Evaluation of a Peer Coach-Led Intervention to Improve Pain Symptoms (ECLIPSE)

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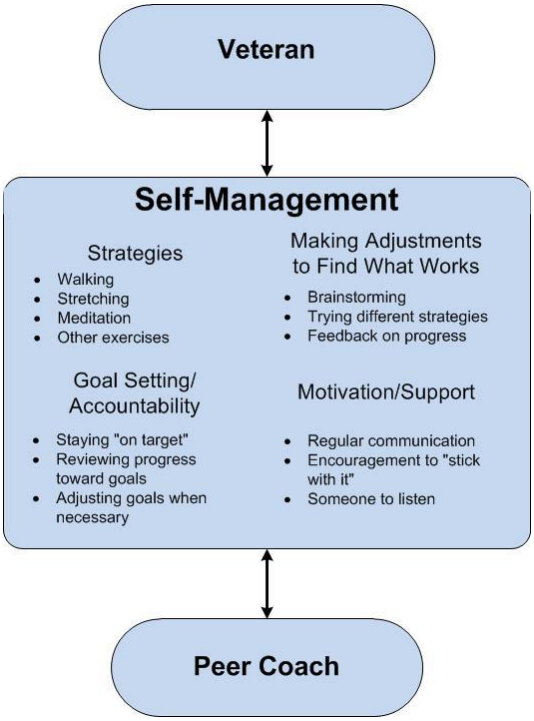
RESEARCH DESIGN AND METHODS

Conceptual Model

Our prior work, described above, informed the conceptual model guiding this study. Our work has consistently demonstrated that pain self-management requires not only the use of specific strategies, such as exercises and activity modification, but also help and support from another person, who serves a larger function beyond teaching strategies. In prior studies, a nurse care manager delivered a self-management curriculum and fulfilled different functions for patients, as the Figure depicts: 1) teaching self-management strategies; 2) finding "what works"; 3) goal setting and accountability to goals; and 4) providing motivation and support.[24,25] Importantly, the top half of this model outlines practical aspects of self-management: the strategies themselves and troubleshooting to find what works for each individual. The bottom half focuses on support, by helping Veterans to stay on target, motivated, and supported. This model closely parallels Dennis et al.'s[31] analysis of the elements of peer support, described in section B3.



Based on our work with Veterans with chronic pain, coupled with studies demonstrating effectiveness of peer support in other chronic conditions, the next step in our research is to explore the effectiveness of placing a peer coach in a role similar to that of the nurse care manager. Although a peer coach does not have a nurse's clinical training, the coach has successfully adopted self-management strategies, and shares many of the same experiences as other Veterans with pain. This unique position potentially places a Veteran peer coach in a stronger position to deliver motivation, support, and accountability—characteristics that Veterans in our prior studies tout as critical to effective self-management. Examining peer coaching for Veterans with chronic pain is a logical next step based on our prior research, and research in other conditions suggests a peer coaching model may be an effective intervention for Veterans with chronic pain, with high potential for implementation across VA.

Overview of Study Design

We will conduct a 2-arm randomized controlled trial with Veterans who have chronic musculoskeletal pain. The trial will compare a 6-month peer coaching self-management intervention with a control group consisting of a 2-hour class on pain and pain self-management. We will compare changes in pain between the two groups (Aim 1) and examine secondary outcomes: self-efficacy, pain coping, patient activation, social support, health-related quality of life, and health service utilization (Aim 2). The 2-arm design will allow for direct comparison between Veterans receiving information on self-management (control), versus receiving self-management information combined with the motivation and support delivered by a peer coach and described in our conceptual model.

In addition to testing the effectiveness of the intervention, we will assess facilitators and barriers to implementation through qualitative interviews with study participants (peer coaches and Veterans from the intervention arm) and PACT staff, where a peer support program would most likely be implemented. The study duration will be 4 years, to allow for peer coach and Veteran recruitment, peer coach training, completion of the 6-month intervention, assessment of outcomes at 6 and 9 months, and the pre-implementation interviews.

Study Sites

Roudebush VAMC (RVAMC) is an urban, university-affiliated tertiary care center which provides health care for more than 50,000 veterans and houses five primary care clinics. An RVAMC expansion clinic, Indy West Clinic, opened in 2010 and will also serve as a study site. RVAMC is the parent facility of three Community-Based Outpatient Clinics (CBOCS), in Terre Haute, Martinsville, and Bloomington, IN. These 9 clinics, which staff 75 primary care providers, will serve as study sites.

