February 2023

To: Senate Health & Human Services Committee
Re: SB23-091—Behavioral Health Services for Medicaid Recipients under 21

Dear Committee Members,

The American Association of University Women (AAUW) is one of the oldest women's organizations in the country, empowering women since 1881. The mission of AAUW is to advance equity for women and girls through research, education and advocacy.

Recent reports have shown that girls and young women are experiencing record levels of mental health issues due to the effects of the COVID pandemic, social media pressure and other causes. Young people who receive Medicaid benefits are under even more stress due to poverty, homelessness and other factors. SB-91 will bring much needed mental health services to these Medicaid recipients. With so many of our youth in crisis, SB-91 is needed now.

AAUW of Colorado strongly supports this bill and requests your YES vote in committee and throughout the process of becoming a law.

Thank you for your consideration,

Su Ryden
AAUW of Colorado Public Policy Co-Director

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American Association of University Women--AAUW is a top-rated 501(c)3 charitable organization whose mission is to advance gender equity for women and girls through research, education, and advocacy.

Rhonda Fields, Chair
Joann Ginal, Vice Chair
Senate Committee on Health & Human Services

Thursday, February 16, 2023

Support of SB 23-091: Access To Behavioral Health Services

I am writing on behalf of Boulder County and Boulder County Public Health to express our support for SB 23-091: Access to Behavioral Health Services. The evidence is overwhelmingly clear that Colorado is in the midst a youth mental health crisis, and action is needed. Suicide is the leading cause of death among Colorado youth ages 10-24, and 40% of middle and high school students in the state reported feelings of depression in 2021.

For the past ten years, improving the mental and behavioral health of youth has been a priority for Boulder County Public Health, and access to mental and behavioral health care and support has been a consistent barrier to community members, especially those living at low-income. Notably, youth living at low-income often experience unique stressors, such as uncertainly related to food and housing, which can increase their risk for poor mental and behavioral health outcomes. As documented in the most recent Mental Health America report, Colorado ranks 21st in the nation for access to behavioral health care, indicating that access to care is not only a local issue but a statewide one. Increased access to behavioral health services is vital to addressing the youth mental health crisis, and by allowing Medicaid recipients under the age of 21 to access behavioral health services without a diagnosis, Colorado youth will have improved access to the services they need to lead happy, healthy lives.

In closing, Boulder County Public Health is committed to helping youth receive the mental and behavioral health care they need. Research conducted by the National Institute on Mental Health demonstrates that half of all lifetime cases of mental illness or substance use begin by age 14, and the passage of SB 23-091 would address a well-documented barrier to behavioral health services for youth and help them receive the right care at the right time. Thank you to the sponsors for introducing SB 23-091, and if you have any questions regarding our support for this bill, please do not hesitate to contact me.

Sincerely,

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www.bouldercountyhealth.org

BOULDER COUNTY PUBLIC HEALTH
Opportunity for a healthy life.

A Study on the Efficacy of

Brain Thrive by 25 Intervention

Provided by

Final External Evaluation Report

Evaluators

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&

Dr. Doug Gove

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Project Director

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Mindworks

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Abstract

This external evaluation report provides evidence related to the efficacy of the *Brain Thrive by 25* intervention. *Brain Thrive by 25* is a behavioral brain-based program. Research that correlates *Brain Thrive by 25* with academic motivation and achievement, underscores the cognitive foundation of learning. The Multivariate Analysis of Covariance (MANCOVA) results of this comprehensive study suggest that while statistically controlling for variables (covariates) of baseline dependent variable pretest measures, classrooms reporting higher levels of implementation of *Brain Thrive by 25* also report statistically significant higher, more healthy and positive levels of behavior related to self-esteem, positive thinking/depression, alcohol, tobacco and other drug use (ATOD), and overall brain system functionality when compared to classrooms reporting none to lower levels of implementation. Utilizing a multivariate approach to assessing the outcomes associated with the implementation of *Brain Thrive by 25*, this study supports that *Brain Thrive by 25* has a positive impact on individuals' brain functions and classrooms seeking to help students improve patterns of thought and behavior highly associated with academic achievement.

I. The Intervention

The *Brain Thrive by 25 Course: 2nd Edition* is a practical brain science course and curriculum which was created to change the way teenagers and young adults learn about, protect, and care for their brain. The course is meant to be adaptable and flexible to fit within a wide variety of educational environments and settings. The goal of the course is to increase student achievement and graduation rates by teaching students (teenagers and young adults) about the importance of brain function and how it relates to everyday living, loving, learning, joy, success, academics, career, and life.

The curriculum is comprised of 12 individual modules:

- Module 1: Brain Basics
- Module 2: Developing Brain Facts
- Module 3: The Prefrontal Cortex and Anterior Cingulate Gyrus
- Module 4: The Basal Ganglia and Deep Limbic System
- Module 5: The Impact of Drugs and Alcohol
- Module 6: Other Ways We Hurt the Brain
- Module 7: Brain Struggles and Mental Health
- Module 8: Understanding Other People's Brains
- Module 9: Killing the Automatic Negative Thoughts (ANTs)
- Module 10: Nutrition and Exercise
- Module 11: Learning and Stress
- Module 12: How to Change the Brain

Support resources for teaching this course include:

- A *Change Your Brain, Change Your Life (Before 25)* curriculum binder with chapters for each module
- PowerPoint presentations for each module for educators to use while teaching
- HD Videos for each module for teachers to show to students
- Guided notes for each module for students to complete while learning
- Activities for each module to enhance teaching and learning
- Additional resources and readings to supplement teaching and learning
- Online support

The 12 modules in this course were designed to be as flexible and adaptable as possible:

- Each module can run from as little as 30 minutes each up to 90 minutes each
- The course can be implemented daily for two weeks, once a week throughout an entire semester, or as a separate course

- The curriculum can be successfully implemented in as few as 8 modules with little extra involvement
- The curriculum can also be expanded to the full 12 modules (and beyond) with included lab-style activities to give deeper connections and allow for more meaningful learning opportunities
- The curriculum has also been successfully adopted and integrated into traditional health, English, physical education, homeroom, advisory, science, English, psychology, freshmen success, and other already existing courses
- Teachers can teach the course with a personally designed approach utilizing the included resources and materials
- Teachers can implement the course while retaining a more supportive role using the included DVD's and other activities
- Teachers can partner with other educators/counselors to implement the curriculum

II. Theoretical Framework

The theoretical underpinnings of *Brain Thrive by 25* are embedded within the individual lessons, teaching strategies, and overall framework of the modules. The long term intended outcome objectives – improved academic achievement, reduced risk behaviors, and evidence of college and career readiness – are the product of all *Brain Thrive by 25* modules, quality implementation and fidelity, and student learning through the curriculum activities. The student learning is aimed at bolstering important protective factors –enhanced social-emotional and brain-based competencies, improved academic attitudes and habits, and sense of purpose and future. The following Table 1 illustrates the logic model and research design behind *Brain Thrive by 25* to support the overall theoretical framework.

