

The SAMSON Trial

An N-of-1 trial of statin, placebo, and no treatment to assess patient symptoms

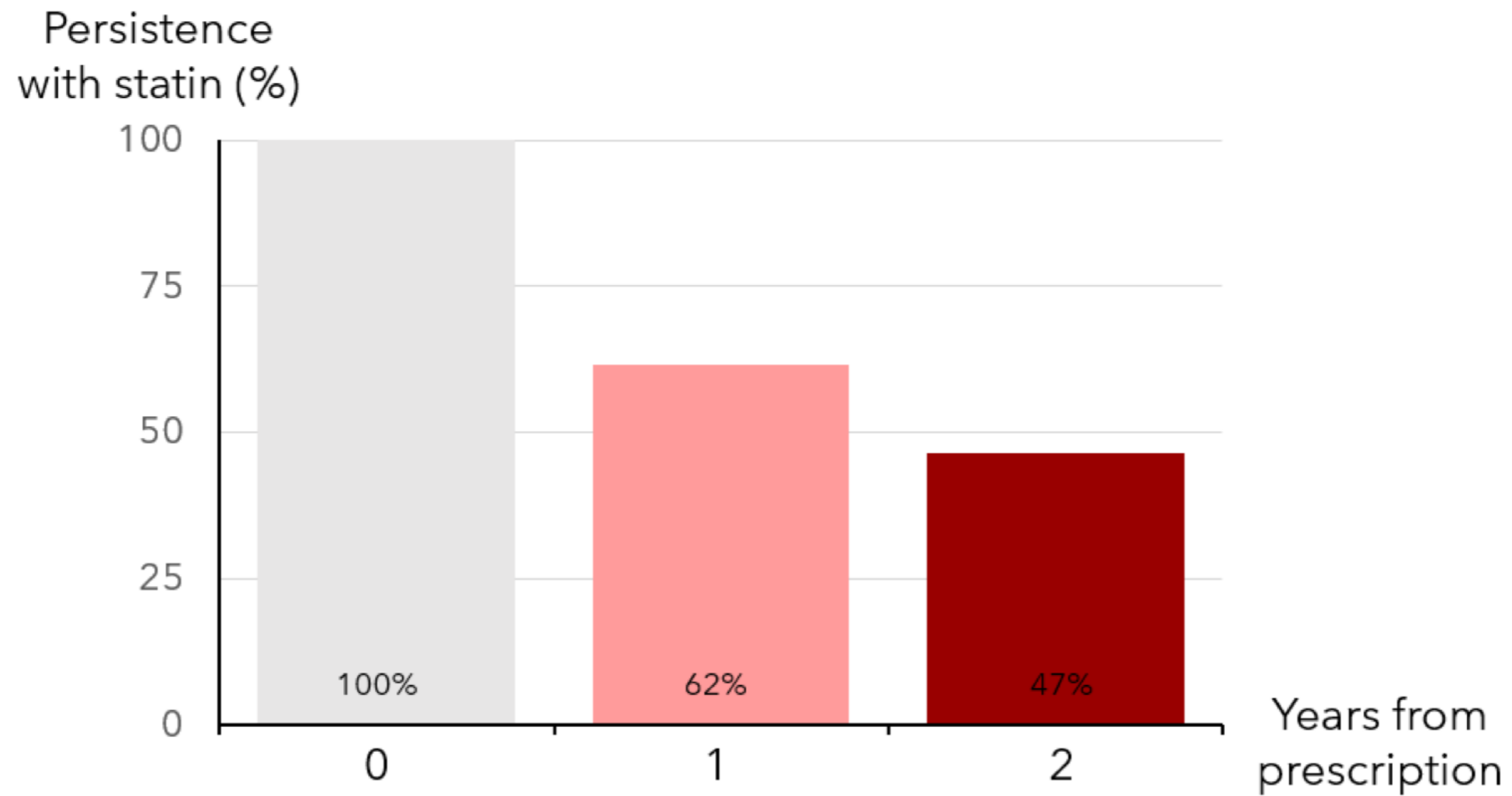
Dr. Matthew Shun-Shin, Clinical Lecturer, Imperial College London
on behalf of the SAMSON trial management group

Disclosures

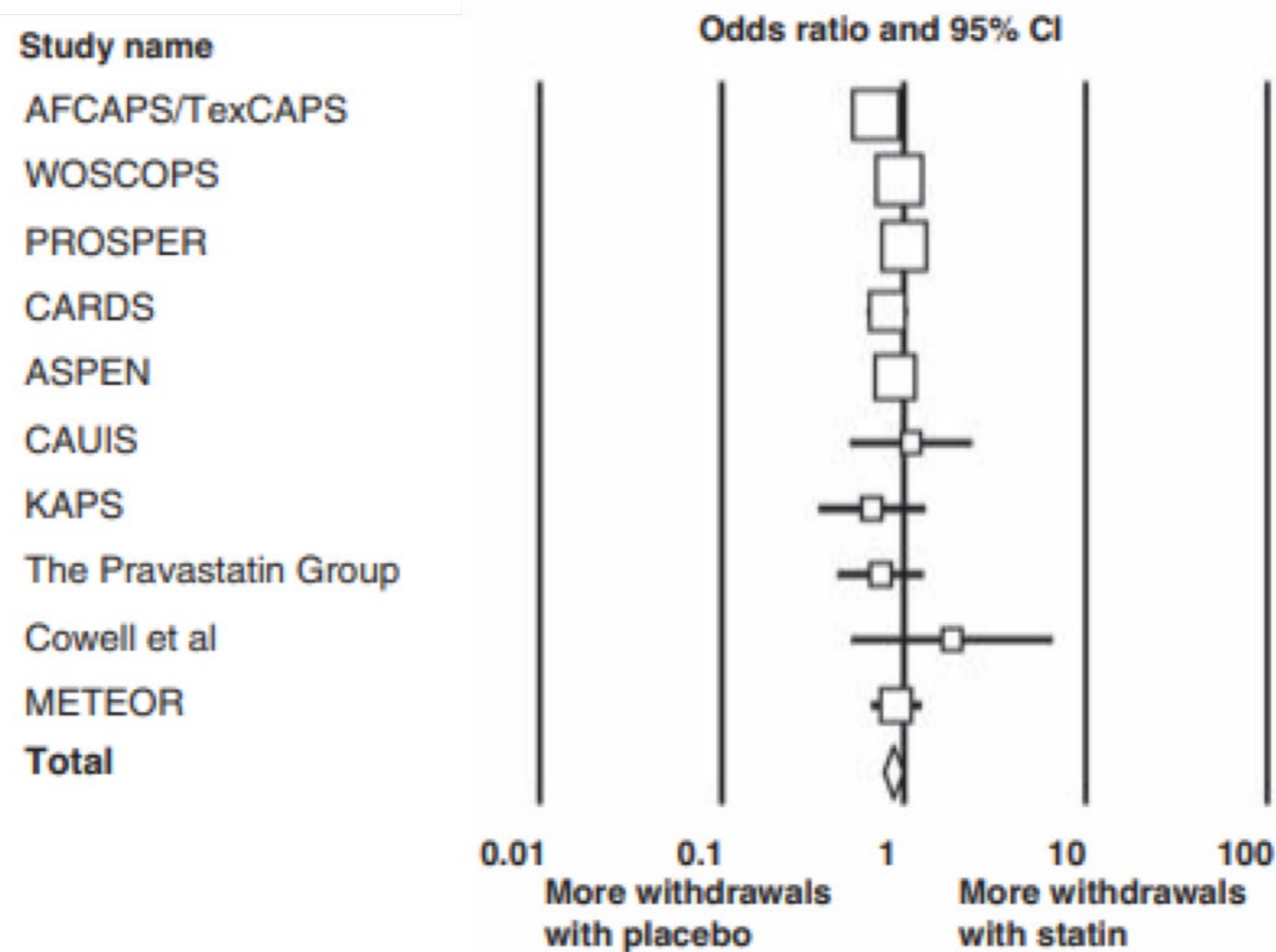
No disclosures

The puzzle

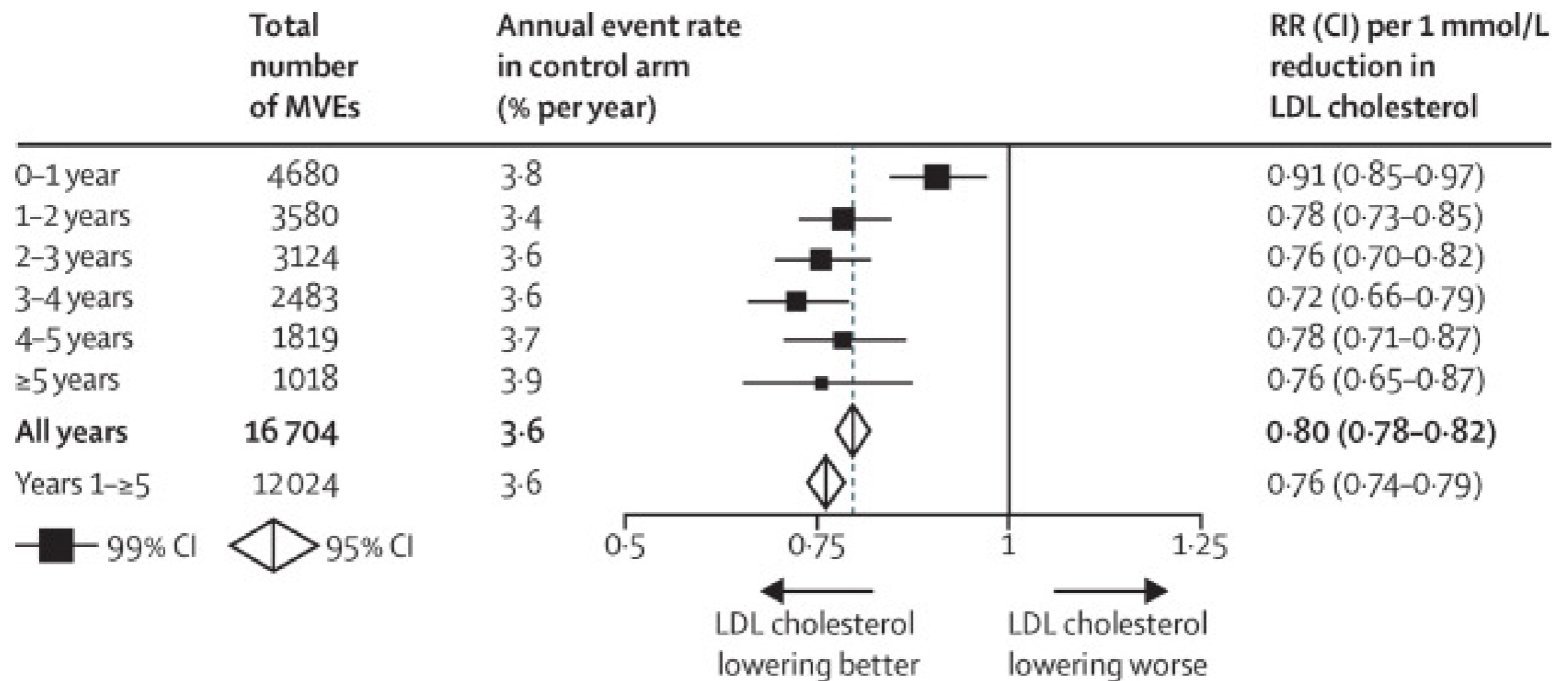
Most people who start statins clinically, abandon them...



