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Original Article

# Assessment of clinical depression metrics in cardiac patients using the patient health Questionnaire-9 before and after phase-II cardiac rehabilitation

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ABSTRACT

Cardiovascular disease remains a leading cause of morbidity and mortality, a fact that is commonly associated with co-morbidities such as clinical depression. While phase II cardiac rehabilitation is an established intervention for those with cardiovascular disease, its effect on patients who also suffer from depression are under studied. Aim: To quantify Pre- and Post-cardiac rehabilitation questionnaire scores collected from a large patient data registry. For this investigation, 27 670 patients completed Patient Health Questionnaire-9 questionnaires both Pre- and Post-rehabilitation (averaging [28.0 ± 8.7] phase II sessions). Findings reveal that questionnaire scores decreased by 40%–48% across all groups, a finding that was independent of assigned sex, race, and ethnicity. Moreover, when data were stratified for questionnaire scores that may indicate major and minor depressive disorder, phase II cardiac rehabilitation outcomes were lower by 61% and 49% respectively. While all groups exhibited lower questionnaire scores following cardiac rehabilitation participation, numerical differences at Pre- and Post-rehabilitation time points indicate that males and White patients have more favorable scores. This latter observation, while not confirmed currently, appears to be linked to referral rates to phase II cardiac rehabilitation, which remain poor for females, racial and ethnic minorities.

## 1. Introduction

Cardiovascular disease (CVD) remains a leading cause of morbidity and mortality in industrialized nations.[1] Importantly, declines in psychological health, including depression, can accompany the acquisition of cardiovascular pathologies, an observation that likely contributes to CVD severity.[2–4] Independent of the disease etiology, depression is among the most common co-morbidities associated with a CVD diagnosis. Moreover, poor clinical outcomes are amplified by having both depression and CVD.[3] Based upon the clear links to CVD morbidity and mortality, in 2014 the American Heart Association (AHA) released a scientific position stand elevating depression as a risk factor for patients with acute coronary syndrome.[5]

In response to the co-morbid threat of CVD and depression, therapeutic exercise – including supervised phase II cardiac rehabilitation (CR) - is among the most potent treatments for those with newly diagnosed CVD.[6,7] Phase-II CR typically encompasses 18–36 sessions of supervised rehabilitative exercise, performed in an outpatient clinical setting, with patient sessions being monitored by trained professionals (e.g., clinical exercise physiologist, nurse, etc.). In addition to the exercise prescription, patient monitoring includes the recording of resting and exercise ECG, vital signs, and educational components such as risk factor monitoring and healthy dietary choices. Given this holistic approach to lifestyle medicine, recent attention has also been placed on the importance of improving patient mental health[8,9]; an emphasis that is important in all forms of chronic disease, including CVD.[10,11] Moreover, exercise is associated with improved depressive symptoms in persons with and without chronic conditions,[10,11] suggestive of the idea that CR is a faceted approach to treating co-morbid conditions such as CVD and depression. Indeed, recent randomized control trials comprehensively demonstrate that CR is an effective treatment against many psychological conditions, including depression.[12] Conversely, CVD patients with diagnosed clinical depression exhibit lower rates of exercise adherence, and are less likely to perform prescribed exercise in CR settings.[13,14]

Based on this understanding, identifying the approximately 40% of

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**Abbreviations:**

| | |
|---|---|
| AACVPR | American Association of Cardiovascular and Pulmonary Rehabilitation |
| AHA | American Heart Association |
| CABG | coronary artery bypass graft |
| CR | cardiac rehabilitation |
| CVD | cardiovascular disease |
| MI | myocardial infarction |
| PAD | peripheral artery disease |
| PCI | percutaneous coronary intervention |
| PHQ-9 | Patient Health Questionnaire-9 |
| Pre | Baseline values collected before cardiac rehabilitation |
| Post | Values collected at the conclusion of cardiac rehabilitation |
| TAVR | transthoracic aortic valve replacement |

