Training and Engaging Patients in Research Data Analysis

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ACTIVATE

ACTIVATE study question and design

- Randomized pragmatic trial for patients on long term opioids (>3 months) in two large, primary care clinics

- Do patients on long term opioids who receive a patient activation intervention in primary care have better outcomes than those in usual care?

- Behavioral intervention vs. usual care
  - 4 group sessions focused on empowering patients to take active role in health care and pain management

ACTIVATE study results

- Enrolled 376 patients over 18 months (2015-2018)
- Patient-reported outcomes at baseline, 6 and 12 months
- Over 90% response rate for 6 and 12 month follow ups

ACTIVATE stakeholders

- 12 clinical and operational stakeholders
  - Primary care, chronic pain, emergency department, pharmacy, psychiatry, chemical dependency (Kaiser)
  - Physicians from county health clinics
  - Patient advocacy organization (ACPA)
  - External researchers (from academia)

ACTIVATE stakeholders

- Patient stakeholders (5)
  - Stigma and marginalization of opioid use heightened importance of patient involvement
  - Three patients from KPNC
  - Two patients from Contra Costa County (FQHC)
  - Varying degrees of pain, opioid use, health
  - Differences in mobility and access to technology

Training and Integration of Stakeholder Groups

- Meet separately with both groups at first
- Basic training for patients (human subjects, study overview)
- Large quarterly meetings with full group

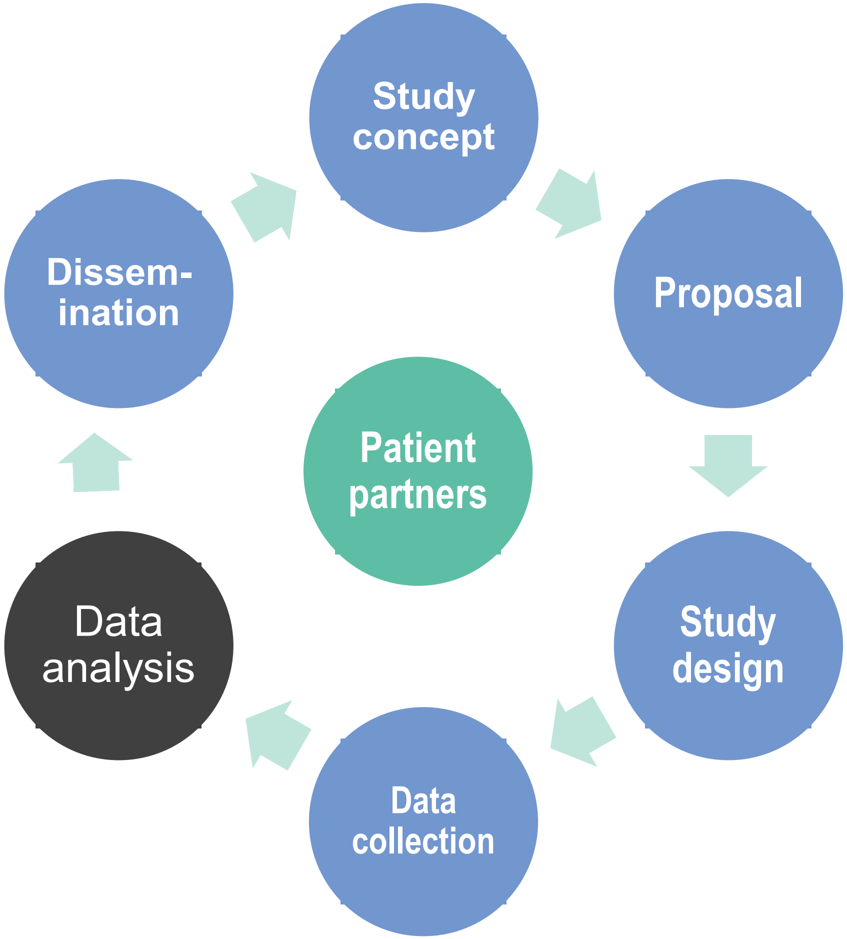
Role of ACTIVATE patient stakeholders

- Developing **research questions**
- Advising on **recruitment strategies**
- Defining **eligibility criteria**
- Identifying relevant **patient-centered outcomes**
- Refined content and format of the **intervention curriculum**
- Increased **empathy and awareness** for research team
- Increased **sensitivity to stigmas and barriers** to care

