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Survey Results

Should the randomized withdrawal design for relapse prevention studies in mood disorders be updated?

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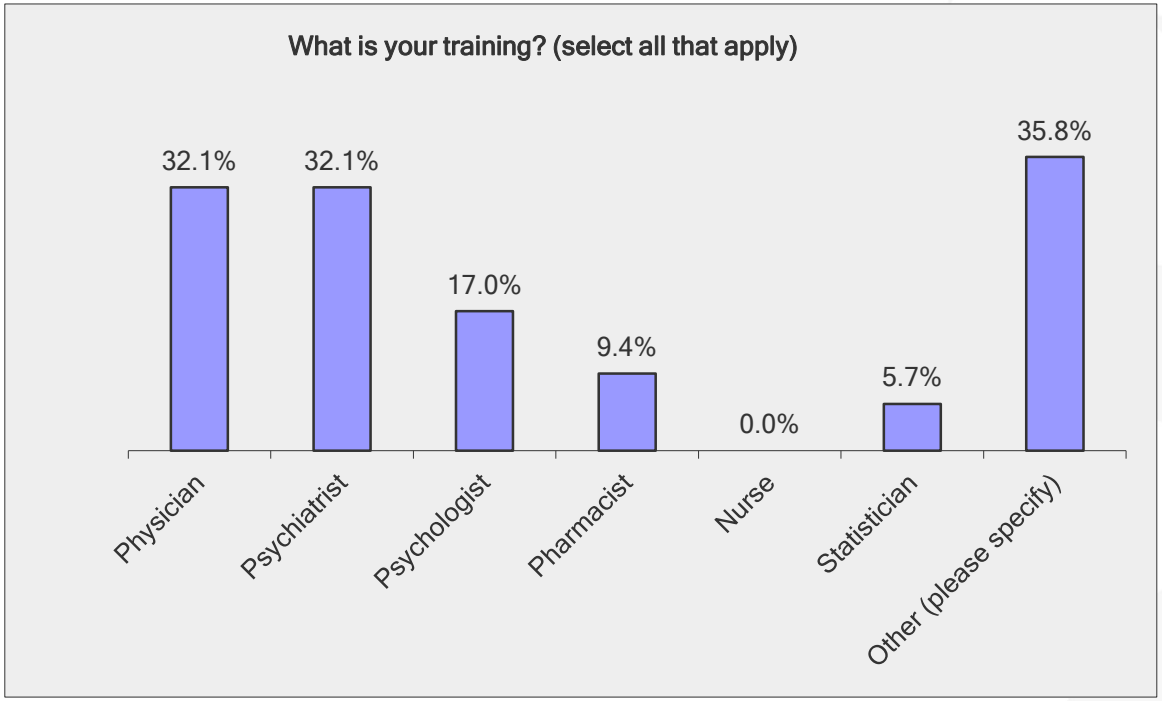
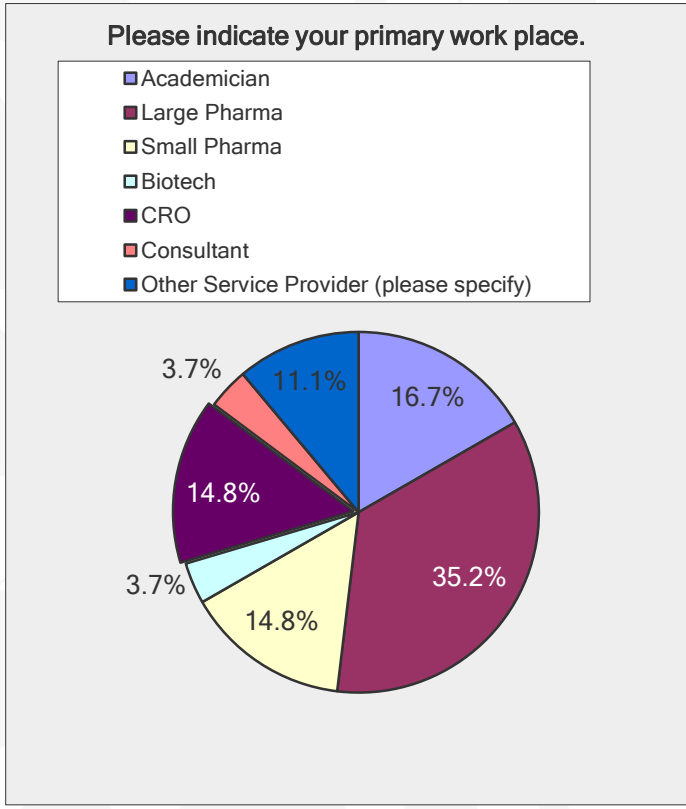
Survey Results

Response rate 15.5% (54 of 354)





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Survey Results

Which alternatives to the Randomized Withdrawal design do you favor?

