Contribution of the RETREAT FRAIL study to the deprescribing of antihypertensive treatments in very old subjects

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Webinar
USDeN Community
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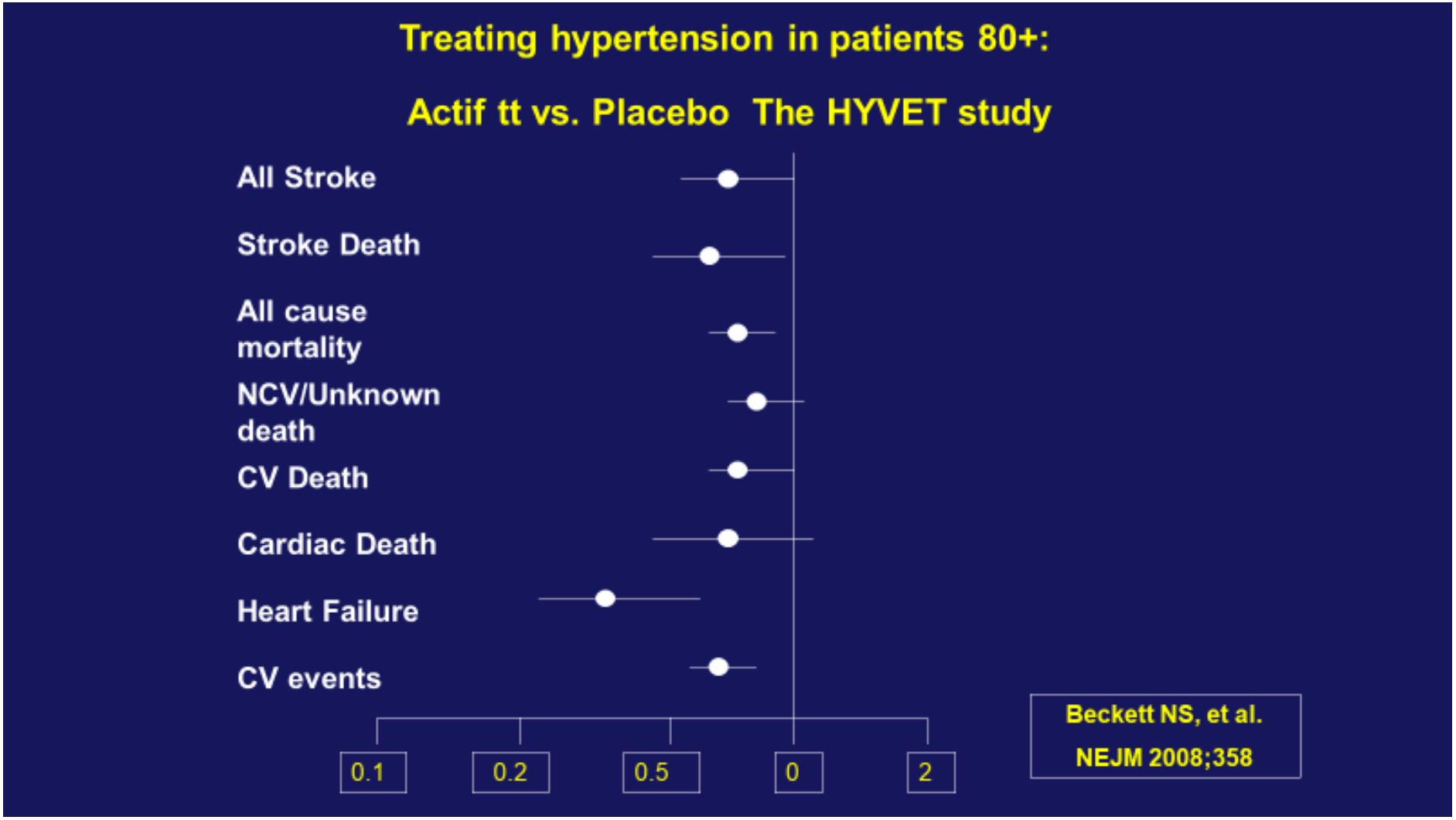
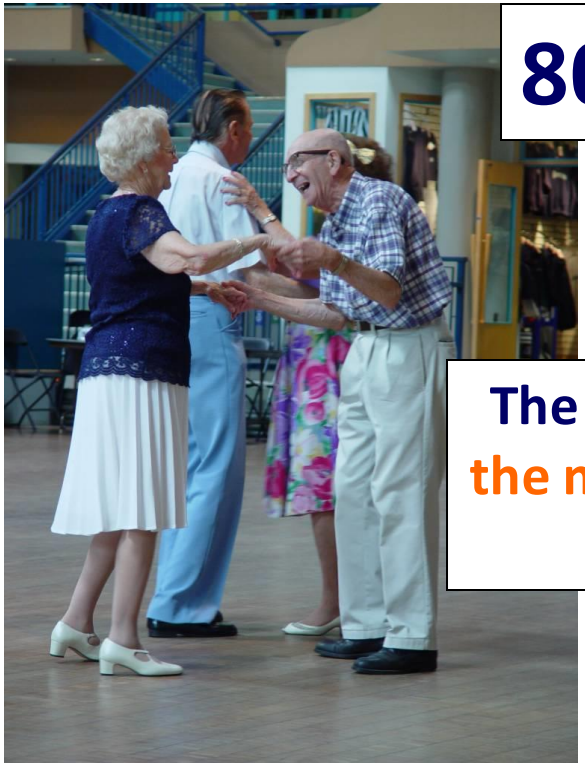
Conflicts of interest:

None

Benefits of antihypertensive treatment in patients 80+ years





80+ years

The most growing and the most heterogeneous population

Should we apply the HYVET conclusions to all 80+ patients?

Warwick *et al. BMC Medicine* (2015) 13:78
DOI 10.1186/s12916-015-0328-1

BMC Medicine

RESEARCH ARTICLE Open Access

No evidence that frailty modifies the positive impact of antihypertensive treatment in very elderly people: an investigation of the impact of frailty upon treatment effect in the HYpertension in the Very Elderly Trial (HYVET) study, a double-blind, placebo-controlled study of antihypertensives in people with hypertension aged 80 and over

Jane Warwick[1*], Emanuela Falaschetti[2], Kenneth Rockwood[3], Arnold Mitnitski[4], Lutgarde Thijs[5], Nigel Beckett[6], Christopher Bulpitt[6] and Ruth Peters[2]

The SPRINT study

Original Investigation

Intensive vs Standard Blood Pressure Control and Cardiovascular Disease Outcomes in Adults Aged ≥75 Years
A Randomized Clinical Trial

Jeff D. Williamson, MD, MHS; Mark A. Supiano, MD; William B. Applegate, MD, MPH; Dan R. Berlowitz, MD; Ruth C. Campbell, MD, MSPH; Glenn M. Chertow, MD; Larry J. Fine, MD; William E. Haley, MD; Amret T. Hawfield, MD; Joachim H. Ix, MD, MAS; Dalane W. Kitzman, MD; John B. Kostis, MD; Marie A. Krousel-Wood, MD; Lenore J. Launer, PhD; Suzanne Oparil, MD; Carlos J. Rodriguez, MD, MPH; Christianne L. Roumie, MD, MPH; Ronald I. Shorr, MD, MS; Kaycee M. Sink, MD, MAS; Virginia G. Wadley, PhD; Paul K. Whelton, MD; Jeffrey Whittle, MD; Nancy F. Woolard; Jackson T. Wright Jr, MD, PhD; Nicholas M. Pajewski, PhD; for the SPRINT Research Group

Exploratory analysis suggested that the benefit of intensive BP control was consistent among persons in this age range who were frail or had reduced gait speed.