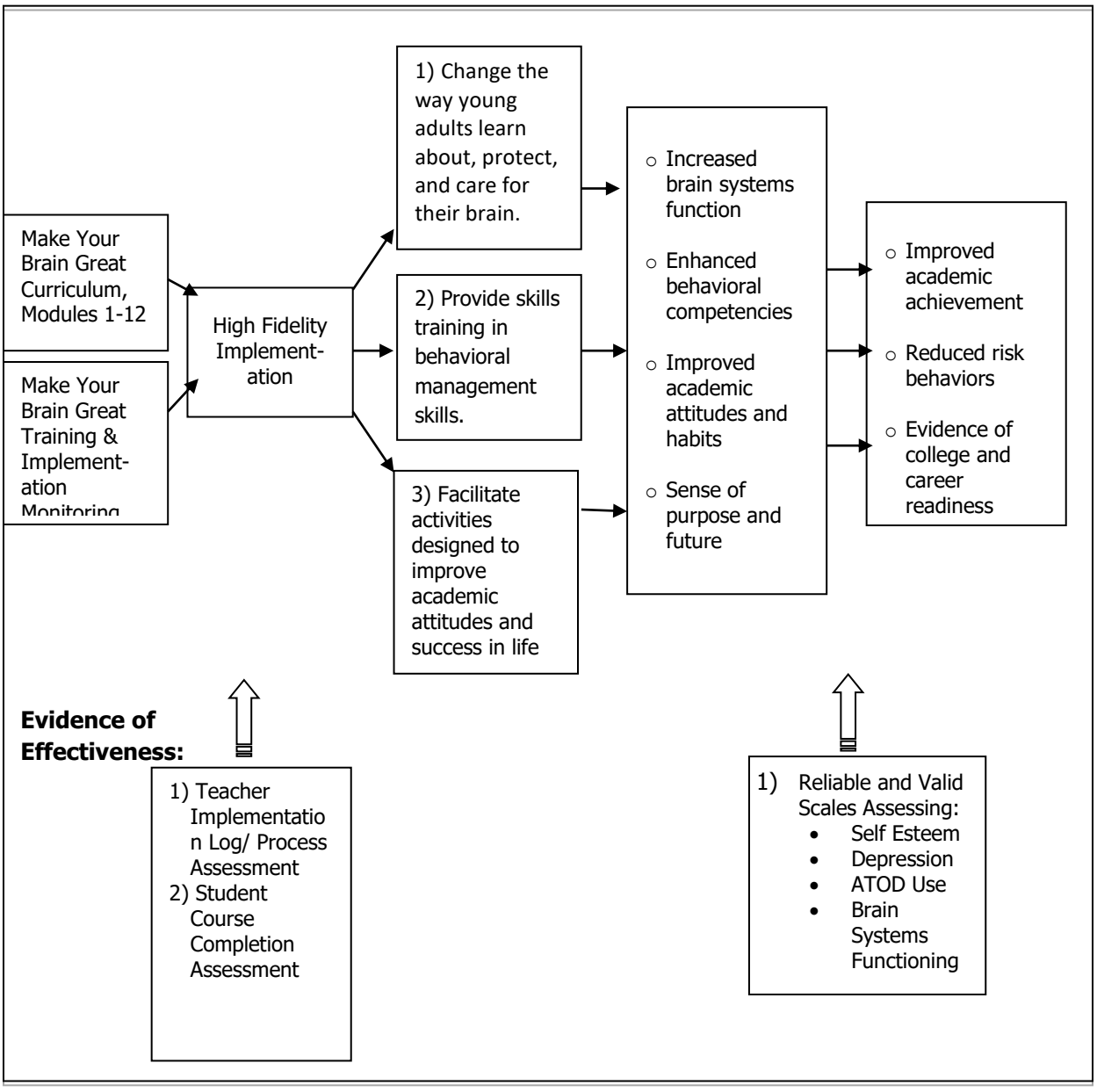
***Teaching Strategies*:**

Teaching strategies employed throughout the curriculum are designed to foster the ABCs of student motivation: autonomy, belonging, and competence (Deci, 1995). In a landmark policy paper concerning the efforts of the country's leading educational associations, Learning First Alliance identified these factors as "basic needs" of young people and central to the learning process. Schools that satisfy these needs benefit from their students' improved attitudes, behavior, and performance (Learning First Alliance, 2001).

According to Edward Deci, having autonomy "means to act in accord with one's self—it means feeling free and volitional in one's actions" (Deci, 1995). Autonomy leads to authenticity in

thought and behavior; without it, students are less likely to pursue learning for its own sake or discover the subjects and types of work that truly engage their interest and attention. In education, autonomy is often referred to as "voice and choice"— students having a say about what they think and what they study. Providing voice and choice requires teachers to be facilitators of learning, rather than imparters of information; this style of teaching is the opposite of the top-down lecture format often employed in traditional high school classrooms.

Table 1: Brain Thrive by 25 Logic Model & Evaluation Measures



III. Rationale/Purpose

> *"If we intervene during these windows of opportunity – during the period between the time when symptoms can be first detected and disorders can be diagnosed – we are more likely to prevent the onset of the disorder and produce lasting and long-term impacts. And if we can intervene even sooner, to promote healthy lifestyles, our potential for reducing the toll of behavioral health problems on individuals, communities, and society is even greater."* - SAMHSA Information Sheet 4: The Developmental Framework

Adolescence is an exciting and challenging time, marked by dramatic changes in physical appearance, cognitive development and abilities, and social and emotional development. As young people move from the relative simplicity and security of childhood to the complexity and uncertainties of adulthood, they seek peers, role models, and social ideals to guide them through the process (Csikszentmihalyi & Larson, 1984; Erikson, 1968). Most adolescents experience some difficulty and confusion during this transition. As a result, they are at greater risk than children for depression, anxiety, substance abuse, violence, self-injurious behavior, and academic failure (Centers for Disease Control and Prevention, 2004; Eccles & Gootman, 2002; Resnick et al., 1997).

Brain Thrive by 25 is a proactive prevention program that fits well within the *Behavioral Health Continuum of Care Model* recommended by SAMHSA. The intervention is designed for both universal and selective intervention at the critical juncture of early-to-mid-adolescence, a high-risk entry point for early substance abuse and mental health issues. *Brain Thrive by 25* addresses the risk factors that lead to behavioral health problems head on by building in a multitude of protective factors into the high school system. Each *Brain Thrive by 25* module is a calculated skill-building opportunity to prepare youth for the temptations and challenges of the adolescent-to-adulthood journey. Please see Table 2 to follow.

Table 2: Brain Thrive by 25 Protective Factors

MIDDLE CHILDHOOD & ADOLESCENT FACTORS	**BRAIN THRIVE BY 25 (EACH MODULE IS RESEARCH-BASED, 45+ MINUTES)**
➢ Coping strategies	Module 1: Brain Basics
➢ Positive social adjustment	Module 2: The Brain Before 25
➢ Peer rejection, isolation, deviant peer groups	Module 3: Prefrontal Cortex & Executive Function
➢ Peer rejection, isolation, deviant peer groups	Module 4: The Cingulate & Cognitive Flexibility
➢ Anxiety, Depression, Anger/Aggression	Module 5: Basal Ganglia & Deep Limbic System
➢ Peer attitudes toward drugs, Societal/community norms about alcohol and drug use	Module 6: Impact of Drugs & Alcohol
➢ Peer rejection, isolation, deviant peer groups	Module 7: Other Ways We Hurt The Brain
➢ Anxiety, Depression, Anger/Aggression	Module 8: Brain Struggles & Mental Health
➢ Peer rejection, isolation, deviant peer groups	Module 9: Understanding Other People's Brain
➢ School failure, Low commitment to school	Module 10: Automatic Negative Thoughts (ANTs)
	Module 11: Nutrition & Physical Exercise
	Module 12: Mental Exercise & Stress Reduction

IV. Methods/Methodology

Study:

Participants-

To recruit a representative sample essential to studying the impact of *Brain Thrive by 25*, participants for this study were selected utilizing a purposive sampling technique. According to Vogt (2007) and Shadish, Cook and Campbell (2002), purposive sampling is probably the most common form of sampling in experiments and curricular evaluation studies, and when random sampling is not possible it provides the avenue needed to select cases that are representative in a purposive sense. Six schools from six states were recruited for the study, resulting in 16 individual classrooms participating in the study. These schools were monitored through the Brain Thrive by 25 Infusion Measure, and then at the time of analyzing final data assigned to comparison (low to no implementation and non-completion of course) or treatment (high fidelity implementation and full course completion) groups. In other words, students in classrooms reporting the teacher did not complete all 12 modules, and thus showing lower implementation scores, were assigned to the comparison sample. The participating students consisted of 335 students in 16 different classrooms across grades 8-12. Table 3,4, and 5 detail the distribution of students by age, ethnicity, and gender.

Table 3: Student Sample by Age

Treatment and Comparison		Frequency
Treatment	12-14 years old	72
	15-17 years old	113
	18-20 years old	16
	Total	201
Comparison	12-14 years old	43
	15-17 years old	90
	18-20 years old	1
	Total	134

Table 3 shows that the largest number of students for both treatment and comparison groups were in the age range of 15-17 years old with the second largest group of students was in the 12-14 age range.

Table 4: Student Sample by Ethnicity

Treatment and Comparison		Frequency
Treatment	Hispanic/Latino	20
	Caucasian/White	128
	Asian	4
	African American/Black	28
	Native American	3
	Other	8
	Multi-National	10
	Total	201
Comparison	Hispanic/Latino	13
	Caucasian/White	82
	Asian	3
	African American/Black	12
	Pacific Islander	2
	Native American	4
	Other	8
	Multi-National	10
	Total	134

Table 4 provides a distribution of the student population by self-identified ethnicity. The largest numbers of students in the treatment and comparison groups report being Caucasian/White. The second largest numbers for the treatment and comparison group are in African American/Black and Hispanic/Latino students respectively.

