Improving Veteran Access to Integrated Management of Low Back Pain

AIM-Back



July 31, 2026

NIH Pragmatic Trials Collaboratory Grand Round

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S. Nicole Hastings, MD, MHS

Team



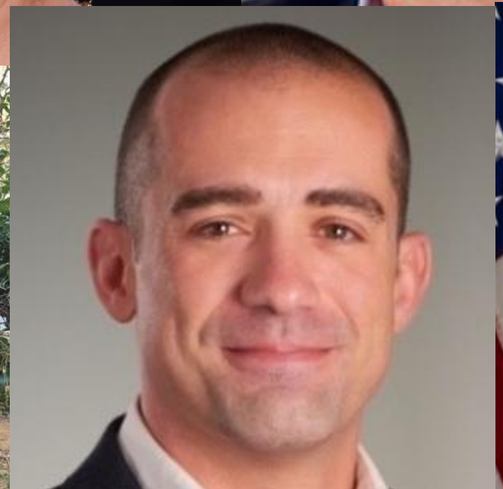















Outline

Goal

- Present overview of the AIM-Back study, share results, and some lessons learned

Review Study Design and Aims

Results

- Enrollment table / Baseline characteristics
- Participant Prevalent Ratio
- Primary outcomes – PROMIS pain interference and physical function
  - Primary and secondary analysis
  - Sensitivity analysis – using all time points
  - Subgroup analysis – High Impact Chronic Pain and Opioid Use

Next steps/ Questions

Background

- Globally, low back pain (LBP) continues to be a leading cause of disability, work loss, and reduced quality of life.
- Veterans, in particular, have higher pain severity of LBP and higher rates of high impact chronic in comparison to non-Veteran populations
- Non-drug treatment options are advocated for in clinical practice guidelines
- Evidence supporting the effectiveness of different delivery methods in real world settings is sorely lacking

- Collectively, these factors motivated the AIM-Back trial

Pathway Descriptions

AIM-Back

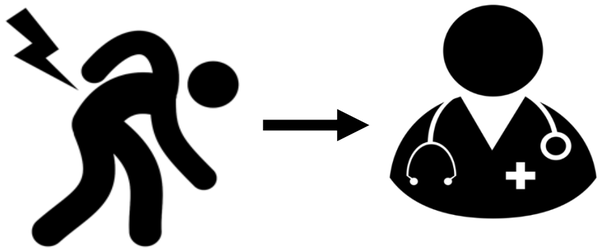
AIM-Back is a 2-armed multisite cluster randomized pragmatic trial focused on increasing access to non-pharmacologic treatment to low back pain (LBP)

1) Sequenced Care Pathway: This pathway provides on site physical therapy to Veterans who are enrolled who then receive telehealth physical activity (PA) training and psychologically-informed practice (PiP) delivered by a central provider

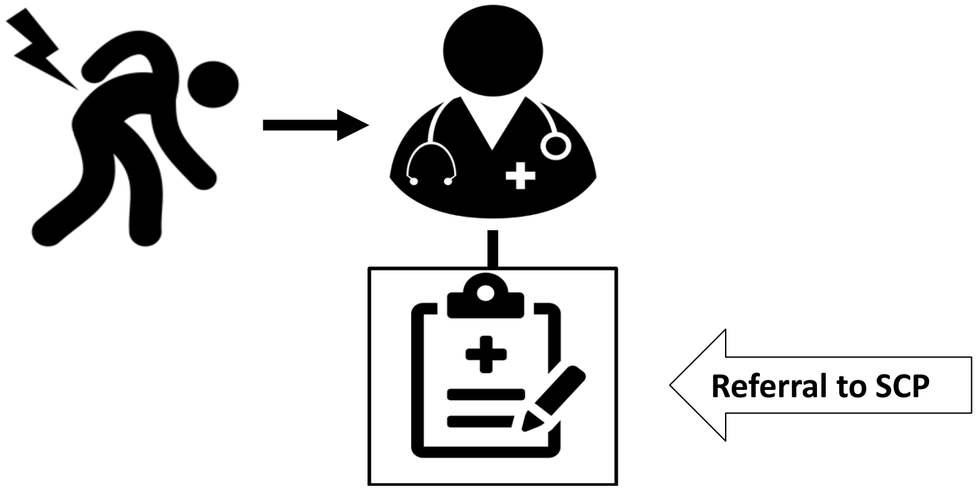
2) Pain Navigator Pathway: A “navigator” in the VA provides practical support with treatment decision-making and scheduling.

Sequenced Care Pathway

AIM-Back

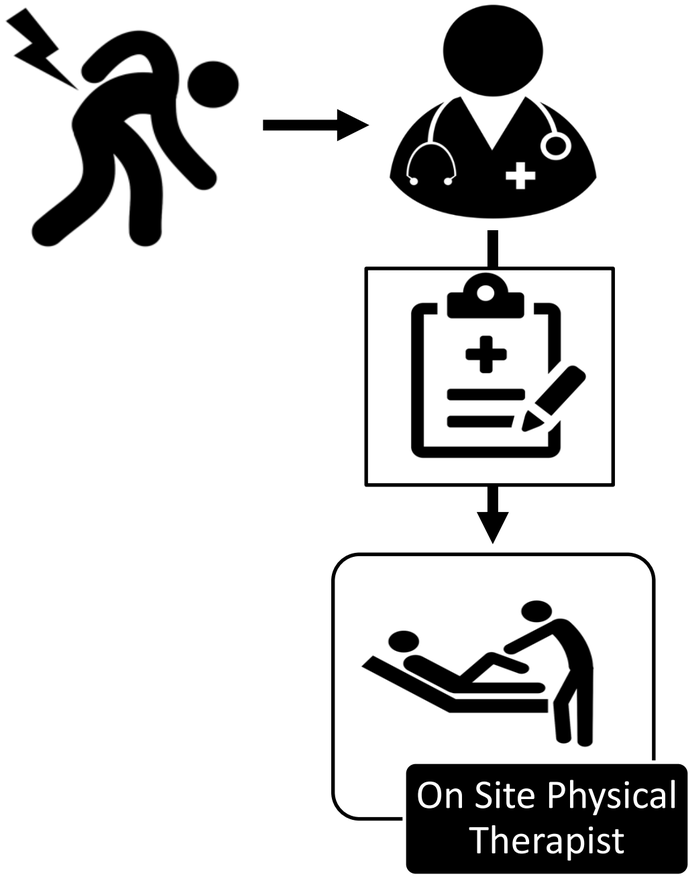


Sequenced Care Pathway



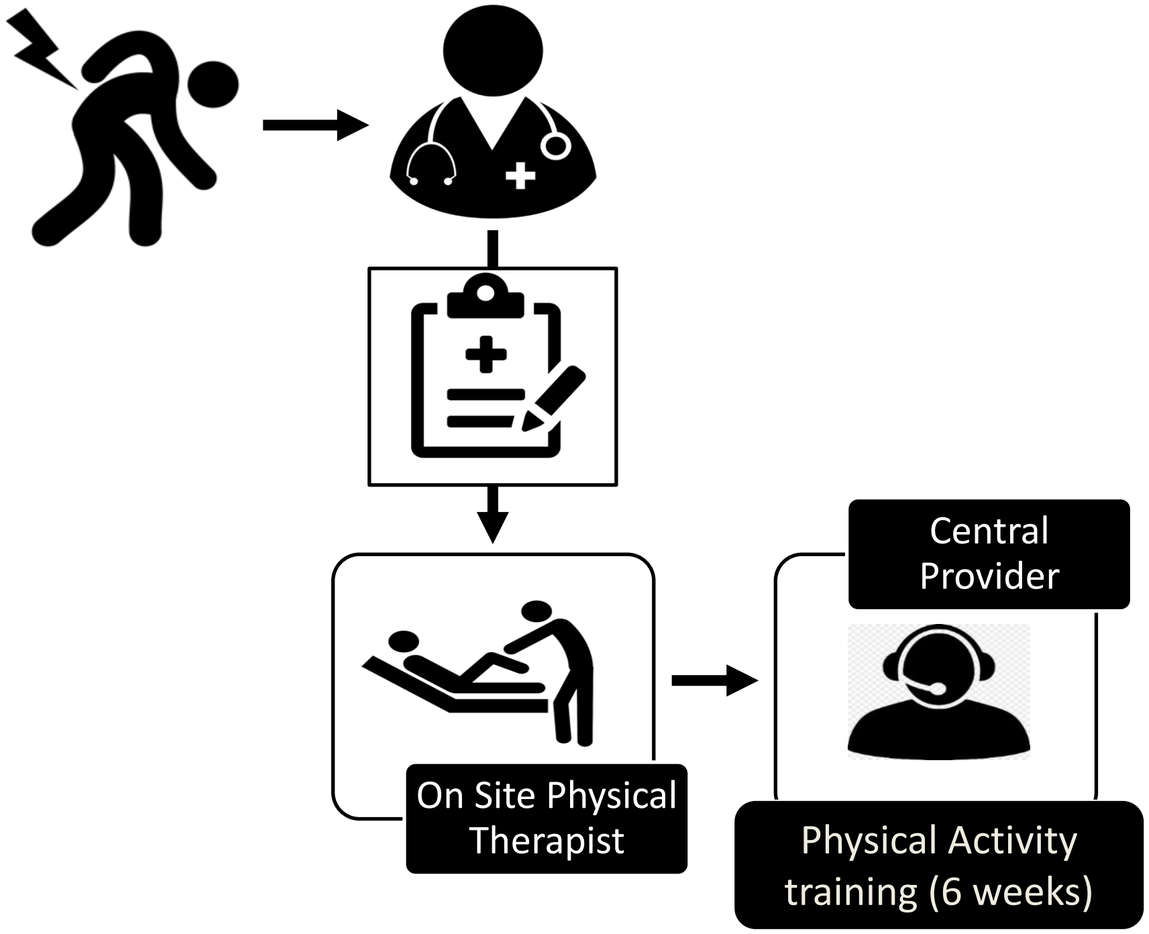
Sequenced Care Pathway

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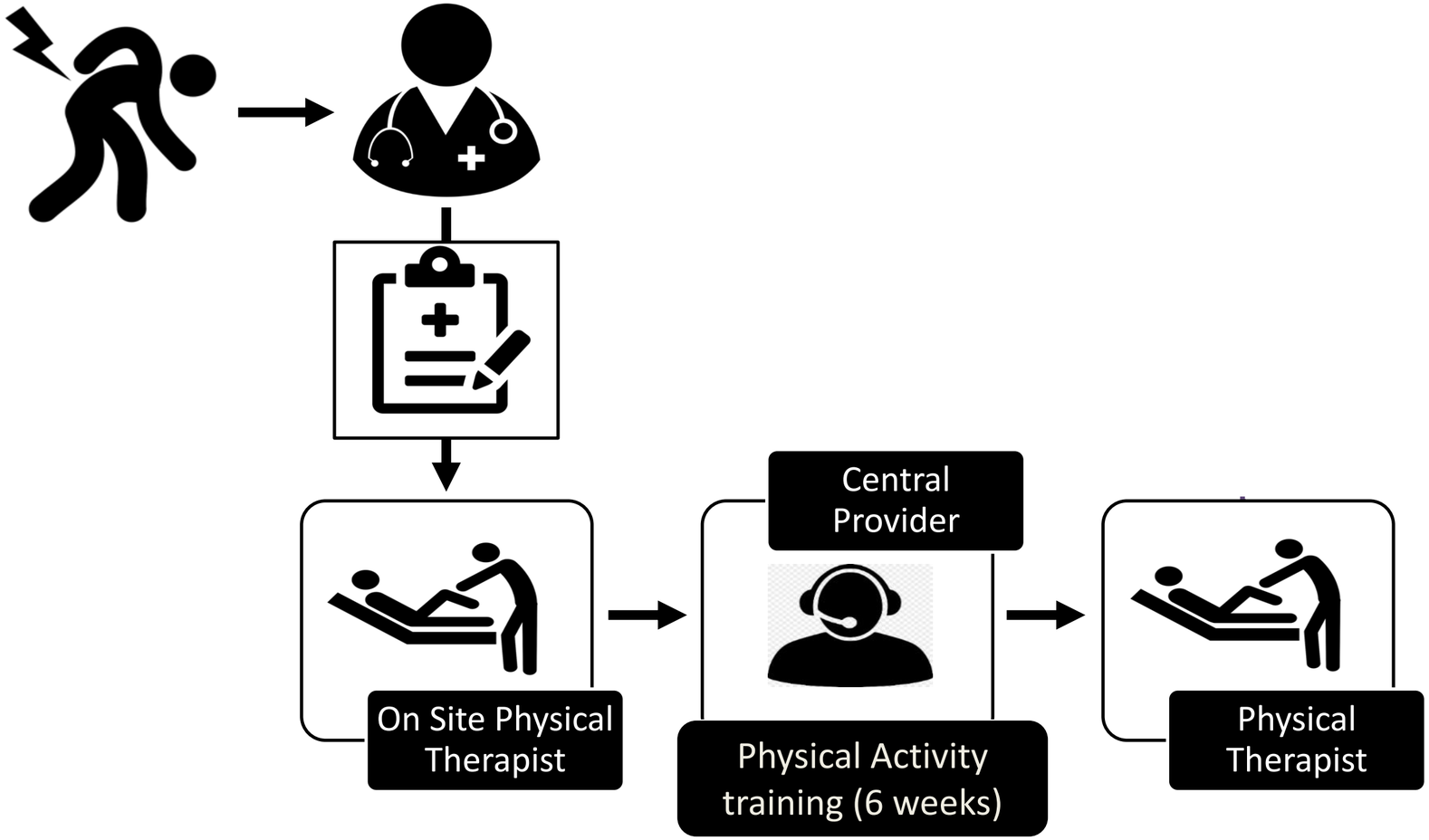
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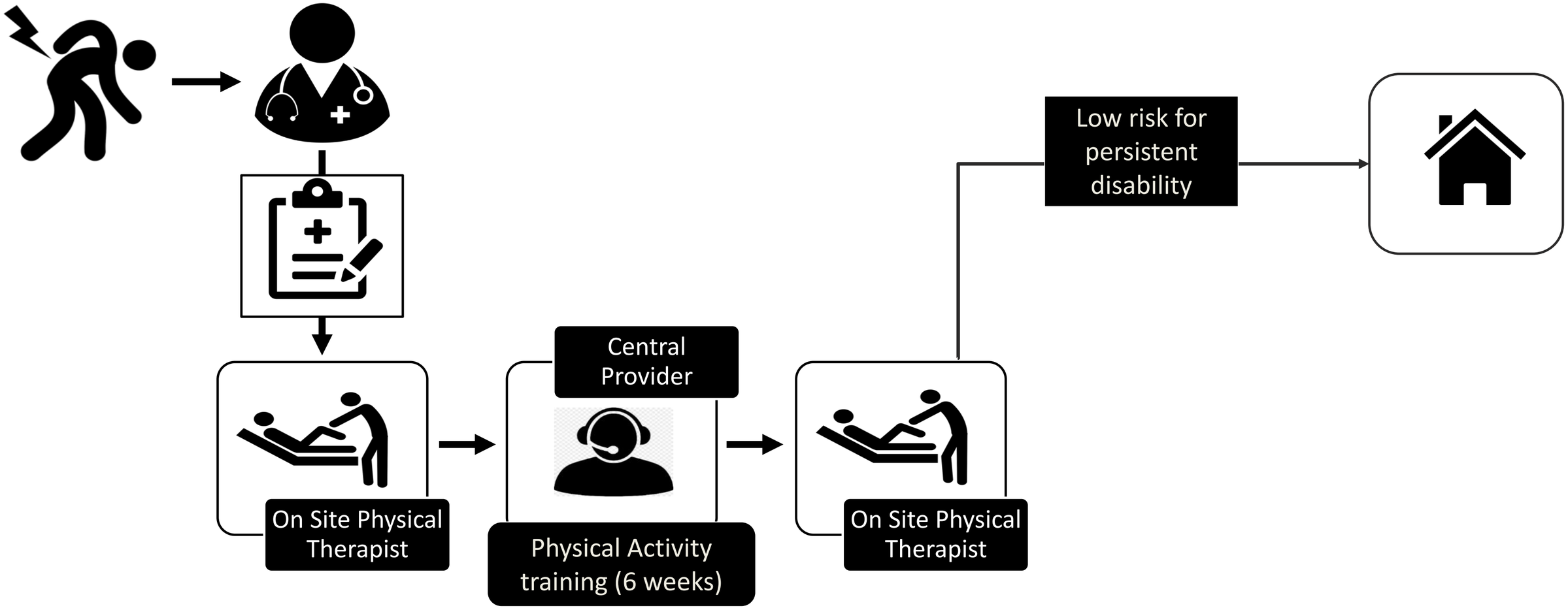
Sequenced Care Pathway

