Moderation of Motivational Interviewing and a Smartphone App Interventions for Improving Physical Outcomes among Patients with Peripheral Artery Disease: Secondary Analysis of a Pilot Randomized Trial

Benjamin Neil Vickers, Yiliang Zhu, Tracie C. Collins

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Benjamin Neil Vickers[1] MS, PhD; Yiliang Zhu[2] MS, PhD; Tracie C. Collins[1] MS, MPH, MD

[1] College of Population Health University of New Mexico Albuquerque US
[2] School of Medicine University of New Mexico Albuquerque US

Corresponding Author:
Benjamin Neil Vickers MS, PhD

College of Population Health
University of New Mexico
MSC 09 5070
1 University of New Mexico
Albuquerque
US

Abstract

Background: In a pilot randomized trial, face-to-face or telephone motivational interviewing was more efficacious than a smartphone application at three months for increasing six-minute walking distance and reducing body weight in patients with peripheral artery disease (PAD).

Objective: To explore whether social determinants of health or sociodemographics might moderate the effects of the two interventions on walking distance and/or weight loss.

Methods: PAD patients were recruited through a convenience sampling of community-dwelling adults in Wichita, Kansas, who were screened for PAD. Participants in the study were randomly assigned to one of two interventions: motivational interviewing (MI) (n = 16) and the smartphone eHealth application (App) (n = 13). The six-minute walking distance change was the primary outcome, and weight loss was a secondary outcome. Five participant characteristics obtained from one survey, seven social determinants of health (SDOH) obtained from a separate patient SDOH screening tool, and adverse childhood experiences (ACEs) obtained from a third tool were all used to assess whether these SDOHs might moderate the intervention effects.

Results: Among MI participants, significant positive moderations of walking distance were observed for those not identifying as non-Hispanic White and those with high school or lower educational attainment. MI participants reporting no health insurance coverage experienced significantly greater weight loss than those with health insurance. Among App participants, those who reported at least one unmet need or concern about a need in the past 12 months had significantly greater walking improvements than those who did not report unmet needs or concerns about needs. Additionally, weight loss was greater among App participants who were either separated or not married.

Conclusions: MI might be more beneficial to PAD patients with lower educational attainment or of racial/ethnicity minority status or without health insurance, and the App might be more beneficial for PAD patients with unmet needs or who are not married or are separated. These results all point toward potentially amplified benefits for PAD patients of socially disadvantaged groups. Further research using larger and representative samples is needed to more conclusively identify and confirm social and demographic moderators of these interventions for PAD patients. Clinical Trial: ClinicalTrials.gov NCT03694652; https://clinicaltrials.gov/ct2/show/NCT03694652

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Benjamin N. Vickers[1], MS, PhD; Yiliang Zhu[2], MS, PhD; Tracie C. Collins[1], MS, MPH, MD
[1]College of Population Health, University of New Mexico, Albuquerque, NM, United States
[2]School of Medicine, University of New Mexico, Albuquerque, NM, United States

Corresponding Author:
Benjamin N. Vickers, MS, PhD
College of Population Health
University of New Mexico
MSC 09 5070
1 University of New Mexico
Albuquerque, NM 87131
United States
Phone: 1 505 272 4979
Email: BNVickers@salud.unm.edu

Abstract

Background: In a pilot randomized trial, face-to-face or telephone motivational interviewing was more efficacious than a smartphone application at three months for increasing six-minute walking distance and reducing body weight in patients with peripheral artery disease (PAD).
Objective: To explore whether social determinants of health or sociodemographics might moderate the effects of the two interventions on walking distance and/or weight loss.
Methods: PAD patients were recruited through a convenience sampling of community-dwelling adults in Wichita, Kansas, who were screened for PAD. Participants in the study were randomly assigned to one of two interventions: motivational interviewing (MI) (n = 16) and the smartphone eHealth application (App) (n = 13). The six-minute walking distance change was the primary outcome, and weight loss was a secondary outcome. Five participant characteristics obtained from one survey, seven social determinants of health (SDOH) obtained from a separate patient SDOH screening tool, and adverse childhood experiences (ACEs) obtained from a third tool were all used to assess whether these SDOHs might moderate the intervention effects.
Results: Among MI participants, significant positive moderations of walking distance were observed for those not identifying as non-Hispanic White and those with high school or lower educational attainment. MI participants reporting no health insurance coverage experienced significantly greater weight loss than those with health insurance. Among App participants, those who reported at least one unmet need or concern about a need in the past 12 months had significantly greater walking improvements than those who did not report unmet needs or concerns about needs. Additionally, weight loss was greater among App participants who were either separated or not married.