CVD patients at risk for minor or major forms of clinical depression has become a recent clinical directive.[5,15] Given the time, financial, and personnel resource constraints typically placed on CR facilities, a rapid and cost-effective means of screening patients at risk for clinical depression remains essential. Candidate screening tools include the self-administered Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 is a nine-question, Likert-type survey that provides rapid insights for individuals at risk for minor or major depressive disorders.[16] Specifically, PHQ-9 scores above a threshold value ($> 4$) indicate patients with elevated risk for clinical depression. Specifically, scores $> 4$ associate with minor depressive disorder, while values $> 10$ associate with major depressive disorder, potentially targeting patients who would then be candidates for psychological intervention strategies.[16]

To date, the role of rehabilitative exercise on PHQ-9 scores is not well defined within the context of cardiac rehabilitation and serves as the impetus for the current clinical investigation. Moreover, the instances of depression appear to be unequally distributed across sexes, races, and ethnicities.[17] Accordingly, we examined the role of phase-II CR on PHQ-9 scores. We examined PHQ-9 scores from more than 27 000 patient records submitted to a data repository from CR programs across the U.S. Statistical analyses examined sex, race/ethnicity, and the severity of their PHQ-9 score at the start of CR and on values at the conclusion of rehabilitation.

## 2. Methods

### 2.1. Cardiac rehabilitation registry and patient data collection

Data for this manuscript were collected from a nationwide data registry, the Montana Outcomes Project, a data registry coordinated by the Cardiovascular Health Program housed within the Montana Department of Public Health and Human Services. The registry contains data from 118 programs throughout the United States, organized according to American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) regions. Submitted data provides benchmark data for participating programs (e.g., age, number of CR visits, diagnosis, exercise capacity, and metrics for various intervening facets such as depression). Importantly, participating programs submit data relevant to their patient approach. Prior to this investigation, a data use agreement was approved (January 13th, 2020) by the University of Montana Institutional Review Board of the corresponding author and the Montana Department of Health and Human Services, which issued an exemption letter for use of the anonymized rehabilitation registry data examined currently. Based on the nature of the data repository, accumulation of anonymized data, input into the system independent of their patient files (free of any identifiable information), informed consent was not obtained.

### 2.2. Patient data subclassifications

Patient characteristic and demographic data were recorded for assigned sex (based on patient self-identification to staff within participating CR programs), race (American Indian, Asian, Black, Other, and White) and Hispanic ethnicity. The primary referring diagnoses of diabetes, previously linked to instances of depression following a cardiac diagnosis,[18] and cardiovascular disease were recorded for patient characterization. Data used in the current investigation utilized records from patients that completed CR.

### 2.3. Patient health questionnaire-9 data collection

The PHQ-9 was completed before the start of ("Pre"), and at the completion of ("Post") CR. PHQ-9 questions pertain to patient perceptions stratified into 9 dimensions: interest/pleasure in doing things, feeling down/depressed/hopeless, sleep hygiene, perceptions of energy, appetite, feeling badly/notions of failure, the ability to concentrate, speed of movement/speaking, and thoughts of self-harm. Each of these dimensions were delivered within a 4-answer response scheme of, "Not at all" (0 points), "several days" (1 point), "More than half the days" (2 points), or "Nearly every day" (3 points).

Values from each dimension of the PHQ-9 questionnaire were summed to produce individual final scores for the Pre and Post rehabilitation timepoints. The lowest possible score was a 0 (i.e. 0 for all dimensions), while the highest possible score was 27 (i.e., 3 for all 9 dimensions). Data from Pre and Post time points were grouped for the total sample, in addition to distributions for sex, race, and ethnicity. Based upon AACVPR criteria outlined in the position document *Performance Measures for Improvement in Depression at Completion of Cardiac Rehabilitation,*[19] Pre and Post timepoint data were also stratified for scores above a PHQ-9 $> 4$ based upon the clinically established PHQ-9 threshold score of $> 4$ to indicate those with elevated risk for clinical intervention.[16] Of the scores which exceeded a PHQ-9 $\geq 4$, scores were stratified for the number of Pre and Post rehabilitation values between 5 and 9 (mild depression), 10–14 (moderate depression), 15–19 (moderately severe depression), and 20–27 (severe depression).[16] Score-stratified means were examined for sex (self-reporting as female or male), race, and ethnicity at the Pre and Post CR timepoints.[19]

### 2.4. Statistical analyses

Statistical tests were performed using SPSS (23.0) software and data are reported as means $\pm$ *SD*. Because the foundational approach of the study was to compare Pre- and Post-PHQ-9 relationships for sex, race, and ethnicity were examined using a Wilcoxon signed (paired) rank *t*-test. The Chronbach's $\alpha = 0.73$, indicating an acceptable internal consistency among the data. Effect sizes ranged from 0.5 to 0.53 for the various relationships examined. Statistical significance was determined when *p*-values exceeded the threshold of $\leq 0.05$, *a priori*.

