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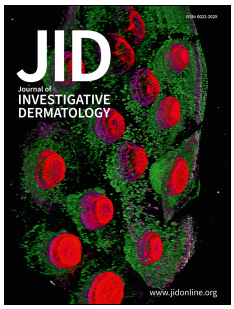

A Care Coordination Model to Prevent Cardiovascular Events in Patients with Psoriatic Disease: A Multicenter Pilot Study

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Title Page

Title: A Care Coordination Model to Prevent Cardiovascular Events in Patients with Psoriatic Disease: A Multicenter Pilot Study

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Short title: Care Coordination to Reduce CVD in Psoriasis

Keywords: psoriasis, screening, risk, statin, acceptability

Abbreviations: Cardiovascular (CV), care coordinator (CC), atherosclerotic cardiovascular disease (ASCVD), primary care provider (PCP), Prevention of Cardiovascular Disease and Mortality in Patients with Psoriasis or Psoriatic Arthritis study (CP3)

Letter

To the Editor

Psoriasis is an inflammatory disease associated with premature mortality, largely explained by an excess risk of cardiovascular (CV) events (Elmets et al., 2019, Gelfand et al., 2006). Dermatology and Cardiology guidelines define psoriasis as a CV risk enhancer warranting more intensive management of traditional CV risk factors (Elmets et al., 2019, Grundy et al., 2019). However, identification and management of these risk factors in patients with psoriasis is insufficient, resulting in preventable morbidity and mortality (Eder et al., 2018). For example, dermatologists only screen psoriasis patients' cholesterol and blood pressure at rates of 3% and 7%, respectively (Song et al., 2023a). Nevertheless, patients, dermatologists, and rheumatologists agree that screening psoriasis patients for CV risk factors is feasible and warranted. However, clinicians express concern about having the time and expertise to act on screening results (Barbieri et al., 2022, Gustafson et al., 2022).

To address this evidence-to-practice gap, we developed and piloted a centralized care coordination model in which the dermatologist or rheumatologist educates the patient about CV risks associated with psoriatic disease, measures the patient's CV risk factors per standard of care guidelines, and refers the patient to a care coordinator (CC) at the National Psoriasis Foundation. The CC calculates the patient's 10-year risk of developing atherosclerotic cardiovascular disease (ASCVD) (American Heart Association, 2018) and meets virtually with the patient to create a guideline-based plan for diet, exercise, and smoking cessation to be implemented with their primary care provider (PCP). For patients with at least 5% 10-year ASCVD risk, the CC provides education on medical management and sends guideline-based treatment recommendations to the

patient's PCP. Specifically, American Heart Association guidelines define psoriasis as a CV risk enhancer, recommending moderate intensity statins or imaging to further assess risk in psoriasis patients with "borderline" (i.e., 5% to <7.5%) 10-year ASCVD risk (Grundy et al., 2019). At-risk patients receive monthly follow-up with the CC until 4-6 months after their initial visit, when CV risk factors are measured again to recalculate the patient's ASCVD risk and to offer additional recommendations. Because prior research has demonstrated that interventions utilizing CCs for patients with comorbid diseases improves patient outcomes and therefore lacks clinical equipoise (Gorin et al., 2017), our study used a single arm without a standard of care comparator.

The pilot study (April 2022 through April 2023) assessed the feasibility and acceptability of this model. We recruited patients aged 40-75 from 4 dermatology and rheumatology sites in the United States during routine clinical care, excluding patients taking a statin or diabetes pharmacotherapy, pregnant or planning pregnancy, or with known CV disease. This study was approved by the Penn Institutional Review Board, and participants provided written, informed consent.

We enrolled 85 patients with psoriatic disease (Figure S1). Mean age was 54, 54% were female, mean BMI was 30, and 8% currently smoked (Table 1). Patients had an average disease duration of 23 years, 74% had psoriatic arthritis (including 49% of patients referred by dermatologists), 78% were currently on biologic therapy, and psoriatic disease was well controlled based on physician- and patient-reported measures. At baseline, mean total cholesterol was 203 mg/dL, mean at-home blood pressure was 121/77 mm Hg, and mean 10-year ASCVD risk was 4.9%. 77% reported moderate to vigorous physical activity at least 3 days per week.

