COORDINATE-Diabetes

A Cluster-Randomized Trial to Improve Care of Patients in Cardiology Clinics with Type 2 Diabetes and Atherosclerotic Cardiovascular Disease [COORDINATE-Diabetes]

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on behalf of the COORDINATE-Diabetes Steering Committee

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Background

High-intensity statins, ACEi/ARBs, and SGLT2i and GLP-1RA are proven to improve outcomes for patients with T2D and ASCVD.

These 3 therapies are underused in clinical practice.

2.7%
on **ALL 3**

37.4%
on **NONE**

Nelson et al. JAHA 2021; 10:e016835

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Objective

To test the impact of a clinic-level, multifaceted intervention on the prescription of 3 key groups of evidence-based therapies.

Coordinate-Diabetes Study Organization

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Study Design

SITES: Cardiology clinics in the US

PARTICIPANTS: T2D and ASCVD

Clinic-level randomization

INTERVENTION (20 sites)	**USUAL CARE** (23 sites)
Multifaceted intervention	Received guidelines

6–12 MONTH FOLLOW-UP

PRIMARY OUTCOME:
Prescription of ALL 3 groups of recommended therapies:

- High-intensity statin:
  Atorvastatin 40–80mg daily OR rosuvastatin 20–40mg daily
- ACEi or ARB
- Antihyperglycemic agent with CV benefit:
  SGLT2i or GLP-1RA

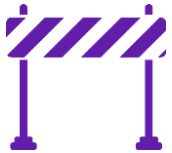
Nelson et al. Am Heart J 2023; 256: 2-12

Participant Population

INCLUSION CRITERIA	EXCLUSION CRITERIA
• Diagnosis of type 2 diabetes • History of at least one: – Coronary artery disease – Peripheral arterial disease – Cerebrovascular disease	• Already prescribed at baseline: – All 3 evidence-based therapies – SGLT2i or GLP-1RA • Absolute contraindication to any of the 3 evidence-based therapies

