# Supplemental Online Content

Simon GE, Shortreed SM, Rossom RC, et al. Effect of offering care management or online dialectical behavior therapy skills training vs usual care on self-harm among adult outpatients with suicidal ideation: a randomized clinical trial. *JAMA*. Published February 15, 2022. doi:10.1001/jama.2022.0423



This supplemental material has been provided by the authors to give readers additional information about their work.

**eAppendix 1. Details of Randomization Procedure**

The study biostatistician (Dr. Shortreed) created separate randomization tables for each health system, stratified by baseline response to PHQ-9 item 9 regarding suicidal ideation ("more than half the days" vs. "nearly every day"). Permuted block randomization was implemented with block sizes of 6 or 9. In each health system, randomization tables were accessible only to programmers implementing eligibility and randomization programs. In each participating health system, eligible participants were automatically identified from health system records once each week, using all records data available up to that point. Randomization occurred automatically and immediately after determination of eligibility. Automatically generated lists of participants newly assigned to either the Care Management or Skills Training interventions were then uploaded to intervention delivery databases accessible to intervention clinical staff.

At the KP Colorado site, an error in the programming of eligibility assessment and a change in the storage of health records databases used to assess eligibility led to an error in eligibility determination for 49 participants. Those 49 participants were originally assigned to the Usual Care group but were re-sampled at a later visit, erroneously considered as still eligible, and erroneously randomized a second time. After this error was discovered in September of 2018, those erroneous second randomizations were handled as follows:

- 17 participants originally assigned to Usual Care were later erroneously assigned to the Care Management group and offered care Management services. Analyses included these participants in the Care Management group using the second randomization date.
- 18 participants originally assigned to Usual Care were later erroneously assigned to the Skills Training group and had potential exposure to the intervention. Analyses included these participants in the Skills Training group using the second randomization date.
- 14 participants originally assigned to Usual Care were later erroneously re-assigned to Usual Care. These participants had no potential exposure to any study intervention, and they were retained in the Usual Care group for all analyses using the original randomization date.

**eAppendix 2. Details of Invitation and Reminder Procedures**

Invitation procedure at KP Colorado, KP Northwest, and KP Washington

After each weekly round of randomization at each site (described in Appendix 1) lists of participants newly assigned to each intervention condition were uploaded to intervention databases at each site. Initial invitation messages were sent in weekly batches, typically on the day following randomization.

- If invitation was accepted, additional intervention services (Care Management or Skills Training) were initiated.
    - For Care Management invitations, acceptance was indicated by replying positively to the invitation message and/or completing the attached risk assessment questionnaire.
    - For Skills training, acceptance was indicated by replying positively to the invitation message and/or visiting the Skills Training website.
- If invitation was actively declined, then participant was not contacted again.
- If invitation message was not read after 3 days, then care manager or skills coach made outreach phone call to offer invitation or (if no answer) leave a reminder message regarding invitation via EHR portal.
- If invitation message was read but not responded to (with either acceptance or refusal) after 3 days, then care manager or skills coach sent a brief reminder message referring to the earlier invitation message.

If no acceptance or refusal of initial invitation, second invitation message was sent 4 weeks after random assignment, following the same protocol as the initial invitation.

If no acceptance or refusal of second invitation, third invitation message was sent 8 weeks after random assignment, following the same protocol as the initial invitation

If no response after three cycles of invitation, then study staff did not initiate any additional messages or calls, but patient might still respond to an earlier invitation or reply to an earlier message.

Invitation procedure at HealthPartners (differed in use of “reminder” messages for those reading but not responding to invitation messages).

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If no acceptance or refusal of second invitation, third invitation message was sent 8 weeks after random assignment, following the same protocol as the initial invitation

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**eAppendix 3. Ascertainment of Fatal Self-harm and Deaths Due to Other Causes**

Each participating health system links membership files to state mortality records to identify date and cause of death for all deaths of people ever receiving care from the health system or enrolled in a health system insurance plan. Linkages occur monthly at HealthPartners and KP Colorado and quarterly at KP Washington. KP Northwest links quarterly to Washington state mortality files (for members/patients residing in Washington) and annually to Oregon state mortality files (for members/patients residing in Oregon). In addition, each health system immediately identifies deaths recorded in medical records (i.e. occurring in health system facilities).

At time of these analyses, state mortality data were available through March 2019 at HealthPartners, KP Colorado, and KP Washington. Thus, these health systems, complete mortality data, including cause of death information, were available for the full 18-month outcome period for all randomized participants. At time of these analyses, complete Washington mortality data were available through March 2020 for KP Northwest members residing in Washington, but only through December 2019 for KP Northwest members residing in Oregon. Consequently, ascertainment of fatal self-harm was missing for up to 3 months for approximately 390 Oregon-residing KP Northwest participants randomized in July, August, or September of 2018, representing approximately 1% of all follow-up time in the full randomized sample.

**eAppendix 4. Exclusion of Randomized Patients With No Follow-up Time**

As described in Appendix 1, participants were automatically identified and randomized each week using health system data warehouse data available as of that time, not including encounters or other data recorded in the prior 24-48 hours. Data regarding disenrollment from a health system insurance plan (an exclusion criterion) could be delayed by up to one month. Weekly randomization occurred 1 to 8 days after the visit at which the eligibility event (response to PHQ-9 item 9) occurred. Using data available at the time of outcome analysis, 238 patients were found to have either died or disenrolled prior to randomization. This could occur in two situations:

- a patient died between the eligibility visit and randomization, but that death had not been recorded in the health system data warehouse at time of eligibility determination
- a patient disenrolled from the health system insurance plan prior to randomization, but that disenrollment had not been recorded in the health system data warehouse at time of eligibility determination

These patients had no follow-up time at risk for self-harm and were not included in any outcome analyses.

**eAppendix 5. Randomized Participants Not Offered Intervention Services**

Identification of participants using health system records attempted to exclude patients unable to participate in interventions due to cognitive impairment, intellectual disability, or limited English proficiency. That eligibility assessment, however, was limited to discrete data recorded in health system data warehouses (e.g. recorded diagnoses of dementia, indicators of needing an interpreter for health care visits).

Upon opening the electronic health record to send invitation messages, intervention clinicians (care managers and skills coaches) could discover indications that sending an invitation would be inappropriate. Those could include documentation of cognitive disability, severe cognitive impairment, incarceration, terminal illness or limited English proficiency. In those cases, study clinicians did not send invitations. 401 randomized participants were excluded from intervention invitations by this process.