86% of patients reported that the CC approach was acceptable and feasible (Table 1). 94% of patients completed baseline laboratory tests, 84% completed at least one at-home blood pressure measurement, and 87% completed their initial visit with a CC. 27% of patients (n=23) had newly identified, previously undiagnosed 10-year ASCVD risk of at least 5%, qualifying them for statin initiation. Of these 23 at-risk patients, 89% of patients repeated lipid tests and home blood pressure measurements approximately 5 months after initial evaluation, and 80% completed additional CC visits. However, only 2 patients (9%) initiated a statin as recommended. One patient had additional testing and was found to have triple-vessel coronary artery disease. The two patients who initiated statins experienced large improvements in CV risk measures (mean change in total cholesterol -104 mg/dL (p=0.03) and -5.3% change in 10-year ASCVD risk score (p=0.03)) (Table 2). At-risk patients who did not initiate recommended statin therapy (n=15) experienced clinically nonsignificant changes in the same measures. There were no reported changes in smoking status and a nonsignificant change in mean physically active days per month of -0.8 days (p=0.75).

In this pilot study embedded in routine clinical care, more than 85% of patients completed CV risk assessment (blood tests, at-home blood pressure recordings, and virtual meetings with the CC), consistent with our prior studies demonstrating that patients are highly motivated to act on CV screening recommendations from their dermatologists or rheumatologists (Barbieri et al., 2022, Gustafson et al., 2022). Importantly, though our sites have extensive expertise in managing psoriatic disease and routinely screen for CV risk factors, 27% of patients had newly identified, clinically significant ASCVD risk warranting statin therapy, and one patient was newly

diagnosed with triple-vessel coronary artery disease. However, despite recommendations provided to at-risk patients and their PCPs, only 2 patients initiated statin therapy. This result may reflect hesitancy to adopt guideline-recommended therapy, consistent with our previous finding that clinicians who treat psoriatic disease frequently encounter statin hesitancy and observe that "a lot of people don't want to take statins" due to fear of side effects (Gustafson et al., 2022). Another potential explanation is that our study clinicians already routinely screen their patients with psoriatic disease for CV risk. Consequently, most of our at-risk patients already initiated statin therapy, making them ineligible for the current study and leaving a pool of more statin-hesitant patients available for participation. Patients who initiated statin therapy experienced large, clinically significant decreases in their cholesterol and predicted CV risk, while those who did not initiate statin therapy experienced no meaningful changes, highlighting the benefits of appropriate CV screening and intervention, which is recommended by the American Academy of Dermatology for all psoriasis patients (Elmets et al., 2019). From our experience, in the absence of dedicated care coordination, CV risk factor screening can be efficiently performed alongside routine dermatological evaluation, including office measurements of blood pressure and weight and the addition of lipid and hemoglobin A1C tests to routine laboratory evaluations for systemic psoriasis treatments. Any identified CV risk factors can be managed by the patient's PCP (Song et al., 2023b). We also recommend collaboration with preventive cardiologists, just as dermatologists collaborate with rheumatologists when psoriatic arthritis is present. Nevertheless, given substantial unmet needs in CV risk factor screening and management for psoriasis patients (Eder et al., 2018) and the strong desire from clinicians and patients for support in CV screening and management (Barbieri et al., 2022, Gustafson et al., 2022), we plan to further assess our care coordination model in a more diverse

population. To that end, the Prevention of Cardiovascular Disease and Mortality in Patients with Psoriasis or Psoriatic Arthritis (CP3) study (ClinicalTrials.gov Identifier: NCT05908240) is currently testing an updated version of this model in a large, national cohort of patients. Overall, this care coordination model shows promise in helping patients manage their CV risks and represents a tremendous opportunity for clinicians to reduce preventable CV morbidity and mortality in patients with psoriatic disease.

Data Availability Statement

Datasets and code related to this article are available by request made to the corresponding author. No large datasets were generated or analyzed in this article.

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Conflict of Interest Statement

MSG has received consultant fees for Kiniksa, BMS, and Horizon therapeutics. JSB has received consulting fees from Dexcel Pharma. REK has received research funding from AbbVie, Amgen, CorEvitas LLC, Janssen-Ortho Inc, UCB and the University of Pennsylvania, he has been on the data safety monitoring board for studies with Eli Lilly and the Pharmaceutical Product Development (PPD) group, and he has been a consultant for Janssen-Ortho Inc and UCB, with all grants paid to his institution. JT receives a research grant from Pfizer Inc. that is paid to the Trustees of the University of Pennsylvania. ZCCF has received research grants from Lilly, LEO Pharma, Regeneron, Sanofi, Tioga, and Vanda for work related to atopic dermatitis and from Menlo Therapeutics and Galderma for work related to prurigo nodularis, and she has also served as consultant for the Asthma and Allergy Foundation of America, National Eczema Association, AbbVie, Incyte Corporation, and Pfizer; and received honoraria for CME work in Atopic Dermatitis sponsored by education grants from Regeneron/Sanofi and Pfizer and from Beirsdorf for work related to skin cancer and sun protection. AWA has served as a research investigator,