Recruitment and Training of Peer Coaches

Recruitment: We have three primary sources for recruiting peer coaches: 1) Veterans who served as peer coaches in IMPPRESS (7 out of 9 expressed interest in serving as a coach again); 2) Veterans who completed the intervention arm of one of our previous chronic pain studies involving pain self-management instruction (ESCAPE, PI: Bair; CAMEO, PI: Bair; SCOPE, PI: Kroenke). In these studies completers were asked for permission to be contacted for future studies. We successfully recruited 10 peer coaches for IMPPRESS in one month using this approach. From these two completed and one ongoing study we have a pool of approximately 250 potential peer coaches. 3) Veterans with chronic pain (see ICD-9 codes in Section D2c) who are recommended by their PCPs. Although we did not need this strategy in IMPPRESS because of successful recruitment of participants from prior studies, one of our co-investigators, Dr. Heisler, has successfully used this method for peer studies of Veterans with diabetes.

Manual: Each peer coach will be given a manual to refer to and serve as a guide during the intervention. The Peer Coach Manual consists of two parts: 1) Self-Management Knowledge (this portion is identical to the Veteran manual), and 2) How to be a Peer Coach. See Table 1. This manual was developed and refined in IMPPRESS, drawing on the study manual from Dr. Bair's ESCAPE trial (Part 1), and on the Peer Specialist Manual used by VHA's Office of Mental Health Services (Part 2, shared by Dan O'Brien-Mazza, Director of VA Peer Support Services, see letter of support). In addition, during IMPPRESS, our study psychologist, Dr. Kukla, developed a section on motivational strategies, grounded in the motivational interviewing literature. The peer coach manual is in Appendix 1.

Training: Three to 4 coach training sessions will be scheduled as coaches are recruited. Once 10 coaches are recruited, a training session will be scheduled, and coaches will be assigned Veterans. This process will continue until all peer coaches are recruited, trained, and matched with Veterans.

Peer coach training will consist of one 3-hour session taught by Carol Kempf, RN. Ms. Kempf has trained peer coaches for IMPPRESS and has delivered self-management instruction to Veterans with chronic pain in several prior studies conducted by Drs. Bair and Kroenke. Each training session will be audio recorded to ensure quality and consistency. Training will emphasize the elements of self-management and support highlighted in the conceptual model (Section D1): 1) self-management strategies/exercises, 2) making adjustments in strategies to find what works, 3) setting and providing accountability to goals, 4) motivating/supporting. Training will be didactic and participative. Particular focus will be on teaching and role-playing to help peer coaches work with their assigned Veterans to accomplish the four intervention

elements listed above. The direct-observation fidelity checklist will be used as a training tool during role-playing.

Table 1. Peer Coach Training	
Part 1: Self-Management Knowledge	**Part 2. "How to be a Peer Coach"**
Chronic Pain Basics	What is a Peer?
-Biopsychosocial Model	Cultural Competence
-Gate Control Theory of Pain	Communication Skills
Relaxation Skills	Managing Crisis and Emergency Situations
Activity Pacing	Motivational Strategies
Cognitive Behavioral Skills	
Self-Care Skills	
Interpersonal Skills	

Peer Coach Supervision: Ms. Kempf will be available on an ongoing basis for consultation with questions or problems. In addition, she will conduct 1) individual "check-in" calls with peer coaches, and 2) regular group supervision ("booster") sessions with peer coaches via conference call. "Check-in" calls will be with individual peer coaches primarily at the beginning of the intervention period to ensure that coaches are successfully making initial contact with their assigned Veterans, to help facilitate this contact when needed, and provide any other individual help or guidance needed. Ms. Kempf will also make individual calls throughout the intervention as needed. All calls will be logged (date/time, peer coach, brief summary, length of call, any other relevant information).

