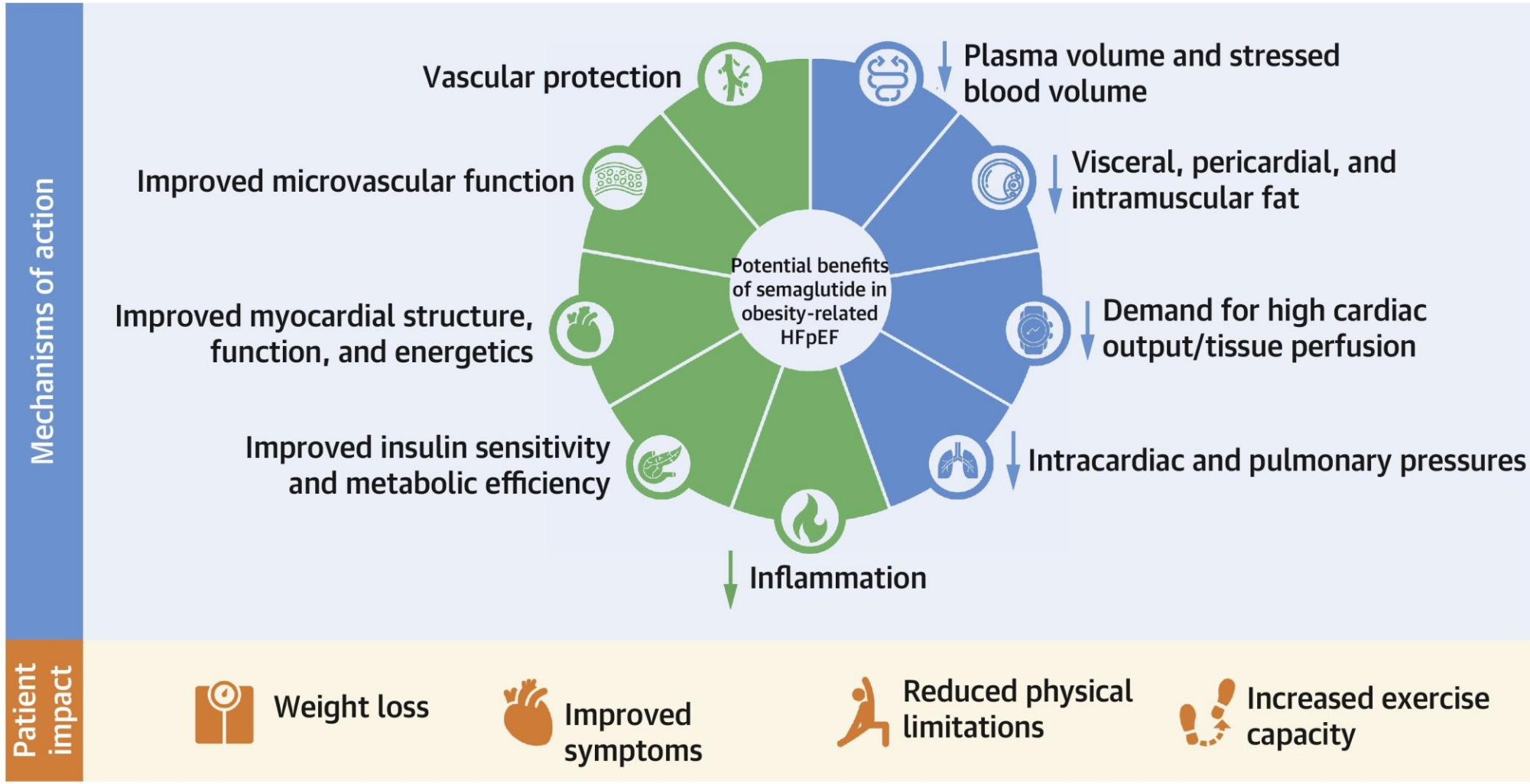
- HFpEF accounts for **more than half** of all heart failure cases, with few efficacious treatments available[1–3]
- The majority of patients with HFpEF have **overweight or obesity**[3]
- The **obesity HFpEF** phenotype has unique clinical and haemodynamic features and is associated with an especially high burden of symptoms and functional impairment[1,4,5]
- There are no approved therapies specifically targeting the obesity phenotype of HFpEF
- **Semaglutide** — a potent, once-weekly GLP-1RA — produces substantial weight loss in individuals with overweight and obesity[6,7]
- **STEP-HFpEF** (NCT04788511) is the first trial to investigate the effects of s.c. semaglutide 2.4 mg once weekly on symptoms, physical limitations and exercise function in people with the obesity phenotype of HFpEF

GLP-1RA, glucagon-like peptide-1 receptor agonist; HFpEF, heart failure with preserved ejection fraction; s.c., subcutaneous; STEP, Semaglutide Treatment Effect in People with obesity.

1. Borlaug BA, et al. Cardiovasc Res. 2023;118(18):3434–3450; 2. McDonagh TA, et al. Eur Heart J. 2021;42:3599–3726; 3. Dunlay SM, et al. Nat Rev Cardiol. 2017;14(10):591–602; 4. Haas M, et al. Circ Heart Fail. 2011;4(3):324–331; 5. Reddy YNV, et al. Mayo Clin Proc. 2019;94(7):1199–1209; 6. Kushner RF, et al. Obesity (Silver Spring). 2020;28:1050–1061; 7. Wegovy™ US prescribing information. Available from: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215256 [accessed 4 May 2023].

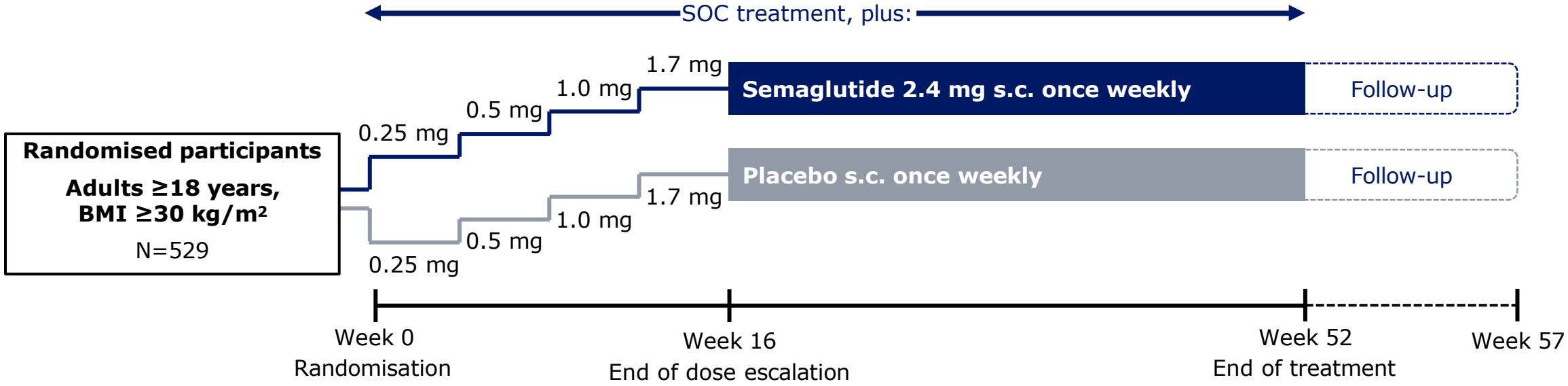
Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

CENTRAL ILLUSTRATION: Potential Mechanisms of Benefit for Semaglutide in Individuals With the Obesity Phenotype of HFpEF



Kosiborod MN, et al. J Am Coll Cardiol HF. 2023;11(8P1):e009664.

STEP-HFpEF trial design



Key inclusion criteria

- LVEF ≥45%, NYHA functional class II–IV, KCCQ-CSS <90 points, 6MWD ≥100 metres, and ≥1 of the following:
  - Elevated left ventricular filling pressures (invasively measured)
  - Elevated natriuretic peptide levels and structural echocardiographic abnormalities
  - HF hospitalisation (previous 12 months) and ongoing requirement for diuretics and/or structural echocardiographic abnormalities

Key exclusion criteria

- Prior/planned bariatric surgery
- Recent self-reported weight change >5 kg (11 lbs)
- Recent adverse CV event or HF hospitalisation
- SBP of >160 mmHg at screening
- HbA_{1c} ≥6.5% or known medical history of diabetes

6MWD, 6-minute walk distance; BMI, body mass index; CV, cardiovascular; echo, echocardiographic; HbA_{1c}, glycated haemoglobin; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; KCCQ-CSS, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; SBP, systolic blood pressure; s.c., subcutaneous; SOC, standard of care; STEP, Semaglutide Treatment Effect in People with obesity.

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Primary and confirmatory secondary endpoints, and testing hierarchy

Dual primary endpoints

- Change in KCCQ-CSS from baseline to week 52
- Percentage change in body weight from baseline to week 52

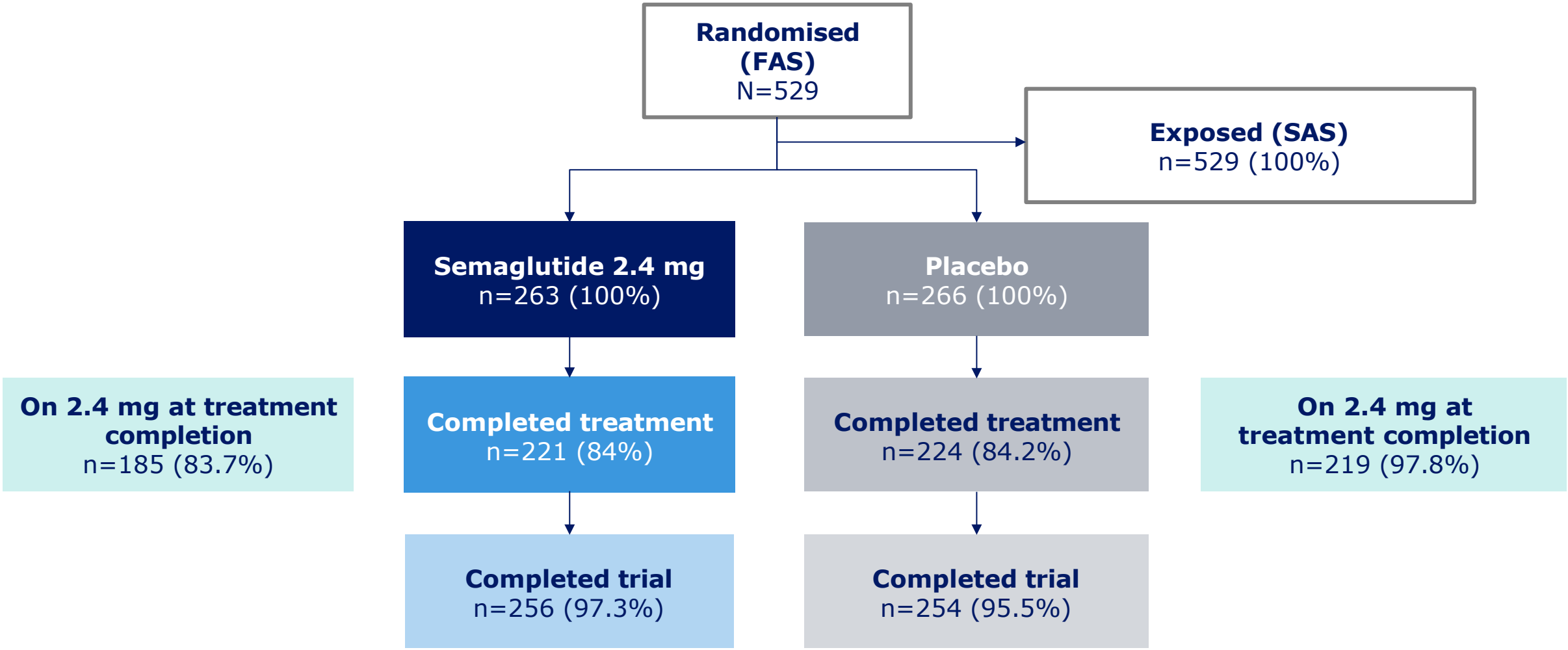
Confirmatory secondary endpoints

- Change in 6MWD from baseline to week 52
- Hierarchical composite endpoint comprising:
  - Time to all-cause death
  - Number of HF events requiring hospitalisation or urgent HF visit
  - Time to first HF event requiring hospitalisation or urgent HF visit
  - Differences of at least 15, 10 and 5 points in KCCQ-CSS change between baseline and week 52
  - Difference of at least 30 metres in 6MWD change between baseline and week 52
- Change in CRP from baseline to week 52

Values of 0.5 and 1 in the figure are weights for alpha-spending in the testing hierarchy. 6MWD, 6-minute walk distance; CRP, C-reactive protein; HF, heart failure; KCCQ-CSS, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score.
Burman CF, et al. Stat Med. 2009;28(5):739–761.

Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

Participant disposition



FAS, full analysis set; SAS, safety analysis set.

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Baseline demographics and clinical characteristics

Characteristic	Semaglutide 2.4 mg n=263	Placebo n=266	Total N=529
Female, n (%)	149 (57)	148 (56)	297 (56)
Age, years	70 (62; 75)	69 (62; 75)	69 (62; 75)
Race,* n (%)			
Black or African American	8 (3)	13 (5)	21 (4)
White	255 (97)	252 (95)	507 (96)
Other	0	1 (0.4)	1 (0.2)
Body weight, kg	105 (92; 120)	105 (92; 122)	105 (92; 121)
BMI, kg/m²	37 (34; 41)	37 (33; 42)	37 (34; 41)
<35 kg/m², n (%)	89 (34)	91 (34)	180 (34)
≥35 kg/m², n (%)	174 (66)	175 (66)	349 (66)
Waist circumference, cm	119 (111; 127)	120 (111; 129)	119 (111; 128)
LVEF, %	57 (50; 60)	57 (50; 60)	57 (50; 60)
NYHA functional class, n (%)			
Class II	183 (70)	167 (63)	350 (66)
Class III–IV	80 (30)	99 (37)	179 (34)
KCCQ-CSS, points	59 (43; 73)	58 (41; 73)	59 (42; 73)
6MWD, metres	316 (251; 386)	326 (232; 392)	320 (240; 389)
NT-proBNP, pg/mL	414 (229; 1014)	500 (205; 1025)	451 (218; 1015)
SBP, mmHg	133 (122; 145)	132 (120; 142)	133 (121; 144)

*Data are median (IQR), unless otherwise indicated and are from the full analysis set; *Race was reported by the investigator.*
6MWD, 6-minute walk distance; BMI, body mass index; IQR, interquartile range; KCCQ-CSS, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; NYHA, New York Heart Association; SBP, systolic blood pressure.

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Comorbidities and concomitant medications at baseline

Parameter	Semaglutide 2.4 mg n=263	Placebo n=266	Total N=529
Comorbidities at screening, n (%)			
Atrial fibrillation	(51) 135	140 (53)	275 (52)
Hypertension	216 (82)	217 (82)	433 (82)
HF medications, n (%)			
Beta blockers	201 (76)	217 (82)	418 (79)
ACEI/ARB/ARNI	210 (80)	214 (81)	424 (80)
Diuretics	207 (79)	220 (83)	427 (81)
Loop diuretics	158 (60)	171 (64)	329 (62)
Thiazides	40 (15)	50 (19)	90 (17)
MRAs	89 (34)	95 (36)	184 (35)
SGLT2i	8 (3.0)	11 (4.1)	19 (3.6)

Data are n (%) and are from the full analysis set.
ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; HF, heart failure; MRA, mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose co-transporter-2 inhibitor.