Multifaceted Intervention

1.
Assessment of local practices and barriers



Clinic-specific assessment of barriers to prescribing the recommended therapies

2.
Development of strategies to overcome those barriers

Development of care pathways to address barriers

Coordination of care between clinicians

Clinician education

Participant educational materials

3.
Audit and feedback

Audit and feedback of quality metrics

Statistical Analysis

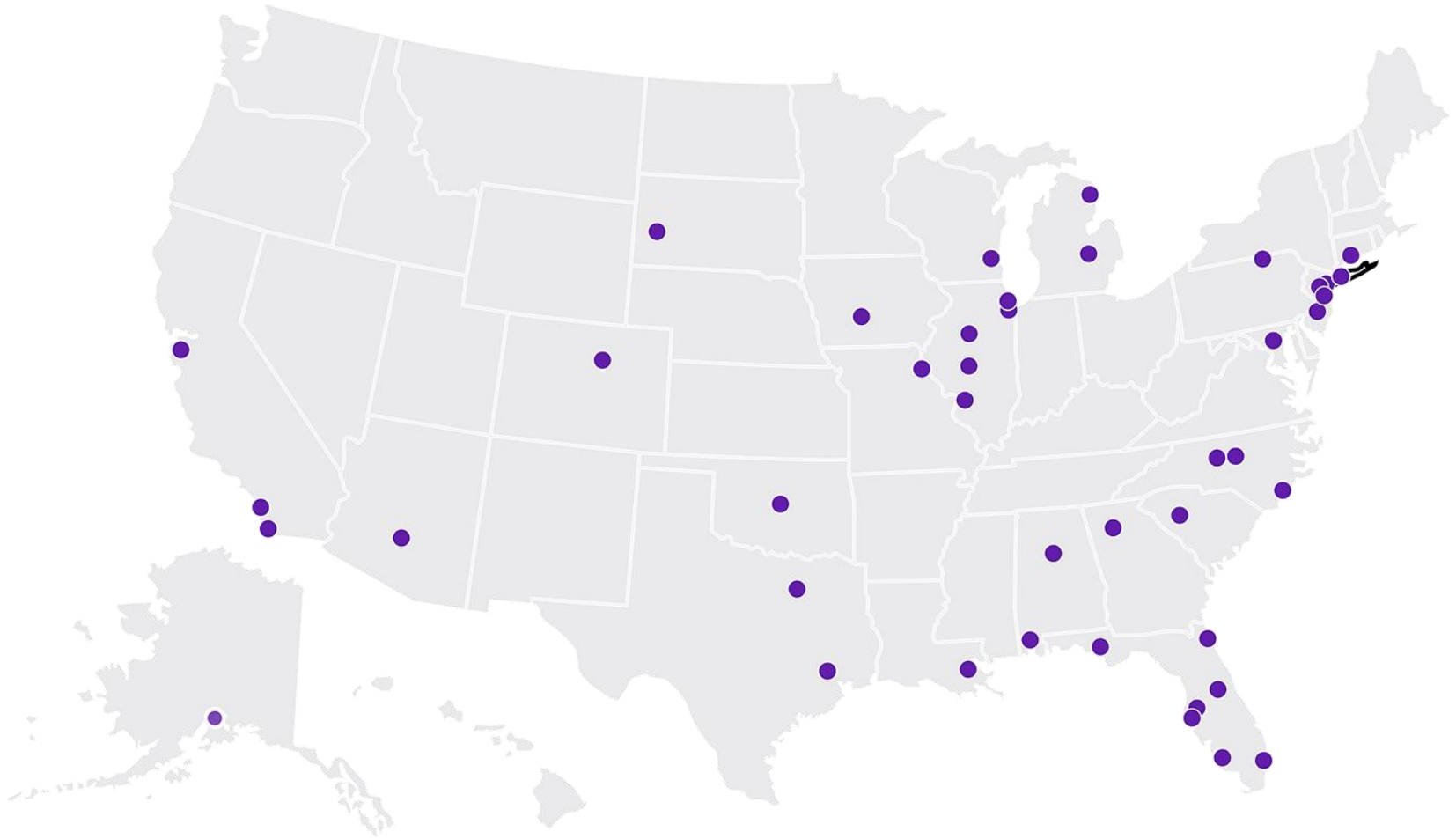
Initially powered at 90%
to detect 10% difference in primary outcome between arms (46 clinics, 30 patients/clinic)

Modified to have 85% power
(42 clinics, 25 patients/clinic) due to difficulties with recruitment during the COVID-19 pandemic

Primary and secondary outcomes
analyzed using a mixed model for repeated measures model, accounting for clustering effect, and with adjustment for baseline factors as potential confounders

Clinical event outcomes
analyzed using a multivariable Cox proportional hazards model

Enrolling Site Characteristics



43
enrolling sites

24
participants enrolled (median)

Baseline composite medication score (median):

1.6
intervention

1.4
usual care

Participant Baseline Characteristics

Outcome	Intervention (N=459)	Usual care (N=590)
Age, median (25th, 75th)	69 (63, 76)	71 (64, 77)
Female	31.4%	32.9%
Race: White	70.6%	81.4%
Black	17.2%	15.9%
Asian/other	8.9%	3.2%
Missing	3.3%	0.2%
Prior coronary artery disease	76.0%	84.7%
Prior stroke/carotid artery disease	27.5%	25.1%
Prior peripheral arterial disease	17.4%	10.2%
Prior heart failure	29.6%	24.6%
Composite medication score: 0	5.9%	9.7%
1	34.2%	38.3%
2	59.9%	52.0%

