CBCH
Center for Behavioral Cardiovascular Health

Columbia University Medical Center

Randomized Trial of Depression Screening after Acute Coronary Syndromes

Results from CODIACS-QOL

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Disclosures

I have no conflicts of interest.

Importance

Depression is present in ~10% of ACS patients[1]

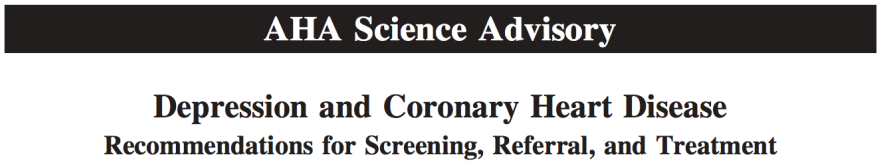
Depression doubles risk of CVD events and mortality, increases health care costs, and lowers quality of life[2,3]

Depression treatments are effective in ACS patients[1]

[1]Nieuwsma et al. *Ann Intern Med.* 2017; [2]Nicholson et al. *Eur Heart J* 2006; [3]Rutledge et al. J Am Coll Cardiol. 2009.

Importance

Professional societies recommend depression screening in ACS patients, with referral of those who screen positive to specialty care[1]


AHA Science Advisory

Depression and Coronary Heart Disease

Recommendations for Screening, Referral, and Treatment

[1]Lichtman et al. *Circulation*. 2008

Importance

RCTs of depression treatments have been limited to treatment-seeking patients

Screening may be harmful

No RCTs of depression screening in ACS patients

Objective

To conduct an RCT that evaluates whether systematically screening ACS patients for depression improves quality of life and depression as compared to usual care.

