Population-based outreach to prevent suicidal behavior among outpatients reporting frequent suicidal ideation

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Susan Shortreed PhD
Kaiser Permanente Washington Health Research Institute
**Our team:**

<table>
<thead>
<tr>
<th>KP Washington</th>
<th>HealthPartners</th>
<th>KP Colorado</th>
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</thead>
<tbody>
<tr>
<td>Greg Simon</td>
<td>Rebecca Rossom</td>
<td>Arne Beck</td>
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<tr>
<td>Susan Shortreed</td>
<td>Caitlin Borgert-Spaniol</td>
<td>Jennifer Boggs</td>
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<tr>
<td>Julie Richards</td>
<td>Sheryl Kane</td>
<td>Lee Ann Quintana</td>
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<tr>
<td>Chester Pabiniak</td>
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<td>Deborah King</td>
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<td>Lisa Shulman</td>
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<td>Ashley Glass</td>
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<td>Jessie Waiamau-Ariota</td>
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<td>Evette Ludman</td>
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<td>Beth Kirlin</td>
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<td>Julia Smith</td>
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</tbody>
</table>

**KP Northwest**

- Greg Clarke
- Phil Crawford
- Sarah Gille

**Supported by NIMH**

UH3MH007755
We 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.

How do we understand that, and where do we go from here?
Where we started

- Routine questionnaires can identify outpatients at increased risk
- We have interventions that work - under specific circumstances.
  - Dialectical Behavior Therapy (DBT) – Structured individual and group therapy significantly reduces repeat self-harm among consenting research volunteers.
  - Cognitive Behavioral Therapy (CBT) – 10-session individual therapy reduced repeat self-harm among consenting research volunteers
  - Care Management interventions improve effectiveness of specific pharmacotherapy or psychotherapy for mood and anxiety disorders.
- Two candidate interventions:
  - DBT skills training (online program supported by coaching)
  - Risk-based care management to facilitate effective outpatient care
- Study question: Should health systems implement either of these programs to reduce risk of suicidal behavior among outpatients reporting frequent suicidal ideation on routinely administered questionnaires?
Design overview

- Four MHRN health systems (HealthPartners, KPWA, KPCO, KPNW)
- Automatically identify adult outpatients completing PHQ9 and reporting suicidal ideation “more than half the days” or “nearly every day”
  - Limit to those currently enrolled and using EHR portal online messaging
  - Exclude for: diagnosis of cognitive impairment, EHR indicator for needing interpreter
- Immediately randomized (concealed tables, permuted blocks of 6 or 9) to:
  - Continued usual care (never contacted)
  - Offer of Care Management program
  - Offer of Skills Training program
- Interventions offered and delivered for up to 12 mos
- Outcome: fatal or non-fatal self-harm over 18 mos following randomization
- Target sample size of 19,500 based on expected event rate of 3.75%
Invitation process (similar for two interventions)

- Initial invitation via EHR online messaging:
  - Expression of caring and concern
  - Description of specific intervention services
  - Abbreviated informed consent info (interventions are part of research, participation is voluntary, free to decline or withdraw)

- Reminder (phone or messaging) if no response in 3 days

- Repeat invitation process 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.
Care Management intervention

- Intended to supplement (not replace) existing outpatient care
- Aimed to incorporate key elements of effective CC/CM interventions
- Systematic outreach on measurement-based (adjustable) schedule
- Structured suicide risk assessments (CSSRS) at each contact
- Risk-based recommendations for outpatient mental health follow-up
- Motivational enhancement and care navigation as indicated
- Communication of recommendations to treating providers
- Outreach primarily via EHR messaging (with telephone as “backup”)
- Higher intensity follow-up in cases of high risk scores (CSSRS >=4)
- Outreach continued up to 12 months after randomization
Skills Training intervention

- Intended to supplement (not replace) existing outpatient care
- Aimed to provide brief/introductory training in specific DBT skills
- Online skills training program:
  - Introduce four skills: mindfulness, mindfulness of current emotion, opposite action, and 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:
  - Tailored reinforcement messages after each visit
  - Reminder messages to those “overdue” for a visit – initially every month and spacing out to every 2 months.
- Reinforcing/reminding continued up to 12 months after randomization
Trial outcomes

- Primary outcome – time to first self-harm event, including:
  - Death attributed to self-harm or undetermined intent (from state mortality data)
  - Encounter diagnosis of intentional self-harm (usually from ED or inpatient)
  - “Potential” events not diagnosed as self-harm, but confirmed by full-text records
    (includes some self-harm without intent to die, as that can’t be distinguished in records)