## 3. Results

The dataset ran from January 2016–December 2019, with 123 sites submitting PHQ-9 data, and 120 sites meeting inclusion criteria (inclusion of demographic data for subsequent analyses). Patients that were discharged having completed 12–36 C R visits were included. Data were not collected after December 2019 due to the potentially confounding effects of the COVID-19 pandemic. Accordingly, 103 sites met these criteria and provided data throughout the investigative time window. Based upon these criteria, 27 670 patient records were examined between January 2016–December 2019. PHQ-9 scores ranged from 0 to 27 in both Pre and Post CR sampling time points.

Grouped characteristic data are presented in Table 1. The mean patient age was 68 years, and patients completed an average of 28.0 phase II CR sessions. Males ($n = 19\ 848$) represented 72% of the patient

**Table 1**
Participant characteristics.

| Participants ($n$) | 27 670 |
|---|---|
| | Mean ($SD$) |
| Phase II visits (days) | 28.0 ± 8.7 |
| Age (years) | 68.1 ± 10.7 |
| Sex | $n$ (%) |
| Female | 7 822 (28.3%) |
| Male | 19 848 (71.7%) |
| Race | $n$ (%) |
| American Indian | 249 (0.9%) |
| Asian | 291 (1.1%) |
| Black | 475 (1.7%) |
| Other | 536 (1.9%) |
| White | 26 119 (94.4%) |
| Ethnicity | $n$ (%) |
| Hispanic | 581 (2.1%) |
| Referring diagnosis | $n$ (%) |
| MI | 1 271 (4.6%) |
| MI/CABG | 1 196 (4.3%) |
| MI/PCI | 5 818 (21.0%) |
| CABG | 5 573 (20.1%) |
| PCI | 7 438 (26.9%) |
| Angina | 840 (3.0%) |
| Heart failure | 3 154 (11.4%) |
| Systolic | 2 104 (66.7%) |
| Diastolic/right side | 554 (17.6%) |
| Undocumented heart failure | 496 (15.7%) |
| Valve replacement/repair | 4 453 (16.1%) |
| PAD | 124 (0.4%) |
| TAVR | 367 (1.3%) |
| Other | 715 (2.6%) |
| With Diabetes | 8 183 (29.6%) |

Data are presented as $n$-values with percentages represented parenthetically (%); MI = myocardial infarction, CABG = coronary artery bypass graft, PCI = percutaneous coronary intervention, PAD = peripheral artery disease, TAVR = transthoracic aortic valve replacement.

records, and 94% were white ($n$ = 26 119). Of the records sampled, almost 30% ($n$ = 8 183) were diagnosed with diabetes. Of the referring cardiovascular diagnoses, most involved revascularization procedures (MI/PCI = 5 818, CABG = 5 573, PCI = 7 438) or valve replacement/repair ($n$ = 4 453).

### 3.1. PHQ-9 scores pre and post cardiac rehabilitation

Pre and Post PHQ-9 scores ranged from 0 to 27. The average Pre and Post rehabilitation PHQ-9 values are presented in Table 2. PHQ-9 values are presented for sex, race, and ethnicity. In addition, because PHQ-9 values which exceed 4 may require further clinical interventions for the treatment of depression,[16] Table 2 also reports the outcomes where PHQ-9 metric scores > 4 for sex distributions. For all patients, the average PHQ-9 response was 4.63 at the Pre-rehabilitation timepoint, while Post rehabilitation scores were 2.70 ($p < 0.001$). When PHQ-9 values were stratified for outcomes above a cumulative metric score of 4, it was observed for all patients that 40.1% of the responses were > 4 at the Pre rehabilitation timepoint (PHQ-9 = 8.85), while only 16.0% exceeded this threshold at the Post rehabilitation (PHQ-9 = 4.58) timepoint.