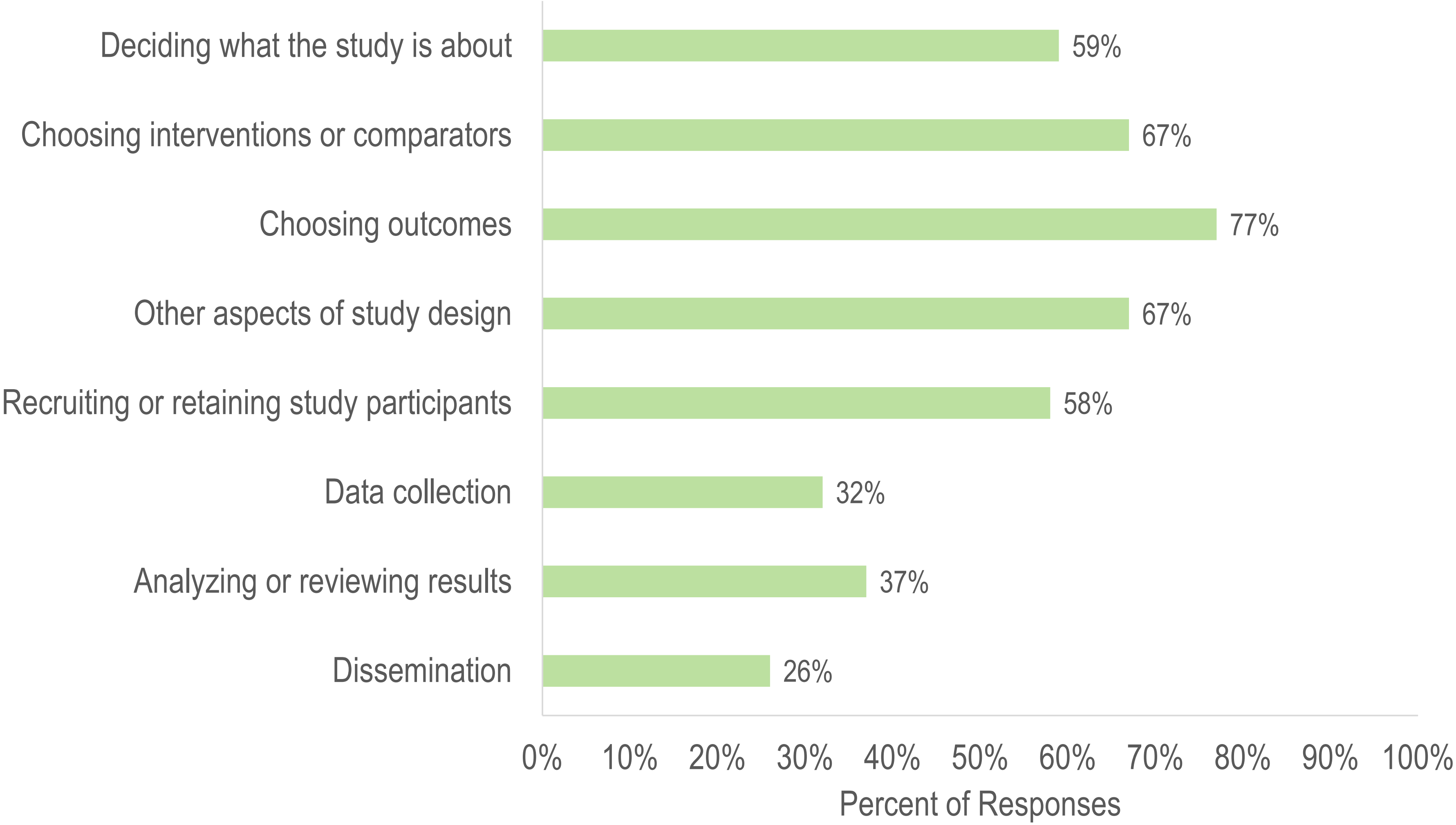
Engagement Challenges

- Keeping engaged during <u>slow</u> phases (data collection)
- Involving patients in <u>later</u> phases (data interpretation and dissemination)

