The association of the Stanford Expectations of Treatment Scale (SETS) with pain and opioid dose expectations during a tapering program

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Introduction

Many calls to reduce opioid prescribing, but not enough research supporting methods/how.

“No good data to guide opioid tapering” (Eccleston et al, 2017)

“Guidelines are too aggressive” (Berna et al, 2015)

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What has prior work looked at?

Past opioid taper studies point to patient willingness to predict taper success.

Patient-Centered Prescription Opioid Tapering in Community Outpatients With Chronic Pain (Darnall et al 2018 JAMA Internal Medicine)

Broader healthcare research indicates patient expectations for treatment play a critical role in treatment outcome.

Implications of Placebo and Nocebo Effects for Clinical Practice: Expert Consensus (Evers et al 2018 Psychotherapy & Psychosomatics)

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What do we still need to do?

Examine the role of patient expectations in the opioid taper process.

What kinds of expectancies are important to measure?

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Our objective

Examine at baseline patient expectations (positive/negative) for an opioid tapering study with their expectations for pain and opioid dose changes to occur during their taper.

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The study: EMPOWER

EFFECTIVE MANAGEMENT OF PAIN AND OPIOID-FREE WAYS TO ENHANCE RELIEF

Study overview

Study Description

- Patient-centered opioid tapering program
  - Collaborative
  - Personalized
  - Voluntary
- Randomized controlled trial
  - Cognitive Behavioral Therapy (pain-CBT)
  - Chronic Pain Self-Management Program (CPSMP)
  - Focus on taper plan
- Pragmatic study, outpatient setting

Study Aims

- Help patients achieve their lowest comfortable opioid dose without increased pain at 12 months
- Comparative effectiveness of two behavioral treatment groups

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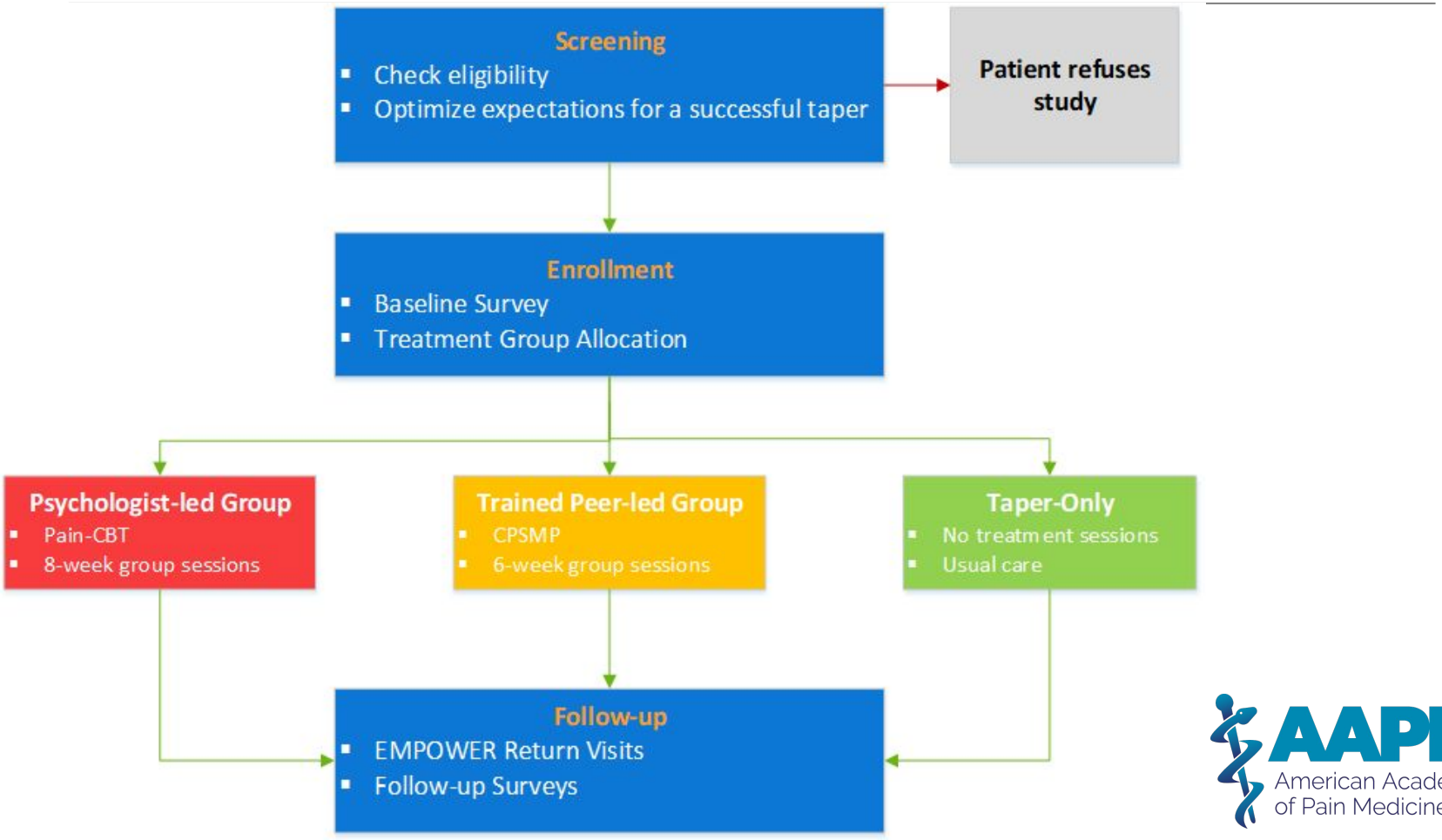
Study design



