Fractional Factorial Study Design Example (With Results)

<u>Disclaimer</u>: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

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The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00055646

Recruitment Status: Completed First Posted: November 1, 2017

Results First Posted: January 30, 2019 Last Update Posted: January 30, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

This is a study using a fractional factorial design to identify intervention strategies intended to reduce depression and anxiety among adolescents attending public high schools. The study also measures salivary cortisol levels, which have sometimes been associated with depression and anxiety, as an exploratory outcome.

Condition or disease	Intervention/treatment	Phase
Depression, Anxiety	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling	Not
	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling	Applicable
	Behavioral: Text Messaging	
	Behavioral: Interactive Exercises	
	Behavioral: Matched Success Story (High)	
	Behavioral: Matched Success Story (Low)	

Detailed Description:

This is a balanced fractional factorial, 2^4-1, resolution IV design study to identify effective intervention strategies to reduce depression and anxiety among adolescents attending public high schools. The study also explores salivary cortisol levels. Individuals who meet the eligibility criteria will be randomized to one of eight conditions with different combinations of the following four factors: counseling, text messages, webbased interactive exercises, and web-based matched success stories.

Each factor will be implemented an equal number of times at high or low levels, or present or absent levels. Each main effect is aliased (confounded) with a three-way interaction of the remaining three factors; however, the effect of each three-way interaction is assumed to be negligible. For this study, the main effects of the factors on posttest outcomes, or the time x factor interactions, are considered the most important. The effects of two-way interactions between factors will not be estimated.

Study Design

Study Type: Interventional

Actual Enrollment: 400 participants

Allocation: Randomized

Intervention Model: Factorial Assignment

Intervention Model Description: Fractional Factorial Design

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: The Charleston Adolescent Wellness Study (CAWS)

Actual Study Start Date: November 1, 2017

Actual Primary Completion Date: May 30, 2018
Actual Study Completion Date: May 30, 2018

Arms and Interventions

Arm	Intervention/treatment				
Experimental: CBT(H), Texts(Y), Interactive(Y), Matched	Behavioral: Cognitive Behavioral Therapy (High) - In-Person				
Success(H)	Counseling				
In-Person Cognitive Behavioral Therapy (CBT) + Text Messaging + Interactive Exercises + Matched Success Story (High)	Participants received school-based, in-person cognitive behavioral therapy from licensed clinical social workers trained to work with adolescents. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access to counseling on an as-needed basis, up to once a week.				
	Behavioral: Text Messaging Participants received short text messages to support their therapy. Texts were sent daily during the 7-month intervention period, including during school holidays. The assumption was that participants who received text messages would read them, although the study technology and participants' mobile devices did not all allow tracking to determine whether participants actually opened each message.				

Arm	Intervention/treatment
	Behavioral: Interactive Exercises
	Participants were given online access to short videos and
	interactive exercises such as quizzes. New interactive sessions
	were available each week during the 7-month intervention period,
	regardless of school holidays. Participants' accessing of and
	interaction with the web-based materials were tracked through an
	online reporting system.
	Behavioral: Matched Success Story (High)
	Participants were given online access to a new story every 2
	weeks about another adolescent who had overcome depression.
	Stories for the "high" matched factor level were tailored to the
	participant's sex, age, grade, and ethnicity. New stories were
	available biweekly for the 7-month intervention period.
Experimental: CBT(H), Texts(Y), Interactive(N), Matched	Behavioral: Cognitive Behavioral Therapy (High) - In-Person
Success(L)	Counseling
In-Person CBT + Text Messaging + Matched Success Story	Participants received school-based, in-person cognitive behavioral
(Low)	therapy from licensed clinical social workers trained to work with
	adolescents. Counseling sessions occurred weekly for 7 months,
Note: Participants in this condition did not have access to the	except during school holidays. During breaks, participants were
interactive exercises.	granted access to counseling on an as-needed basis, up to once a
	week.

Arm	Intervention/treatment
	Behavioral: Text Messaging
	Participants received short text messages to support their therapy.
	Texts were sent daily during the 7-month intervention period,
	including during school holidays. The assumption was that
	participants who received text messages would read them,
	although the study technology and participants' mobile devices did
	not all allow tracking to determine whether participants actually
	opened each message.
	Behavioral: Matched Success Story (Low)
	Participants were given online access to a new story every 2
	weeks about another adolescent who had overcome depression.
	Stories for the "low" matched factor level were matched only to the
	participant's sex. New stories were available biweekly for the 7-
	month intervention period.
Experimental: CBT(H), Texts(N), Interactive(Y), Matched	Behavioral: Cognitive Behavioral Therapy (High) - In-Person
Success(L)	Counseling
In-Person CBT + Interactive Exercises + Matched Success	Participants received school-based, in-person cognitive behavioral
Story (Low)	therapy from licensed clinical social workers trained to work with
	adolescents. Counseling sessions occurred weekly for 7 months,
Note: Participants in this condition did not receive text	except during school holidays. During breaks, participants were
messages.	granted access to counseling on an as-needed basis, up to once a
	week.