Data analysis: the mysterious "black box" of patient engagement



Phases of PCORI projects that partners are engaged



Patient engagement resources are now plentiful but still limited on topic of data analysis

https://www.pcori.org/engagement-resources

Phases of Research

Implementation *(11)*

Participant Recruitment/Retention *(7)*

Dissemination *(5)*

Evaluation *(4)*

Translation *(3)*

Study/Project Design *(2)*

Engagement in data phase

- Why are patient partners typically underutilized in this area?
    - Time consuming!
    - Impact is uncertain!
    - Variety of education and experience
    - Perception and beliefs (only for scientists)

Training patient partners in ACTIVATE study

- Seven one-hour lessons via Web Ex
  - Basic research concepts (different study designs, generating study hypothesis, randomization, bias)
  - Research instruments (surveys, etc.)
  - Data collection
  - Data formats (tables, graphs)
  - Basic statistics (risk estimates, C.I., p-values)
  - Causality vs association
  - Clinical vs statistical significance

Training patient partners

- Additional topics
  - Questionnaire to data set (evolution of a survey question: questionnaire development>online survey>data dictionary>data cleaning >SAS output>final results table)
  - Reading journal articles (YouTube)
  - Data privacy (see PORTAL toolkit)

Variety of learning techniques

- Discussion (e.g., how to use different study designs to look at a particular research question, like the effect of medication on people with given condition)
- Assignments
  - Coding unstructured data
  - Creating narrative from baseline characteristics of study population, using tools we learned and personal experience (tell a story with data: who, when, where and how)
  - Using PICO method to evaluate different studies

Variety of learning techniques

The PICO approach

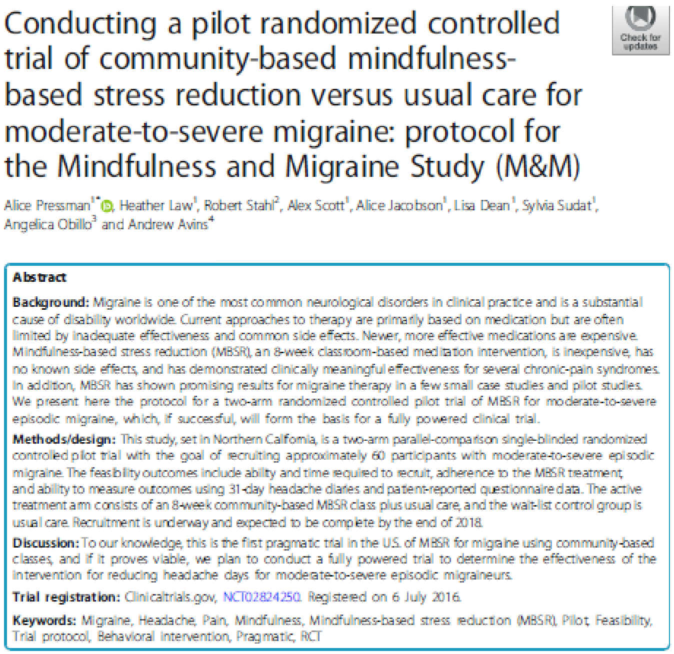
Population: Population impacted by the research questions, often based on a specific health problem or care delivery system

Intervention: The main treatment, test, or approach for the health problem/care delivery system under investigation

Comparator: Alternative treatment, test, or approach to the main intervention (may be multiple comparators)

Outcome: Measurable effect of the intervention/comparator (lab value, test result, quality of life measure, etc.)

Using the PICO approach to evaluate studies



Conducting a pilot randomized controlled trial of community-based mindfulness-based stress reduction versus usual care for moderate-to-severe migraine: protocol for the Mindfulness and Migraine Study (M&M)

Alice Pressman[1*], Heather Law[1], Robert Stahl[2], Alex Scott[1], Alice Jacobson[1], Lisa Dean[1], Sylvia Sudat[1], Angelica Obillo[3] and Andrew Avins[4]

Abstract

Background: Migraine is one of the most common neurological disorders in clinical practice and is a substantial cause of disability worldwide. Current approaches to therapy are primarily based on medication but are often limited by inadequate effectiveness and common side effects. Newer, more effective medications are expensive. Mindfulness-based stress reduction (MBSR), an 8-week classroom-based meditation intervention, is inexpensive, has no known side effects, and has demonstrated clinically meaningful effectiveness for several chronic-pain syndromes. In addition, MBSR has shown promising results for migraine therapy in a few small case studies and pilot studies. We present here the protocol for a two-arm randomized controlled pilot trial of MBSR for moderate-to-severe episodic migraine, which, if successful, will form the basis for a fully powered clinical trial.