Primary Outcome

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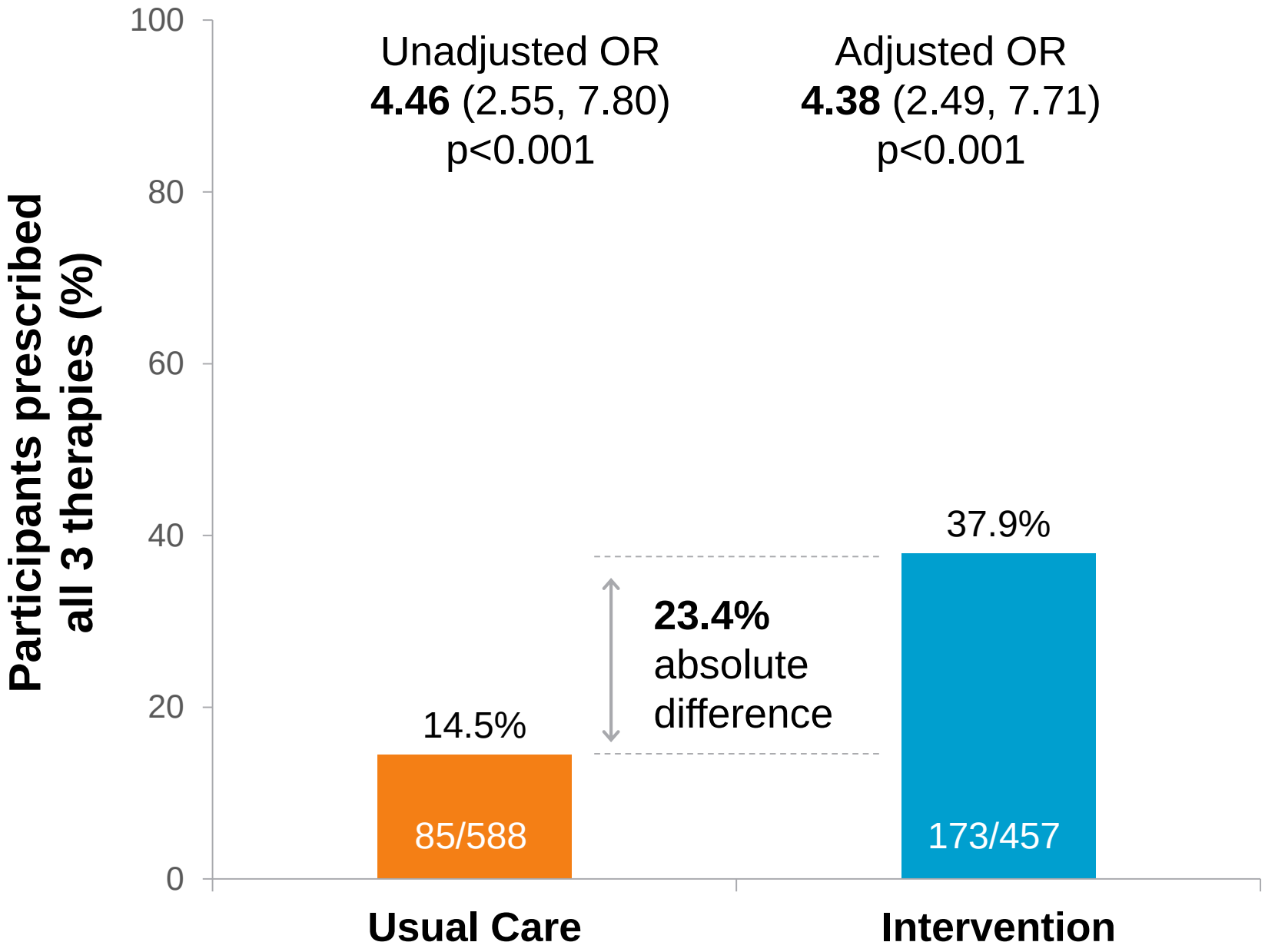
Primary Outcome



Secondary Outcomes

Outcome	Intervention No. (%) (N=457)	Usual care No. (%) (N=588)	Adjusted Odds ratio (95% CI)	P value
Prescribed at last follow up:				
High-intensity statin	323/457 (70.7)	334/588 (56.8)	1.73 (1.06 to 2.83)	0.029
ACEi/ARB	372/457 (81.4)	402/588 (68.4)	1.82 (1.14 to 2.91)	0.013
SGLT2i or GLP-1RA*	276/457 (60.4)	209/588 (35.5)	3.11 (2.08 to 4.64)	<0.001

Adjusted for clustering effect, site type (urban vs. non-urban), age, sex, race, baseline composite score, Charlson comorbidity index, baseline systolic BP, baseline diastolic BP, time, and time-by-treatment interaction