clinicaltrials.gov identifier: NCT01993017

Setting

4 healthcare systems

Recruitment from Nov 2013 – April 2017

Eligibility

Inclusions

≥ 21 years

ACS within 2-12 months

English or Spanish speaking

Exclusions

Prior or current depression

Life-expectancy < 1 year

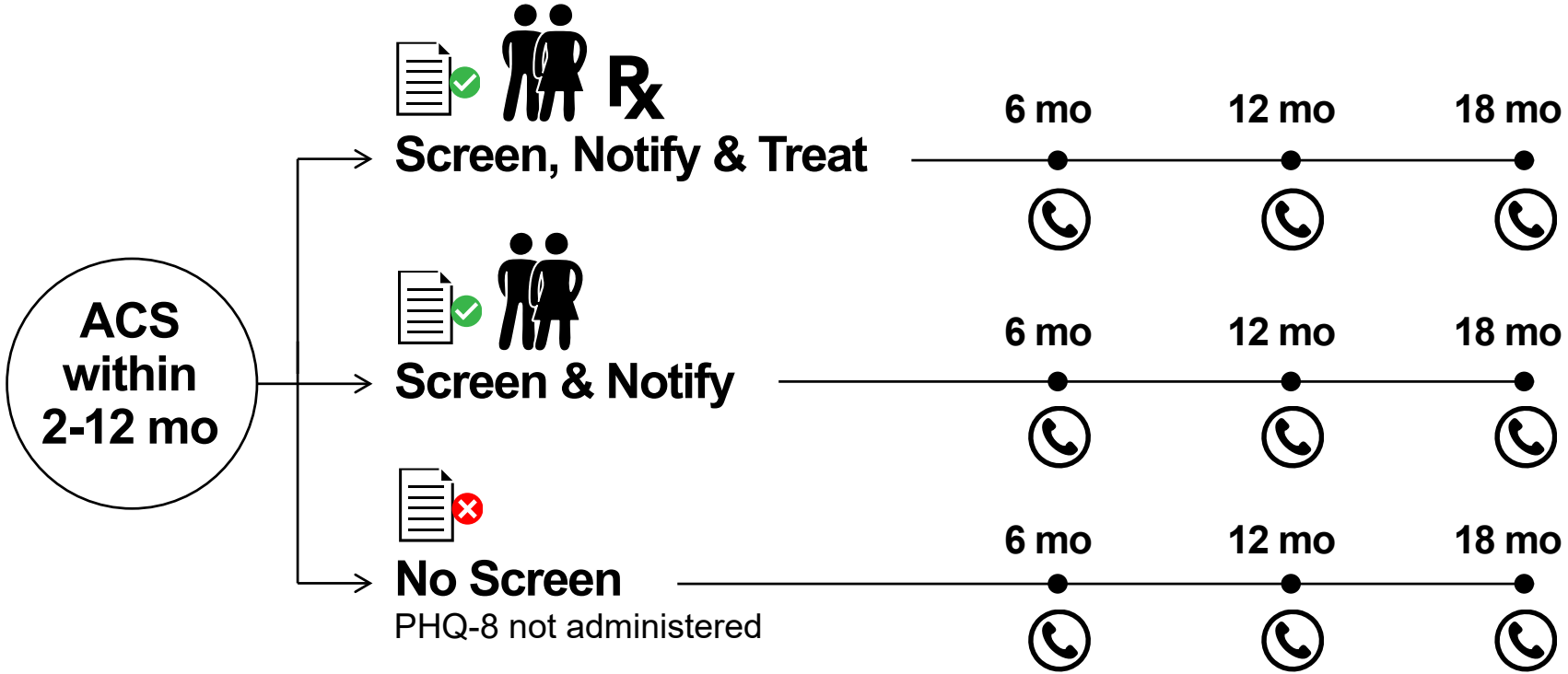
Severe mental illness

Severe physical illness

Dementia

Pregnancy

Design & Interventions



Outcomes

Primary Outcome

Change in QALYs from baseline to 18-mo[1]

Secondary Outcomes

Cumulative depression-free days across 18-mo

Depressive symptoms (CESD-10)

Harms

Antidepressant side-effects, bleeding

All-cause mortality

[1]QALYs, Quality Adjusted Life Years: calculated from utilities derived from the SF-12 using SF-6D transformation

Statistical Analyses

2-step gate-keeping test: ANOVA used to calculate F-test for 3-group difference in change in QALY score; paired t-tests planned if F-test p-value < .05

