NOHARM Study Provides Non-Pharmacological Options to Manage Pain After Surgery

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ABSTRACT

Opioids are used to manage post-operative pain but can lead to unintended consequences such as long-term use and addiction. **N**on-pharmacological **O**ptions in post-operative **H**ospital-based **A**nd **R**ehabilitative pain **M**anagement (NOHARM) is a pragmatic clinical trial designed to test an approach that provides patient education and support for using alternative non-pharmacological treatments for pain that may reduce or eliminate the need for opioids. The study involves 32 Mayo Clinic surgical practices throughout the Mayo Clinic Enterprise, which form 22 clusters. Clusters were randomized to 5 groups, and each group will "go live" with the intervention at 7-month intervals. Qualifying patients have resources populate their patient portal prior to their surgery. This includes the Healing After Surgery (HAS) Guide, a link to the HAS webpage, and the study phone number. The HAS Guide describes 13 non-pharmacological pain care (NPPC) modalities (See Table 1). Patients select which modalities they are interested in pursuing and these selection auto-populate their electronic health record (EHR). Surgical and clinical staff support patient modality selections and educate patients on how to self-administer the modalities once they leave the hospital. Surveys are used to follow patient progress. 57,543 patients have been enrolled with 30,570 patients receiving the intervention. The last group of practices will go live on July 3, 2023, and we are currently pulling our first large data set for analysis. We anticipate including these NPPC modalities to surgical pain standard of care will be beneficial to our patients and decrease the need for opioids in treating surgical pain

STUDY DESIGN

Pragmatic Clinical Trials

Pragmatic clinical trials seek to determine the effectiveness of an intervention in a real-world setting to inform clinical decision making (Roland and Torgerson, 1998).

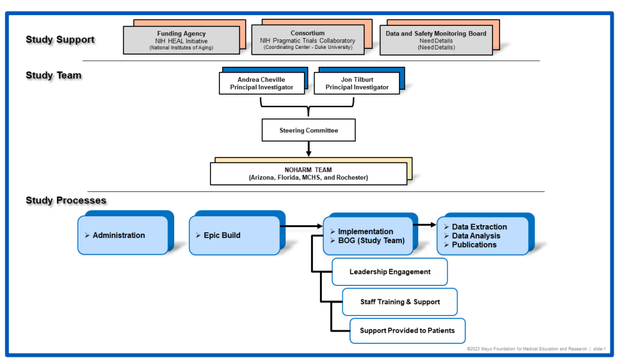

Figure 1: Organizational Structure of the NOHARM Study

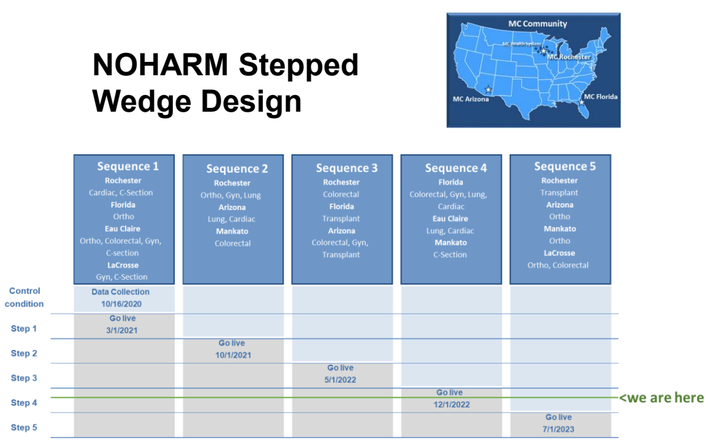

Figure 2: The NOHARM Study is an Enterprise wide, Stepped-Wedge Cluster-Randomized Pragmatic Clinical Trial