Group supervision ("booster") telephone sessions will be conducted by Ms. Kempf every 2 weeks for the first 2 months of the intervention period, after which time they will occur monthly. (Frequency of meetings can be adjusted if needed.) This was the schedule followed in IMPPRESS. These "booster" supervision sessions are relatively informal, involving discussion among peer coaches on how their calls/meetings with Veterans are going and providing follow-up tips on communication strategies and reinforcement. Many peer coaches in IMPPRESS found these booster sessions to be more helpful than the initial training, since they were able to discuss practical situations and problems as they arose. Booster sessions serve several key functions: 1) "Getting things going" at the beginning of the intervention when peer coaches and Veterans are making initial contact; 2) Reminding peer coaches to contact their Veterans regularly; 3) Troubleshooting issues or questions; 4) Providing additional training on the use of motivational strategies to address any difficulties with Veterans' goal attainment; 5) Providing motivation, encouragement, and reinforcement of their roles as peer coaches; and 6) Serving as a tool to check and maintain intervention fidelity.[46-48] An added benefit of these regular calls in IMPPRESS was the peer coaches developed a sense of camaraderie and community among themselves as they shared stories of their experiences in the study. This culminated with a pizza party for the coaches at the end of the intervention period. Because these sessions involve multiple study participants, coaches are instructed not to use participant names when talking about their assigned partners, to protect participants' private health information. Ms. Kempf will keep detailed field notes documenting the content and duration of these calls, as we did in IMPPRESS.

Recruitment of Veterans

Our Center's Data Management Group will run a query in CPRS (Computerized Patient Record System) to identify potentially eligible patients, who will be recruited from 9 clinics: Roudebush VAMC's 5 primary care clinics, the Indy West Clinic, and the 3 Community-Based Outpatient Clinics (CBOCs) at Bloomington, Martinsville, and Terre Haute. Veterans with musculoskeletal pain (ICD-9 codes 715, 719, 721, 722, 723, 724, 726, 729.0, 729.1, 729.3, 729.5, 738.4, 738.5) will be identified. Primary care providers (PCPs) will be contacted to gain permission to recruit their patients. We have successfully used this recruitment method in

several past studies, with over 90% of PCPs agreeing to allow access to their patients. For IMPPRESS, we successfully recruited 20 patients in 6 weeks using this method, after needing permission from only 2 PCPs to achieve our recruitment goal. Based on this experience, we anticipate little difficulty recruiting from multiple PCPs' panels across 9 clinics.

Inclusion/Exclusion Criteria: Once potentially eligible Veterans are identified and PCPs have granted permission to recruit, we will contact Veterans to identify those who meet study inclusion/exclusion criteria. Potential participants will be told that we are conducting a study to learn how Veterans can help other Veterans with chronic pain management, and that they will be randomly assigned either to the Veteran peer coach group or to the group receiving a pain self-management class. Eligible patients must 1) have musculoskeletal pain in the low back, cervical spine, or extremities (hip, knee, or shoulder) for ≥3 months; 2) have at least moderate pain severity, defined by pain ≥ 5 on a 0 (no pain) to 10 (worst pain imaginable) scale; and 3) indicate willingness to engage in phone or in-person contact on a regular basis with another Veteran. We have identified approximately 26,000 unique outpatients who meet criteria 1 and 2. Patients will be excluded if the electronic medical record indicates a diagnosis of a psychotic disorder (e.g., ICD-9 codes 295-295.9 for schizophrenia), current substance dependence (e.g., ICD-9 codes 304-304.9), severe medical conditions precluding participation (e.g., NY Heart Association Class III or IV heart failure, ICD-9 codes 428-428.9), or if the eligibility screener given to prospective participants reveals active suicidal ideation, severe hearing or speech impairment, or pending surgery for a musculoskeletal condition (e.g., back surgery).

Control Arm

Veterans will be randomized to either the peer coaching arm or a control group consisting of a 2-hour class in pain "basics" and pain self-management. In this class, topics listed in Part 1 (Self-Management Knowledge) of Table 1 will be reviewed (e.g., chronic pain basics, relaxation skills, activity pacing), and Veterans will be given a set of pamphlets related to pain self-management. Ms. Kempf will lead the control group class; she has taught similar classes in other studies. Control participants will complete baseline assessments just prior to the class, to help encourage class attendance. (They receive compensation for assessments, see D3). We estimate offering one class per month during the study, with more offered as needed during heavier recruitment periods. To maximize attendance, some classes will be offered in the evening.