Williamson J et al, JAMA, 2016 Volume 315

Main Exclusion Criteria in HYVET:

- Living in NHs
- Limited autonomy
- Clinical dementia
- Heart failure needing treatment with ACEI, ARA, Diuretics
- SBP<140mmHg in upright position
- Renal failure
- Patients presenting a high probability of having a major health problem during the 5 year follow-up period.

Main Exclusion Criteria in SPRINT:

- Living in NHs.
- Type 2 diabetes
- History of stroke
- Symptomatic heart failure within the past 6 months or reduced LVEF (<35%)
- Clinical diagnosis of/or treatment for dementia
- Expected survival of less than 3 years
- Unintentional weight loss (>10% of body weight) during the last 6 months,
- SBP of less than 110 mm Hg following 1 minute of standing.

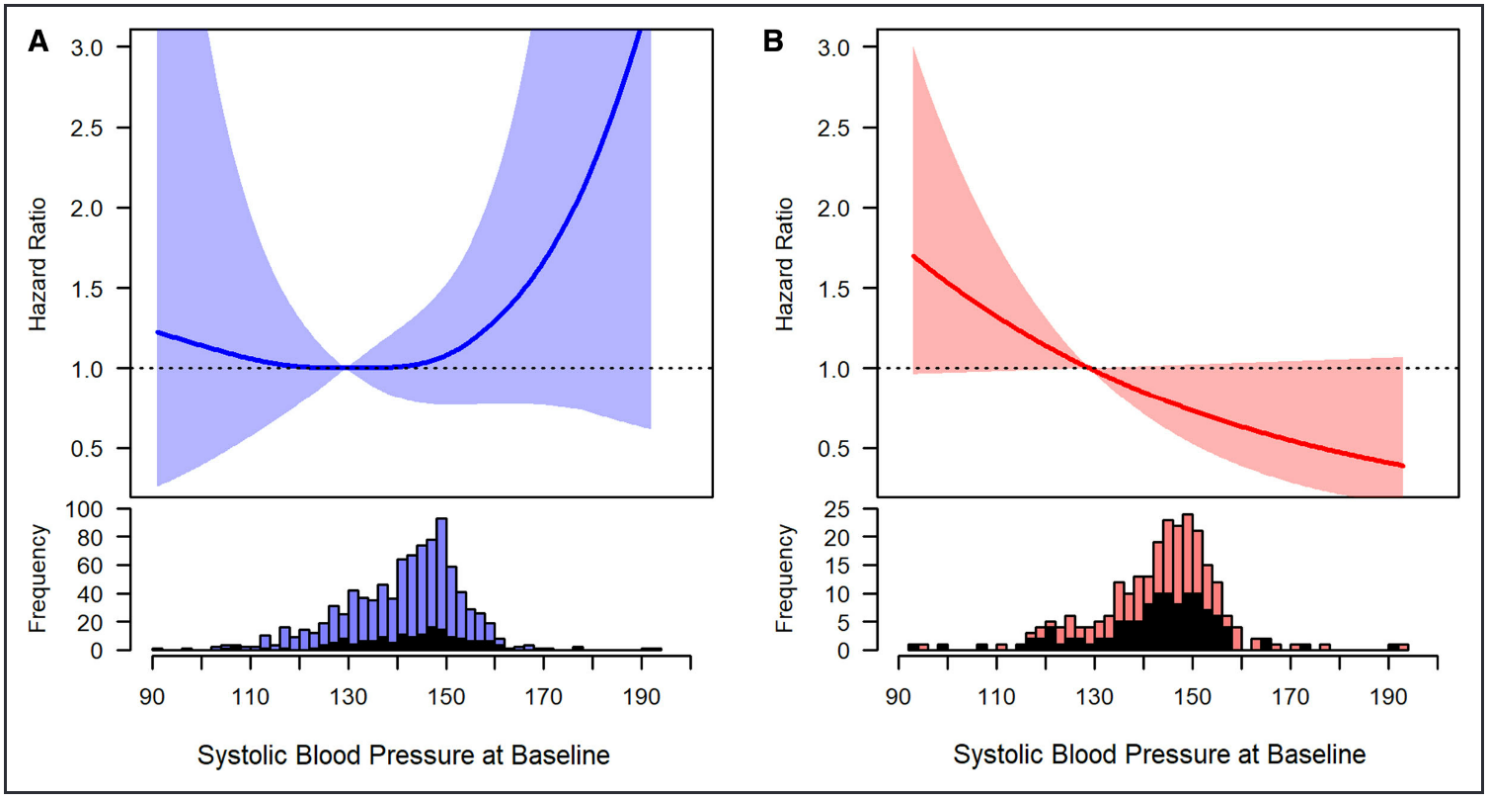
Hypertension

ORIGINAL ARTICLE

Systolic Blood Pressure and Mortality in Community-Dwelling Older Adults: Frailty as an Effect Modifier

Kaj-Marko Kremer, Ulrike Braisch, Dietrich Rothenbacher, Michael Denkinger, Dhayana Dallmeier; for the ActiFE Study Group