scientific advisor, or speaker to AbbVie, Almirall, Arcutis, ASLAN, Beiersdorf, BI, BMS, EPI, Incyte, Leo, UCB, Janssen, Lilly, Mindera, Nimbus, Novartis, Ortho Dermatologics, Sun, Dermavant, Dermira, Sanofi, Regeneron, and Pfizer. NNM is a consultant for Novartis, BMS, Sun, Amgen, Lilly, has served as an investigator for Novartis, Amgen, Janssen, Abbvie and is a board member of the American Society of Preventive Cardiology. RSB is principal at Implementation Science & Practice, LLC, and she receives royalties from Oxford University Press, consulting fees from United Behavioral Health and OptumLabs, and serves on the advisory boards for Optum Behavioral Health, AIM Youth Mental Health Foundation, and the Klingenstein Third Generation Foundation outside of the submitted work. ARO has the following disclosures: Consulting/Advisory Boards for Abbvie, Amgen, BMS, Celgene, Corrona, Gilead, GSK, Happify Health, Janssen, Lilly, Novartis, Pfizer, UCB; Grants from Abbvie to Penn, Janssen to Penn, Novartis to Penn, Pfizer to Penn, Amgen to Forward/NDB, BMS to Forward/NDB; Other Funding from NIAMS, Rheumatology Research Foundation, National Psoriasis Foundation, University of Pennsylvania. JMG served as a consultant for Abbvie, Artax (DSMB), BMS, Boehringer Ingelheim, Celldex (DSMB), FIDE (which is sponsored by multiple pharmaceutical companies) GSK, Inmagene (DSMB), Twill, Lilly (DMC), Leo, Moonlake (DSMB), Janssen Biologics, Novartis Corp, UCB (DSMB), Neuroderm (DSMB), and Veolia North America receiving honoraria; and receives research grants (to the Trustees of the University of Pennsylvania) from Amgen, BMS, and Pfizer Inc.; and received payment for continuing medical education work related to psoriasis that was supported indirectly pharmaceutical sponsors; and is a co-patent holder of resiquimod for treatment of cutaneous T cell lymphoma; and is a Deputy Editor for the *Journal of Investigative Dermatology* receiving honoraria from the Society for Investigative Dermatology, is Chief Medical Editor for Healio

Dermatology (receiving honoraria) and is a member of the Board of Directors for the International Psoriasis Council and the Medical Dermatology Society, receiving no honoraria.

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Author Contributions Statement

Conceptualization: JMG, ARO, MSG, JSB, DBS, JT; Data Curation: DBS, RF; Formal Analysis: WBS, DBS, AN, RF; Funding Acquisition: JMG; Methodology: JMG, ARO, MSG, JSB, DBS, JT, AMA, NNM, RSB, REK, PJM, ETC; Project Administration: SB, AN; Supervision: JMG, SB Validation: DBS; Writing – Original Draft: WBS, JMG; Writing – Review & Editing: WBS, MSG, JSB, DBS, SB, AN, RF, REK, PJM, ETC, JT, AWA, NNM, RSB, ARO, JMG

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Table 1. Patient Demographics, Psoriatic Disease Severity, Baseline Cardiovascular Risk Factors, Medication Recommendations, and Acceptability and Feasibility.

	All Patients (n=85)	At-Risk* Patients Analyzed for Intervention Effectiveness (n=17)
Variable	**Mean (SD) or n (%)**	
Demographics		
Age (years)	54 (9)	64 (7)
Female	46 (54%)	6 (35%)
White	78 (92%)	16 (94%)
Dermatology patients (recruited by 5 providers at 2 sites)	43 (51%)	7 (41%)
Rheumatology patients (recruited by 7 providers at 2 sites)	42 (49%)	10 (59%)
Psoriatic Disease Burden		
Duration of psoriatic disease (years)	23 (14)	27 (13)
Body Surface Area (BSA) involvement	1.2 (1.6)	0.8 (0.7)
Physician Global Assessment (PGA)	1.0 (1.0)	0.7 (0.7)
Dermatology Life Quality Index (DLQI)	3.6 (4.7)[1]	2.9 (3.8)
Psoriatic Arthritis Impact of Disease (PsAID, rheumatology patients only)	3.6 (2.4)[2], n=42	3.5 (1.7), n=10
History of psoriatic arthritis	63 (74%)	14 (82%)
History of psoriatic arthritis (among dermatology patients)[3]	21 (49%), n=43	4 (57%), n=7
Active Therapies for Psoriatic Disease		
Any biologic therapy	66 (78%)	13 (76%)
Tumor necrosis factor (TNF) inhibitor	20 (24%)	3 (18%)
Interleukin-23 (IL-23) inhibitor or interleukin-12/interleukin-23 (IL-12/23) inhibitor	17 (20%)	6 (35%)
Interleukin-17 (IL-17) inhibitor	17 (20%)	3 (18%)
Abatacept (CTLA4-Ig)	1 (1%)	1 (1%)
Any small molecule inhibitor	26 (31%)	6 (35%)
Methotrexate	13 (15%)	2 (12%)
Apremilast	7 (8%)	1 (6%)
Leflunomide	1 (1%)	0 (0%)
Janus kinase (JAK) inhibitor	5 (6%)	3 (18%)
Systemic steroids	5 (6%)	0 (0%)
Phototherapy	3 (4%)	0 (0%)
Baseline Cardiovascular Risk Factors		
Systolic blood pressure, at-home	121 (10)	123 (9)
Diastolic blood pressure, at-home	77 (8)	75 (8)
BMI (kg/m^2)	30 (6)	31 (6)
Total cholesterol (mg/dL)	203 (31)	198 (29)