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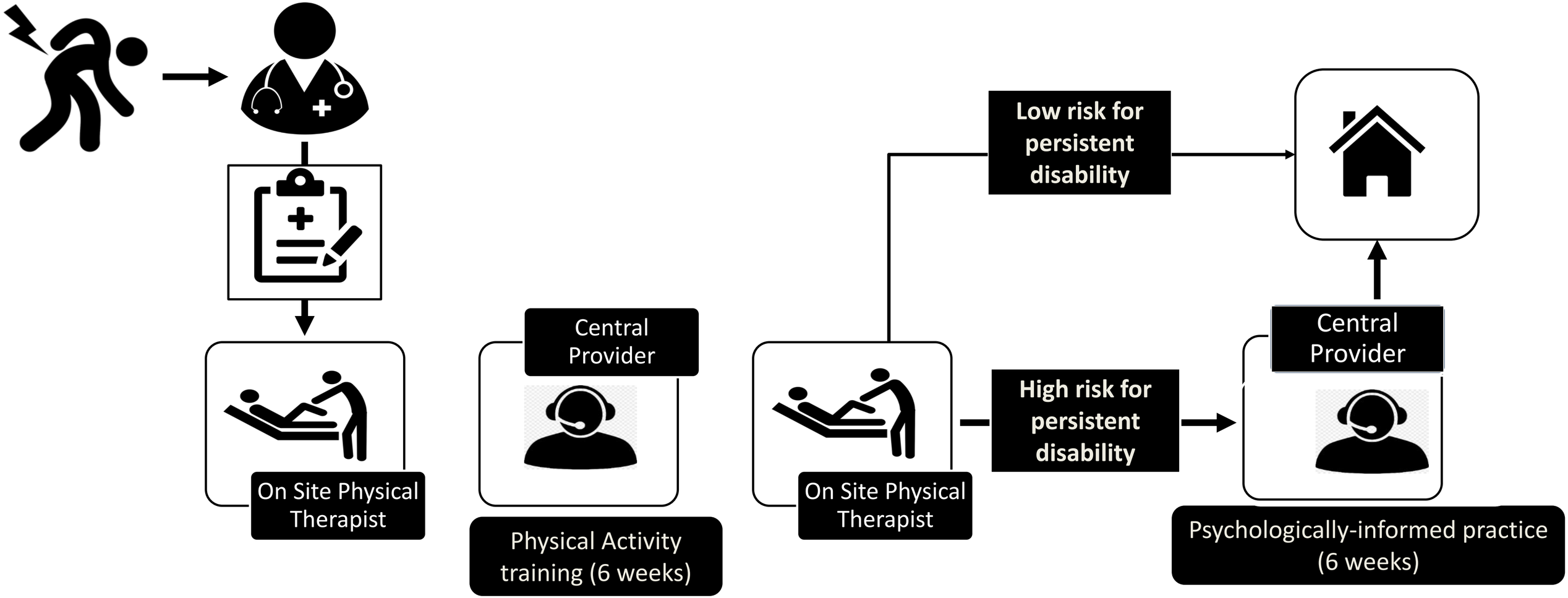
Sequenced Care Pathway

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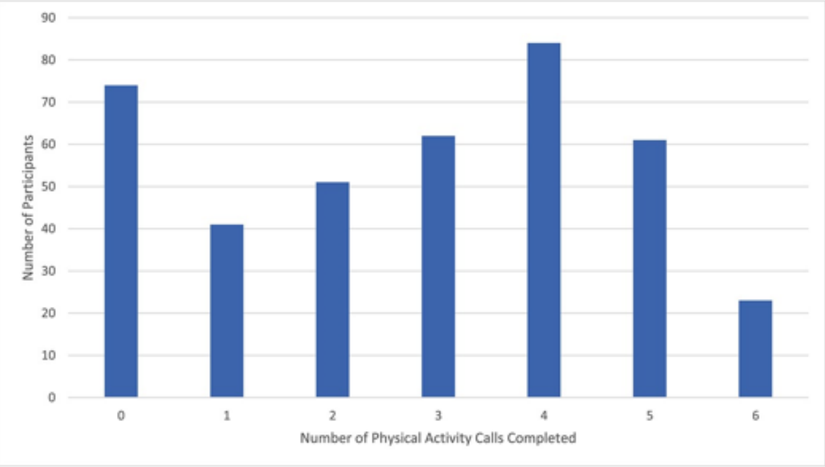
Sequenced Care Pathway

AIM-Back



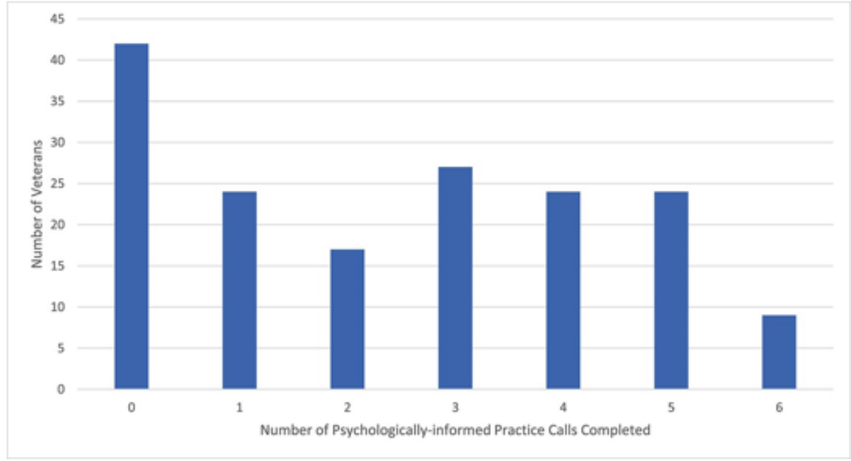
Sequenced Care Pathway Patient Activity

Figure 3 Distribution of physical activity calls completed between the veteran and the central provider among veterans ...



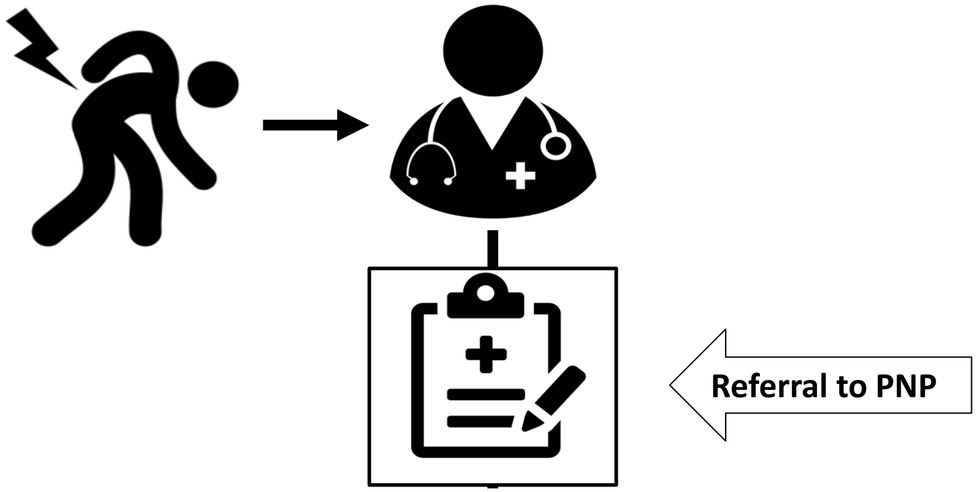
Phys Ther, Volume 104, Issue 2, February 2024, pzad127, https://doi.org/10.1093/ptj/pzad127
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Figure 4 Distribution of psychologically informed practice (PiP) calls completed between the veteran and the central ...

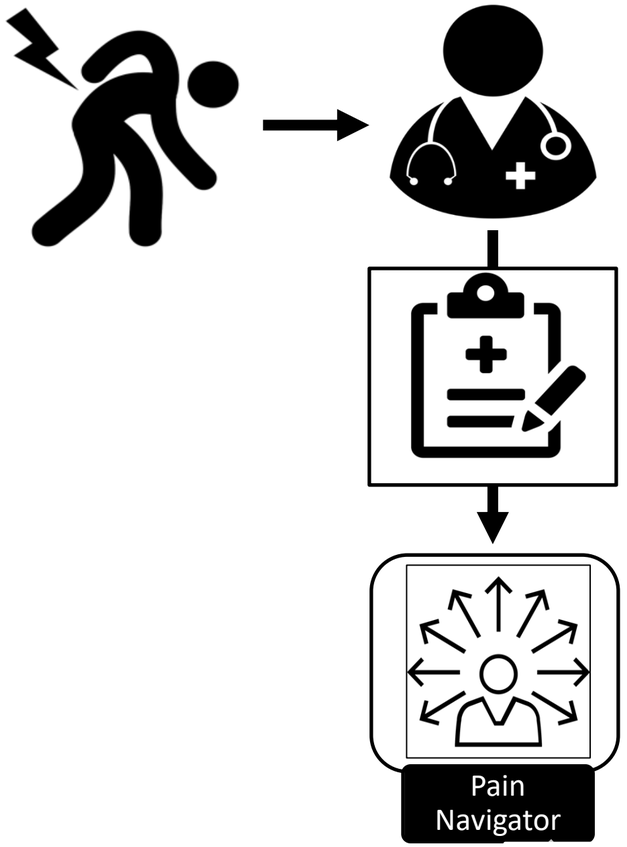


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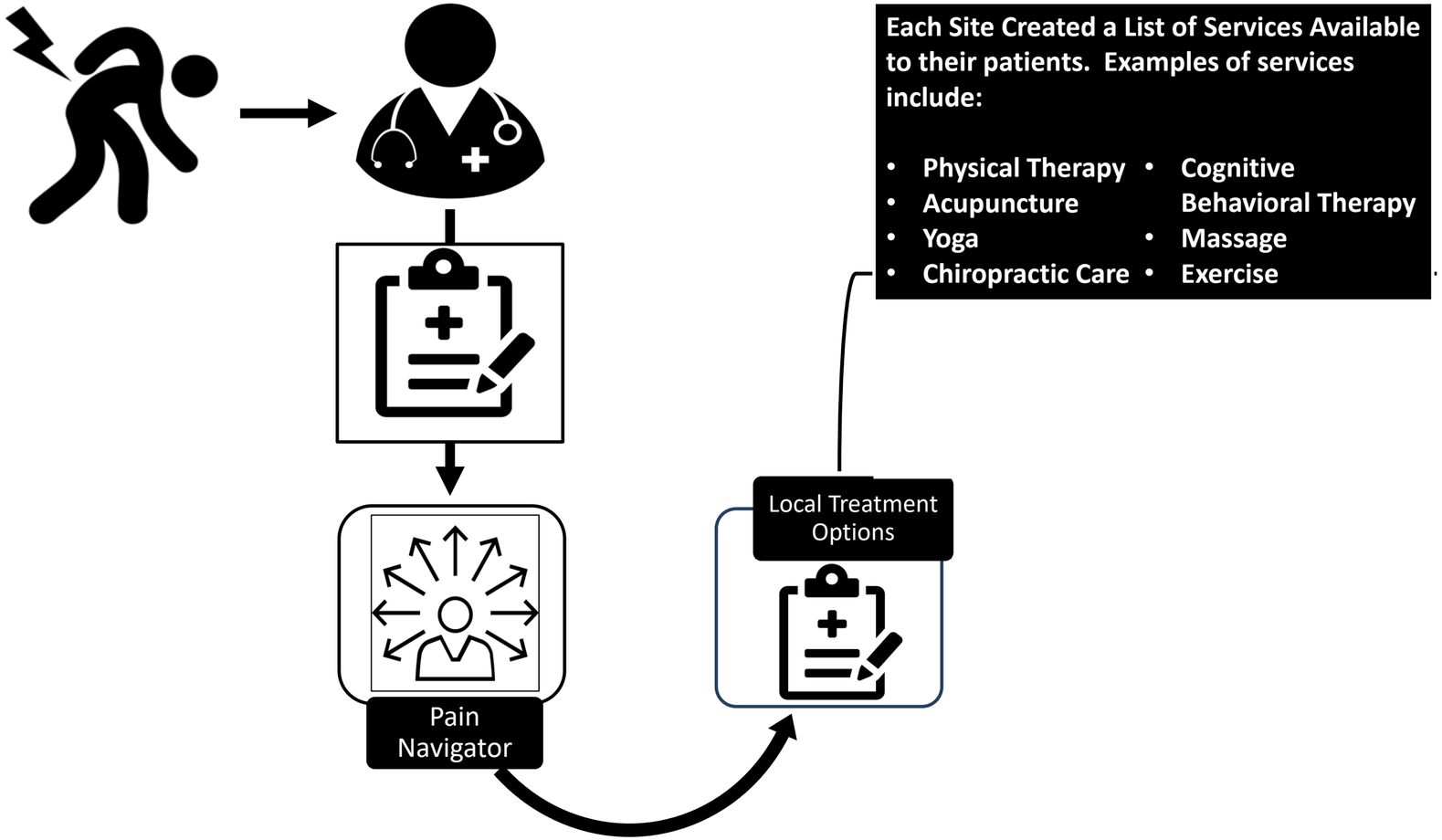
Pain Navigator Pathway