In addition, KP Northwest required review of eligible participants by treating mental health clinicians prior to invitation. Clinicians were allowed to "opt out" any participant for whom the clinician thought a study invitation would be clinically inappropriate. An additional 32 randomized patients were excluded from intervention invitations by this process.

All randomized patients excluded by either of these processes were included in outcome analyses and analyzed according to initial treatment assignment.

**eAppendix 6. Review of Clinical Text to Identify Self-harm Events Not Coded by Treating Clinicians**

For each enrolled participant, health system electronic health record and insurance claims data identified all encounters in any setting (outpatient, emergency department, or inpatient) with any injury or poisoning diagnosis during 18 months after each participant's date of randomization, including encounters at external facilities identified by insurance claims. Injury and poisoning codes occurring in this sample were sorted into three groups for potential record review. The first group, codes indicating undetermined intent, included all injury codes in the range of Y21 through Y33 as well as codes for poisoning (T36 through T65) and asphyxiation (T71) that included a specifier for undetermined intent. The second group, c odes indicating accidental intent, included codes for poisoning (T36 through T65) and asphyxiation (T71) that included a specifier for accidental intent. The third group, Injury codes without coding of intent, included codes in the range from S00 through T32 that were not accompanied by an external cause code in the range from V00 through Y99.

All ICD-10-CM codes occurring in this sample in these three groups were then rated by a panel of five trial investigators (GS, RR, AB, GC, JB) with experience in use of health records data for suicide epidemiology and prevention research. Given our previous finding that codes for undetermined intent were often accompanied by documentation of self-harm, we presumed a relatively high rate of true self-harm events in that group. Consequently, investigators were asked to identify specific codes in the undetermined intent group that were unlikely to represent self-harm so that those could be excluded from chart review. Codes identified as unlikely mechanisms of self-harm by at least three investigators were excluded from further review, with all other codes in that group included. Conversely, we presumed a relatively low rate of true self-harm events among injuries or poisonings coded as accidents or injuries without coding of intent. Consequently, investigators were asked to identify specific codes in those groups indicating common or likely mechanisms of self-harm. Those identified as common mechanisms of self-harm by at least three investigators were selected for further review, with all other codes in those groups excluded.

The resulting code lists were then used to select specific injury or poisoning events for review of full-text clinical notes. Reviewable events were defined by occurrence of at least one reviewable diagnosis code (as described above) if there was no diagnosis code indicating definite self-harm occurring on the same day or any previous day (e.g. an injury or poisoning event with diagnostic codes for both self-harm and undetermined intent on the same day was not reviewed). This scheme was consistent with the study aim of measuring time to first self-harm event after randomization. A single injury or poisoning event could be selected based on diagnosis codes in two different groups (e.g. a code for poisoning of undetermined intent and a code for injury without coding of intent occurring on the same day). To preserve blinding regarding intervention group assignment, this review process was separated into two steps: extraction of relevant text by chart abstractors (not involved in intervention delivery) at each site followed by classification of that extracted and de-identified text by a separate panel of raters blinded to intervention group assignment and study site.

Chart abstractors were instructed to consider records of any encounters (outpatient, emergency department, inpatient, and telephone encounters) within 14 days before or after the date of the selected diagnosis. Abstractors identified and copied any text during that time period relevant to the intent of the injury or poisoning selected for review, including nursing notes, treating clinicians' notes, and direct quotes from patients. Abstractors were advised to specifically identify text that would clarify presence or absence of self-harm intent, including both suicidal intent and intentional self-harm not necessarily accompanied by intent to die (i.e. non-suicidal self-injury). Abstraction typically began with any encounter on the diagnosis data, extending to encounters before and after that date until clear documentation of intent was identified or until all encounters during the interval were reviewed. Abstractors redacted any information that might reveal study intervention group assignment, any information that might allow re-identification of individual patients, and any information that might identify healthcare providers or facilities.

All relevant text for each event were then presented to a panel of six study investigators, with each event considered by three raters and each rater considering approximately half of all events. Raters were instructed to rate each injury/poisoning event as self-harm (a forced-choice rating of yes or no) and a separate three-level (high/medium/low) rating of confidence in that self-harm classification.

Descriptive analyses of ratings examined the distribution of confidence ratings and agreement among reviewers regarding self-harm classification. Those analyses informed selection of a threshold of confidence ratings. Subsequent descriptive analyses examined the distribution of rater's self-harm classifications limited to events with adequate ratings of confidence.

Responsible institutional review boards at each participating health system reviewed and approved all trial procedures, including the chart review work described here.

## RESULTS

Among all injury and poisoning diagnoses recorded in the study sample during the follow-up period, records data included 50 ICD-10 CM diagnosis codes for injuries or poisonings with undetermined intent, 94 codes for injuries or poisonings coded as accidental, and 3702 codes for injuries not accompanied by coding of intent. Among undetermined intent codes, the panel of investigators classified 43 as plausible mechanisms of self-harm (i.e. included in review) and classified 7 as unlikely mechanisms for self-harm (i.e. excluded from review). Among accidental injury/poisoning codes, the panel of investigators identified 26 as common mechanisms of self-harm (i.e. included in review). Among injury codes with no coding of intent, the panel of investigators identified 46 as common mechanisms of self-harm (i.e. included in review). The most frequent included and excluded codes in each group are shown in Table 1, and a complete list is available from the corresponding author on request.

The selected list of undetermined intent codes identified 156 injury or poisoning events in this patient sample. Of those events, 70 had a definite self-harm code recorded on the same day, and 14 had a self-harm code recorded on a previous day, leaving 72 undetermined intent events to be reviewed. The selected list of accidental intent codes identified 308 injury or poisoning events in this patient sample. Of those events, 63 events had a definite self-harm code recorded on the same day, and 26 had a definite self-harm code recorded on a previous day, leaving 219 accidental events to be reviewed. The selected list of injury codes without coding of intent identified 499 injury events in this sample. Of those events, 121 had a definite self-harm code recorded on the same day, and 62 had a definite self-harm code recorded on a previous day, leaving 316 injury events without coding of intent to be reviewed.

Review of clinical notes for all encounters within 14 days before or after each of those events found no relevant text (i.e. no encounters with any mention of injury or poisoning) in 12 (17%) of undetermined intent events, 46 (21%) of accidental intent events, and 28 (9%) of injury events without coding of intent. Exclusion of those events left 60 events receiving a code for undetermined intent, 173 events receiving a code for accidental intent, and 288 injury events with no coding of intent. Because some events received codes in more than one category, the total number of unique events was 508.