When PHQ-9 values were stratified for values > 4, females exhibited a 4.32-point decrease in the mean PHQ-9 score ($p < 0.001$), reflecting a 48% average improvement at the Post rehabilitation timepoint. Similarly, when outcomes were examined for male PHQ-9 scores > 4, a 4.25-point decrease in the mean value ($p < 0.001$) existed, reflecting a comparable 49% average improvement at the Post rehabilitation timepoint.

Mean PHQ-9 scores > 4 were quantified for race and ethnicity at the Pre and Post rehabilitation timepoints. For all five racial categories, and for those who were ethnically Hispanic, significant Pre-to-Post rehabilitation improvements in the average PHQ-9 score were observed ($p < 0.001$). The percent decrease in PHQ-9 scores was comparable between the six race/ethnic subgroups, with −44.4% decrease in Black patients, −44.8% decrease in Asian patients, a decrease of −46.8% in American Indian patients, a −48.3% decrease in Whites, to a −52.7% decrease in Other patients. Similarly, patients with Hispanic ethnicity showed an improvement of 46.7% in Pre to Post PHQ-9 average scores.

**Table 2**
Patient health questionnaire-9 values pre and post cardiac rehabilitation, with stratification for sex, race and ethnicity.

| Total sample | Pre | Post | $p$-value |
|---|---|---|---|
| All patients ($n$ = 27 670) | 4.6 ± 4.4 | 2.7 ± 3.4 | ***< 0.001*** |
| Patients with Pre PHQ-9 > 4.0 ($n$ = 11 104) | 8.9 ± 4.0 | 4.6 ± 4.1 | ***< 0.001*** |
| **Sex** | Pre | Post | $p$-value |
| Females with Pre PHQ-9 > 4.0 ($n$ = 3 651) | 9.1 ± 4.1 | 4.8 ± 4.1 | ***< 0.001*** |
| Males with Pre PHQ-9 > 4.0 ($n$ = 7 453) | 8.8 ± 3.9 | 4.5 ± 4.1 | ***< 0.001*** |
| **Race** | Pre | Post | $p$-value |
| American Indian with Pre PHQ-9 > 4.0 ($n$ = 92) | 9.6 ± 3.8 | 5.1 ± 4.7 | ***< 0.001*** |
| Asian with Pre PHQ-9 > 4.0 ($n$ = 115) | 9.2 ± 4.5 | 5.1 ± 5.3 | ***< 0.001*** |
| Black with Pre PHQ-9 > 4.0 ($n$ = 222) | 9.9 ± 4.6 | 5.5 ± 4.6 | ***< 0.001*** |
| Other with Pre PHQ-9 > 4.0 ($n$ = 232) | 9.3 ± 4.1 | 4.4 ± 4.3 | ***< 0.001*** |
| White with Pre PHQ-9 > 4.0 ($n$ = 10 443) | 8.8 ± 4.0 | 4.6 ± 4.1 | ***< 0.001*** |
| **Ethnicity** | Pre | Post | $p$-value |
| Hispanic with Pre PHQ-9 > 4.0 ($n$ = 234) | 9.5 ± 4.1 | 5.1 ± 4.6 | ***< 0.001*** |

Data are presented as means ± $SD$ and means with percentages relative to all patients. Pre values reflect baseline measures, while Post values reflect outcomes at the conclusion of cardiac rehabilitation. Wilcoxon signed rank tests were used to compare Pre and Post values. ***Bold/italicized*** $p$-values reflect a statistical difference between Pre and Post rehabilitation values.

### 3.2. Score stratification for PHQ-9 values 4

For Pre PHQ-9 scores that were greater than 4, we further stratified patient outcomes for metric values of increasing severity (Fig. 1). Within this data subset, Pre- and Post-rehabilitation PHQ-9 score severity increased inversely to patient frequency within those respective categories. From Pre-to Post-CR, 60% of patients were able to achieve a Post PHQ-9 score < 5. In addition, the percent reduction of patients in each of the PHQ-9 severity categories decreased from Pre to Post-CR: 57.7% in the mild depression category (5–9); −64.4% in moderate depression (10–14), −66.6% moderately severe depression (15–19) and −66.5% in severe depression (20–27).