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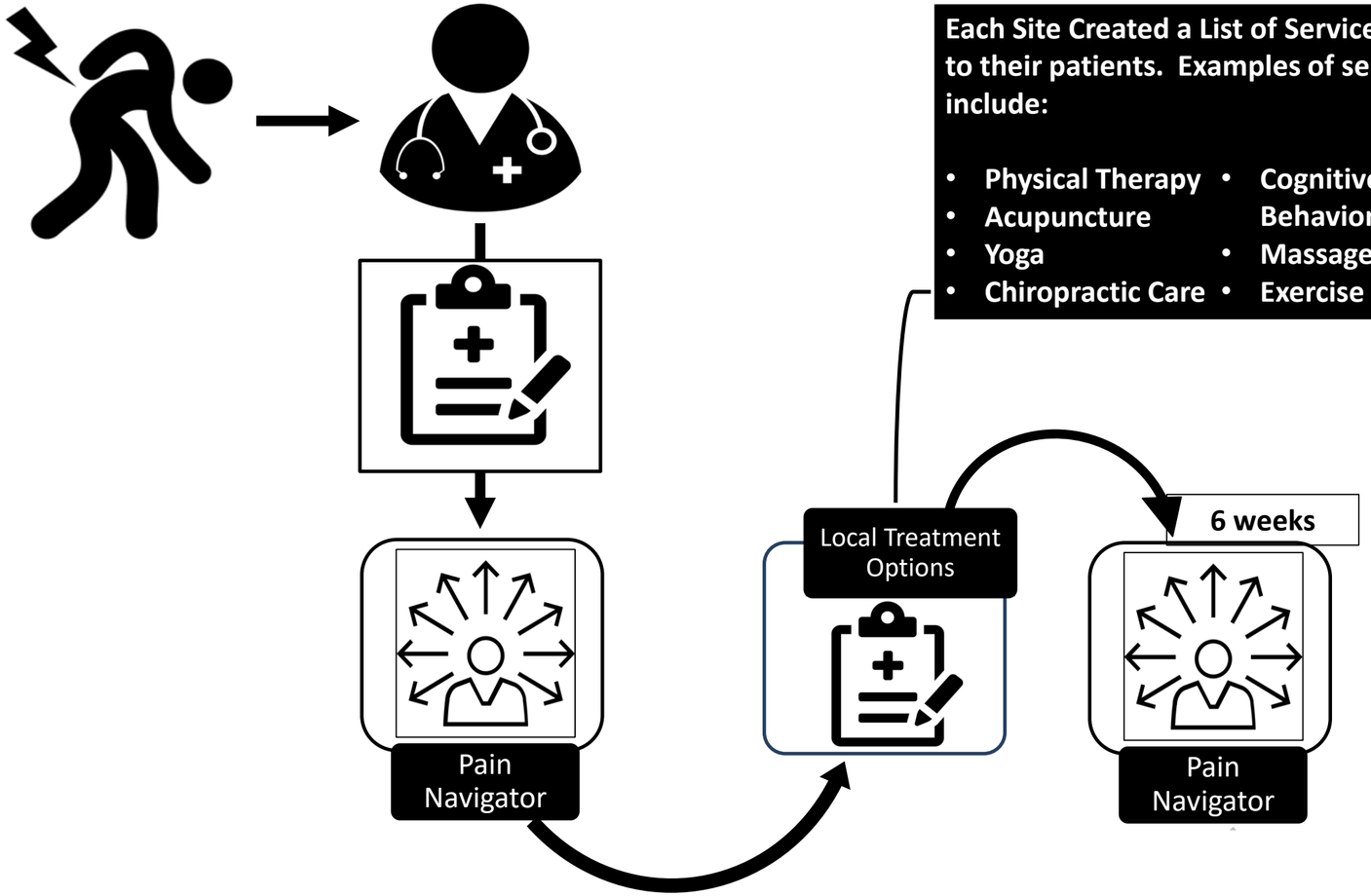
Pain Navigator Pathway



Each Site Created a List of Services Available to their patients. Examples of services include:

- **Physical Therapy**
- **Acupuncture**
- **Yoga**
- **Chiropractic Care**
- **Cognitive Behavioral Therapy**
- **Massage**
- **Exercise**

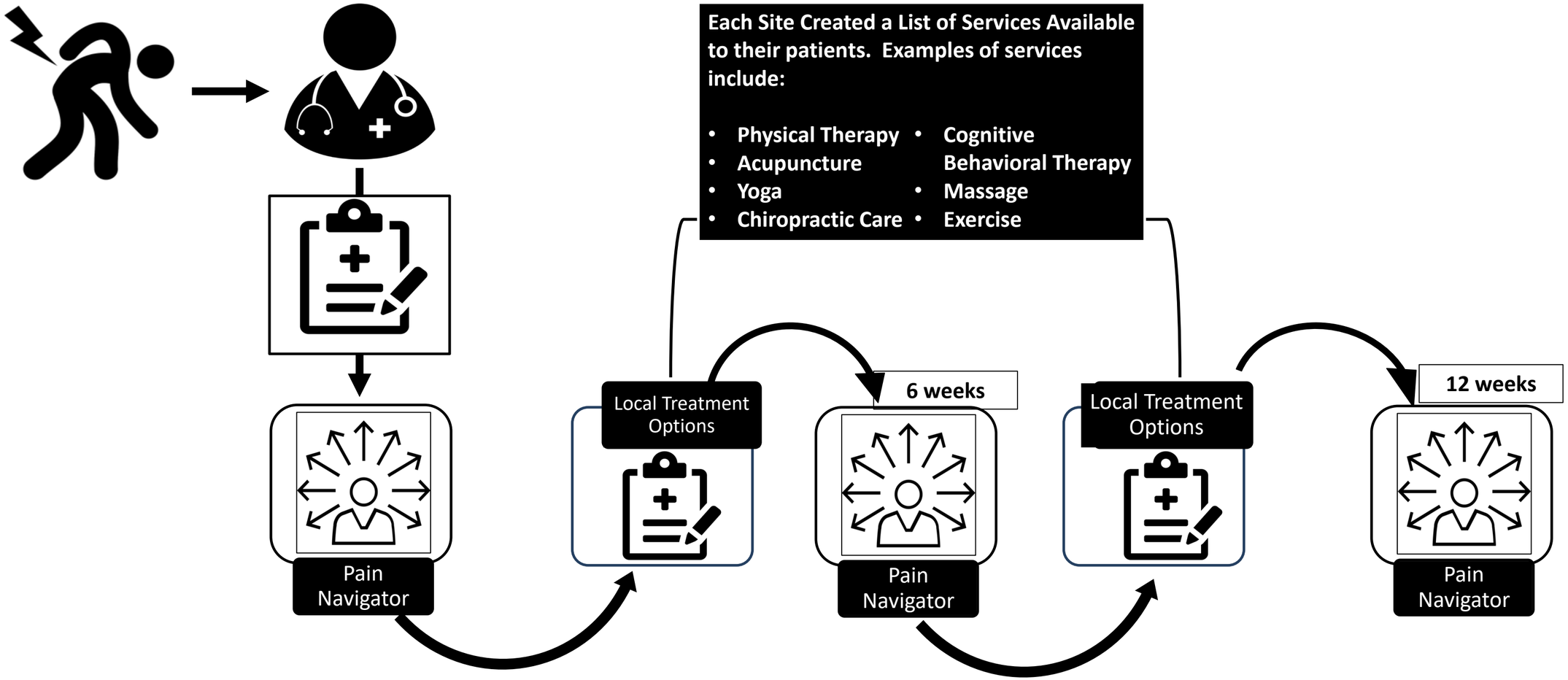
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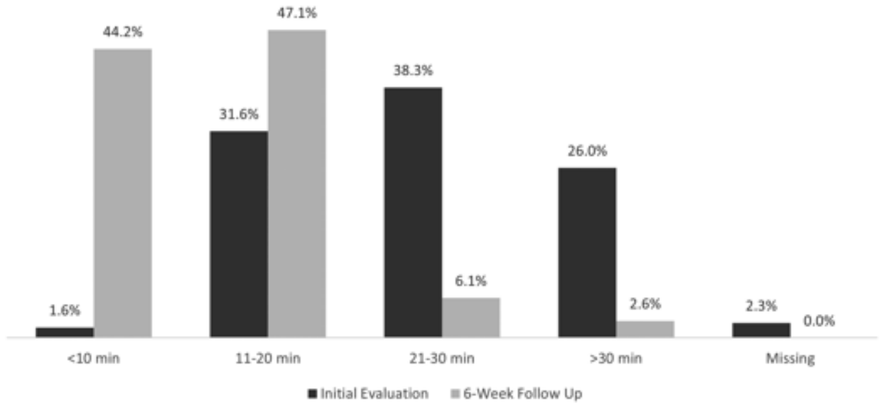
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Pain Navigator Pathway



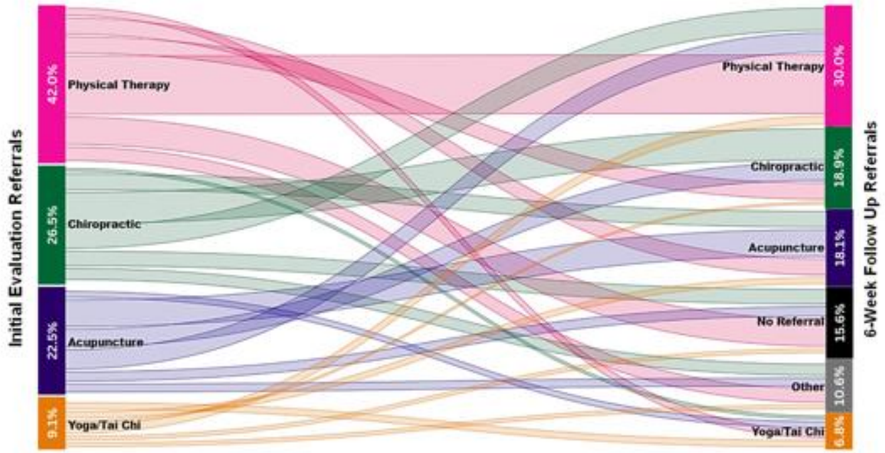
Pain Navigator Pathway Veteran Activity

Figure 2. Navigator time spent with Veteran at initial visit and 6-week follow-up. This figure depicts the distribution ...



Pain Med, Volume 25, Issue Supplement_1, November 2024, Pages S83–S90, https://doi.org/10.1093/pm/pnae074
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Figure 3. Sankey plot demonstrating variations in care routes at six week follow-up. The left side of this figure shows ...