LDL (mg/dL)	123 (28)	119 (26)
HDL (mg/dL)	56 (14)	57 (15)
HbA1c (%)	5.5 (0.4)	5.4 (0.3)
Current smoking	7 (8%)	2 (12%)
Former smoking	26 (31%)	6 (35%)
Days of recreational exercise of at least 30 minutes over the last month	11 (9)	15 (10)
Vigorous activity for at least 30 minutes at least 3 times per week	19 (22%)	2 (12%)
Moderate activity at least 3 times per week	47 (55%)	9 (53%)
Seldomly active	17 (20%)	6 (35%)
10-year ASCVD risk score (%)	4.9 (4.9)	11.4 (5.3)
Newly identified ≥5% 10-year ASCVD risk	23 (27%)	17 (100%)
Recommendations		
Statin recommended	23 (27%)	17 (100%)
Blood pressure medication recommended	28 (33%)	3 (18%)
Acceptability and Feasibility		
Care coordinator model is acceptable	73 (86%)	15 (88%)
Care coordinator model is feasible	73 (86%)	16 (94%)
Obtained baseline lipid laboratory tests	80 (94%)	17 (100%)
Completed baseline 6 at-home blood pressure measurements	65 (76%)	17 (100%)
Completed at least 1 at-home blood pressure measurement	72 (85%)	17 (100%)
Completed initial visit with care coordinator	74 (87%)	17 (100%)

*Defined as ≥5% 10-year predicted risk of developing atherosclerotic cardiovascular disease.
[1]Corresponds to a small effect on health-related quality of life
[2]Corresponds to a patient-acceptable symptom state
[3]100% of patients referred from rheumatologists (n=42) had psoriatic arthritis

Table 2. Intervention Effectiveness and Changes in Cardiovascular Risk Measures.

Variable	Mean change (95% CI), p-value
Change in cardiovascular risk factors on reassessment in patients recommended for statin therapy, overall (n=17)	
Total cholesterol (mg/dL)	-17 (-36, 1.6), p=0.07
LDL (mg/dL)	-15 (-33, 3.5), p=0.10
HDL (mg/dL)	-0.5 (-3.6, 2.6), p=0.74
Systolic blood pressure (mmHg)	1.2 (-3.2, 5.5), p=0.57
Diastolic blood pressure (mmHg)	-0.6 (-3.4, 2.1), p=0.63
10-year ASCVD risk score	-0.2% (-1.5%, 1.1%), p=0.71
Patients who stopped smoking (n=2)	0 (0%)
Physically active days per month	-0.8 (-6.3, 4.7), p=0.75
Patients who changed their physical activity intensity	0 (0%)
Change in cardiovascular risk factors on reassessment in patients recommended for statin therapy who initiated a statin (n=2)	
Total cholesterol (mg/dL)	-104 (-167, -40), p=0.03
LDL (mg/dL)	-96 (-318, 127), p=0.12
HDL (mg/dL)	-1.0 (-90, 88), p=0.91
Systolic blood pressure (mmHg)	-3.0 (-79, 73), p=0.70
Diastolic blood pressure (mmHg)	-0.5 (-70, 69), p=0.94
10-year ASCVD risk score	-5.3% (-8.7%, -1.8%), p=0.03
Change in cardiovascular risk factors on reassessment in patients recommended for statin therapy who did not initiate a statin (n=15)	
Total cholesterol (mg/dL)	-5.8 (-16, 4.4), p=0.24
LDL (mg/dL)	-3.4 (-11, 4.4), p=0.37
HDL (mg/dL)	-0.4 (-3.7, 2.8), p=0.78
Systolic blood pressure (mmHg)	1.7 (-3.0, 6.5), p=0.45
Diastolic blood pressure (mmHg)	-0.7 (-3.7, 2.3), p=0.64
10-year ASCVD risk score	0.5% (-0.4%, 1.4%), p=0.27

Supplementary Figure S1. Flow Diagram of Study Enrollment, Participation, and Analysis.