Table 5: Student Sample by Gender

Treatment and Comparison		Frequency
Treatment	Male	78
	Female	118
	Other	5
	Total	201
Comparison	Male	63
	Female	70
	Other	1
	Total	134

Table 5 shows that both the treatment and comparison group students reported a higher number of female students than male students with a small number of students selecting other when being asked to self-identify their gender. These data provide an overall picture of comparability across the treatment and comparison sample. Statistical tests used to verify this comparability will be discussed later in the analyses section of this report.

The students were enrolled in a *Brain Thrive by 25* course (spanning 9 to 12 weeks) to help improve their brain functions and prepare for the challenges of life. The study collected pretest and posttest data on 16 different classrooms within the six schools teaching the courses with varying degrees of implementation utilizing the *Brain Thrive by 25* curriculum. The courses were taught by 12 different teachers. The students were administered the survey at the time of pretest before the course began and 9-12 weeks later at a posttest when the course ended. The survey administered to all participants under the age of 18 provided opportunity for passive consent and surveys were administered in accordance with guidelines for research with human participants (American Psychological Association and the IRB of institutions involved).

Design-

This study utilized an experimental based Pretest to Posttest Design (Shadish, Cook & Campbell; 2002). This design was employed because the *Brain Thrive by 25* curriculum is typically utilized by teachers with a specific group of students during a limited amount of time in specific classrooms (ranging from a few weeks to a semester long course). Furthermore, this study was completed by an outside evaluation company, Multi-Dimensional Education, Inc. (www.MDedInc.com), and funded by *Brain Thrive by 25*. The funding for this study allowed for the implementation of a Pretest to Posttest Design, capable of providing initial evidence as to the efficacy of the curriculum when implemented according to the recommendations of the curriculum developers.

There are other reasons that support the design utilized in this study. Given schools are over surveyed in today's education world it has become quite apparent that recruiting schools currently not working with *Brain Thrive by 25* to complete another survey unconnected to their

accountability or curricular demands would be a very difficult task without financial incentives. Thus, limiting the study's ability to recruit and pretest a large enough sample to safely randomly assign students or classrooms to experimental and control groups (unconnected to *Brain Thrive by 25*). Furthermore, with the unheard of challenges schools face today, and the heavy focus on implementing social and emotional learning and related efforts such as Response to Interventions (RTIs) to combat behavior challenges, and ongoing issues of bullying and in school violence, one would be hard pressed to find control schools not currently doing some form of intervention to improve the behavior and cognition of students.

Therefore this study focused on an adequate sample of schools wanting to explore or implement *Brain Thrive by 25*. Through the use of a reliable process assessment measuring the infusion of the intervention, and staying in close contact with teachers during the study, the process assessment score documented the classrooms with students who did or did not complete the whole course and the level of implementation and infusion experienced; thus providing a dichotomous independent grouping variable designating classrooms falling into the two categories of comparison and treatment. This is a common procedure utilized within the social and behavioral sciences for numerous reasons. As is often found in many experimental studies, even though experimental samples (e.g., schools or classrooms/teachers) often initially agree to do the intervention with rigor, what is often found is that schools and teachers seem to reflect more of a dichotomy of infusion. Therefore, through analyzing the process data and communication logs, this study documented the level of *Brain Thrive by 25* curriculum being infused (ranging from high to low or no implementation, and which students completed the whole course (even though the school had requested the curriculum and requested teachers to utilize the program). Thus the sample of 16 classrooms was divided into high infusion/full completion and low infusion/non-completion sub-sets. This provided the groupings needed to study treatment and comparison schools. This procedure complies with the findings by Angold et al. (2000) and Howard et al. (1986). The analysis and results to follow document that the intervention produced a number of statistically significant positive behavior outcomes for high infusion treatment schools (or more specifically classrooms) greater than their comparison counterparts.

Please note the majority of data utilized in the analysis of this study was collected via online surveys administered according to a strict protocol under controlled group settings and following APA guidelines. Each form of the pretest and posttest surveys utilized allowed participants to skip questions they did not feel comfortable answering. As a result, with such a large sample of students taking part, some of the questions on the surveys were not answered by all students. To account for such missing data, initial data cleaning exercises included some cases being excluded from data analysis because of missing data. The syntax applied and listwise deletion approach taken for missing data and this approach will be addressed in more detail to follow.

Measures-

To assess the fidelity of the intervention, or more specifically the level of quality implementation of the intervention and the completion or non-completion of the course, the *Brain Thrive by 25* Infusion Measure was administered to the participating teacher samples. The infusion measure underwent intensive development, piloting and testing before use in this study. The development of the infusion assessment was started through an extensive review of the *Brain Thrive by 25* curriculum and procedures. The procedures taken for the process evaluation development were designed to insure face, content and evidence of predictive validity.

Specifically, the final twelve-item teacher infusion measure was developed to measure level of training, quality of implementation, quantity and frequency of implementation, as well as level of course completion, and produced an alpha coefficient of .74. The *Brain Thrive by 25* Infusion Measure score was then used to create an independent variable capable of distinguishing between the treatment (high implementation) and comparison (low implementation) groups.

To measure the dependent variables that organizations such as SAMSHA and *Brain Thrive by 25* identify as important to helping schools and students, and provide variables to be used as covariates, the following scales and assessment tools were utilized and served as pretest and posttest measures for this study.

The Rosenberg's Self-Esteem Scale, is a 10-item scale that measures global self-worth by assessing both positive and negative feelings about the self. The scale is believed to be uni-dimensional. All items from the original 4-point Likert scale tool were adapted for this study

to be answered using a 5-point Likert scale format; thus providing more consistency with the other scales utilized and yet still ranging from strongly agree to strongly disagree. Historically, this scale has exhibited strong reliability and validity. According to Gray-Little, Williams and Hancock (1997), the Rosenberg Self-Esteem Scale, a widely used self-report instrument for evaluating individual self-esteem. The Rosenberg Self-Esteem Scale presented high ratings in reliability areas; internal consistency was 0.77, minimum Coefficient of Reproducibility was at least 0.90 (Rosenberg, 1965). A varied selection of independent studies each using such samples as – parents, men over 60, high school students, and civil servants – showed alpha coefficients ranging from 0.72 to 0.87. Test-retest reliability for the 2-week interval was calculated at 0.85, the 7-month interval was calculated at 0.63 (Silber & Tippett, 1965, Shorkey & Whiteman, 1978). In this study the Rosenberg Self-Esteem Scale had a .88 alpha coefficient for the pretest and a .89 for the posttest.

Zung's Depression Scale, is a self-reporting scale composed of 20-item scales that was developed to measure depressive symptoms using 4-point scales. The scale was originally designed to assess depression in patients with depressive disorders. Psychometric research has provided substantial evidence on the reliability and validity of the scale with normal subjects and patients with depressive disorders (Fukuda & Kobayashi,1973; Zung, 1965). For this study the scale was adapted to a 5-point likert scale, and had a .80 alpha coefficient for the pretest and a .81 for the posttest.

SCI Exercise Self-Efficacy Scale, is a reliable instrument with high internal consistency and scale integrity. The content validity and face validity have also been successfully demonstrated (Kroll, Kehn, Ho, & Groah; 2007). This measure includes 10 items on a 4-point Likert scale. This measure was adopted for this study to determine if the intervention had significant impact on self-reported attitudes toward exercise, as addressed in the *Brain Thrive by 25* Intervention.

Pittsburgh Sleep Quality Index (PSQI- for this study Sleep Scale), is a self-report questionnaire that assesses sleep quality over a 1-month time interval. It consists of 19 individual items generating seven "component" scores: subjective sleep quality, sleep latency (i.e., how long it takes to fall asleep), sleep duration, habitual sleep efficiency (i.e., the

percentage of time in bed that one is asleep), sleep disturbances, use of sleeping medication, and daytime dysfunction. The questionnaire has been used in many settings, including research and clinical activities, and has been used in the diagnosis of sleep disorders. The PSQI is intended to be a standardized sleep questionnaire for clinicians and researchers to use with ease. The survey contains 19 questions, each weighted on a 0-3 interval scale. A global PSQI score is taken from the survey, with lower scores correlating to better sleep quality. Clinical studies have found the PSQI to be reliable and valid in the assessment of sleep problems to some degree, but more so with self-reported sleep problems and depression-related symptoms than actigraphic measures (Grandner, Kripke, Yoon, & Youngstedt; 2006).

MDed Alcohol, Tobacco MDed Alcohol, Tobacco and Other Drugs (ATOD) Scale and Other Drugs (ATOD) Scale, is a five item scale that measures the level of use from a student's self-reported perspective. In past studies, the ATOD has produced an alpha coefficient of .92 (Corrigan, Grove, & Gargani, 2012). These ATOD, when compared to reports from previous schools studied by Multi-Dimensional Education, showed strong face, content and predictive validity. The MDed ATOD scale has been used by MDed in numerous evaluation projects, and for this study, serves as a scale for student behavior ATOD. The ATOD scales produced high reliability in this study with .89 at pretest and .92 at posttest.

