Fractional Factorial Study Design Example (With Results)

Disclaimer: 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).

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 Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling Behavioral: Text Messaging Behavioral: Interactive Exercises Behavioral: Matched Success Story (High) Behavioral: Matched Success Story (Low)	Not Applicable

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, web-based 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 Success(H) In-Person Cognitive Behavioral Therapy (CBT) + Text Messaging + Interactive Exercises + Matched Success Story (High)	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling 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 Success(L) In-Person CBT + Text Messaging + Matched Success Story (Low) Note: Participants in this condition did not have access to the interactive exercises.	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling 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.

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Experimental: CBT(H), Texts(N), Interactive(Y), Matched Success(L) In-Person CBT + Interactive Exercises + Matched Success Story (Low) Note: Participants in this condition did not receive text messages.	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling 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.

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Experimental: CBT(H), Texts(N), Interactive(N), Matched Success(H) 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.	Behavioral: Cognitive Behavioral Therapy (High) - In-Person Counseling 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) Web-Based CBT + Text Messaging + Interactive Exercises + Matched Success Story (Low)	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling 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.

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Experimental: CBT(L), Texts(Y), Interactive(N), Matched Success(H) Web-Based CBT + Text Messaging + Matched Success Story (High) Note: Participants in this condition did not have access to the interactive exercises.	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling 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.

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Experimental: CBT(L), Texts(N), Interactive(N), Matched Success(L) Web-Based CBT + Matched Success Story (Low) Note: Participants in this condition did not receive text messages and did not have access to the interactive exercises.	Behavioral: Cognitive Behavioral Therapy (Low) - Web-Based Counseling 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: 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:

1. 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 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.

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

		interactive exercises.	text messages.	to the interactive exercises.		interactive exercises.	receive text messages.	to the interactive exercises.
Period Title: **Overall 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

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

	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 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 Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 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 Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 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	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	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 or Other Pacific Islander	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%
	Black or African American	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%
	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 than one race	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%
	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%
Region of Enrollment Measure Type: Count of Participants Unit of measure: Participants										
United States	Number Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 participants

		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 Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 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 Analyzed	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	50 participants	400 participants

		1 2.0%	3 6.0%	1 2.0%	2 4.0%	1 2.0%	3 6.0%	4 8.0%	3 6.0%	18 4.5%

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 Overview	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
	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 Test of Hypothesis	P-Value	0.780
	Comments	Main effect of therapy type (in-person vs. web-based cognitive behavioral therapy). F statistic = 0.061
	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 2

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

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

▼ Statistical Analysis 4

	Comparison Group Selection	Text Messaging (Yes), Text Messaging (No)

Statistical Analysis Overview	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.049
	Comments	Main effect of text messaging (yes vs. no). F statistic = 2.049
	Method	ANOVA
	Comments	[Not specified]

▼ Statistical Analysis 5

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

▼ Statistical Analysis 6

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

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

▼ Statistical Analysis 7

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

▼ Statistical Analysis 8

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

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

▼ Statistical Analysis 9

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

▼ Statistical Analysis 10

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

▼ Statistical Analysis 11

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

▼ Statistical Analysis 12

Statistical Analysis Overview	Comparison Group Selection	Web-Based Matched Success Stories (High), Web-Based Matched Success Stories (Low)
	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 Test of Hypothesis	Method	ANOVA
	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 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: 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 1

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

▼Statistical Analysis 4

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

▼ Statistical Analysis 5

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

▼ Statistical Analysis 6

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

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

▼Statistical Analysis 7

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

▼Statistical Analysis 8

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

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

▼Statistical Analysis 9

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

▼Statistical Analysis 10

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

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

▼Statistical Analysis 11

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

▼Statistical Analysis 12

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

Statistical Test of Hypothesis	P-Value	0.030
	Comments	Interaction effect of time x factor for matched success stories. F statistic = 2.107
	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)

	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 1

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

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Cognitive Behavioral Therapy (High) - In-Person Counseling, Cognitive Behavioral Therapy (Low) - Web-Based Counseling
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]
	P-Value	< 0.001

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

▼ Statistical Analysis 4

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

▼ Statistical Analysis 5

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

	Comments	[Not specified]

▼ Statistical Analysis 6

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

▼ Statistical Analysis 7

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

▼ Statistical Analysis 8

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

▼ Statistical Analysis 9

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

▼ Statistical Analysis 10

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

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

▼ Statistical Analysis 11

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

▼ Statistical Analysis 12

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

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

Adverse Events

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

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

All-Cause Mortality

	CBT(H), Texts(Y), Interactive (Y), Matched Success(H)	**CBT(H), Texts(Y), Interactive (N), Matched Success(L)**	**CBT(H), Texts(N), Interactive (Y), Matched Success(L)**	**CBT(H), Texts(N), Interactive (N), Matched Success(H)**	**CBT(L), Texts(Y), Interactive (Y), Matched Success(L)**	**CBT(L), Texts(Y), Interactive (N), Matched Success(H)**	**CBT(L), Texts(N), Interactive (Y), Matched Success(H)**	**CBT(L), Texts(N), Interact(N), Matched Success(L)**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	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 Adverse Events

	CBT(H), Texts(Y), Interactive (Y), Matched Success(H)	CBT(H), Texts(Y), Interactive (N), Matched Success(L)	CBT(H), Texts(N), Interactive (Y), Matched Success(L)	CBT(H), Texts(N), Interactive (N), Matched Success(H)	CBT(L), Texts(Y), Interactive (Y), Matched Success(L)	CBT(L), Texts(Y), Interactive (N), Matched Success(H)	CBT(L), Texts(N), Interactive (Y), Matched Success(H)	CBT(L), Texts(N), Interact(N), Matched Success(L)
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	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 Threshold for Reporting Other Adverse Events	0%

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

Results Point of Contact

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