(A) non-frail **(B) frail**

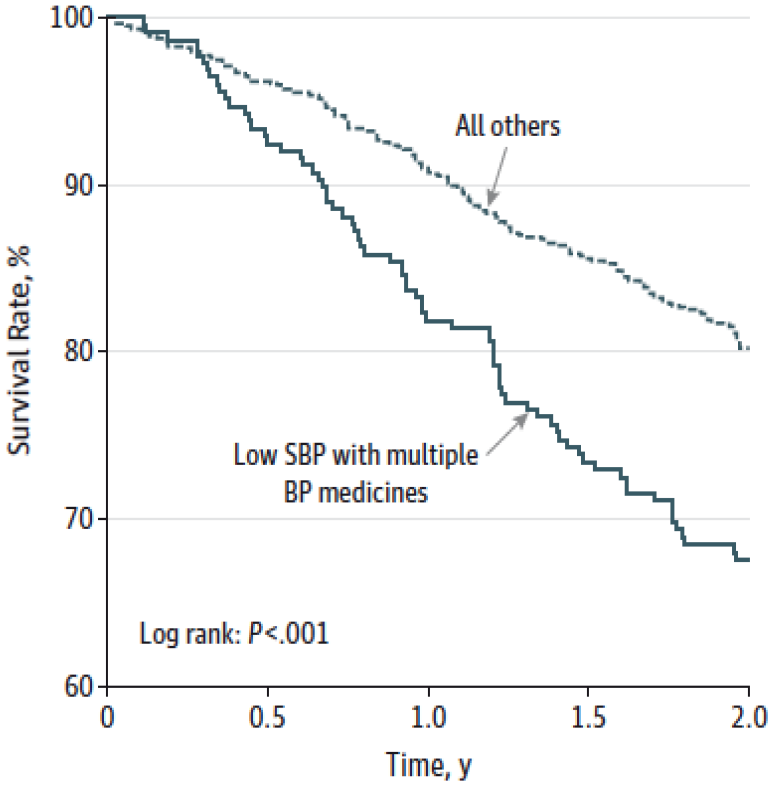


Adjusted for age, sex, education, smoking, DBP, sleep disturbance, and anti-Htn medication.

Kremer K et al, *Hypertension*. 2022

PARTAGE observational study: Patients aged 80+ living in Nursing Homes

Kaplan-Meier Survival Curves in Patients With Low Systolic Blood Pressure (SBP) Receiving Multiple BP Medicines and All Other Groups

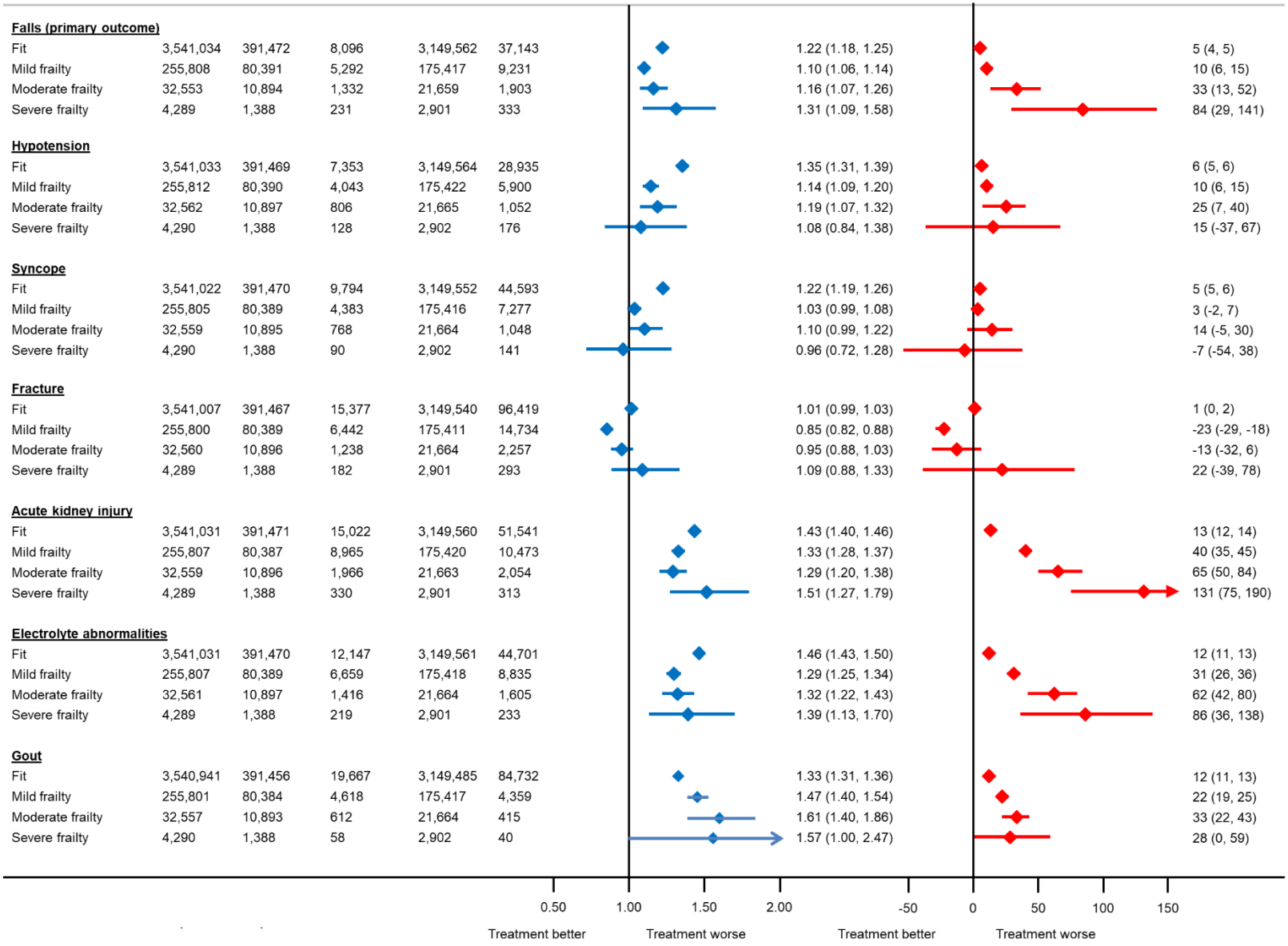


Two-fold increase in mortality in the group with SBP<130mmHg with >1 antihypertensive medications

Benetos A. et al, *JAMA Int Med* 2015

Adverse events by frailty status (age-adjusted)