Table 3 displays the distribution of confidence ratings and inter-rate agreement in each diagnosis group for events in with any relevant clinical text available for review. Raters expressed high confidence in ratings (summed confidence score of 6 or higher) for 77% of events coded as undetermined intent, 88% of events coded as accidents, and 95% of injuries without coding of intent. Agreement among reviewers was consistent with those confidence ratings; classification of self-harm was unanimous for the vast majority of events with high confidence ratings and a minority of events with low confidence ratings.

Table 4 displays the distribution of self-harm ratings in each of the three diagnosis groups, limited to events with confidence scores of six or greater. In none of the groups, even with high confidence ratings, was the proportion of events with a majority of yes ratings higher than 19%. The total number of events with summed confidence score of six or greater and at least two reviewers classifying as self-harm was 58, including 9 events originally coded as undetermined intent, 8 originally coded as accidents, and 41 without coding of intent. 44 of these events occurred prior to censoring and were the first potential event for an enrolled participant. Those 44 events were included as self-harm events in primary outcome analyses.

**eTable 1. Most Common Injury and Poisoning Diagnosis Codes Selected for Inclusion and Exclusion in Chart Review Validation of Self-harm Codes**

See eAppendix 6 for explanation.

| | Included in record review | Excluded from record review |
|---|---|---|
| **Undetermined Intent** | T50.904A – Poisoning by unspecified drug, undetermined intent<br>T42.4X4A – Poisoning by benzodiazepine, undetermined intent<br>T65.94XA – Toxic effect of unspecified substance, undetermined intent<br>T51.94XA – Toxic effect of unspecified alcohol, undetermined intent<br>T43.594A – Poisoning by antipsychotics, undetermined intent | T63.304A – Toxic effect of spider venom, undetermined intent<br>T63.444A – Toxic effect of bee venom, undetermined intent<br>T63.464A – Toxic effect of wasp venom, undetermined intent<br>T59.3X4A – Toxic effect of lacrimogenic gas, undetermined intent<br>T63.484A – Toxic effect of other arthropod venom, undetermined intent |
| **Accidental** | T42.4X1A – Poisoning by benzodiazepine, accidental<br>T43.591A – Poisoning by antipsychotic, accidental<br>T40.2X1A – Poisoning by other opioid, accidental<br>T40.601A – Poisoning by unspecified narcotic, accidental<br>T42.6X1A – Poisoning by antiepileptic or sedative/hypnotic, accidental | T50.901A – Poisoning by unspecified drug, accidental<br>T63.441A – Toxic effect of bee venom, accidental<br>T63.481A – Toxic effect of other arthropod venom, accidental<br>T56.891A - Toxic effect of other metals, accidental<br>T63.461A – Toxic effect of wasp venom, accidental |
| **No Coding of Intent** | S51.812A – Laceration without foreign body of left forearm<br>S51.811A - Laceration without foreign body of right forearm<br>S61.512A - Laceration without foreign body of left wrist<br>S61.511A – Laceration without foreign body of right wrist<br>S51.802A – Unspecified open wound of left forearm | S09.90XA – Unspecified injury of head<br>S39.012A – Strain of muscle, fascia, and tendon of lower back<br>S16.1XXA – Strain of muscle, fascia, and tendon of neck<br>T14.8XXA – Other injury of unspecified body region<br>S93.401A – Sprain of unspecified ligament of right ankle |

**eTable 2. Examples of Abstracted Text and Rater Classifications From Chart Review Validation of Self-harm Codes**

See eAppendix 6 for explanation.

| Relevant text extracted from clinical notes | Self-Harm Ratings | | | Confidence Ratings | | |
|---|---|---|---|---|---|---|
| Presents to UC post cutting on her wrists | Yes | Yes | Yes | High | Medium | Medium |
| She was assaulted. | No | No | No | High | High | High |
| Presents unresponsive in laboratory. She was just seen in in clinic for planned detox medical clearance. She had just come to lab as part of medical clearance assessment. Her partner says she drank wine this morning, estimates around 8 ounces. She has access to Ativan. She does not have access to opiates. She had ETOH withdraw seizure last week per PC physician who was evaluating her for detox today. | No | No | No | Medium | Low | High |
| Pt brought to [hospital] after motor vehicle accident where pt sustained closed sternum fracture. Regarding his car accident... He took his father's car to [Location] to gamble and drink, and he reports having no memory of getting in his car and driving or the accident. He tells me he does not know if it was a suicide attempt. | No | No | No | Low | Low | Low |

**eTable 3. Distribution of Rater Confidence and Inter-rater Agreement for Chart Review Validation of Self-harm Codes**

See eAppendix 6 for explanation. Confidence scores calculated as sum of three individual rater scores where 1=low confidence, 2=medium confidence, and 3=high confidence.

| | Coded As Undetermined Intent | | Coded as Accidental Intent | | Injury with No Coding of Intent | |
|---|---|---|---|---|---|---|
| Summed Confidence score | Number Total=60 | All three reviewers agreed N (%) | Number Total=173 | All three reviewers agreed N (%) | Number Total=288 | All three reviewers agreed N (%) |
| 3 | 5 | 2 (40%) | 7 | 1 (14%) | 3 | 1 (33%) |
| 4 | 3 | 1 (33%) | 6 | 1 (17%) | 5 | 4 (80%) |
| 5 | 6 | 2 (33%) | 8 | 5 (63%) | 5 | 3 (60%) |
| 6 | 13 | 10 (77%) | 23 | 18 (78%) | 12 | 9 (75%) |
| 7 | 6 | 6 (100%) | 32 | 28 (88%) | 22 | 18 (81%) |
| 8 | 11 | 11 (100%) | 29 | 28 (97%) | 36 | 34 (94%) |
| 9 | 16 | 16 (100%) | 68 | 67 (99%) | 205 | 204 (99%) |

**eTable 4. Distribution of Self-harm Ratings From Chart Review Validation of Self-harm Codes**

See eAppendix 6 for explanation. Llimited to events with text available and summed confidence score of 6 or higher.

| | All 3 No<br>N (%) | 2 No / 1 Yes<br>N (%) | 1 No / 2 Yes<br>N (%) | All 3 Yes<br>N (%) |
|---|---|---|---|---|
| Undetermined Intent | 36(78%) | 1 (2%) | 2 (4%) | 7 (15%) |
| Accidental Intent | 137 (90%) | 7 (5%) | 4 (3%) | 4 (3%) |
| No Intent Coding | 233 (85%) | 1 (0.4%) | 9 (3%) | 32 (12%) |