- Censored at time of health system disenrollment or death from cause other than self-harm

- Secondary analyses (planned and declared in advance):
  - Narrower: Limited to self-harm resulting in death or hospitalization
  - Broader: Include “potential” events even if not confirmed by clinical text
Blinding

- Usual Care participants never contacted – unaware of study
- Participants assigned to each intervention aware of assignment, but not aware of other intervention or usual care group
- Health outpatient system clinicians aware of intervention assignments, but not assignments to usual care
- Emergency and inpatient clinicians not notified of study or individual assignments, but might have access to outpatient records
Pragmatic Design Features

- Participants identified automatically from existing clinical records
- Broad and simple eligibility criteria, with no “baseline” assessment
- Randomly assign all eligible, regardless of motivation or engagement
- Comparison to usual care, since that is the policy question.
- Participants free to decline or withdraw from any intervention services.
- Outcomes assessed from clinical and vital statistics records.
- Analysis by intent to treat, regardless of intervention uptake or participation

(Not so pragmatic: Intervention was delivered by centralized team with regular monitoring and supervision)
18,882 health plan members completing PHQ-9 questionnaires at outpatient visits and:
- Reporting suicidal ideation “more than half” or “nearly every day”
- Using online messaging via EHR patient portal

Random Assignment

Allocated to Usual Care (n = 6256)
- Contributed time to analysis (n = 6187)
  - Full 18 months follow-up (n=4456)
  - Censored before 18 months (n=1731)
  - No follow-up time (n = 69)

Allocated to Care Management (n = 6314)
- Offered Care Management (n = 6113)
- Not Offered Care Management (n = 201)
- Contributed time to analysis (n = 6230)
  - Full 18 months follow-up (n=4474)
  - Censored before 18 months (n=1756)
  - No follow-up time (n = 84)

Allocated to DBT Skills Training (n = 6312)
- Offered DBT Skills Training (n = 6080)
- Not Offered DBT Skills Training (n = 232)
- Contributed time to analysis (n = 6227)
  - Full 18 months follow-up (n=4504)
  - Censored before 18 months (n=1723)
  - No follow-up time (n = 85)
## Analytic sample

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>Care Management</th>
<th>Skills Training</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=6187</td>
<td>n=6230</td>
<td>n=6227</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>4,188 (67.7%)</td>
<td>4,195 (67.3%)</td>
<td>4,160 (66.8%)</td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>1,457 (23.6%)</td>
<td>1,438 (23.1%)</td>
<td>1,440 (23.1%)</td>
</tr>
<tr>
<td>30-44</td>
<td>1,756 (28.4%)</td>
<td>1,747 (28.0%)</td>
<td>1,797 (28.9%)</td>
</tr>
<tr>
<td>45-64</td>
<td>2,067 (33.4%)</td>
<td>2,069 (33.2%)</td>
<td>2,056 (33.0%)</td>
</tr>
<tr>
<td>65+</td>
<td>907 (14.7%)</td>
<td>976 (15.7%)</td>
<td>934 (15.0%)</td>
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<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
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<tr>
<td>Non-Hispanic White</td>
<td>4,561 (73.7%)</td>
<td>4,723 (75.8%)</td>
<td>4,651 (74.7%)</td>
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<tr>
<td>Hispanic</td>
<td>595 (8.6%)</td>
<td>495 (7.9%)</td>
<td>486 (7.8%)</td>
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<tr>
<td>Asian, Non-Hispanic</td>
<td>194 (3.1%)</td>
<td>179 (2.9%)</td>
<td>183 (2.9%)</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>237 (3.8%)</td>
<td>241 (3.9%)</td>
<td>272 (4.4%)</td>
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<tr>
<td>American Indian, Non-Hispanic</td>
<td>35 (0.6%)</td>
<td>56 (0.9%)</td>
<td>42 (0.7%)</td>
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<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>23 (0.4%)</td>
<td>24 (0.4%)</td>
<td>29 (0.5%)</td>
</tr>
<tr>
<td>More than one</td>
<td>203 (3.3%)</td>
<td>170 (2.7%)</td>
<td>188 (3.0%)</td>
</tr>
<tr>
<td>Other or not recorded</td>
<td>399 (6.5%)</td>
<td>342 (5.5%)</td>
<td>376 (6.0%)</td>
</tr>
<tr>
<td><strong>Location of Index Visit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Health Specialty Clinic</td>
<td>3,040 (49.1%)</td>
<td>3,071 (49.3%)</td>
<td>3,111 (50.0)</td>
</tr>
<tr>
<td>General Medical Clinic</td>
<td>3,147 (50.9%)</td>
<td>3,159 (50.7%)</td>
<td>3,116 (50.0)</td>
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<tr>
<td><strong>Baseline PHQ9 Item 9 Score</strong></td>
<td></td>
<td></td>
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<tr>
<td>More than half the days</td>
<td>4141 (66.9%)</td>
<td>4180 (67.1%)</td>
<td>4177 (67.1%)</td>
</tr>
<tr>
<td>Nearly every day</td>
<td>2046 (33.1%)</td>
<td>2050 (32.9%)</td>
<td>2050 (32.9%)</td>
</tr>
<tr>
<td><strong>Diagnoses recorded in past year</strong></td>
<td></td>
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</tr>
<tr>
<td>Depressive disorder</td>
<td>4058 (65.6%)</td>
<td>4077 (65.4%)</td>
<td>4020 (64.6%)</td>
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<tr>
<td>Anxiety disorder</td>
<td>3653 (59.0%)</td>
<td>3692 (59.3%)</td>
<td>3700 (59.4%)</td>
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<tr>
<td>Bipolar disorder</td>
<td>621 (10.0%)</td>
<td>689 (11.1%)</td>
<td>686 (11.0%)</td>
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<tr>
<td>Drug use disorder</td>
<td>451 (7.3%)</td>
<td>462 (7.4%)</td>
<td>469 (7.5%)</td>
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<tr>
<td>Alcohol use disorder</td>
<td>349 (5.6%)</td>
<td>395 (6.3%)</td>
<td>364 (5.8%)</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>510 (8.2%)</td>
<td>528 (8.5%)</td>
<td>561 (9.0%)</td>
</tr>
<tr>
<td>Self-harm injury or poisoning</td>
<td>141 (2.3%)</td>
<td>126 (2.0%)</td>
<td>148 (2.4%)</td>
</tr>
<tr>
<td><strong>Service use in past year</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mental health hospitalization</td>
<td>614 (9.9%)</td>
<td>656 (10.5%)</td>
<td>652 (10.5%)</td>
</tr>
<tr>
<td>Mental health emergency dept. visit</td>
<td>983 (15.9%)</td>
<td>1000 (16.1%)</td>
<td>1059 (17.0%)</td>
</tr>
</tbody>
</table>
## Intervention participation