Severity stratification of Pre and Post PHQ-9 scores that exceeded 4 are presented for sex in Fig. 2. For females, 46.6% ($n$ = 3 651) of Pre-rehabilitation PHQ-9 scores exceeded 4, while for males 37.5% ($n$ = 7 453) of scores exceeded this threshold value. Fig. 2A presents female and male distributions for PHQ-9 values > 4. Further stratification of PHQ-9 values revealed similar percentages for females and males within the 4 categorical break points: 5–9 (females = 65.8%, males = 68.7%), 10–14 (females = 22.8%, males = 22.0), 15–19 (females = 8.3%, males = 7.2%), 20–27 (females = 3.0%, males = 2.1%). The cohort of PHQ-9 scores from Fig. 2A are presented in Fig. 2B for the Post-rehabilitation period. Importantly, 58.6% of female scores, and 60.8% of male scores, were < 5 at the Post-rehabilitation measurement. Similarly, the percentage of severity categorization scores which remained > 4 were lower for both males and females at all 4 levels: 5–9 (females = 30.0%, −35.8% vs Pre-; males = 27.9%, −40.8% vs Pre-), 10–14 (females = 7.8%, −15% vs Pre-; males = 8.0%, −14% vs Pre-), 15–19 (females = 2.7%, −5.6 vs Pre-; males = 2.5%, −4.7% vs Pre-), 20–27 (females = 0.9%, −2.1% vs Pre-; males = 0.7%, −1.4% vs Pre-).

## 4. Discussion

Serious medical conditions are frequently associated with an elevated risk for clinical depression,[2] a finding that is potentiated for many

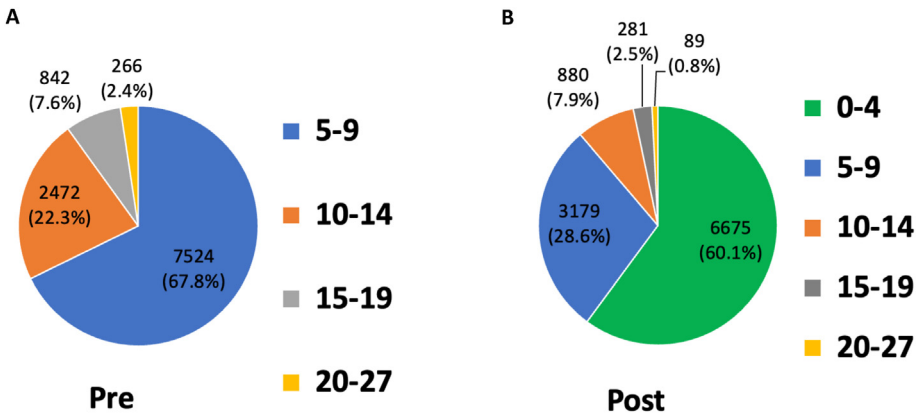


**Fig. 1. Pre- and Post-rehabilitation distributions of Patient Health Questionnaire-9 (PHQ-9) scores for baseline values > 4 for females and males.** Pre values reflect baseline measures, while Post values reflect outcomes at the conclusion of cardiac rehabilitation. A) Pre-rehabilitation PHQ-9 scores > 4 are distributed by for score severity, 5–9, 10–14, 15–19, and 20–27. B) Pre-rehabilitation scores > 4 are further distributed for PHQ-9 severity at the Post-rehabilitation time point, including values 0–4. As compared to Pre-rehabilitation scores, PHQ-9 severity score levels were improved in the Post-rehabilitation evaluation period. Importantly, at the Post-rehabilitation time point, the majority of patient scores were 0–4.