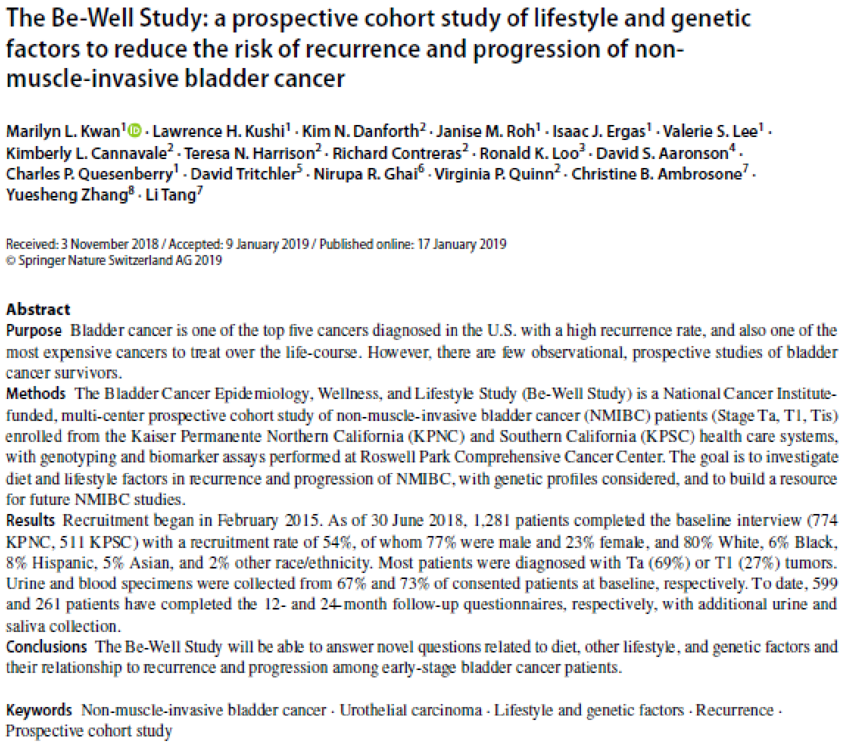
Methods/design: This study, set in Northern California, is a two-arm parallel-comparison single-blinded randomized controlled pilot trial with the goal of recruiting approximately 60 participants with moderate-to-severe episodic migraine. The feasibility outcomes include ability and time required to recruit, adherence to the MBSR treatment, and ability to measure outcomes using 31-day headache diaries and patient-reported questionnaire data. The active treatment arm consists of an 8-week community-based MBSR class plus usual care, and the wait-list control group is usual care. Recruitment is underway and expected to be complete by the end of 2018.

Discussion: To our knowledge, this is the first pragmatic trial in the U.S. of MBSR for migraine using community-based classes, and if it proves viable, we plan to conduct a fully powered trial to determine the effectiveness of the intervention for reducing headache days for moderate-to-severe episodic migraineurs.

Trial registration: Clinicaltrials.gov, NCT02824250. Registered on 6 July 2016.

Keywords: Migraine, Headache, Pain, Mindfulness, Mindfulness-based stress reduction (MBSR), Pilot, Feasibility, Trial protocol, Behavioral intervention, Pragmatic, RCT

	Study 1	Study 2	Study 3
Population			
Intervention			
Comparator			
Outcome			
Time Frame			
Setting			



The Be-Well Study: a prospective cohort study of lifestyle and genetic factors to reduce the risk of recurrence and progression of non-muscle-invasive bladder cancer

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Abstract

Purpose Bladder cancer is one of the top five cancers diagnosed in the U.S. with a high recurrence rate, and also one of the most expensive cancers to treat over the life-course. However, there are few observational, prospective studies of bladder cancer survivors.

Methods The Bladder Cancer Epidemiology, Wellness, and Lifestyle Study (Be-Well Study) is a National Cancer Institute-funded, multi-center prospective cohort study of non-muscle-invasive bladder cancer (NMIBC) patients (Stage Ta, T1, Tis) enrolled from the Kaiser Permanente Northern California (KPNC) and Southern California (KPSC) health care systems, with genotyping and biomarker assays performed at Roswell Park Comprehensive Cancer Center. The goal is to investigate diet and lifestyle factors in recurrence and progression of NMIBC, with genetic profiles considered, and to build a resource for future NMIBC studies.