Brain Systems Index, is a 24 item scale with a 5-point Likert scales response option. The Brain Systems Index is closely related to the curriculum material provides in the *Brain Thrive by 25* Intervention. The items on this assessment link to specific aspects of the module curriculum. The Brain Systems Index was used as a uni-variate measure in the analysis of pretest to posttest differences. Reliability for this measure was strong with internal consistency of .94 demonstrated on pretest and posttest. Past research suggest the scale has strong face and content reliability, as well as initial pretest/posttest analysis supporting initial criterion validity.

These scales were utilized to create the study's pre and posttest that the participating students completed. The pretest was administered prior to the implementation of any *Brain Thrive by 25* Curriculum, and the posttest was administered 9-12 weeks later following varying levels of implementation. Teachers were provided with a copy of the pre-posttest and a short protocol to follow for administration. Students were tracked utilizing the teachers name and a confidential

code, thus allowing the pre and posttest data to be matched and tracked at the individual level. The following table provides you with pretest and posttest reliabilities for the scales utilized.

Table 6: Cronbach Alphas by Measure

Scales Used for Pretest and Posttest Survey	Pretest Reliability	Posttest Reliability
Rosenberg's Self-Esteem Scale	.88	.89
Zung's Depression Scale	.80	.81
SCI Exercise Self-Efficacy Scale	.91	.91
Pittsburgh Sleep Quality Index	.80	.80
MDed ATOD Scale	.89	.92
Brain Systems Index	.94	.94

Analysis-

As the first step to account for missing data, a listwise deletion approach was conducted (Barladi & Enders, 2010). Prior to performing the listwise deletion process, however, to configure mean scores for the scales utilized in the study, a 75% threshold was set within the analysis syntax used to clean and recode data. This means if participants did not answer at least 75% of the questions for each scale assessed by the survey, the composite variable syntax did not compute the mean scores for the answers provided. This helped to provide further detail to identify which cases were to be eliminated via the listwise deletion process. This allowed for further cleaning of missing data.

Utilizing the posttest survey data as dependent variables, along with the pretest scores as covariates, and process evaluation measurements to create an independent grouping variable comparing high implementation to those of the comparison group putting little to no implementation of the *Brain Thrive by 25* program in place, a Multivariate Analysis of Covariance (MANCOVA) was performed. When more than one dependent variable exists, it is not recommended to run multiple univariate tests. This is mainly due to the fact that multiple Analysis of Variance (ANOVA) run separately cannot take into account the pattern of covariation among dependent measures (Stevens, 2002). A MANCOVA allows for multiple covariates to be entered into the analysis and statistically controlled. Therefore, this analysis

sought to assess the dependent variables together and to control for confounding variables, more specifically baseline assessments of students perceptions and behaviors.

V. Results/Findings

After the pretest data was collected, cleaned, and coded, an Analysis of Variance (ANOVA) and descriptive analysis was used to verify the level of homogeneity and comparability which existed between the students of the participating teachers. At the time of the pretest, none of the variables assessed showed any significant differences between the teachers. When this ANOVA was ran again at the end of the study on the pretest data, once process data was collected to determine which group the teachers fell into (high vs low implementation), once again no statistical significance was identified on the pretest composite variables being measured.

Once posttest data and process data were added, Multivariate analysis of Covariance (MANCOVA) was used to analyze and identify statistically significant differences on the posttest survey's composite variable scores (Dependent Variables) between the treatment (high implementers) and comparison (low implementers) groups (Independent Variables). The MANCOVAs performed also used pretest composite variable scores as covariates.
Thus, a one-way between-groups multivariate analysis of covariance was performed to investigate differences between varying levels of implementation of the *Brain Thrive by 25*. Pretest composite scale scores were used as covariates. Using the posttest variable composite scores, six dependent variables were used: self-esteem, depression, exercise efficacy, sleep quality, alcohol tobacco and other drug use, and brain systems functioning. The independent variable was level of implementation. Preliminary assumption testing was conducted to check for normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance Matrices, and multicollinearity, with no serious violations noted. Multivariate tests confirm there were numerous positive statistically significant differences between students in classrooms receiving higher levels of *Brain Thrive by 25* (Treatment Group) and lower levels of *Brain Thrive by 25* as well as statistically significant differences between treatment and comparison groups: F (5, 316) = 4.86, p = .001; Pillai's Trace = .122; partial eta squared = .122.

Tests of Between Subjects identified significant difference on four of the six variables measured with treatment group students reporting higher or more positive perceptions of self-esteem, depression, alcohol tobacco and other drug use, and brain systems functioning. Effect sizes range from small to medium according to Cohen (1977).

Table 7: Variable Score Tests of Between Subjects

Dependent Variable	F	Sig.	Partial Eta Squared
Self-Esteem	8.99	.003	.027
Depression	7.50	.007	.023
Exercise Efficacy	1.76	.185	.005
Sleep Quality	.80	.373	.002
ATOD	25.90	.001	.074
Brain Systems	8.13	.005	.024

Mean scores show that on four of six variables, treatment groups had statistically significant better or higher scores than comparison groups. Please note that for depression, sleep quality, ATOD and brain systems, higher mean scores represent worse outcomes.

Table 8: Mean Differences between Groups

Dimensions	Groups	Mean	SD	N
Self-Esteem	Low Implementers	31.72	6.63	134
	High Implementers	33.61	6.67	201
	Total	**32.86**	**6.71**	**335**
Depression	Low Implementers	44.34	8.86	134
	High Implementers	42.63	8.71	201
	Total	**43.31**	**8.80**	**335**
Exercise Efficacy	Low Implementers	32.43	7.93	134
	High Implementers	33.26	8.31	201
	Total	**32.93**	**8.16**	**335**
Sleep Quality	Low Implementers	25.57	7.79	134

	High Implementers	25.00	7.94	201
	Total	**25.23**	**7.87**	**335**
ATOD	Low Implementers	10.57	6.36	134
	High Implementers	7.94	5.32	201
	Total	**8.99**	**5.89**	**335**
Brain Systems	Low Implementers	62.57	18.15	134
	High Implementers	59.36	17.62	201
	Total	**60.64**	**17.88**	**335**

VI. Discussion, Limitations, and Conclusions

This comprehensive evaluation report on the externally performed study exploring the efficacy of *Brain Thrive by 25* provides evidence that this promising intervention is helping schools help students. *Brain Thrive by 25* is helping schools to help their students improve behavior and thought patterns essential to creating and developing healthier learning climates, teacher-student relationships, educational attitudes and developmental perspectives needed to help students rise above the challenges of today. The intervention produced numerous positive behavioral outcomes showing that after receiving high fidelity instruction based upon the *Brain Thrive by 25* curriculum, students in high implementation *Brain Thrive by 25* classrooms reported a multi-dimensional array of much higher perceptions than counterparts in low implementation *Brain Thrive by 25* classrooms.

When the *Brain Thrive by 25* curriculum is implemented with high fidelity, participating students experience improvements in self-esteem, positive thinking/depression, alcohol tobacco and other drug use, and overall brain functions.

The results of this study suggest that high implementation of *Brain Thrive by 25* in middle school or high school settings is associated with statistically significant in attitudes and self-report behaviors. Given the pretest was based on assessing the baseline preexisting perceptions and attitudes of the participating students, and then used to balance out posttest scores accordingly, further supports the interventions relationship to higher posttest scores.

Such positive behavioral outcomes were obtained with strict attention to quality of research. Survey data was collected under APA guidelines and via a survey instrument utilizing multiple scales with existing reliability and validity evidence. The fidelity of the intervention was measured as well with a reliable and valid Infusion Measure. The study reduced validity threats to the findings through a multivariate analysis capable of encompassing many of the variables at work. Additionally, the study statistically controlled for covariates such as pretest levels, and with specificity addressed missing data.

Furthermore, when the analysis digs deeper and shows how four of the six variables assessed in the study were statistically significant with high implementers having the higher or better mean scores, this reinforces that *Brain Thrive by 25* is contributing positively to change. The only two variables that did not produce significance were exercise efficacy and sleep quality. But even these two scales still showed the mean scores trending higher for high implementation classroom students. The power of this study rests in the findings across the board, where students in the high implementation *Brain Thrive by 25* classrooms that had been exposed to the curriculum more in-depth were much more positive in their attitudes, perceptions and brain system function ability.