...yet placebo-controlled trials do not show excess withdrawals in the statin arm



No-one: 'Statins saved my life'



Everyone: 'Statins caused
my muscle ache'

Everyone: 'Statins caused
my head ache'

Everyone: 'Statins caused
my hair loss'

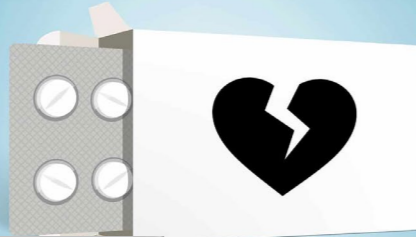
Google:

WHAT HAPPENS TO YOUR BODY WHEN YOU TAKE STATINS

LOWERS CHOLESTEROL

Essential for cells to function.
30% of brain made of it.
Makes vital hormones.
Low levels result in weakness & degenerative disease.

Statins work by blocking the production of cholesterol in your liver.



you have already had a heart attack, conclusive evidence they prevent heart disease.



Side Effects of STATIN MEDICATIONS

WEAKNESS OF LIMBS

LOSS OF HANDS

MUSCLE PAIN

PROBLEMS

STATIN DRUGS Side Effects

and the Misguided War on Cholesterol

By Duane Graveline

ZOCOR
PRIVACHOL
LIPITOR
MEVACOR
CRESTOR
VYTORIN
LESICO

Statins lower Cholesterol

Statins lower LDL by cutdown liver's production. It also stops Co Q & Dolichols; both vital for your health. Do you truly need Statin? Are all statin the same? 10 Shocking Side Effects of Statins drug



What are Common Statin Drug Side Effects?

Side-Effects-Site.com

- Muscle Pain
- Memory Loss
- Rhabdomyolysis
- Fatigue
- I don't know. I just take the drugs my doctor tells me to

Don't let Big Pharma ruin your health. Wake up to the cholesterol con!

- Muscle aches
- Joint pains
- Impotence
- Extreme lethargy
- Tinnitus
- Weakness
- Weight gain
- Cloudy urine.
- Hopelessness
- Memory loss
- Rage beyond reason
- Personality change
- Getting old quickly

STATINS KILL !!!

CHOLESTEROL DOES NOT

What your doctor know

Educate yourself: thincs.org, stopped_our_statins, [statins side effects](http://statins_side_effects)

Side Effects
ous and
Pervasive than You
are Told

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Methods

Methods



4 statin
months

Methods



4 statin
months



4 placebo
months

Methods



4 statin
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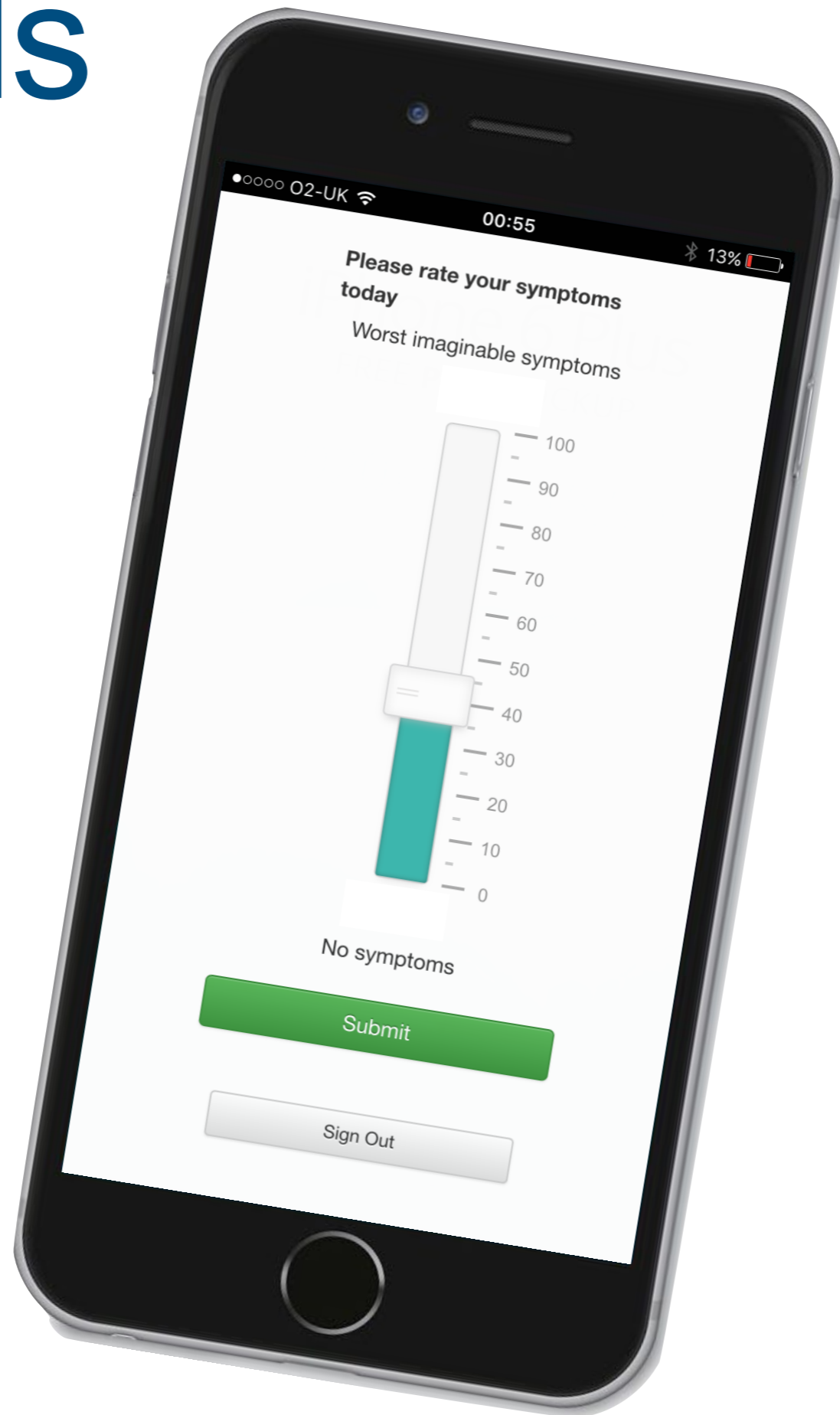


4 placebo
months

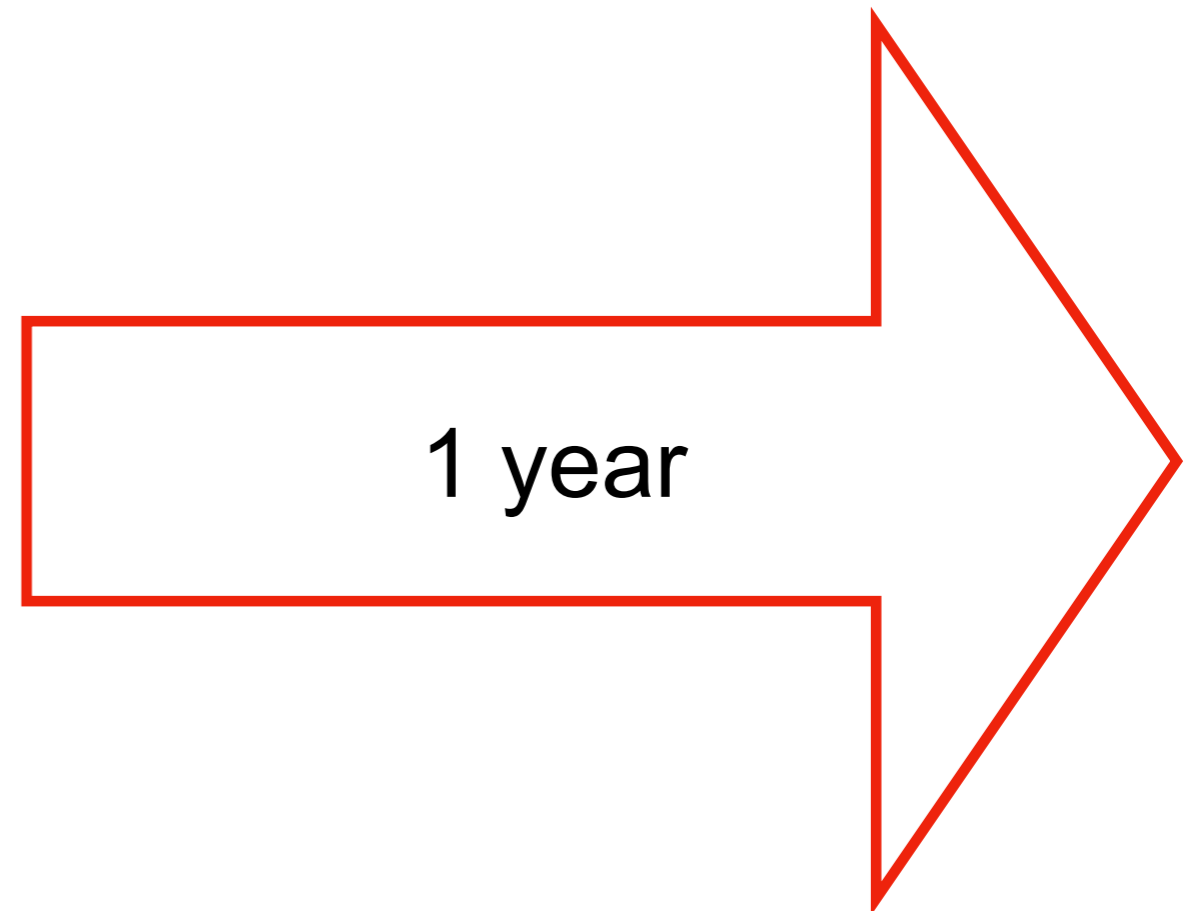
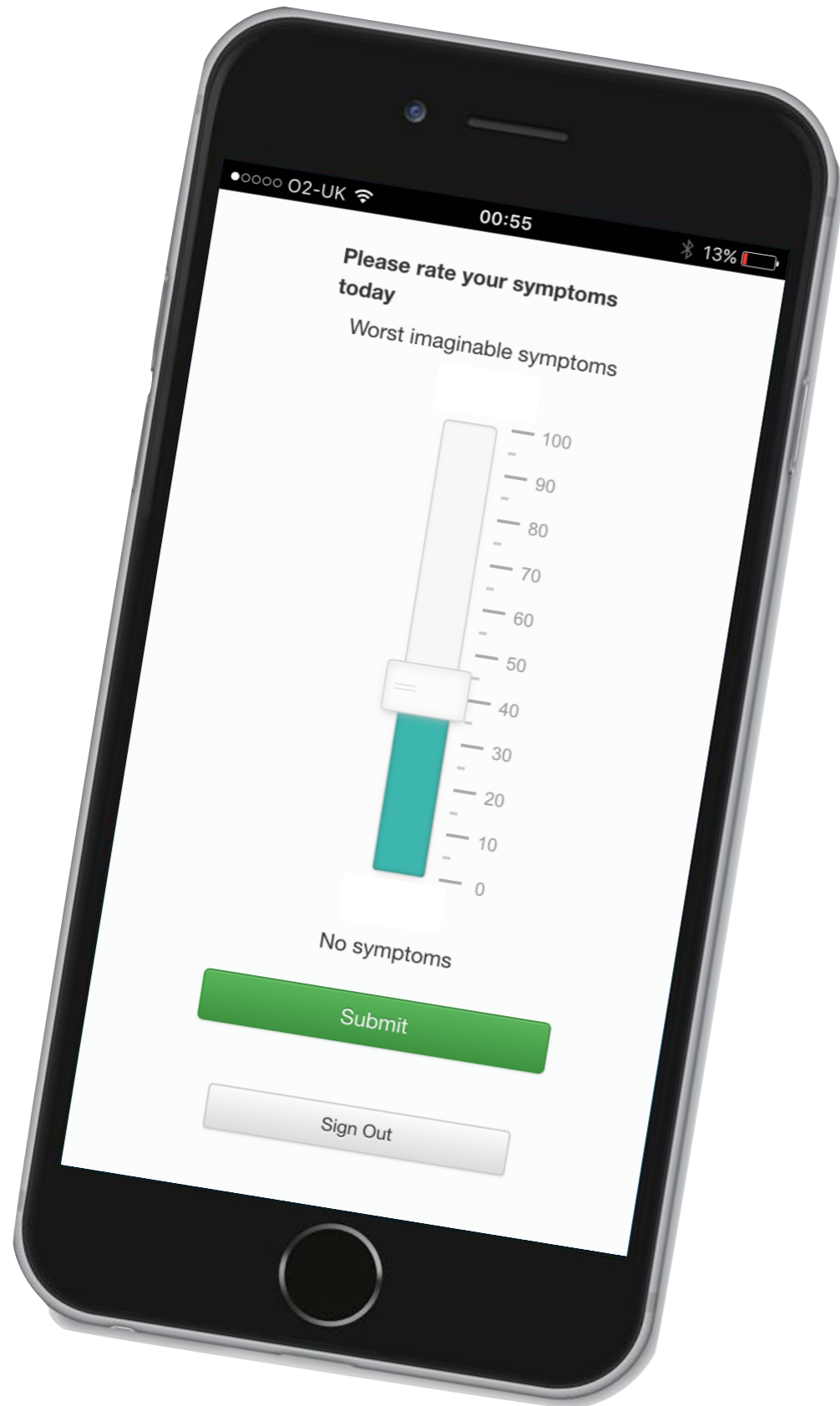