All analyses intent-to-treat

Missing data handled with multiple imputation

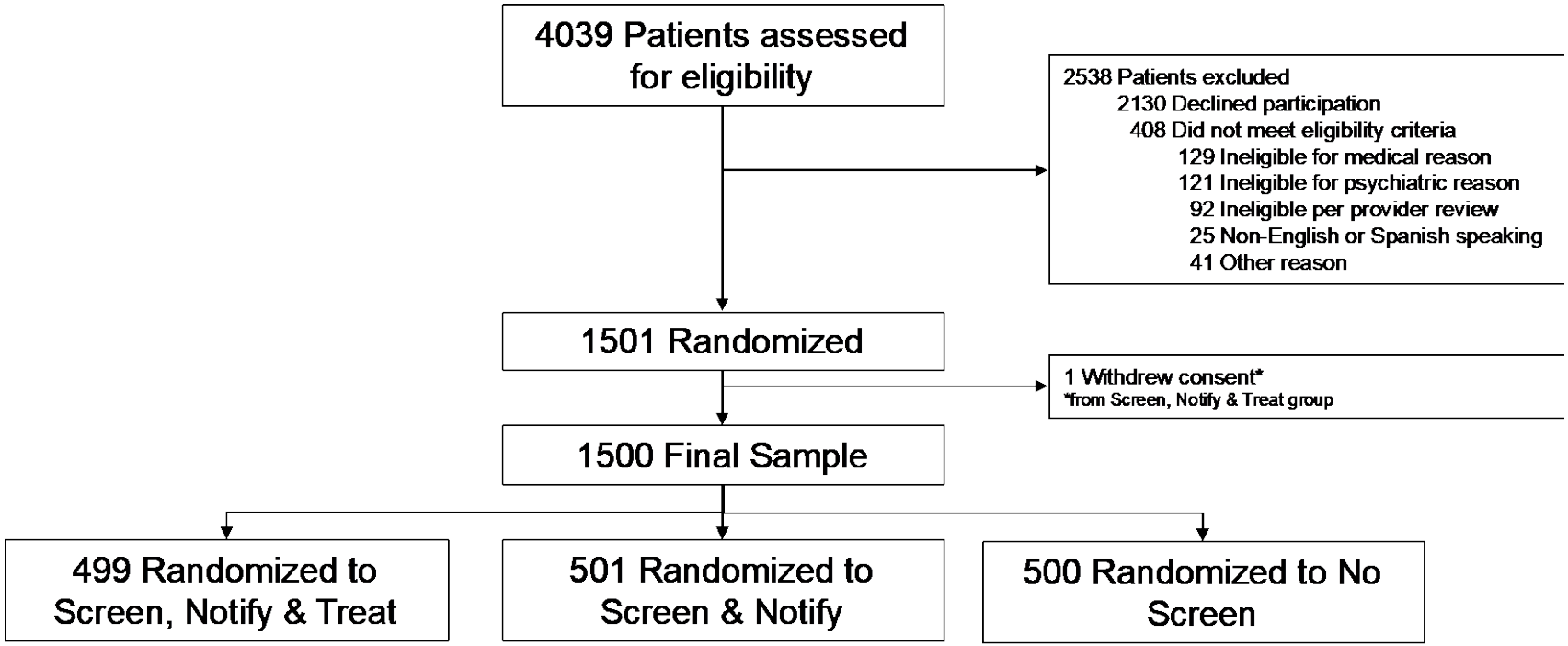
Sample Size

500 participants per group provided 80% power to detect clinically significant difference in change in QALYs for a 2-sided t-test at 5% level

Assumptions:

- 20% screen positive for depression
- net improvement in QALYs of 0.155 over 18-months for depressed ACS patients in Screen, Notify & Treat group
- 5% loss to follow-up

Participant Flowchart



Participant Characteristics