<table>
<thead>
<tr>
<th></th>
<th>Care Management n=6230</th>
<th>Skills Training n=6227</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not offered intervention</strong>¹ (n, %)</td>
<td>201 (3.2%)</td>
<td>232 (3.7%)</td>
</tr>
<tr>
<td><strong>Actively declined invitation</strong> (n, %)</td>
<td>1345 (21.6%)</td>
<td>799 (12.8%)</td>
</tr>
<tr>
<td><strong>No response after 3 invitations</strong> (n, %)</td>
<td>2757 (44.3%)</td>
<td>2780 (44.6%)</td>
</tr>
<tr>
<td><strong>Ever engaged in intervention</strong>² (n, %)</td>
<td>1927 (30.9%)</td>
<td>2416 (38.8%)</td>
</tr>
<tr>
<td><strong>Engaged beyond 3 months</strong>³ (n, %)</td>
<td>1612 (25.9%)</td>
<td>767 (12.3%)</td>
</tr>
<tr>
<td><strong>Engaged beyond 6 months</strong>³ (n, %)</td>
<td>1392 (22.3%)</td>
<td>268 (4.3%)</td>
</tr>
<tr>
<td><strong>Engaged beyond 9 months</strong>³ (n, %)</td>
<td>1049 (16.8%)</td>
<td>117 (1.9%)</td>
</tr>
</tbody>
</table>

**Notes:**

1 – Determined by treating clinicians or study staff to be unable to participate in intervention due advanced illness, significant cognitive impairment, or other reasons (see Appendix 5 for details)

2 – Ever actively engaged in intervention, regardless of subsequent participation or withdrawal

3 – Definitions of engagement specific to each intervention:

- Engaged in Care Management if ANY of below during interval:
  - Completed study risk assessment
  - Sent online message to care manager
  - Had telephone encounter with care manager

- Engaged in Skills Training if ANY of below:
  - Visited online skills training intervention
  - Sent online message to skills coach
  - Had telephone encounter with skills coach
Data and Safety Monitoring

