

Redesign?

Suicide prevention outreach trial (SPOT)

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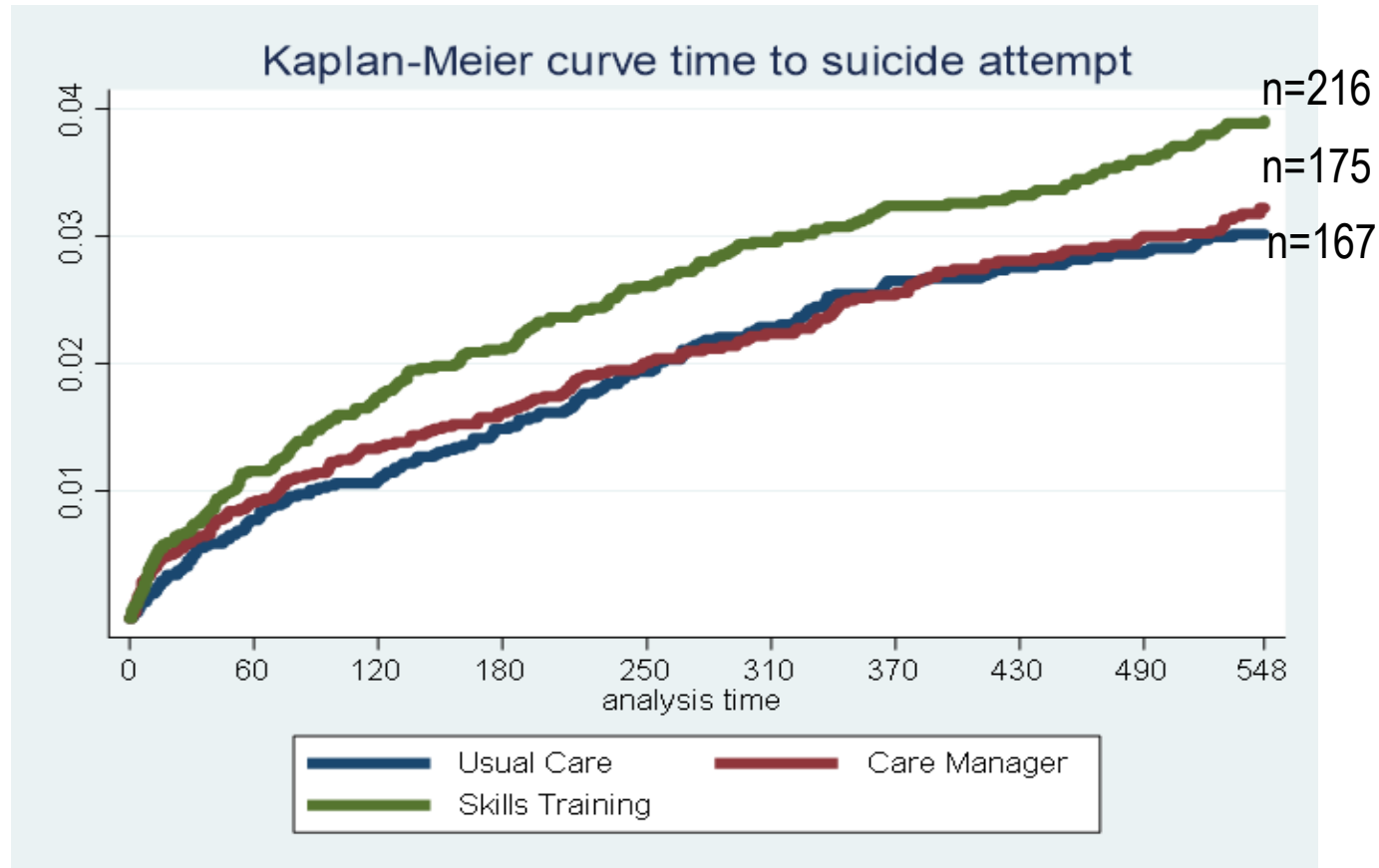
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Start with the ending:

- Studied whether either of two low-intensity outreach interventions could reduce risk of self-harm or suicide attempt among people who report frequent suicidal ideation.
- We did not find that either intervention reduced risk.
- One of the interventions may have actually INCREASED risk.
- In light of this disappointing result (and extra years of experience), we would not change study design.