Arm	Intervention/treatment
	Behavioral: Interactive Exercises Participants were given online access to short videos and interactive exercises such as quizzes. New interactive sessions were available each week during the 7-month intervention period, regardless of school holidays. Participants' accessing of and interaction with the web-based materials were tracked through an online reporting system.
	Behavioral: Matched Success Story (Low) Participants were given online access to a new story every 2 weeks about another adolescent who had overcome depression. Stories for the "low" matched factor level were matched only to the participant's sex. New stories were available biweekly for the 7-month intervention period.
Experimental: CBT(H), Texts(N), Interactive(N), Matched Success(H)	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling
In-Person CBT + Matched Success Story (High) Note: Participants in this condition did not receive text messages and did not have access to the interactive exercises.	Participants received school-based, in-person cognitive behavioral therapy from licensed clinical social workers trained to work with adolescents. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access to counseling on an as-needed basis, up to once a week.

Arm	Intervention/treatment
	Behavioral: Matched Success Story (High) Participants were given online access to a new story every 2 weeks about another adolescent who had overcome depression. Stories for the "high" matched factor level were tailored to the participant's sex, age, grade, and ethnicity. New stories were available biweekly for the 7-month intervention period.
Experimental: CBT(L), Texts(Y), Interactive(Y), Matched Success(L)	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Web-Based CBT + Text Messaging + Interactive Exercises + Matched Success Story (Low)	Participants received web-based cognitive behavioral therapy from licensed clinical social workers trained to work with adolescents. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access to counseling on an as-needed basis, up to once a week.
	Behavioral: Text Messaging Participants received short text messages to support their therapy. Texts were sent daily during the 7-month intervention period, including during school holidays. The assumption was that participants who received text messages would read them, although the study technology and participants' mobile devices did not all allow tracking to determine whether participants actually opened each message.

Arm	Intervention/treatment
	Behavioral: Interactive Exercises Participants were given online access to short videos and interactive exercises such as quizzes. New interactive sessions were available each week during the 7-month intervention period, regardless of school holidays. Participants' accessing of and interaction with the web-based materials were tracked through an online reporting system.
	Behavioral: Matched Success Story (Low) Participants were given online access to a new story every 2 weeks about another adolescent who had overcome depression. Stories for the "low" matched factor level were matched only to the participant's sex. New stories were available biweekly for the 7-month intervention period.
Experimental: CBT(L), Texts(Y), Interactive(N), Matched Success(H)	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Web-Based CBT + Text Messaging + Matched Success Story (High)	Participants received web-based cognitive behavioral therapy from licensed clinical social workers trained to work with adolescents. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access
Note: Participants in this condition did not have access to the interactive exercises.	to counseling on an as-needed basis, up to once a week.

Arm	Intervention/treatment
	Behavioral: Text Messaging
	Participants received short text messages to support their therapy.
	Texts were sent daily during the 7-month intervention period,
	including during school holidays. The assumption was that
	participants who received text messages would read them,
	although the study technology and participants' mobile devices did
	not all allow tracking to determine whether participants actually
	opened each message.
	Behavioral: Matched Success Story (High)
	Participants were given online access to a new story every 2
	weeks about another adolescent who had overcome depression.
	Stories for the "high" matched factor level were tailored to the
	participant's sex, age, grade, and ethnicity. New stories were
	available biweekly for the 7-month intervention period.
Experimental: CBT(L), Texts(N), Interactive(Y), Matched	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based
Success(H)	Counseling
Web-Based CBT + Interactive Exercises + Matched Success	Participants received web-based cognitive behavioral therapy from
Story (High)	licensed clinical social workers trained to work with adolescents.
	Counseling sessions occurred weekly for 7 months, except during
Note: Participants in this condition did not receive text	school holidays. During breaks, participants were granted access
messages.	to counseling on an as-needed basis, up to once a week.