Limitations

This study did have several limitations. One limitation is the lack of an unrelated control group and random assignment. In the world of evaluation, however, especially when it comes to evaluating students within the education setting, without extensive incentives and resources accomplishing either is often an insurmountable challenge. Regardless, no matter if one claims to have an unrelated sample to serve as a control group, and even pretests them far before the intervention starts, there is likely contamination, bias and error that need to be mitigated. Furthermore, when studies measure the impact of a program focused on social and emotional learning (SEL) or behavioral issues, some of the most popular efforts at work in our schools today, the challenges get even harder to find a true control school sample not doing similar effort comparable to the intervention. Experimental research capable of suggesting some causal relationship exists can only be achieved when a control group who shows no sign of improvement during the first part of the experimental design realizes such gains upon once

receiving the intervention; and then through multiple study replication the same gain persist. These are just a few of the reasons why any study, be it experimental or quasi-experimental, will have some degree of imperfection that questions the validity of the findings.

A second limitation to this study that is experienced in most studies seeking to control variables is the sheer number of controls that often erode the power of an intervention while maximizing the number of controls. In this study we included as many control variables as we could reasonably capture given time and resource constraints. To this end we also included all of the control variables we had at our disposal. Finding the results we did with maximum controls highlights that the intervention effect did persist even as controls took away from the overall power.

Conclusions

Brain Thrive by 25 is an intervention focused on helping educators help students succeed. *Brain Thrive by 25* focuses on the most challenging times in many young adult's lives, that time in middle school and high school. The materials were highly regarded by the educators interviewed during this study. The implementation materials, training and support resources are considered to be valuable and very worthwhile tools for educators. The analysis in this report provides evidence it holds great promise for helping others help students. Future efforts of research related to *Brain Thrive by 25* should seek to replicate studies such as this one and if possible employ additional rigorous study methods to examine the same outcomes variables contained in this study. *Brain Thrive by 25* is a cost-effective, teacher-friendly, and student-engaging method of embedding prevention methods into public, private, and alternative schools.

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Dear Members of the Senate Health & Human Services Committee:

On behalf of Rose Community Foundation, I write to express our support for Senate Bill 23-091 (Access to Behavioral Health Services) and respectfully encourage members of the committee to vote in favor.

As a community foundation representing and investing in the seven-county Greater Denver region, we work closely with a wide range of nonprofits that are on the ground serving individuals and communities furthest from opportunity. Over the past few years, these nonprofit partners have increasingly shared that mental health is one of the primary issues facing young people in our community, and that gaps in access to behavioral health care have only been exacerbated since the start of the COVID-19 pandemic.

Rose Community Foundation is concerned to learn that, unlike children who are covered under private plans, Coloradans under 20 years of age who are insured by Medicaid are required to receive a behavioral health diagnosis before they can receive care. This requirement creates a major barrier to receiving timely behavioral health care and places the burden of a lasting behavioral health diagnosis on kids who do receive care. Children insured by Medicaid are already more likely to have a behavioral health condition; requiring our least-resourced youth to jump through additional hoops is undoubtedly keeping children who need behavioral health supports from receiving the critical services they need.

We are pleased to see bipartisan support for this common-sense legislation that would open a pathway to care without putting the burden on youth and families who are already experiencing difficult life circumstances. All Colorado families and communities are better off when our state makes it easier for children struggling with behavioral health challenges to get the help they need.

Rose Community Foundation proudly joins our partners in the nonprofit sector, along with behavioral health experts and concerned families, who support this important bill to improve the health, well-being, and futures of our state's youth.

Lindy Eichenbaum Lent
President and CEO, Rose Community Foundation

inseparable

409 7th St Northwest, Suite 305
Washington, D.C. 20004
February 7, 2023

Colorado General Assembly
200 E. Colfax Ace
Denver, CO 80203

Via electronic submission

RE: SUPPORT FOR HB23-091, Access To Behavioral Health Services

Dear Chair Fields and Members of the Committee:

On behalf of Inseparable, a growing movement of people working to advance policy solutions that reflect the belief that the health of our minds cannot be separate from the health of our bodies, I am writing to urge you to support HB23-091: Access to Behavioral Health Services.

Inseparable is focused on closing the treatment gap for the millions of Americans with mental health conditions who are not getting the help they need, improving crisis response services, and getting youth help early.

The mental health challenges facing youth and young adults today are so alarming that the Children's Hospital Colorado declared an emergency in 2021, which was followed by the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, and the Children's Hospital Association issuing a joint statement of a national emergency in mental health.[1] Just this week, the Centers for Disease Control and Prevention (CDC) released data showing that, in 2021, over four in ten (42%) high school students felt persistently sad or hopeless.[2] The CDC noted that, in particular, "female students and LGBTQ+ students are experiencing alarming rates of violence, poor mental health, and suicidal thoughts and behaviors."

The poor mental health experienced by children and youth has many causes, including the impact of stressful or traumatic life experiences. When youth experience mental health challenges, it can affect their academic performance, their relationships with their teachers, parents, friends and family, and even their health and safety. Fortunately, prevention and early intervention work. Getting help early not only improves outcomes, it can keep a person's

[1] AAP-AACAP-CHA Declaration of a National Emergency in Adolescent Mental Health. (10/19/2021). Retrieved from https://www.aap.org/en/advocacy/childand-adolescent-healthy-mental-development/aap-aacap-cha-declaration-of-a-national-emergency-in-child-and-adolescent-mental-health/.
[2] Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention. Youth Risk Behavior Survey: Data Summary & Trends Report, 2011-2021.

mental health condition from worsening. Requiring a mental health diagnosis to access services creates barriers to getting the very help that could mitigate—or even prevent—a diagnosable condition. Recognizing this conundrum, other states has extended eligibility for mental health services to children and youth under the age of 21 who have experienced certain life experiences that put them at risk for mental health challenges. We believe Colorado should do the same.

HB23-091 represents an innovative and transformative step in reducing stigma and improving access to care. **Inseparable respectfully requests that the Committee pass this vital legislation and continue Colorado's admirable efforts to support youth mental health.**

Respectfully,

Angela Kimball
Sr Vice President of Advocacy & Public Policy

What Did STAR*D Teach Us? Results From a Large-Scale, Practical, Clinical Trial for Patients With Depression

Bradley N. Gaynes, M.D., M.P.H.
Diane Warden, Ph.D., M.B.A.
Madhukar H. Trivedi, M.D.
Stephen R. Wisniewski, Ph.D.
Maurizio Fava, M.D.
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The authors provide an overview of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study (www.star-d.org), a large-scale practical clinical trial to determine which of several treatments are the most effective "next-steps" for patients with major depressive disorder whose symptoms do not remit or who cannot tolerate an initial treatment and, if needed, ensuing treatments. Entry criteria were broadly defined and inclusive, and patients were enrolled from psychiatric and primary care clinics. All participants began on citalopram and were managed by clinic physicians, who followed an algorithm-guided acute-phase treatment through five visits over 12 weeks. At the end of each sequence, patients whose depression had not fully remitted were eligible for subsequent randomized trials in a sequence of up to three clinical trials. In general, remission rates in the study clinics were lower than expected, suggesting the need for several steps to achieve remission for most patients. There was no clear medication "winner" for patients whose depression did not remit after one or more aggressive medication trials. Both switching and augmenting appeared to be reasonable options when an initial antidepressant treatment failed, although these two strategies could not be directly compared. Further, the likelihood of remission after two vigorous medication trials substantially decreased, and remission would likely require more complicated medication regimens for which the existing evidence base is quite thin. STAR*D demonstrated that inclusion of more real-world patients in clinical trials is both feasible and informative. Policy implications of the findings, as well as the study's limitations, are discussed. (*Psychiatric Services* 60:1439–1445, 2009)

Dr. Gaynes is affiliated with the Department of Psychiatry, University of North Carolina School of Medicine, CB #7160, Chapel Hill, NC 27599 (e-mail: bgaynes@med.unc.edu). Dr. Warden, Dr. Trivedi, and Dr. Rush are with the Department of Psychiatry, University of Texas Southwestern Medical Center at Dallas. Currently Dr. Rush is also with the Duke–National University of Singapore. Dr. Wisniewski is with the Epidemiology Data Center, Graduate School of Public Health, University of Pittsburgh. Dr. Fava is with the Depression Clinical and Research Program, Massachusetts General Hospital, Harvard Medical School, Boston. *This article is part of a special section on the STAR*D trial (Sequenced Treatment Alternatives to Relieve Depression) and the implications of its findings for practice and policy. Grayson S. Norquist, M.D., M.S.P.H., served as guest editor of the special section.*

Depression affects one in eight persons in the United States (1) and is projected to become the second leading cause of disability in the world by the year 2020 (2). However, generalizable evidence from clinical trials to inform treatment selection and sequencing is quite limited. Most clinical trial participants are recruited by advertisement rather than from representative practice settings. Eligibility criteria often exclude persons who have coexisting general medical or psychiatric disorders or who are taking medication other than antidepressants (3,4). Those with chronic depression or current suicidal ideation are also excluded (1,5). Consequently, the available "evidence" from clinical trials involves a largely "pure," uncomplicated population of depressed patients that is rarely seen by most practicing clinicians (6).