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Pathway Related Publications

AIM-Back

CLINICAL TRIALS
Journal of the Society for Clinical Trials

Partner engagement for planning and development of non-pharmacological care pathways in the AIM-Back trial

PTJ Physical Therapy & Rehabilitation Journal

If you build it, will they come? Patient and provider use of a novel hybrid telehealth care pathway for low back pain

frontiers

Telehealth delivery of physical therapist-led interventions for persons with chronic low back pain in underserved communities: lessons from pragmatic clinical trials

Pain Medicine

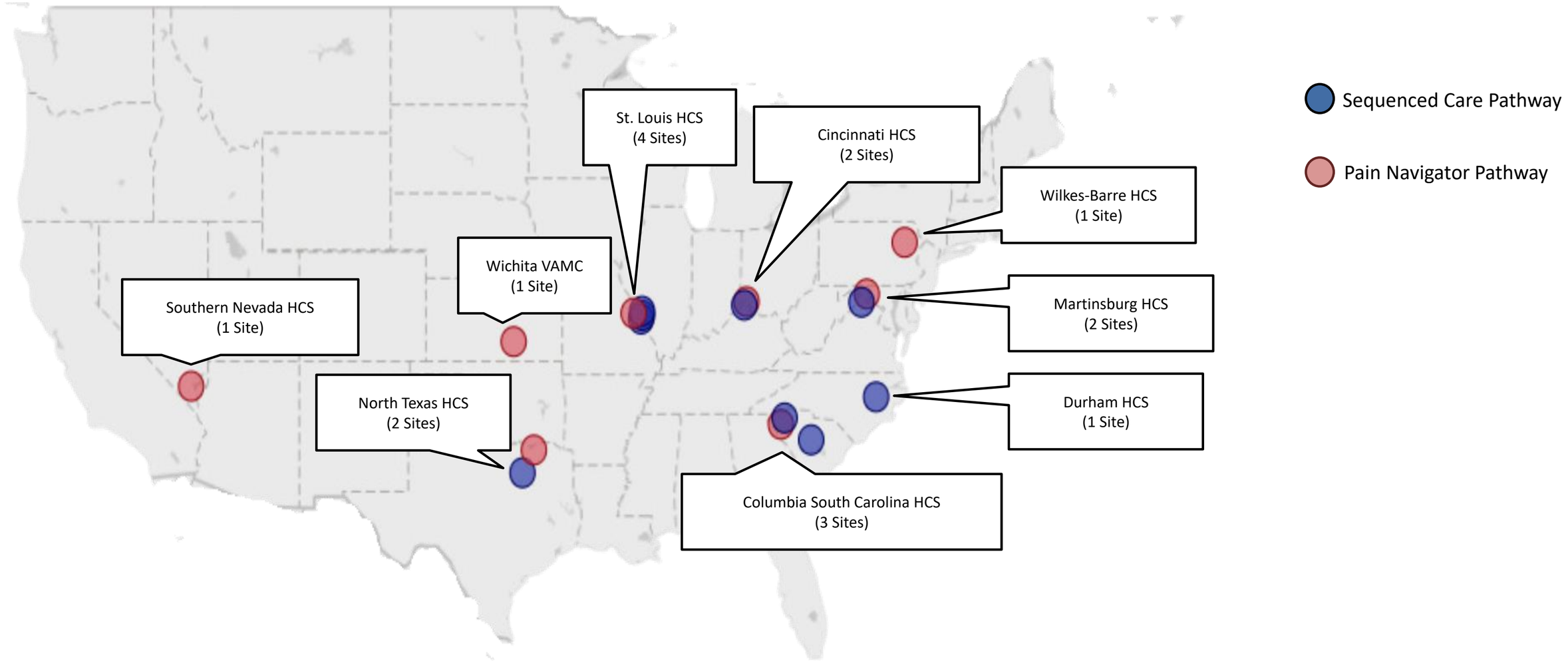
Improving Veteran Access to Integrated Management of Back Pain (AIM-Back): Protocol for an Embedded Pragmatic Cluster-Randomized Trial

The implementation of a pain navigator program in the department of Veterans Affairs'(VA) health care systems: a cluster randomized pragmatic clinical trial

Setting- 17 clinics

AIM-Back

Cluster randomized trial – 19 clinics randomized; 2 clinics dropped out



Specific AIMs

AIM-Back

AIM-1 CO-PRIMARY HYPOTHESES

*The Sequenced Care Pathway (SCP) will result in **lower pain interference** and/or **greater improvement in physical function** when compared to coordinated, pain navigator pathway (PNP) at 3-months.*

AIM-1 SECONDARY HYPOTHESES

*In a subset of eligible veterans that are enrolled for surveys, SCP program will result in **improved pain interference and physical function** when compared to the PNP at 3, 6 and 12-months.*

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Specific AIMs

AIM-Back

AIM-2 SUB-GROUP ANALYSIS

*Effect of SCP program on **pain interference and/or physical function** compared to PNP program will differ **based on High Impact Chronic Pain (HICP) vs. no HICP** at baseline*

*Effect of SCP program on **pain interference and/or physical function** compared to PNP program will differ will differ **based on Opioid Use vs. Opioid naïve** in the 12-months prior to referral*

Outcomes /Subgroup Definitions

PROMIS Pain Interference (Short Form 4a)

- A valid and reliable measure of self-reported pain. The instrument measures the self-reported consequences of pain across aspects of life including social, cognitive, emotional, physical and recreational activities; this instrument refers to the past seven days.

PROMIS Physical Function (Short Form 4a)

- A valid and reliable measure of self-reported physical function. This includes the functioning of one's central regions (neck, back), as well as instrumental activities of daily living, such as running errands.

Chronic Pain

- Defined as high impact chronic pain that limits a person's ability to work or participate in daily activities on most days or every day

Opioid Use

- Opioid prescription in time frame (12-months prior to AIM-BACK referral (baseline))

Results

Table 2 Clinic Characteristics

	Overall N=17	PNP N=9	SCP N=8
Clinic Characteristics (at start of enrollment)^			
Number of participating primary care providers at clinic, mean	13.7	13.6	13.9
Number of Community Clinics	9	4	5
Mean Pain Scores	4.2	4.2	4.2
Mean Age (years)	61.3	61.4	61.1
Mean Opioid use (%)	17.7	18.2	17.1

^ Number of participating primary providers was based on number of providers at clinic at time of recruitment; Mean pain scores, age and opioid use were based on lower back pain patient visits at clinic for 6-month period prior to clinic enrollment (8/2020 for block 1, and 11/2021 for block 2) from data pull of electronic health record data - at this time have mean scores only, did not need variability measure for constrained randomization process

Table 1

George S.Z. et al. 2024 'Cohort Profile: Baseline Characteristics of Veterans from Improving Veteran Access to Integrated Management of Back Pain (AIM-Back) – an Embedded Pragmatic, Cluster Randomized Trial in the United States' Medrxiv preprint

Sample Size

Referral Cohort n= 2767	EHR Sample n=1817	Survey Sample n= 996

Mean Age

Referral Cohort n= 2767		EHR Sample n=1817		Survey Sample n= 996	
SCP	PNP	SCP	PNP	SCP	PNP
52.0	52.2	53.4	52.7	51.4	52.0

Gender by Sample

	Referral Cohort n= 2767		EHR Sample n=1817		Survey Sample n= 996	
	SCP	PNP	SCP	PNP	SCP	PNP
Male	86.9	89.4	86.4	89.1	87.4	90.8
Female	13.1	10.6	13.6	10.9	12.6	9.2

Race by Sample

HICP by Sample

Opioid Use by Sample

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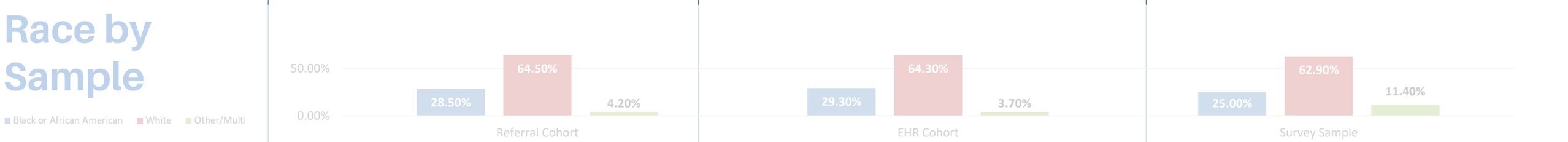
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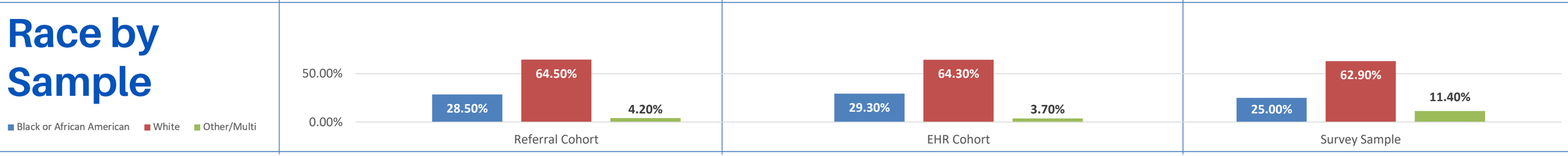
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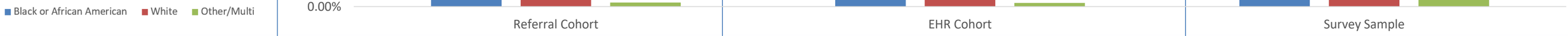
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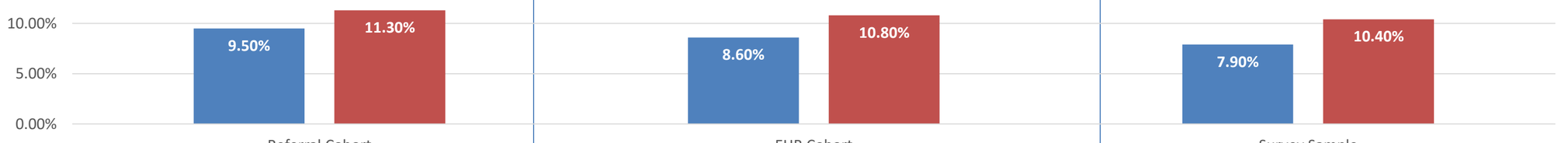


Table 3 Participation to Prevalence Ratio (PPR)

AIM-Back

PPR is a ratio of those within a specific demographic who participated (Referrals) relative to those of that same demographic who were eligible to participate from the local clinical environment (LBP Visits).

	Pain Navigator Pathway									Sequence Care Pathway							
	Clinic 1	Clinic 2	Clinic 3	Clinic 4	Clinic 5	Clinic 6	Clinic 7	Clinic 8	Clinic 9	Clinic 10	Clinic 11	Clinic 12	Clinic 13	Clinic 14	Clinic 15	Clinic 16	Clinic 17
LBP Visits	1795	1580	1378	1146	1116	884	858	801	545	2193	1997	1550	1510	1339	508	504	224
Referrals	182	155	162	218	103	171	167	153	170	178	171	180	184	213	176	74	110
Age																	
<50	1.6	1.1	1.4	1.6	2.2	1.7	1.6	1.9	2.1	1.6	1.6	1.5	1.3	1.5	1.6	1.4	1.9
50-64	1	1	1	0.9	1.2	1.1	1.1	0.9	0.9	0.7	1.3	1.2	1.1	1	0.9	1.2	0.7
65-74	0.8	1.1	0.7	0.7	0.6	0.7	0.5	0.6	0.7	0.2	0.6	0.7	0.7	0.6	0.7	0.8	0.7
>=75	0.4	0.4	0.7	0.7	0.2	0.4	0.4	0.3	0.6	0.5	0.3	0.5	0.6	1	0.8	0.4	0.4
Sex																	
M	1	1	0.9	1	0.9	0.9	0.9	1	0.9	0.9	0.9	1	1	1	1	0.9	1
F	1	1.5	3.9	0.8	1.8	1.6	2.5	1.1	2.2	1.6	2.5	1.3	1.2	1.2	1.2	1.7	1.4
Ethnicity																	
HISPANIC	1.2	1.4	1.4	1.9	2.4	1.6	6	1.5	1.8	1.4	2.5	1.2	1.2	1	1.7	1.7	0.9
NOT HISPANIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Race																	
BLACK	1.5	1.4	1	0.9	1.8	1	0.9	1.3	1.1	1.1	1.3	1.3	1	2.2	0.9	1.3	1
WHITE	1	1	1	1	0.9	1.1	0.9	0.9	0.9	0.8	0.8	0.9	1.1	0.9	1	0.6	1

Underrepresentation	Proportional Representation	Overrepresentation

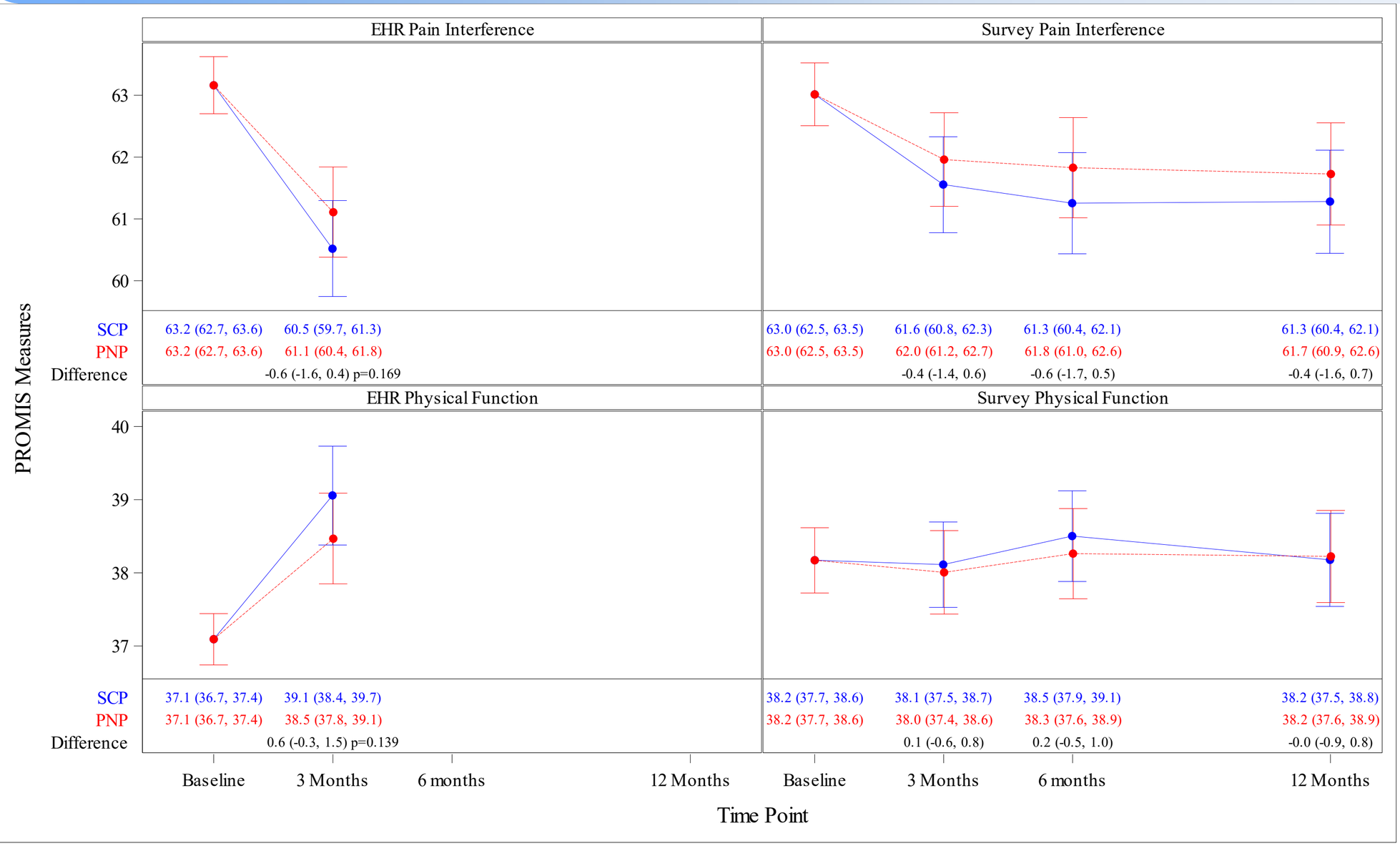
Analysis Methods

PRIMARY ANALYSIS – EHR SAMPLE

Hierarchical linear mixed-effects model were fit including random effects for clinics and time by clinics and an unstructured covariance was used for repeated measures of outcomes for Veterans