Arm	Intervention/treatment
	Behavioral: Interactive Exercises
	Participants were given online access to short videos and
	interactive exercises such as quizzes. New interactive sessions
	were available each week during the 7-month intervention period,
	regardless of school holidays. Participants' accessing of and
	interaction with the web-based materials were tracked through an
	online reporting system.
	Behavioral: Matched Success Story (High)
	Participants were given online access to a new story every 2
	weeks about another adolescent who had overcome depression.
	Stories for the "high" matched factor level were tailored to the
	participant's sex, age, grade, and ethnicity. New stories were
	available biweekly for the 7-month intervention period.
Experimental: CBT(L), Texts(N), Interactive(N), Matched	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based
Success(L)	Counseling
Web-Based CBT + Matched Success Story (Low)	Participants received web-based cognitive behavioral therapy from
	licensed clinical social workers trained to work with adolescents.
Note: Participants in this condition did not receive text	Counseling sessions occurred weekly for 7 months, except during
messages and did not have access to the interactive exercises.	school holidays. During breaks, participants were granted access
	to counseling on an as-needed basis, up to once a week.
	Behavioral: Matched Success Story (Low)

Arm	Intervention/treatment			
	Participants were given online access to a new story every 2			
	weeks about another adolescent who had overcome depression.			
	Stories for the "low" matched factor level level were matched only			
	to the participant's sex. New stories were available biweekly for the			
	7-month intervention period.			

Outcome Measures

Primary Outcome Measures:

- 1. Pre- and Post-intervention Scores on the Center for Epidemiological Studies Depression Scale (CES-D) [Time Frame: Pre-intervention (during the first counseling session) and post-intervention (at 7 months, during the last counseling session)]
 - The CES-D is a 20-item measure that rates how often patients experience symptoms associated with depression. Responses are scored 0 (none of the time) to 3 (most or all of the time) for each item. Responses are summed for a final score ranging from 0 to 60, with higher scores indicating worse outcomes, i.e., higher levels of depression.
- 2. Pre- and Post-intervention Scores on the Hospital Anxiety and Depression Scale Anxiety Subscale (HADS-A) [Time Frame: Pre-intervention (during the first counseling session) and post-intervention (at 7 months, during the last counseling session)]

 Anxiety was measured using the seven-item HADS-A. Each item is scored from 0 (most positive answer) to 3 (most negative answer), resulting in a total possible score of 0 to 21. Higher total scores indicate worse outcomes, i.e., higher levels of anxiety.

Other Outcome Measures:

Pre- and Post-intervention Salivary Cortisol Levels [Time Frame: Pre-intervention (30 minutes after waking the day after the first counseling session) and post-intervention (at 7 months, 30 minutes after waking the day after the last counseling session)]
 During the first counseling session, participants were provided with a Salivette sampling kit to collect saliva samples at home, 30 minutes after waking in the morning. They were asked to not eat, drink, smoke, chew gum, brush their teeth, or use mouthwash for at

per liter (nmol/l), with a range of 9 to 33 reported in studies of nondepressed people. Higher cortisol levels are associated with higher levels of anxiety.

Eligibility Criteria

Ages Eligible for Study: 13 Years to 19 Years (Child, Adult)

Sexes Eligible for Study: Both Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Parental permission for participants < 18 years old
- Assessed with mild to moderate depression during screening for study (Center for Epidemiological Studies Depression Scale [CES-D] score between 9 and 39)
- An adolescent enrolled in freshman, sophomore, or junior classes
- · Access to a cell phone
- Access to the internet

Exclusion Criteria:

- Assessed with severe depression (CES-D score > 39) during screening for study
- Enrolled in senior class
- Currently receiving psychotherapy, medication therapy, or both for depression

Contacts and Locations

Locations

United States, South Carolina

Charleston University College of Arts and Sciences



Charleston, South Carolina, United States, 29425

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] May 30, 2017

More Information

Responsible Party: PRS Results Training

ClinicalTrials.gov Identifier: NCT00055646

Other Study ID Numbers: TTTFractionalFactorialR

First Posted: November 1, 2017

Results First Posted: January 30, 2019

Last Update Posted: January 30, 2019

Last Verified: December 2018

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No



Study Results

Participant Flow

Recruitment Details	Participants were recruited from public high schools in Charleston, SC.
Pre-assignment Details	

Arm/Group Title	CBT(H),	CBT(H),	CBT(H),	CBT(H),	CBT(L),	CBT(L),	CBT(L),	CBT(L),
	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),
	Interactive(Y),	Interactive(N),	Interactive(Y),	Interactive(N),	Interactive(Y),	Interactive(N),	Interactive(Y),	Interactive(N),
	Matched							
	Success(H)	Success(L)	Success(L)	Success(H)	Success(L)	Success(H)	Success(H)	Success(L)
▼Arm/Group	In-Person	In-Person	In-Person	In-Person	Web-Based	Web-Based	Web-Based	Web-Based
Description	Cognitive	CBT + Text	CBT +	CBT +	CBT + Text	CBT + Text	CBT +	CBT +
	Behavioral	Messaging +	Interactive	Matched	Messaging +	Messaging +	Interactive	Matched
	Therapy	Matched	Exercises +	Success	Interactive	Matched	Exercises +	Success
	(CBT) + Text	Success	Matched	Story (High)	Exercises +	Success	Matched	Story (Low)
	Messaging +	Story (Low)	Success	Note:	Matched	Story (High)	Success	Note:
	Interactive	Note:	Story (Low)	Participants in	Success	Note:	Story (High)	Participants in
	Exercises +	Participants in	Note:	this condition	Story (Low)	Participants in	Note:	this condition
	Matched	this condition	Participants	did not		this condition	Participants in	did not
	Success	did not have	in this	receive text		did not have	this condition	receive text
	Story (High)	access to the	condition did	messages or		access to the	did not	messages or
			not receive	have access				have access