In addition, the care delivered in these efficacy trials, which involves using interviewer-administered measures and frequent and time-intensive follow-up interviews, blinding patients and physicians to treatment, and employing fixed dosing strategies, does not reflect what is and can be done in real-world practices. The available evidence may not translate to the care provided by practicing psychiatrists and primary care physicians (7). Further, the bulk of the evidence base is for patients who have yet to experience treatment failure in

their current episode of depression, even though only about a third of patients achieve remission after a single treatment (8). Management of most patients after one or more failed treatments is not evidence based.

To address these knowledge deficits, the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study (www.star-d.org), a large-scale clinical trial funded by the National Institutes of Health, aimed to develop and evaluate feasible treatment strategies to improve clinical outcomes for more representative, "real-world" outpatients with one or more prior failed treatments. The study created its own prospectively defined sample of treatment-resistant patients from a pool of patients currently experiencing a major depressive episode for subsequent inclusion in a series of up to five prospective treatments. Specifically, STAR*D aimed to determine which of several treatments are the most effective "next-step" treatments for patients whose symptoms do not remit or who cannot tolerate the initial treatment and, if needed, ensuing treatments. This article provides an overview of the design, methods, and results of STAR*D, with attention to the implications and limitations of the trial.

The rationale and design of STAR*D

Design

The rationale and design of the study have been fully described elsewhere (3,4,9). STAR*D is the largest prospective clinical trial of major depressive disorder ever conducted. It was a multicenter, nationwide association of 14 university-based regional centers, which oversaw a total of 23 participating psychiatric clinics and 18 primary care clinics. Enrollment began in 2000, with follow-up completed in 2004. All enrolled patients began on a single selective serotonin reuptake inhibitor (SSRI) (citalopram) and were managed by clinic physicians, who followed an algorithm-guided acute phase treatment through five visits over a 12-week course. Dosing was aggressive and focused on maximizing the tolerable dose; if patients who were tolerating a medication had not achieved remission (that is, complete recovery from the depressive episode) by any of the critical decision points (weeks 4, 6, and 9), the algorithm recommended increasing the dose. Patients whose depression did not remit after this initial treatment were able to participate in a sequence of up to three randomized clinical trials or levels. For example, at the end of level 1, patients whose depression had not fully recovered were eligible to participate in level 2 (Figure 1).

Treatment assignments were made using an equipoise stratified randomized design (10). To reflect treatment decisions in clinical practice, patients were allowed to choose among acceptable options (for example, to switch to a different treatment or augment the current treatment with an additional treatment). Participants could opt out of certain strategies as long as there were at least two possible options to which they might be randomly assigned.

Participants

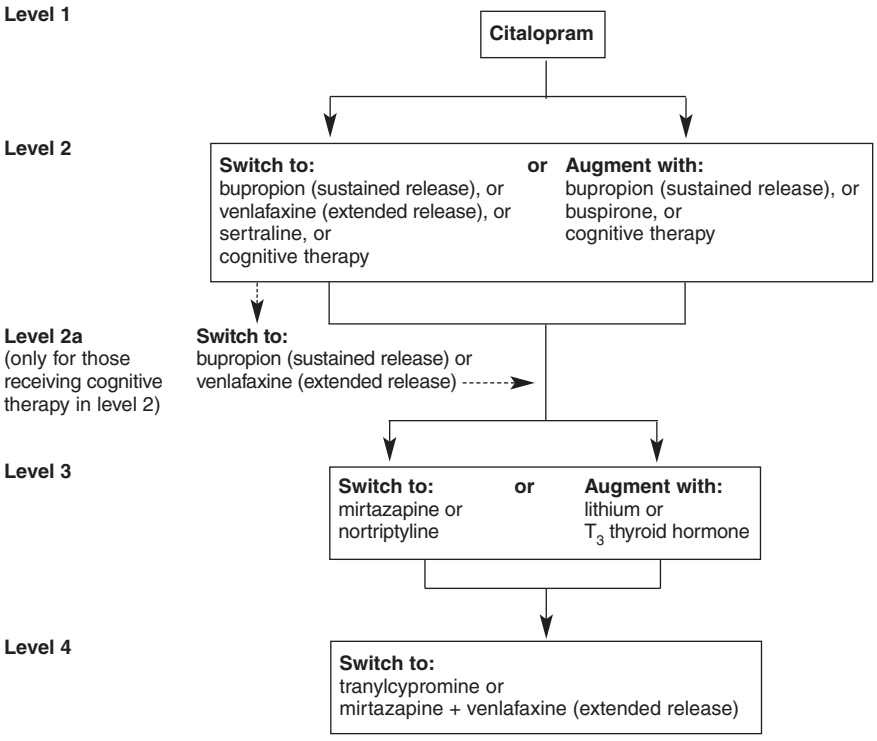
Study entry criteria were broadly defined and inclusive. Patients had to have nonpsychotic major depressive disorder identified by clinicians and confirmed with a symptom checklist based on *DSM-IV-TR* (11), for which antidepressant treatment is recommended. Patients, whose ages ranged from 18 to 75, had to score of ≥14 on the 17-item Hamilton Rating Scale for Depression (HAM-D) (12) and could not have a primary diagnosis of bipolar disorder, obsessive-compulsive disorder, or an eating disorder or have a history of a seizure disorder. A total of 4,041 patients were enrolled in the first level of treatment, making STAR*D the largest prospective clinical trial of depression ever conducted.

Setting

Both primary and specialty care sites that provided care to public- and private-sector patients were selected on the basis of having sufficient numbers of patients, sufficient numbers of clinicians, sufficient administrative support, and sufficient numbers of patients from racial-ethnic minority groups to ensure that the study population would mirror the U.S. census data and that results would be widely generalizable. The median number of

Figure 1

STAR*D treatment levels



clinicians was 14 at the 18 primary care sites and 12 at the 23 specialty sites. Three-quarters of the facilities were privately owned, and approximately two-thirds were freestanding (not hospital based).

Measures

The primary research outcome was the standard definition of remission as measured by the HAM-D (13). Assessments were conducted by treatment-blinded raters at exit from each treatment level. A secondary instrument, the 16-item Quick Inventory of Depressive Symptomatology–Self-Report (QIDS-SR), was administered at each clinic visit, and remission was measured as a score of ≤5. Because the QIDS-SR was most often successfully collected at a time point closer to when a patient exited a level, the QIDS-SR provided more frequent assessment points during the acute phase and may have been a slightly better reflection of actual remission. The group of patients who improved but whose symptoms did not completely remit was defined as those who showed a ≥50% reduction in QIDS-SR score from baseline to the last assessment in the level.

Intervention

A systematic approach to treatment called measurement-based care was used that can be easily implemented in busy primary care or psychiatric settings (14,15). Measurement-based care involves the routine use of symptom and side-effect measurement, with guidance on when and how to modify medication dosages at critical decision points.

STAR*D results

Level 1 outcomes

A total of 2,876 individuals with analyzable data completed level 1 treatment. Measurement-based care was feasible and led to an average citalopram dosage of greater than 40 mg per day, indicating that high-quality care was delivered in these real-world settings. Remission rates were 27% as measured by HAM-D and 33% as measured by QIDS-SR, and response rates were 47% as measured by QIDS-SR. For those whose symptoms remitted, the mean time to remission was approximately 47 days. Factors that increased the chance of remission included being Caucasian, female, and employed and having more years of education and income. Factors associated with lower remission rates were greater chronicity of the current episode, more concurrent psychiatric disorders (especially anxiety disorders or drug abuse), greater degree of general medical comorbidity, and lower levels of functioning and quality of life at baseline.

On average, patients required nearly seven weeks of measurement-based care to achieve remission. Notably, approximately half of the patients who ultimately remitted did so after six weeks, and 40% of those who achieved remission required eight or more weeks to do so (15).