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Inclusion Criteria

- 18-85 years old
- Chronic pain (not related to cancer) for at least 6 months
- Taking ≥ 10 MEDD of prescription opioids daily for at least 3 months
- No moderate or severe Opioid Use Disorder (OUD)
- Not pregnant
- English fluent
- Appropriate for group classes
- Interested in tapering

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Demographics

- n = 210 patients
- 55.8% Male
- Race & ethnicity breakdown:
  - 85.0% Caucasian
  - 3.0% more than one race
  - 6.5% Hispanic
- Income breakdown:
  - 44.7% less than $50,000/yr household income
  - 7.5% greater than $150,000/yr household income
- Four state study: CA, AZ, CO, UT

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Variables and Measures

- Stanford Expectations of Treatment Scale
  - Positive and negative expectations for tapering experience
- Pain Expectations
- Opioid Dose Reduction Expectations

Detailed in *Comparative Effectiveness of Cognitive Behavioral Therapy for Chronic Pain and Chronic Pain Self-Management within the Context of Voluntary Patient-Centered Prescription Opioid Tapering: The EMPOWER Study Protocol* (Darnall et al 2020)
doi.org/10.1093/pm/pnz285
ClinicalTrials.gov Identifier: NCT03445988

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Variables: Stanford Expectations of Treatment Scale or SETS

- Example items:
  - “Reducing my opioids will be helpful for me.”
  - “I have fears about reducing my opioids.”
  - “I have confidence in working with my doctor to reduce my opioids.”
  - “I am nervous about possible negative effects of reducing my opioids.”
- Each is scored on a Numeric Rating Scale from 0 - 10

Validated in *Development of the Stanford Expectations of Treatment Scale (SETS): A tool for measuring patient outcome expectancy in clinical trials* (Younger et al 2012) doi.org/10.1177/1740774512465064

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Variables: Pain Expectations

- "Over the course of the study, I expect my pain to:"
  - "Improve substantially"
  - "Improve somewhat"
  - "Remain about the same"
  - "Worsen somewhat"
  - "Worsen substantially"

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Variables: Opioid Dose Expectations

- “Over the course of the study, I expect my pain to:”
  - "How much do you expect your opioid dose will DECREASE (%) over the duration of the 12 month study period?”

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Methods

Poly-ordinal logistic regression to examine the relationship between SETS positive and negative with pain expectations.

Linear Modeling to investigate the relationship between the SETS positive and negative scores with opioid taper expectations.