		interactive exercises.	text messages.	to the interactive exercises.		interactive exercises.	receive text messages.	to the interactive exercises.
Period Title: Over	all Study							
Started	50	50	50	50	50	50	50	50
Completed [1]	40 [2]	40 [3]	40 [4]	40	40 [2]	40 [3]	40 [4]	40
Not Completed	10	10	10	10	10	10	10	10
Reason Not Completed								
Lost to Follow- up	4	4	4	4	4	4	4	4
Withdrawal by Subject	5	5	5	5	5	5	5	5
Lost Phone	1	1	0	0	1	1	0	0
Didn't Provide Salivary Cortisol Samples	0	0	1	1	0	0	1	1

^[1] Completed all pre- and post-intervention assessments and >12 CBT sessions; accessed stories >6x

^[2] Also maintained cell service for the entire study and accessed >12 interactive exercises

^[3] Also maintained cell service for the entire study

^[4] Also accessed >12 interactive exercises

Baseline Characteristics

	CBT(H), Texts(Y),	CBT(H), Texts(Y),	CBT(H), Texts(N),	CBT(H), Texts(N),	CBT(L), Texts(Y),	CBT(L), Texts(Y),	CBT(L), Texts(N),	CBT(L), Texts(N),	
Arm/Group Title	Interactive (Y),	Interactive (N),	Total						
	Matched								
	Success(H)	Success(L)	Success(L)	Success(H)	Success(L)	Success(H)	Success(H)	Success(L)	
▶ Arm/Group Description	In-Person	In-Person	In-Person	In-Person	Web-Based	Web-Based	Web-Based	Web-Based	Total of all
	Cognitive	CBT + Text	CBT +	CBT +	CBT + Text	CBT + Text	CBT +	CBT +	reporting
	Behavioral	Messaging	Interactive	Matched	Messaging	Messaging	Interactive	Matched	groups
	Ther	+ Ma	Exercis	Success	+ ln	+ Ma	Exercis	Success	
				Sto				Sto	
Overall Number of Baseline Participants	50	50	50	50	50	50	50	50	400
▼ Baseline Analysis Population Description	[Not Specified	d]				'			
Age, Continuous									
Mean									
(Standard Deviation)									
Unit of									
measure:									
years									

	Number	50	50	50	50	50	50	50	50	400
	Analyzed	participants	participants	participants	participants	participants	participants	participants	participants	participants
		16.1 (2.2)	15.9 (1.9)	15.8 (1.1)	16.3 (1.5)	15.5 (2.0)	15.3 (1.4)	16.4 (1.8)	16.5 (1.2)	16.0 (1.7)
Sex: Female,										
Male										
Measure										
Type: Count										
of										
Participants										
Unit of										
measure:										
Participants										
	Number	50	50	50	50	50	50	50	50	400
	Analyzed	participants	participants	participants	participants	participants	participants	participants	participants	participants
	Female	30 60.0%	32 64.0%	26 52.0%	27 54.0%	29 58.0%	31 62.0%	26 52.0%	28 56.0%	229 57.3%
	Male	20 40.0%	18 36.0%	24 48.0%	23 46.0%	21 42.0%	19 38.0%	24 48.0%	22 44.0%	171 42.8%
Ethnicity (NIH/OMB)										
Measure										
Type: Count										
of Participants										
Unit of										
measure:										
Participants										
	Number	50	50	50	50	50	50	50	50	400
	Analyzed	participants	participants	participants	participants	participants	participants	participants	participants	participants

	Hispanic or Latino	6 12.0%	10 20.0%	7 14.0%	5 10.0%	3 6.0%	11 22.0%	8 16.0%	4 8.0%	54 13.5%
	Not Hispanic or Latino	44 88.0%	40 80.0%	43 86.0%	45 90.0%	47 94.0%	39 78.0%	42 84.0%	46 92.0%	346 86.5%
	Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants										
	Number Analyzed	50 participants	400 participants							
	American Indian or Alaska Native	0 0.0%	1 2.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.0%	0 0.0%	2 0.5%
	Asian	3 6.0%	4 8.0%	2 4.0%	1 2.0%	5 10.0%	6 12.0%	4 8.0%	0 0.0%	25 6.3%