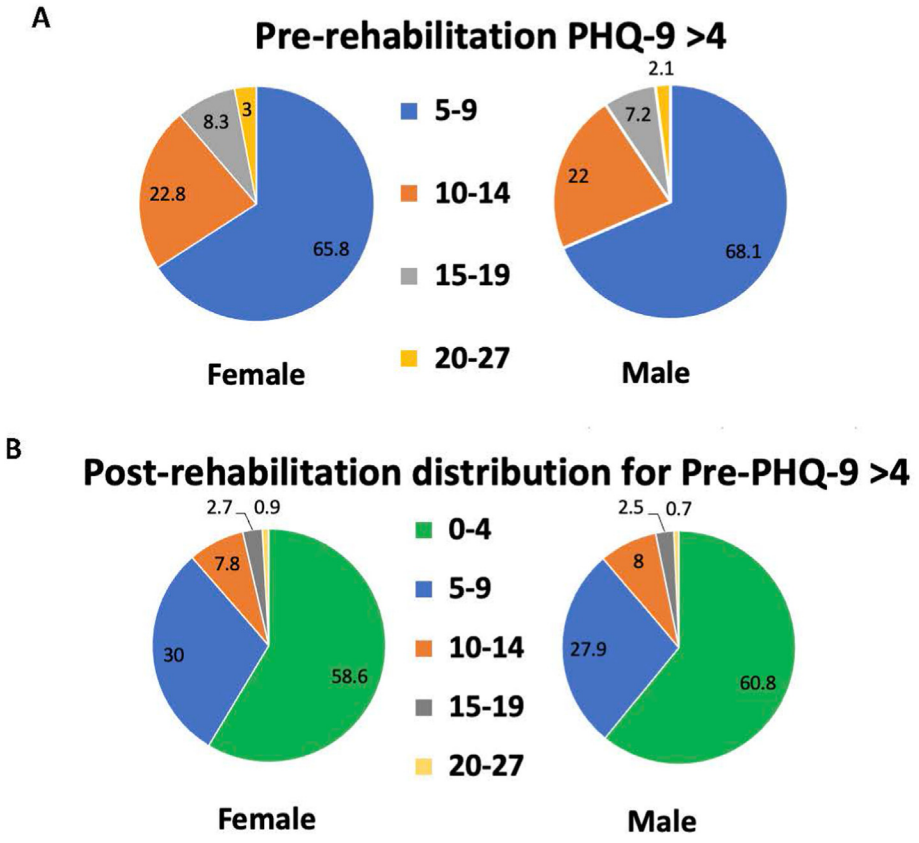


**Fig. 2. Pre- and Post-rehabilitation distributions of Patient Health Questionnaire-9 (PHQ-9) scores for baseline values > 4 for self-reporting females and males.** Pre values reflect baseline measures, while Post values reflect outcomes at the conclusion of cardiac rehabilitation. A) Pre-rehabilitation PHQ-9 scores > 4 are distributed by assigned sex for score severity, 5–9, 10–14, 15–19, and 20–27. B) Pre-rehabilitation scores > 4 are further distributed by sex for PHQ-9 severity at the Post-rehabilitation time point, including values 0–4. As compared to Pre-rehabilitation scores, all female and male PHQ-9 severity score levels were improved in the Post-rehabilitation evaluation period. Importantly, at the Post-rehabilitation time point, the majority of female and male scores were 0–4.

chronic diseases such as the major forms of CVD.[15] Moreover, it cannot be overlooked that declines in psychological health, including clinical depression, contribute to the advancement of CVD pathology.[3,4] In response to this understanding, early studies indicate that patients referred to CR are at elevated risk for depressive episodes, while participation in cardio-rehabilitative programming also benefits indices of clinical depression.[9–12] Extending upon this work, the key finding from this investigation of more than 27 000 patient records from a data repository in the U.S. that included PHQ-9 survey scores – an essential metric for rapidly identifying those at risk for clinical depression – were significantly lower following participation in phase-II CR. Unique to this investigation, the large sample size enabled broad investigation of Pre-to-Post-rehabilitation PHQ-9 scores, in addition to the novel opportunity to explore outcomes in traditionally underrepresented groups (e.g., comparisons by assigned sex, race, and Hispanic ethnicity).