Conclusions: MI might be more beneficial to PAD patients with lower educational attainment or of racial/ethnicity minority status or without health insurance, and the App might be more beneficial for PAD patients with unmet needs or who are not married or are separated. These results all point toward potentially amplified benefits for PAD patients of socially disadvantaged groups. Further research using larger and representative samples is needed to more conclusively identify and confirm social and demographic moderators of these interventions for PAD patients.

Trial Registration: ClinicalTrials.gov NCT03694652; https://clinicaltrials.gov/ct2/show/NCT03694652

Keywords: peripheral artery disease; motivational interviewing; smartphone app; health disparities; social determinants of health; physical activity

Introduction

Peripheral artery disease (PAD) is a disabling illness that affects approximately 5% of adults in their late forties to 18% of adults in their late eighties in high-income nations [1]. PAD is estimated to affect more than 12 million Americans and 200 million people globally [2]. In the U.S., an estimated 19, 22, and 30 percent of non-Hispanic White, Hispanic, and non-Hispanic Black persons, respectively, will experience incident PAD in a lifespan that reaches 80 years [3]. Symptomatic PAD (objective evidence of PAD with exertional leg symptoms) has a profound impact on walking ability, including a reduction in walking distance, speed, and stair-climbing ability [4]. These outcomes, in turn, are predictive of a greater mortality risk [4]. Physical inactivity and obesity, common among U.S. adults, are significant risk factors for progression of PAD and its adverse outcomes [5]. Prior trials have demonstrated the efficacy of walking therapy in improving function in patients with symptomatic PAD [6,7]. To date, successful walking therapy interventions have largely been delivered through face-to-face and/or telephone counseling [8-11]. The widespread adoption of walking interventions has been hindered by their labor-intensive staffing requirements. The use of a smartphone app avoids this limitation by offering an accessible platform available to most Americans. Smartphone usage permeates all ages, cultures, and socioeconomic backgrounds.

Collins et al. [12] conducted a randomized trial among patients with peripheral artery disease (PAD) to assess the comparative efficacy of a novel smartphone eHealth app (App) versus a motivational interviewing (MI) technique for improving several outcomes at three months post-intervention. The details of the study, including the inclusion and exclusion criteria, participant recruitment, trial procedures, and descriptions of the interventions were reported in Collins et al [12]. The authors reported significantly greater improvements with MI compared to the App in the primary outcome (six-minute walking distance, $p = 0.03$) and in one secondary outcome (weight loss, $p = 0.01$). Although additional data on participant demographics and social determinants of health (SDOHs) were collected in this pilot study, an in-depth analysis of the potential moderation of

intervention effects by these factors was not previously conducted.

Therefore, this secondary analysis was undertaken to probe the potential moderation of the MI and App effects observed in the original pilot study by participant demographics and SDOHs. This was conducted with a primary aim toward exploring new hypotheses concerning any differential effectiveness of the App, and especially of the more efficacious MI. This effort should help guide future developments, enhancements, and applications of PAD interventions.

Methods

The current study was a secondary analysis of the randomized controlled trial (RCT) conducted by Collins et al [12].

ORIGINAL STUDY SETTING, SAMPLE, AND DESIGN. PAD patients were recruited by a convenience sampling of community-dwelling adults in Wichita, Kansas, who were screened for PAD. The study design was a non-stratified randomized controlled trial (RCT) with two intervention groups: the App served as the experimental intervention, and motivational interviewing (MI) served as the comparison group. The pilot RCT had an initial sample size (N = 29) that exceeded the estimated sample size (n = 26; 13 per group) to achieve 80 percent power to detect a greater than 50-meter difference in walking distance change between the two intervention groups. Without stratification at baseline, thirteen participants were randomly assigned to the App and 16 participants to MI. Four participants had been lost to follow-up by three-months post-intervention, two from each intervention group [12]. For detailed information describing the App and MI interventions administered, please see the original article [12].

POTENTIAL MODERATORS: SOCIAL DETERMINANTS OF HEALTH. "Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" [13]. SDOHs can be grouped into five domains: "Economic Stability, Education Access and

Quality, Health Care Access and Quality, Neighborhood and Built Environment, and Social and Community Context" [13]. We obtained five participant characteristic variables (see "***Participant Characteristics***" below) that are surrogates of SDOHs in association with the first domain (income), the second domain (educational attainment), and the fifth domain (gender, ethnicity/race, and marital status). The seven SDOHs (see "***PRAPARE Screening Tool***" below) from the Protocol for Responding to and Assessing Patient Assets, Risks, and Experiences (PRAPARE) [14] addressed three SDOH domains: economic stability, health care access and quality, and social and community context. One PRAPARE item addressed stress [14]. While SDOHs are social conditions that can impact health, a key pathway through which these conditions can adversely affect health is when they induce stress [15]. Therefore, stress was considered as a proxy of SDOHs.