4 empty
months

Methods



Methods

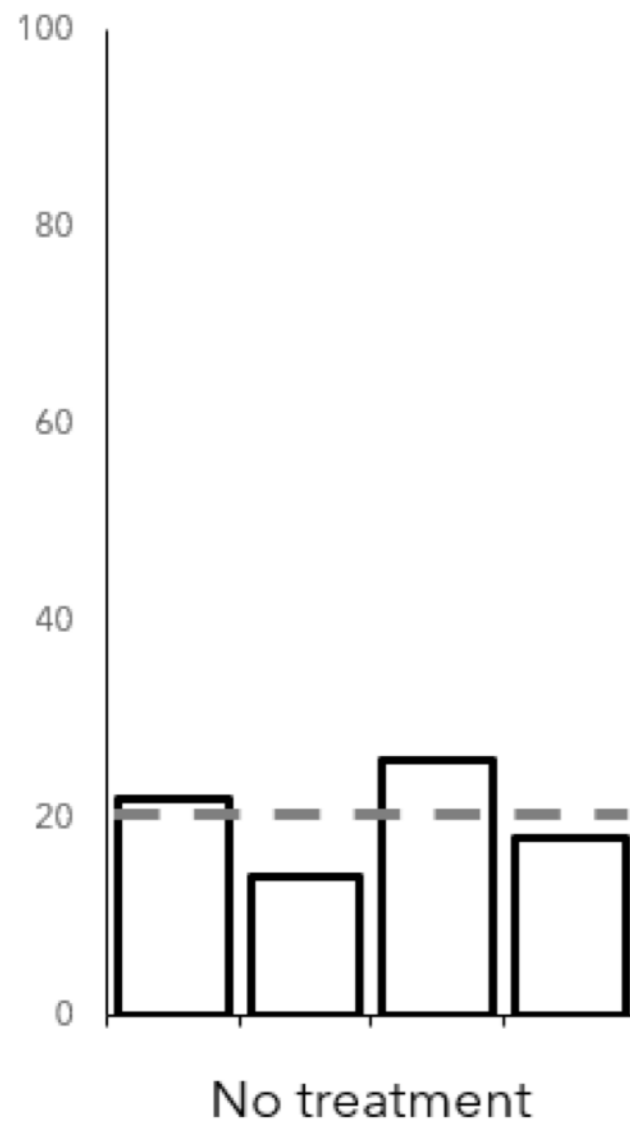


Outcome measures

Symptom burden

Simulated data for 1 patient

Side-effect
burden

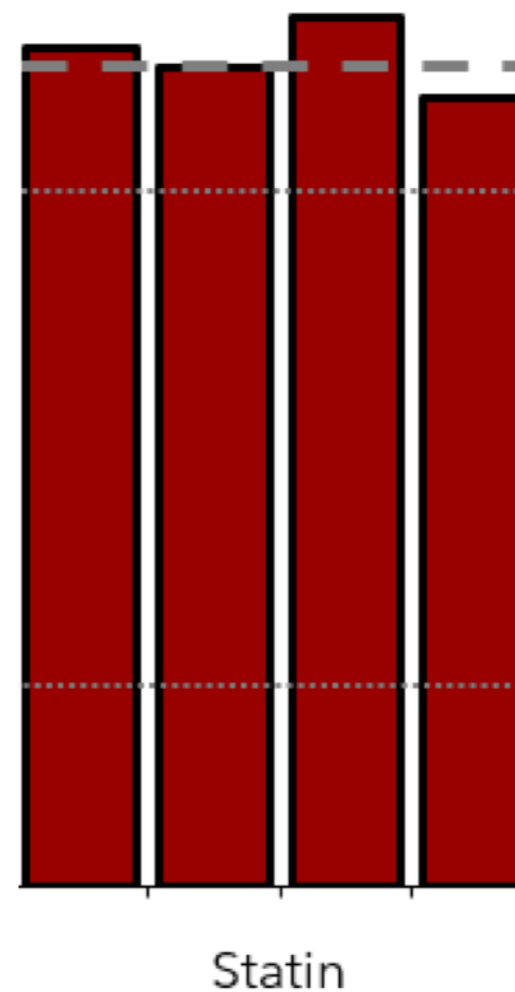
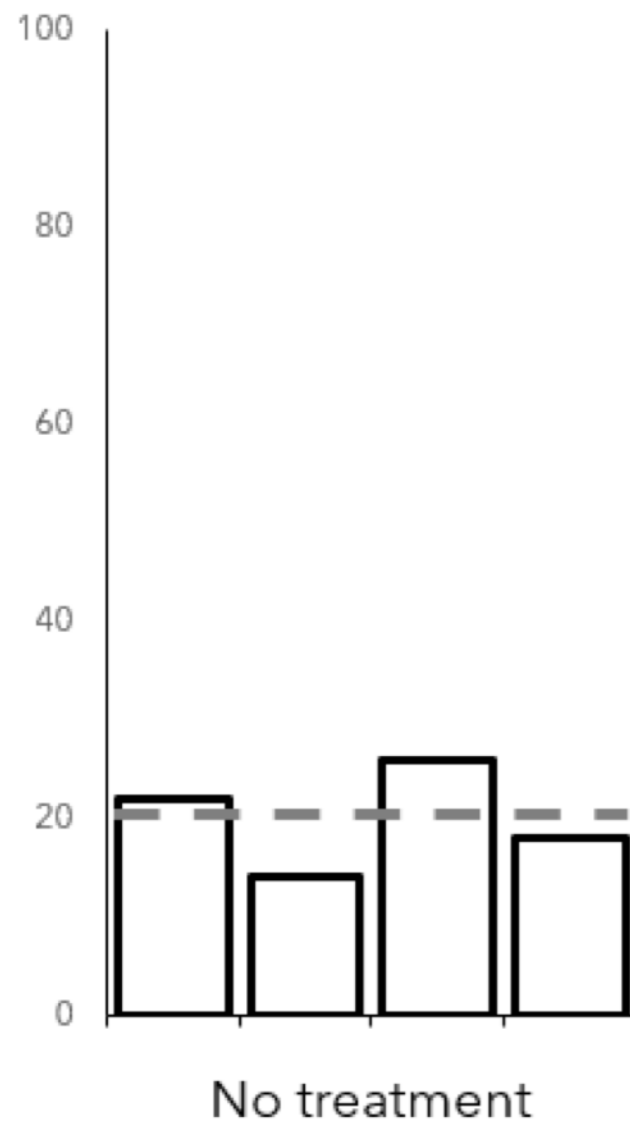


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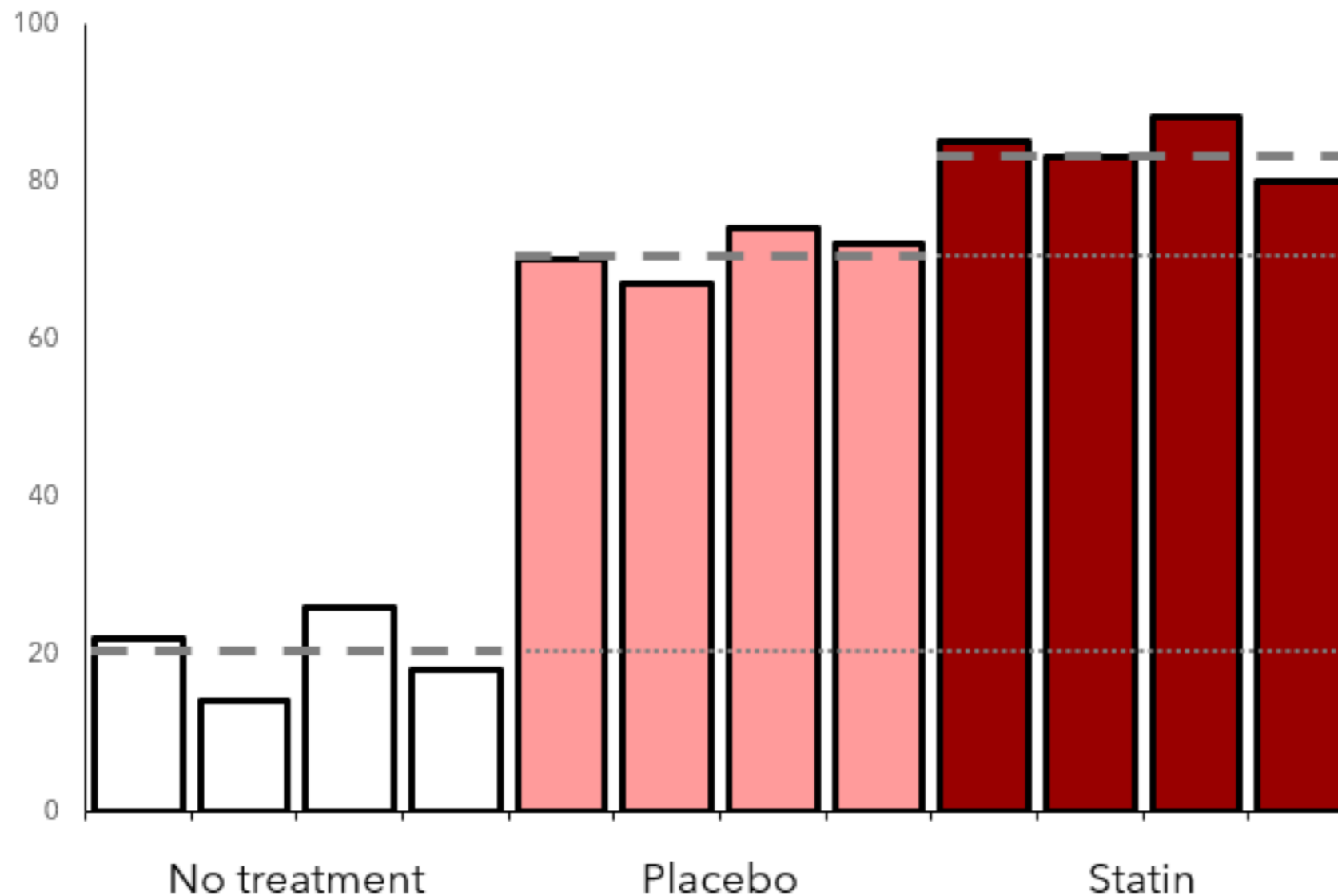