Peer Coach-Veteran Sessions

Method of Contact: Participants will choose whether they want to meet in person or have telephone contacts (or a combination). In IMPPRESS, most chose to have subsequent meetings over the phone for convenience. Prior peer mentoring studies with Veterans have used a mix of in-person and telephone contacts and have had positive results.[11,49]

Frequency of Contacts/Meetings: Peer coaches will be asked to contact/meet with Veterans a minimum of two times per month via telephone or in-person. Ms. Kempf, in her booster sessions and individual calls with coaches, will monitor and help to encourage contacts at this interval.

Manual: Veterans will be given a manual identical to Section 1 of the peer coaches' manual (i.e., without the section on being a peer coach). (See Table 1, Column 1)

Content of Contacts: As we have learned from our other pain self-management studies and IMPPRESS, the content of each meeting is variable depending on a Veteran's particular needs.[23-25] However, regardless of specific content (i.e., the specific self-management

strategies discussed), coaches will be asked to 1) review self-management strategies/exercises (based on manual, See Table 1, Column 1), 2) help the Veteran to make adjustments if strategies are not working, 3) help the Veteran to set, follow up on, and be accountable to goals, 4) and motivate and listen to the Veteran. As part of this motivation, coaches will be encouraged to discuss their personal experiences with pain self-management and how they overcame obstacles or handled setbacks and frustrations, and to feel free to engage in conversation that is social in nature if comfortable and appropriate for the situation. Coaches will not advise on medications or medical questions, but will recommend Veterans see their physicians.

Record of Contacts: Peer coaches will be asked to log their sessions with each Veteran, including, date, length, format (phone, in-person), brief notes on content, and any other pertinent information, to allow us to track number and content of contacts. Study staff will maintain regular contact with the peer coaches to ensure logs are being completed, to facilitate collection of logs, and to offer feedback (i.e., if details are missing, or if the peer coach is doing an exceptional job with logs). Logs are simple, straightforward, and typically take less than 5 minutes to complete.

Optimizing Intervention Fidelity: We will employ the following facilitation strategies to optimize fidelity to the intervention: 1) a detailed intervention manual; 2) peer coach training; 3) regular peer coach booster sessions; 4) observer-rated fidelity assessment with feedback to coaches during intervention (which reinforces the importance of protocol adherence and provides constructive feedback to maintain strengths and identify areas for improvement).[50,51]

Data Collection Protocol for Primary and Secondary Measures (Aims 1 and 2)

Assessments will be given at baseline, 6 and 9 months. Participants (intervention and control) will receive $30 per assessment. We will administer the same measures to peer coaches and Veterans, because research suggests peer coaches also benefit from peer interventions. Moreover, we want to determine whether the peers experience any negative effects related to their participation.[52]

After obtaining informed consent, a research assistant will administer a baseline assessment to gather socio-demographic data, review the Veteran's history with an emphasis on previous and current pain treatments, and administer measures of primary and secondary outcomes. These assessments will take approximately 30 minutes each.

Aim 1 (Primary Outcome): To compare 6- and 9-month effects of peer-supported chronic pain self-management versus controls on overall pain. Overall pain will be measured with the Brief Pain Inventory (BPI) total score. The BPI was developed to assess the severity of pain and the impact of pain on daily functioning, and has been validated in primary care studies.[6,53] The BPI is the average of two scores: pain intensity and pain interference. The pain intensity score is an average of 4 ratings of 0 (no pain) to 10 (pain as bad as you can imagine) for current, least, worst, and average pain in the past week. The BPI pain interference score averages seven ratings, 0 (does not interfere) to 10 (interferes completely), of interference with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. The BPI total score will be used as the primary outcome measure because BPI total has been shown to be highly responsive to change in clinical trials.[54,55] The BPI has been shown to have strong internal consistency in its original validation study (Cronbach's α = 0.77),[53] the SCAMP study (α = .83),[6] and IMPPRESS (α = .88); and the BPI assesses the two most important domains—severity and interference—recommended for pain studies.[56]

Aim 2 (Secondary Outcome Measures): To compare 6- and 9-month effects of peer-supported chronic pain self-management versus controls on self-efficacy, pain coping,

patient activation, social support, health-related quality of life, and health service utilization. We will measure self-efficacy with the Arthritis Self-Efficacy Scale,[57] a 6-item measure that our team has used in prior studies.[5,58] Patients respond to each item with their degree of certainty on a scale ranging from 1 (very uncertain) to 10 (very certain). In the SCAMP study (with primary care patients, including 40% Veterans, with pain and depression), this scale had high internal consistency (Cronbach's α=.88).[58]

Pain coping will be measured with the Pain Catastrophizing Scale, a 13-item scale that assesses catastrophizing—a pain belief that has been found to be a strong predictor of poor treatment response. Validation studies have found strong evidence of criterion-related, concurrent, and discriminant validity.[59] In IMPPRESS this scale had high internal consistency (Cronbach's α=.95).