Using a clinically established PHQ-9 threshold score of > 4 to indicate those with elevated risk for clinical intervention,[16] ~40.2% of our patients recorded scores that exceed a metric value of 4 at the start of their CR program. The percentage of patients exhibiting PHQ-9 threshold scores at the end of phase-II CR were lowered to 16% of the total patient sample. Similarly, application of a more rigorous threshold to inform when clinical interventions are warranted (PHQ-9 ≥ 10) for Major Depressive Disorder.[20,21] In this latter instance, the percentage of scores of ≥ 10 dropped from 12.9% Pre-rehabilitation to 4.5% at the Post-rehabilitation timepoint. These remarkable outcomes highlight the potential value of rehabilitative exercise on co-morbidities such as clinical depression, in addition to direct improvements to cardiovascular health and the prevention of disease recurrence. Given the clear benefits of phase II CR in mitigating the PHQ-9 scores of patients with a variety of cardiovascular and metabolic conditions,[22,23] it is unfortunate that the current investigation revealed the underrepresentation of females (28% of the patient sample), in addition to persons from various non-White

races (5.6% of the patient sample), and those of Hispanic ethnicity (2.1% of the patient sample). While outside the scope of this investigation, solely focused on PHQ-9 metrics of depression, these data reinforce prior observations of sex-, race-, and ethnic-based inequities when it comes to patient referrals and medical access to CR.[24]

### 4.1. Assigned sex

When normalized for the CVD diagnoses, clinical evidence indicates that the treatment offered to women and men are not equal.[25] Indeed, a recent landmark study indicated that patient-wide referral and adherence rates (e.g., 29% referrals, 8% completing 36 sessions) favored males 3:2 at the initiation of CR.[26] Disparities based on assigned sex, whether cause, effect, or some combination therein, extend to metrics of depression.[4] For instance, a recently conducted and comprehensive examination of patients with CVD revealed a clear delineation in the average PHQ-9 scores recorded by men and women with heart failure.[17] however the influence of rehabilitative exercise was not examined. Moreover, a recent investigation identified female cardiac patients as more likely than males to exhibit depressive symptoms, and less likely to experience improvements following intervention.[23] In the current study female patients exhibited comparable PHQ-9 values to males, albeit numerically lower in all instances. The reasons for these observed differences are currently unresolved, likely subject to numerous intervening factors, and should be the subject of future investigations.

Our investigation is the first to examine assigned sex-dependent PHQ-9 scoring before and after CR using a large database of program-submitted responses. While female PHQ-9 values dropped significantly at the Post-rehabilitation time point, when comparing mean values to male counterparts, female scores were + 28% Pre- and + 19% Post-rehabilitation. Similarly, when PHQ-9 values were stratified according to metric score severity and assigned sex, males had a lower proportion of cases at each of the 4 PHQ-9 scoring levels (5–9, 10–14, 15–19, and 20–27). Despite these differences, both assigned sexes exhibited comparable drops in Pre-to-Post values for PHQ-9 scores $< 4$ and $< 10$. Accordingly, the dramatic improvement in patients that moved below the respective thresholds for exploring a clinical intervention was similar for self-reporting females and males in the Post-rehabilitation period. Based on these marked improvements across both sexes, it seems plausible that more equitable referral policies would likely improve the existing disparities between female and male patients, although additional research is needed to confirm or refute this tentative conclusion.

### 4.2. Race/ethnicity

As with sex, people of certain racial and ethnic groups are more likely to suffer from significant psychological conditions, including clinical depression.[4] Moreover, prior investigations demonstrated that patients racially or ethnically classified as non-White were under represented in CR.[24,27] Indeed, the aforementioned landmark study found that white patients are referred at a rate of 2:1 as compared to non-white counterparts.[26] Collectively, these findings indicate that certain racial and ethnic groups are more likely to suffer from co-morbid CVD and psychological conditions, while less likely to receive adequate treatment. With respect to the current study, under representation for persons from American Indian, Asian, and Black racial categories, in addition to persons of Hispanic ethnicity, remains a problematic reality in outpatient CR settings. As was the case with female-to-male analyses, comparisons across race and ethnicity indicated that PHQ-9 scores improve between 37.7% and 59.1% across the races and ethnicities examined currently. This important finding emphasizes the fact that clinical depression impacts all individuals, and that the rehabilitative process is a potent intervention for mitigating the deleterious impacts of depression. Moreover, this finding provides indirect evidence for improving racial and ethnic equity in rehabilitative health care, at least as it applies to PHQ-9 outcomes. That is, our data suggest that strategies for improving referrals to phase II CR are likely to extend to instances of clinical depression, independent of an individuals' race or ethnicity. To this end, additional research is needed to better quantify the extent to which the salubrious effects of CR may, or may not extend to traditionally underrepresented racial and ethnic groups in the phase II setting.