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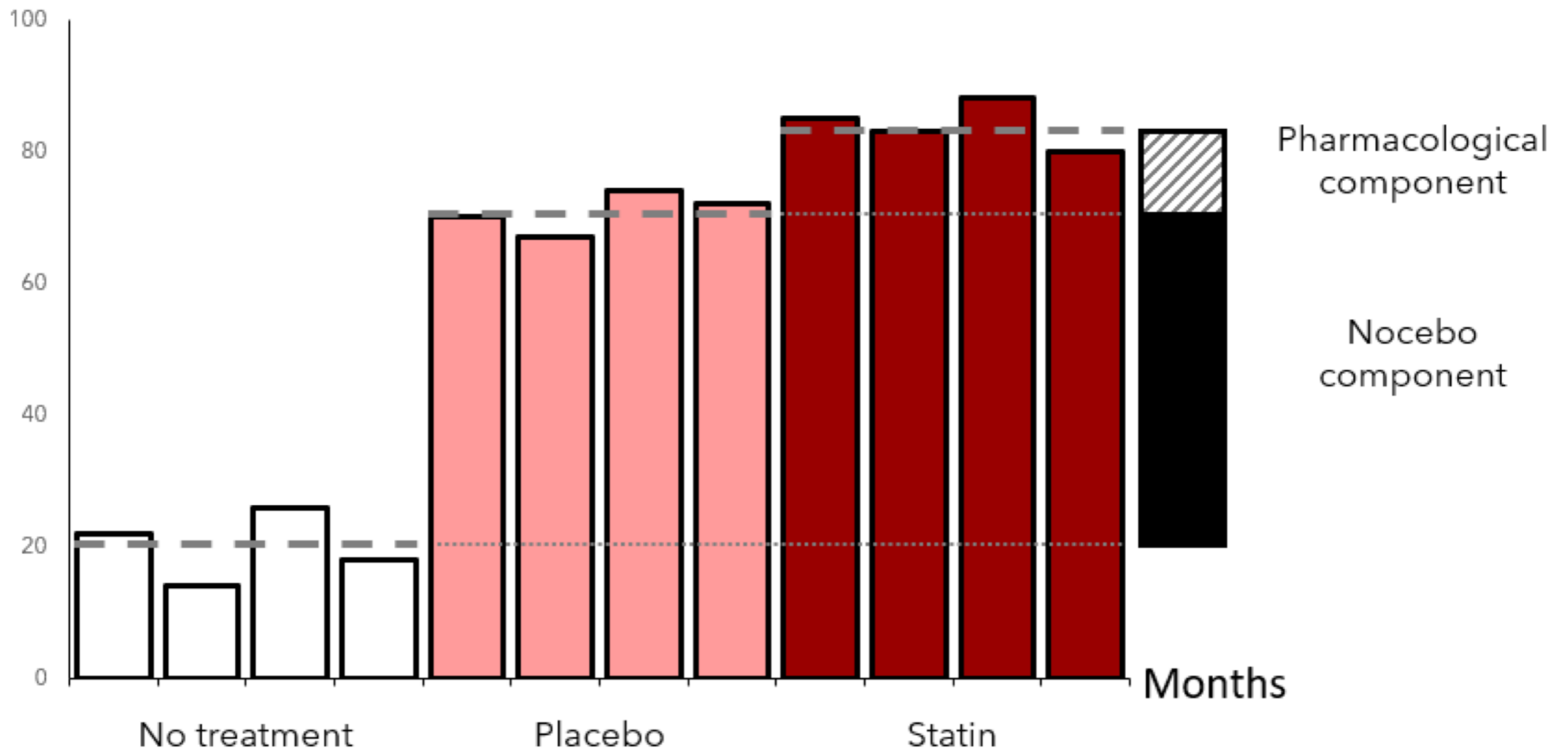


Outcome measures

1 Symptom burden

Simulated data for 1 patient

Side-effect burden



Outcomes measures

(2) Percentage of patients taking a statin after 6 months

Methods

Pragmatic RCT

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Pragmatic RCT

Reasonable duration

One year

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Multiple cross-over

12 Jars, 4 of each type

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One month long enough for symptoms

Patients with symptoms within 2 weeks

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Individualised answer for each patient

Personalised results at 1 year

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Personalised results at 1 year

Evaluate longer-term impact

Review 6 months after participation

Results - Recruitment

Attended for screening
n = 62

Randomized
n = 60

Received intervention
n = 60

Completed at least 1
month of trial
n = 60

Symptom burden end-point

Responded to 6 month
post-trial follow-up
n = 59

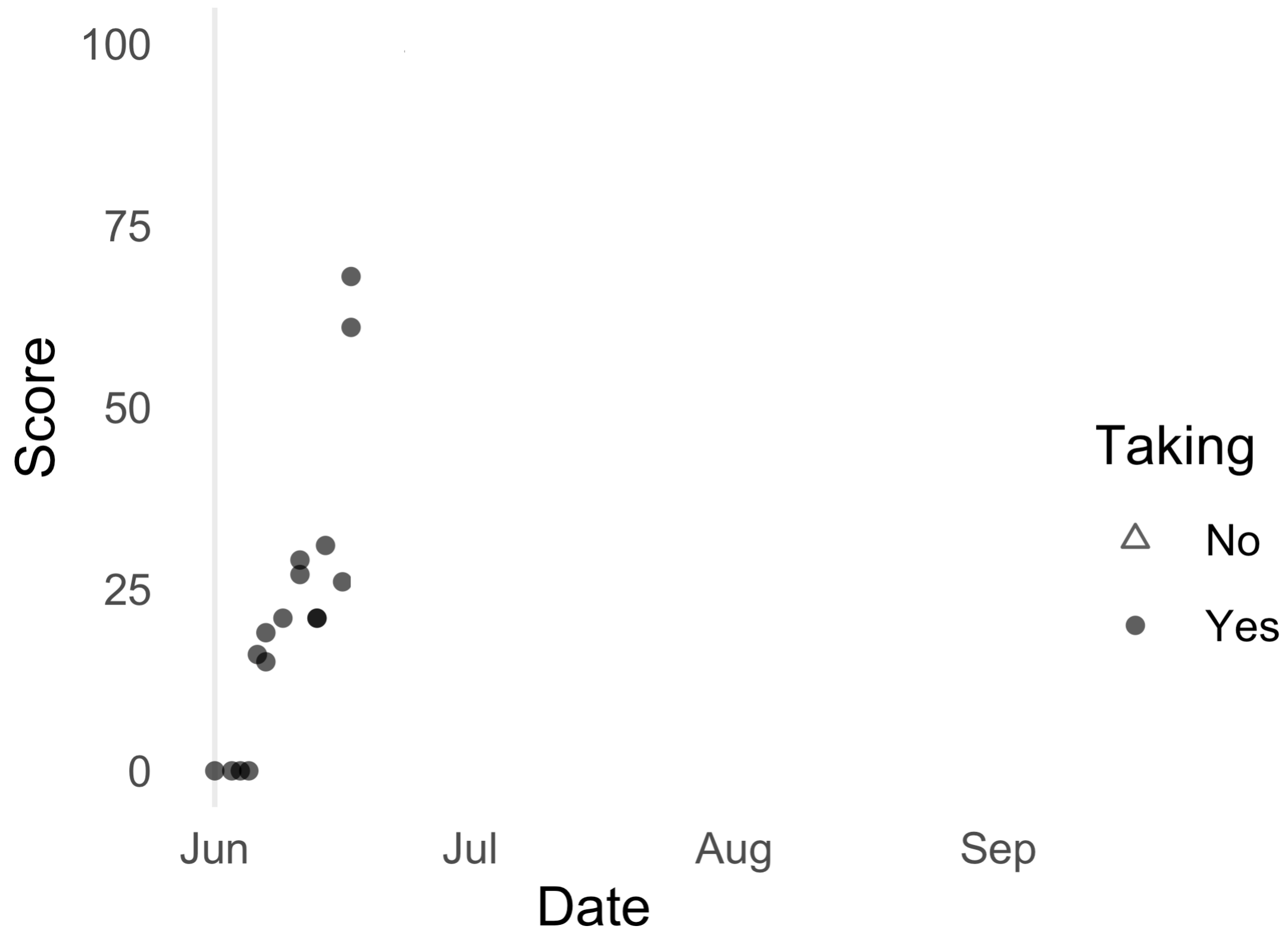
Medication end-point

Results - Trial population

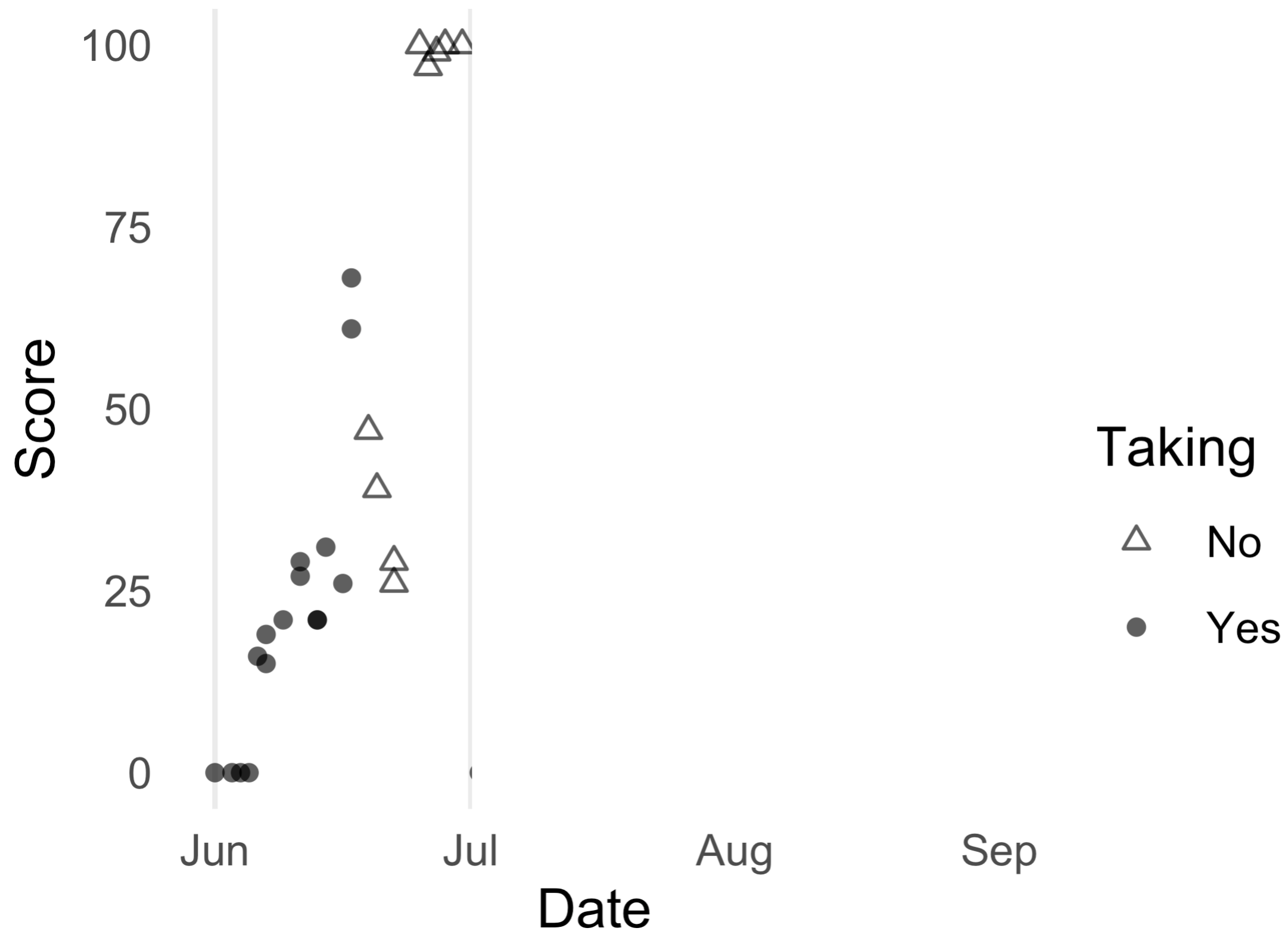
Age (years)	65.5 (8.6)
Gender	
Male	35 (58.3)
Female	25 (41.7)
Ethnicity	
White	54 (90.0)
Black	1 (1.7)
Asian	3 (5.0)
Mixed	2 (3.3)
Height (cm)	169 (8)
Weight (kg)	82.0 (19.0)
BMI	29.1 (6.7)
Number of statins previous tried	
1	17
2	20
3	11
4	7
5	3
Previous statin duration (years)	2.84 (4.65)
Systolic blood pressure (mmHg)	139.1 (17.3)
Diastolic blood pressure (mmHg)	77.5 (8.9)
LDL-C (mmol/L)	4.16 (1.07)
Current indication for statin	
Primary prevention	46 (76.7%)
Secondary prevention	14 (23.3%)
History of diabetes	4 (7%)
QRISK-2 10-year risk (primary prevention participants only)	24.3% (13.6)
Number of concomitant medications	4.72 (3.28)