Level 2 outcomes

After consideration of patient preference, 727 patients were randomly assigned to the switch strategy option in level 2. Nearly one-quarter of patients achieved remission when switched to measurement-based care–guided treatment with sertraline (a "within class" SSRI switch), venlafaxine-XR (a serotonin-norepinephrine reuptake inhibitor), or bupropion-SR (a norepinephrine and dopamine reuptake inhibitor) (16). Remission rates for bupropion-SR (21% by HAM-D and 26% by QIDS-SR), sertraline (18% and 27%), and venlafaxine-XR (25% for both) were neither statistically nor clinically different by either measure. Mean daily dosage at the final visit for bupropion-SR was 282.7 mg, for sertraline it was 135.5 mg, and for venlafaxine-XR was it 193.6 mg. Of note, the dosage of venlafaxine was less likely to approach the protocol-recommended maximum than that of either of the other two drugs. The overall side effect burden and the rate of serious adverse events did not differ significantly among the three medications.

Moderators of remission were also studied but offered little help in the selection of antidepressants after an initial treatment failure. Neither clinical symptom patterns (including anxious, atypical, and melancholic features) nor standard demographic measures were of clear value in recommending any particular medication for a second step treatment (17).

Augmentation strategy. After consideration of patient preference, 565 patients were randomly assigned to the augmentation strategy option in level 2. Augmentation of citalopram with bupropion-SR or buspirone led to similar rates of remission as measured by the HAM-D (30% and 30%, respectively) and by the QIDS-SR (39% and 33%, respectively) (18). However, on an alternative outcome measure, bupropion-SR was associated with a greater total reduction in QIDS-SR scores than buspirone (25% compared with 17%, $p<.04$). Mean daily dosages at the end of level 2 were 267.5 mg of bupropion-SR and 40.9 mg of buspirone. Of note, augmentation with bupropion-SR was slightly better tolerated than buspirone (intolerable for 13% compared with 21% for buspirone, $p<.001$). Overall, these results indicate that the choice of either augmentation agent did not produce substantial clinical differences in efficacy.

The data collected did not allow direct comparison of the benefits of switching versus augmenting. Patient preferences were a part of the equipoise randomization strategy, and most patients preferred either augmentation or switching at level 2 (19). Consequently, patient groups were not equivalent at the point of randomization at the beginning of level 2; the augmentation group at level 2 was somewhat less depressed than the group that switched.

Cognitive therapy. Of those for whom cognitive therapy was acceptable, 182 patients were randomly assigned either to the cognitive therapy switch option or to augmentation of citalopram with cognitive therapy. Remission rates did not differ between those who switched to cognitive therapy (31%) and those who switched medications (31% and 27% remission, respectively) nor were there differences in response or time to remission or response (20). Switching to cognitive therapy was better tolerated than switching to a different antidepressant. Augmentation results were also similar. Remission rates did not differ between augmentation

with cognitive therapy and augmentation with medication (31% and 33% remission). Response rates and tolerability were also similar. However, augmentation of citalopram with medication was more rapidly effective than augmentation with cognitive therapy (40 days compared with 55 days, p<.022).

Level 3

Switch strategy. A total of 235 patients switched medications in level 3. For those whose symptoms did not remit after two antidepressant medication trials, the likelihood of recovery did not differ significantly between patients who switched to mirtazapine and those who switched to nortriptyline (21). Remission rates for mirtazapine (mean exit dosage of 42.1 mg per day) were 12% as measured by the HAM-D and 8% by the QIDS-SR. The rates for nortriptyline (mean exit dosage of 96.8 mg per day) were 20% and 12%, respectively. QIDS-SR response rates were also similar (13% for mirtazapine and 17% for nortriptyline). Further, tolerability or side-effect burden did not differ significantly between the two treatments.

Consequently, after two consecutive unsuccessful antidepressant trials, a change in pharmacologic mechanism did not affect the likelihood of remission. Also, switching to a third antidepressant single-agent treatment resulted in lower remission rates than in the first two levels.

Augmentation strategy. Medication augmentation was employed for 142 patients in level 3. Similarly, after two failed antidepressant medication treatments (levels 1 and 2), augmentation with a second agent at level 3 was less effective than augmentation at level 2 (22). Remission rates for lithium augmentation (mean exit dosage of 859.9 mg per day) were 16% as measured by the HAM-D and 13% by the QIDS-SR. For T_3 thyroid hormone augmentation (mean exit dosage of 45.2 micrograms per day) the rates were 25% for both measures. QIDS-SR response rates were 16% for lithium augmentation and 23% for T_3 augmentation. Although these treatment rates did not differ statistically, T_3 was less frequently associated with side effects (p=.045) and with treatment discontinuation because of side effects (23% discontinued compared with 10%, p=.027). When a clinician is considering an augmentation trial, T_3 may have advantages over lithium in effectiveness and tolerability. Further, T_3 offers the advantages of ease of use and no need for blood level monitoring.

Level 4

The switch strategy was employed for 109 patients in level 4. Patients who reached level 4 had failed three aggressive, consecutive, antidepressant trials and had a highly treatment-resistant depressive illness. Remission rates for the combination of mirtazapine (mean dosage of 35.7 mg per day) and venlafaxine-XR (mean dosage of 210.3 mg per day) were 14% as measured by the HAM-D and 16% by the QIDS-SR. For the monoamine oxidase inhibitor tranylcypromine (mean dosage of 36.9 mg per day), rates were 7% by the HAM-D and 14% by the QIDS-SR (23). Response rates as measured by the QIDS-SR were 24% with the combination and 12% with tranylcypromine. Neither remission nor response rates differed significantly between the combination and tranylcypromine. However, the combination was associated with greater symptomatic improvement and less attrition because of side effects. This comparison is limited by the lower likelihood of an adequate dosage and adequate duration of treatment for patients taking tranylcypromine. Overall, even though clinical outcomes were similar for both groups, the lower likelihood of attrition because of side effect burden and the absence of dietary and concomitant drug restrictions suggest that the combination has some advantages.

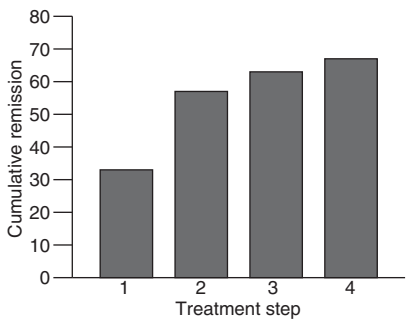
Cumulative remission rate and long-term follow-up

Over the course of the four levels of treatment, the theoretical cumulative remission rate was 67% (see Figure 2). Remission was more likely to occur during the first two treatment levels (20%–30%) than during levels 3 and 4 (10%–20%).

Patients with a clinically meaningful response, preferably remission, in any of the four levels could enter into a 12-month naturalistic follow-up phase. Those who had required more treatment levels had higher relapse rates during this phase (24). Also, patients in remission at any level had a better prognosis than those who merely responded, which again provides support for using remission as the preferred aim of treatment.

Figure 2

Cumulative remission rate by STAR*D treatment level



STAR*D limitations

Although the selection of certain study design elements successfully addressed some primary concerns, such as generalizability and feasibility in real-world practice, the selection came with some clear tradeoffs. First, because patient preference was built into the randomization strategy and patients clearly demonstrated distinct preferences (with the vast majority electing either the switch or augmentation strategies), differences in depressive severity at entrance to the next level and small samples precluded direct comparison of switching and augmenting strategies. Indeed, those who switched to a new medication had more severe illness than those who received augmentation or cognitive therapy.

Thus, if a patient did not achieve remission after treatment in levels 1 and 2, we do not know whether switching medications or augmenting with a second medication led to a better outcome. Similarly, even if a patient had a partial response, STAR*D could not evaluate whether augmentation would have led to a better outcome than switching.

Second, fewer patients than expected selected cognitive therapy, which prevented a more comprehensive assessment of its role. The lower rate of selection of cognitive therapy was likely attributable to the requirement that study participants accept medication (citalopram) as the initial treatment (level 1 entry), which may have biased selection toward individuals who preferred medication. Other likely factors were additional copayments for cognitive therapy or the need to visit an additional provider at another site.

Third, level 1 did not include either a placebo or usual-care control group, which may limit conclusions about remission rates for an initial antidepressant trial. For example, the remission rates approximate what might be expected in eight-week placebo-controlled clinical trials, although such standard efficacy trials do not enroll the diverse population that STAR*D did, which may suggest higher placebo response rates in the traditional trials. However, inclusion of a placebo arm is likely to lead to inclusion of a sample that can limit generalizability of findings, and the aim of STAR*D was not to determine whether treatment is more effective than placebo but rather to show how effective it can be in a representative, community population.