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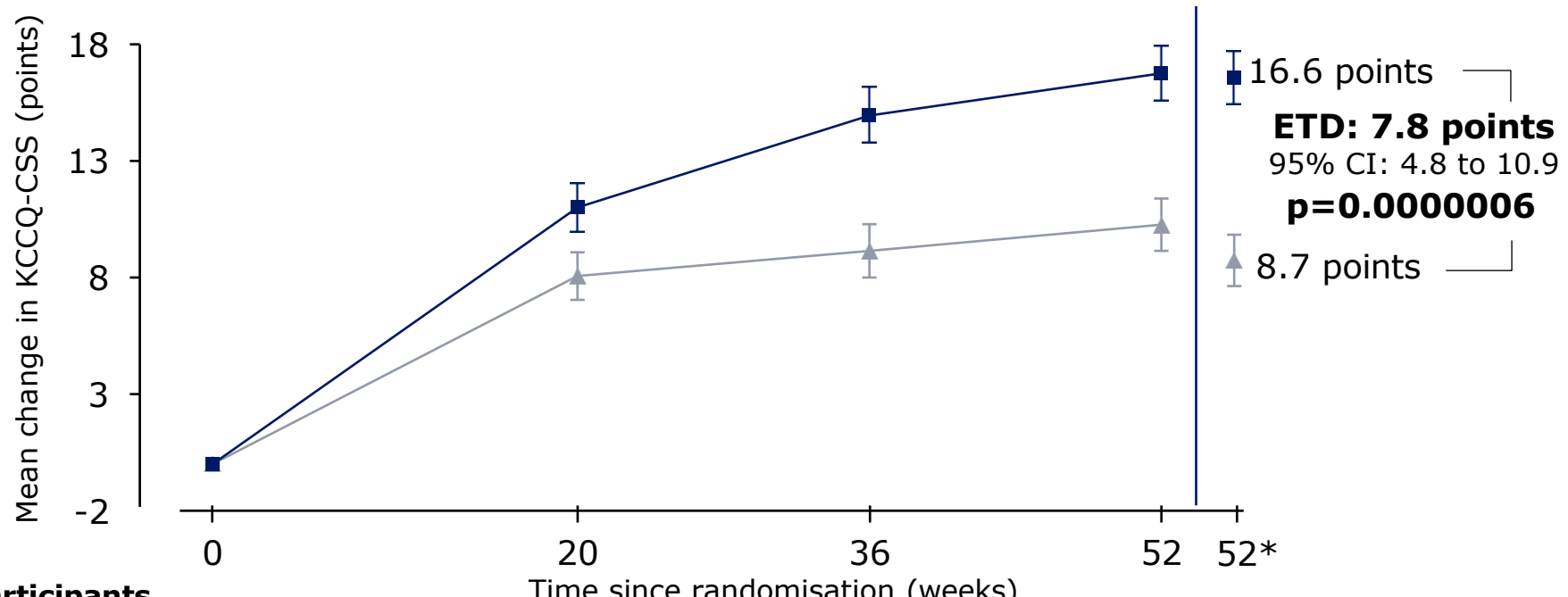
Change from baseline to week 52 in KCCQ-CSS

Dual primary endpoints



Participants					
Sema 2.4 mg	263	249	225	243	263
Placebo	266	242	217	237	266

Overall mean baseline KCCQ-CSS (points) 56.7

Semaglutide 2.4 mg Placebo

*Data are for the treatment policy estimand. *Data are estimated mean changes from baseline to week 52 for the treatment policy estimand using ANCOVA and an imputation approach for missing data. ANCOVA, analysis of covariance; CI, confidence interval; ETD, estimated treatment difference; KCCQ-CSS, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score; sema, semaglutide.*

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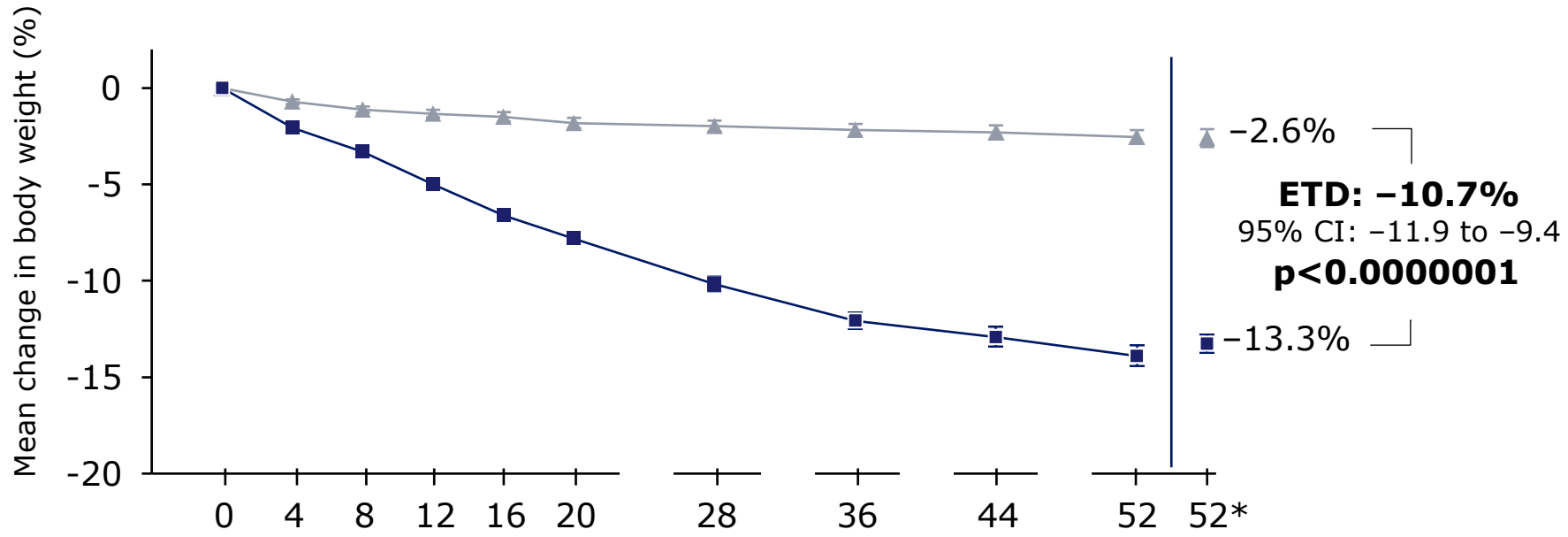
Change from baseline to week 52 in body weight

Dual primary endpoints



*Data are for the treatment policy estimand. *Data are estimated mean changes from baseline to week 52 for the treatment policy estimand using ANCOVA and an imputation approach for missing data. ANCOVA, analysis of covariance; CI, confidence interval; ETD, estimated treatment difference; sema, semaglutide.*

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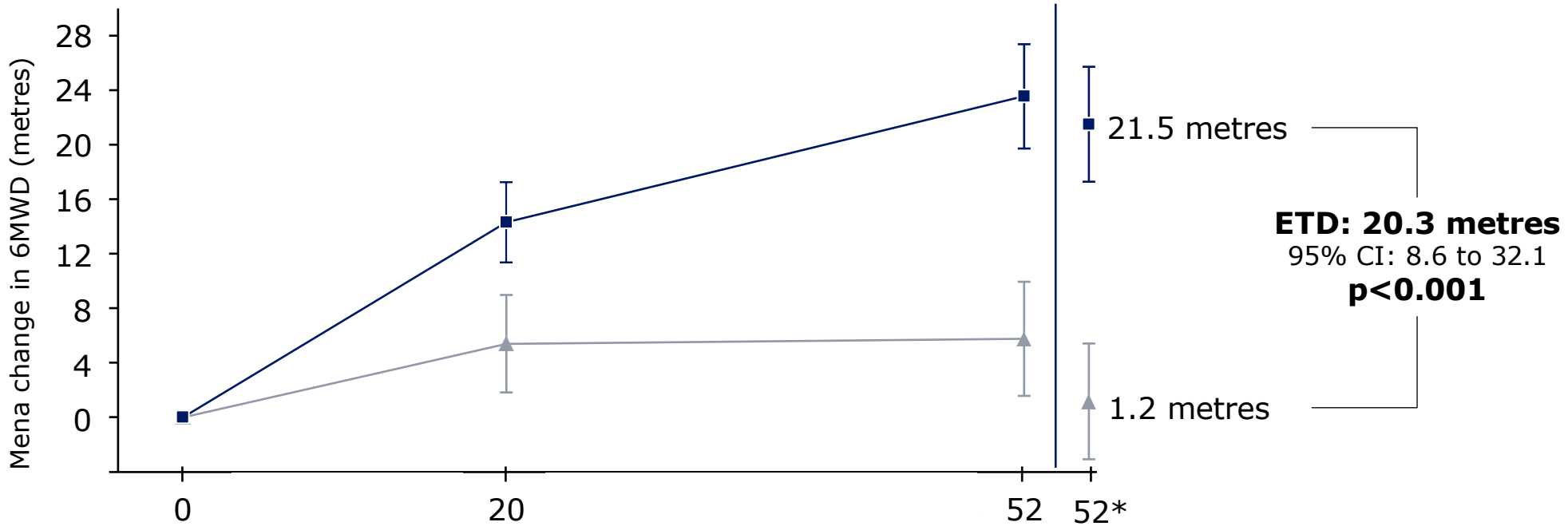
Change from baseline to week 52 in 6MWD

Confirmatory secondary endpoints



Participants				
Sema 2.4 mg	263	245	240	263
Placebo	266	232	225	266

Overall mean baseline 6MWD (m) 317.1

Semaglutide 2.4 mg Placebo

*Data are for the treatment policy estimand. *Data are estimated mean changes from baseline to week 52 for the treatment policy estimand using ANCOVA and an imputation approach for missing data. 6MWD, 6-minute walk distance; CI, confidence interval; ETD, estimated treatment difference; sema, semaglutide.*

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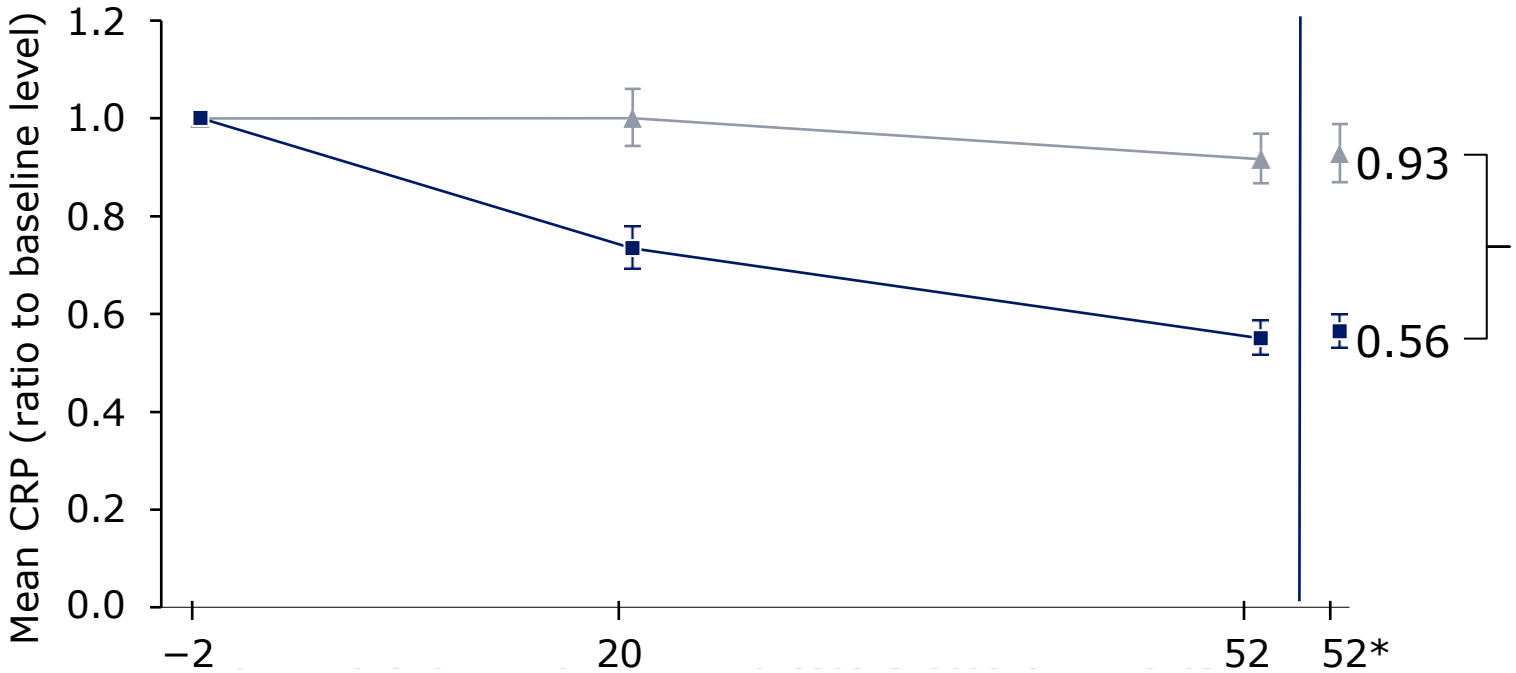
Change from baseline (screening) to week 52 in CRP

Confirmatory secondary endpoints



ETR: 0.61
95% CI: 0.51 to 0.72
p<0.001

Participants				
Sema 2.4 mg	263	245	240	263
Placebo	266	232	225	266

Overall median baseline CRP (mg/L) 3.8

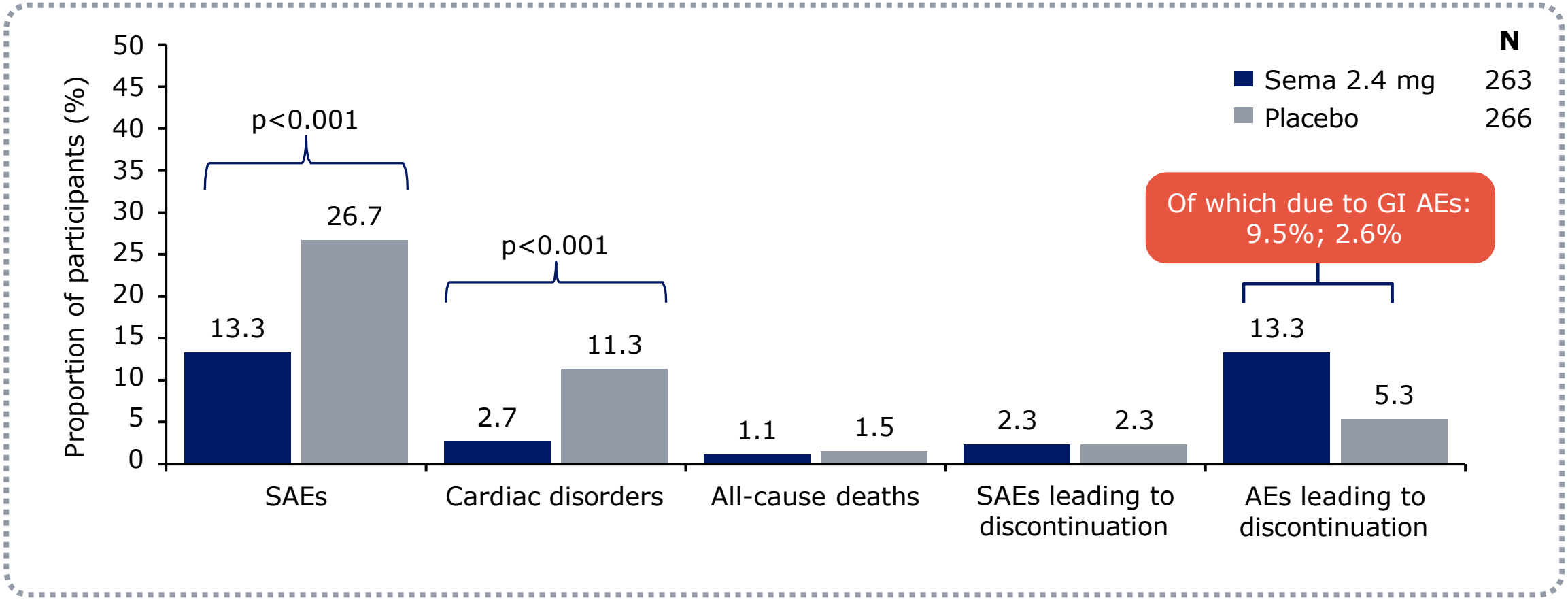
Semaglutide 2.4 mg Placebo

*Data are for the treatment policy estimand. *Data are estimated mean changes from screening at week -2 to week 52 for the treatment policy estimand using ANCOVA and an imputation approach for missing data.*
CI, confidence interval; CRP, C-reactive protein; ETR, estimated treatment ratio; sema, semaglutide.

Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

Safety overview

On-treatment period



The overall comparison of serious adverse events (SAEs), as well as the most frequently reported SAEs between the two treatment groups was performed post-hoc using Fisher's exact test and reported using unadjusted two-sided p values (p values are only shown for SAE groups with a frequency above 5% in either treatment group). AE, adverse event; GI, gastrointestinal; SAE, serious adverse event; sema, semaglutide.

Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

Conclusions

In patients with heart failure with preserved ejection fraction and obesity, treatment with semaglutide (2.4 mg) led to larger reductions in symptoms and physical limitations, greater improvements in exercise function, and greater weight loss than placebo.

HF, heart failure; HFpEF, heart failure with preserved ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; SAE, serious adverse event.

Kosiborod MN, et al. Presented at the European Society of Cardiology Congress, 25–28 August 2023.

The HEART-FID Trial

Efficacy and Safety of Ferric Carboxymaltose as Treatment for Heart Failure with Iron Deficiency

On behalf the HEART-FID Investigators and Participants

August 26, 2023

Background

- Iron deficiency (ID) is common in patients with heart failure with reduced ejection fraction (HFrEF) and it is associated with worse symptoms and adverse prognosis.
- IV ferric carboxymaltose (FCM) improves quality of life and exercise capacity in HFrEF with ID. (FAIR-HF, CONFIRM-HF, EFFECT-HF)
- AFFIRM-AHF, IRONMAN and meta-analyses suggested potential benefits with IV iron on HF hospitalizations without a significant effect on mortality.
  - Thus, further evidence is needed regarding the effect of FCM on clinical events.

Ponikowski P, *et al. Lancet* 2020;396(10266):1895-1904.
Kalra PR, *et al. Lancet* 2022;400(10369):2199-2209.
Graham FJ, *et al. Eur J Heart Fail* 2023;25(4):528-537.
Anker SD, *et al. Eur J Heart Fail* 2023 (in press).

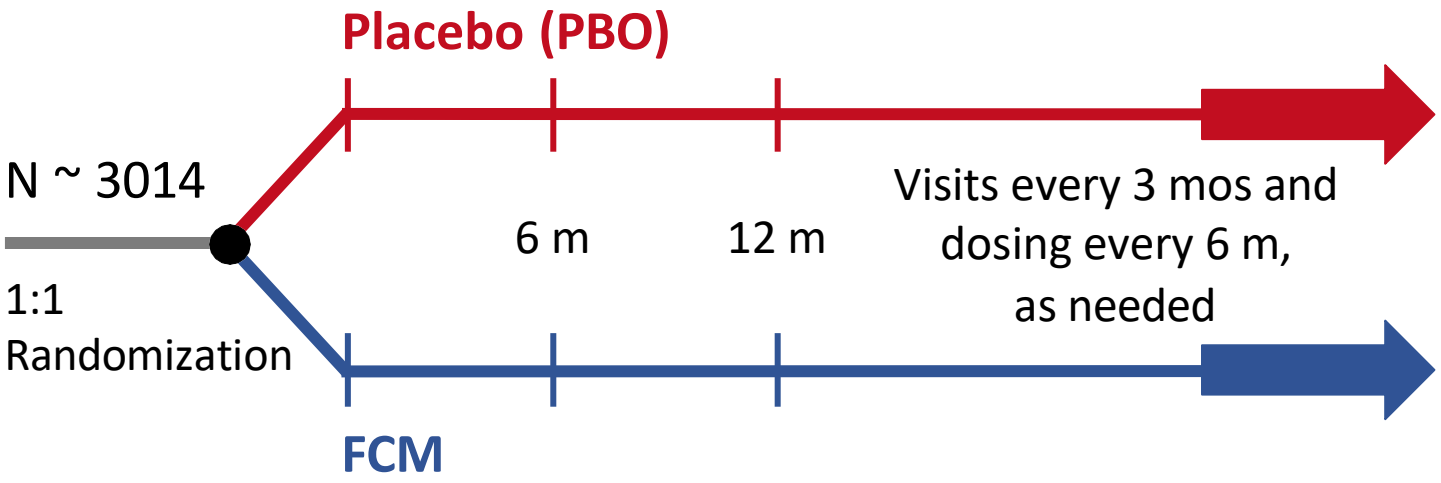
Mentz RJ, *et al. Circ Heart Fail* 2021;14(5):e008100

Design

Double-blind, placebo-controlled, event-driven RCT

HEART-FID

Chronic HFrEF (EF ≤40%) with Iron Deficiency*



FCM Dosing (every 6 m based on labs†)	
<50 kg	≥50kg
Two doses of **15 mg/kg** separated by 7 days	Two doses of **750 mg** separated by 7 days

†Once iron replete, transition to placebo; blinding maintained

Primary Endpoint:

Hierarchical Composite:

All-cause mortality (12 m)

HF hospitalizations (12 m)

Change in 6-MWD (6 m)

Top Secondary Endpoint:

CV death or HF hospitalization

Key Inclusion Criteria:

- *Iron deficiency
  - Ferritin <100 ng/mL or
  - 100-300 ng/mL + TSAT <20%
- HF hosp (12 m) or ↑ NT-proBNP (90 d) [>600 pg/mL (NSR) or >1000 pg/mL (AF)]

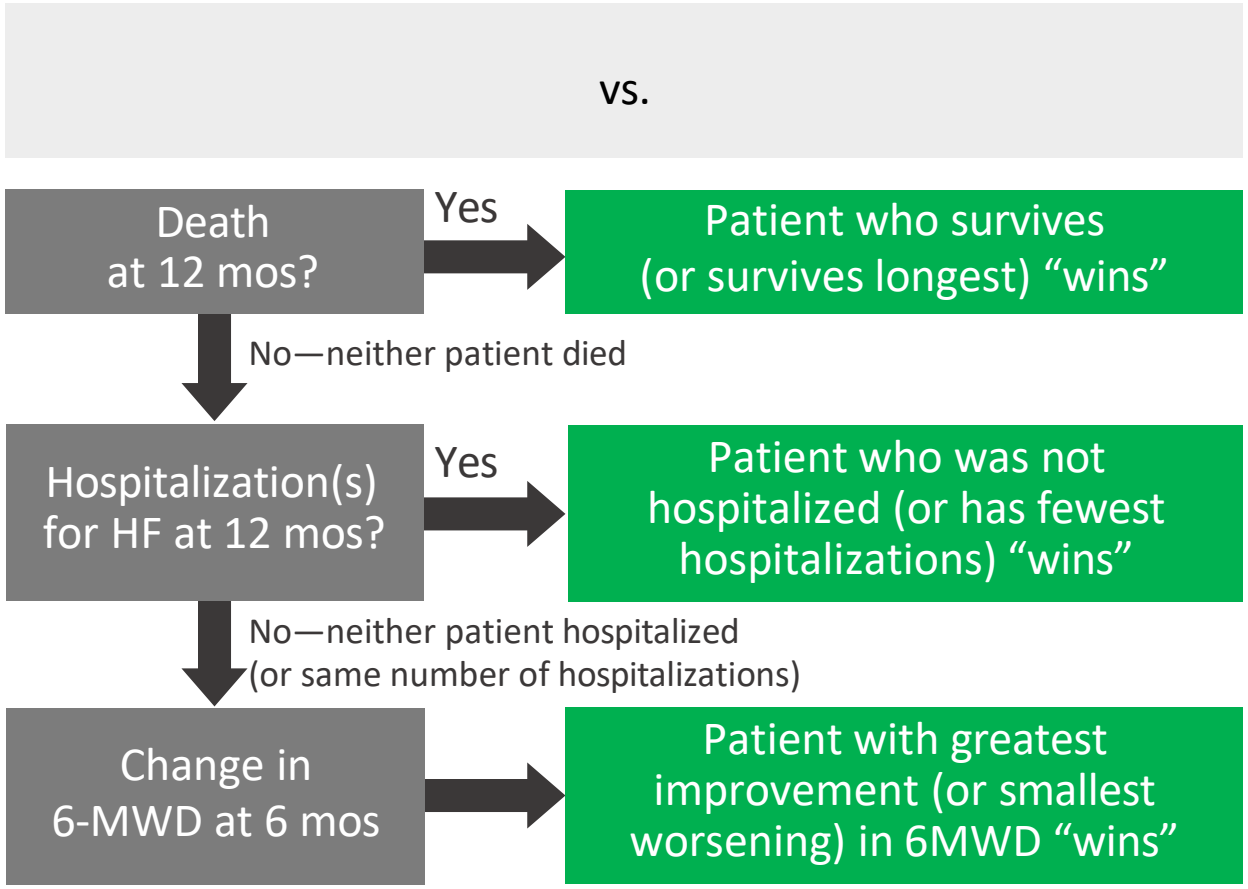
Mentz RJ, *et al. Circ Heart Fail 2021*

ClinicalTrials.gov Identifier: NCT03037931

Statistical Methods

HEART-FID

HIERARCHICAL PRIMARY ENDPOINT



PRIMARY METHODOLOGY:

Patients ranked from lowest to highest based on hierarchical composite

- Wilcoxon-Mann-Whitney test: Compared sum of ranks
- 2-sided significance of **0.01** (US regulatory purposes)
- Estimated 90% power with 1507 per group (N=3014)

P-value (Wilcoxon-Mann-Whitney test) < 0.01

TO SUPPORT CLINICAL INTERPRETATION — WIN RATIO:

Each participant from FCM group ranked for comparison with each participant from control group

TOP SECONDARY ENDPOINT

- Time to CV death or HF hospitalization
  - 2-sided significance level of **0.04**
- Anticipated HR set at 0.80
  - Target **771 participants** with an event
  - Estimated 90% power

Mentz RJ, *et al. Circ Heart Fail* 2021

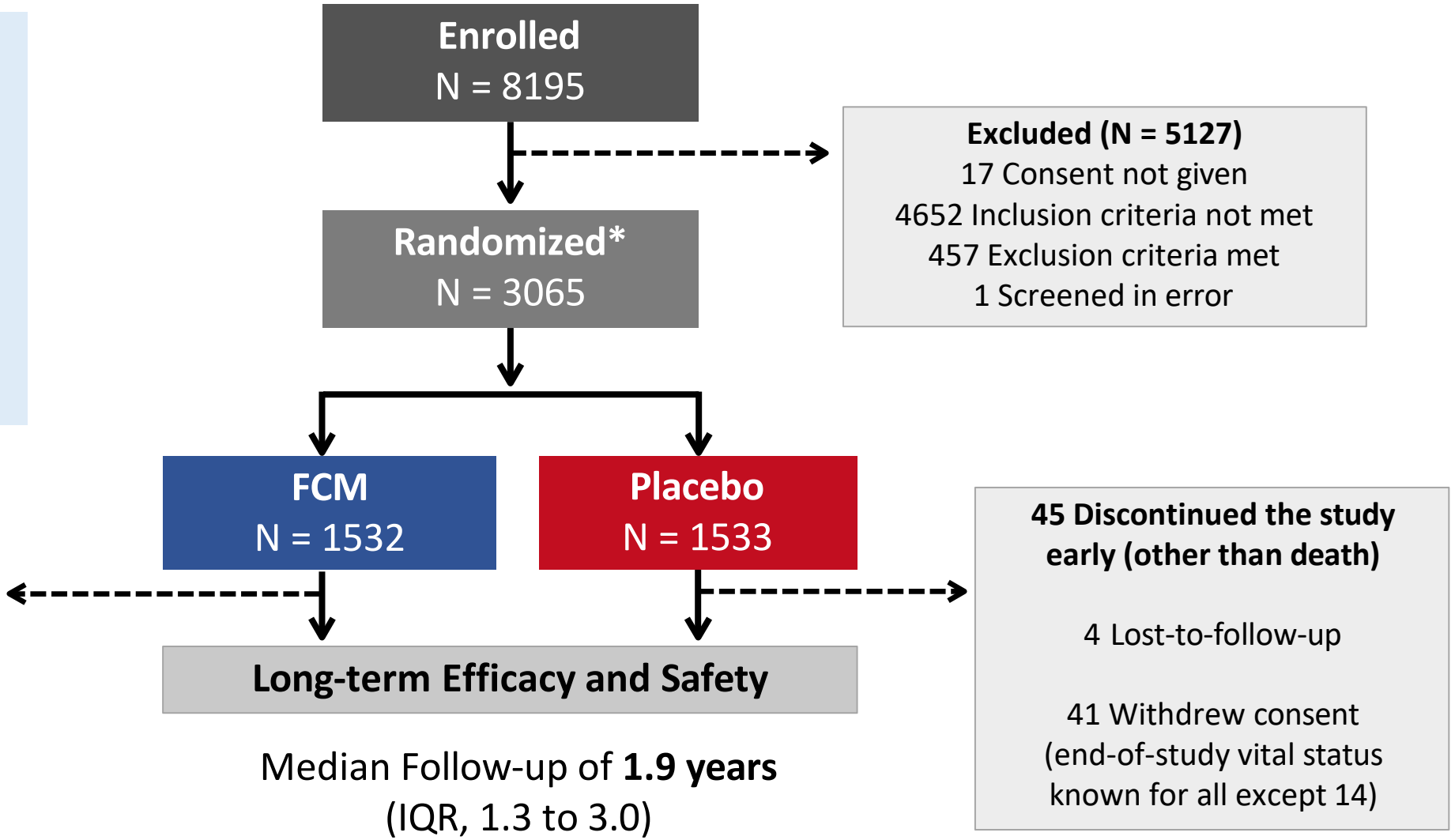
Study Execution

HEART-FID

ENROLLMENT BEGAN
March 2017

RECRUITMENT ENDED
November 2021

FOLLOW-UP ENDED
February 2023



Duke Clinical Research Institute

*3 patients randomized twice

Baseline Characteristics

HEART-FID

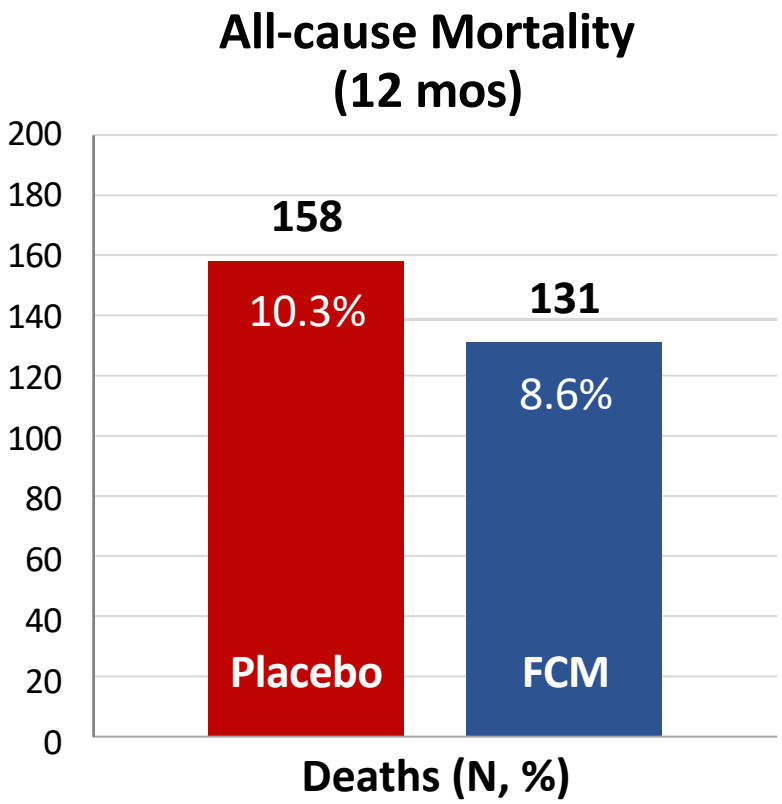
Characteristics	FCM (N=1532)	Placebo (N=1533)
Age (yr)	69±11	69±11
Women	33%	35%
White race	86%	86%
Black race	11%	10%
North America	47%	47%
Asia Pacific	7%	7%
Europe	46%	46%
EF (%)	31 ± 7	31 ± 7
NYHA II / III-IV	52% / 48%	54% / 46%
Ischemic etiology	61%	59%
NT-proBNP (pg/mL)	1486 (727, 3045)	1424 (710, 2884)
Hemoglobin (g/dL)	12.6 ± 1.4	12.5 ± 1.4
eGFR (mL/min/1.73m^2)	59 ± 22	61 ± 22
ACEi or ARB / ARNI	59% / 30%	60% / 29%
Beta-blocker	92%	93%
MRA	56%	55%
SGLT2i	8%	7%