Results - Unblinding visit

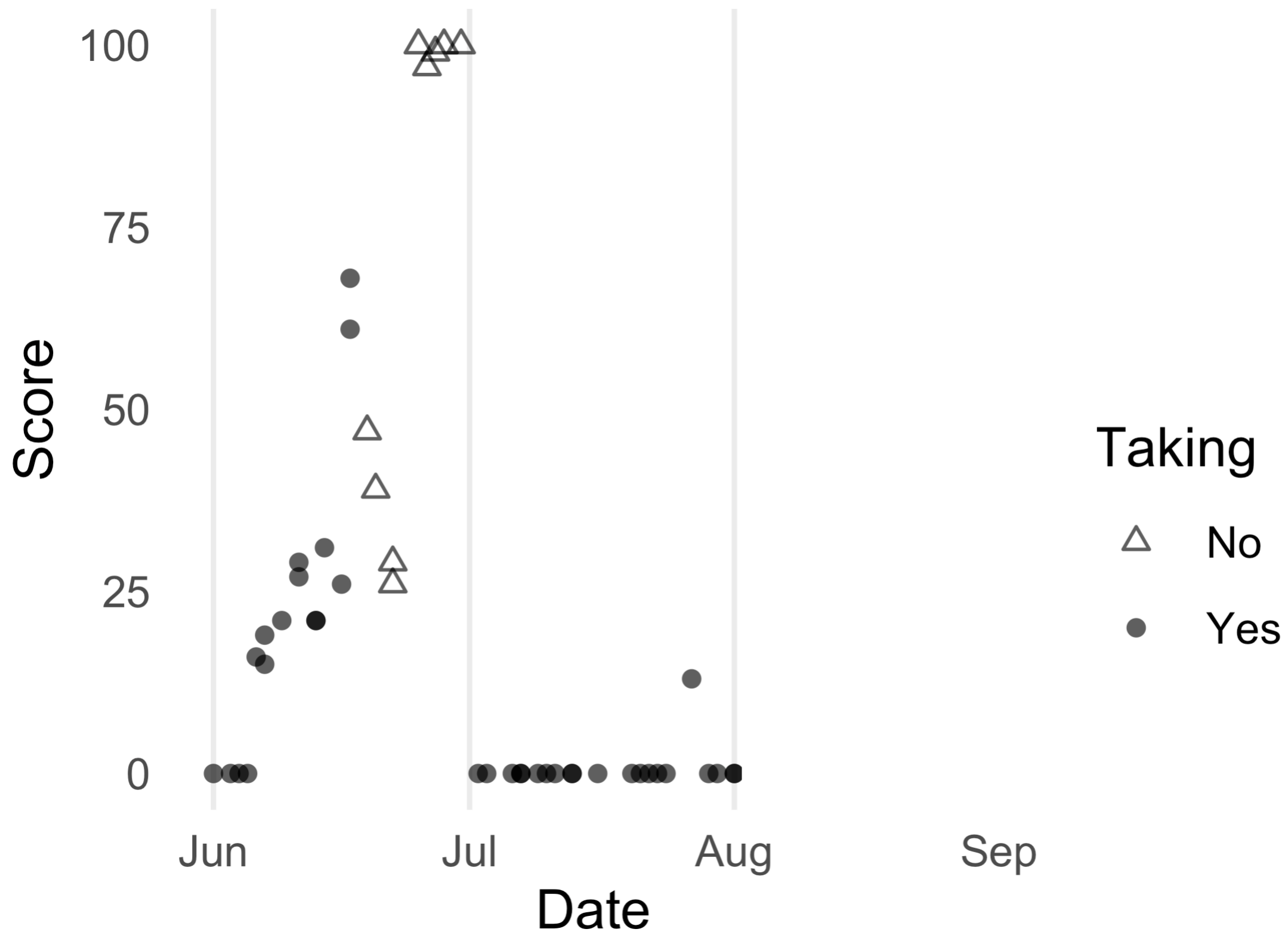
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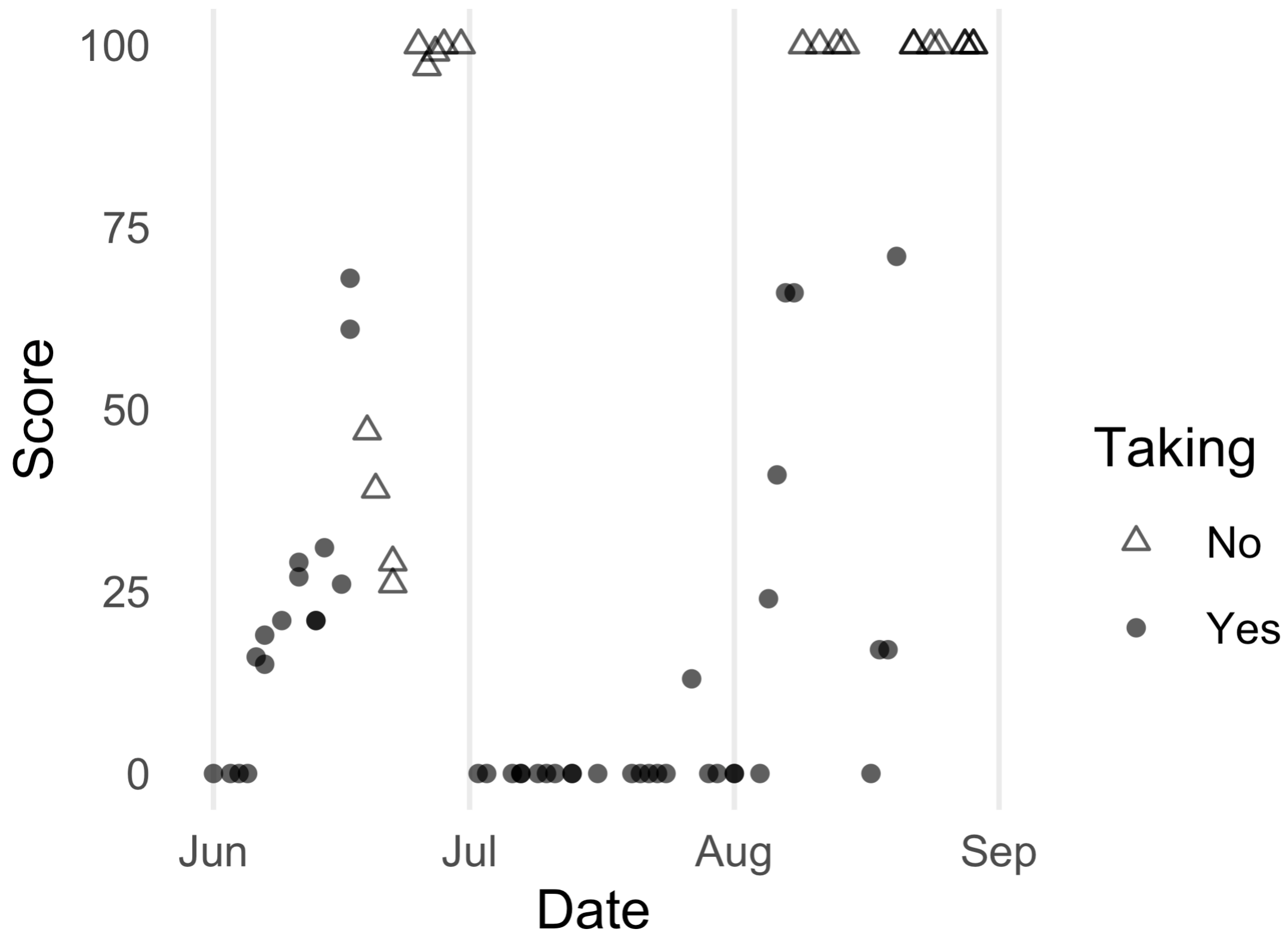
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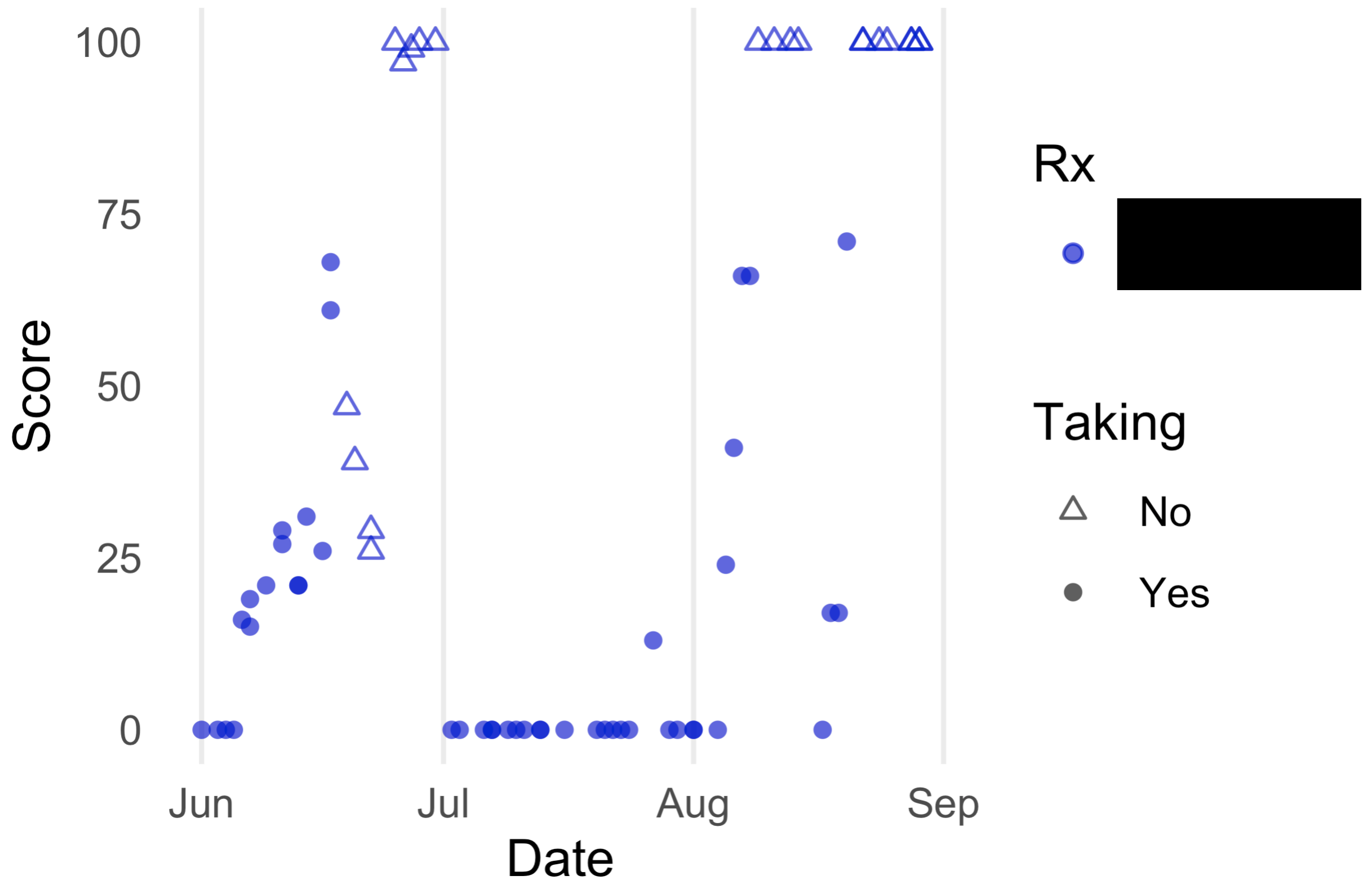