Additionally, an adverse childhood experiences (ACEs) variable [16] (see "***Adverse Childhood Experiences***" below) was included as an SDOH. Similar to the ways that present-life stress associated with adverse social conditions can lead to undesirable health outcomes, adverse childhood experiences can be not only life-course stressors with both proximal impacts on health but also distal predictors and precursors of later-life stressors, contributing to outcomes like premature mortality and increased chronic disease risks [17].

Participant Characteristics. The Lifestyle and Clinical Survey [18] was used to collect participant characteristics; gender, ethnicity/race, marital status, educational attainment, and annual household income were examined as potential effect moderators. There were nine males and 20 females. Ethnicity/race included non-Hispanic White (n = 20) and a combined "other" category (n = 9). Marital status was classified as "currently married" (but not separated) (n = 9) and a combined category of separated or not currently married (including widows/widowers) (n = 20). Educational attainment included "college graduates or higher" (n = 10), "trade school or some college education" (n = 12), and "high school graduate or lower" (n = 7). Annual household income was dichotomized into "higher" (≥ $30,000) (n = 13) and "lower" (< $30,000) (n = 14).

Adverse Childhood Experiences (ACEs). The Adverse Childhood Experiences Questionnaire assesses the occurrence of potentially traumatic events from the first 18 years of life that might have a substantial impact on lifelong health [16]. Each of the 10 items in ACEs asks about childhood exposure to a specific kind of adverse experience (0: did not occur vs. 1: did occur). We used the total score of the ten ACEs items to define four ordinal categories: 3+ ACEs, 2 ACEs, 1 ACE, and none.

PRAPARE Screening Tool. The 21-item PRAPARE [14] was used to construct seven additional SDOHs derived from either single items or from combining similar items (see items 1-7 under PREPARE Screening Tool in the Tables). Item 1 was whether or not the participant had ever been discharged from military service. Item 2 was whether the participant lives alone or with any family members. Item 3 was whether or not the participant was currently employed. Item 4 was health insurance status in three categories: private insurance, Medicare or other public insurance, and none/ uninsured. For Item 5, several PRAPARE options for unmet needs or concerns about needs in the past year were combined into “any” versus “none.” These needs/concerns involved clothing, utilities, child care, medicine or healthcare, phone access, transportation, and “other.” Item 6 measured social support in two categories based on the frequency of the participant seeing or talking to people close to them: six or more times a week and five or fewer times a week. Last, Item 7 measured a participant’s stress at three levels: “not at all,” “a little bit”/“somewhat,” and “quite a bit”/“very much.”

STATISTICAL ANALYSIS. The analysis was focused on whether the overall effects of the two interventions on the outcomes of walking distance change and weight loss might be moderated by the SDOHs selected for this study (described above). Within each intervention group, we reported pseudomedians of baseline six-minute walking distance and body weight, both overall and within each stratum of each potential moderator. A “pseudomedian” in this study is a one-sample Hodges-Lehmann (HL) estimator, which is the median of the $n*(n+1)/2$ Walsh averages within a sample [19].

Walsh averages are the arithmetic means of all possible pairings of observations within a sample with *n* observations [19]. The pseudomedians of outcome changes (i.e., the intervention effects) at three months post-intervention, both overall and within the moderator strata, were also calculated.

Potential moderation effects were tested using 95% confidence intervals for the two-sample HL location shift [20] between pairwise moderator strata within each intervention group. For potential moderators with more than two strata, one stratum was designated as the reference group for the others. The HL location shift is the median of the *m***n* measures of difference between the *m* observations from one sample each uniquely paired with the *n* observations in the second sample [20].

Since an HL location shift requires a cross-sample paired-observation difference for the generation of every unit of analysis, and an HL pseudomedian involves only within-sample paired differences for each unit of analysis, the location shift between two samples should be similar to, but not necessarily the same, as the difference in pseudomedian between the two samples. Nonetheless, there are a few advantages to using these one-sample and two-sample HL estimators in this study. First, given the small sample size, the HL estimators are applicable for non-normal data distributions, which are common in small samples. Second, the HL estimators are designed to protect a small sample from the undue influence of outliers. Last, the observation pairing methods, both for one-sample and two-sample HL estimators, tend to add units of analysis to the sample, which boosts statistical power.

ETHICAL CONSIDERATIONS

"The University of Kansas Medical Center institutional review board approved this study, and participants gave informed consent. This clinical trial was registered at ClinicalTrials.gov [NCT03694652]" [12].