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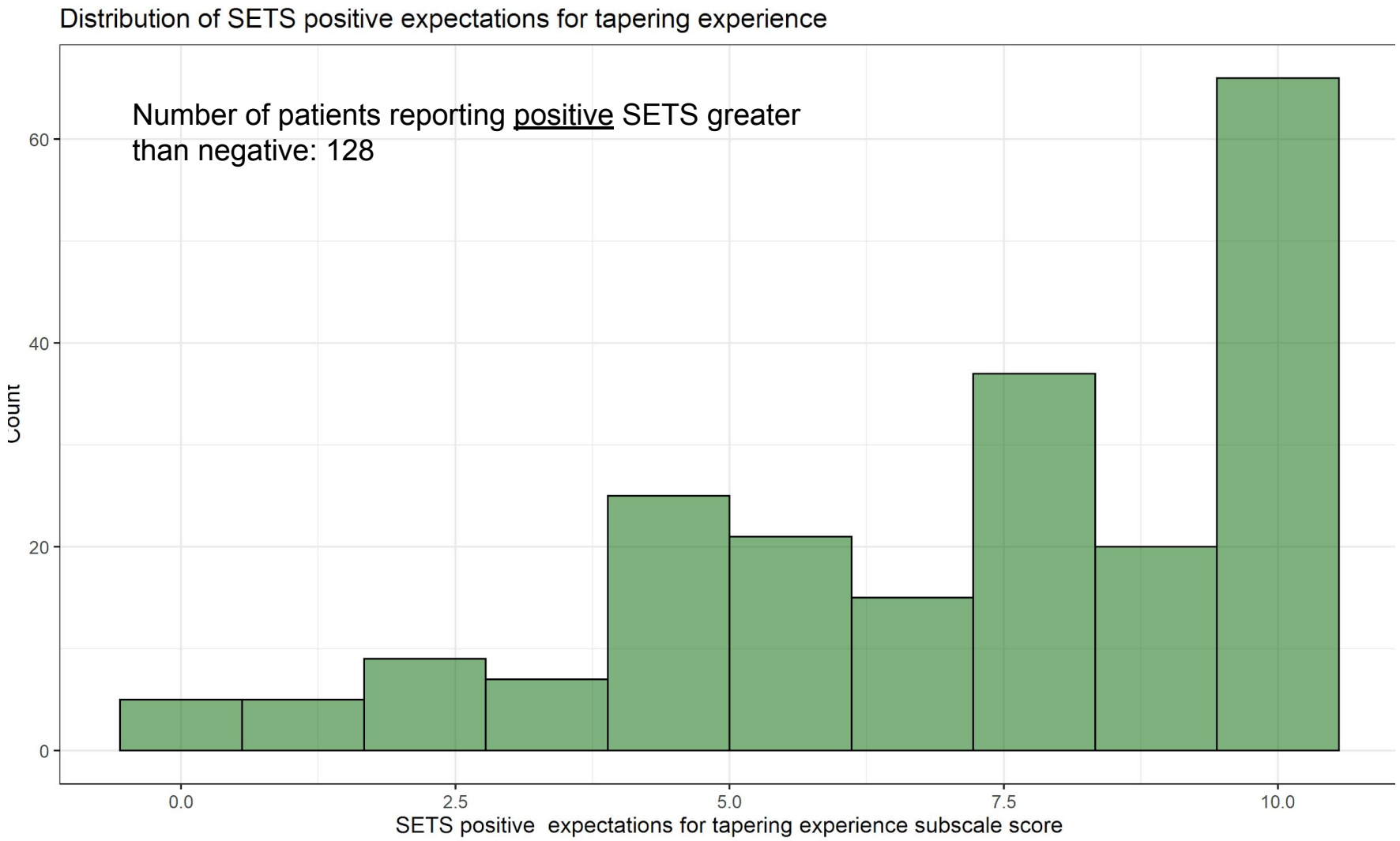
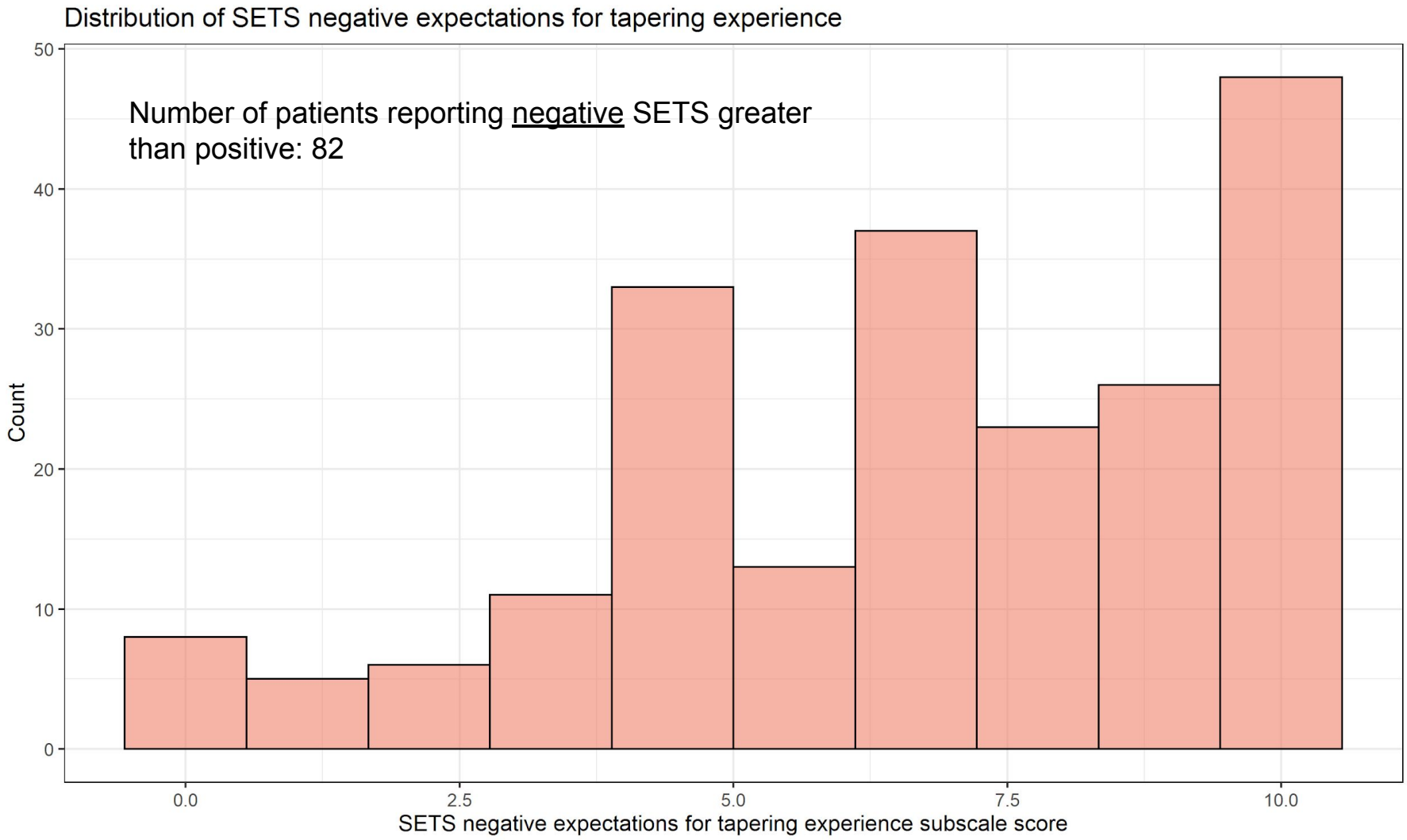
Results