**eTable 5. Use of Specific Components of the Online Skills Training Program**

Number and proportion of participants offered Skills Training intervention who visited components of online training program by month after randomization.

| | Months 1-3 | Months 4-6 | Months 7-9 | Months 10-12 |
|---|---|---|---|---|
| Mindfulness Module | | | | |
| Any Visit | 901 (14%) | 117 (2%) | 30 (<1%) | 18 (<1%) |
| Beyond Introduction[a] | 550 (9%) | 72 (1%) | 18 (<1%) | 9 (<1%) |
| Homework[b] | 150 (2%) | 18 (<1%) | 11 (<1%) | 2 (<1%) |
| Mindfulness of Current Emotion Module | | | | |
| Any Visit | 419 (7%) | 98 (2%) | 33 (<1%) | 12 (<1%) |
| Beyond Introduction[a] | 247 (4%) | 80 (1%) | 22 (<1%) | 6 (<1%) |
| Homework[b] | 83 (1%) | 21 (<1%) | 4 (<1%) | 1 (<1%) |
| Opposite Action Module | | | | |
| Any Visit | 439 (7%) | 101 (2%) | 25 (<1%) | 13 (<1%) |
| Beyond Introduction[a] | 262 (4%) | 69 (1%) | 17 (<1%) | 8 (<1%) |
| Homework[b] | 72 (1%) | 11 (<1%) | 6 (<1%) | 1 (<1%) |
| Paced Breathing Module | | | | |
| Any Visit | 296 (5%) | 63 (1%) | 14 (<1%) | 8 (<1%) |
| Beyond Introduction[a] | 151 (2%) | 37 (1%) | 8 (<1%) | 5 (<1%) |
| Homework[b] | 58 (1%) | 15 (<1%) | 3 (<1%) | 0 (0%) |

Notes:

a – Includes any visit beyond initial introductory video. Could include instructional videos by clinicians, personal accounts by people with lived experience, or examples of homework practice.

b – Visit to page to create personal homework plan.

**eTable 6. Subgroup Analyses and Tests for Interaction Effects**

Table displays hazard ratios with confidence limits (from proportional hazards models) comparing each intervention group to usual care group in across a range of subgroups. Reported p-values represent tests for significant interaction effect or difference across subgroups (e.g. does relative hazard in Care Management group vs. usual care group differ significantly between subgroups defined by baseline PHQ9 Item 9 score) – for 28 interaction tests overall.

| | Care Management vs. Usual Care | | Skills Training vs. Usual Care | |
|---|---|---|---|---|
| | Hazard Ratio (95% CI) | p-value for interaction | Hazard Ratio (95% CI) | p-value for interaction |
| PHQ 9 Item 9 Score | | 0.56 | | 0.20 |
| More than half the days (ref) | 1.14 (0.85 – 1.52) | | 1.45 (1.10 – 1.90) | |
| Nearly every day | 1.00 (0.72 – 1.38) | | 1.10 (0.80 – 1.52) | |
| Study Site | | 0.80 | | 0.97 |
| Site 1 (ref) | 1.37 (0.81 – 2.29) | | 1.28 (0.76 – 2.16) | |
| Site 2 | 1.01 (0.67 – 1.53) | | 1.22 (0.82 – 1.81) | |
| Site 3 | 1.01 (0.66 – 1.54) | | 1.27 (0.84 – 1.90) | |
| Site 4 | 1.04 (0.70 – 1.54) | | 1.38 (0.96 – 2.00) | |
| Randomization Year | | 0.55 | | 0.86 |
| 2016 | 1.06 (0.68 – 1.65) | | 1.14 (0.74 – 1.77) | |
| 2017 | 1.01 (0.72 – 1.43) | | 1.41 (1.03 – 1.94) | |
| 2018 | 1.38 (0.89 – 2.14) | | 1.18 (0.75 – 1.87) | |
| 2019 (ref) | 0.82 (0.45 – 1.51) | | 1.34 (0.78 – 2.30) | |
| Diagnoses Recorded and Services Used in 5 years Prior to Randomization | | | | |
| Depressive disorder | | 0.48 | | 0.99 |
| Yes | 1.05 (0.84 – 1.32) | | 1.29 (1.05 – 1.60) | |
| No (ref) | 1.40 (0.65 – 2.98) | | 1.29 (0.59 – 2.81) | |
| Anxiety disorder | | 0.71 | | 0.570 |
| Yes | 1.06 (0.84 – 1.33) | | 1.32 (1.06 – 1.65) | |
| No (ref) | 1.19 (0.66 – 2.12) | | 1.10 (0.61 – 1.99) | |
| Bipolar disorder | | 0.89 | | 0.78 |
| Yes | 1.04 (0.68 – 1.58) | | 1.35 (0.91 – 2.01) | |
| No (ref) | 1.07 (0.84 – 1.38) | | 1.26 (0.99 – 1.61) | |
| Drug use disorder | | 0.30 | | 0.23 |
| Yes | 1.32 (0.85 – 2.04) | | 1.61 (1.06 – 2.45) | |
| No (ref) | 1.01 (0.79 – 1.29) | | 1.20 (0.95 – 1.53) | |
| Alcohol use disorder | | 0.54 | | 0.96 |
| Yes | 0.93 (0.60 – 1.46) | | 1.27 (0.83 – 1.93) | |
| No (ref) | 1.10 (0.86 – 1.40) | | 1.28 (1.01 – 1.63) | |
| Personality disorder | | 0.03 | | 0.27 |
| Yes | 0.76 (0.51 – 1.11) | | 1.10 (0.78 – 1.55) | |
| No (ref) | 1.27 (0.98 – 1.65) | | 1.40 (1.08 – 1.81) | |
| Self-harm injury or poisoning | | 0.96 | | 0.30 |
| Yes | 1.10 (0.70 – 1.73) | | 1.58 (1.04 – 2.40) | |
| No (ref) | 1.08 (0.85 – 1.38) | | 1.22 (0.96 – 1.55) | |

**eTable 6 continued – Subgroup Analyses and Tests for Interaction Effects**

Table displays hazard ratios with confidence limits (from proportional hazards models) comparing each intervention group to usual care group in across a range of subgroups. Reported p-values represent tests for significant interaction effect or difference across subgroups (e.g. does relative hazard in Care Management group vs. usual care group differ significantly between subgroups defined by baseline PHQ9 Item 9 score).