	Native Hawaiian	0	0.0%	0	0.0%	1	2.0%	0	0.0%	0	0.0%	1	2.0%	0	0.0%	0	0.0%	2	0.5%
	or Other																		
	Pacific																		
	Islander																		
	Black or	10	20.0%	15	30.0%	12	24.0%	16	32.0%	13	26.0%	14	28.0%	20	40.0%	11	22.0%	111	27.8%
	African																		
	American																		
-	White	37	74.0%	30	60.0%	35	70.0%	33	66.0%	32	64.0%	29	58.0%	25	50.0%	39	78.0%	260	65.0%
	More	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	than one																		
	race																		
	Unknown	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	or Not																		
	Reported																		
Region of																			
Enrollment																			
Measure																			
Type: Count																			
of																			
Participants																			
Unit of																			
measure:																			
Participants																			
United States	Number Analyzed	50 partici		5 partici			50 ipants		50 cipants		50 cipants		50 sipants		50 cipants		50 cipants		00 cipants

		50 100.0%	50 100.0%	50 100.0%	50 100.0%	50 100.0%	50 100.0%	50 100.0%	50 100.0%	400 100.0%
Previous										
In-School										
Suspensions										
Measure										
Type: Count										
of										
Participants										
Unit of										
measure:										
Participants										
	Number	50	50	50	50	50	50	50	50	400
	Analyzed	participants	participants	participants	participants	participants	participants	participants	participants	participants
		9 18.0%	2 4.0%	7 14.0%	6 12.0%	8 16.0%	4 8.0%	2 4.0%	7 14.0%	45 11.3%
Repeated a										
Grade										
Measure										
Type: Count										
of										
Participants										
Unit of										
measure:										
Participants										
	Number	50	50	50	50	50	50	50	50	400
	Analyzed	participants	participants	participants	participants	participants	participants	participants	participants	participants



4.	18	6.0%	3	8.0%	4	6.0%	3	2.0%	1	4.0%	2	2.0%	1	6.0%	3	2.0%	1			
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Outcome Measures

1. Primary Outcome

Title	Pre- and Post-intervention Scores on the Center for Epidemiological Studies Depression Scale (CES-D)
▼ Description	The CES-D is a 20-item measure that rates how often patients experience symptoms associated with depression. Responses are scored 0 (none of the time) to 3 (most or all of the time) for each item. Responses are summed for a final score ranging from 0 to 60, with higher scores indicating worse outcomes, i.e., higher levels of depression.
Time Frame	Pre-intervention (during the first counseling session) and post-intervention (at 7 months, during the last counseling session)

▼ Outcome Measure Data

▼ Analysis Population Description

All participants who received the noted level of each factor and completed both the pre- and post-intervention assessments were combined for this analysis.

Arm/Group Title	Cognitive Behavioral Therapy (High) - In-Person Counseling	Cognitive Behavioral Therapy (Low) - Web-Based Counseling	Text Messaging (Yes)	Text Messaging (No)	Web-Based Interactive Exercises (Yes)	Web-Based Interactive Exercises (No)	Web-Based Matched Success Stories (High)	Web-Based Matched Success Stories (Low)
▼ Arm/Group Description:	Participants received school-based,	Participants received web-based cognitive	Participants received short text messages	Participants in the "no" text message factor level	Participants were given online access to	Web-based interactive exercises were not	Participants were given online access to a	Participants were given online access to a

	in-person cognitive behavioral therapy. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access to counseling on an as-needed basis, up to once a week.	behavioral therapy. Counseling sessions occurred weekly for 7 months, except during school holidays. During breaks, participants were granted access to counseling on an as-needed basis, up to once a week.	to support their therapy. Texts were sent daily during the 7-month intervention period.	received no text messages.	short videos and interactive exercises such as quizzes. New interactive sessions were available each week during the 7-month intervention period.	available to participants in the "no" interactive factor level.	new story every 2 weeks about another adolescent who had overcome depression. Stories for the "high" matched factor level were tailored to the participant's sex, age, grade, and ethnicity. New stories were available biweekly for the 7-month intervention period.	new story every 2 weeks about another adolescent who had overcome depression. Stories for the "low" matched factor level were matched only to the participant's sex. New stories were available biweekly for the 7-month intervention period.
Overall Number of Participants Analyzed	160	160	160	160	160	160	160	160