Results

PRIMARY OUTCOME – WALKING DISTANCE

Table 1 displays the baseline six-minute walking distance pseudomedians in meters by intervention, both overall and by strata of the potential moderators. Additionally, Table 1 shows the HL location shift between the interventions, with 95% confidence intervals, both overall and within moderator strata. A confidence interval that does not contain zero denotes a significant location shift or difference in central tendency in baseline walking distance between the intervention groups, either overall or within the given moderator stratum.

Table 1: Six-minute walking distances (pseudomedian[a] meters) at baseline by intervention group[a] and location shifts (L.S.)[b] between intervention groups by social determinants of health

Study Variable	MI (n=16)[a]	App (n=13)[a]	L.S. (95% C.I.)[b]
Overall Sample	264 meters	322 meters	***58 (2, 126)****
Sex			
Female (n=20)	252 (n=11)	319 (n=9)	***72 (2, 155)****
Male (n=9)	297 (n=5)	335 (n=4)	17 (-174, 200)
Ethnicity/Race			
Non-Hispanic White (n=20)	283 (n=11)	307 (n=9)	29 (-60, 137)
Other (n=9)	229 (n=5)	338 (n=4)	***99 (10, 217)****
Marital Status			
Married (not separated) (n=9)	254 (n=3)	323 (n=6)	58 (-157, 232)
Separated or not married (n=20)	264 (n=13)	317 (n=7)	51 (-18, 137)
Educational Attainment			
College graduate or higher (n=10)	282 (n=5)	352 (n=5)	***75 (4, 145)****
Trade school or some college (n=12)	261 (n=7)	274 (n=5)	-2 (-120, 198)
High school graduate or lower (n=7)	231 (n=4)	336 (n=3)	130 (-84, 232)
Annual Household Income (missing=2)			
≥ $30,000 (n=13)	267 (n=6)	362 (n=7)	44 (-15, 200)
< $30,000 (n=14)	244 (n=9)	291 (n=5)	64 (-30, 146)
Adverse Childhood Experiences (ACEs)			
Sum of ACEs			
3 or more ACEs (n=9)	180 (n=5)	333 (n=4)	156 (-30, 351)
2 ACEs (n=5)	339 (n=3)	360 (n=2)	20 (-17, 60)
1 ACE (n=8)	299 (n=5)	268 (n=3)	-50 (-161, 168)
No ACEs (n=7)	229 (n=3)	312 (n=4)	84 (-18, 156)
PRAPARE Screening Tool			
1. Discharged from Military Service (missing=1)			

Yes (n=4)	185 (n=2)	339 (n=2)	154 (-32, 339)
No (n=24)	262 (n=13)	314 (n=11)	51 (-17, 126)
2. Living with any Family Members			
Yes (n=12)	218 (n=7)	365 (n=5)	***136 (50, 244)****
No (n=17)	295 (n=9)	302 (n=8)	-2 (-83, 84)
3. Employed			
Yes (n=13)	330 (n=6)	360 (n=7)	28 (-35, 107)
No(n=16)	234 (n=10)	275 (n=6)	41 (-44, 155)
4. Health Insurance			
Private (n=8)	272 (n=3)	303 (n=5)	55 (-161, 232)
Medicare/other public (n=17)	245 (n=11)	316 (n=6)	64 (-23, 157)
None/uninsured (n=4)	307 (n=2)	339 (n=2)	32 (-2, 65)
5. Number of Unmet Needs/Concerns			
One or more (n=9)	310 (n=5)	323 (n=4)	12 (-174, 137)
None (n=20)	234 (n=11)	322 (n=9)	***82 (10, 166)****
6. Frequency of Seeing/Talking to People Close to You (missing=1)			
6+ times a week (n=14)	288 (n=9)	344 (n=5)	53 (-47, 137)
<6 times a week (n=14)	226 (n=7)	323 (n=7)	94 (-10, 198)
7. Stress (missing=1)			
Quite a bit or very much (n=6)	256 (n=5)	308 (n=1)	84 (-60, 128)
A little bit or somewhat (n=15)	244 (n=6)	352 (n=9)	92 (-4, 227)
Not at all (n=7)	292 (n=5)	291 (n=2)	-17 (-76, 84)

Notes: [a] MI= motivational interview, App = smartphone app; Hodges-Lehmann (HL) pseudomedians
[b] HL location shifts (L.S.; from MI to App) and their 95% confidence intervals (C.I.) reported
***** A significant location shift between intervention groups

At baseline, the App group had a slightly greater walking distance with a significant location shift of 58 meters. This result was driven by intervention group differences within females, the "other" ethnicity/race category, among those with college graduate or higher educational attainment, among those living with any family members, and among those reporting no unmet needs or concerns about needs in the past 12 months. These differences between the intervention groups were due exclusively to random assignment to the intervention groups. Also, these results were not independent but involved slight variations in the arrangement of the same participants according to the moderator response categories.