- Data and safety monitoring board (DSMB) met 3 times a year to monitor for patient safety and trial progress
  - Recruitment process and intervention uptake
  - High-risk outreach procedures adherence
  - Complaints or other adverse events
  - Interim analyses to identify a signal of increased risk
    - Safety outcome same as primary trial outcome: suicide attempt
    - Data limitations for monitoring: delay in suicide death data, chart review was conducted at trial completion
  - Bonus of data monitoring - many quality assurance (QA) test of data
    - Very valuable
  - Very limited information for both QA and safety comparisons early on
    - Rare outcome
Complexities of monitoring in SPOT study

- National Institute of Mental Health sponsored DSMB
  - No study team members had direct interaction with DSMB
  - NIMH representative for our trial was there to answer questions
  - Pragmatic trial, relying on “live” EHR data different from many other trials

- KPWA IRB ruled: for individuals who actively refused an intervention their outcome information could not be included in interim monitoring
  - A priori it was known some people would refuse intervention
    - About 20-25% of participants in intervention arms actively refused intervention
  - Biased comparison, two step procedure of signal
  - During monitoring if a signal was detected programmers has IRB permission to gather outcome data on all participants
The unexpected happened – on the last look

- A signal was detected in analyst for the last DSMB report
  - Prepared April/May 2019, DSMB reviewed report in June 2019
  - Last patient planned to be randomized Sept 2019
- Programmers repulled data including all participants including those who active refused study interventions
- Analyses rerun and signal dropped below the signal threshold
  - DSMB recommended continuing trial to compete planned enrollment
Lessons I have taken away

- For trials with interim monitoring of serious outcome: at least two biostatisticians should be funded on the project
  - Thank you, Andrea Cook!

- All participants randomized should be included in interim monitoring
  - At the time, excluding “active refusers” from interim analyses seemed like a reasonable compromise between beneficence and autonomy
  - Now we know better!

- Interaction with DSMB is essential
Primary outcome: First fatal or non-fatal self-harm

Kaplan-Meier curve time to suicide attempt

- Care Management vs. Usual Care: $X^2=0.26$, $p=0.561$
- Skills Training vs. Usual Care: $X^2=5.36$, $p=0.02$

Hazard Ratios from Cox Model
- Care Management vs. Usual Care: $1.07$ (0.86 – 1.353)
- Skills Training vs. Usual Care: $1.29$ (1.05 – 1.659)

n=216
n=175
n=167
Lots of questions:

- Did we make a simple mistake (like mixing up group labels)?
- Could ascertainment of self-harm have been biased?
- Where and how did increased risk in skills training group occur?
Threat to validity: Biased ascertainment of self-harm

- Exposure to intervention could affect:
  - Likelihood of seeking health care after self-harm
  - Likelihood that self-harm intent would be revealed/detected/recorded

- Secondary analyses intended to address this:
  - Limitation to more severe events – assumes that care-seeking would be less “discretionary”
  - Including “potential events” even if not confirmed – attempts to remove any difference in revealing/detecting self-harm intent

Note: Surveys regarding self-harm are definitely NOT the solution to this potential problem.
Secondary analyses (planned and declared)
Narrower: Self-harm leading to death or hospitalization
Secondary analyses (planned in advance)
Broader: Add “potential” self-harm not confirmed by chart review
Subgroup analyses: PHQ9 item 9 score at randomization

KM curve time to suicide attempt PHQ=2

KM curve time to hospitalized SPOT outcome PHQ=3
Subgroup analyses: Study site
## Other subgroup analyses