*Or HbA1c<7% on metformin alone

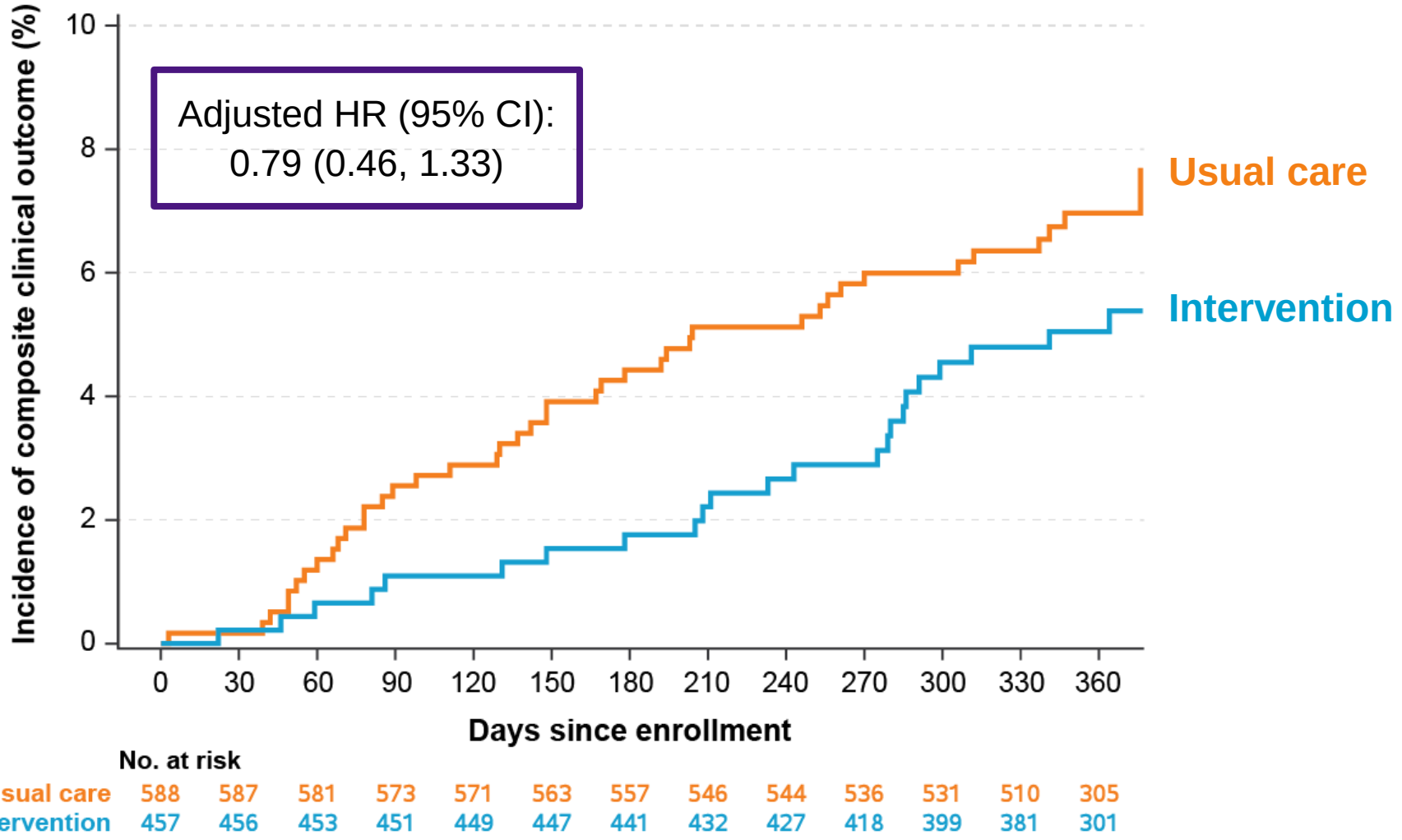
Secondary Outcomes: Risk Factors

	% Available	Intervention (n=459) Difference	Usual care (N=590) Difference	Adjusted difference in differences† Estimate (95% CI)	P value
sBP	82.9%	-2.31	0.91	-1.99 (-4.34, 0.36)	0.0961
dBP	82.9%	-1.61	-0.44	-0.39 (-1.83, 1.05)	0.5946
HbA1c	48.0%	-0.17	-0.00	-0.05 (-0.34, 0.25)	0.7495
LDL-C	43.6%	-4.14	-5.30	0.61 (-5.24, 6.46)	0.8379

† Adjusted for site type (urban vs. non-urban), patient age, sex, race, baseline composite score, Charlson comorbidity index, baseline systolic BP, baseline diastolic BP