Subgroup	Total population	Intervention population	Intervention events	Control population	Control events	Adjusted Hazard ratio (95% CI)	Absolute risk difference (additional events per 10,000 patients per year) (95% CI)
Falls (primary outcome)							
Fit	3,541,034	391,472	8,096	3,149,562	37,143	1.22 (1.18, 1.25)	5 (4, 5)
Mild frailty	255,808	80,391	5,292	175,417	9,231	1.10 (1.06, 1.14)	10 (6, 15)
Moderate frailty	32,553	10,894	1,332	21,659	1,903	1.16 (1.07, 1.26)	33 (13, 52)
Severe frailty	4,289	1,388	231	2,901	333	1.31 (1.09, 1.58)	84 (29, 141)
Hypotension							
Fit	3,541,033	391,469	7,353	3,149,564	28,935	1.35 (1.31, 1.39)	6 (5, 6)
Mild frailty	255,812	80,390	4,043	175,422	5,900	1.14 (1.09, 1.20)	10 (6, 15)
Moderate frailty	32,562	10,897	806	21,665	1,052	1.19 (1.07, 1.32)	25 (7, 40)
Severe frailty	4,290	1,388	128	2,902	176	1.08 (0.84, 1.38)	15 (-37, 67)
Syncope							
Fit	3,541,022	391,470	9,794	3,149,552	44,593	1.22 (1.19, 1.26)	5 (5, 6)
Mild frailty	255,805	80,389	4,383	175,416	7,277	1.03 (0.99, 1.08)	3 (-2, 7)
Moderate frailty	32,559	10,895	768	21,664	1,048	1.10 (0.99, 1.22)	14 (-5, 30)
Severe frailty	4,290	1,388	90	2,902	141	0.96 (0.72, 1.28)	-7 (-54, 38)
Fracture							
Fit	3,541,007	391,467	15,377	3,149,540	96,419	1.01 (0.99, 1.03)	1 (0, 2)
Mild frailty	255,800	80,389	6,442	175,411	14,734	0.85 (0.82, 0.88)	-23 (-29, -18)
Moderate frailty	32,560	10,896	1,238	21,664	2,257	0.95 (0.88, 1.03)	-13 (-32, 6)
Severe frailty	4,289	1,388	182	2,901	293	1.09 (0.88, 1.33)	22 (-39, 78)
Acute kidney injury							
Fit	3,541,031	391,471	15,022	3,149,560	51,541	1.43 (1.40, 1.46)	13 (12, 14)
Mild frailty	255,807	80,387	8,965	175,420	10,473	1.33 (1.28, 1.37)	40 (35, 45)
Moderate frailty	32,559	10,896	1,966	21,663	2,054	1.29 (1.20, 1.38)	65 (50, 84)
Severe frailty	4,289	1,388	330	2,901	313	1.51 (1.27, 1.79)	131 (75, 190)
Electrolyte abnormalities							
Fit	3,541,031	391,470	12,147	3,149,561	44,701	1.46 (1.43, 1.50)	12 (11, 13)
Mild frailty	255,807	80,389	6,659	175,418	8,835	1.29 (1.25, 1.34)	31 (26, 36)
Moderate frailty	32,561	10,897	1,416	21,664	1,605	1.32 (1.22, 1.43)	62 (42, 80)
Severe frailty	4,289	1,388	219	2,901	233	1.39 (1.13, 1.70)	86 (36, 138)
Gout							
Fit	3,540,941	391,456	19,667	3,149,485	84,732	1.33 (1.31, 1.36)	12 (11, 13)
Mild frailty	255,801	80,384	4,618	175,417	4,359	1.47 (1.40, 1.54)	22 (19, 25)
Moderate frailty	32,557	10,893	612	21,664	415	1.61 (1.40, 1.86)	33 (22, 43)
Severe frailty	4,290	1,388	58	2,902	40	1.57 (1.00, 2.47)	28 (0, 59)



J Sheppard et al, *Plus One* 2023

Should we apply the HYVET conclusions to all 80+ patients?

Unexplored questions in very old subjects:

- Can we decrease mortality rates among patients with low SBP under combination antihypertensive therapy if we reduce the number of antihypertensive drugs?
- Which are the risks and the benefits of deprescribing antihypertensive drugs?
- Does the frailty level modify the benefit/risk ratio of therapeutic strategies?

RETREAT-FRAIL
Multicenter RCT in Nursing Homes (NHs)

ClinicalTrials.gov number, NCT03453268

- **Patients ≥ 80 years living in NHs, with a SBP<130 mmHg under >1 anti-Htn drugs, were randomized (1:1) in two parallel groups:**

  - intervention group: step-down of antihypertensive treatment

  - control group: usual care

Primary end point: All-cause mortality

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Reduction of Antihypertensive Treatment in Nursing Home Residents

Athanase Benetos, M.D., Ph.D.,[1,2] Sylvie Gautier, M.D.,[1,2] Anne Freminet, M.S.N.,[1] Alice Metz, M.S.N.,[1] Carlos Labat, B.Sc.,[2] Ioannis Georgiopoulos, M.D.,[1] François Bertin-Hugault, M.D.,[3] Jean-Baptiste Beuscart, M.D., Ph.D.,[4] Olivier Hanon, M.D., Ph.D.,[5] Patrick Karcher, M.D.,[6] Patrick Manckoundia, M.D., Ph.D.,[7] Jean-Luc Novella, M.D., Ph.D.,[8] Abdourahmane Diallo, Ph.D.,[9] Eric Vicaut, M.D., Ph.D.,[9] and Patrick Rossignol, M.D., Ph.D.,[10,11] for the RETREAT-FRAIL Study Group*

N Engl J Med 2025;393:1990-2000

End points at the longest follow-up

(minimum, 24 months and maximum, 48 months)

Primary end point

All-cause mortality

- **Secondary end points**
- Systolic and Diastolic BP
- Number of antihypertensive medications
- Major adverse cardiovascular events (MACE)
- Non-cardiovascular deaths
- COVID-19 related deaths
- Number of falls
- Number of fractures
- Clinical Frailty Scale
- ADL (autonomy)
- MMSE (cognition)
- SPPB (gait/balance)
- Handgrip (muscle force)
- EQ-5D-3L score (quality of life)
- Total number of medications

Eligibility Criteria

Inclusion criteria

Patients:

- 80 years or older.
- Living in a nursing home (NH),
- With systolic BP<130 mmHg.
- Treated for hypertension with 2 or more antihypertensive drugs.
- Stable antihypertensive treatment during
- the last 3 months.
- Enrollment in the social security plan.
- Having signed an informed consent (patients or legal representatives if applicable).

Exclusion criteria

Patients:

- In which none of antihypertensive drugs can be stopped because of simultaneous indications for other cardiovascular diseases.
- With estimated life expectancy <3 months.
- Patient who has already been included in this study.

Medication discontinuation algorithm

All patients before inclusion

LIST 1

"List 1"
The medications without compelling indications for each patient are placed in List 1 and are withdrawn in sequential order from 1 to 9.