Presented as %, Mean ± SD or median (IQR)

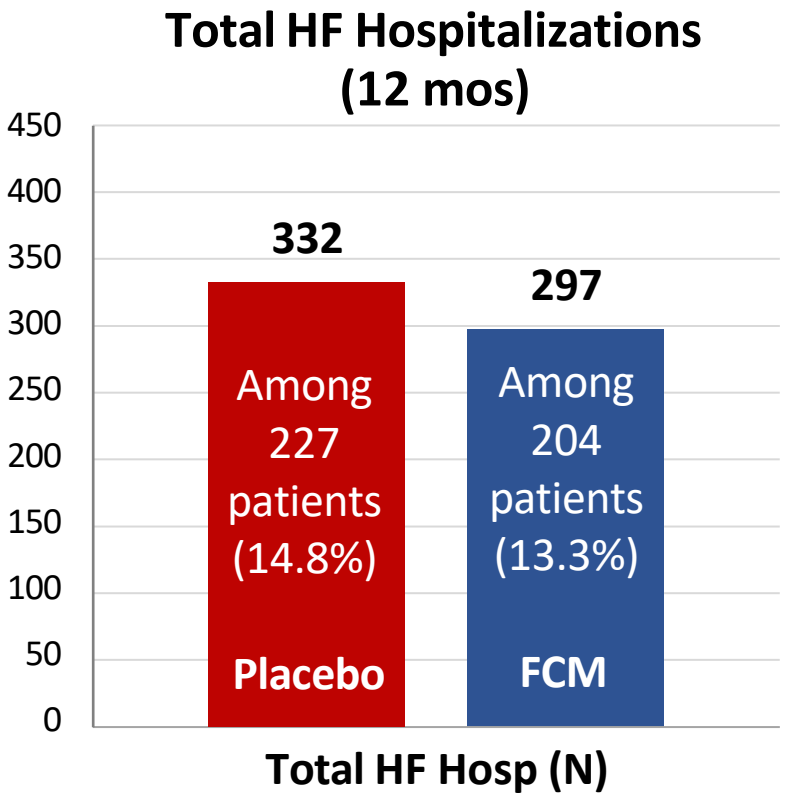
Primary Hierarchical Endpoint

HEART-FID

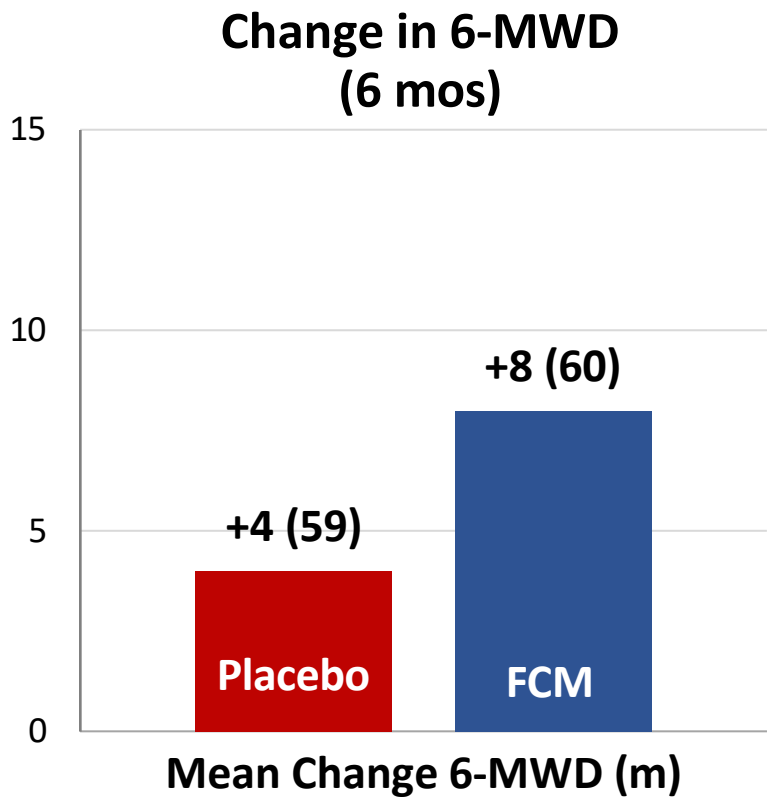
P-value (Wilcoxon-Mann-Whitney test) = 0.019



1.7% ARR



270 fewer HF hospitalization days

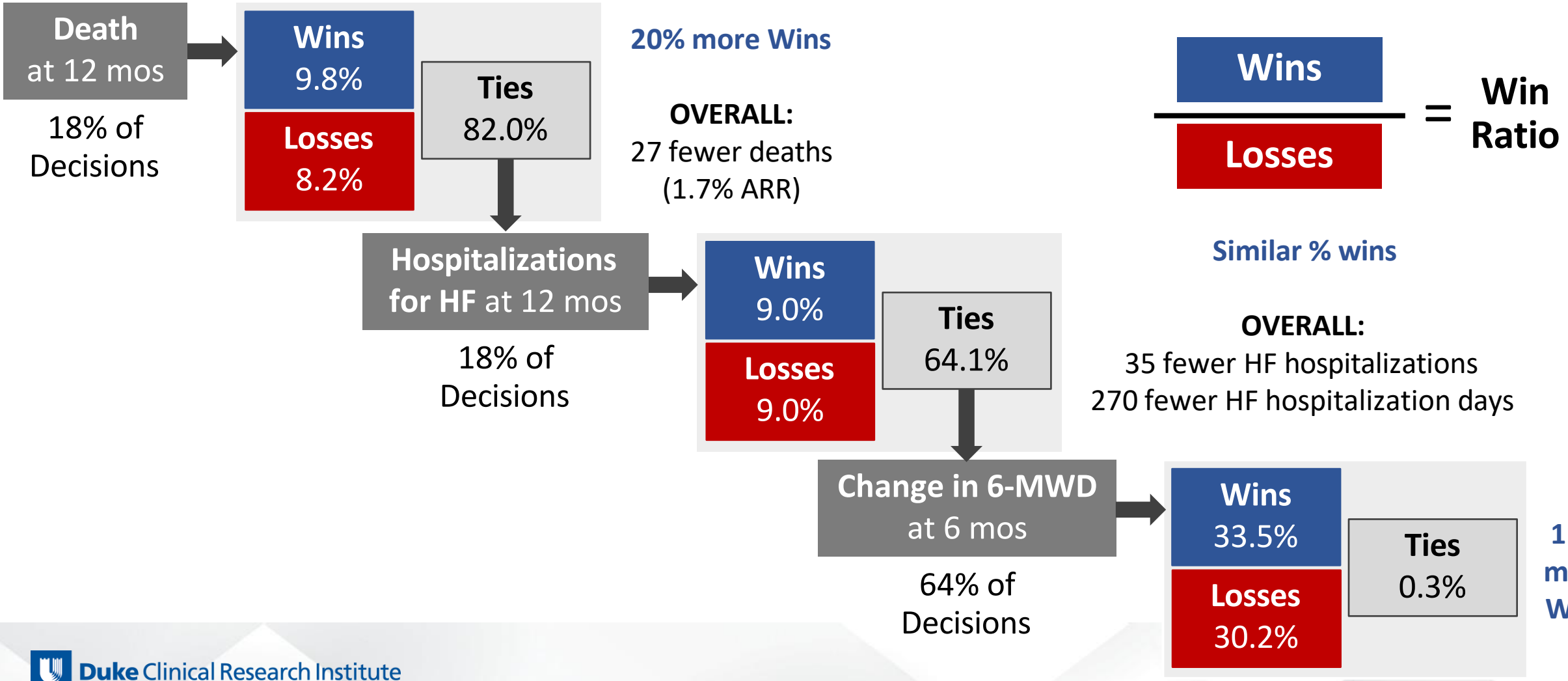


+4 meter benefit

Primary Endpoint: Win Ratio

Overall Win Ratio (99%CI) = 1.10 (0.99, 1.23)

1st Imputed Dataset:



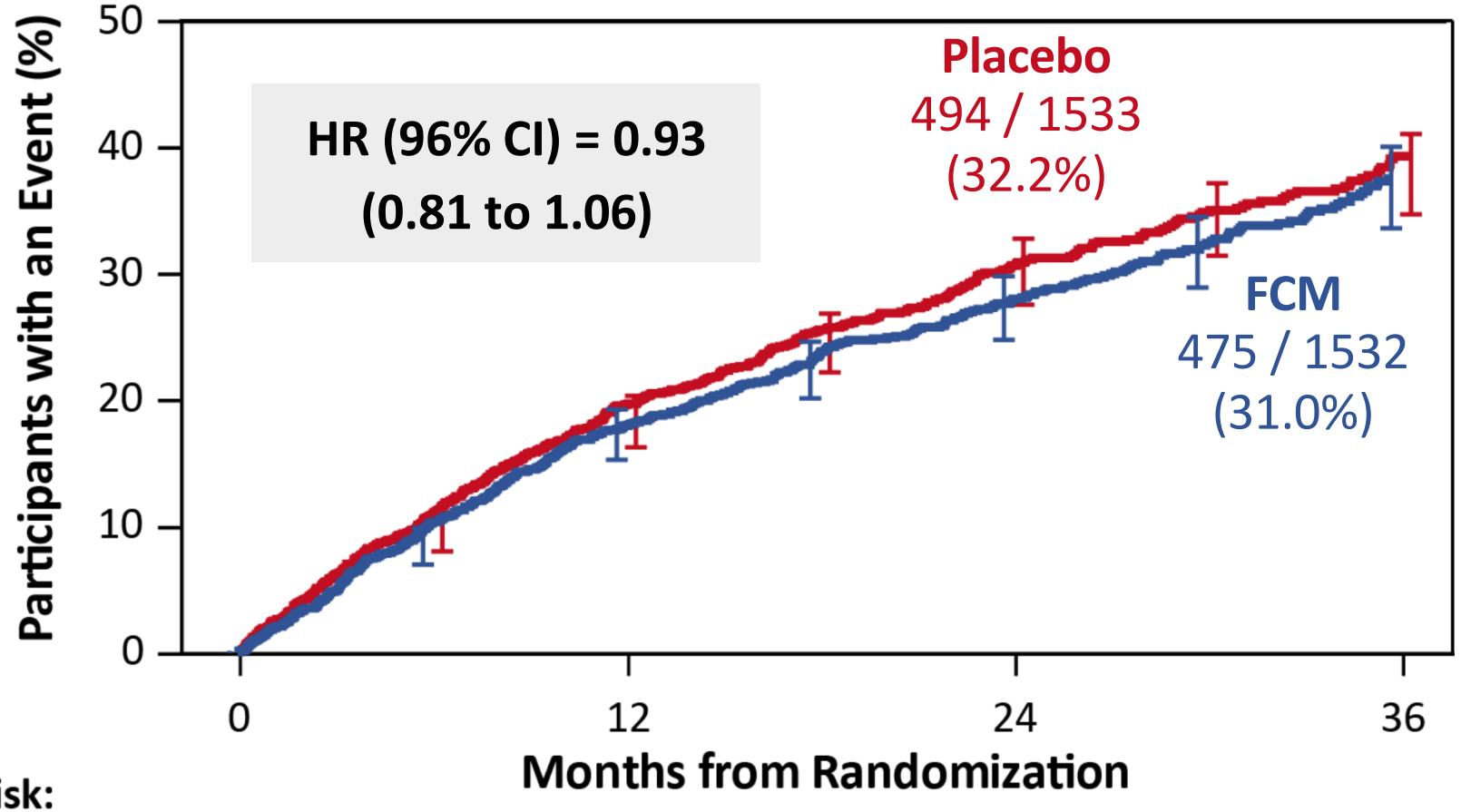
Top Secondary Endpoint

HEART-FID

Time to Cardiovascular Death or First HF Hospitalization

Target **771** patients with a first event

Observed **969** patients with an event

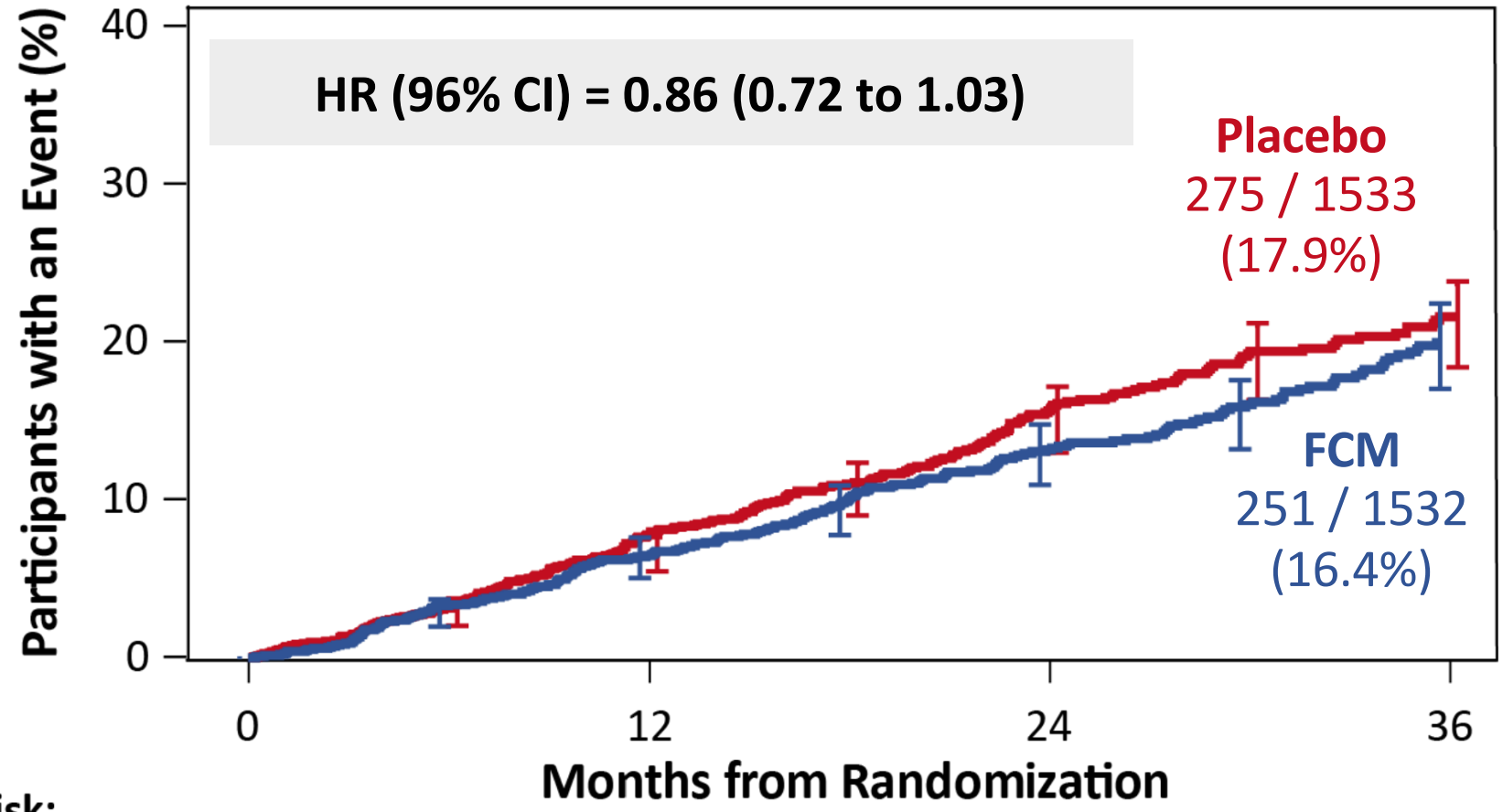


17.3 (PBO) vs. 16.0 (FCM) events per 100 patient years

Number at Risk:							
FCM	1532	1390	1219	913	642	429	314
Placebo	1533	1369	1189	872	610	410	291