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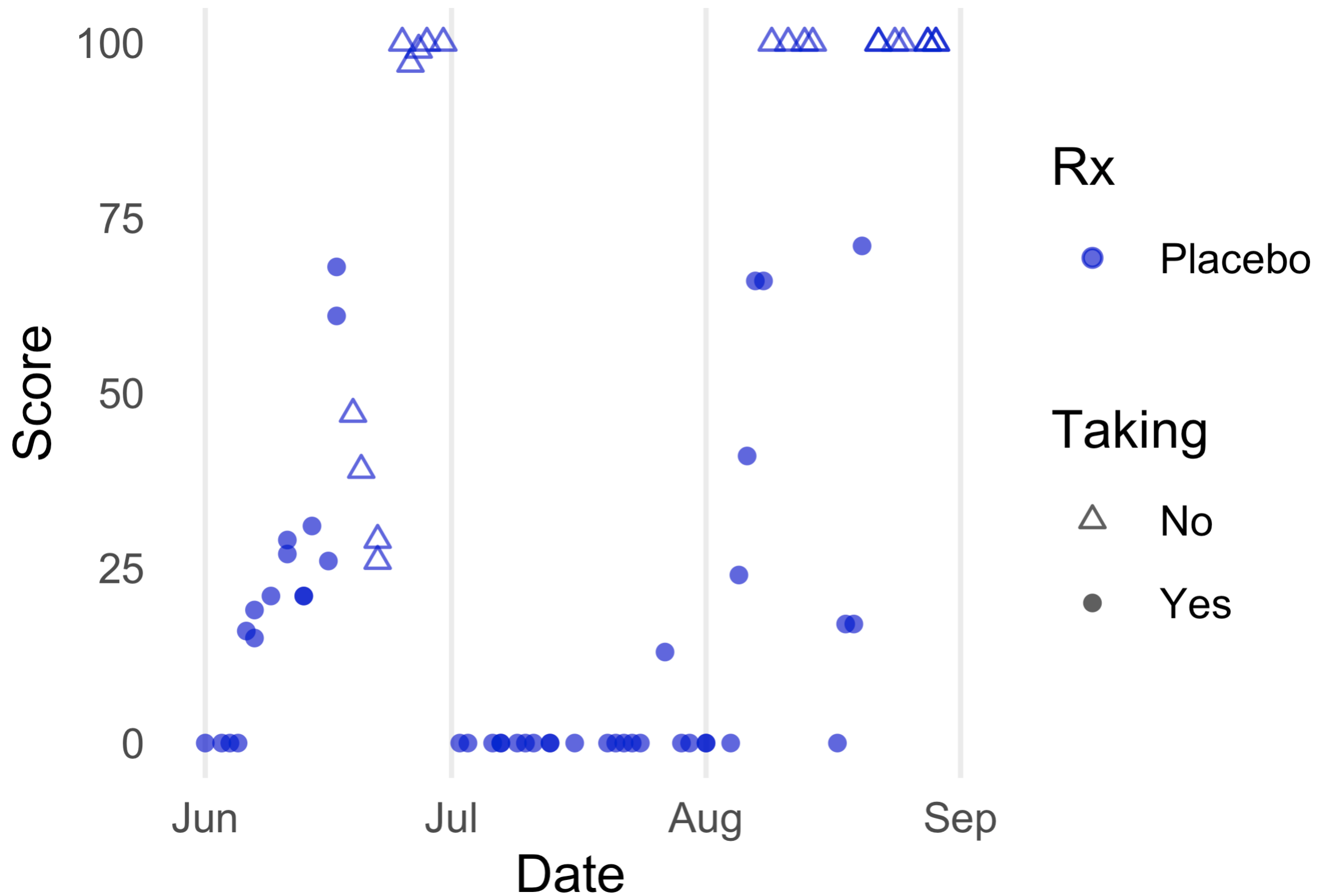
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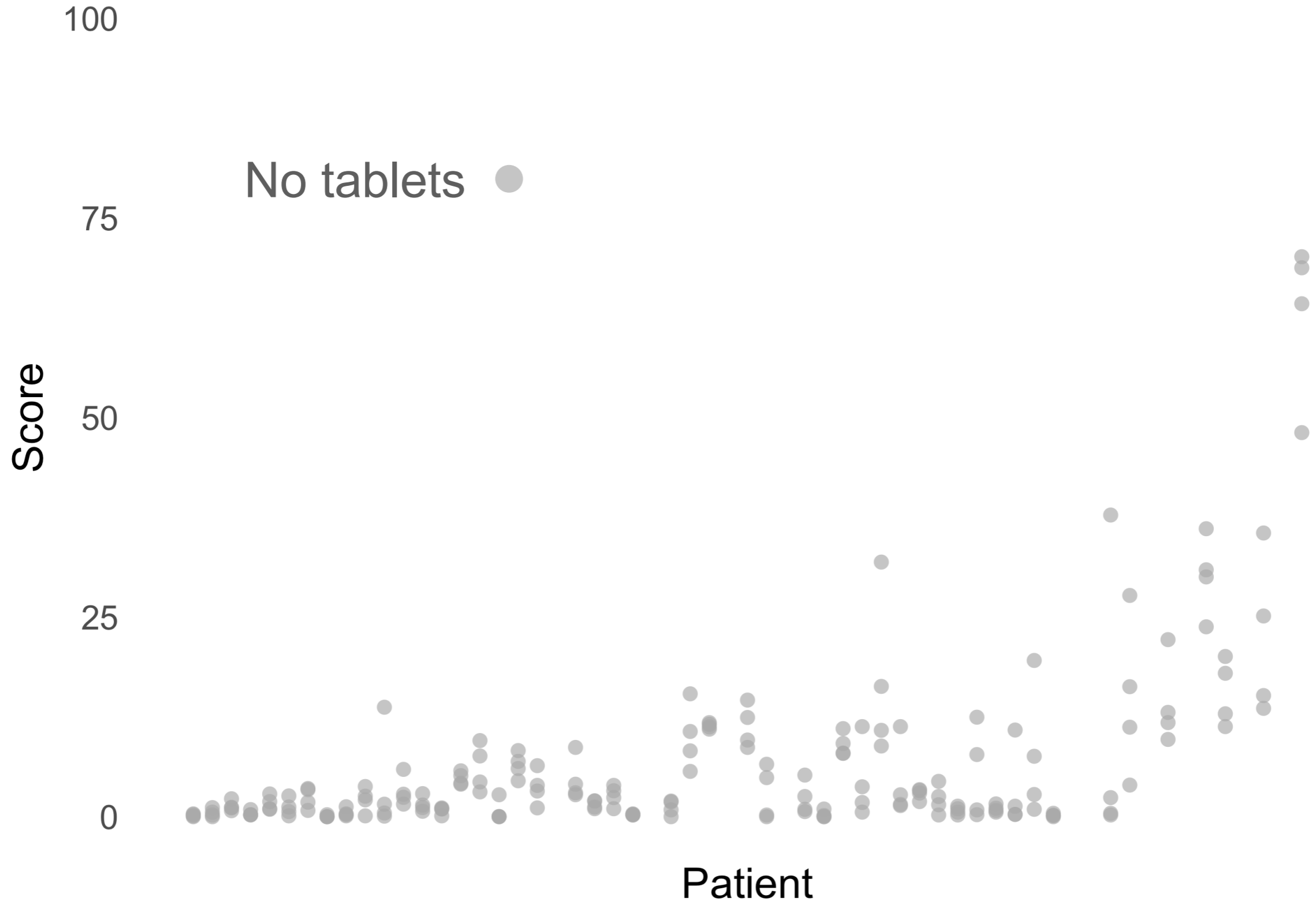