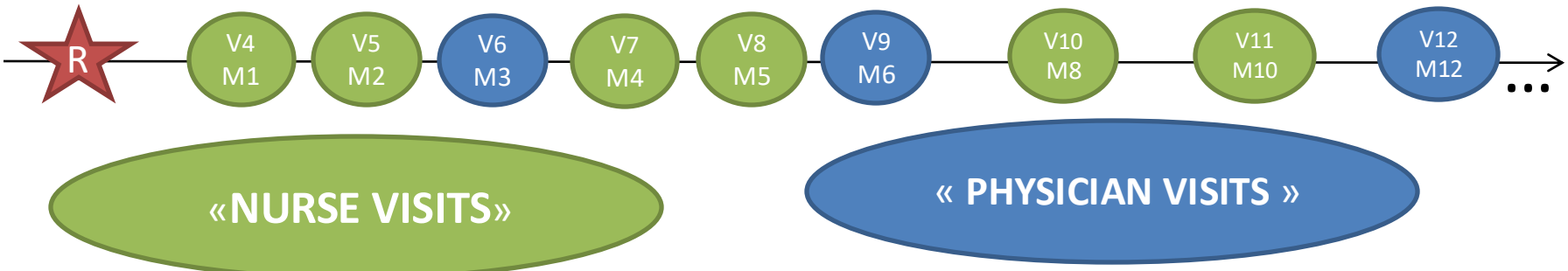
1. Central agent
2. Alpha blocker
3. Loop diuretic
4. Non-DHP CCB
5. Beta blocker
6. ARBs / Anti-aldosterone
7. ACEi
8. Thiazide diuretic
9. CCB DHP

"List 2"
Medications not to be withdrawn due to the presence of compelling indications.

Loop diuretic	Fluid retention due to heart failure ?
Non-DHP CCB	Coronary heart disease ?
Beta blocker	Heart failure* or coronary heart disease ?
ARBs / Anti-aldosterone	Heart failure* or diabetic nephropathy ?
ACEi	Heart failure* post infarct, or diabetic nephropathy ?

LIST 2

Organisation of the follow-up



Monthly M1 to M6, then every 2 months

Data collected

- **Treatments (Anti-Htn, Other)**
- **BP measurements**
- **Adverse events (AE) and serious AE**

M0, M3, M6, then every 6 months

Data collected

- **« Nurse visit »**
- **Clinical examination**
- **SPPB, ADL, handgrip, MMSE**
- **EQ-5D** (once yearly)

Anti-Htn treatment adaptation in the intervention group

Clinical characteristics at baseline (1)

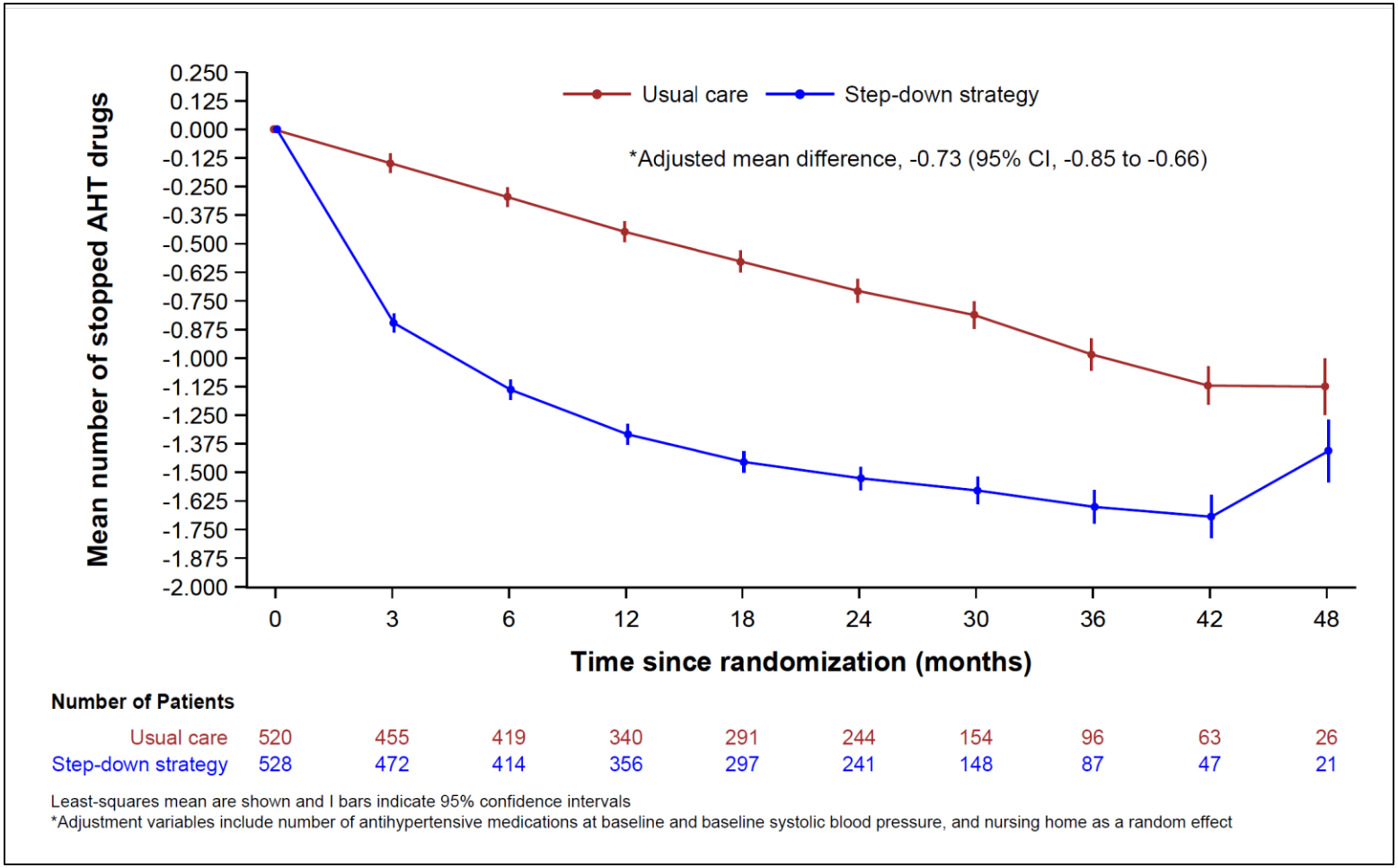
Table 1. Characteristics of the Patients at Baseline (Intention-to-Treat Population).*