Table 2 displays the pseudomedian walking distance changes at three months post-intervention from baseline by intervention, both overall and within moderator strata. The examination of potential moderations of the intervention-specific effects occurred between moderator strata using HL location shifts with 95% confidence intervals.

Table 2: Changes in six-minute walking distances (pseudomedian[a] meters) by intervention group[a] from baseline to three-months post-intervention and location shifts (L.S.)[b] between strata of social determinants of health by intervention group

Study Variable	MI (n=14)[a]	L.S. (95% C.I.)[b]	App (n=11)[a]	L.S. (95% C.I.)[b]
Overall by Intervention‡	+41 meters		+8 meters	
Sex				
Female	+41 (n=9)	3 (-150, 46)	+7 (n=7)	-4 (-60, 33)
Male	+43 (n=5)	reference	+11 (n=4)	reference
Ethnicity/Race				
Non-Hispanic White (single race)	+17 (n=9)	***-44 (-169, -16)****	+11 (n=8)	21 (-39, 60)
Other	+66 (n=5)	ref.	-7 (n=3)	ref.
Marital Status				
Married (not separated)	+92 (n=2)	105 (-88, 298)	-2 (n=5)	-10 (-60, 34)
Separated or not married	+40 (n=12)	ref.	+10 (n=6)	ref.
Educational Attainment				
College graduate or higher	+49 (n=5)	***-91 (-172, -11)****	+8 (n=5)	-6 (-67, 82)
Trade school or some college	+8 (n=7)	***-146 (-298, -7)****	+3 (n=3)	-12 (-60, 69)
High school graduate or lower	+136 (n=2)	ref.	+7 (n=3)	ref.
Annual Household Income (missing=1)				
≥ $30,000	+35 (n=6)	-7 (-74, 140)	-1 (n=7)	-20 (-67, 15)
< $30,000	+47 (n=7)	ref.	+15 (n=4)	ref.
Adverse Childhood Experiences (ACEs)				
Sum of ACEs				
3 or more ACEs	+51 (n=5)	ref.	+16 (n=3)	ref.
2 ACEs	+32 (n=3)	-24 (-172, 140)	-2 (n=2)	-18 (-43, 6)
1 ACE	+23 (n=5)	-11 (-150, 148)	-2 (n=2)	-19 (-82, 44)
No ACEs	+39 (n=1)	-22 (-160, 137)	+5 (n=4)	-13 (-50, 15)
PRAPARE Screening Tool				
1. Discharged from Military Service (missing=1)				
Yes	+29 (n=2)	-13 (-172, 129)	+15 (n=2)	12 (-34, 67)
No	+41 (n=11)	ref.	+3 (n=9)	ref.
2. Living with any Family Members				
Yes	+56 (n=6)	38 (-8, 158)	+8 (n=5)	0 (-32, 53)
No	+19 (n=8)	ref.	+9 (n=6)	ref.
3. Employed				
Yes	+35 (n=6)	-6 (-66, 140)	+3 (n=6)	-10 (-60, 29)
No	+44 (n=8)	ref.	+14 (n=5)	ref.
4. Health Insurance				
Private	+80 (n=3)	ref.	-2 (n=4)	ref.
Medicare/other public	+30 (n=9)	-44 (-215, 85)	+8 (n=6)	11 (-46, 69)
None/uninsured	+52 (n=2)	-21 (-158, 88)	+15 (n=1)	17 (-32, 67)
5. Number of Unmet Needs/Concerns				
One or more	+32 (n=4)	-16 (-93, 57)	+31 (n=3)	***32 (2, 82)****
None	+47 (n=10)	ref.	-1 (n=8)	ref.
6. Frequency of Seeing/Talking to People Close to You (missing=1)				
6+ times a week	+49 (n=9)	21 (-138, 137)	+10 (n=5)	15 (-15, 65)
<6 times a week	+29 (n=5)	ref.	-5 (n=5)	ref.
7. Stress (missing=1)				

Quite a bit or very much	+45 (n=4)	4 (-156, 215)	N/A (n=0)	N/A
A little bit or somewhat	+48 (n=5)	20 (-66, 77)	+2 (n=8)	-3 (-65, 28)
Not at all	+35 (n=5)	ref.	+8 (n=2)	ref.