- Predictors in models include indicator(s) for time effect and indicator(s) for treatment interacting with the time effect (s)
- Clinic-level covariates in models used in the covariate constrained randomization
  - average pain scores, clinic location (main medical center/community clinic), number of participating primary care providers, average level of opioid exposure of LBP patients at clinic, and average age of LBP patients at clinic
- Patient-level baseline covariates included in models
  - age, race, high impact chronic pain, CAN score (comorbidity measure); mean/mode imputation for missing CAN scores and race

Results- EHR Sample (n=1817)Survey Sample (n=996)



- *No difference between arms in PROMIS outcomes at 3-months*
  - *Reduction of pain interference in both arms; Improvement in physical function in both arms*
- *ICC for pain interference = 0.0; ICC for physical function=0.008*

Analysis Methods

SENSITIVITY ANALYSIS – EHR SAMPLE include all time points (EHR and survey)

Data Structure

- All measurement time points (EHR and/or survey, min=1 and max=8)
- Zero time point is EHR baseline, time denoted as days from EHR baseline
- Excluded n=43 surveys that were more than 60 days prior to EHR baseline

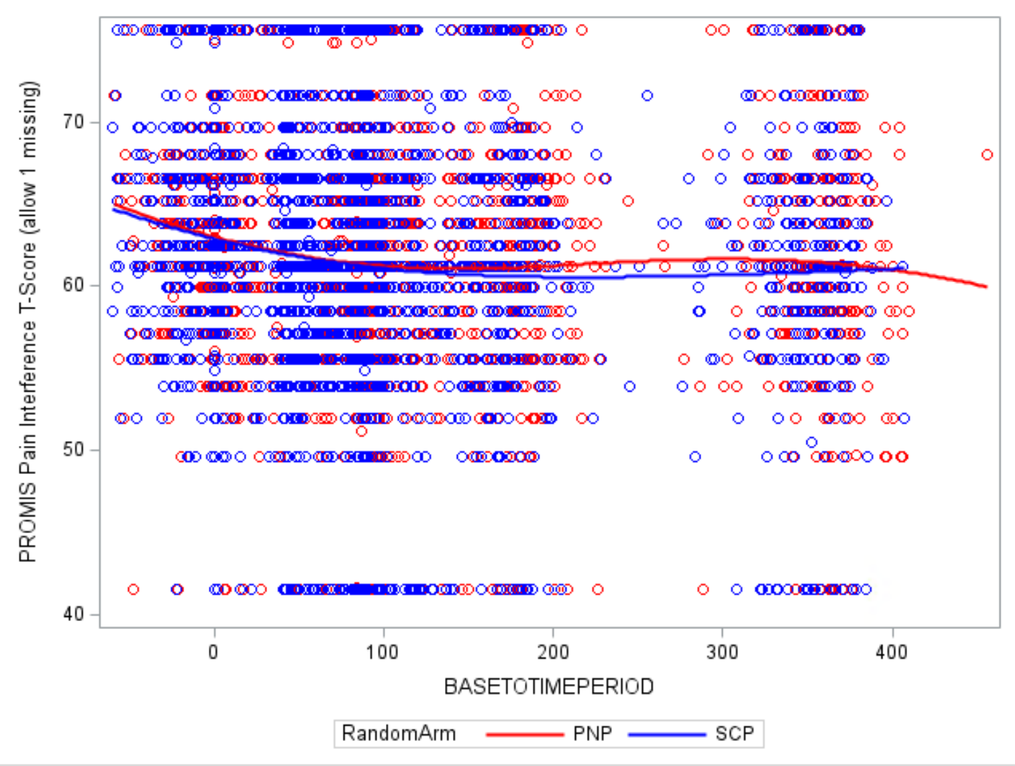
Hierarchical penalized spline mixed-effects model

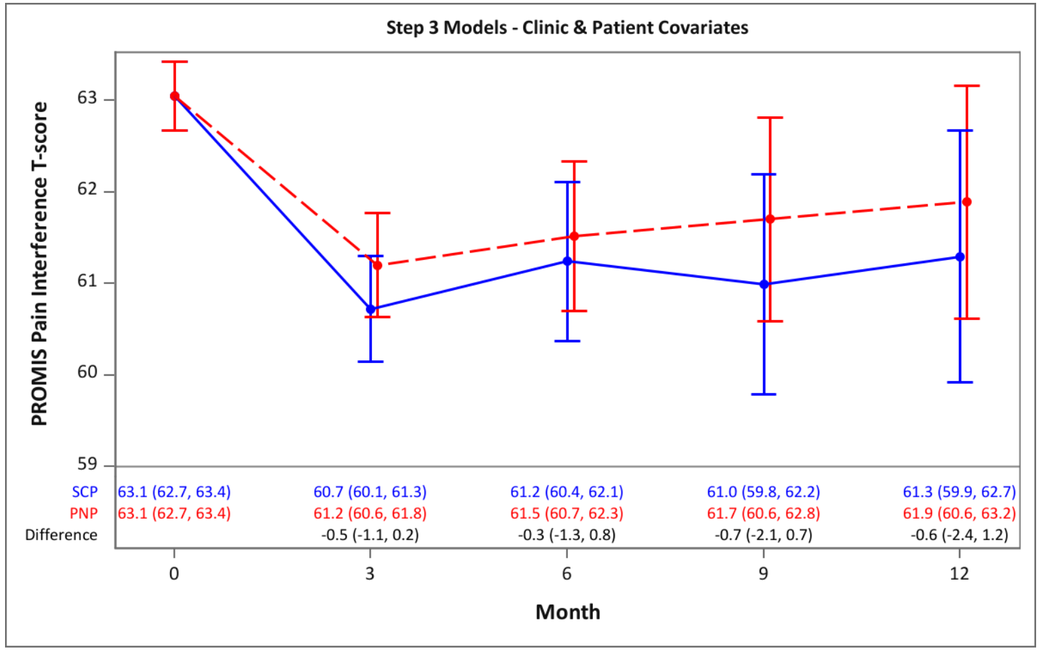
- Piecewise linear functions with prespecified knots included as fixed and random effects at the population-average level
- Linear time with knots at 3, 6 and 9 months interacting with treatment
- Random effects for clinics and clinic by time and subject level random intercept and slope

Results- All Touch Points

PROMIS Pain Interference

- **Mean number of measurements per subject=3.7; 82.9% have 2 or more measurements**



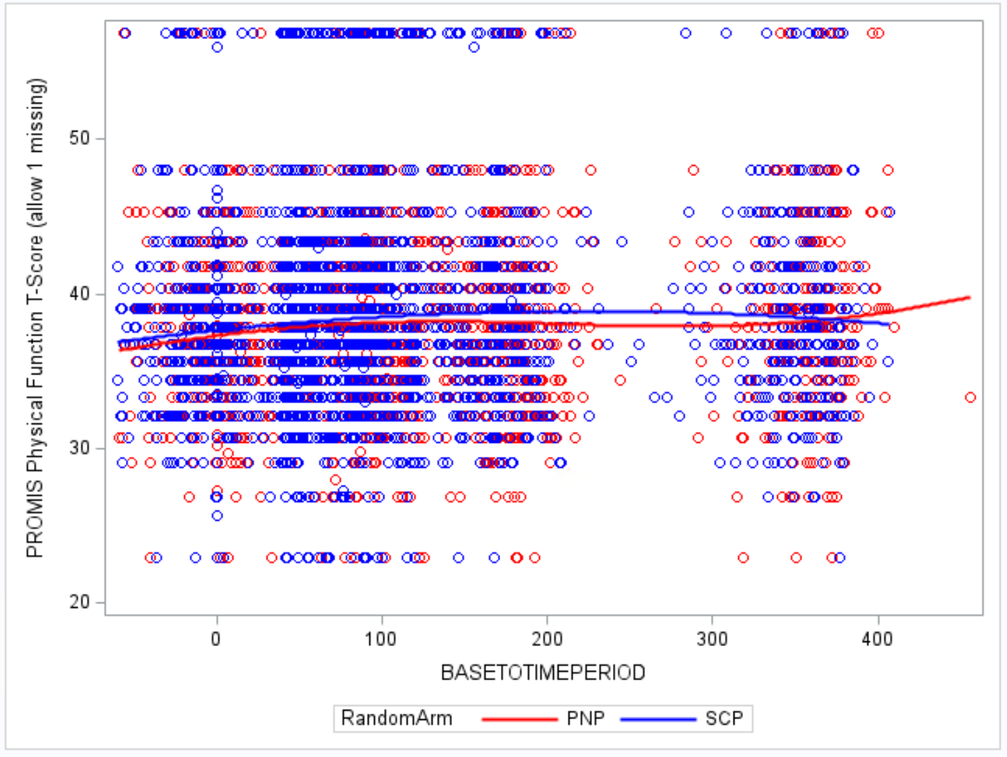


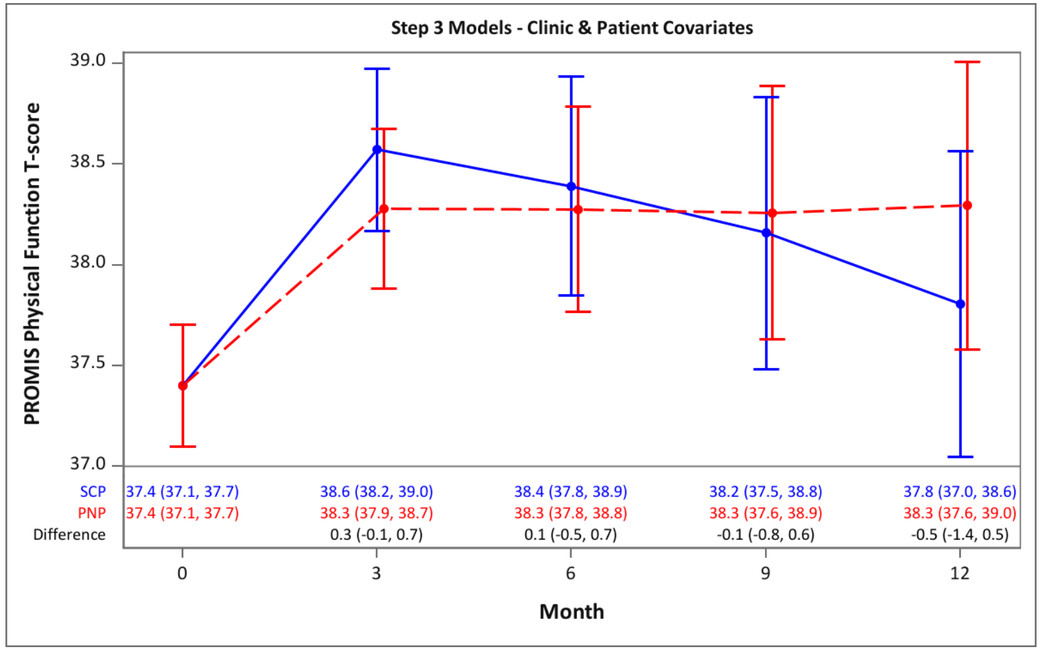
- *No difference between arms at any time point; similar difference at 3-months to primary EHR analysis*
  - *Reduction of pain interference in both arms*