Characteristic	Step-Down Strategy (N=528)	Usual Care (N=520)	Total (N=1048)
Age — yr	90.0±4.8	90.1±5.3	90.1±5.0
Female sex — no. (%)	423 (80.1)	423 (81.3)	846 (80.7)
Weight — kg†	64.9±14.8	65.2±15.0	65.1±14.9
Height — m‡	1.59±0.09	1.58±0.09	1.59±0.09
Body-mass index§	25.9±5.6	26.3±5.8	26.1±5.7
Systolic blood pressure — mm Hg¶	113±11	114±11	114±11
Diastolic blood pressure — mm Hg¶	65±10	65±10	65±10
Heart rate — beats/min¶	72±12	71±12	71±12
MMSE score‖	13.5±10.0	13.3±10.1	13.4±10.0
ADL score**	3.1±2.0	3.2±2.0	3.1±2.0
SPPB score††	1.2 ±1.9	1.2 ±2.0	1.2 ±1.9
EQ-5D-3L questionnaire score ‡‡	0.431±0.407	0.468±0.398	0.449±0.403
Peak muscular force — kg§§	11.7±6.4	12.0±6.8	12.0±6.8
Clinical Frailty Scale score — no./total no. (%)¶¶			
1, 2, or 3 Fit and doing well	47/525 (9.0)	52/514 (10.1)	99/1039 (9.5)
4 or 5 Mildly frail	147/525 (28.0)	164/514 (31.9)	311/1039 (29.9)
6 Moderately frail	118/525 (22.5)	111/514 (21.6)	229/1039 (22.0)
7 or 8 Severely frail	213/525 (40.6)	187/514 (36.4)	400/1039 (38.5)
Medications‖‖			
No. of list 1 and list 2 antihypertensive medications	2.6±0.7	2.5±0.7	2.5±0.7
No. of concomitant medications	6.7±3.2	6.7±2.8	6.7±3.0

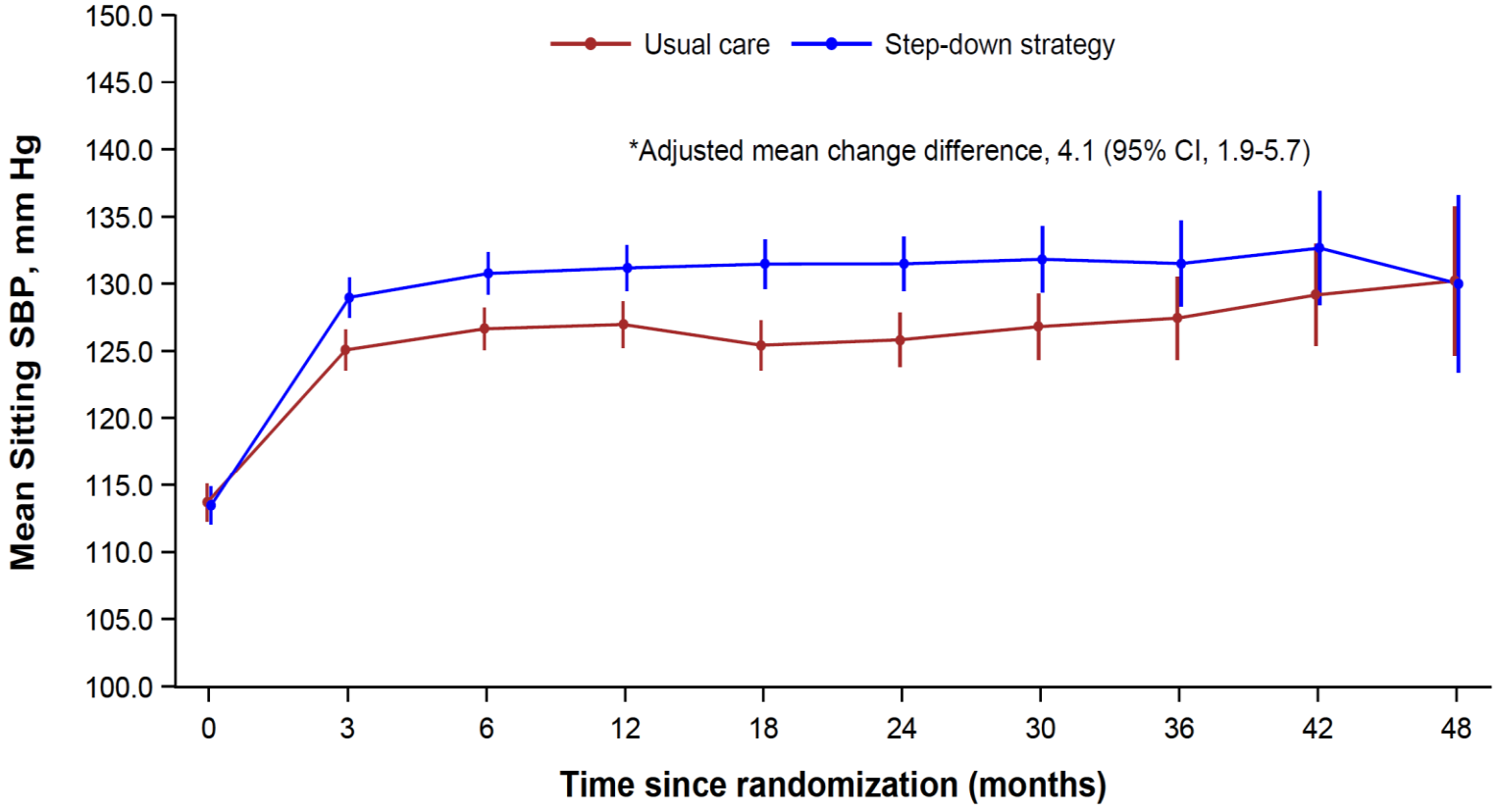
Clinical characteristics at baseline (2)

	Step-down strategy N=528	Usual care N=520	Total N=1048
Medical history and risk factors			
Atrial fibrillation — no. (%)	211 (40.0)	202 (38.8)	413 (39.4)
Peripheral arterial disease — no. (%)	52 (9.8)	49 (9.4)	101 (9.6)
Chronic heart failure — no. (%)	128 (24.2)	118 (22.7)	246 (23.5)
Coronary heart disease — no. (%)	100 (18.9)	101 (19.4)	201 (19.2)
Stroke — no. (%)	97 (18.4)	103 (19.8)	200 (19.1)
Transient Ischemic attack — no. (%)	30 (5.7)	35 (6.7)	65 (6.2)
Dementia — no. (%)	252 (47.7)	229 (44.0)	481 (45.9)
Parkinson's disease — no. (%)	14 (2.7)	20 (3.8)	34 (3.2)
Other neurological diseases — no. (%)	97 (18.4)	108 (20.8)	205 (19.6)
Severe mobility impairment* — no. (%)	238 (45.1)	237 (45.6)	475 (45.3)
Diabetes — no. (%)	123 (23.3)	122 (23.5)	245 (23.4)
Diabetic nephropathy — no. (%)	10 (1.9)	18 (3.5)	28 (2.7)
Severe renal insufficiency — no. (%)	25 (4.7)	29 (5.6)	54 (5.2)
Current smoker — no. (%)	19 (3.6)	5 (1.0)	24 (2.3)
Dyslipidemia — no. (%)	152 (28.8)	158 (30.4)	310 (29.6)
Cancer — no. (%)	133 (25.2)	121 (23.3)	254 (24.2)
Surgical history — no. (%)	435 (82.4)	422 (81.2)	857 (81.8)
Fracture previous 12 months — no./total no. (%)	28/515 (5.4)	33/506 (6.5)	61/1021 (6.0)