Notes: [a] MI= motivational interview, App = smartphone app; Hodges-Lehmann (HL) pseudomedians
[b] HL location shifts (L.S.; from reference to shown) and their 95% confidence intervals (C.I.) reported
‡ The MI group had a significantly greater walking distance change than the App group; Wilcoxon test (exact p=0.0333, rank-biserial correlation: 0.506)
***** Indicates a significant pairwise walking distance change location shift from the reference stratum to the shown stratum within an intervention group

Three significant moderations were observed in Table 2. First, among the MI group, the "other" ethnicity/race participants had a greater walking distance improvement compared to the non-Hispanic White participants. Second, the MI participants with high school graduate or lower educational attainment had greater walking increases compared to the higher educational attainment participants. Third, among the App group, participants reporting at least one unmet need or concern about needs had a walking increase location shift of 32 meters; App participants reporting no unmet needs nor concerns about needs in the past 12 months had no overall walking improvement with a one-meter pseudomedian decrease post-intervention.

A pattern emerged among the significant intervention moderations in Table 2. In all instances, regardless of the intervention, categories of participants commonly accepted as representing social disadvantages experienced greater post-intervention effects.

SECONDARY OUTCOME – BODY WEIGHT

Table 3 displays the baseline pseudomedian body weights (95% CIs) by intervention, both overall and within strata of the potential moderators. HL location shifts with 95% confidence intervals were used to assess for differences in baseline body weights between intervention groups, both overall and within moderator strata, due to random assignment. There were significant differences in baseline body weights between the two interventions for five variables. Body weights were greater at baseline in the MI group among participants with annual household incomes of $30,000 or greater, among those with prior military service, among those currently employed, among those with no health insurance, and among those reporting "quite a bit" or "very much" stress. As

with Table 1, these baseline results were not independent of one another but may involve some overlap based on variations in moderator response categories being applied to the same participants.

Table 3: Body weights (pseudomedian[a] Lbs.) at baseline by intervention group[a] and location shifts (L.S.)[b] between intervention groups by social determinants of health

Study Variable	MI (n=16)[a]	App (n=13)[a]	L.S. (95% C.I.)[b]
Overall Sample	238 Lbs.	216 Lbs.	-14 (-65, 24)
Sex			
Female (n=20)	250 (n=11)	208 (n=9)	-23 (-101, 21)
Male (n=9)	231 (n=5)	230 (n=4)	5 (-90, 210)
Ethnicity/Race			
Non-Hispanic White (single race) (n=20)	250 (n=11)	213 (n=9)	-28 (-87, 18)
Other (n=9)	219 (n=5)	224 (n=4)	14 (-166, 210)
Marital Status			
Married (not separated) (n=9)	242 (n=3)	232 (n=6)	3 (-107, 208)
Separated or not married (n=20)	244 (n=13)	206 (n=7)	-22 (-95, 18)
Educational Attainment			
College graduate or higher (n=10)	232 (n=5)	216 (n=5)	-13 (-73, 148)
Trade school or some college (n=12)	278 (n=7)	231 (n=5)	-57 (-135, 43)
High school graduate or lower (n=7)	187 (n=4)	195 (n=3)	-3 (-85, 55)
Annual Household Income (missing=2)			
≥ $30,000 (n=13)	285 (n=6)	209 (n=7)	***-71 (-134, -26)****
< $30,000 (n=14)	207 (n=9)	210 (n=5)	7 (-87, 56)
Adverse Childhood Experiences (ACEs)			
Sum of ACEs			
3 or more ACEs (n=9)	281 (n=5)	222 (n=4)	-71 (-166, 56)
2 ACEs (n=5)	263 (n=3)	189 (n=2)	-81 (-141, 7)
1 ACE (n=8)	216 (n=5)	210 (n=3)	-4 (-107, 118)
No ACEs (n=7)	198 (n=3)	223 (n=4)	33 (-30, 208)
PRAPARE Screening Tool			
1. Discharged from Military Service (missing=1)			
Yes (n=4)	310 (n=2)	220 (n=2)	***-90 (-143, -38)****
No (n=24)	224 (n=13)	217 (n=11)	-3 (-57, 34)
2. Living with any Family Members			
Yes (n=12)	264 (n=7)	225 (n=5)	-31 (-126, 38)
No (n=17)	229 (n=9)	205 (n=8)	-4 (-79, 43)
3. Employed			
Yes (n=13)	266 (n=6)	203 (n=7)	***-67 (-107, -7)****
No(n=16)	223 (n=10)	241 (n=6)	23 (-58, 111)
4. Health Insurance			
Private (n=8)	235 (n=3)	189 (n=5)	-51 (-85, 111)
Medicare/other public (n=17)	232 (n=11)	235 (n=6)	20 (-63, 71)
None/uninsured (n=4)	300 (n=2)	209 (n=2)	***-92 (-135, -48)****
5. Number of Unmet Needs/Concerns			
One or more (n=9)	221 (n=5)	204 (n=4)	-6 (-135,