Median Follow-up of **1.9 years** (IQR, 1.3 to 3.0)

Time to CV Death



8.2 (PBO) vs. 7.2 (FCM) events per 100 patient years

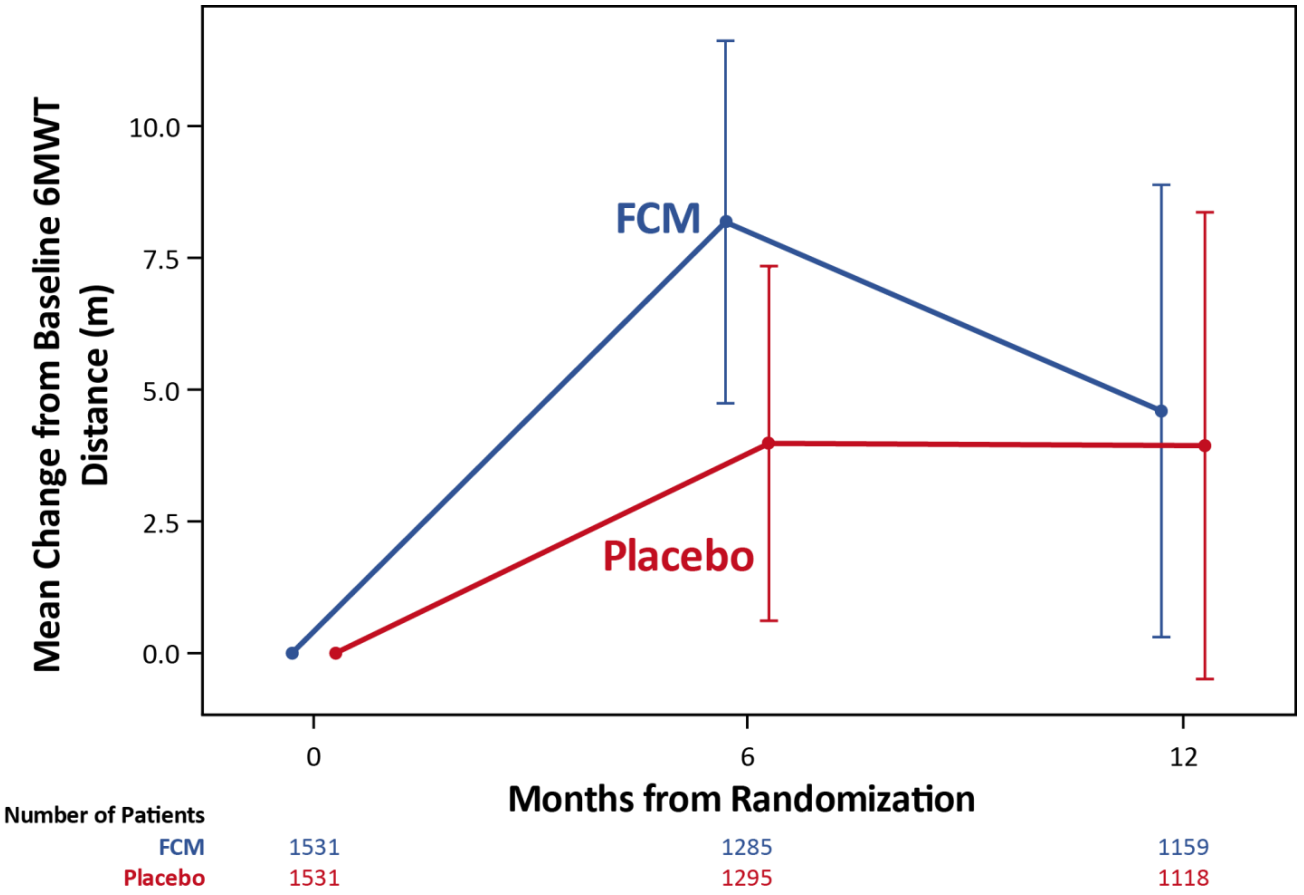
Number at Risk:

FCM	1532	1474	1380	1076	792	558	423
Placebo	1533	1470	1352	1037	747	516	387

Duke Clinical Research Institute

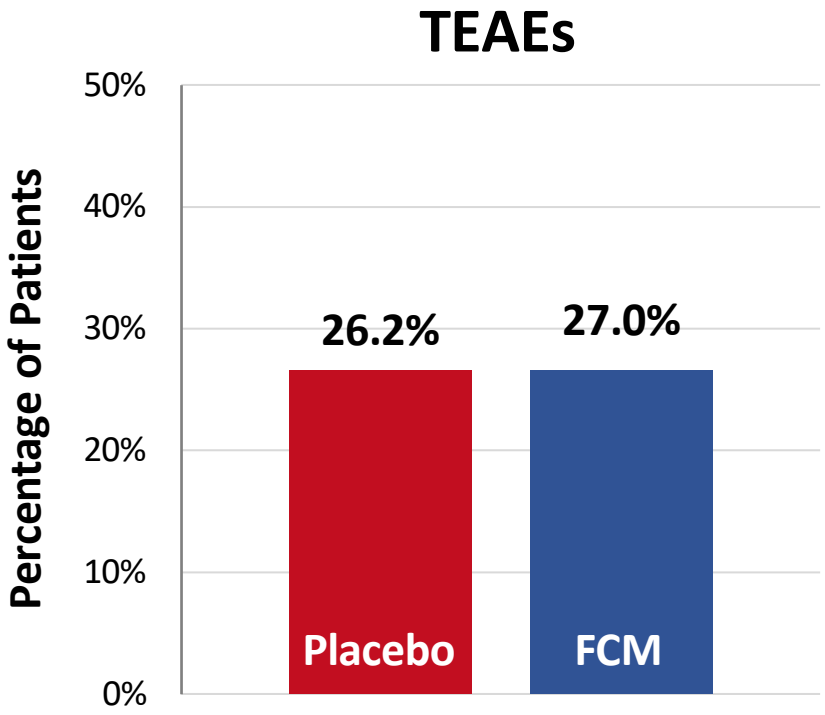
Median Follow-up of **1.9 years** (IQR, 1.3 to 3.0)

Change in 6-MWD (from Baseline to 12 m)



	6 mos	12 mos
LS mean difference (96% CI)	4 meters (-1, 9)	0 meters (-6, 6)

Safety: Treatment Emergent AEs



	FCM	Placebo
Hypophosphatemia	1	0
Hypersensitivity / Anaphylactoid reactions	7	1

- **Hypophosphatemia (N=1)**
  - *Unrelated to study drug (PI assessment)*; resolved and study drug was continued
- **Angioedema (N=2)**
  - 1 *probably related to study drug (PI assessment)* - facial edema of moderate severity; resolved in hours with oral therapy
- **Hypersensitivity (N=5)**
  - 3 *probably related to study drug (PI assessment)* - 1 of these being severe; all patients recovering

Summary

- HEART-FID is the **largest study** to assess the **long-term safety and efficacy** of IV FCM in HFrEF + ID.
- **Well-powered** for the primary and top secondary endpoint.
- FCM appeared **safe** and resulted in **modest improvement** for the hierarchical endpoint of all-cause mortality, HF hospitalizations and 6-MWD.
  - This did not achieve the pre-specified statistical significance level based on a higher US regulatory threshold (P=0.019 with specified level of 0.01).
  - While the observed differences in the primary endpoint were driven by the wins in death, the other components contributed to a larger proportion of decisions in the analysis.

The totality of evidence with IV FCM from prior studies assessing symptomatic and functional status endpoints combined with clinical outcomes studies including HEART-FID, show overall safety and clinical benefits of IV FCM in HFrEF with ID.

STRONG-HF

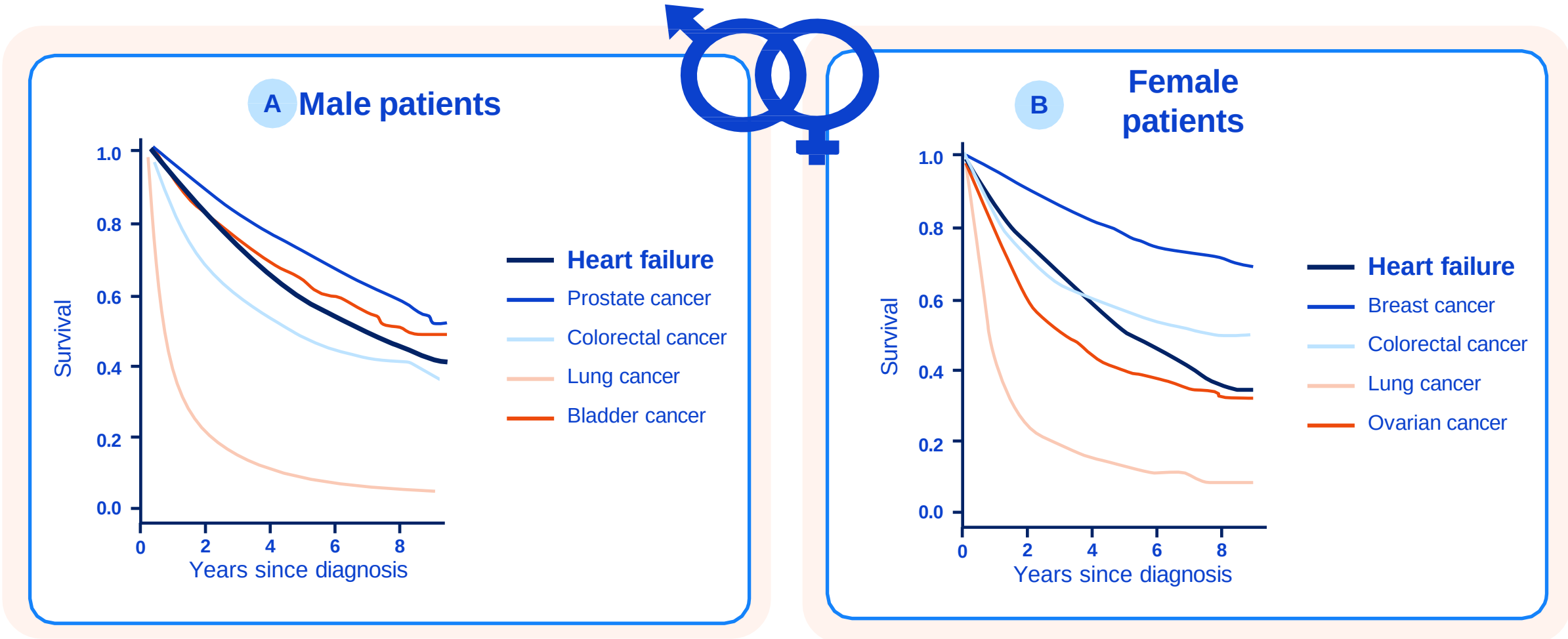
CONTEMPORARY POST-DISCHARGE MANAGEMENT IN HEART-FAILURE

Safety, tolerability and efficacy of up-titration of guideline-directed medical therapies for acute heart failure (STRONG-HF): a multinational, open-label, randomised, trial

***Mebazaa A**, Davison B, Chioncel O, Cohen-Solal A, Diaz R, Filippatos G, Metra M, Ponikowski P, Sliwa K, Voors AA, Edwards C, Novosadova M, Takagi K, Damasceno A, Saidu H, Gayat E, Pang PS, Celutkiene J, Cotter G. Safety, tolerability and efficacy of up-titration of guideline-directed medical therapies for acute heart failure (STRONG-HF): a multinational, open-label, randomised, trial. **Lancet**. 2022 Dec 3;400(10367):1938-1952.*

HF is as deadly as multiple types of cancer

HF has a lower 10-year survival rate than breast or prostate cancer



Mamas M.A. et al., Eur J Heart Fail. 2017 Sep;19(9):1095-1104

HF, heart failure

GDMT is effective in preventing mortality[1]

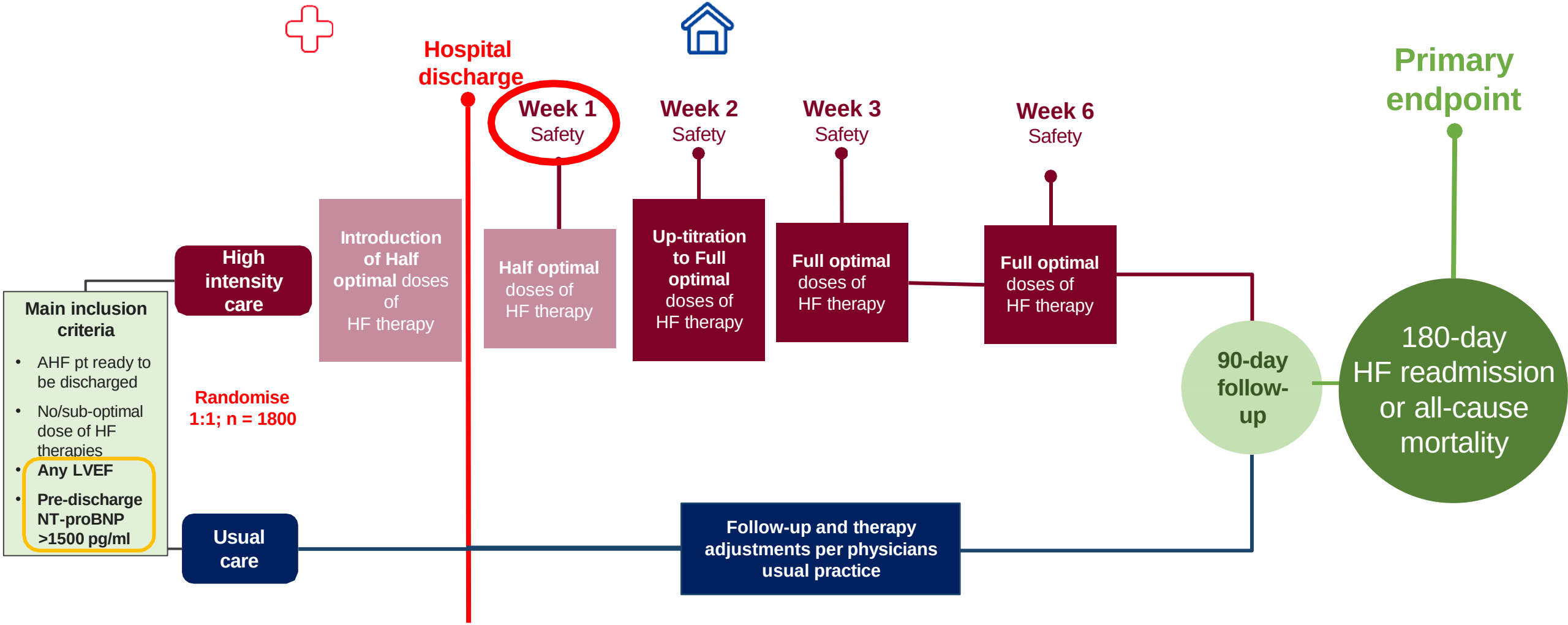
Combined therapy effect on all-cause mortality in HFrEF across meta-analyses[1]