| | Care Management vs. Usual Care | | Skills Training vs. Usual Care | |
|---|---|---|---|---|
| | Hazard Ratio (95% CI) | p-value for interaction | Hazard Ratio (95% CI) | p-value for interaction |
| Any injury or poisoning | | 0.02 | | 0.20 |
| Yes | 0.92 (0.71 – 1.18) | | 1.20 (0.94 – 1.52) | |
| No (ref) | 1.60 (1.06 – 2.42) | | 1.64 (1.09 – 2.46) | |
| Mental health hospitalization | | 0.10 | | 0.74 |
| Yes | 0.86 (0.61 – 1.20) | | 1.24 (0.91 – 1.70) | |
| No (ref) | 1.24 (0.93 – 1.63) | | 1.34 (1.02 – 1.76) | |
| Mental health emergency dept. visit | | 0.34 | | 0.52 |
| Yes | 0.97 (0.72 – 1.31) | | 1.36 (1.03 – 1.79) | |
| No (ref) | 1.20 (0.88 – 1.63) | | 1.18 (0.87 – 1.62) | |
| Predicted risk of self-harm over 90 days following randomization | | 0.34 | | 0.96 |
| < 0.5% (ref) | 1.44 (0.89 – 2.33) | | 1.34 (0.82 – 2.19) | |
| 0.5% to 1% | 1.03 (0.66 – 1.63) | | 1.29 (0.85 – 1.97) | |
| >=1% | 0.95 (0.72 – 1.27) | | 1.24 (0.95 – 1.62) | |

**eTable 7. Comparison of Baseline Characteristics by Level of Intervention Participation in Care Management Intervention**

Excludes 193 patients randomized to offer of Care Management but not actually offered intervention (see eAppendix 5).

| | Declined n=1345 | No response n=2777 | Engaged < 3 months n=303 | Engaged > 3 months n=1612 | Test Statistic |
|---|---|---|---|---|---|
| Sex | | | | | $\chi^2$=15.8, df=3, p=0.001 |
| Female | 912 (67.8%) | 1807 (65.1%) | 200 (66.0%) | 1142 (70.8%) | |
| Male | 433 (32.2%) | 970 (34.9%) | 103 (34.0%) | 470 (29.2%) | |
| Age Group | | | | | $\chi^2$=274, df=9, p<0.001 |
| 18-29 | 199 (14.8%) | 805 (29.0%) | 81 (26.7%) | 308 (19.1%) | |
| 30-44 | 318 (23.6%) | 831 (29.9%) | 93 (30.7%) | 459 (28.5%) | |
| 45-64 | 481 (35.8%) | 802 (28.9%) | 97 (32.0%) | 641 (39.8%) | |
| 65+ | 347 (25.8%) | 339 (12.2%) | 32 (10.6%) | 204 (12.7%) | |
| Race/Ethnicity | | | | | $\chi^2$=56, df=21, p<0.001 |
| American Indian, Non-Hispanic | 13 (1.0%) | 27 (1.0%) | 1 (0.3%) | 15 (0.9%) | |
| Asian, Non-Hispanic | 43 (3.2%) | 89 (3.2%) | 7 (2.3%) | 35 (2.2%) | |
| Black, Non-Hispanic | 43 (3.2%) | 126 (4.5%) | 7 (2.3%) | 57 (3.5%) | |
| Hispanic | 65 (4.8%) | 247 (8.9%) | 25 (8.3%) | 135 (8.4%) | |
| More than one | 23 (1.7%) | 85 (3.1%) | 8 (2.6%) | 50 (3.1%) | |
| Native Hawaiian or Pacific Islander | 6 (0.4%) | 9 (0.3%) | 4 (1.3%) | 5 (0.3%) | |
| Non-Hispanic White | 1085 (80.7%) | 2038 (73.4%) | 237 (78.2%) | 1221 (75.7%) | |
| Other or not recorded | 67 (5.0%) | 156 (5.6%) | 14 (4.6%) | 94 (5.8%) | |
| Location of Index Visit | | | | | $\chi^2$=39.3, df=3, p<0.001 |
| Mental Health Specialty Clinic | 647 (48.1%) | 1267 (45.6%) | 170 (56.1%) | 880 (54.6%) | |
| General Medical Clinic | 698 (51.9%) | 1510 (54.4%) | 133 (43.9%) | 732 (45.4%) | |
| Baseline PHQ9 Item 9 Score | | | | | $\chi^2$=3.8, df=3, p=0.28 |
| More than half the days | 896 (66.6%) | 1876 (67.6%) | 188 (62.0%) | 1081 (67.1%) | |
| Nearly every day | 449 (33.4%) | 901 (32.4%) | 115 (38.0%) | 531 (32.9%) | |
| Diagnoses recorded in past year | | | | | |
| Depressive disorder | 830 (61.7%) | 1774 (63.9%) | 212 (70.0%) | 1144 (71.0%) | $\chi^2$=35.8, df=3, p<0.001 |
| Anxiety disorder | 758 (56.4%) | 1592 (57.3%) | 196 (64.7%) | 1033 (64.1%) | $\chi^2$=28.2, df=3, p<0.001 |
| Bipolar disorder | 146 (10.9%) | 274 (9.9%) | 43 (14.2%) | 207 (12.8%) | $\chi^2$=12.3, df=3, p=0.007 |
| Drug use disorder | 84 (6.2%) | 208 (7.5%) | 34 (11.2%) | 115 (7.1%) | $\chi^2$=9.3, df=3, p=0.03 |
| Personality disorder | 78 (5.8%) | 227 (8.2%) | 37 (12.2%) | 170 (10.5%) | $\chi^2$=27.1, df=3, p<0.001 |
| Alcohol use disorder | 55 (4.1%) | 216 (7.8%) | 23 (7.6%) | 87 (5.4%) | $\chi^2$=24.5, df=3, p<0.001 |
| Self-harm injury or poisoning | 18 (1.3%) | 53 (1.9%) | 8 (2.6%) | 39 (2.4%) | $\chi^2$=5.3, df=3, p=0.15 |
| Schizophrenia spectrum psychosis | 17 (1.3%) | 31 (1.1%) | 4 (1.3%) | 15 (0.9%) | $\chi^2$=0.9, df=3, p=0.83 |
| Service use in past year | | | | | |
| Mental health hospitalization[a] | 115 (8.6%) | 298 (10.7%) | 39 (12.9%) | 171 (10.6%) | $\chi^2$=7.3, df=3, p=0.06 |
| Mental health emergency dept. visit[a] | 171 (12.7%) | 462 (16.6%) | 63 (20.8%) | 265 (16.4%) | $\chi^2$=17.1, df=3, p=0.001 |