Results- All Touch Points

PROMIS Physical Function

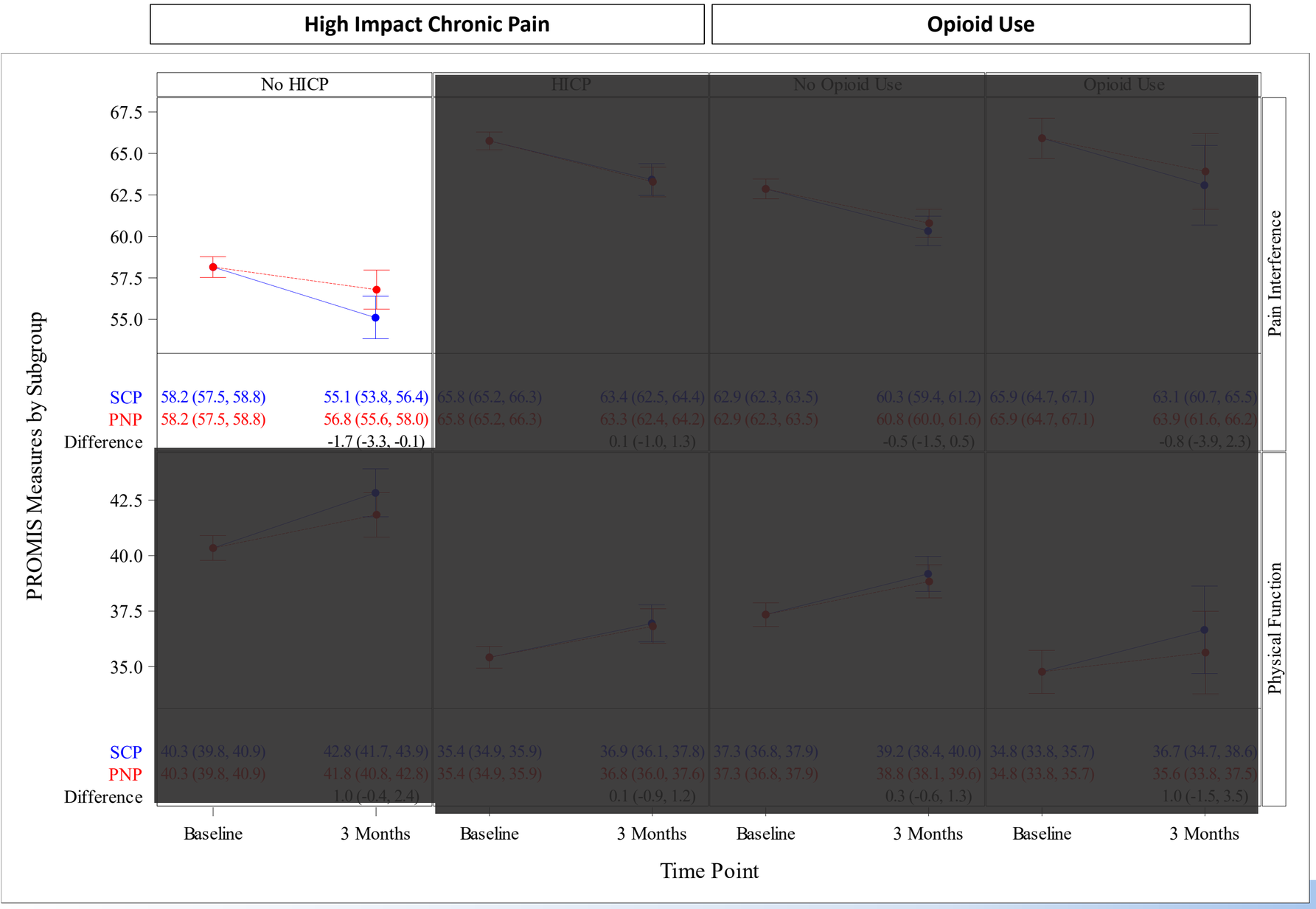
- **Mean number of measurements per subject=3.7; 82.9% have 2 or more measurements**





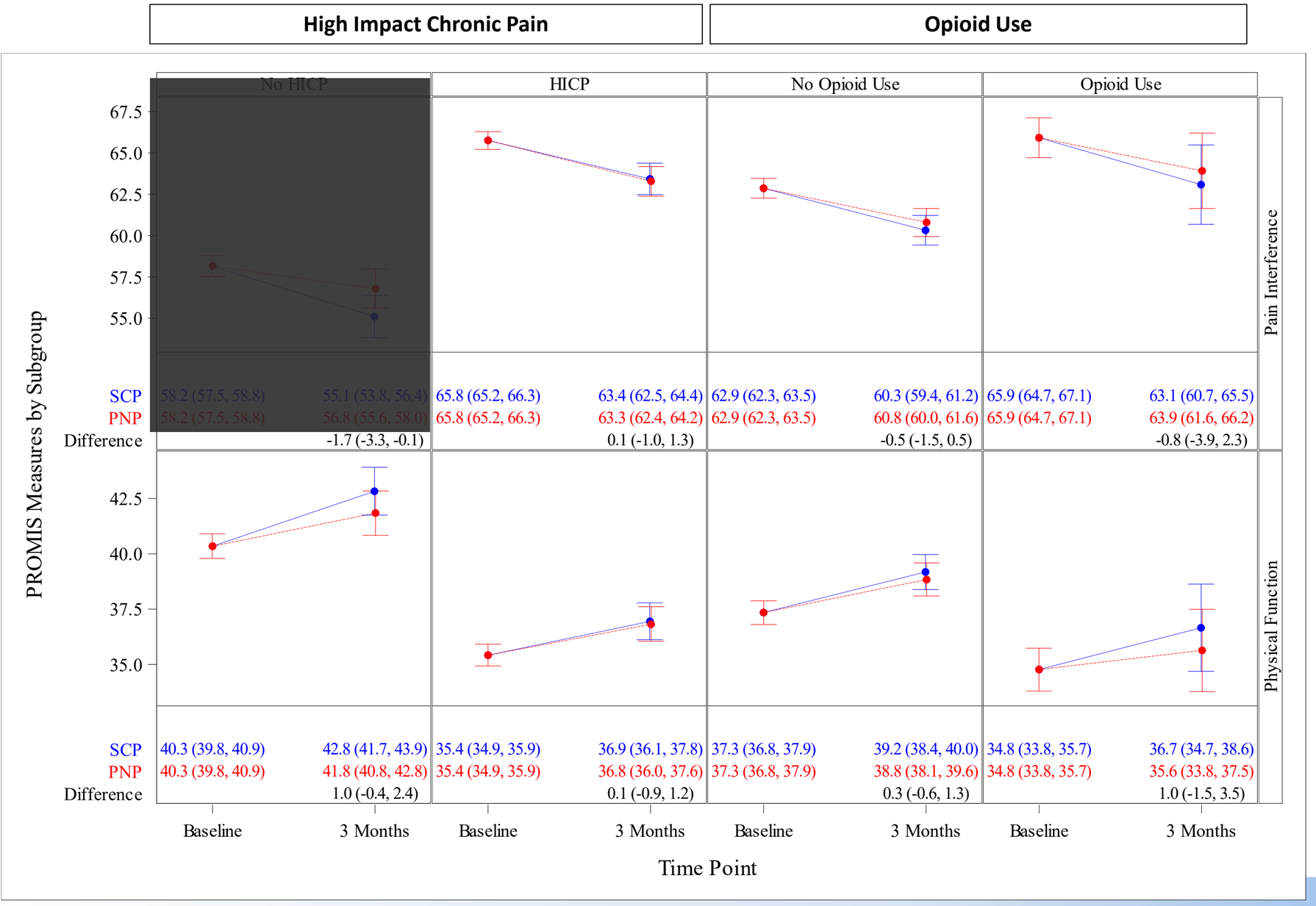
- *No difference between arms at any time point; similar difference at 3-months to primary EHR analysis*
  - *Improvement of physical function in both arms*

Results- Subgroups



- *Difference between SCP and PNP 3 month change in pain interference by HICP status is 1.8 (97.5% CI -0.2,3.8) p=0.0394 ; SCP "better" than PNP in Veterans without HICP*

Results- Subgroups



- *No differential treatment effect by HICP status for physical function -0.9 (97.5% CI -2.4,0.7) p=0.23*
- *No differential treatment effect by Opioid use for pain interference 0.6 (97.5% CI -1.7,2.8) p=0.57*
- *No differential treatment effect by Opioid use for physical function 0.7 (97.5% CI -1.3,2.2) p=0.55*

Key Takeaways



Comparative Effectiveness

<u>There was no pathway superiority:</u> SCP and PNP had similar, clinical meaningful improvements in physical function and pain interference outcomes

These results are published (George et al, *JAMA Netw Open, 2026*)



Chronic Pain Status

<u>There may be opportunities to target delivery:</u> Veterans without HICP assigned to the SCP saw greater improvements in pain interference

These findings are in review (Research Letter, *PTJ*)



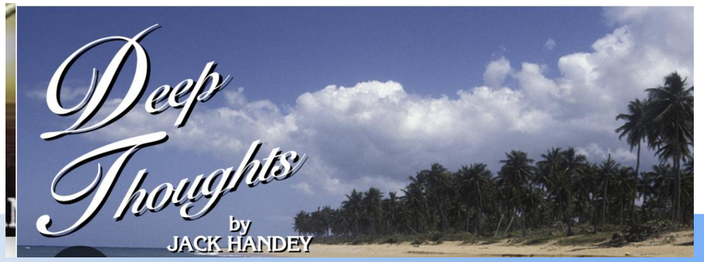
Opioid Use

<u>Opioid use did not impact outcomes</u>: SCP and PNP had similar improvements in primary outcomes for Veterans taking opioids for pain management

Reflections

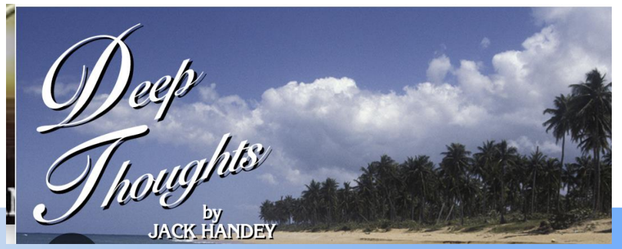
- In peer-review there was little to no interest in the pre-specified subgroup analyses

- Electronic health record and routine clinical visits for 3 month follow up capture was challenging
  - Even with survey cohort remained low for clinical trials
  - But not for real world data



Reflections

- First trial we are aware of to compare 2 different care pathways/models for LBP
  - All 48 trials included in 2025 Cochrane Review used usual care comparators
  - Our lack of usual care comparator was intentional (we thought it would be a barrier to site recruitment)
  - But not having usual care was a limitation scientifically in interpreting whether what we observed was regression to the mean



Next for the Field?

- Test different care pathways/models in US health system
- Work towards answering “does it work” along with “for whom does it work differently (better)” or “how does this work (causal mediation)” in the same trial
  - AIM-Back subgroup analyses suggested opportunities for tailoring treatments
- Follow-up work funded by PCORI
  - Comparator is usual care and have multilevel subgroup, mediation analyses, and implementation evaluation

Thank You!

Acknowledgements

- NIH/NCCIH Funding UG/UH3 Mechanism
- All Primary Care Providers that referred into the AIM-Back program
- The Physical Therapists who delivered the Sequenced Care Pathway
- The Physical Therapists, Occupational Therapist, Chiropractor, Nurses, Physicians, and Whole Health Coaches that delivered the Pain Navigator Pathway
- All Veterans who participated in the clinical program or survey for the AIM-Back study
- Our Research Teams at the Durham VA and Duke University
- Our Partners
  - Pain Management Collaboratory
  - Veteran's Research Engagement Panel

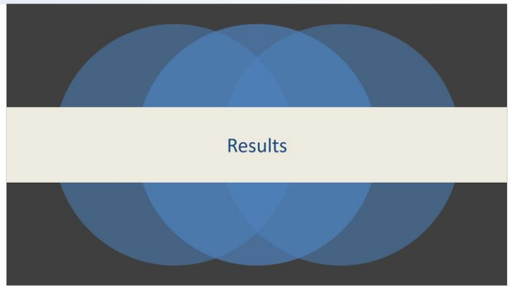
AIM-Back

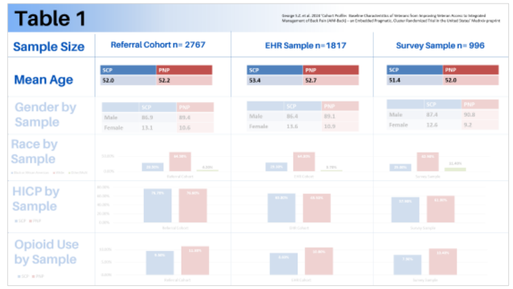
painmanagementcollaboratory.org/improving-veteran-access/

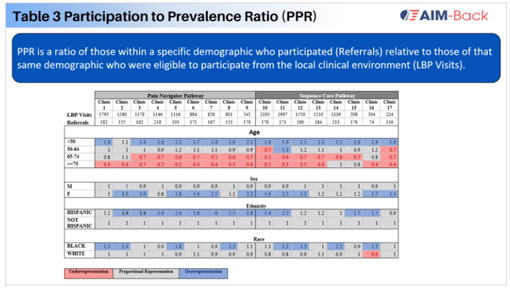
vhaduraimback@va.gov

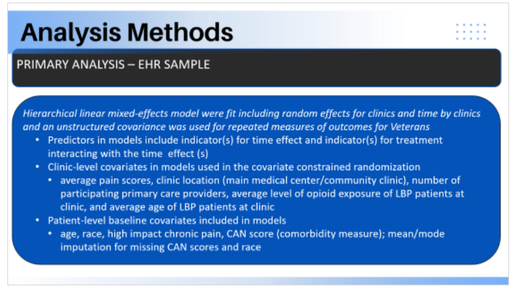
Questions and Comments

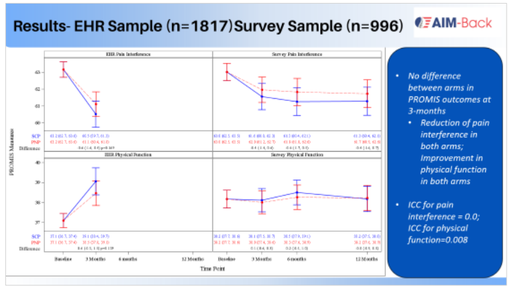
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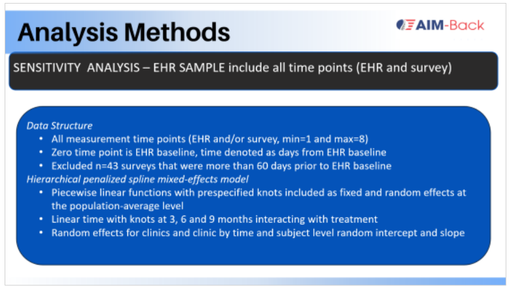