### 4.3. Study limitations

A key limitation of the current investigation pertains to the non-diagnostic nature of the PHQ-9 screening tool. Indeed, while the PHQ-9 is not diagnostic in and of itself, it is often incorporated in the process of individual diagnoses in outpatient settings such as phase II CR. In addition, it must be acknowledged that the PHQ-9 metric improvements observed currently cannot distinguish between the independent effects of exercise as opposed to the psychosocial benefits of CR participation. Moreover, when used in large data sets, as is the case in the current investigation which examined more than 27 000 patient records, the PHQ-9 is highly predictive of clinical instances of clinical depression,[20,21] although recent systematic analyses suggest alternative assessment tools (e.g., Beck Depression Inventory-2, BDI-II) may exhibit even better validity in this patient population.[8] Accordingly, limitations inherent to the PHQ-9 as an incomplete metric of clinical depression are partially mitigated by the size of the current investigation. The current dataset utilized submitted records with both Pre and Post PHQ-9 values, and as such these findings should not be applied to patients that do not complete CR due to depression, or other limiting factors such as patients residing in urban versus rural area. Another important limitation which warrants additional study is the degree to which various races and ethnic groups (in addition to assigned sex) were represented. Similarly, limitations in the dataset granularity for certain health details prevented the examination of potentially important relationships between PHQ-9 scores and disease sub-groups (e.g., type 1 diabetic versus type II diabetic patients) and will require additional investigation. Finally, due to the anonymized nature of this dataset, it is possible that patients who receive multiple courses of CR (due to different diagnoses) are included more than once.

## 5. Conclusion

A prominent medical review recently summarized the links between psychological health and CVD, *"we are very good at treating disease, but often not as good at treating the person"*.[4] Indeed, psychological conditions such as depression can precede a diagnosis of CVD, only to be amplified post event.[2–4] The data presented in this investigation provide clear evidence that participation in phase II CR improves outcomes of depression, as indicated by the use of the PHQ-9 screening tool. Improvements in PHQ-9 scores, ranged from 37.7% to 59.1%, an overarching result that was independent of assigned sex, race, or ethnicity. Similarly, the number of patients with Pre-rehabilitation scores which exceeded the thresholds for both minor (PHQ-9 $> 4$) and major depressive disorder (PHQ-9 $> 10$) dropped by 24% and 8.4% respectively. Finally, while Post-CR PHQ-9 scores were lower independent of sex, race, and ethnicity, numerical differences between groups indicated that males and White patients exhibited more favorable scores both Pre- and Post-rehabilitation, a fact that appears to be linked to referral rates.[24,26] Accordingly, findings from this investigation strongly suggest that clinical depression as a co-morbidity of CVD could be addressed in all individuals by strategically improving CR referral rates to under-represented groups. Moreover, given the psychological spectrum of conditions related to this topic (e.g., anxiety, thoughts of suicide/self-harm, etc.), additional research is needed to better understand the faceted interactions of CVD and CR, on comprehensive psychological health.

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None to report.

## Submission statement

All authors have read and agree with manuscript content. This manuscript has not been published elsewhere, and is not under current review at an alternative journal.

## Ethical approval statement

Given the nature of the data registry, utilizing anonymized data input independent of patient files (excluding any patient identifiers), informed consent was not obtained for these data. However, data use agreements were obtained between the Montana Outcomes Project/the Montana Department of Health and Human Services prior to data upload to the registry. Separately, a data use agreement was obtained between the Montana Department of Health and Human Services and the University of Montana under the supervision and approval of the University of Montana Institutional Review Board.

## Authors' contributions

JCQ provided data interpretation, manuscript preparation, and editing. MM participated in study design, data interpretation, manuscript preparation, and editing. CO participated in study design, data analysis, data interpretation, manuscript preparation, and editing. CF participated in study design, data interpretation, manuscript preparation, and editing.

## Conflict of interest

JCQ is an Editorial Board Member for Sports Medicine and Health Science and was not involved in the editorial review or the decision to publish this article. Otherwise, there are no conflicts of interest to report.

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none to reportAll authors have read and approved the manuscript.

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