55)			
None (n=20)	255 (n=11)	225 (n=9)	-15 (-79, 36)
6. Frequency of Seeing/Talking to People Close to You (missing=1)			
6+ times a week (n=14)	251 (n=9)	212 (n=5)	-41 (-113, 30)
<6 times a week (n=14)	227 (n=7)	234 (n=7)	-3 (-85, 101)
7. Stress (missing=1)			
Quite a bit or very much (n=6)	199 (n=5)	185 (n=1)	***-9 (-71, -3)****
A little bit or somewhat (n=15)	266 (n=6)	221 (n=9)	-37 (-133, 43)
Not at all (n=7)	258 (n=5)	235 (n=2)	-23 (-113, 88)

Notes: [a] MI= motivational interview, App = smartphone app; Hodges-Lehmann (HL) pseudomedians
[b] HL location shifts (L.S.; from MI to App) and their 95% confidence intervals (C.I.) reported
* A significant location shift between intervention groups

For weight change (Table 4), one significant moderation was observed for the MI group, and two significant moderations were observed for the App group. Among the MI participants, those reporting no health insurance experienced significantly greater weight loss than MI participants with health insurance. Among App participants, those who were separated or not married experienced weight loss. Overall, App participants who were married (not separated) did not experience weight loss. Although participants who reported two ACEs had the greatest weight loss among the App group, no ordinal trend was observed between the number of ACEs and weight loss, so this result is considered a random artifact of the sample. Despite Table 4 concerning a different outcome than Table 2, we observe in Table 4 a continuation of the pattern from Table 2. Regardless of the intervention under consideration, an amplified intervention effect was occasionally observed among PAD patients with socially vulnerable or disadvantaged positions.

Table 4: Body weight changes (pseudomedian[a] Lbs.) by intervention group[a] from baseline to three-months post-intervention and location shifts (L.S.)[b] between strata of social determinants of health by intervention group

Study Variable	**MI (n=14)[a]**	**L.S. (95% C.I.)[b]**	**App (n=11)[a]**	**L.S. (95% C.I.)[b]**
Overall by Intervention‡	-10 Lbs.		-2 Lbs.	
Sex				
Female	-10 (n=9)	0 (-20, 18)	-3 (n=7)	-2 (-5, 1)
Male	-10 (n=5)	reference	0 (n=4)	reference
Ethnicity/Race				
Non-Hispanic White (single race)	-9 (n=9)	2 (-17, 20)	-2 (n=8)	1 (-3, 4)
Other	-11 (n=5)	ref.	-2 (n=3)	ref.
Marital Status				
Married (not separated)	-8 (n=2)	3 (-34, 45)	0 (n=5)	***3 (0.00, 5)****

Separated or not married	-10 (n=12)	ref.	-3 (n=6)	ref.
Educational Attainment				
College graduate or higher	-13 (n=5)	2 (-15, 8)	-2 (n=5)	-2 (-5, 2)
Trade school or some college	-8 (n=7)	4 (-38, 34)	-3 (n=3)	-2 (-6, 2)
High school graduate or lower	-11 (n=2)	ref.	0 (n=3)	ref.
Annual Household Income (missing=1)				
≥ $30,000	-18 (n=6)	-15 (-40, 3)	-2 (n=7)	-1 (-5, 2)
< $30,000	-6 (n=7)	ref.	-1 (n=4)	ref.
Adverse Childhood Experiences (ACEs)				
Sum of ACEs				
3 or more ACEs	-7 (n=5)	ref.	-2 (n=3)	ref.
2 ACEs	-28 (n=3)	-24 (-72, 15)	-4 (n=2)	***-2 (-4, -0.40)****
1 ACE	-7 (n=5)	4 (-30, 17)	+1 (n=2)	2 (-0.40, 5)
No ACEs	-7 (n=1)	4 (-30, 17)	-2 (n=4)	0 (-3, 3)
PRAPARE Screening Tool				
1. Discharged from Military Service (missing=1)				
Yes	-1 (n=2)	21 (-30, 72)	-3 (n=2)	-1 (-5, 2)
No	-9 (n=11)	ref.	-2 (n=9)	ref.
2. Living with any Family Members				
Yes	-10 (n=6)	-1 (-15, 31)	-2 (n=5)	-1 (-4, 2)
No	-10 (n=8)	ref.	-2 (n=6)	ref.
3. Employed				
Yes	-11 (n=6)	-6 (-34, 14)	-2 (n=6)	-1 (-4, 3)
No	-8 (n=8)	ref.	-1 (n=5)	ref.
4. Health Insurance				
Private	-10 (n=3)	ref.	-2 (n=4)	ref.
Medicare/other public	-7 (n=9)	3 (-17, 34)	-2 (n=6)	0 (-5, 4)
None/uninsured	-33 (n=2)	***-24 (-42, -7)****	-2 (n=1)	0 (-3, 2)
5. Number of Unmet Needs/Concerns				
One or more	-10 (n=4)	-5 (-38, 15)	-1 (n=3)	1 (-3, 5)
None	-9 (n=10)	ref.	-2 (n=8)	ref.
6. Frequency of Seeing/Talking to People Close to You (missing=1)				
6+ times a week	-11 (n=9)	-8 (-34, 8)	-3 (n=5)	-2 (-4, 0.40)
<6 times a week	-4 (n=5)	ref.	-1 (n=5)	ref.
7. Stress (missing=1)				
Quite a bit or very much	-9 (n=4)	4 (-156, 215)	N/A (n=0)	N/A
A little bit or somewhat	-11 (n=5)	20 (-66, 77)	-2 (n=8)	-3 (-65, 28)
Not at all	-15 (n=5)	ref.	-2 (n=2)	ref.