Mean (Standard Deviation) Unit of Measure: units on a scale								
Pre-intervention	25.62 (6.81)	24.33 (7.11)	25.01 (6.97)	25.59 (5.99)	23.31 (7.09)	25.61 (6.59)	25.61 (6.79)	24.99 (6.91)
Post- intervention	18.99 (7.32)	20.38 (7.98)	19.65 (7.65)	22.45 (6.01)	17.57 (8.09)	23.55 (5.89)	18.53 (7.31)	18.06 (8.11)

▼ Statistical Analysis 1

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	We designed the study to have 80% power at α = 0.05 to detect a significant effect for the main effect of a factor for all three outcomes. All analyses were performed with SAS 9.4 software (SAS Institute).
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.780
Test of Hypothesis	Comments	Main effect of therapy type (in-person vs. web-based cognitive behavioral therapy). F statistic = 0.061
	Method	ANOVA
	Comments	[Not specified]

Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral
	Therapy (Low) - Web-Based Counseling

Statistical	Comments	[Not specified]
Analysis	Type of Statistical Test	Other
Overview	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of Hypothesis	Comments	Main effect of time across both levels of cognitive behavioral therapy. F statistic = 15.27
	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 3

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for cognitive behavioral therapy. F statistic = 3.871
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Comparison Group	Selection Text Messaging (Yes), Text M	essaging (No)
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Statistical	Comments	[Not specified]
Analysis	Type of Statistical Test	Other
Overview	Comments	[Not specified]
Statistical	P-Value	0.049
Test of	Comments	Main effect of text messaging (yes vs. no). F statistic = 2.049
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 5

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	<0.001
Test of	Comments	Main effect of time across both levels of text messaging. F statistic = 12.268
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other

	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for text messaging. F statistic = 3.204
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 7

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of interactive exercises (yes vs. no). F statistic = 5.021
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
	P-Value	< 0.001

Statistical	Comments	Main effect of time across both levels of interactive exercises. F statistic = 11.258
Test of	Method	ANOVA
Hypothesis	Comments	[Not specified]

▼ Statistical Analysis 9

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for interactive exercises. F statistic = 5.312
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories
Analysis		(Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
	P-Value	0.073
	Comments	Main effect of matched success stories (high vs. low). F statistic = 0.661

Statistical	Method	ANOVA
Test of Hypothesis	Comments	[Not specified]

▼ Statistical Analysis 11

Statistical Analysis	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories (Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of matched success stories. F statistic = 20.221
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical Analysis	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories (Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
	P-Value	0.050
	Comments	Interaction effect of time x factor for matched success stories. F statistic = 0.217

Statistical	Method	ANOVA
Test of	0	
Hypothesis	Comments	[Not specified]

2. Primary Outcome

Title	Pre- and Post-intervention Scores on the Hospital Anxiety and Depression Scale Anxiety Subscale (HADS-A)
▼ Description	Anxiety was measured using the seven-item HADS-A. Each item is scored from 0 (most positive answer) to 3 (most negative answer), resulting in a total possible score of 0 to 21. Higher total scores indicate worse outcomes, i.e., higher levels of anxiety.
Time Frame	Pre-intervention (during the first counseling session) and post-intervention (at 7 months, during the last counseling session)

▼ Outcome Measure Data

▼ Analysis Population Description

All participants who received the noted level of each factor and completed both the pre- and post-intervention assessments were combined for this analysis.

Arm/Group Title	Cognitive Behavioral Therapy (High) - In-Person Counseling	Cognitive Behavioral Therapy (Low) - Web-Based Counseling	Text Messaging (Yes)	Text Messaging (No)	Web-Based Interactive Exercises (Yes)	Web-Based Interactive Exercises (No)	Web-Based Matched Success Stories (High)	Web-Based Matched Success Stories (Low)
Arm/Group Description:	· ·	Participants received web-based cog	Participants received short text me	Participants in the "no" text messa	Participants were given online acce	Web-based interactive exercises wer	Participants were given online acce	Participants were given online acce

Overall Number	160	160	160	160	160	160	160	160
of Participants								
Analyzed								
Mean (Standard Deviation)								
Unit of Measure: units on a scale								
Pre-intervention	9.81 (2.57)	9.56 (2.58)	9.68 (2.56)	9.82 (2.53)	9.69 (2.57)	9.68 (2.54)	9.81 (2.57)	9.86 (3.02)
Post- intervention	7.46 (3.01)	8.30 (2.97)	7.46 (2.95)	9.01 (2.10)	7.85 (3.01)	7.76 (2.83)	7.61 (2.95)	9.12 (2.29)

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of Hypothesis	Comments	Main effect of therapy type (in-person vs. web-based cognitive behavioral therapy). F statistic = 0.358
	Method	ANOVA
	Comments	[Not specified]