	Response Percent
True maintenance study 1: Add Study Med vs Pbo for subjects meeting remission criteria **without changing** other medications	27.1%
True maintenance study 2: Add Study Med vs Pbo for subjects meeting remission criteria for subjects remaining well **after tapering** off effective acute treatment	14.6%
Maintenance of Effect: Randomize to Study Med A vs Comparator B in a blinded manner during acute phase and compare duration of well phase (assume any subject not reaching well status within a pre-determined acute treatment phase would discontinue.)	39.6%
Other: Please describe	18.8%

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Outcome criteria

For the alternative trial design chosen in question 8, which outcome criteria do you think best?

% remaining well for at least 6 months	**46.3%**
Time before adding/changing treatment	**31.7%**
% meeting recurrence criteria within 12 months of recovery	**22.0%**

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Survey Results

What duration of stability period prior to randomization is best for Relapse Prevention trials?		
Answer Options	Response Percent	Response Count
8 weeks	26.0%	13
12 weeks	48.0%	24
16 weeks	10.0%	5
20 weeks	4.0%	2
Greater than 20 weeks	12.0%	6

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Survey Results

Good ways to define criteria for relapse:

Answer Options	Definitely yes	Probably yes	Unsure	Probably no	Definitely no
Total scores on standard outcome scales are adequate	9	17	3	11	3
Number of scale items above a severity threshold	7	18	12	5	1
Full DSM criteria for a new episode	8	10	8	9	6
Pre-specified subthreshold criteria (Roughening)	5	15	15	6	1
Clinician Judgement	8	10	11	11	3
All cause discontinuation	2	15	7	14	5
Time to intervention	11	18	7	3	3
Number of clinical adjustments required	3	11	16	8	4
Time to intervention for mood symptoms	11	24	4	3	1
Time to any intervention	3	10	12	11	6

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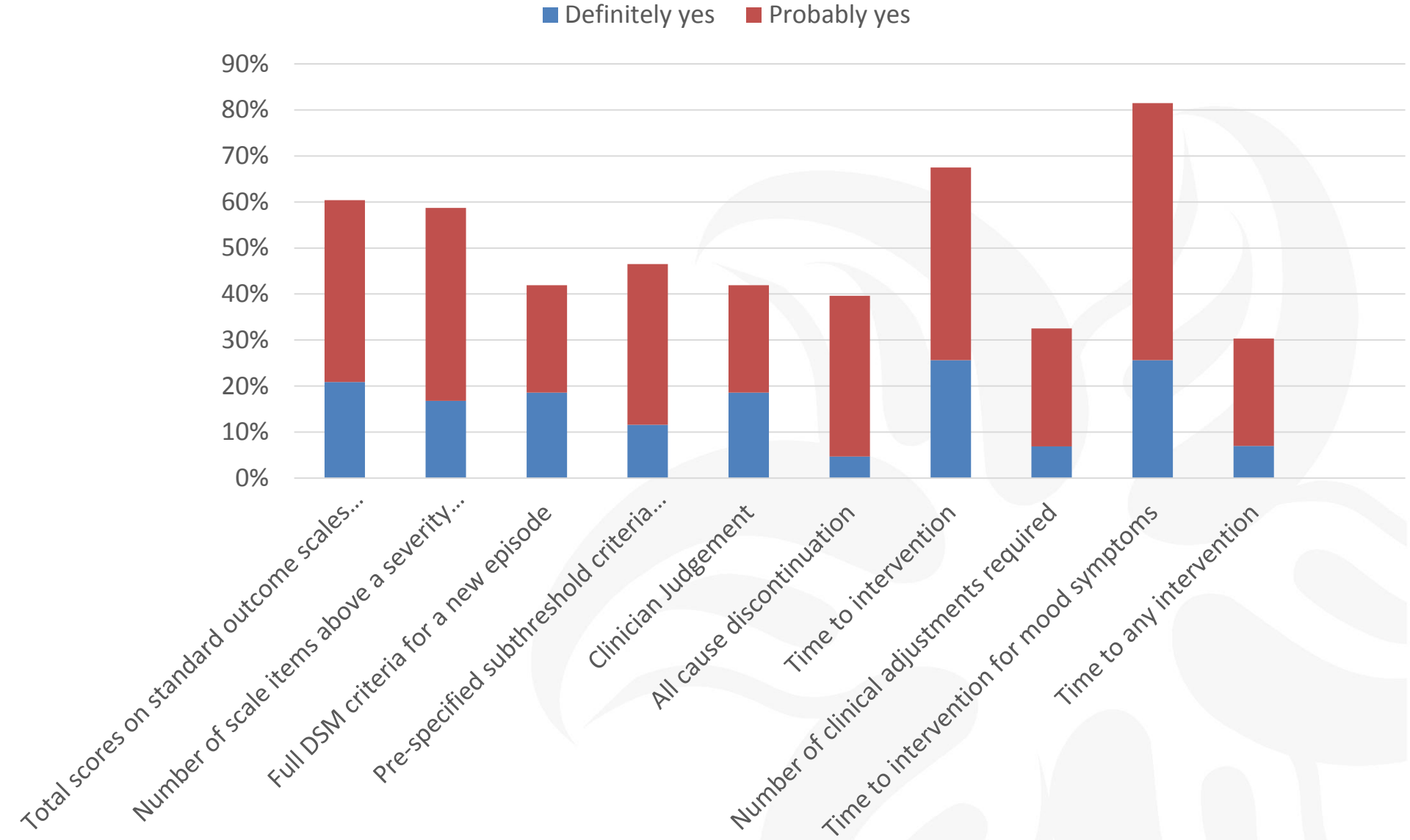
Good ways to define criteria for relapse:



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Regarding patient reported relapse measures:						
Answer Options	Definitely yes	Probably yes	Unsure	Probably no	Definitely no	Response Count
A PRO should always be included as an end point in Relapse Prevention trials.	16	15	4	4	4	43
A PRO should be the primary endpoint in Relapse Prevention trials.	0	5	12	17	9	43
PROs should only be secondary endpoint.	6	26	7	2	2	43
In a composite definition a PRO would count the same as a relapse defined by a Clinician rated outcome measure.	1	16	10	12	4	43
Not necessary to have a PRO as an outcome measure.	2	7	5	16	13	43

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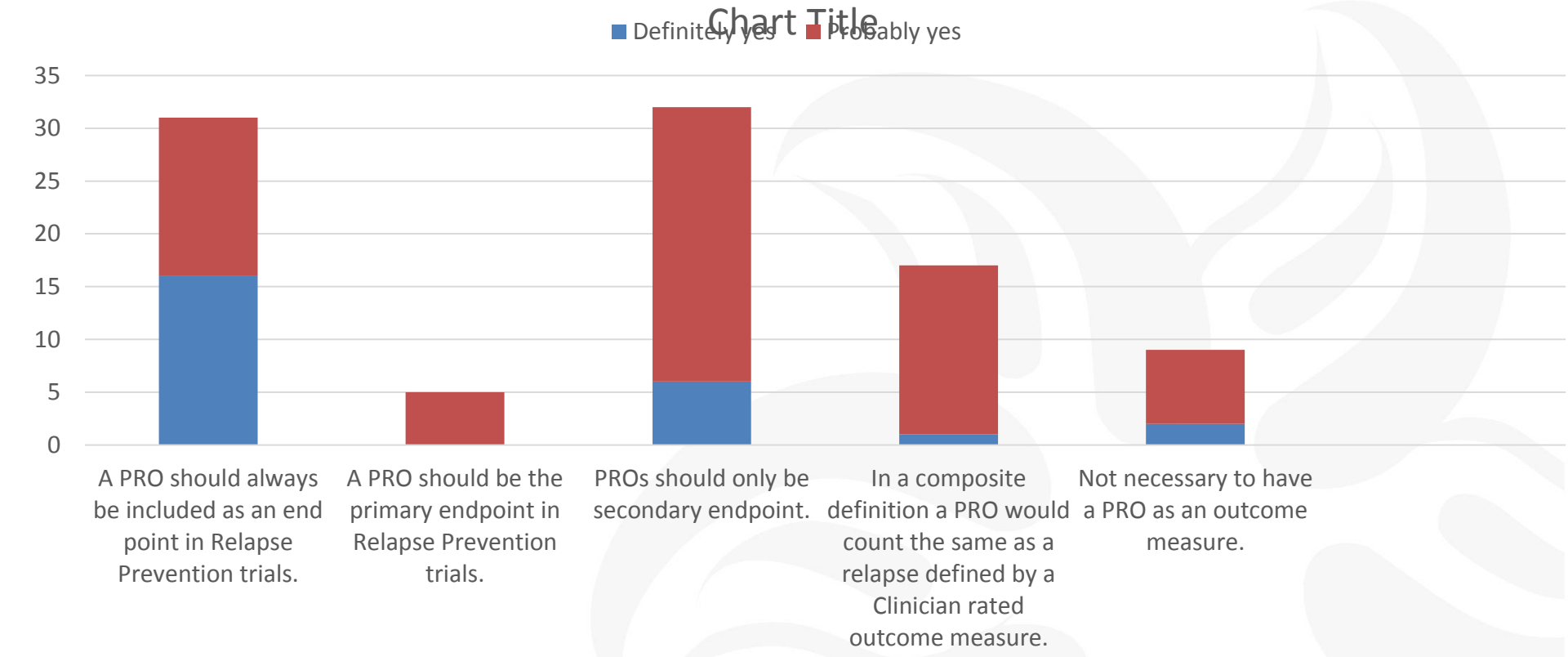
PRO as an end point in Relapse Prevention trials.



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Should pre-specified 'roughening' be included as an endpoint in Relapse Prevention trials?	
Answer Options	Response Percent
Yes	61.4%
No	38.6%

Should pre-specified 'necessary clinical adjustment of treatment' be included as an endpoint in Relapse Prevention trials?	
Answer Options	Response Percent
Yes	84.1%
No	15.9%