Number of the “List 1” antihypertensive drugs interrupted over the follow-up period of 38.4 months



SBP over the follow-up period



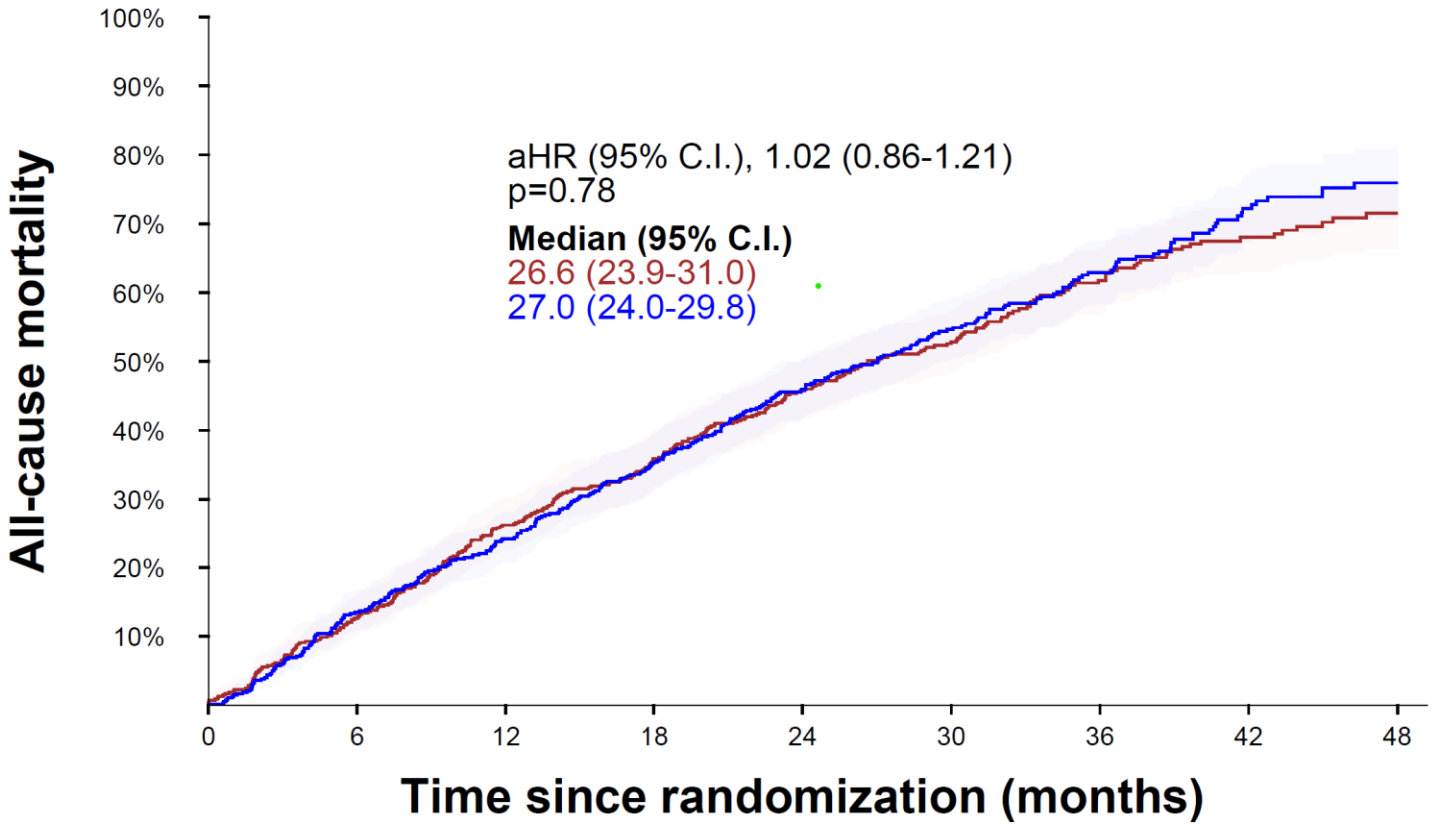
Number of Patients

Usual care	520	446	408	338	284	230	149	92	59	27
Step-down strategy	528	463	409	353	290	237	147	86	47	19

Least-squares mean are shown and I bars indicate 95% confidence intervals
*Adjustment variables include baseline systolic blood pressure, and nursing home as a random effect

Time-to-event analysis of the primary end point.

The Kaplan–Meier curves for the primary end point (all-cause mortality) show a median survival of 27.0 (24.0-29.8) months in the step-down strategy group and 26.6 (23.9-31.0) months in the usual care group.



No. at Risk

Usual care	520	446	374	325	266	175	107	62	8
Step-down strategy	528	446	387	330	267	172	101	51	8

Time-to-Event Analysis of All-Cause Mortality
Abbreviation: aHR, adjusted hazard ratio

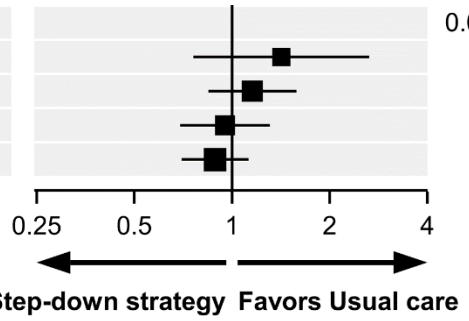
Benetos A et al, N Engl J Med 2025;393:1990-2000

Impact of step down of antihypertensive treatment on all-cause mortality according to the level of frailty.

Forest plot of all-cause mortality according to the Clinical Frailty Scale (CFS) score.

The p-value for the interaction between therapeutic strategy and frailty level was p = 0.08, indicating a trend for more benefits from the step-down strategy in the frailest patients and the opposite for the fittest patients.

Subgroup	Step-down strategy events/total(%)	Usual care events/total(%)	Adjusted HR** (95% CI)	PValue*
Clinical Frailty Scale				0.08
CFS score 1–3 (fit or managing well)	21/47 (44·7%)	19/52 (36·5%)	1·42 (0·76 to 2·64)	
CFS score 4–5 (vulnerable and mildly frail)	78/147 (53·1%)	80/164 (48·8%)	1·16 (0·84 to 1·58)	
CFS score 6 (moderately frail)	79/118 (66·9%)	76/111 (68·5%)	0·95 (0·69 to 1·31)	
CFS score 7-8 (severely and very severely frail)	146/213 (68·5%)	134/187 (71·7%)	0·89 (0·70 to 1·12)	



Primary and secondary end points

(mean follow up period of 38.4 months)

Table 3. Primary and Secondary End Points.

