

Patients with Any Degree of  
Suicidal Ideation and Behavior  
**SHOULD BE** Included in Clinical Trials?

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# Disclosures/Conflicts

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- No bias, conflict of interest or industry involvement

# Imperative to include people with SIB

- People with SIB represent many of people who will receive the treatment
- Just because someone is thinking of suicide does not mean they are at risk for dying by suicide
- Need to learn about real world efficacy
- Excluding people with SIB does not insure that no one in the trial will be at risk

# The imperative to include

- Is it ethical to exclude people who may benefit from treatment?
  - Risk of suicide is high without treatment
- Death by suicide is a rare event
  - Cancer trials do not exclude people who may die by cancer
- Discrimination against people with a mental health conditions from trials
- Clinical trial is often last resort for participants

# Rationale for inclusion of people with SIB

- Eliminating people with SIB in depression studies reflect only a subtype of people
- SIB occurs across diagnoses
  - Important to study SIB across studies
- SIB is an entity that must be studied in its own right
  - There are treatments specific for SIB

There are scientific and clinical costs to excluding  
people with SIB

# We have the capacity to include

- We have tools available for inclusion
  - Assessments to monitor SIB and risk
  - Safety planning and other brief tools for managing suicidal behavior
  - Plan for action if SIB emerges
- Given the range of SIB we can specify inclusion criteria based on the intervention and resources available

# If you must exclude people:

- Remember it may feel like their last hope
- Respect that they are suffering and in tremendous pain
- Offer them options
  
- STARR911



Who do you want to benefit  
from your treatment?

Who do you think out to be  
excluded from your treatment?