Primary outcome: First fatal or non-fatal self-harm



Log-rank Chi-square:

- Care Management vs. Usual Care: $X^2=0.37$, $p=0.54$
- Skills Training vs. Usual Care: $X^2=6.92$, $p=.0085$

Hazard Ratios from Cox Model

- Care Management vs. Usual Care: 1.09 (0.88 – 1.35)
- Skills Training vs. Usual Care: 1.33 (1.09 – 1.63)

SPOT: design decisions

- Study question: Should health systems implement either of these programs (Care Management or DBT Skills with Coach) to reduce risk of suicidal behavior among outpatients reporting frequent suicidal ideation on routinely administered questionnaires?

SPOT: design decisions (PICOT), population

- Study question: Should health systems implement either of these programs (Care Management or DBT Skills with Coach) to reduce risk of suicidal behavior among outpatients reporting frequent suicidal ideation on routinely administered questionnaires?
 - All individuals enrolled in participating health systems (HealthPartners, Colorado, Northwest, Washington regions of Kaiser Permanente) who responded with a 2 or 3 to on item 9 of the patient health questionnaire (PHQ)
 - Had to use MyChart (or equivalent)
 - PHQ item 9: “Thoughts that you would be better off dead, or of hurting yourself in some way?” (Not at all, several days, more than half the day, nearly every day)
 - Randomized 18,882 individuals to one of three randomization arms
 - Equal randomization stratified on PHQ item 9 response and health system
 - Much wider range of baseline risk in SPOT than many suicide prevention trials

SPOT: design decisions(PICOT), intervention

- Offer of two active interventions
 1. Dialectical behavior therapy (DBT) Skills training (online program with coach)
 2. Risk-based care management to facilitate outpatient care
 - Both interventions lower intensity than previously studied, delivered centrally to individuals (no group component)
- Invitation process (i.e., offer of interventions)
 - Initial invitation via electronic health record (EHR) online messaging included:
 - Expression of caring and concern, description of specific intervention services
 - Abbreviated informed consent information (interventions are part of research, participation is voluntary, free to decline or withdraw)
 - Reminder if no response in 3 days, repeat invitation 4 and 8 weeks later if no response
 - If no response after 3 “cycles” of invitation – not contacted again but could accept intervention services throughout 12-month period.

SPOT: design decisions(PICOT), intervention

- DBT skills training (online program supported by coaching)
 - Online program aimed to provide brief/introductory training in specific DBT skills
 - Mindfulness, mindfulness of current emotion, opposite action, paced breathing
 - Brief video description, video instruction from clinicians, examples from people with lived experience
 - Encouragement to commit to specific practice (with “homework” pages)
 - Coaching support provided tailored reinforcement messages after each visit
 - Reminder messages to visit for up to 12 months after randomization
- Risk-based care management to facilitate outpatient care
 - Aimed to incorporate key elements of effective CC/CM interventions
 - Systematic outreach and assessment on measurement-based (adjustable) schedule
 - Risk-based recommendations for outpatient mental health follow-up
 - Outreach continued up to 12 months after randomization

SPOT: design decisions(PICOT), comparison

- Compared each intervention to usual care
- “Zelen” design – compared all individuals randomized regardless of uptake of intervention
 - Invitation process part of intervention evaluation
 - No requirement to accept (or even consider) potential intervention
 - Based on post-hoc analyses of suicidal behavior risk and engagement
 - SPOT team hypothesis: (repeatedly) reaching out to individuals with services they are not interested in may be harmful

SPOT: design decisions (PICOT), outcome

- Outcome: suicide attempt, fatal or non-fatal
 - Fatal suicide attempts identified from state death certificates
 - Any death coded with self-harm intent
 - Non-fatal suicide attempts identified from electronic health records
 - Injury or poisoning coded with self-harm intent
 - Select injuries or poisonings coded with undermined or accidental intent, or no intent recorded, were chart reviewed to assess self-harm intent
 - Blinded assessment of ICD codes of injuries or poisonings for common self-harm mechanism, for example
 - » Accidental overdose of antidepressant medication, reviewed
 - » Accidental bee sting, not reviewed
 - 3 blinded reviewers read text extracted from clinical notes of injury or poisoning
 - » Was self-harm intent documented and rated confidence

SPOT: design decisions(PICOT), timing

- Primary outcome: suicide attempt, fatal or non-fatal in 18 months after randomization
 - Interventions could be on going for up to 12 months
 - 6-month maintenance phase included
- Censored at time of health system disenrollment or death from cause other than self-harm

Other lessons (I) learned

- Data safety and monitoring boards (DSMBs) important for pragmatic trials
 - If serious outcome, have more than one person responsible for reports
- Regular quality assurance (QA) important for pragmatic trials relying on automated data sources such as electronic health records
 - Side effect of DSMB reports for SPOT
 - Fold some QA into open DSMB reports like enrollment