**eTable 8. Comparison of Baseline Characteristics by Level of Intervention Participation in Skills Training Intervention**

Excludes 216 patients randomized to offer of Care Management but not actually offered intervention (see eAppendix 5).

| | Declined n=799 | No response n=2796 | Engaged < 3 months n=1649 | Engaged > 3 months n=767 | Test Statistic |
|---|---|---|---|---|---|
| Sex | | | | | $\chi2=37.8$, df=3, p<0.001 |
| Female | 545 (68.2%) | 1766 (63.2%) | 1183 (71.7%) | 532 (69.4%) | |
| Male | 254 (31.8%) | 1030 (36.8%) | 466 (28.3%) | 235 (30.6%) | |
| Age Group | | | | | $\chi2=310$, df=9, p<0.001 |
| 18-29 | 96 (12.0%) | 809 (28.9%) | 395 (24.0%) | 96 (12.5%) | |
| 30-44 | 182 (22.8%) | 847 (30.3%) | 515 (31.2%) | 200 (26.1%) | |
| 45-64 | 298 (37.3%) | 812 (29.0%) | 546 (33.1%) | 338 (44.1%) | |
| 65+ | 223 (27.9%) | 328 (11.7%) | 193 (11.7%) | 133 (17.3%) | |
| Race/Ethnicity | | | | | $\chi2=61$, df=21, p<0.001 |
| American Indian, Non-Hispanic | 3 (0.4%) | 21 (0.8%) | 14 (0.8%) | 4 (0.5%) | |
| Asian, Non-Hispanic | 21 (2.6%) | 93 (3.3%) | 41 (2.5%) | 18 (2.3%) | |
| Black, Non-Hispanic | 11 (1.4%) | 146 (5.2%) | 75 (4.5%) | 35 (4.6%) | |
| Hispanic | 41 (5.1%) | 208 (7.4%) | 145 (8.8%) | 58 (7.6%) | |
| More than one | 19 (2.4%) | 82 (2.9%) | 55 (3.3%) | 30 (3.9%) | |
| Native Hawaiian or Pacific Islander | 4 (0.5%) | 14 (0.5%) | 7 (0.4%) | 4 (0.5%) | |
| Non-Hispanic White | 673 (84.2%) | 2059 (73.6%) | 1205 (73.1%) | 569 (74.2%) | |
| Other or not recorded | 27 (3.4%) | 173 (6.2%) | 107 (6.5%) | 49 (6.4%) | |
| Location of Index Visit | | | | | $\chi2=51$, df=3, p<0.001 |
| Mental Health Specialty Clinic | 355 (44.4%) | 1308 (46.8%) | 890 (54.0%) | 444 (57.9%) | |
| General Medical Clinic | 444 (55.6%) | 1488 (53.2%) | 759 (46.0%) | 323 (42.1%) | |
| Baseline PHQ9 Item 9 Score | | | | | $\chi2=1.2$, df=3, p=0.76 |
| More than half the days | 523 (65.5%) | 1887 (67.5%) | 1107 (67.1%) | 516 (67.3%) | |
| Nearly every day | 276 (34.5%) | 909 (32.5%) | 542 (32.9%) | 251 (32.7%) | |
| Diagnoses recorded in past year | | | | | |
| Depressive disorder | 485 (60.7%) | 1751 (62.6%) | 1106 (67.1%) | 539 (70.3%) | $\chi2=25.3$, df=3, p<0.001 |
| Anxiety disorder | 419 (52.4%) | 1655 (59.2%) | 1018 (61.7%) | 477 (62.2%) | $\chi2=22.3$, df=3, p<0.001 |
| Bipolar disorder | 73 (9.1%) | 278 (9.9%) | 211 (12.8%) | 106 (13.8%) | $\chi2=17.5$, df=3, p=0.001 |
| Drug use disorder | 53 (6.6%) | 238 (8.5%) | 122 (7.4%) | 42 (5.5%) | $\chi2=9.4$, df=3, p=0.02 |
| Personality disorder | 61 (7.6%) | 250 (8.9%) | 155 (9.4%) | 74 (9.6%) | $\chi2=2.5$, df=3, p=0.47 |
| Alcohol use disorder | 32 (4.0%) | 186 (6.7%) | 86 (5.2%) | 39 (5.1%) | $\chi2=10.2$, df=3, p=0.02 |
| Self-harm injury or poisoning | 18 (2.3%) | 72 (2.6%) | 43 (2.6%) | 12 (1.6%) | $\chi2=3$, df=3, p=0.39 |
| Schizophrenia spectrum psychosis | 11 (1.4%) | 42 (1.5%) | 11 (0.7%) | 7 (0.9%) | $\chi2=6.9$, df=3, p=0.07 |
| Service use in past year | | | | | |
| Mental health hospitalization[a] | 86 (10.8%) | 280 (10.0%) | 167 (10.1%) | 86 (11.2%) | $\chi2=1.2$, df=3, p=0.76 |
| Mental health emergency dept. visit[a] | 130 (16.3%) | 496 (17.7%) | 262 (15.9%) | 125 (16.3%) | $\chi2=3$, df=3, p=0.39 |

**eTable 9. Comparison of Self-harm Rates by Level of Intervention Participation**

Hazard ratios and confidence limits from separate proportional hazards models within each intervention group.