Notes: [a] MI= motivational interview, App = smartphone app; Hodges-Lehmann (HL) pseudomedians [b] HL location shifts (L.S.; from reference to shown) and their 95% confidence intervals (C.I.) reported

‡ The MI group had a significantly greater weight loss than the App group; Wilcoxon test (t-approximated p=0.0107, rank-biserial correlation: -0.662)

* Indicates a significant pairwise body weight change location shift from the reference stratum to the shown stratum within an intervention group

Discussion

Despite a small final sample size of 25, Collins et al. [12] reported significantly greater improvements with MI compared to the smartphone App among PAD patients for the primary outcome of six-minute walking distance improvement and the secondary outcome of weight loss at three months post-intervention. The relatively large effect size differences between the two interventions contributed to the significant conclusions. Observed differences in baseline walking distances and body weights between participants randomly assigned to MI and the App were significant, suggesting that even with the random assignments, ensuring balanced samples across interventions was somewhat problematic, and this was a noteworthy aspect of the preliminary and formative nature of the results.

The fact that MI impacts on increasing walking distance were significantly greater among minorities (“other” ethnicity/race category) and among those with lower educational attainment (high school graduate or lower), as well as being greater among those with unmet needs or concerns about unmet needs among App participants, was possibly counterintuitive. For example, one might predict that the social capital associated with positions of social advantage would interact with interventions to possibly amplify intervention effects. Similarly, MI had a greater impact on weight loss among those with no health insurance, and the App had a greater impact on weight loss among those who were either separated or not married. Together, these potential moderating effects have generated a new hypothesis: PAD patients with socially disadvantaged statuses might benefit more from these interventions compared to PAD patients with greater social advantages. Given that baseline adverse health disparities tend to be more common among socially disadvantaged groups, the amplified benefits that were consistently toward socially disadvantaged groups should work toward reducing disparities post-intervention while simultaneously improving the health status of all PAD patients, especially among those receiving the more efficacious MI intervention.

As a pilot study with convenience sampling and a small sample size, the study findings have limited generalizability. Consequently, this supplemental analysis aimed only at exploring possible

intervention moderators among a list of SDOHs and did not enable any inferential conclusions. Based on these results, our recommendation is that future studies of the MI and App interventions for PAD patients investigate specific intervention effects for subgroups of patients as determined by SDOHs and socioeconomic factors.

In conclusion, this supplemental analysis of the Collins et al. [12] pilot RCT revealed potentially beneficial moderations of both MI and App effects for addressing health disparities related to positions of social disadvantage among patients with peripheral artery disease (PAD). Future research on the PAD interventions of motivational interviewing and smartphone apps should assess these and other potential moderations by social determinants of health.

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Conflicts of Interest

None declared.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

TC et al. [12] collected data. BV wrote the first draft of the manuscript and conducted the data analyses. YZ and TC provided advising for the data analyses. BV, YZ, and TC provided critical review and language for the final draft of the manuscript.

Abbreviations

ACE(s) – adverse childhood experience(s)
App – smartphone app (i.e., application)
C.I. – confidence interval
MI – motivational interviewing
PAD – peripheral artery disease
RCT – randomized controlled trial
SDOH(s) – social determinant(s) of health

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