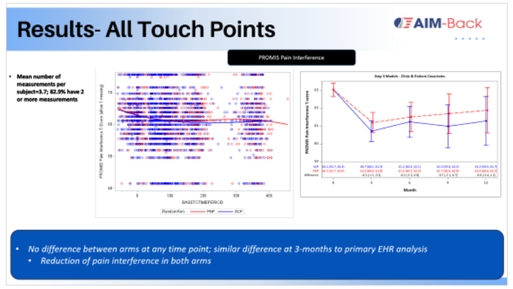


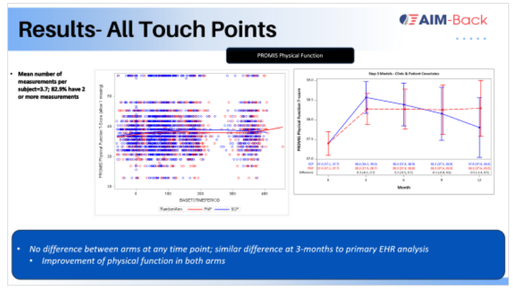


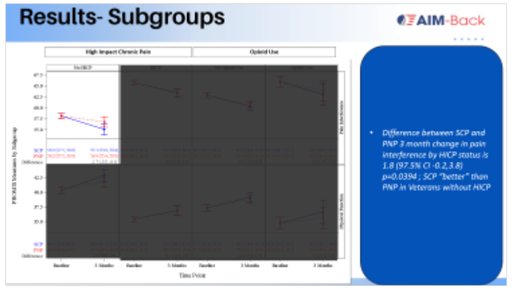




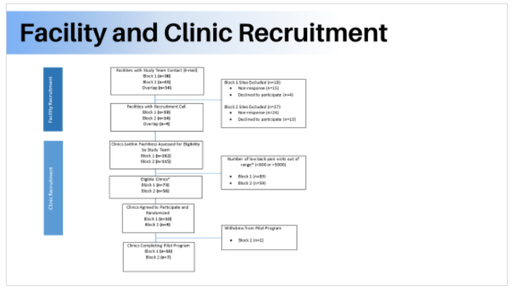












Facility and Clinic Recruitment

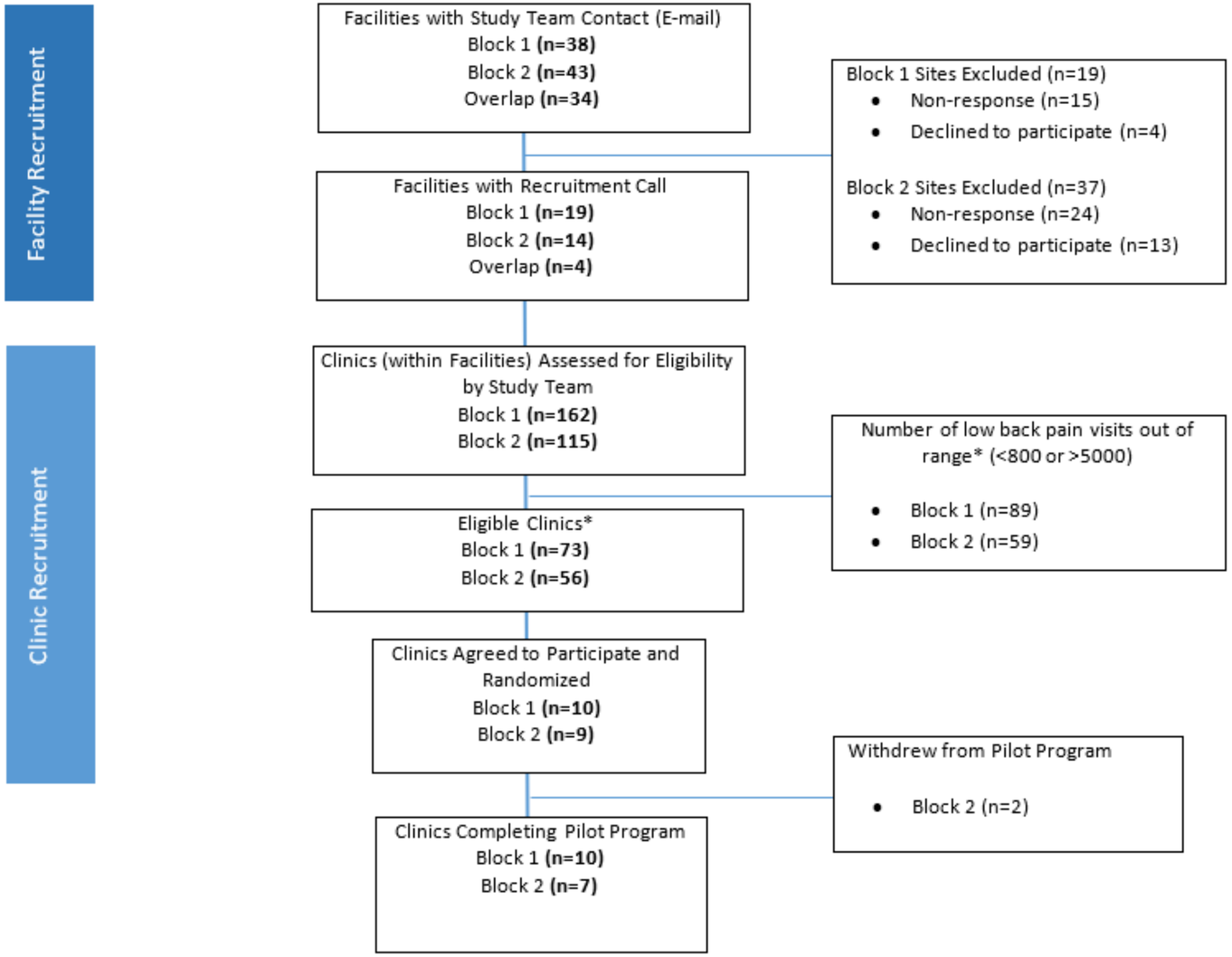


Table 3a PROMIS Outcomes Survey Sample (n=197) not enrolled in AIM-BACK

	Survey Sample n=197	
Characteristic	**PNP sites N=81**	**SCP sites N=116**
PROMIS-SF Pain Interference T-Score PROMIS-S *Mean (SD) N*		
Baseline	63.0 (6.9) 80	64.1 (6.3) 115
3-month	62.6 (6.7) 66	63.1 (7.4) 85
6-month	63.7 (7.1) 72	62.6 (7.6) 72
12-month	61.9 (7.6) 54	62.9 (7.9) 72
PROMIS-SF Physical Function T-Score *Mean (SD) N*		
Baseline	38.7 (6.1) 80	38.0 (5.7) 116
3-month	38.1 (6.0) 66	38.5 (6.5) 85
6-month	37.5 (5.7) 61	38.3 (6.0) 72
12-month	37.7 (5.6) 54	38.5 (6.1) 72

Table 4a Baseline outcomes by missing 3-month follow-up

	EHR Sample (n=1817)	
	Missing 3M follow-up	**Not Missing 3M follow-up**
Outcome Measure *Mean (SD) N*		
PROMIS Pain Interference	63.0 (6.5) 694	63.3 (6.9) 1100
PROMIS Physical Function	37.2 (5.4) 698	37.0 (5.2) 1104
PROMIS Sleep Disturbance	58.2 (8.4) 696	58.4 (8.3) 1104
CDC HICP	0.6 (0.5) 711	0.7 (0.5) 1106
NIH Chronicity	0.9 (0.3) 711	0.9 (0.3) 1106

Table 5 Adherence metrics for delivery of AIM-BACK pathways

PNP			SCP		
Session	Metric	n (%)	Session	Metric	n (%)
Initial baseline	Visit	1006 (100%)	Initial baseline	Visit	811 (100%)
	1 or more referral(s) issued	997 (99.1%)		1 or more pain modulation and/or pain neuroscience education completed	745 (91.9%)
			Physical activity coaching sessions	Mean (SD)^	2.4 (1.9)
				1 or more	625 (77.1%)
6-week Follow-up$	Visit	582 (57.9%)	6-week Follow-up$	Visit	532 (65.6%)
	1 or more referral(s) issued	412 (70.8%)		1 or more pain modulation and/or pain neuroscience education completed	336 (63.2%)
				Start Back Tool High/Medium Risk	377 (70.9%)
			Psychologically-informed practice (PiP) sessions*	Mean (SD)^	1.9 (2.0)
				1 or more	218 (57.8%)
3-month Follow-up&	Visit	472 (46.9%)	3-month Follow-up&	Visit	425 (52.4%)
	Received recommended services (VA or non-VA)	370 (78.4%)			

^Mean (SD) for number of PT session for those with at least 1 PT session: 3.1(1.5); Mean (SD) for number of PiP session for those with at least 1 PiP: 3.3(1.6).
$There were n=35 Veterans with multiple 6-week follow-up visits in PNP arm (32 with 2 visits, 3 with 3) and n=18 in SCP arm (17 with 2 visits, 1 with 3).
*PiP sessions for n=377 stratified to high/medium risk – there were an additional 7 subjects with missing 6-week follow-up (n=6) or stratified to low risk (n=1) that received at least one PiP call.
&There were n=8 Veterans with two 3-month follow-up visits in PNP arm and n=1 in SCP arm.

Enrollment

Clinic	Final Enrollment	Completed 3M Follow-up (%)*	Final Analysis 3M Follow-up (%)^
Sequence Care Pathway			
(544BZ) GREENVILLE SC	129	82 (63.6)	92 (71.3)
(657A0) ST. LOUIS MO-JB	121	74 (61.2)	70 (57.9)
(613GC) STEPHENS CITY WV	119	46 (38.7)	68 (57.1)
(558GA) GREENVILLE NC	119	60 (50.4)	57 (47.9)
(544) COLUMBIA SC	115	69 (60.0)	74 (64.3)
(549) DALLAS, TX	100	42 (42.0)	48 (48.0)
(539GD) FLORENCE CBOC	67	25 (37.3)	30 (44.8)
(657GB) ST. LOUIS MO CBOC	41	27 (65.9)	22 (53.7)
	811	**424(52.4)**	**461(56.8)**
Pain Navigator Pathway			
(657) ST. LOUIS MO-JC	129	84 (65.1)	69 (53.5)
(544GD) ANDERSON SC CBOC	124	68 (54.8)	63 (50.8)
(593GE) SOUTHEAST PCC	119	42 (35.3)	45 (37.8)
(693) WILKES-BARRE, PA	118	40 (33.9)	69 (58.5)
(589A7) ROBERT J. DOLE	114	61 (53.5)	59 (51.8)
(657GD) ST. CHARLES MO CBOC	109	47 (43.1)	47 (43.1)
(613) MARTINSBURG WV	108	69 (63.9)	81 (75.0)
(539) CINCINNATI	103	38 (36.9)	62 (60.2)
(549A4) BONHAM, TX	82	23 (28.0)	42 (51.2)
	1006	**472(46.9)**	**537(53.4)**
Total	**1817**	**897 (49.4)**	**998 (54.9)**

*** Attended 3 Months visit; ^ missing and out of window completed 3M follow-up boosted by surveys in window**

Timeline of Activities

AIM-Back

19 clinics randomized

Cluster Randomization

Wave 1 Randomization :October 2020
Wave 2 Randomization: October 2021



Timeline of Activities

AIM-Back

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FY21 FY22 FY23 FY24 FY25

17 clinics enrolled Veterans

Enrollment

Enrollment Program/Survey Launch: February 2021
Final Enrollment Date: February 2024
Total Enrollment: 1817
Total Baseline Surveys: 996

Timeline of Activities

AIM-Back

19 clinics randomized

Cluster Randomization

Wave 1 Randomization :October 2020
Wave 2 Randomization: October 2021

1817 Participating Veterans

Offboarding

Final 3 Month Follow Up (Clinical): May 2024
Final 3 Month Follow up Survey: April 2024
Final 12 Month Survey Completed: January 2025

FY21 | FY22 | FY23 | FY24 | FY25

17 clinics enrolled Veterans

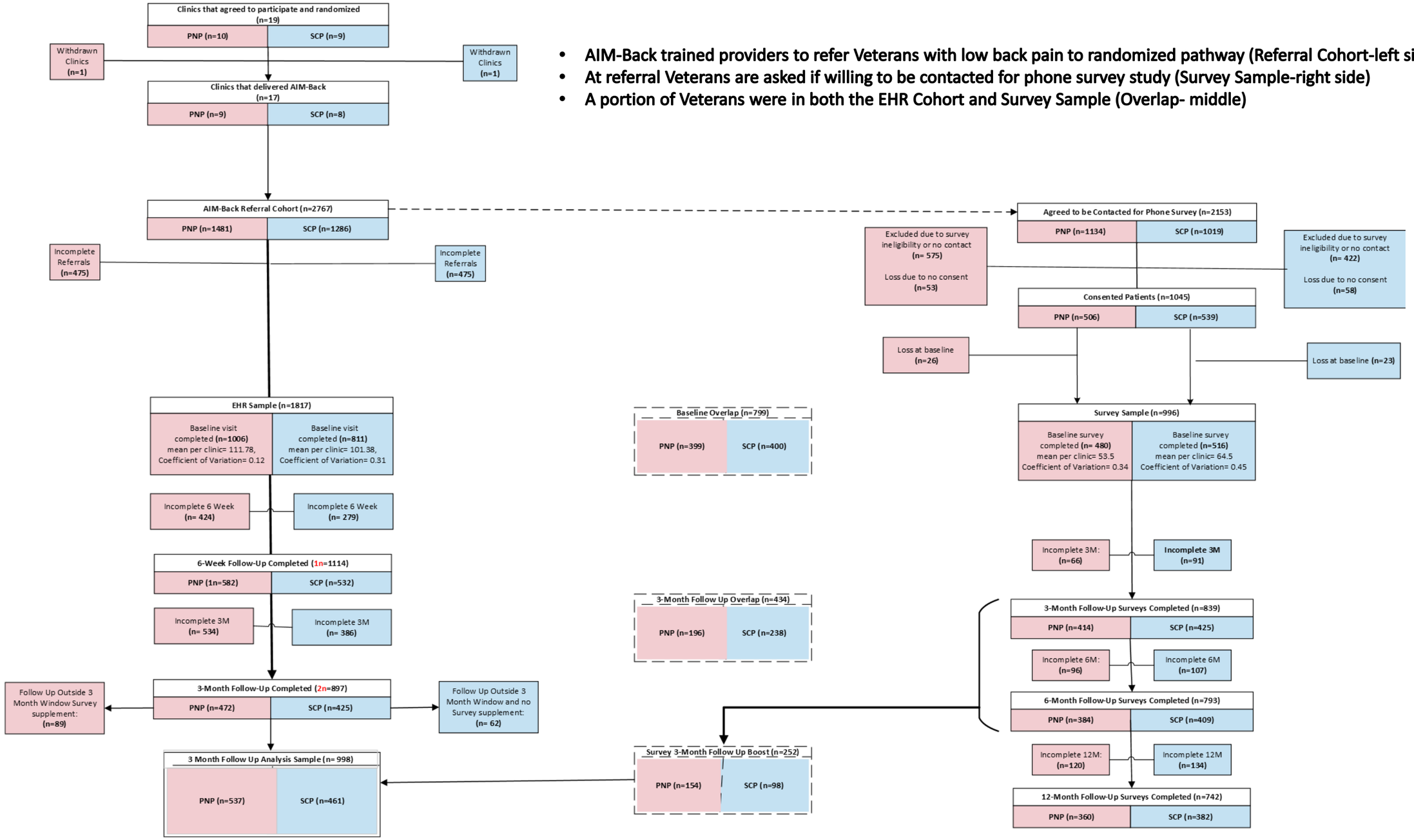
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CONSORT