Secondary Outcomes: Clinical Events

Composite outcome:
All-cause mortality or hospitalization for MI, stroke, decompensated HF, or urgent revascularization (coronary, carotid, peripheral)



Limitations

- Selected sites and patients may not be representative of broader US or international population
- Because of the COVID pandemic, the intervention was delivered remotely and was thus less intensive than originally designed

Conclusions

A coordinated, multifaceted intervention **increased prescription** of 3 groups of evidence-based therapies in adults with T2D and ASCVD

Clinical Implications

- Evidence-based therapies are under-used in clinical practice, and there is little high-quality data on how to improve this.
- This multifaceted intervention is effective in increasing the prescription of evidence-based therapies in adults with T2D and ASCVD.
- The next step is to scale this intervention across cardiology practices in order to improve the quality of care being delivered broadly.

COORDINATE-Diabetes Website

www.coordinatediabetes.org

Acknowledgements

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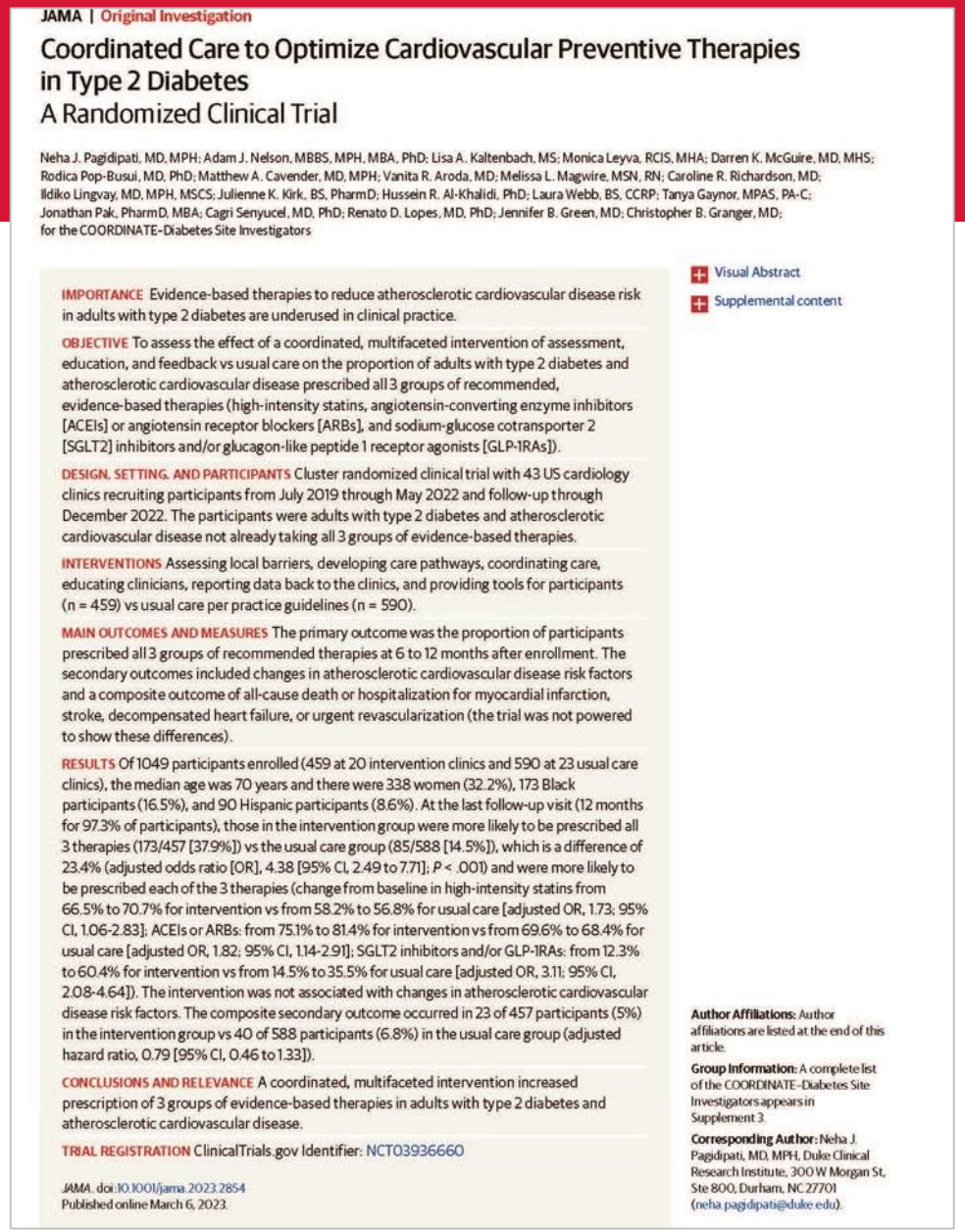