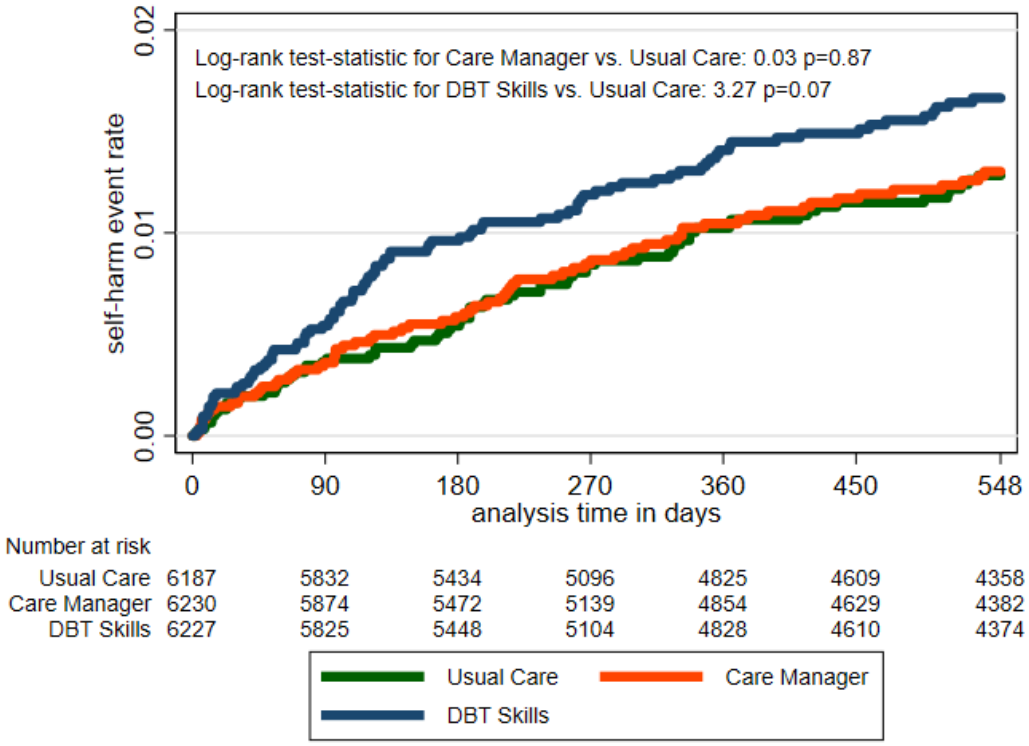
| | Offered Care Management | | Offered Skills Training | |
|---|---|---|---|---|
| | Hazard Ratio | 95% CI | Hazard Ratio | 95% CI |
| Never responded | Ref | - | Ref | - |
| Declined | 0.74 | 0.45 – 1.20 | 0.37 | 0.18 – 0.77 |
| Engaged 3 months or less | 2.13 | 1.19 – 3.79 | 1.54 | 1.13 – 2.11 |
| Engaged > 3 months | 1.37 | 0.96 – 1.94 | 1.12 | 0.70 – 1.78 |

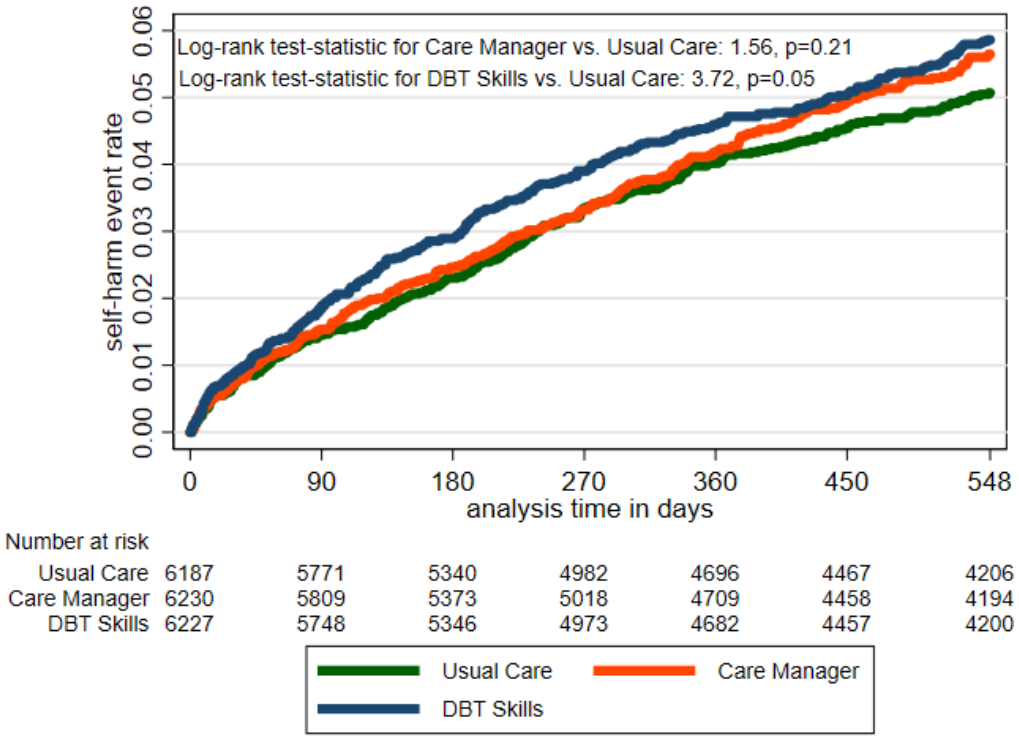
**eTable 10. Distribution of Utilization of Specific Non-study Health Services of 12 Months After Randomization**

| | Care Management | Skills Training | Usual Care |
|---|---|---|---|
| **Days with a Mental Health Specialty Outpatient Visits** | **N (%)** | **N (%)** | **N (%)** |
| 0 Days | 5,091 (82.29) | 5,196 (83.40) | 5,147 (82.66) |
| 1 to 3 Days | 933 (15.08) | 882 (14.16) | 905 (14.53) |
| 4 to 6 Days | 111 (1.79) | 119 (1.91) | 132 (2.12) |
| 7 to 9 Days | 41 (0.66) | 20 (0.32) | 25 (0.40) |
| 10 to 12 Days | 4 (0.06) | 7 (0.11) | 12 (0.19) |
| > 13 Days | 7 (0.11) | 6 (0.10) | 6 (0.10) |
| **Days with a Primary Care Visits with Any Mental Health Diagnosis** | | | |
| 0 Days | 5,722 (92.48) | 5,727 (91.93) | 5,723 (91.91) |
| 1 to 3 Days | 446 (7.21) | 485 (7.78) | 489 (7.85) |
| 4 to 6 Days | 11 (0.18) | 13 (0.21) | 11 (0.18) |
| > 7 Days | 8 (0.13) | 5 (0.08) | 4 (0.06) |
| **Days with an Emergency Department Visits with Any Mental Health Diagnosis** | | | |
| 0 Days | 6,112 (98.79) | 6,147 (98.67) | 6,146 (98.70) |
| 1 Day | 61 (0.99) | 66 (1.06) | 65 (1.04) |
| > 1 Days | 12 (0.23) | 17 (0.27) | 16 (0.26) |
| **Hospitalizations with Any Mental Health Diagnosis** | | | |
| 0 Admissions | 6,138 (99.21) | 6,176 (99.13) | 6,168 (99.05) |
| 1 Admissions | 45 (0.73) | 50 (0.80) | 54 (0.87) |
| > 1 Admissions | 4 (0.06) | 4 (0.06) | 5 (0.08) |