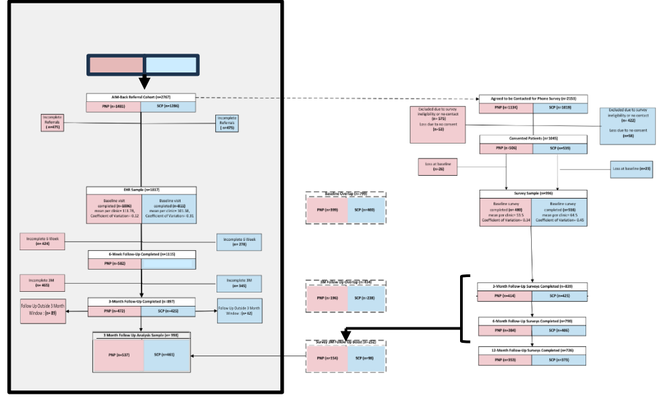
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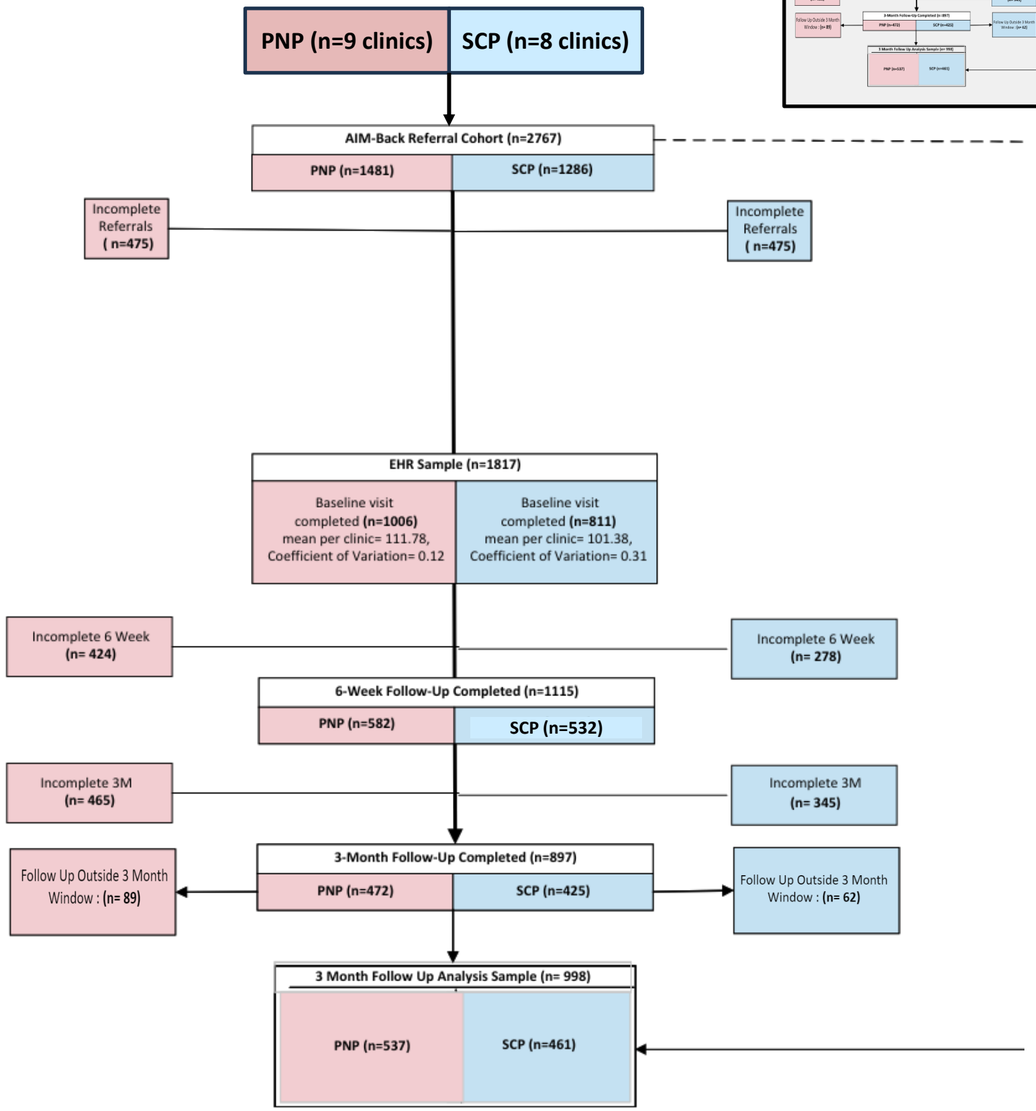
- AIM-Back trained providers to refer Veterans with low back pain to randomized pathway (Referral Cohort-left side)
- At referral Veterans are asked if willing to be contacted for phone survey study (Survey Sample-right side)
- A portion of Veterans were in both the EHR Cohort and Survey Sample (Overlap- middle)



CONSORT- EHR/Referral

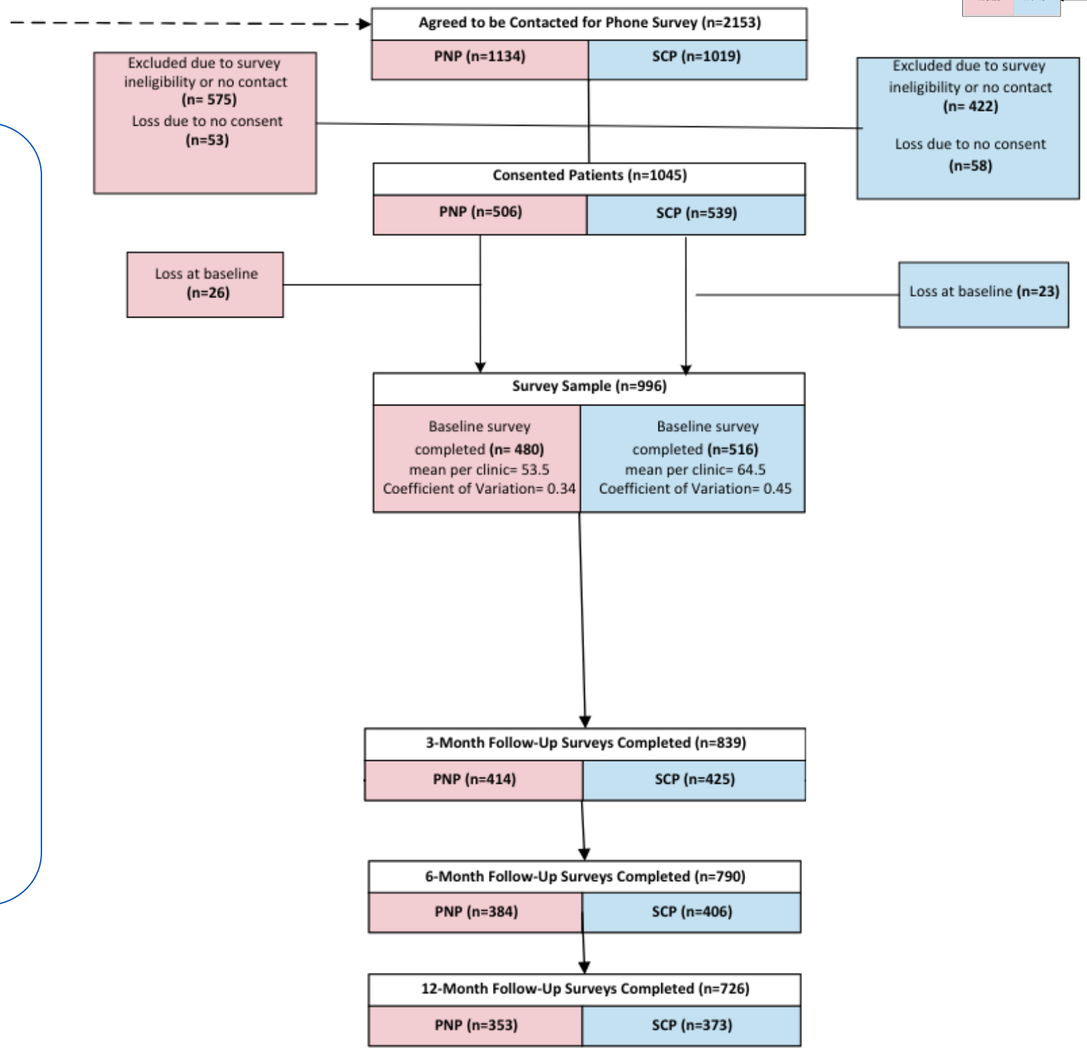
- **2767 Veterans Referred (Referral Cohort)**
- **1817 Veterans Enrolled (EHR Sample)**
- **998 Veterans with 3 Month Follow Up (54.9%)**



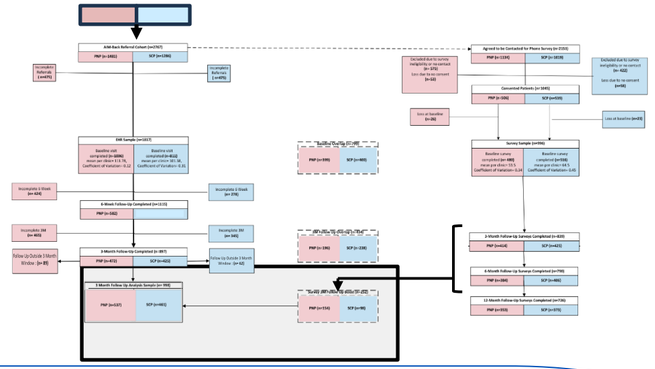


CONSORT- Survey Sample

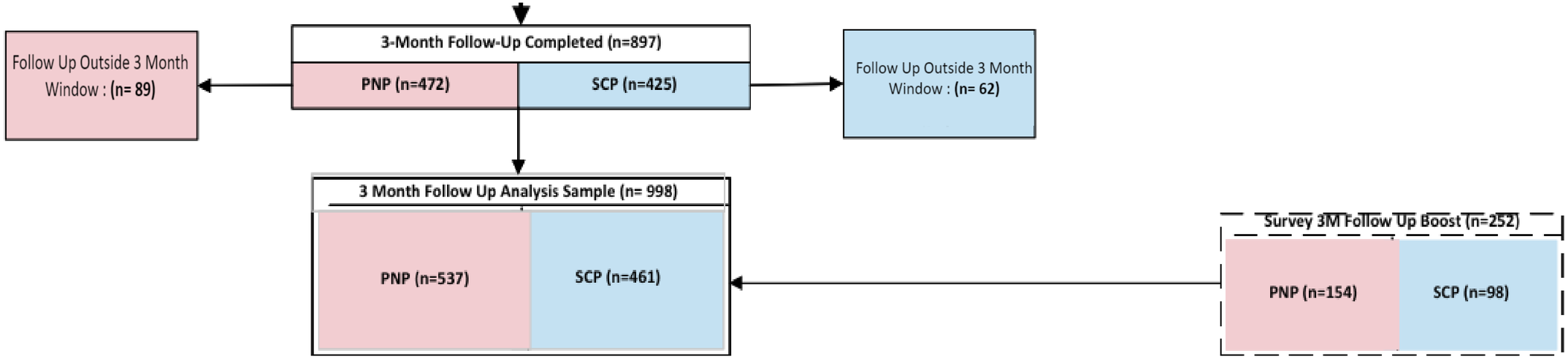
- **2153 Veterans Agreed to Be Contacted**
- **996 Veterans Enrolled in Surveys**
- **839 Veterans completed 3 Month Follow Up (84.2%)**



Final Analysis 3M Follow Up



- **746 Veterans in the EHR Cohort Completed a 3M visit in the follow up window (41.1%)**
- **252 Veterans who missed their EHR 3M Follow up were added from having a survey in the follow up window**
- **998 Veterans with 3M follow up outcomes were included in the Final Analysis (54.9%)**



Veteran Feedback



“I have recommended this to others. It seems like the therapy is making a difference.” -Wilkes Barre VAMC Pennsylvania

“I used to agree that my back pain is terrible and never going to get better, now I disagree. The exercises to strengthen to my core have really helped my back and also my hip. I really appreciate everything everybody has done.” Dallas VAMC

“I want to shout from the rafters how great my physical therapist in KY was. She was wonderful. Gave me great instruction, arranged for me to get a traction table and TENS unit. She was one of those rare people who listens to you and remembers appt. to appt. what you talked about. I moved last month and now have to get established with a new VA.” Florence CBOC

Veteran Feedback



“Because of the study, "I was able to get into chiropractic, massage, acupuncture, with the pain management side (navigator), and with great communication with primary care, I am doing so much better (90% better), I could barely walk coming into this program..."
Bonham CBOC

“My physical therapist has been wonderful. She got me from stuck in the bed to functional. I do my stretches every day.”
Florence CBOC