[▼] Statistical Analysis 2

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of Hypothesis	Comments	Main effect of time across both levels of cognitive behavioral therapy. F statistic = 5.211
	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 3

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for cognitive behavioral therapy. F statistic = 1.573
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.822
Test of	Comments	Main effect of text messaging (yes vs. no). F statistic = 1.025
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 5

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of text messaging. F statistic = 4.373
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Comments	[Not specified]

Statistical	Type of Statistical Test	Other
Analysis Overview	Comments	[Not specified]
Statistical	P-Value	0.047
Test of	Comments	Interaction effect of time x factor for text messaging. F statistic = 2.035
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 7

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.120
Test of	Comments	Main effect of interactive exercises (yes vs. no). F statistic = 0.061
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other

	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of interactive exercises. F statistic = 5.427
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 9

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.050
Test of	Comments	Interaction effect of time x factor for interactive exercises. F statistic = 0.116
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories
Analysis		(Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical	P-Value	0.060
Test of	Comments	Main effect of matched success stories (high vs. low). F statistic = 0.946
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 11

Statistical Analysis	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories (Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.009
Test of	Comments	Main effect of time across both levels of matched success stories. F statistic = 4.244
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statist Anal		Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories
·	·		(Low)
Overv	riew	Comments	[Not specified]
		Type of Statistical Test	Other
		Comments	[Not specified]

Statistical	P-Value	0.030
Test of	Comments	Interaction effect of time x factor for matched success stories. F statistic = 2.107
Hypothesis	Method	ANOVA
	Comments	[Not specified]

3. Other Pre-specified Outcome

Title	Pre- and Post-intervention Salivary Cortisol Levels
▼ Description	During the first counseling session, participants were provided with a Salivette sampling kit to collect saliva samples at home, 30 minutes after waking in the morning. They were asked to not eat, drink, smoke, chew gum, brush their teeth, or use mouthwash for at least 30 minutes prior to providing the sample, which they collected by chewing on a synthetic cotton roll. Participants brought their sample kits to school the same day, and the samples were analyzed that day. Cortisol, a stress hormone, is measured in nanomoles per liter (nmol/l), with a range of 9 to 33 reported in studies of nondepressed people. Higher cortisol levels are associated with higher levels of anxiety.
Time Frame	Pre-intervention (30 minutes after waking the day after the first counseling session) and post-intervention (at 7 months, 30 minutes after waking the day after the last counseling session)

▼Outcome Measure Data

▼ Analysis Population Description

All participants who received the noted level of each factor and completed both the pre- and post-intervention assessments were combined for this analysis.

Arm/Group Title	Cognitive Behavioral Therapy (High) -	Cognitive Behavioral Therapy (Low) -	Text Messaging (Yes)	Text Messaging (No)	Web-Based Interactive Exercises (Yes)	Web-Based Interactive Exercises (No)	Web-Based Matched Success Stories (High)	Web-Based Matched Success Stories (Low)	
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	In-Person Counseling	Web-Based Counseling						
► Arm/Group Description:	Participants received school-based,	Participants received web-based cog	Participants received short text me	Participants in the "no" text messa	Participants were given online acce	Web-based interactive exercises wer	Participants were given online acce	Participants were given online acce
Overall Number of Participants Analyzed	160	160	160	160	160	160	160	160
Mean (Standard Deviation) Unit of Measure: nmol/L								
Pre-intervention	19.54 (11.99)	28.22 (9.58)	27.1 (15.62)	22.3 (12.33)	26.3 (7.91)	30.1 (13.24)	26.7 (12.65)	17.9 (18.71)
Post- intervention	10.35 (13.63)	26.31 (8.78)	17.3 (10.60)	20.28 (10.27)	18.6 (8.98)	29.4 (9.25)	16.9 (11.63)	14.21 (13.12)

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of Hypothesis	Comments	Main effect of therapy type (in-person vs. web-based cognitive behavioral therapy). F statistic = 14.940

Method	ANOVA
Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of Hypothesis	Comments	Main effect of time across both levels of cognitive behavioral therapy. F statistic = 16.021
	Method	ANOVA
	Comments	[Not specified]

Statis	istical	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral
Ana	alysis		Therapy (Low) - Web-Based Counseling
Over	rview	Comments	[Not specified]
		Type of Statistical Test	Other
		Comments	[Not specified]
		P-Value	< 0.001

Statistical	Comments	Interaction effect of time x factor for cognitive behavioral therapy. F statistic = 10.508
Test of	Method	ANOVA
Hypothesis	Comments	[Not specified]

▼ Statistical Analysis 4

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	0.877
Test of	Comments	Main effect of text messaging (yes vs. no). F statistic = 1.104
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of text messaging. F statistic = 17.060
Hypothesis	Method	ANOVA