**eFigure 1. Kaplan Meier Curves for Planned Secondary Analyses of Severe Self-harm and Broader Definition of Self-harm**

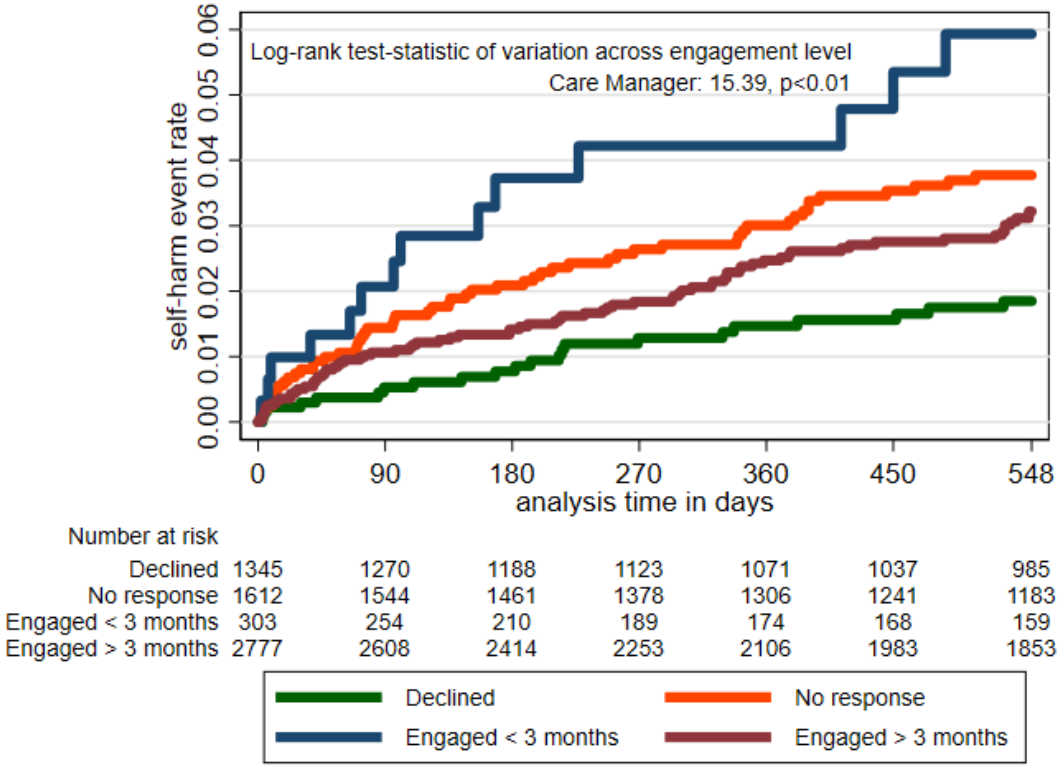
Top panel displays time until first self-harm event leading to death or hospitalization. Bottom panel displays time until first injury or poisoning event that could represent self-harm, even if not confirmed by review of clinical text (see eAppendix 6).

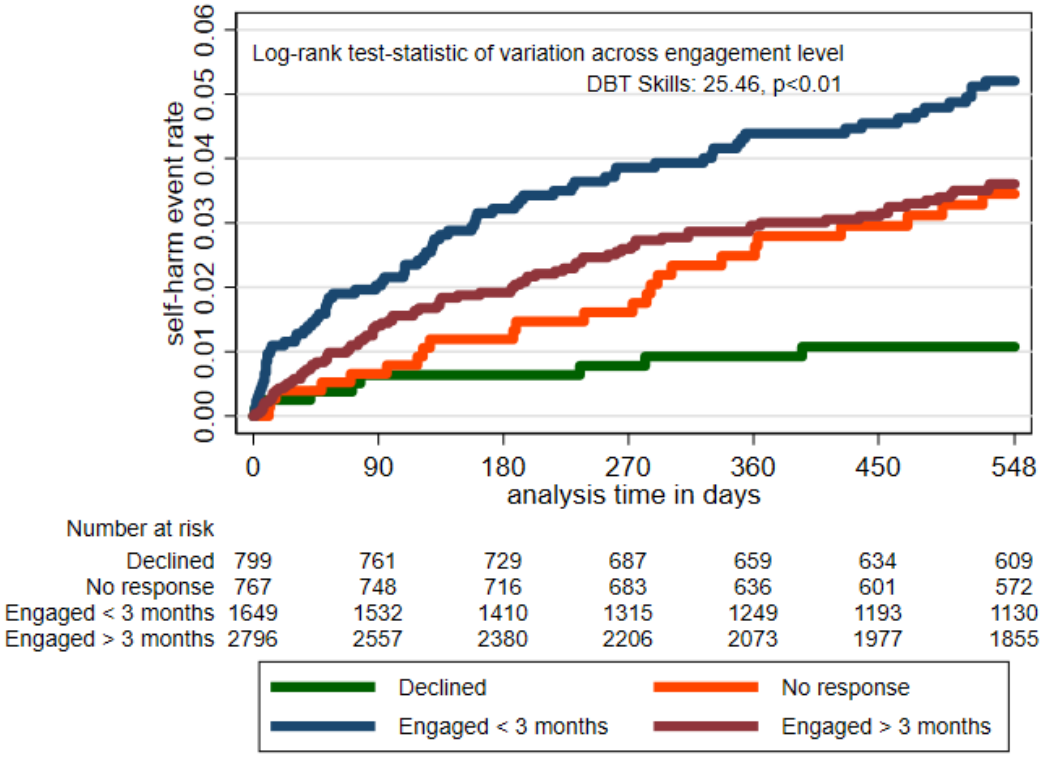




**eFigure 2. Comparison of Self-harm Rates by Level of Intervention Participation**

See Table 2 for definitions of intervention participation.



**eFigure 3. Log-Log Plot for Evaluation of Proportional Hazards Assumption**

Parallel curves after 30 days (equal to 3.4 on log scale) indicate no violation of proportional hazards assumption.