Distribution of SETS positive expectations for tapering experience
Number of patients reporting positive SETS greater than negative: 128
Count
60
40
20
0
0.0
2.5
5.0
7.5
10.0
SETS positive expectations for tapering experience subscale score


Distribution of SETS negative expectations for tapering experience
Number of patients reporting negative SETS greater than positive: 82
Count
50
40
30
20
10
0
0.0
2.5
5.0
7.5
10.0
SETS negative expectations for tapering experience subscale score

Poly-Ordinal Regression of Pain Expectation

Predictor	Odds Ratio	Lower 95 CI	Upper 95 CI	McFadden's pseudo-R^2	p-value
SETS Positive	0.784	0.711	0.864	0.039	$p < 0.001$
SETS Negative	1.215	1.108	1.335	0.027	$p < 0.001$

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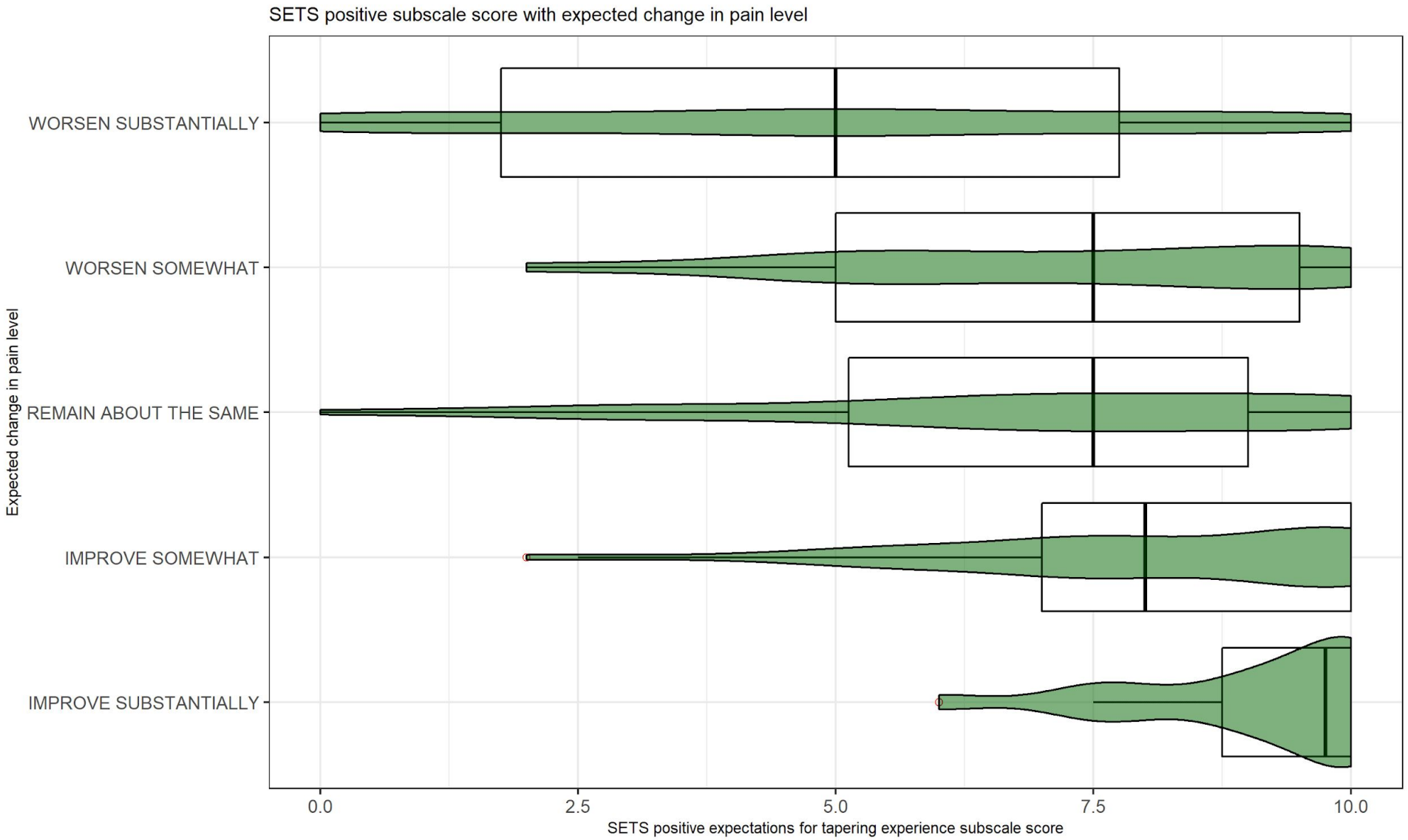
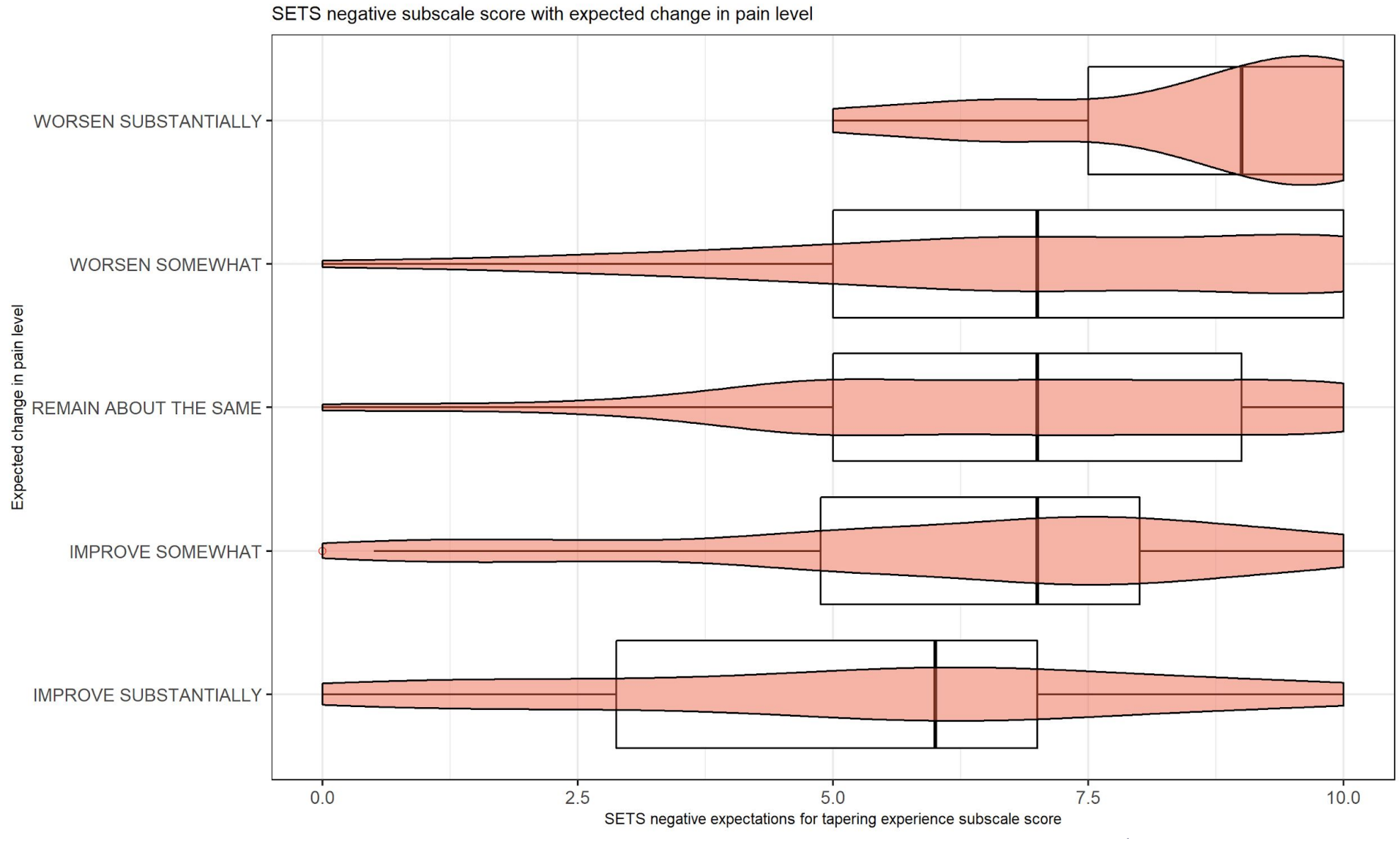
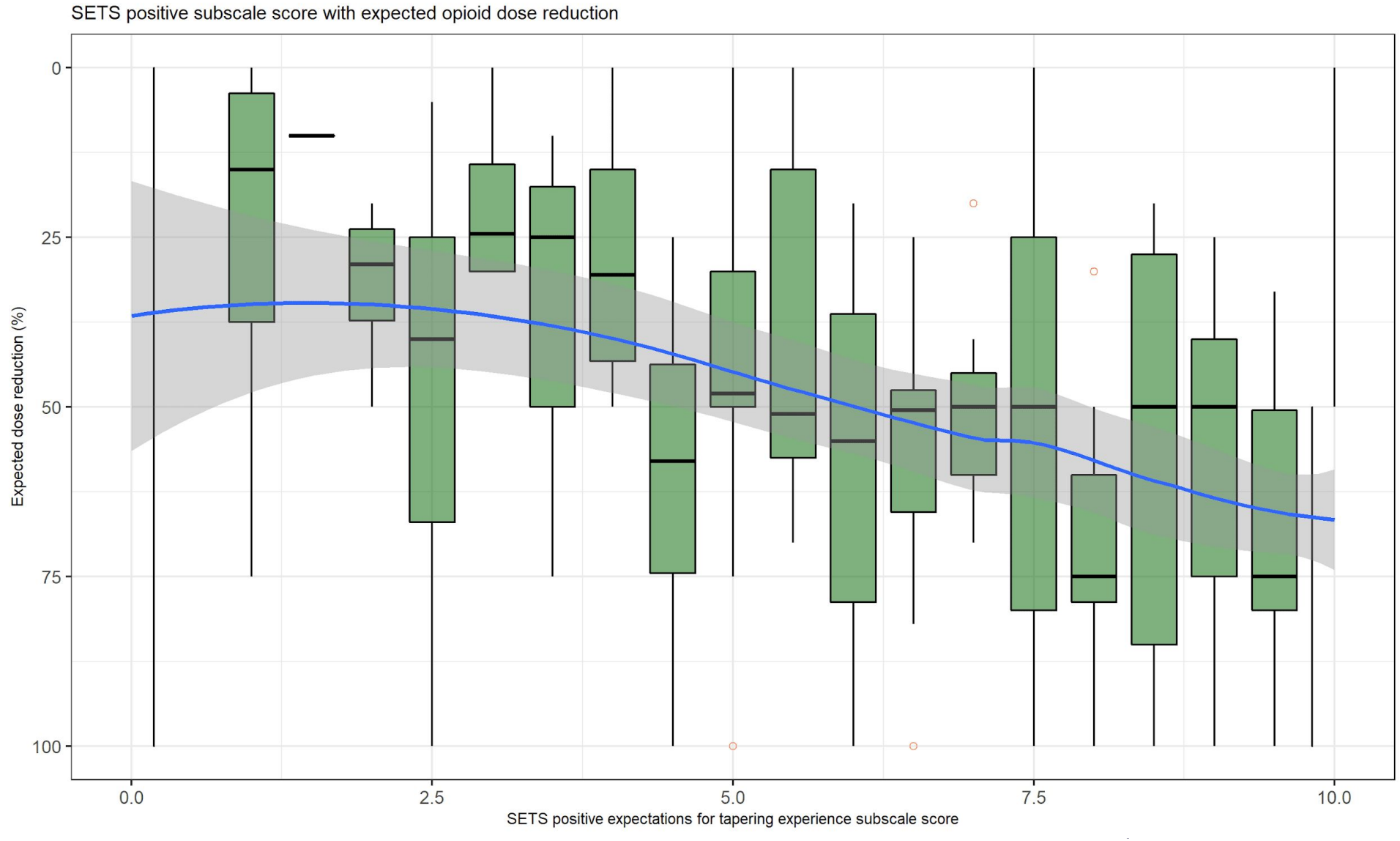
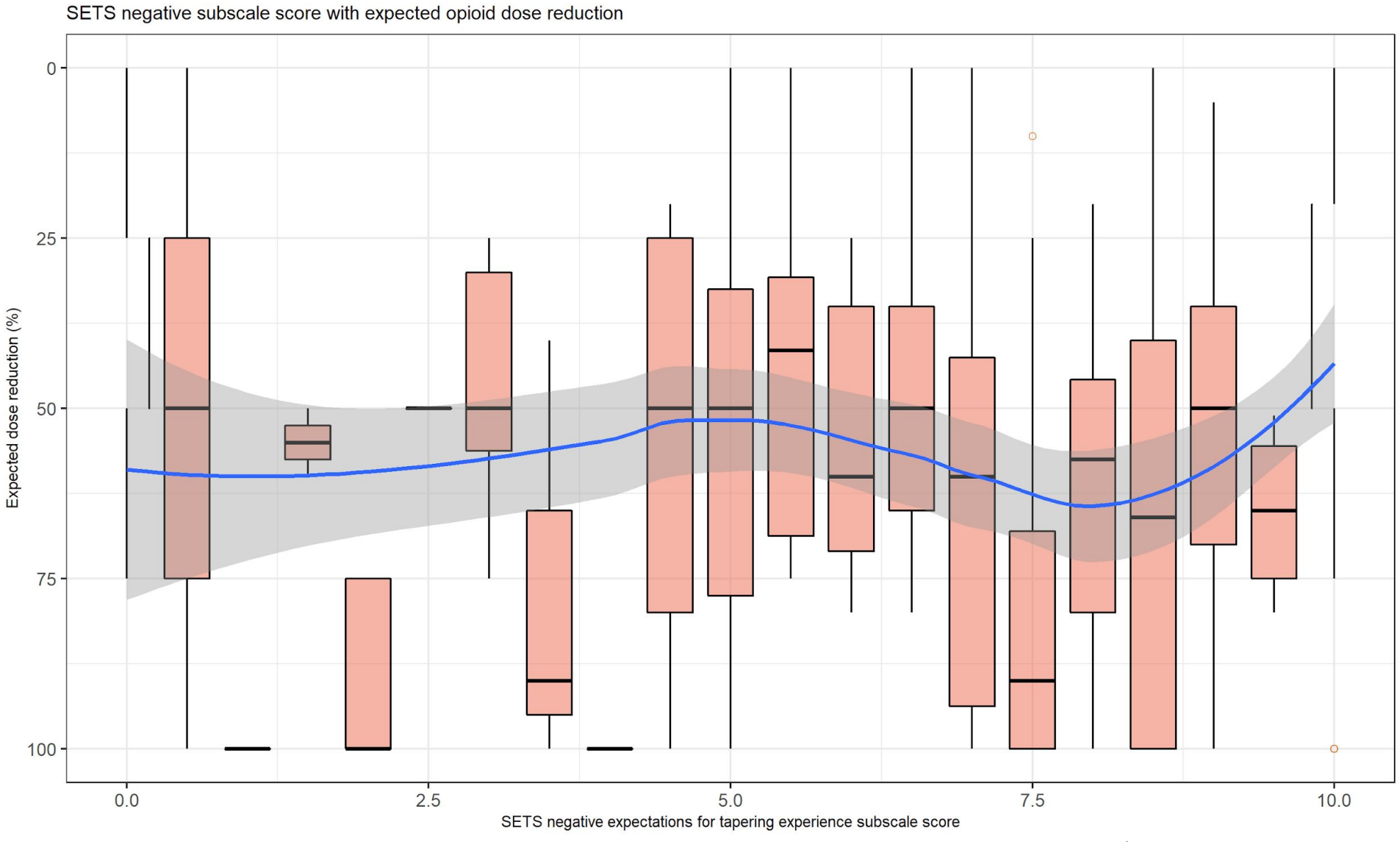