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Care Management vs. Usual Care</th>
<th>Skills Training vs. Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard Ratio (95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td><strong>PHQ 9 Item 9</strong></td>
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<tr>
<td>Nearly every day (ref: More than half the days)</td>
<td>0.88 (0.57 – 1.35)</td>
<td>0.555</td>
</tr>
<tr>
<td><strong>Site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ref: Site 1</td>
<td>0.796</td>
<td>0.974</td>
</tr>
<tr>
<td>Site 2</td>
<td>0.74 (0.38 – 1.44)</td>
<td>0.95 (0.49 – 1.83)</td>
</tr>
<tr>
<td>Site 3</td>
<td>0.74 (0.38 – 1.44)</td>
<td>0.99 (0.51 – 1.92)</td>
</tr>
<tr>
<td>Site 4</td>
<td>0.76 (0.40 – 1.46)</td>
<td>1.08 (0.57 – 2.05)</td>
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<tr>
<td><strong>Randomization Year</strong> (ref: 2019)</td>
<td></td>
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<tr>
<td>2016</td>
<td>1.29 (0.61 – 2.74)</td>
<td>0.86 (0.43 – 1.72)</td>
</tr>
<tr>
<td>2017</td>
<td>1.24 (0.62 – 2.49)</td>
<td>1.06 (0.57 – 1.97)</td>
</tr>
<tr>
<td>2018</td>
<td>1.68 (0.79 – 3.57)</td>
<td>0.88 (0.43 – 1.79)</td>
</tr>
<tr>
<td><strong>Diagnoses recorded in the past 5 years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ref: No diagnoses in the past 5 years</td>
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</tr>
<tr>
<td>Depressive disorder</td>
<td>0.75 (0.34 – 1.66)</td>
<td>0.485</td>
</tr>
<tr>
<td>Anxiety disorder</td>
<td>0.89 (0.48 – 1.67)</td>
<td>0.718</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>0.97 (0.59 – 1.58)</td>
<td>0.898</td>
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<tr>
<td>Drug use disorder</td>
<td>1.31 (0.79 – 2.16)</td>
<td>0.297</td>
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<tr>
<td>Alcohol use disorder</td>
<td>0.86 (0.51 – 1.42)</td>
<td>0.548</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>0.60 (0.37 – 0.95)</td>
<td>0.030</td>
</tr>
<tr>
<td>Self-harm injury or poisoning</td>
<td>1.01 (0.60 – 1.69)</td>
<td>0.976</td>
</tr>
<tr>
<td>Any injury or poisoning</td>
<td>0.57 (0.35 – 0.93)</td>
<td>0.024*</td>
</tr>
<tr>
<td><strong>Service use in past year</strong></td>
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<td></td>
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<tr>
<td>ref: No utilization in the past 5 years</td>
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<tr>
<td>Mental health hospitalization</td>
<td>0.69 (0.45 – 1.08)</td>
<td>0.103</td>
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<tr>
<td>Mental health emergency dept. visit</td>
<td>0.81 (0.53 – 1.25)</td>
<td>0.346</td>
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<tr>
<td><strong>Suicide Risk Prediction at Index Visit</strong></td>
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<tr>
<td>ref: 0% to 0.5% predicted risk</td>
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<tr>
<td>0.5% to 1% predicted risk</td>
<td>0.72 (0.37 – 1.40)</td>
<td>0.97 (0.50 – 1.85)</td>
</tr>
<tr>
<td>1% through 100% predicted risk</td>
<td>0.66 (0.38 – 1.16)</td>
<td>0.93 (0.53 – 1.62)</td>
</tr>
</tbody>
</table>
Use of non-study mental health services

Mental health outpatient visits

ED visits with mental health diagnosis

Primary care outpatient visits with a mental health diagnosis

Inpatient stays with mental health diagnosis
"As treated" comparison: Where is the increased risk?

### Table

<table>
<thead>
<tr>
<th>Category</th>
<th>Care Management n=6188</th>
<th>Skills Training n=6228</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not offered intervention</td>
<td>193 (3.1%)</td>
<td>217 (3.5%)</td>
</tr>
<tr>
<td>Actively declined invitation</td>
<td>1345 (21.6%)</td>
<td>799 (12.8%)</td>
</tr>
<tr>
<td>No response after 3 invitations</td>
<td>2777 (44.6%)</td>
<td>2796 (44.9%)</td>
</tr>
<tr>
<td>Ever engaged in intervention</td>
<td>1951 (31.7%)</td>
<td>2416 (38.9%)</td>
</tr>
<tr>
<td>Engaged beyond 3 months</td>
<td>1622 (26.0%)</td>
<td>777 (12.5%)</td>
</tr>
<tr>
<td>Engaged beyond 6 months</td>
<td>1400 (22.5%)</td>
<td>274 (4.4%)</td>
</tr>
<tr>
<td>Engaged beyond 9 months</td>
<td>1055 (16.9%)</td>
<td>119 (1.9%)</td>
</tr>
</tbody>
</table>

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**Notes:**

1. Not offered intervention
2. Ever engaged in intervention
3. Engaged beyond 3, 6, 9 months
In context

- This sample vs. previous clinical trials (DBT, CBT, ketamine)
  - Much wider range of baseline risk
  - No requirement to accept (or even consider) participating

- This care management vs. effective programs
  - Generally lower intensity, delivered by online messaging
  - Not focused on any specific psychotherapy or pharmacotherapy

- This Skills Training vs. effective DBT
  - Much lower intensity
  - Narrower range of skills
  - No group component
Did we skip a step?

- Samples of a few hundred
- Motivated/engaged participants
- More intensive and standardized interventions

What belongs in this gap?

- Samples of tens of thousands
- “All comers” regardless of engagement or motivation
- Low intensity and more variable interventions