Early initiation of GDMT is key and leads to significant life-years gains and reduction in all-cause mortality[1]

1. Stawiarski K, Ramakrishna H. J Cardiothorac Vasc Anesth 2022;36:1820-1822.

Study design

STRONG-HF
CONTEMPORARY POST-DISCHARGE MANAGEMENT IN HEART-FAILURE



HF therapy: combining ACEi/ARB/ARNi & BB & MRA
Safety = clinical exam & biology (NT-proBNP, K, Creat, hemoglobin)

Mebazaa A et al, Lancet 2022

Titration of oral diuretics

STRONG-HF suggests NT-proBNP can be used to monitor patients for GDMT up-titration

Up-titration

Pause up-titration

Loop diuretics

↗ **NT-proBNP > 10%***

Or Congestion assessed by physical examination

↘ **NT-proBNP**

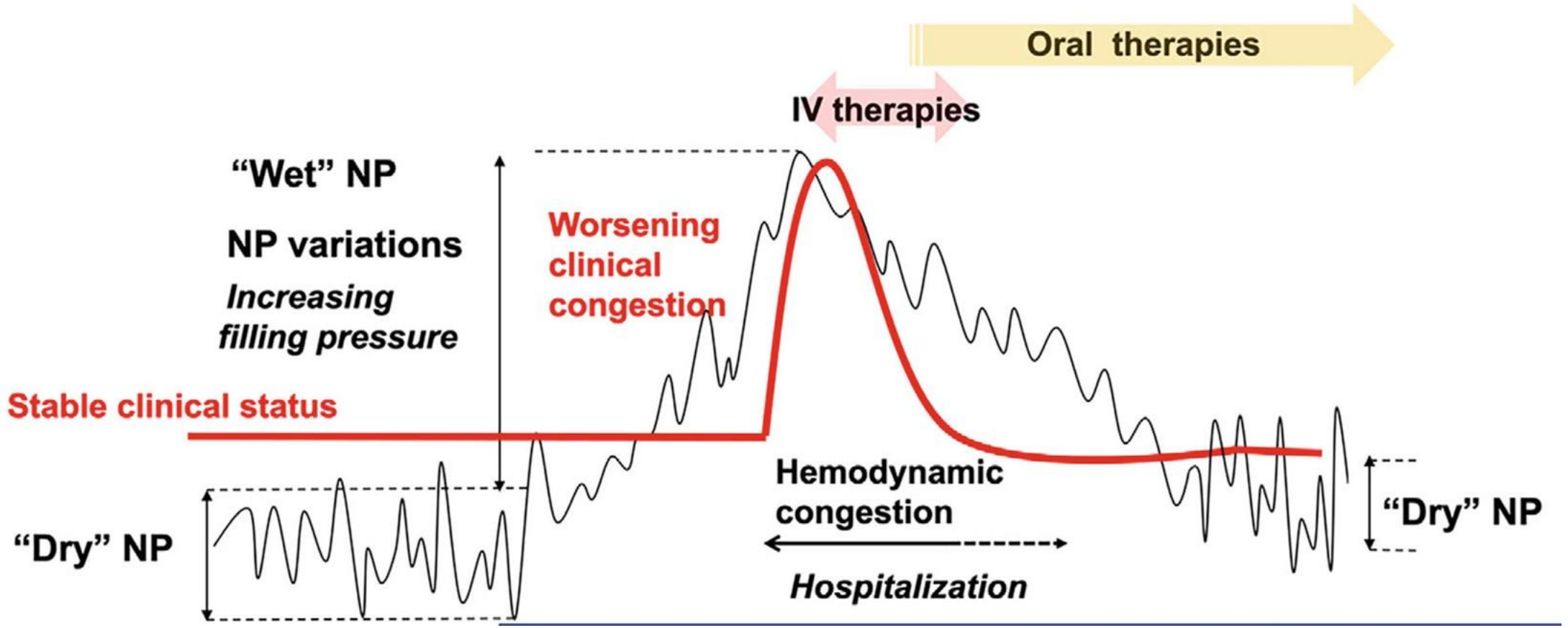
and no congestion assessed by physical examination

Titration of oral GDMT

STRONG-HF suggests NT-proBNP can be used to monitor patients for GDMT uptitration

	Up-titration	Pause up-titration
β blockers	↘ **NT-proBNP** And HR ≥ 55 bpm And SBP ≥ 95 mmHG	↗ **NT-proBNP > 10%*** **Or** HR < 55 bpm **Or** SBP < 95 mmHG
ACEi ARB ARNi MRA	SBP ≥ 95 mmHg And K+ ≤ 5.0 mmol/L And eGFR ≥ 30 mL/min/1.73m^2	SBP < 95 mmHg **Or** K+ > 5.0 mmol/L **Or** eGFR < 30 mL/min/1.73m^2

Natriuretic peptides: the most rapid and accurate marker of congestion

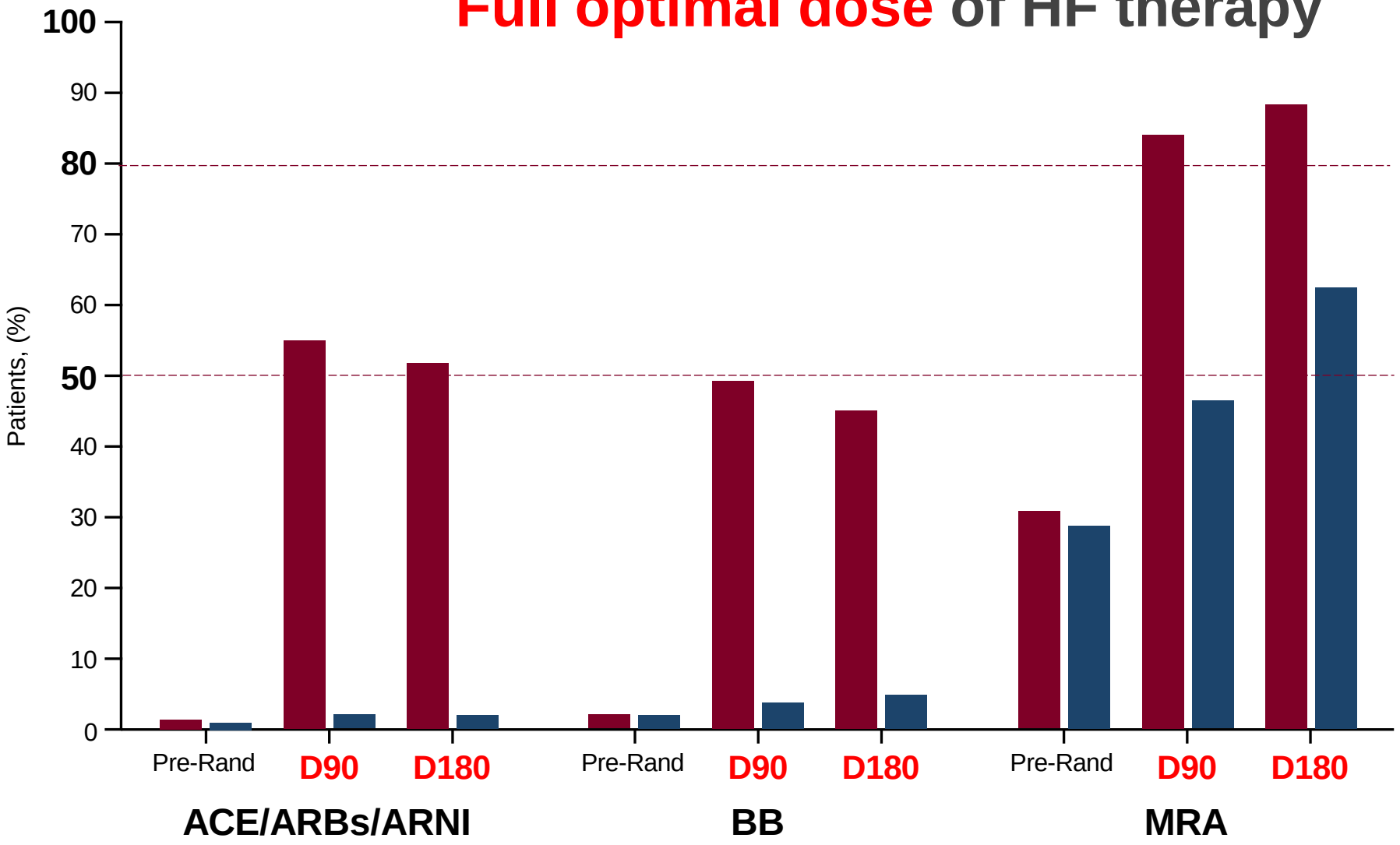


Tsutsui et al, Eur J Heart Failure, 2023

STRONG-HF
CONTEMPORARY POST-DISCHARGE MANAGEMENT IN HEART-FAILURE

Oral HF therapies prescribed in high intensity and usual care

Full optimal dose of HF therapy



High Intensity Care

≥ Full optimal dose

Usual Care

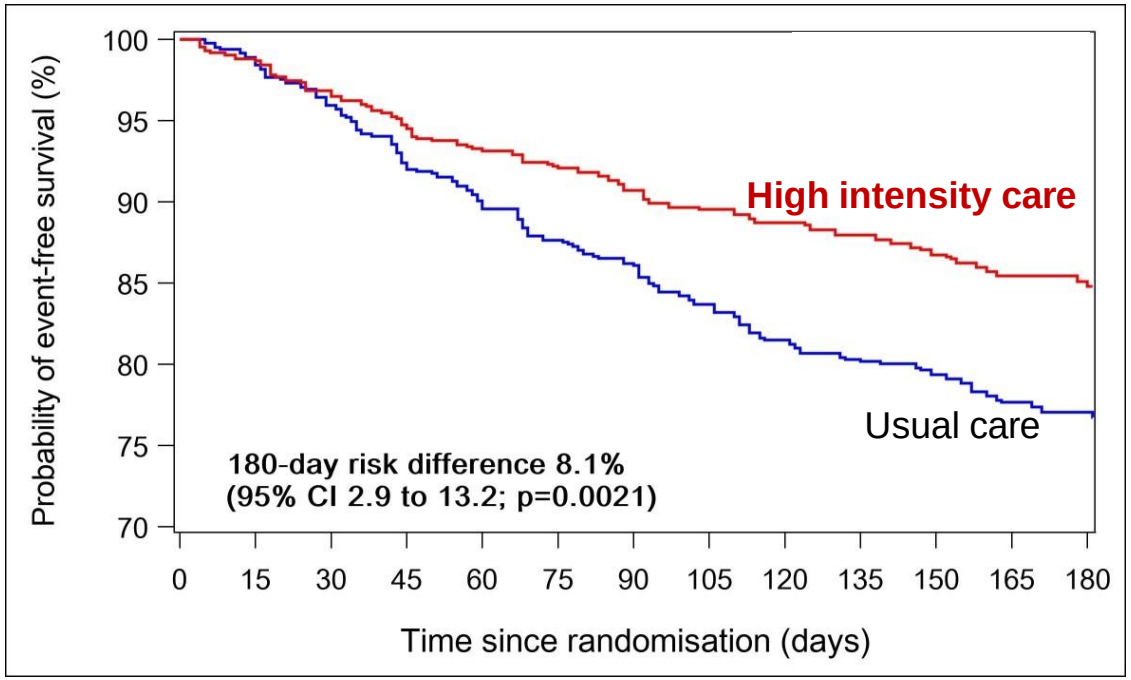
≥ Full optimal dose

Mebazaa A et al, Lancet 2022

STRONG-HF
CONTEMPORARY POST-DISCHARGE MANAGEMENT IN HEART-FAILURE

Primary endpoint:

180-Day Readmission for HF or All-Cause Death

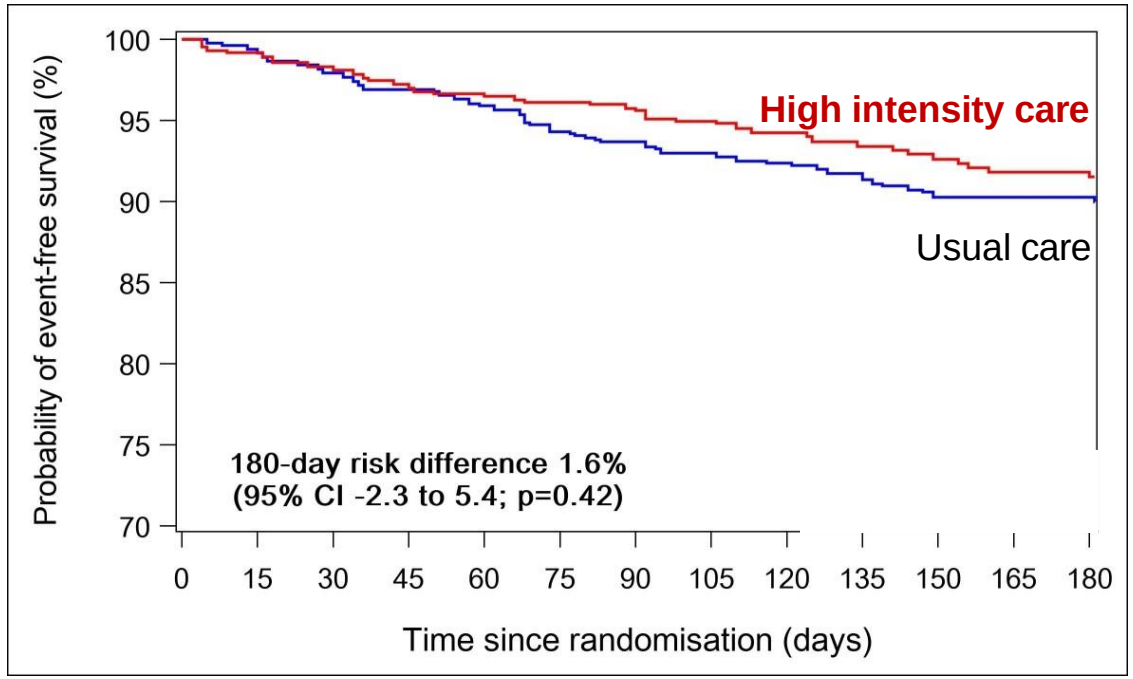


Secondary endpoints:

Change from Baseline to Day 90 in EQ-5D VAS

High Intensity	Usual Care	Treatment effect	P value
10.7 (0.9)	7.2 (0.9)	3.5 (1.7 to 5.2)	< 0.0001