	Screen, Notify & Treat (n = 499)	Screen & Notify (n = 501)	No Screen (n = 500)
Age in years, mean (SD)	66.2 (11.3)	65.8 (11.7)	65.8 (11.7)
Male	71.5%	72.7%	71.0%
White	70.7%	73.5%	71.8%
Hispanic	16.4%	17.6%	14.8%
Education, high school or lower	38.7%	35.7%	33.7%
Married	64.2%	67.5%	62.9%
Employed	41.7%	39.6%	40.9%

Screening Outcomes

Screen, Notify & Treat

Screen & Notify

No Screen

1500 Final Sample

499 Screen, Notify & Treat

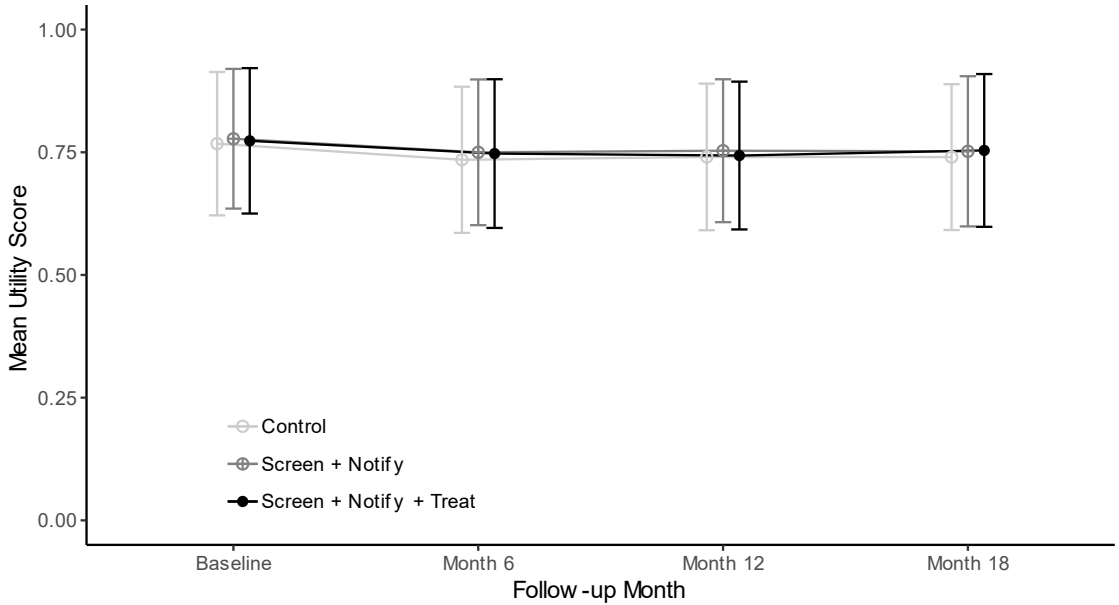
- 38 (7.6%) Depressed
  - 14 Chose PST
  - 4 Chose Meds
  - 10 Chose PST & Meds
  - 10 Declined study tx