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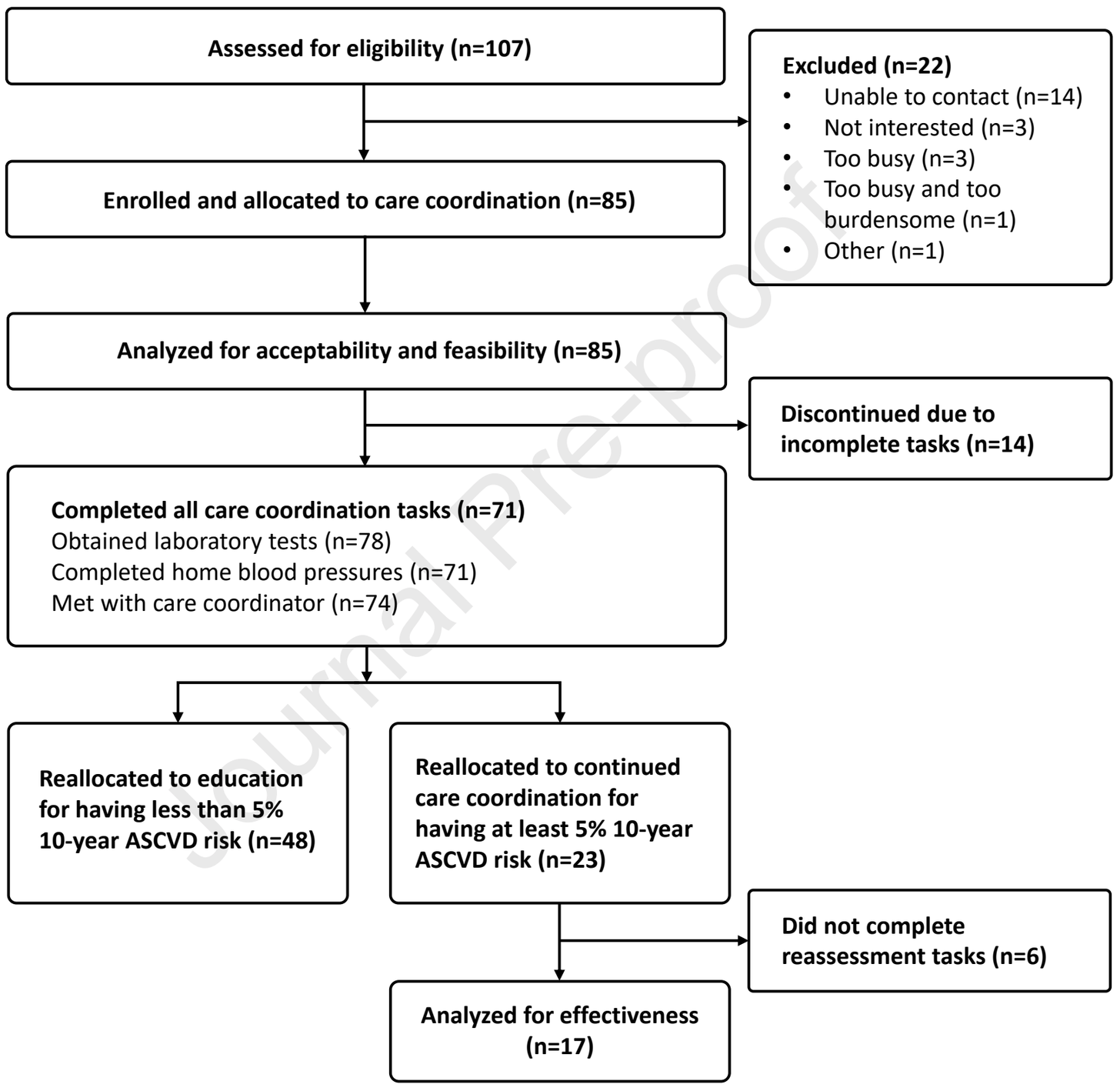

Supplementary Figure S1. Flow Diagram of Study Enrollment, Participation, and Analysis.