180-Day All-Cause Death

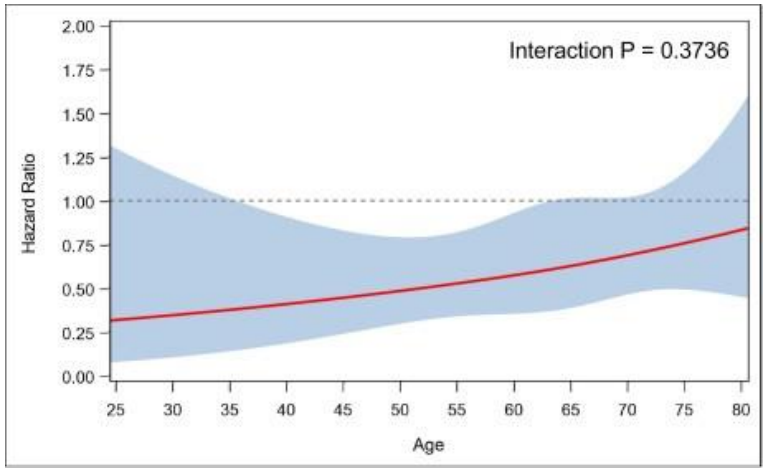


Mebazaa A et al, Lancet 2022

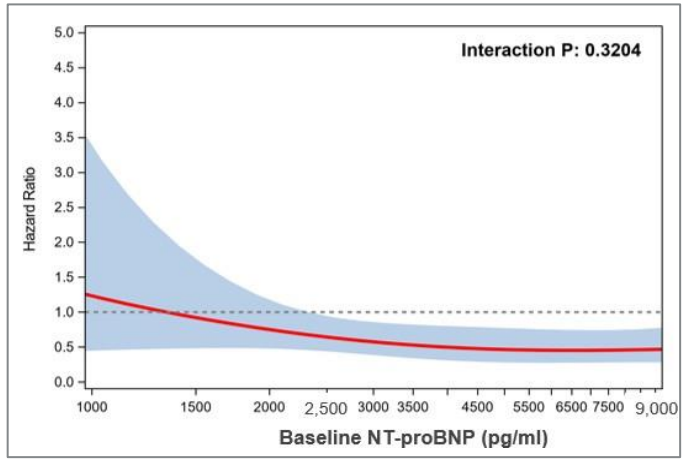
All-cause death or HF-hospitalisation at day 180

Pre specified sub-analysis

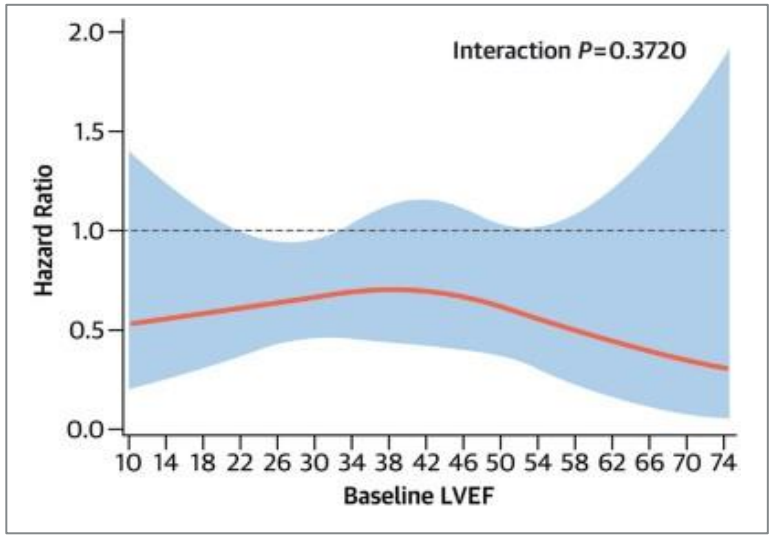
Age



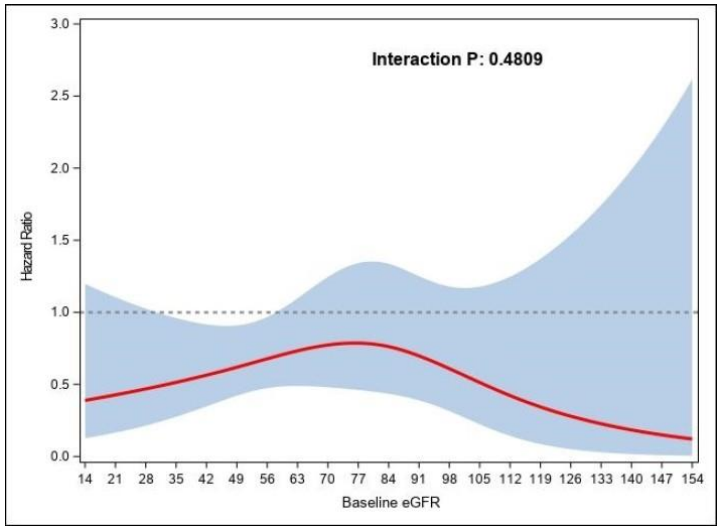
Nt-proBNP



LVEF



eGFR



Pagnesi M, J Am Coll Cardiol, 2023; 81: 2131-2144 *Mattia Arrigo et al, Eur J Heart Fail, 2023* *Mariana Adamo et al, Eur Heart J, 2023-* *J. Ter Maaten et al, Late breaker ESC HF, 2023*

STRONG-HF: Safety

There was no significant difference in SAEs between arms for up to 90-days follow-up

Most commonly observed AEs

Parameter	High-intensity care (n=542)	Usual care (n=536)
Overall	223 (41%)	158 (29%)
Cardiac failure	79 (15%)	73 (14%)
Hypotension	27 (5%)	2 (<1%)
Hyperkalaemia	18 (3%)	0 (0%)
Renal impairment	14 (3%)	1 (<1%)

Most commonly observed SAEs

Parameter	High-intensity care (n=542)	Usual care (n=536)
Overall	88 (16%)	92 (17%)
Cardiac failure	38 (7%)	47 (9%)
Sudden death	5 (1%)	10 (2%)
Viral pneumonia	7 (1%)	3 (1%)

Fatal SAEs occurred in 25 (5%) of patients receiving high-intensity care and 32 (6%) receiving usual care

Mebazaa-A et al. Lancet. 2022 Dec 3;400(10367):1938-1952

AE, adverse event; SAE, serious adverse event

Conclusions: Patients will ❤ STRONG-HF

- **Rapid up-titration of HF therapies under close follow-up (exam, NT-proBNP):**

  is **safe** & **reduces** HF readmissions or all-cause deaths & **improves** patients' QoL.

  In STRONG-HF, intensive up-titration of neurohormonal blockade was associated with more efficient decongestion at day 90 (across all analysed indices), which was achieved despite a lower dose of diuretics.

- Next challenge: Rapid education to implement the STRONG-HF procedure into daily practice

Mebazaa A et al Lancet 2022

ESC Congress 2023 Amsterdam
Onsite & Online, 25-28 August

MESSAGE-HF Trial:
Telemonitoring after a Recent Heart Failure Admission

Luis E. Rohde, MD ScD and Felix Ramires, MD PhD

On behalf of the MESSAGE-HF Investigators

BEM CUIDADO · hcor ASSOCIAÇÃO BENEFICENTE SÍRIA · HOSPITAL MOINHOS DE VENTO · PROADI-SUS Programa de Apoio ao Desenvolvimento Institucional do Sistema Único de Saúde

Reasons for HF Decompensation

Decompensation cause	% (n=1,250)
Infection	22.7
Poor medication adherence	29.9
Increased ingestion of sodium and water *	8.9
Acute valvular disease	6.6
Cardiac arrhythmia	12.5
Pulmonary embolism	0.4
Others	32.4

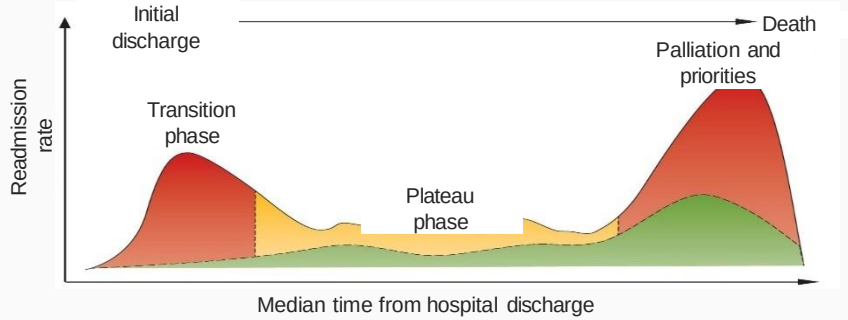
Arq Bras Cardiol. 2015; 104(6):433-442

MESSAGE-HF Trial Hypothesis

A multifaceted strategy to promote **education and self-care** based on **SMS messages and telephone contacts** could **reduce NT-proBNP** levels after a recent hospitalization for acutely decompensated HF, **compared to standard of care**.

MESSAGE-HF Inclusion Criteria

ADHF admission and HFrEF (LVEF < 40%)



VULNERABLE PHASE

Screening → **Randomization**

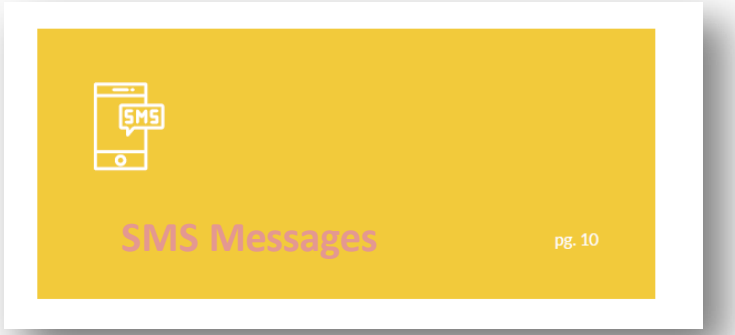
Hospital Admission | **Hospital Discharge** | **Day 30** | **Day 60**

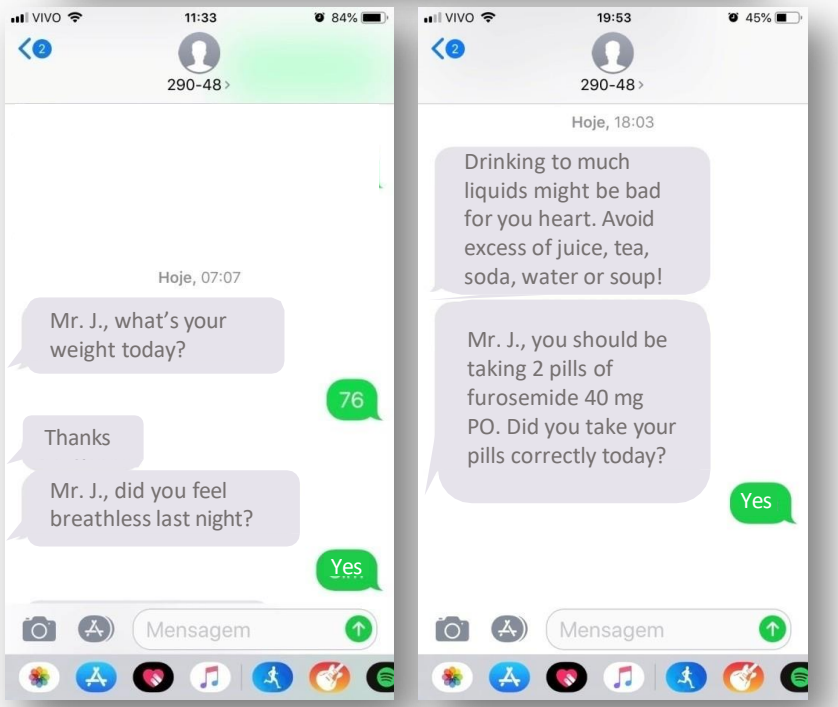
MESSAGE-HF Groups

2. Intervention Group

- Outpatient Visits pg. 10
- SMS Messages pg. 10
- Diuretic adjustment pg. 10
- Telephone Calls pg. 10
- Help Center pg. 10

2. Intervention Group



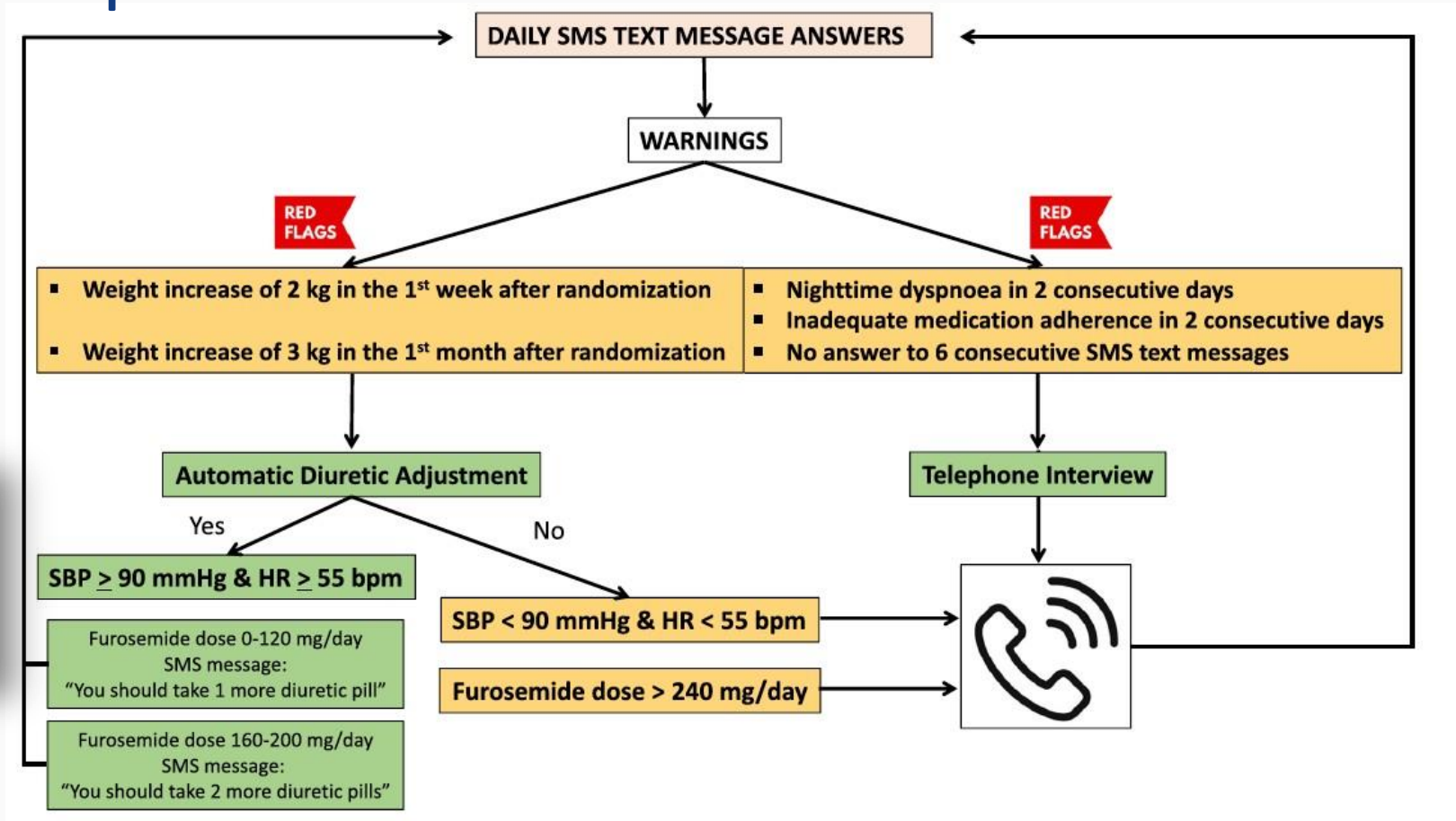


4 daily messages in the first 30 days:

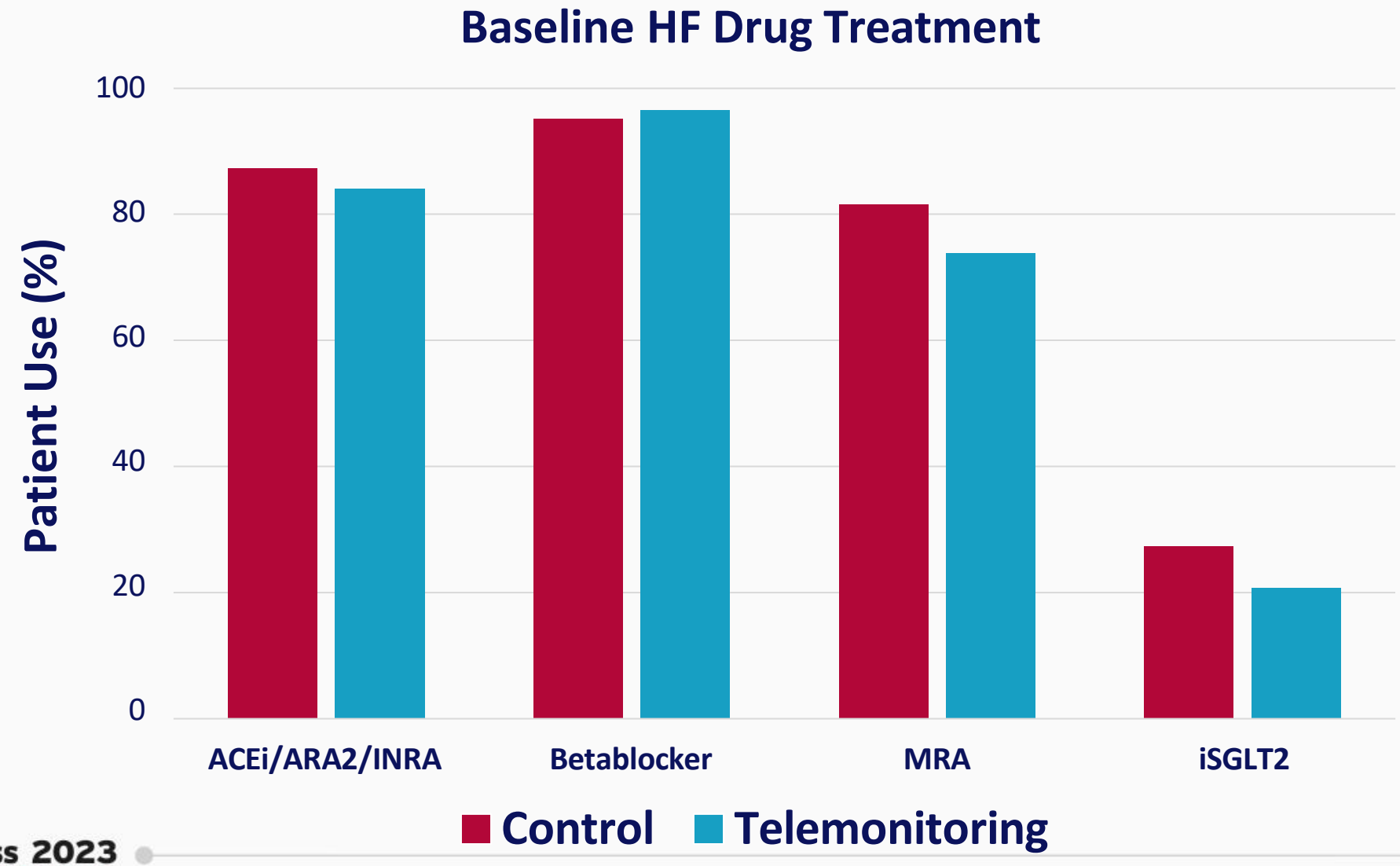
- 1 Educational Message
- 3 Feedback Messages with Simple Questions

RED FLAG
> **2 kg** increase in the **first week** after discharge
> **3 kg** increase in the **first month** after discharge
2 consecutive days with **nocturnal symptoms**
2 consecutive responses of **inappropriate use of medication**
No response from **5 consecutive messages**

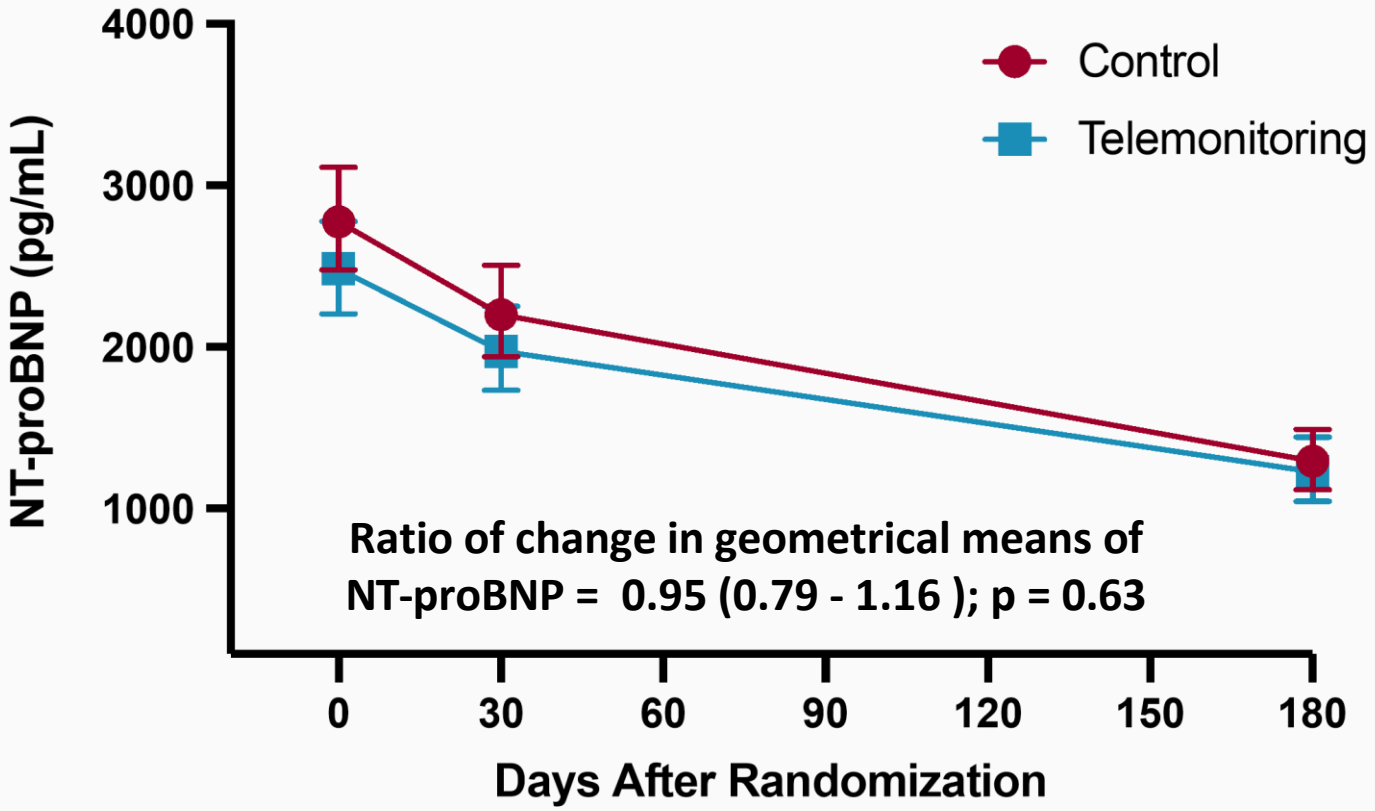
2. Intervention Group



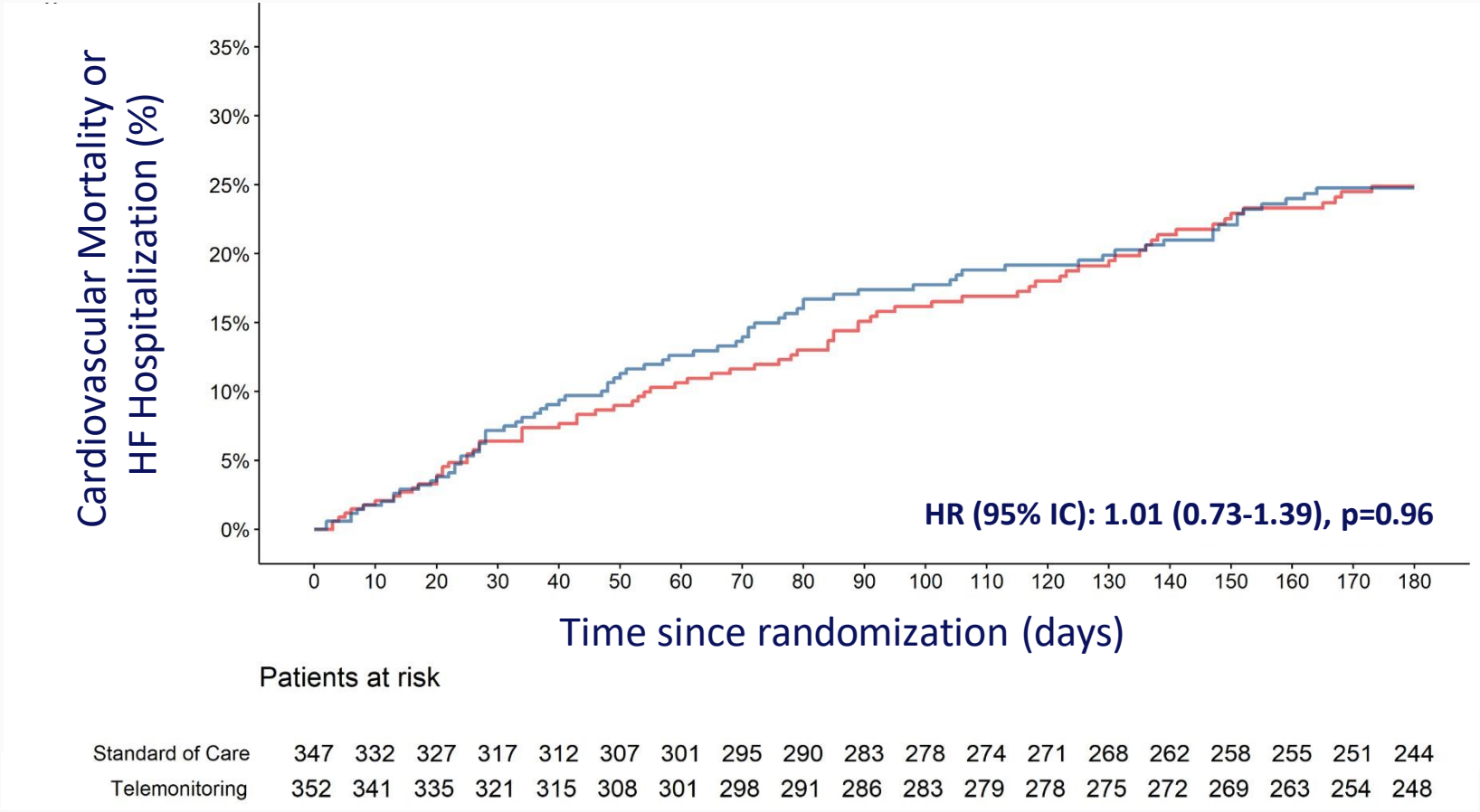
Baseline Characteristics



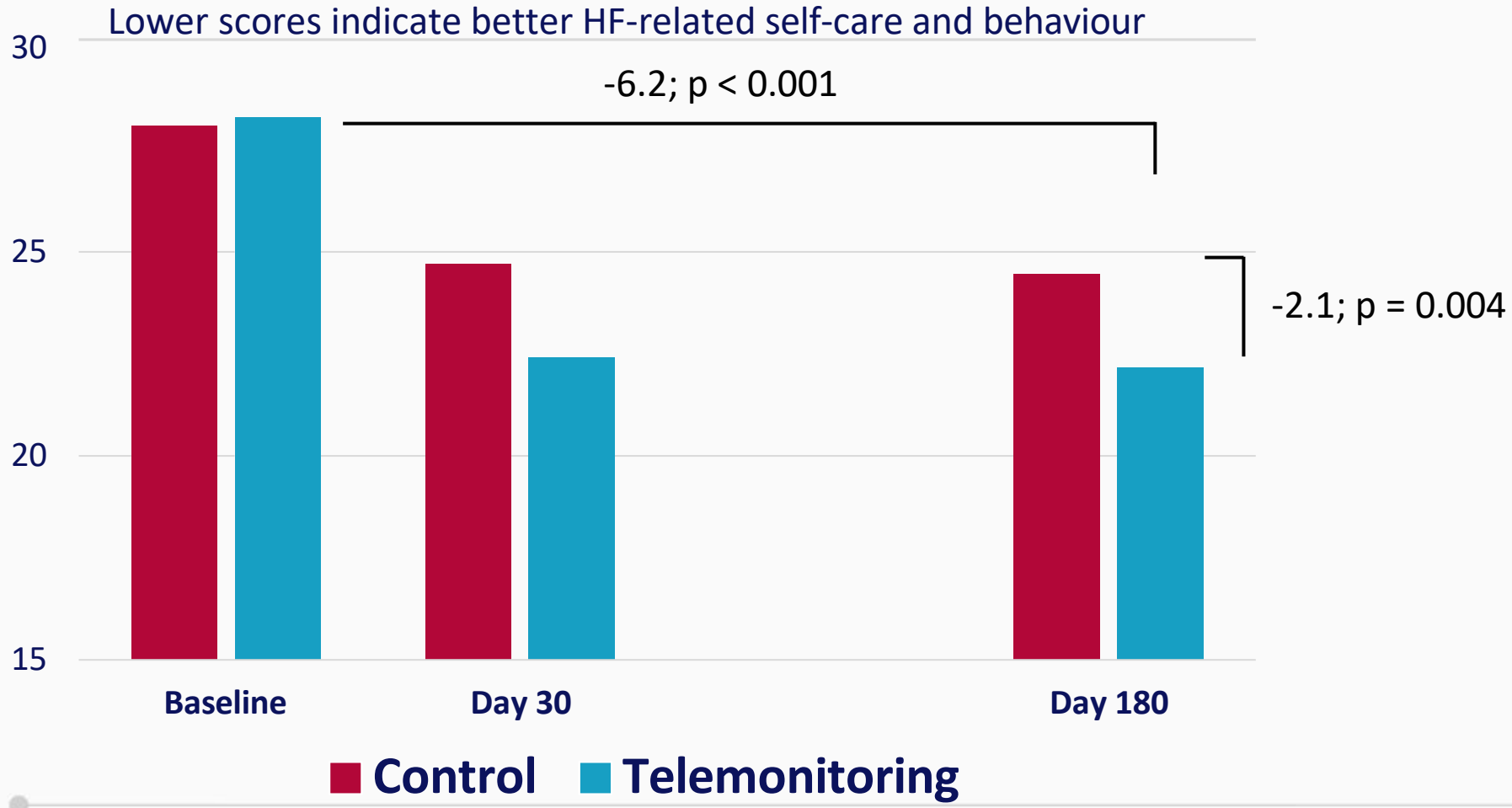
Primary Endpoint



Secondary Endpoints



European HF Self-care Behaviour Scale



Final Conclusions

- The MESSAGE-HF trial demonstrated that an **intensive and tailored** self-care promotion strategy based on automated text messaging and telephone calls was **feasible, well-accepted** and **increased** scales of **HF self-care**, but had **no effect** on **NT-proBNP levels** or on a composite hierarchical outcome in patients with a **recent HF admission** in Brazil.

Thank you