501 Screen & Notify

- 33 (6.6%) Depressed

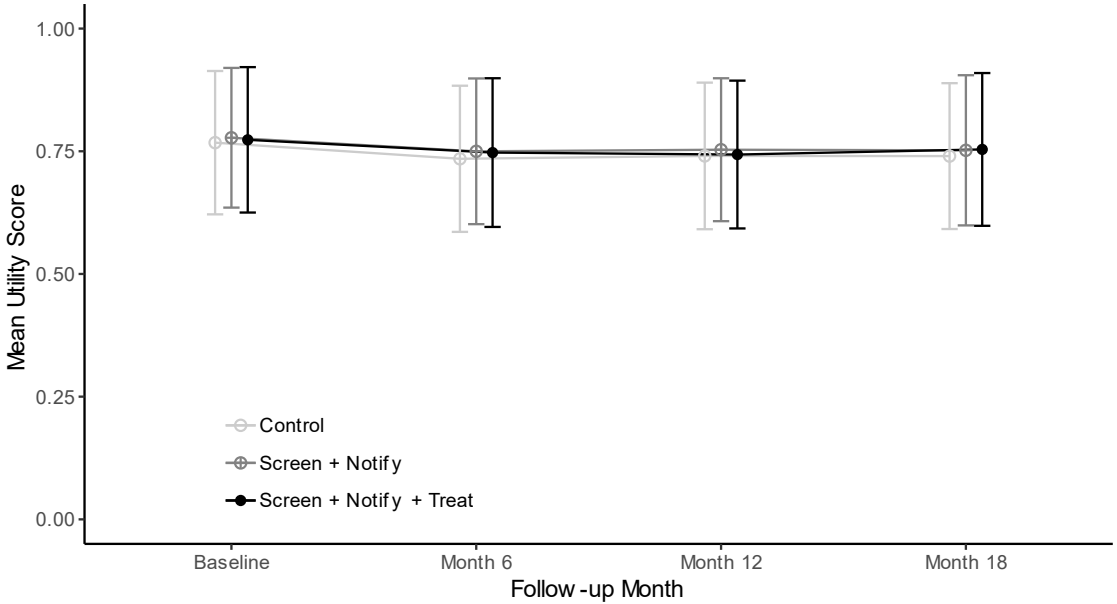
500 No Screen

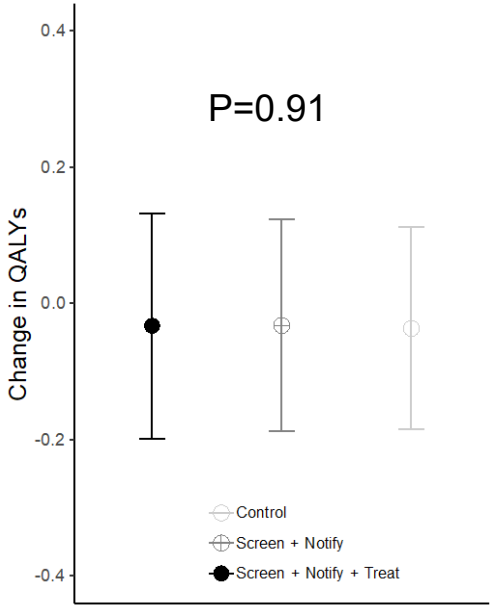
Utilities and Change in QALYs



Utilities were derived from the SF-12 using SF-6D transformation

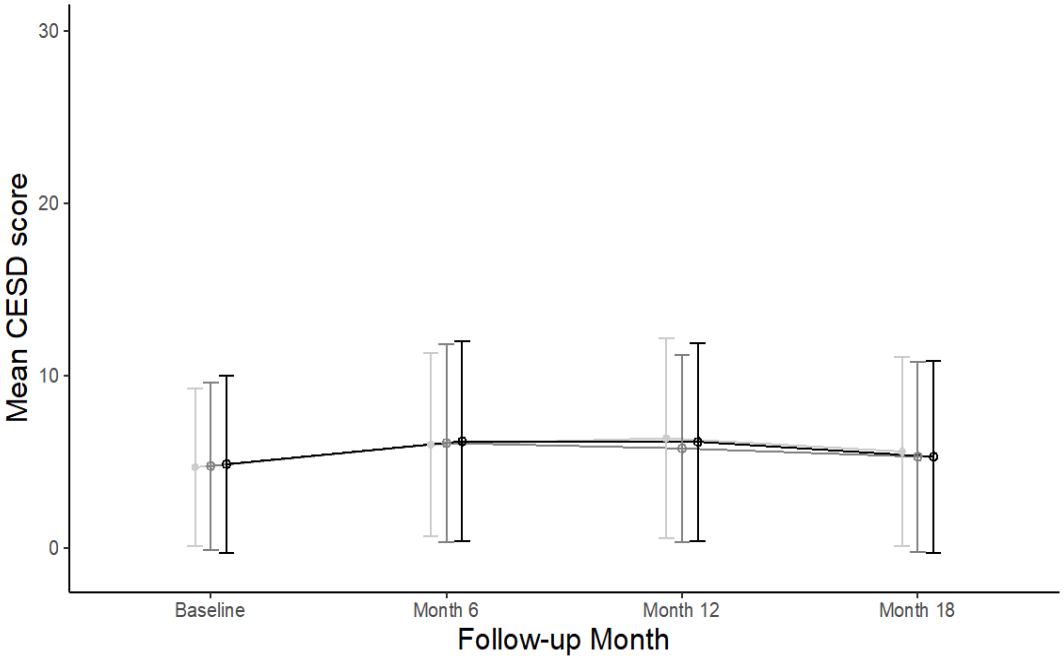
Utilities and Change in QALYs



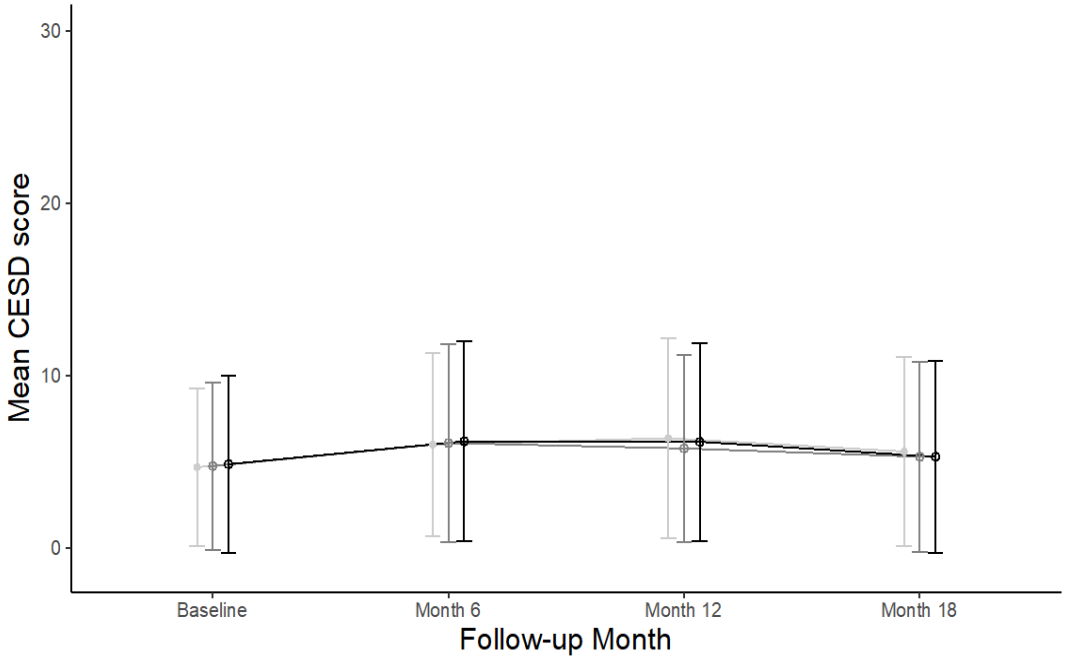


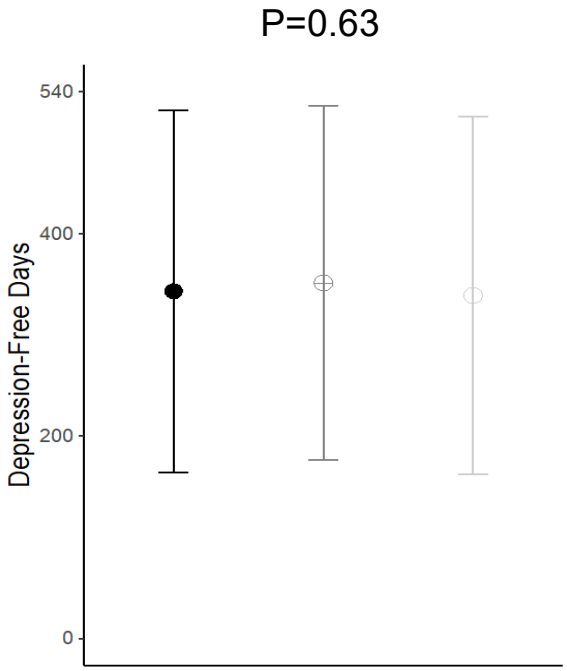
QALYs, Quality Adjusted Life Years

Depressive Symptoms and Depression-Free Days



Depressive Symptoms and Depression-Free Days





Harms

No differences in bleeding, appetite, drowsiness, or GI upset across the 6-, 12-, and 18-month time points

No differences in mortality at 18-month (4.5% died)

Conclusions

Depression screening with or without providing treatment did not alter QALYs or depression, nor increase harms

The prevalence of positive depression screens with systematic depression screening was only 7%