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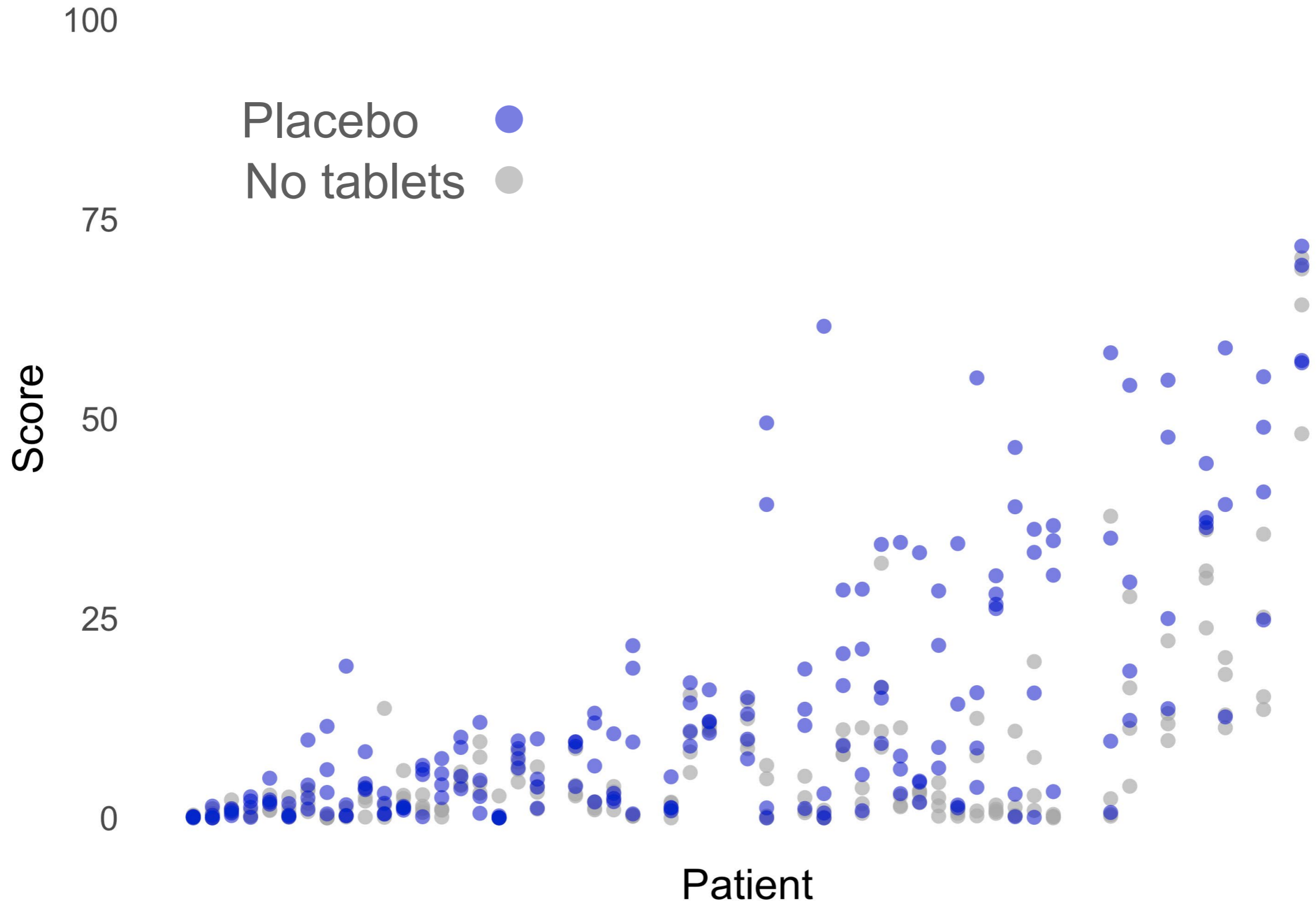


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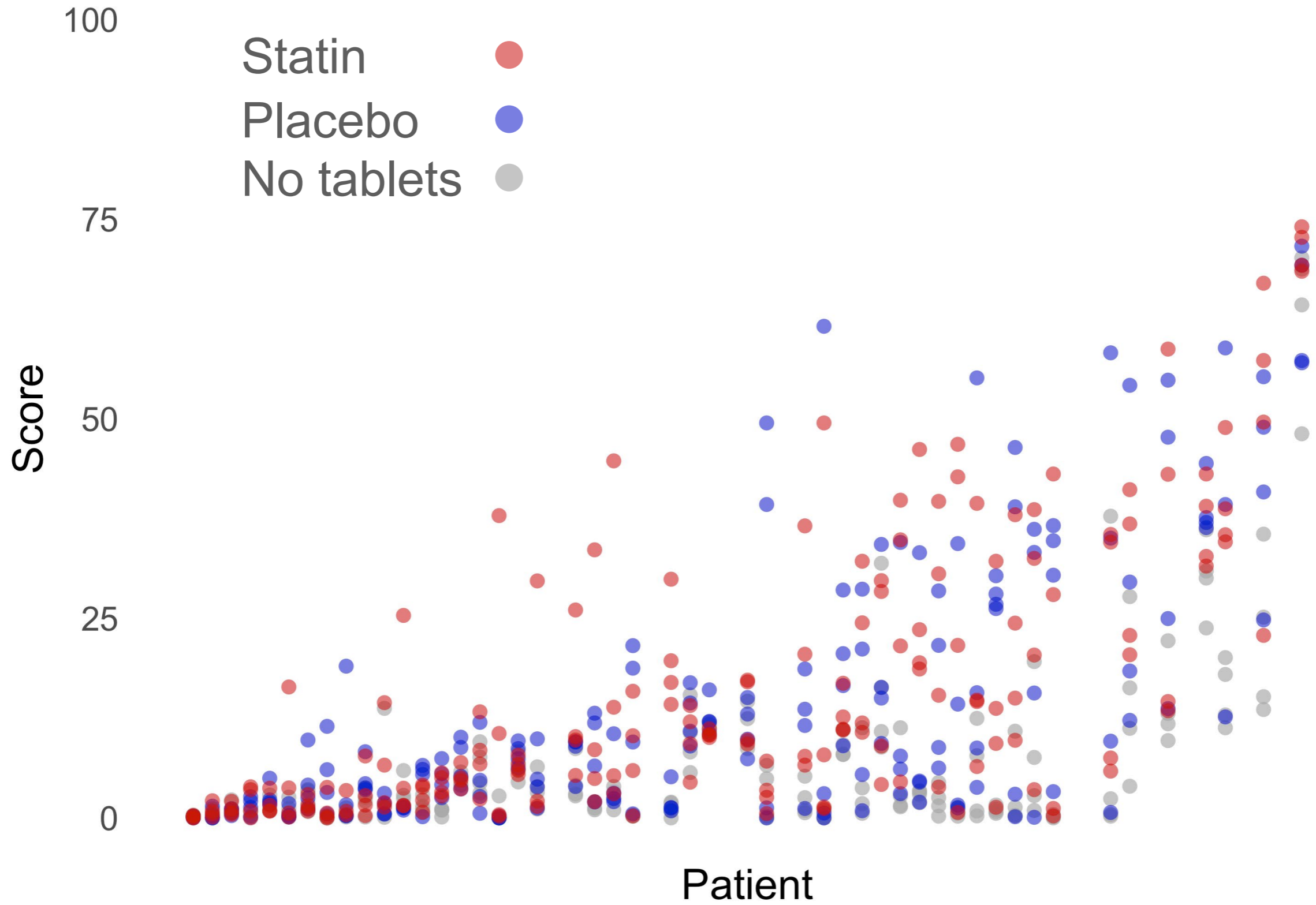
Results