Patient activation will be measured with the Patient Activation Measure (PAM) Short Form, a 13-item scale that assesses patient knowledge, skill, and confidence for self-management of one's chronic health condition.[60] The PAM has been demonstrated reliable and valid in a variety of studies, including IMPPRESS and other work by our team, with reliability ranging from α =.87-.88.[13,34,60,61]

Social support will be assessed through the Multidimensional Scale of Perceived Social Support. The MSPSS includes 12, 7-point Likert scale items. The test-retest reliability and internal consistency is high, ranging from α=.84-.95 across a variety of studies, including IMPPRESS.[62,63]

Health-related quality of life will be measured with the RAND SF-36, developed as part of the Medical Outcomes Study. [64]

Health care utilization will be assessed using procedures similar to those we have used in prior studies.[6] Our Data Management group will run CPRS queries for each participant over the 9-month intervention period to identify the following: outpatient visits, ED visits, phone visits, non-opioid and opioid analgesic prescriptions.

Other Measures

1) Sociodemographics: age, sex, race, education, marital and job status, income
2) Pain Treatment History questionnaire (includes current therapy for pain)

Because depression, anxiety, and pain are common comorbid conditions,[68,69] we will also administer the following measures:

3) Depression: PHQ-8[70]; 4) Anxiety: GAD-7[71]

Data Analysis

Sample Size Determination. Our sample size is calculated based on estimated intervention effect on the primary outcome, the Brief Pain Inventory (BPI) total score, a continuous measure. Effect sizes for the BPI in past studies by our team have ranged from .4 to .6. Because this is our first large-scale trial with peer coaches, we will conservatively power the study based on an effect size of .4. To test for a significant difference between the BPI change from baseline to the primary 6-month endpoint between the treatment and control arm, will use a linear mixed model.[72] With a two-sided test and a Type I error of .05, we will have 80% power to detect a .4 effect size with 102 Veterans and 34 peer coaches in the treatment group and 80 Veterans in the control arm, assuming equal variance across the two treatment arms, 3 Veterans per peer coach, and an intra-class correlation (ICC) in the treatment group of .3, which was observed in IMPRESS.[73] (A smaller N is required in the control group because they are not nested within peer coaches.) In our prior chronic pain trials at RVAMC, retention rates were >90%. With a conservative 15% attrition rate, we will need 120 (102/.85) Veterans in the treatment arm, 40

coaches, and 95 (80/.85) Veterans in the control arm, for a total N = 215 Veterans and N = 40 coaches. We plan an intent-to-treat analysis approach.

Consistent with previous studies at RVAMC, the sample will include at least 15% minorities, reflecting the demographics of our medical center. In our SCAMP study, Blacks comprised 16% of the Veteran sample and 13% in ESCAPE. We do not plan to over-sample minorities or power sufficiently to explore racial differences in treatment response. The racial/ethnic composition of RVAMC and participating CBOCs makes exploring racial differences in treatment response impractical unless we employed special efforts to recruit minorities other than Blacks.

Randomization. Veterans will be randomly assigned to one of the two study arms using a table of random numbers generated by our statistician, Dr. Daggy. To obtain the random treatment assignment for the 215 Veterans, five blocks of 43 Veterans will be used, and random treatment allocation will occur within each block to maintain the allocation ratio consistently across blocks. This block size is large enough to prevent investigators and research staff from guessing which treatment comes next in the sequence, while still allowing the allocation ratio to remain consistent.

Data Analysis: Baseline Comparability. Because of the size of this study, it is expected that randomization will produce treatment groups that are comparable and balanced. To test this assumption, we will tabulate baseline characteristics of participants and assess for potential imbalance in variables such as sociodemographics, depression, and anxiety across study arms. Additionally, descriptive statistics for baseline characteristics of peer coaches will be assessed (e.g., treatment history, including opioid use). Continuous variables will be assessed with graphical displays and summary statistics (means, standard deviation, range, etc.). Frequency distributions and percentages will be calculated for categorical data.