Limitations

Individuals with history of depression were excluded

Underpowered to detect smaller benefits

Depression screening may have occurred in the “No screen” group

Screening was conducted in context of research study

Implications →

Systematic depression screening may not be warranted

Depression screening guidelines may need to be reconsidered

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Questions

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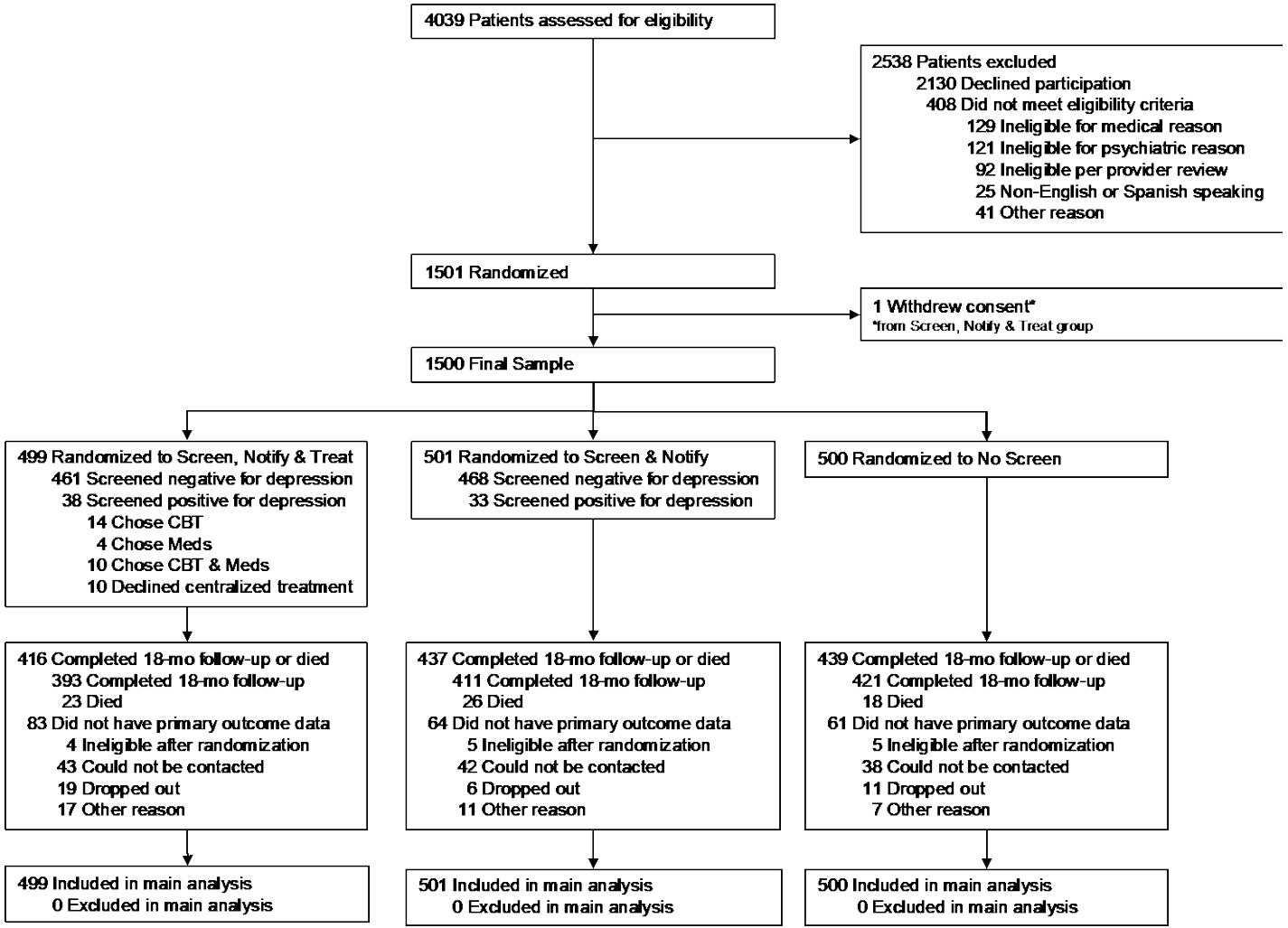
Thank you.

Extra Slides


4039 Patients assessed for eligibility
2538 Patients excluded
2130 Declined participation
408 Did not meet eligibility criteria
129 Ineligible for medical reason
121 Ineligible for psychiatric reason
92 Ineligible per provider review
25 Non-English or Spanish speaking
41 Other reason
1501 Randomized
1 Withdrew consent*
*from Screen, Notify & Treat group
1500 Final Sample
499 Randomized to Screen, Notify & Treat
461 Screened negative for depression
38 Screened positive for depression
14 Chose CBT
4 Chose Meds
10 Chose CBT & Meds
10 Declined centralized treatment
501 Randomized to Screen & Notify
468 Screened negative for depression
33 Screened positive for depression
500 Randomized to No Screen
416 Completed 18-mo follow-up or died
393 Completed 18-mo follow-up
23 Died
83 Did not have primary outcome data
4 Ineligible after randomization
43 Could not be contacted
19 Dropped out
17 Other reason
437 Completed 18-mo follow-up or died
411 Completed 18-mo follow-up
26 Died
64 Did not have primary outcome data
5 Ineligible after randomization
42 Could not be contacted
6 Dropped out
11 Other reason
439 Completed 18-mo follow-up or died
421 Completed 18-mo follow-up
18 Died
61 Did not have primary outcome data
5 Ineligible after randomization
38 Could not be contacted
11 Dropped out
7 Other reason
499 Included in main analysis
0 Excluded in main analysis
501 Included in main analysis
0 Excluded in main analysis
500 Included in main analysis
0 Excluded in main analysis

Depressive Symptoms (PHQ-8)