Results Recruitment began in February 2015. As of 30 June 2018, 1,281 patients completed the baseline interview (774 KPNC, 511 KPSC) with a recruitment rate of 54%, of whom 77% were male and 23% female, and 80% White, 6% Black, 8% Hispanic, 5% Asian, and 2% other race/ethnicity. Most patients were diagnosed with Ta (69%) or T1 (27%) tumors. Urine and blood specimens were collected from 67% and 73% of consented patients at baseline, respectively. To date, 599 and 261 patients have completed the 12- and 24-month follow-up questionnaires, respectively, with additional urine and saliva collection.

Conclusions The Be-Well Study will be able to answer novel questions related to diet, other lifestyle, and genetic factors and their relationship to recurrence and progression among early-stage bladder cancer patients.

Keywords Non-muscle-invasive bladder cancer · Urothelial carcinoma · Lifestyle and genetic factors · Recurrence · Prospective cohort study

Making predictions

Baseline use of online portal

Ways kp.org has been used, n(%)	Total (n=376)	Intervention (n=189)	Usual Care (n=187)	P value
Emailed doctor	322 (85.6)	165 (87.3)	157 (84.0)	.64
Check lab results	317 (84.3)	160 (84.7)	157 (84.0)	.98
Schedule appt	252 (67.0)	128 (67.7)	124 (66.3)	.96
Ordered Rx refill	274 (72.9)	139 (73.5)	135 (72.2)	.96
Used Healthy Lifestyle Programs	89 (23.7)	47 (24.9)	42 (22.5)	.86

Patient partners predicted the use of online healthy living classes would increase for Intervention group after 6 months, and they did! And look at that p-value! Wow!

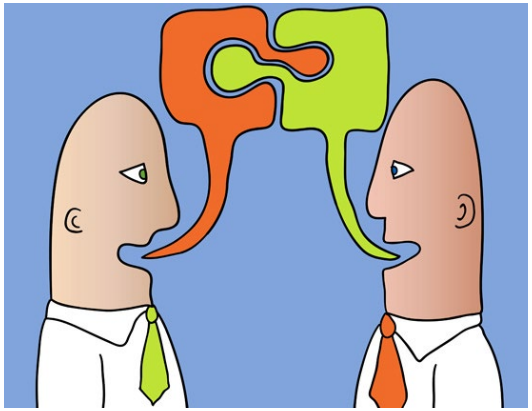
6 month follow up use of online portal

Ways kp.org has been used, n(%)	Total (n=376)	Intervention (n=189)	Usual Care (n=187)	P value
Emailed doctor	291 (82.9)	147 (85.0)	144 (80.9)	.31
Check lab results	244 (69.5)	119 (68.8)	125 (70.2)	.77
Schedule appt	209 (59.5)	110 (63.6)	99 (55.6)	.13
Ordered Rx refill	259 (73.8)	131 (75.7)	128 (71.9)	.42
Used Healthy Lifestyle Programs	118 (33.6)	68 (39.3)	50 (28.1)	.03

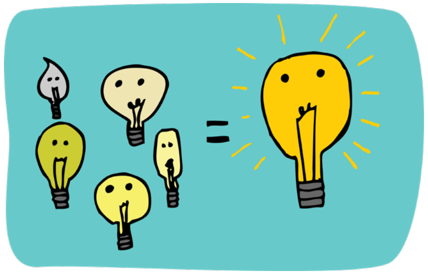
Personal connections and insights

Why is there such a big discrepancy between years in pain and years in treatment?

	Total (n=376)
How long have you been in pain? *Years, mean(sd)*	14.6 (12.2)
How long have you been seeking treatment for pain? *Years, mean(sd)*	12.7 (10.9)
How long have you been taking prescription opioids? *Years, mean(sd)*	9.0 (8.3)



Why was self-reported depression at baseline much lower than expected in both groups?

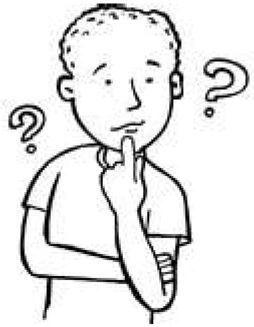


	Total (n=376)	Intervention (n=189)	Usual Care (n=187)	P value
PHQ-9 Score, mean (sd)	6.8 (5.3)	6.7 (5.3)	7.0 (5.3)	.64

Thinking critically

Baseline self-reported opioid use

	Intervention (n=189)	Usual Care (n=187)	P value
In past 2 weeks, # days take Rx opioids? mean (SD)	11.6 (3.6)	12.5 (3.1)	0.019



Why is there a difference between self-report and EHR data? Which to use and when?