End Points	Step-Down Strategy (N = 528)	Usual Care (N = 520)	Adjusted Effect Measure (95% CI)*	P Value†
Primary end point: death from any cause				
Intention-to-treat analysis — no. (%)	326 (61.7)	313 (60.2)	1.02 (0.86–1.21)‡	0.78
Per-protocol analysis — no./total no. (%)§	311/499 (62.3)	305/497 (61.4)	1.04 (0.87–1.23)‡	
Secondary end points				
Death from noncardiovascular causes — no. (%)	284 (53.8)	278 (53.5)	1.00 (0.83–1.19)¶	
Acute heart failure — no. (%)	67 (12.7)	57 (11.0)	1.19 (0.80–1.78)‖	
No. of falls	0.81 (2.08)	0.71 (2.21)	1.14 (0.84–1.51)**	
No. of fractures	0.03 (3.71)	0.04 (3.32)	0.80 (0.51–1.26)**	
Death from Covid-19 — no. (%)	6 (1.1)	16 (3.1)	0.38 (0.10–1.00)††	
Composite of major adverse cardiovascular events — no. (%)‡‡	102 (19.3)	90 (17.3)	1.15 (0.84–1.56)§§	

Changes from baseline per year in scores measuring cognition, autonomy, gait/balance, muscle force and quality of life

End point	Step-down strategy LS-means (95% CI)	Usual care LS-means (95% CI)	Step-down strategy vs. Usual care Adjusted† LS-means difference or IRR (95% CI)*
MMSE — score/yr	-2.12 (-2.73 to -1.89)[b]	-1.89 (-2.46 to -1.63)[b]	-0.23 (-0.80 to 0.36)[b]
ADL — score/yr	-0.43 (-0.44 to -0.31)[b]	-0.46 (-0.40 to -0.31)[b]	0.02 (-0.01 to 0.15)[b]
SPPB — score/yr	-0.28 (-0.52 to -0.19)[b]	-0.29 (-0.41 to -0.24)[b]	0.01 (-0.19 to 0.16)[b]
Peak muscular force — kg/yr	-1.75 (-2.12 to -1.23)[b]	-1.80 (-1.94 to -1.31)[b]	0.05 (-0.41 to 0.66)[b]
EQ-5D-3L — score/yr	-0.10 (-0.17 to -0.02)[b]	-0.07 (-0.09 to -0.01)[b]	-0.04 (-0.11 to 0.05)[b]

Values are mean least square-means (95% CI) and least square-means difference (95% CI). Positive values indicate an increase (improvement) over time, while negative numbers indicate a reduction.

Only patients with baseline data and at least one post-randomization data were included in these analyses.

LS denotes least squares, CI confidence interval and NH denotes nursing home.

†Adjusting for baseline end points and baseline systolic blood pressure, including NH as a random effect.

*CIs for secondary end points have not been adjusted for multiplicity and may not be used in place of hypothesis testing.

[b]Bias-Corrected and accelerated bootstrap method using 10,000 replications.

Number of serious adverse events (SAE)

	Step-down strategy N=528	Usual care N=520	Total N=1048
Total number of SAE * — no.	**132**	**128**	**260**
Infectious diseases	45	49	94
Pulmonary and respiratory diseases (other than infectious)	21	21	42
Cancers	14	16	30
Alteration of general health status and anemias (not bleeding-related)	17	15	32
Bleeding	12	13	25
Gastrointestinal diseases	14	7	21
Neurological diseases	5	2	7
Other	4	5	9

* SAE that are part of the primary (all-cause mortality) or secondary (MACE, falls and fractures) end points are already reported and for this reason they are not reported here.

Summary

- RETREAT-FRAIL is the first RCT to evaluate the long-term effects of antihypertensive treatment step-down on mortality, morbidity and several geriatric parameters, in a large, mainly female, population of frail, very old patients with SBP<130 mmHg under >1 antihypertensive drugs.
- The step-down strategy did not reduce all-cause mortality (primary end point) over a follow-up period of more than 3 years.
- The step-down strategy led to a long-term reduction in antihypertensive medications, resulting in a moderate increase in BP.
- RETREA-FRAIL showed that an antihypertensive medication step-down strategy does not have a clinically relevant effect on all-cause mortality, and has no apparent effect on functional capacities, MACE, or on other SAE.

Benetos A et al, N Engl J Med 2025;393:1990-2000

The contribution of the RETREAT-FRAIL trial

Deprescription of antihypertensive treatment could be considered in very old subjects with low blood pressure, especially in the frailest ones, in which polypharmacy is a major problem.

Deprescription is a prescription, and as any other prescription, it must comply with strict rules, indications and contraindications and regular monitoring of patients

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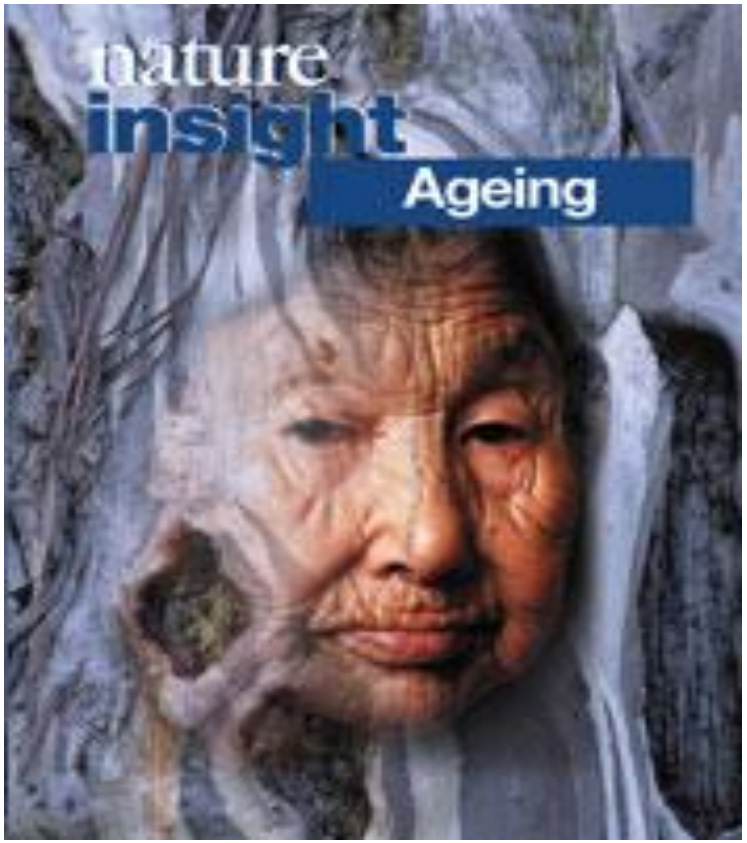

Thank you for your attention