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▼ Statistical Analysis 6

Statistical	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for text messaging. F statistic = 11.230
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 7

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of interactive exercises (yes vs. no). F statistic = 8.853
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of interactive exercises. F statistic = 12.124
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 9

Statistical	Comparison Group Selection	Web-Based Interactive Exercises (Yes), Web-Based Interactive Exercises (No)
Analysis	Comments	[Not specified]
Overview	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for interactive exercises. F statistic = 10.104
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Co	omparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories
		(Low)

Statistical	Comments	[Not specified]
Analysis	Type of Statistical Test	Other
Overview	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of matched success stories (high vs. low). F statistic = 6.967
Hypothesis	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 11

Statistical Analysis	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories (Low)
Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Main effect of time across both levels of matched success stories. F statistic = 19.471
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories
	(Low)

Statistical	Comments	[Not specified]
Analysis	Type of Statistical Test	Other
Overview	Comments	[Not specified]
Statistical	P-Value	< 0.001
Test of	Comments	Interaction effect of time x factor for matched success stories. F statistic = 8.819
Hypothesis	Method	ANOVA
	Comments	[Not specified]

Adverse Events

Time Frame	7-month intervention period
Adverse Event	Counselors reported psychiatric disorders identified during their sessions (either in person or web based) to CAWS staff
Reporting	after the session in which they identified the disorder had ended. School personnel reported truancy and in-school
Description	suspensions. Researchers obtained police reports for participants who were arrested during the study.
Source	[Not specified]
Vocabulary Name	
for Table Default	
Collection	Non-systematic Assessment
Approach for	
Table Default	

Arm/Group Title	CBT(H),	CBT(H),	CBT(H),	CBT(H),	CBT(L),	CBT(L),	CBT(L),	CBT(L),
	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),
	Interactive							
	(Y), Matched	(N), Matched						
	Success(H)	Success(L)	Success(L)	Success(H)	Success(L)	Success(H)	Success(H)	Success(L)
Arm/Group	In-Person	In-Person	In-Person	In-Person	Web-Based	Web-Based	Web-Based	Web-Based
Description	Cognitive	CBT + Text	CBT +	CBT +	CBT + Text	CBT + Text	CBT +	CBT +
	Behavioral	Messaging +	Interactive	Matched	Messaging +	Messaging +	Interactive	Matched
	Ther	Ма	Exercis	Success	In	Ma	Exercis	Success
				Sto				Sto

All-Cause Mortality

	CBT(H),	CBT(H),	CBT(H),	CBT(H),	CBT(L),	CBT(L),	CBT(L),	CBT(L),
	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),
	Interactive	Interact(N),						
	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	Matched
	Success(H)	Matched	Success(L)	Matched	Success(L)	Matched	Success(H)	Success(L)
		Success(L)		Success(H)		Success(H)		
	Affected / at							
	Risk (%)							
Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)

▼ Serious Advers	se Events							
	CBT(H),	CBT(H),	CBT(H),	CBT(H),	CBT(L),	CBT(L),	CBT(L),	CBT(L),
	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),
	Interactive	Interact(N),						
	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	Matched
	Success(H)	Matched	Success(L)	Matched	Success(L)	Matched	Success(H)	Success(L)
		Success(L)		Success(H)		Success(H)		
	Affected / at							
	Risk (%)							
Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)

▼ Other (Not Including Serious) Adverse Events

Frequency	0%							
Threshold for								
Reporting Other								
Adverse Events								
	CBT(H),	CBT(H),	CBT(H),	CBT(H),	CBT(L),	CBT(L),	CBT(L),	CBT(L),
	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),	Texts(Y),	Texts(Y),	Texts(N),	Texts(N),
	Interactive	Interact(N),						
	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	(N),	(Y), Matched	Matched
	Success(H)	Matched	Success(L)	Matched	Success(L)	Matched	Success(H)	Success(L)
		Success(L)		Success(H)		Success(H)		
	Affected / at							
	Risk (%)							
Total	1/50 (2%)	2/50 (4%)	1/50 (2%)	2/50 (4%)	3/50 (6%)	4/50 (8%)	4/50 (8%)	7/50 (14%)

Social Circumstances								
Felony arrest *[1]	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
In-school suspension *	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Misdemeanor arrest * [2]	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
Running away *	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Truancy *	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
Psychiatric disorders								
Psychiatric disorder *[3]	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)

^{*} Indicates events were collected by non-systematic assessment

- [1] For example, fighting, drug possession
- [2] For example, stealing, drug possession
- [3] In addition to the mild-to-moderate depression diagnosed at baseline. None were serious enough to require residential mental health treatment.

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

All Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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