INTERVENTION

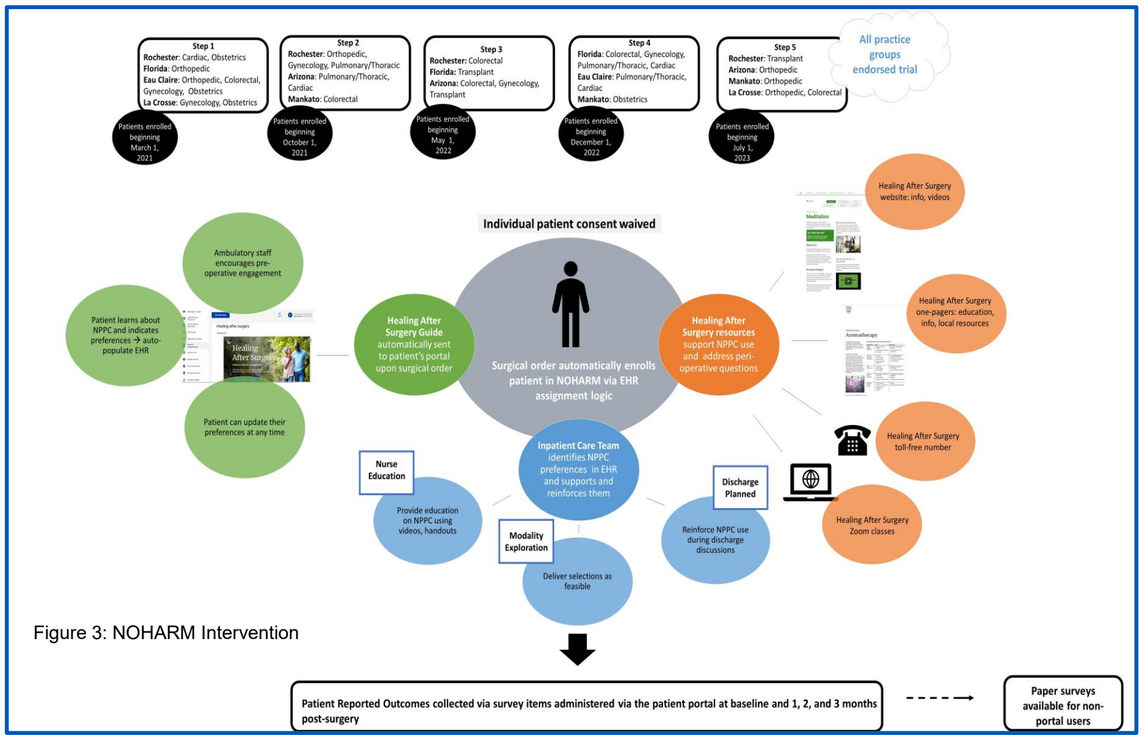

Figure 3: NOHARM Intervention

Non-Pharmacological Pain Care Techniques

Movement	Relaxation	Physical
• Walking	• Meditation	• Acupressure
• Yoga	• Relaxed Breathing	• Massage
• Tai Chi	• Music Listening	• Cold or Heat
	• Guided Imagery	• TENS
	• Muscle Relaxation	
	• Aromatherapy	

Table 1: Patients are offered non- pharmacological techniques to help manage pain after surgery.