Data Analysis for Aim 1. We will summarize total BPI score at each time point (baseline, 6, and 9 months) for both study arms. To compare the primary outcome of total BPI score at each time point relative to baseline between two treatment arms, we will use a linear mixed-effects model fit to all time points. This model will allow us to compare the change in BPI from baseline to 6 months (primary endpoint) between treatment groups, while accounting for the correlation of measurements from the same Veteran/peer coach and adjusting for confounding factors. Fixed effects in the model will include an indicator for treatment group, time (baseline, 6, and 9 months.), treatment group by time interaction, and covariates found to differ significantly between treatment and control arm. Random effects will include a random patient-specific intercept and a random effect for peer coach within the treatment arm only. Additionally, the variance may be allowed to differ between treatment and control arms. Because this is a randomized trial design we do not expect covariates to significantly differ between the two groups. However, if there are statistically significant differences, these covariates will be included in the model. The linear mixed model for subject i in therapy group j at time k is

$$y_{ijk} = \beta_{10} + b_i + x_{ijk}'\beta + \gamma_{11}t_{ij1} + \gamma_{12}t_{ij2} + (1 - I_{ijk})r_{ijk} + (\beta_{20} + b_i + \gamma_{21}t_{ij1} + \gamma_{22}t_{ij2} + u_j + e_{ijk})I_{ijk}$$

where I_{ijk} is an indicator if patient is assigned to the treatment group, x_{ijk} is a vector of fixed covariates, t_{ij1} is an indicator for the 6-month time point, t_{ij2} is the indicator for the 9-month time point, $b_i \sim N(0, \varepsilon^2)$ are patient-specific intercepts, $\mu_j \sim N(0, \sigma_j^2)$ is the random effect due to peer coach j, $e_{ijk} \sim N(0, \sigma_T^2)$ and $r_{ijk} \sim N(0, \sigma_C^2)$ are the residual errors for each treatment group. All analyses will include checking of assumptions and model fit. Our statistical model, which accounts for nesting of Veterans within peer coaches, will allow us to calculate the intra-class

correlation (ICC) in the treatment group to evaluate whether there are substantial variations among peer coaches. In secondary analyses, we will also look at the BPI subscales of pain intensity and interference separately, using a similar mixed-model approach and adjusting for multiple comparisons using the Šidák method to maintain the overall confidence at 95% and to adjust for multiple comparisons. To determine if fidelity moderates patient outcomes, we will include the peer coach fidelity score by treatment group interaction and the interaction (fidelity score by time by treatment group) for the 9-month time point in the model above.

Data Analysis for Aim 2. Secondary measures of self-efficacy, pain coping, patient activation, social support, and health-related quality of life are continuous measures; thus the linear mixed-effects model described above will also be appropriate to analyze these measures. If a linear mixed model does not seem appropriate for a given scale, then a generalized linear mixed-effects model will be used. Since there will be a number of secondary outcomes, we will use the Šidák method. Health care utilization (number of ED visits, hospitalizations, outpatient visits, telephone visits, and analgesic prescriptions, including opioids) over the 9-month intervention will be analyzed using a generalized linear mixed model, assuming the counts follow a Poisson or negative binomial distribution. Explanatory variables in the model will include treatment indicator and, if necessary, a random effect for peer coach within the treatment group only. Covariates that significantly differ between groups will be included. If counts include a high proportion of zeros, a zero-inflated count model may be required.[74]

Missing Data. We conservatively anticipate 10-15% attrition based on our prior studies, which had attrition rates <10%. Attrition is reflected in the sample size calculation. We will compare patient demographic characteristics between those who withdraw and those who do not to verify whether there are characteristics that discriminate dropouts. If the dropout mechanism appears to be Missing At Random,[75] we will simply use all observed outcomes for the analysis. Under circumstances where power loss is of concern, we will use multiple imputation procedures to make use of all relevant observed variables. If data are found to be Missing Not At Random (MNAR), we will use appropriate models (i.e., selection models,[76] pattern mixture models[77]) to account for the missing data mechanism.

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