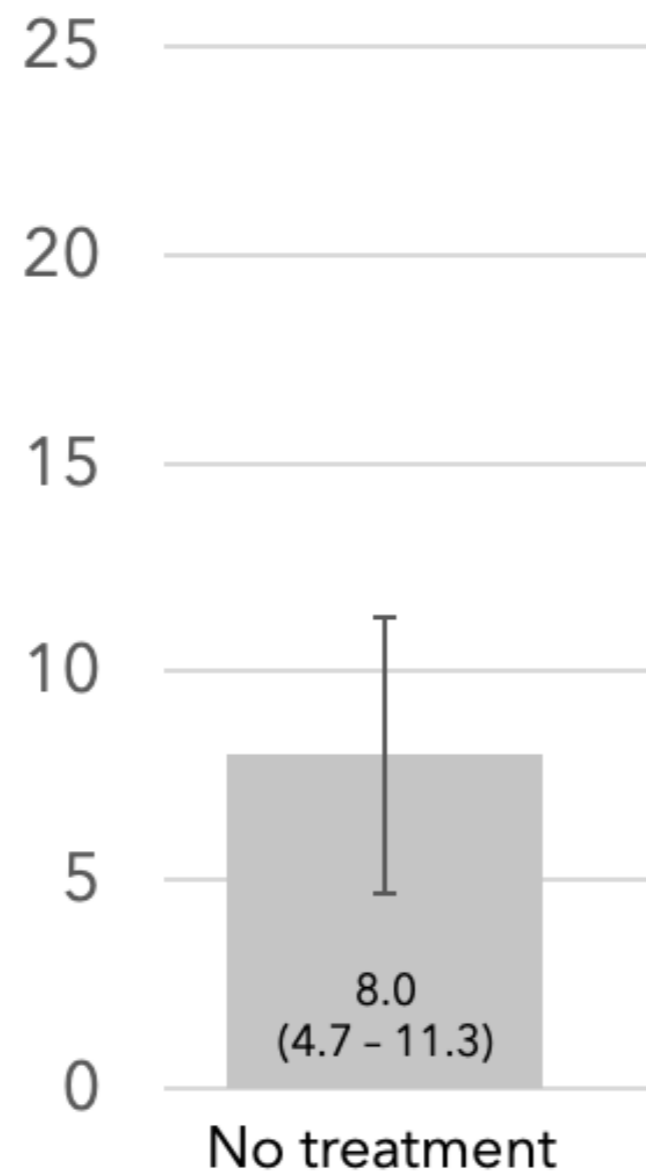
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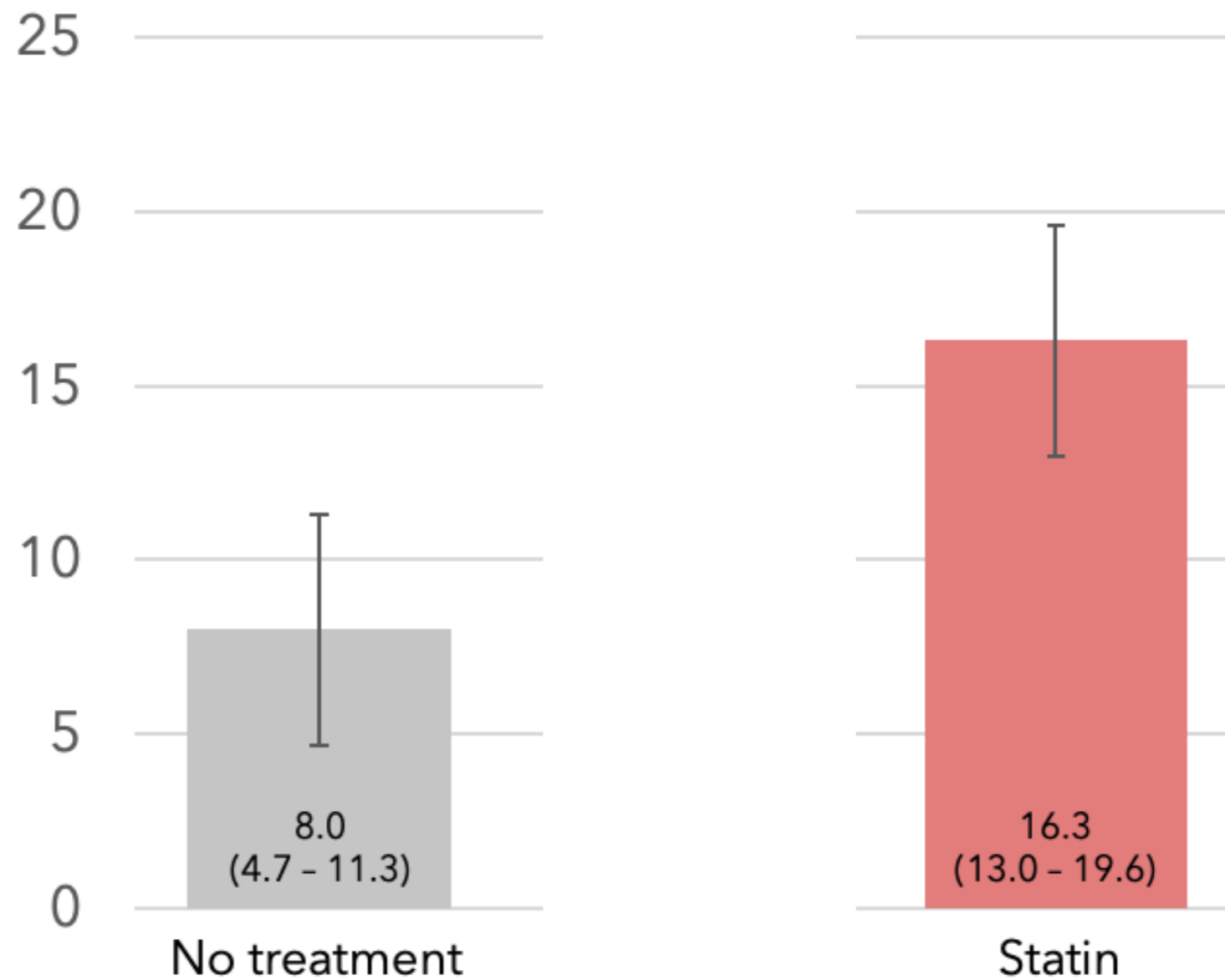
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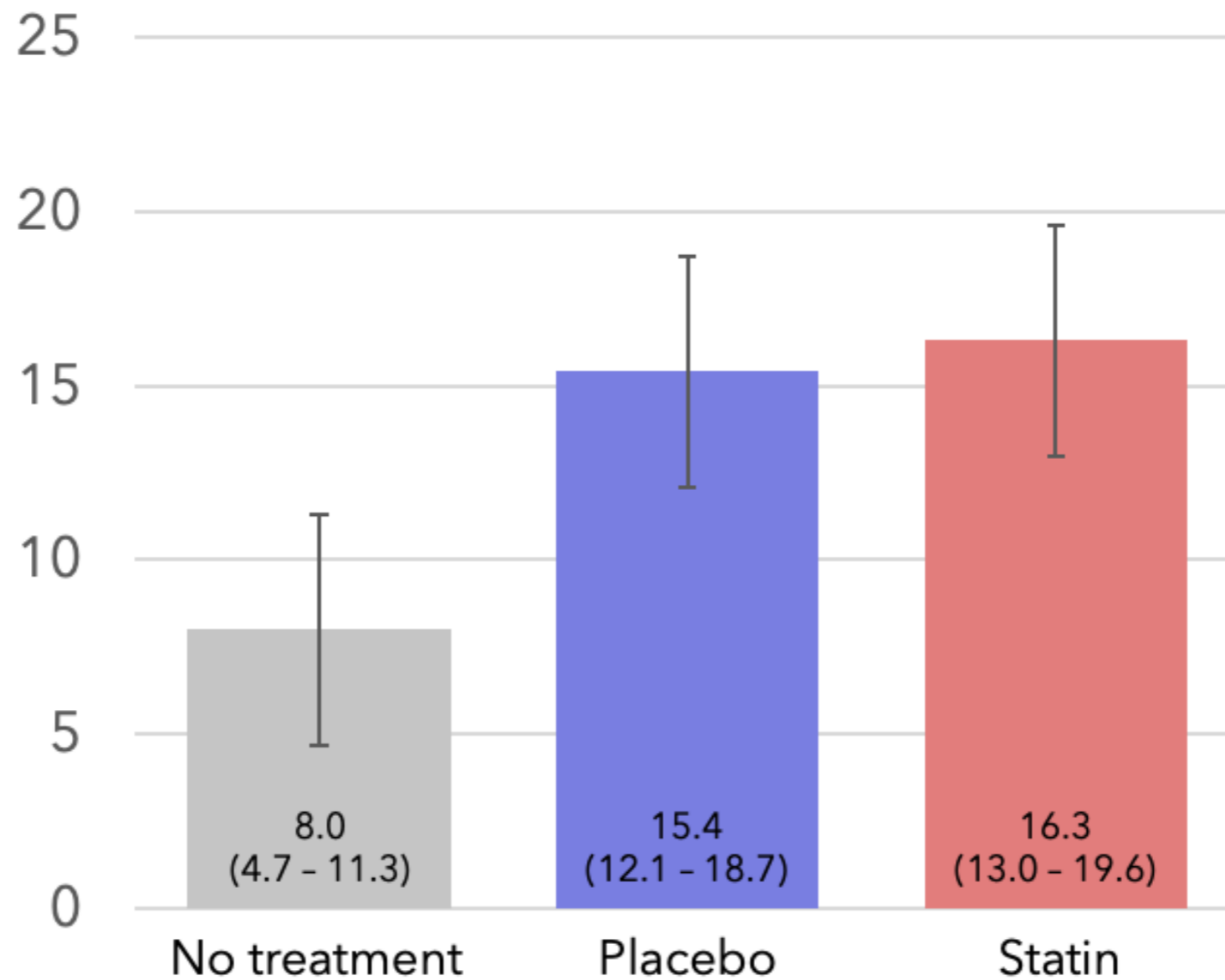
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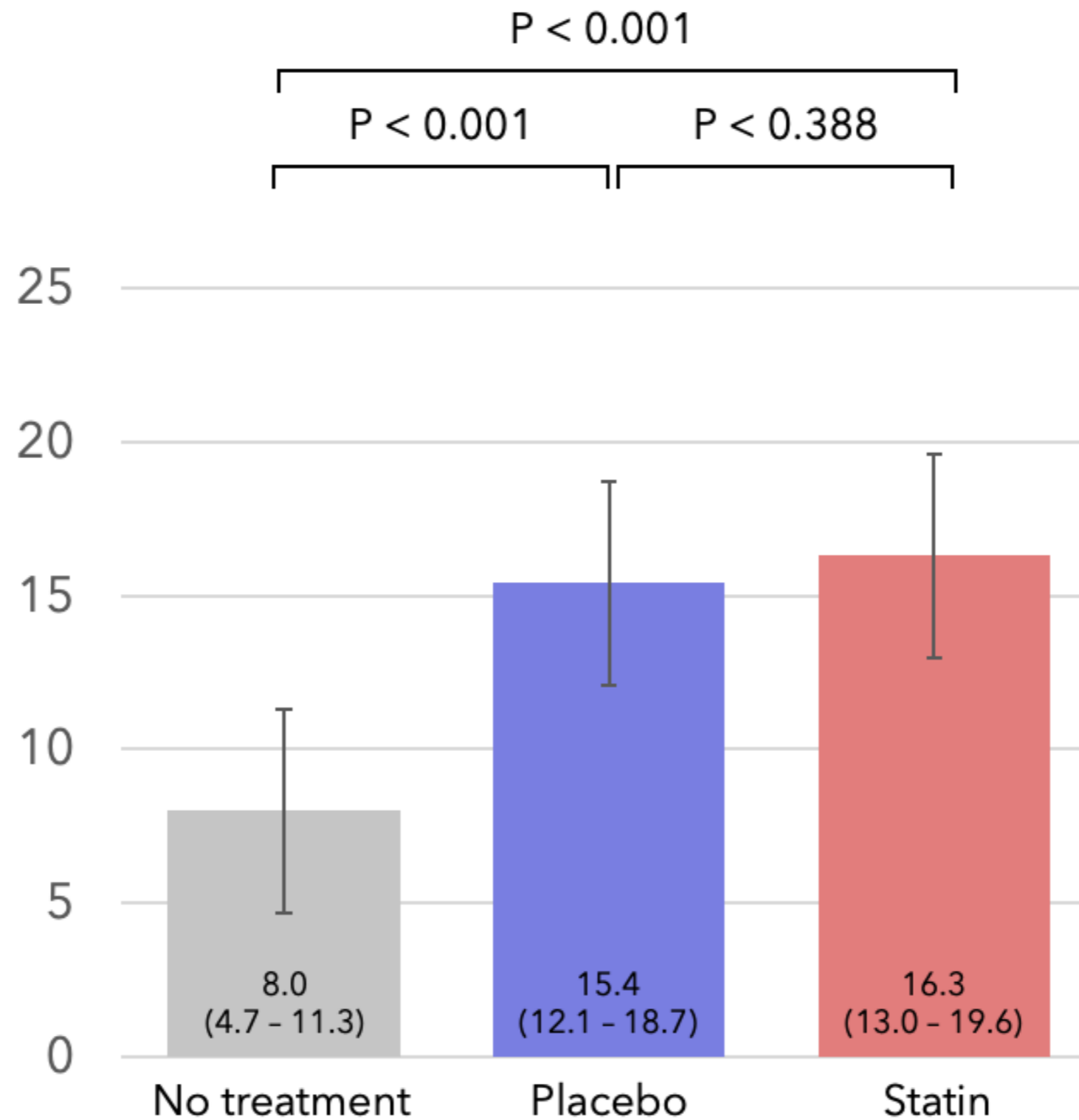
Results



Results



Results



Nocebo proportion: 0.9

6 months later,

30/60

were back clinically
on a statin

What we have learnt

**Statin tablets really do
induce powerful symptoms**

Formal documentation

Fixed protocol

Statin tablet

Statin tablet

Statin tablet

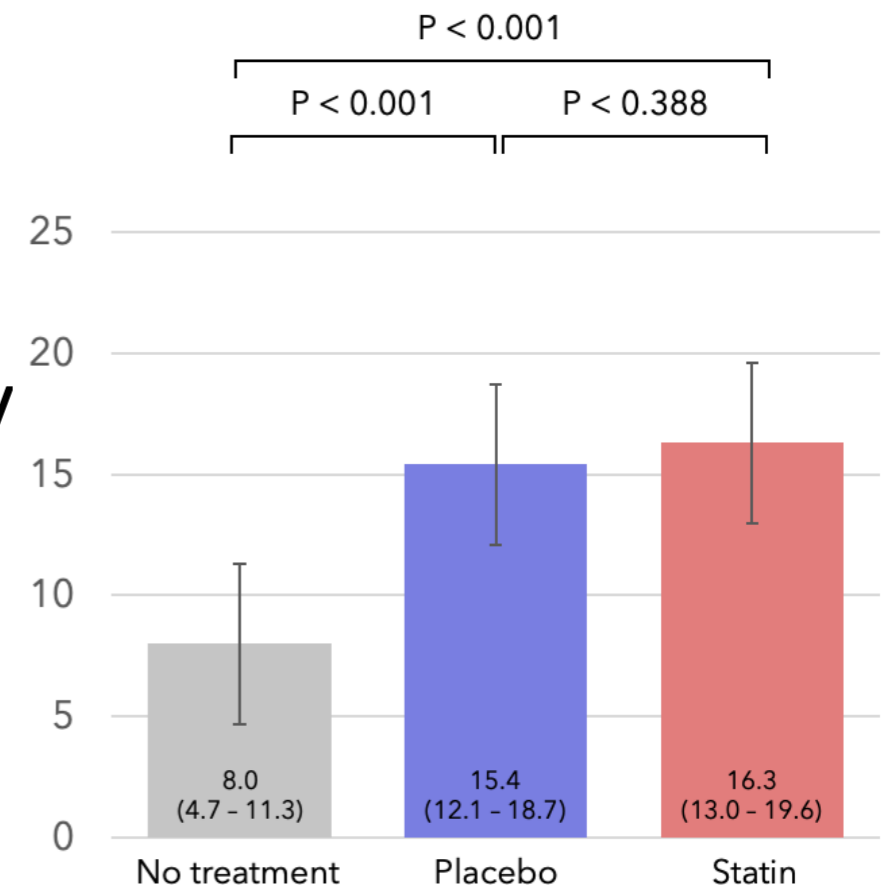
Conclusion

Patients really do get side-effects when taking statin tablets

But 90% of these side-effects are elicited by placebo tablets too

An N-of-1 trial with no treatment periods revealed this to patients clearly enough for 50% of them to successfully restart statins clinically

Side-effects on statin tablets are mainly caused by the act of taking tablets, not what is in them.



Statin tablet