Baseline opioid use from EHR

	Intervention (n=189)	Usual Care (n=187)	P value
Daily morphine milligram equivalent in 6mo. prior to baseline, mg, mean (SD)	35.8 (68.9)	32.1 (43.8)	.54

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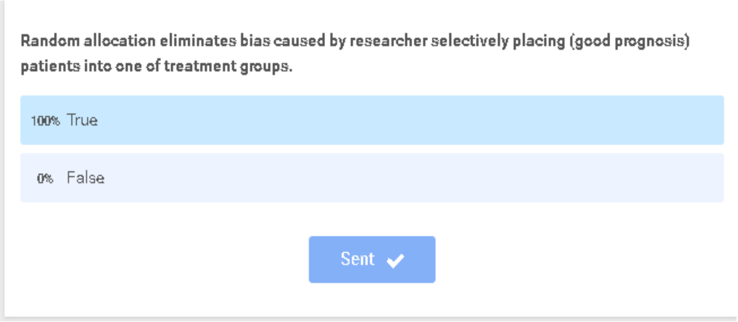
Insights on follow-up data and the effect on dissemination

	Intervention (n=166)	Usual Care (n=176)	P value
How do you currently manage pain? n(%)			
Opioid meds from doctor	133 (80)	153 (87)	.09
Non-opioid med from doctor	33 (20)	50 (28)	.07
Over the counter med	75 (45)	80 (45)	.96
Complementary/Alternative med	25 (15)	17 (10)	.13
Meditation, relaxation, mindfulness	61 (37)	34 (19)	<.001
Pain classes or therapy	9 (5)	3 (2)	.06
Massage/other bodywork	39 (23)	35 (20)	.42
Exercise, stretching, or physical therapy	127 (77)	100 (57)	<.001

- Are there different messages for different target audiences?

Assessing understanding

- Teach back method (presenting to each other and to the group)
- Real time anonymous polls



Random allocation eliminates bias caused by researcher selectively placing (good prognosis) patients into one of treatment groups.

100% True

0% False

https://www.sli.do/

Anonymous fun way to get feedback!

Measuring Impact (impact on process of engagement)

- Impact on PI, clinicians and research staff
- Impact on patient partners
  - Increased confidence and skills
  - Increased involvement in engagement work
    - Attended conferences
    - Future engagement
    - Started Facebook Live on fibromyalgia
  - Increased health literacy

- *“I will never look at a table or figure the same!”*
- *“I found that analyzing the data piece by piece eventually told a story…Very cool stuff!”*

Measuring Impact (impact on study findings)

- Improved legitimacy of results
- Enhanced interpretation of data
  - Depression lower than expected in both groups at baseline
  - Pain severity and opioid dose not as important to patients as other measures like function, quality of life, etc.
  - Openness to non-opioid alternatives (due to stricter prescribing policies)
  - Experiential and low cost (accessible) parts of curriculum (e.g., mindfulness exercise, accessing online patient portal) more likely to be sustained

Reflections and Suggestions

- Provide **Research 101** training in the beginning (in addition to training on how to be patient stakeholder, human subjects training and study-specific training)
- Make data training an iterative process (spread out over course of the study, and provide refreshers at beginning of each session)
- Provide comprehensive glossary
- Provide additional online learning resources

Reflections and Suggestions

- Incorporate hands-on learning as much as possible
- Check in often and request feedback on topics and content
- ***Utilize staff who are interested in teaching or excited about the opportunity or topic (interns, recent graduates, etc.)***
- ***Request adequate funding for entire life cycle of project (through dissemination)***

Resources for Engaging Patients in Data Analysis

- *Talking about Data and Analysis* September 2016; sponsored by PCORI in partnership with Abt, Kaiser Permanente Washington Health Research
- PORTAL's Patient Engagement Toolkit, Kaiser Permanente Center for Health Research: https://research.kpchr.org/Patient-Engagement-Toolkit
- PCORI Methodology 101: Training booklet for patients and stakeholders: https://www.pcori.org/sites/default/files/PCORI-Methodology-101-Training-Booklet-and-Resource-Guide.pdf
- https://www.pcori.org/engagement-resources
  - Search for "Research 101" slides