RESULTS

Participants

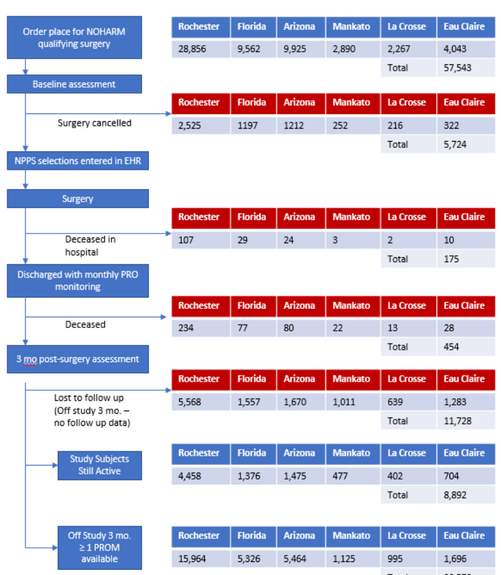

Figure 4: Participant flow and cumulative, site-specific tracking

Study Demographics

Characteristics		Rochester Number	%	Florida Number	%	Arizona Number	%	Eau Claire Number	%	La Crosse Number	%	Mankato Number	%	Total Number	%
Total Enrolled:															
Gender	Female	16836	58.3%	5737	60.0%	5447	54.9%	2701	66.8%	1649	72.7%	2039	70.6%	34409	59.8%
	Male	11987	41.5%	3821	40.0%	4476	45.1%	1342	33.2%	618	27.3%	850	29.4%	23094	40.1%
	Unknown	33	0.1%	4	0.0%	2	0.0%	0	0.0%	0	0.0%	1	0.0%	40	0.1%
Ethnicity	Hispanic or Latino	800	2.8%	513	5.4%	1116	11.2%	58	1.4%	68	3.0%	135	4.7%	2690	4.7%
	Not Hispanic or Latino	27350	94.8%	8782	91.8%	8584	86.5%	3970	98.2%	2188	96.5%	2703	93.5%	53577	93.1%
	Unknown	706	2.4%	267	2.8%	225	2.3%	15	0.4%	11	0.5%	52	1.8%	1276	2.2%
Race	American Indian/Alaskan Native	151	0.5%	18	0.2%	158	1.6%	20	0.5%	6	0.3%	6	0.2%	359	0.6%
	Asian	591	2.0%	185	1.9%	336	3.4%	38	0.9%	19	0.8%	20	0.7%	1189	2.1%
	Black or African American	736	2.6%	963	10.1%	376	3.8%	31	0.8%	35	1.5%	89	3.1%	2230	3.9%
	Native Hawaiian or Other Pacific Islander	27	0.1%	11	0.1%	41	0.4%	3	0.1%	3	0.1%	6	0.2%	91	0.2%
	White	26538	92.0%	8077	84.5%	8654	87.2%	3923	97.0%	2156	95.1%	2702	93.5%	52050	90.5%
	More than one race	87	0.3%	31	0.3%	61	0.6%	10	0.2%	6	0.3%	5	0.2%	200	0.3%
	Unknown	726	2.5%	277	2.9%	299	3.0%	18	0.4%	42	1.9%	62	2.1%	1424	2.5%
Age	Mean	58.97		61.93		60.15		57.30		56.27		55.75		59.28	
	Median	62		64		63		62		60		61		63	
	Standard Deviation	16.33		13.68		15.23		18.34		17.75		19.75		16.22	
	Minimum	18		18		18		19		18		18		18	
	Maximum	103		102		101		106		100		99		106	

Table 2: The demographics of the NOHARM study are predominately non-Hispanic white patients.

NEXT STEPS

- All surgical units will be live with the intervention starting on July 3, when Tranche 5 goes live.
- The first large data pull for the study is currently in process for subgroup analysis and primary study outcomes.
- Papers in process focused on
  - Study Design
  - Cancer Pain
  - Post Operative Care
  - TENS Muscle Stimulation
  - Total Knee Arthroplasty
  - Rurality
  - Native American Population

CONCLUSIONS

As we move to onboarding the last of our surgical units, the NOHARM intervention will mature and prepare for integration into standard clinical practice.

NOHARM TEAM

Thank YOU! The NOHARM Team ☺

REFERENCES

1. Redmond, S., Mayo Clinic NOHARM Research Team., Tilburt, J. and Cheville, A. Non-pharmacological Options in Postoperative Hospital-Based and Rehabilitation Pain Management (NOHARM): Protocol for a Stepped-Wedge Cluster-Randomized Pragmatic Clinical Trial. Pain Ther. 11, 1037–1053 (2022). https://doi.org/10.1007/s40122-022-00393-x
2. Roland, M., Torgerson, D.J., *et al.*, What are pragmatic trials?. BMJ, 316, 285 (1998).

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