JAMA | Original Investigation

Coordinated Care to Optimize Cardiovascular Preventive Therapies in Type 2 Diabetes
A Randomized Clinical Trial

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IMPORTANCE Evidence-based therapies to reduce atherosclerotic cardiovascular disease risk in adults with type 2 diabetes are underused in clinical practice.

OBJECTIVE To assess the effect of a coordinated, multifaceted intervention of assessment, education, and feedback vs usual care on the proportion of adults with type 2 diabetes and atherosclerotic cardiovascular disease prescribed all 3 groups of recommended, evidence-based therapies (high-intensity statins, angiotensin-converting enzyme inhibitors [ACEIs] or angiotensin receptor blockers [ARBs], and sodium-glucose cotransporter 2 [SGLT2] inhibitors and/or glucagon-like peptide 1 receptor agonists [GLP-1RAs]).

DESIGN, SETTING, AND PARTICIPANTS Cluster randomized clinical trial with 43 US cardiology clinics recruiting participants from July 2019 through May 2022 and follow-up through December 2022. The participants were adults with type 2 diabetes and atherosclerotic cardiovascular disease not already taking all 3 groups of evidence-based therapies.

INTERVENTIONS Assessing local barriers, developing care pathways, coordinating care, educating clinicians, reporting data back to the clinics, and providing tools for participants (n = 459) vs usual care per practice guidelines (n = 590).

MAIN OUTCOMES AND MEASURES The primary outcome was the proportion of participants prescribed all 3 groups of recommended therapies at 6 to 12 months after enrollment. The secondary outcomes included changes in atherosclerotic cardiovascular disease risk factors and a composite outcome of all-cause death or hospitalization for myocardial infarction, stroke, decompensated heart failure, or urgent revascularization (the trial was not powered to show these differences).

RESULTS Of 1049 participants enrolled (459 at 20 intervention clinics and 590 at 23 usual care clinics), the median age was 70 years and there were 338 women (32.2%), 173 Black participants (16.5%), and 90 Hispanic participants (8.6%). At the last follow-up visit (12 months for 97.3% of participants), those in the intervention group were more likely to be prescribed all 3 therapies (173/457 [37.9%]) vs the usual care group (85/588 [14.5%]), which is a difference of 23.4% (adjusted odds ratio [OR], 4.38 [95% CI, 2.49 to 7.71]; $P < .001$) and were more likely to be prescribed each of the 3 therapies (change from baseline in high-intensity statins from 66.5% to 70.7% for intervention vs from 58.2% to 56.8% for usual care [adjusted OR, 1.73; 95% CI, 1.06-2.83]; ACEIs or ARBs: from 75.1% to 81.4% for intervention vs from 69.6% to 68.4% for usual care [adjusted OR, 1.82; 95% CI, 1.14-2.91]; SGLT2 inhibitors and/or GLP-1RAs: from 12.3% to 60.4% for intervention vs from 14.5% to 35.5% for usual care [adjusted OR, 3.11; 95% CI, 2.08-4.64]). The intervention was not associated with changes in atherosclerotic cardiovascular disease risk factors. The composite secondary outcome occurred in 23 of 457 participants (5%) in the intervention group vs 40 of 588 participants (6.8%) in the usual care group (adjusted hazard ratio, 0.79 [95% CI, 0.46 to 1.33]).

CONCLUSIONS AND RELEVANCE A coordinated, multifaceted intervention increased prescription of 3 groups of evidence-based therapies in adults with type 2 diabetes and atherosclerotic cardiovascular disease.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03936660

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Visual Abstract
Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: A complete list of the COORDINATE-Diabetes Site Investigators appears in Supplement 3.

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