SETS positive subscale score with expected change in pain level
WORSEN SUBSTANTIALLY
WORSEN SOMEWHAT
REMAIN ABOUT THE SAME
IMPROVE SOMEWHAT
IMPROVE SUBSTANTIALLY
Expected change in pain level
0.0
2.5
5.0
7.5
10.0
SETS positive expectations for tapering experience subscale score


SETS negative subscale score with expected change in pain level
WORSEN SUBSTANTIALLY
WORSEN SOMEWHAT
REMAIN ABOUT THE SAME
IMPROVE SOMEWHAT
IMPROVE SUBSTANTIALLY
Expected change in pain level
0.0
2.5
5.0
7.5
10.0
SETS negative expectations for tapering experience subscale score

Linear Regression of Opioid Reduction Expectation

Predictor	Coefficient	Lower 95 CI	Upper 95 CI	R^2	p-value
SETS Positive	4.010	2.577	5.444	0.123	$p < 0.001$
SETS Negative	-1.257	-2.771	0.257	0.008	0.103


SETS positive subscale score with expected opioid dose reduction
Expected dose reduction (%)
0
25
50
75
100
0.0
2.5
5.0
7.5
10.0
SETS positive expectations for tapering experience subscale score


SETS negative subscale score with expected opioid dose reduction
Expected dose reduction (%)
0
25
50
75
100
0.0
2.5
5.0
7.5
10.0
SETS negative expectations for tapering experience subscale score

Conclusions

- Prior to the start of a taper, SETS positive expectations for the tapering experience is associated with:
  - Lower expected pain intensity
  - Larger expected opioid dose reductions
- The inverse is true for the SETS negative expectations for taper experience (for pain expectations only).

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Limitations and future work

- Limitations:
  - Selection bias in the population examined
  - Small sample size
  - Did not control for treatment site

- Future directions:
  - Investigate influencing expectations to improve outcome in future studies

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Takeaways

- Important for physician/clinician to help patient with **setting expectations** before starting an opioid tapering program.
- **Early intervention** to change preconceived notions about treatment can increase benefits and minimize adverse effects.
- **Moving forward**: we may be able to help set positive expectations by focusing on collaborative decision making and close communication.

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