Fourth, the study did not require dosage changes; instead, it used measurement-based care to guide treatment, which reflects use of guidelines in real-world practice. As a result, the trials of STAR*D medications may have been at a lower-than-recommended dosages, as may have happened for some patients who received venlafaxine-XR and tranylcypromine. A difference in the likelihood of having an antidepressant trial at a therapeutic dosage limits the direct comparison of effectiveness of the medications. For example, comparison of venlafaxine at a low-to-moderate dosage and sertraline at a dosage closer to the therapeutic level might unfairly favor a sertraline outcome.

Fifth, the results provide data on the average proportion of patients who are likely to respond to a particular medication or treatment strategy. However, the results do not tell us which patients will respond to which treatments.

Further limitations unrelated to the STAR*D design also can restrict its applicability to current treatments. Since the study was designed approximately a decade ago, not all currently available and employed treatment options were examined. For example, augmentation strategies did not include second-generation antipsychotics, mood stabilizers, or psychostimulants.

Implications of STAR*D findings

STAR*D has key features that define it as an effectiveness trial (25). Design elements such as broadly inclusive selection criteria and enrollment of patients from primary and specialty settings and with multiple concurrent medical and psychiatric illnesses give STAR*D results high external validity. Comparison of STAR*D participants with the U.S. population highlights the generalizability. The racial-ethnic composition of the enrolled participants approximates that of the U.S. population on the basis of data from the 2000 Census, and the distribution of depressive severity seen in STAR*D participants is consistent with the spectrum reported by Kessler and colleagues (1) in a nationally representative sample (10% mild, 38% moderate, 39% severe, and 13% very severe). Both facts suggest that the sample was representative of depressed patients in the United States. Further, the participants' ability to choose which clinic to attend and what treatments were acceptable alternatives mirrors what happens in routine clinical practice, which also enhances the generalizability of these results.

Clinical implications

The primary implications of the STAR*D findings are summarized below.

♦ Remission rates in these representative clinics, in general, were lower than expected on the basis of clinical efficacy trials of antidepressants, which typically report remission rates of 35% to 40% (9), suggesting the need for several steps to achieve remission for most patients.

♦ There is no clear medication "winner" for patients whose depression does not remit after one or more aggressive medication trials.

♦ Both switching and augmenting are reasonable options for patients after an initial antidepressant treatment has failed.

♦ It may take longer to reach remission than expected, and thus medication trials of at least eight weeks with at least moderately aggressive dosing may be necessary.

♦ Cognitive therapy is a well-tolerated treatment option for patients when an antidepressant treatment fails, and the outcomes patients achieve appear equivalent to those they would have achieved with the trial of a new medication. At the same time, it should be noted that augmentation of citalopram with medication was more rapidly effective than augmentation with cognitive therapy.

♦ Pharmacologic differences between psychotropic medications do not translate into meaningful clinical differences, although tolerability differs.

♦ Neither standard sociodemographic measures nor the symptom patterns that were measured in STAR*D (including anxious, atypical, and melancholic features) predicted a differential benefit from the available switch options at level 2, suggesting that the common practice of selecting treatments based on symptom patterns has little empirical support (17).

♦ The likelihood of remission after two vigorous medication trials substantially decreases, and remission likely requires more complicated medication regimens for which the existing evidence base is quite thin. Thus an empirically supported definition for treatment-resistant depression seems to be two antidepressant failures.

♦ No statistically significant difference in outcome was found between patients treated in primary care and psychiatric settings when measurement-based care was used in level 1 (26) or level 2 (17). Thus primary care physicians, who manage the majority of depressed patients, can be reasonable providers of depression care for at least the first two treatment steps.

♦ The finding that about two-thirds of patients may be expected to reach remission with up to four treatment

attempts is encouraging for this disabling illness. Continued treatment attempts, even beyond a second treatment failure, do yield results for some patients.

♦ Longer-term outcomes supported remission as the preferred goal of treatment. During the naturalistic follow-up phase, lower relapse rates were found among participants who entered follow-up in remission than for those who were not (27).

♦ An important predictor of relapse was greater axis I or III comorbidity. The greater the number of acute treatment steps required from before entry to follow-up (that is, the greater the degree of treatment resistance), the greater the risk of relapse (27).

Policy implications

STAR*D policy implications are summarized below.

♦ Inclusion of more real-world patients in clinical trials is both feasible and informative. For example, of the group of participants enrolled as a result of the broadly inclusive selection criteria used by STAR*D, only one-fourth would have been enrolled in a standard phase III clinical trial. Results of STAR*'D suggest that broader phase III inclusion criteria would increase generalizability of results to real-world practice, which might reduce placebo response and remission rates (reducing the risk of failed trials) but with some increased risk of adverse events (6).

♦ The choice of medications for formularies must be carefully considered. Because there was no antidepressant "winner" and the chance of remission did not clearly differ by medication choice, some may argue that formularies can be restricted because of antidepressant equivalence. However, some findings would argue for a broader formulary. For example, antidepressant medications differed in the likelihood of particular side effects, and at this time tolerance cannot be readily predicted. Further, given the multiple treatment steps needed for most participants, availability of a large armamentarium of treatments seems prudent, especially given our inability to predict who will respond to what medication. Finally, given the similar likelihood of response to treatments at level 1 and 2 (some of which have generic formulations) and the inability to predict who will respond better to a particular treatment, available generic antidepressants seem reasonable choices for these first two medication trials.

♦ Measurement-based care—that is, using brief, easy-to-administer instruments to monitor depression severity and side effects, following an evidence-based treatment algorithm, making decisions at key time points, and having remission as a goal of treatment—is a feasible strategy that can be adapted in real-world practice settings—both psychiatric and primary care settings (14,15).

♦ Referral guidelines can incorporate the findings that most patients with depressive illness can be adequately treated in primary care for at least two antidepressant trials when measurement-based care is used, thereby reducing the rate of premature referral to psychiatric clinics.

♦ The large number of patients with either recurrent major depressive disorder or with chronic major depressive episodes (>75% in this study), the fact that only about half the patients reached remission after two treatments, and the poor long-term outcomes for patients when two or more acute treatments failed all suggest the need for more evidence to guide the effective treatment of treatment-resistant depression.

Conclusions

STAR*D was a seminal, large-scale, practical clinical trial that provided a great deal of data for clinicians, researchers, and policy makers. The findings are still being actively discussed, analyzed, and disseminated, and the acute-treatment data set is now available in the public domain to allow further analysis. The research infrastructure, which continues as the Depression Trials Network (www.DTN.com), has completed enrollment for two separate clinical trials whose design was guided, in part, by the findings of STAR*D.

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Senate Health & Human Services
02/16/2023 01:30 PM
SB23-091 Access To Behavioral Health Services
Typed Text of Testimony Submitted

Name, Position, Representing	Typed Text of Testimony
Andrew Rose For COMBINE	COMBINE represents Medicaid mental health care providers who are contracted with the RAEs. We support this reduction in the 'medical necessity' requirement, which will no longer be "meets criteria for a diagnosis" and will become "is under 21 years old." This is helpful. While we're not sure how many people will realize the lower threshold for access, this may add some pressure on child therapists who are currently loaded and have wait lists. So overall we'd like Assembly support for the Medicaid workforce, as we don't currently have enough children specialists. We know the Assembly supports providers generally, and desires more child specialists, so here are some specifics that will increase Medicaid participation: Network Adequacy is a challenge with definitions in several places (CO Option, Title 10, RAE contracts). We need a summer committee to develop real network adequacy standards. Commercial payers cannot charge fees on our payments, but Medicaid was left out of HB1116. We seek a fix. Family/couple rates to equal or exceed individual rates. The state can do this with minimum rates. 3 years in on this. Couple therapy is crucial for securely attached kiddos, which reduces 'psychopathy' in society. HCPF to move along on minimum rate setting, not take five years. HCPF has admitted they have the power to set minimum rates. REAs to deliver provider support, not have people in Asia answering our calls and passing us around. We want RAE reporting about provider support (number of calls, was the issue responded to, was the provider satisfied with the response) and we want regulation on provider support (minimum number of provider supporters, Colorado based workers, etc). Are RAEs giving Colorado what Colorado is paying them to give? There needs to be a bill that mandates RAE output reporting. How many sessions? Center care? IPN care? B3 services?

	BHA to expand provider directories to include outpatient care and we need availability information in that database. In regards, Andrew Rose Chair, Legislative Committee, COMBINE Director, Boulder Emotional Wellness