Making Friends with Yourself: A Depression Prevention Program for Adolescents

NCT number NCT03270943
Document Date 03/01/2021

STUDY PROTOCOL

Making Friends With Yourself: A Depression Prevention Program For Adolescents

Short Name**: The **S.M.A.R.T.** Project**: Stress Management and Resilience Training for Teens

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STUDY PROTOCOL

Making Friends with Yourself: A Depression Prevention Program for Adolescents

Short Name: The S.M.A.R.T. Project: Stress Management and Resilience Training for Teens

A trial designed to refine and feasibility-test a mindfulness-based self-compassion intervention and an attention-control intervention with 80 adolescents with subsyndromal depression.

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Supported by:

The National Center of Complementary and Integrative Health

Grant Number: 1 R34 AT008822-01A1

Study Intervention Provided by:

Not applicable

Sponsor of IND (IDE):

Not applicable

TOOL REVISION HISTORY

Version 1.1

Version Date: 1 March 2021
Summary of Revisions Made:

- The PROMIS Pediatric Depression Scale was used as the measure in the time-to-event analysis because it was collected weekly rather than only 5 times at irregular intervals like the SMFQ.
- Christine Lathren added as a Research Associate to supervise the Project Manager.

Version 1.0

Version Date: 3 January 2020
Summary of Revisions Made:

- Section __: Inclusion/Exclusion
    a. Removed lower limit for QIDS due to QIDS, DISC-IV, clinical assessment, SMFQ, and PROMIS not all measuring the same levels of depression.
- The team decided not to hold an orientation session, so as to reduce burden on the parents and adolescent participants. The content of the control group curricula was updated. Study Pages site was added. The name of the study was changed to ensure that participants are blinded to what the investigators consider the active intervention. The two programs will be described as two different programs to reduce stress and enhance well-being in high school students. Updated consents and measures are added.
- Changes to the Safety Plan necessitated an update to the protocol. Chloe Brown is added as a research assistant.

Version 0.1

Version Date: 1 July 2015
Summary of Revisions Made:

- Initial master protocol

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PRÉCIS

Study Title

Making Friends with Yourself: A Depression Prevention Program for Adolescents (aka The S.M.A.R.T. Project: Stress Management and Resilience Training for Teens)

Objectives

The primary objective of this research project is to refine, manualize, and test the feasibility of the a mindfulness-based self-compassion program and an attention control program focused on developing healthy behaviors known to reduce depressive symptoms (e.g., exercise, healthy food choices, sleep hygiene, relationship skills) for 14-17 year-old adolescents with subsyndromal depression. Refinement of procedure manuals for adolescent participants and instructors will ensure that future interventions are delivered in a consistent and reproducible fashion.

A secondary objective is to test the feasibility of randomizing participants to the two educational programs. Results will guide the development of an adequately powered clinical trial in terms of recruitment needs and logistics; subjects' acceptance of the treatment and control programs; equivalence of the credibility of the two programs; and subjects' willingness to complete assessment instruments, adhere to study protocols, and complete the study.

Another secondary objective is to explore primary and secondary outcomes and mediators in response to the mindfulness-based program, including incident depression (primary outcome), change in depressive symptoms and resilience (secondary outcomes) and rumination, negative cognitive style, and shame (potential mediators).

Design and Outcomes

Four cohorts of adolescents, each with 20 participants, will be recruited. In each cohort, twenty individuals will be randomized with 10 each in the mindful self-compassion group (Making Friends with Yourself) and the healthy behavior skills group. In addition, each adolescent will be accompanied by a parent (n=80). Adolescents complete brief weekly questionnaires to assess depressive symptoms as well as a longer set of online questionnaires at baseline, weeks 4 and 8 of the intervention, and 3 and 36 weeks post-intervention. Parents complete a questionnaire at baseline, 3 and 36 weeks post-intervention.

Interventions and Duration

Both education intervention groups meet once a week for 1 hour and 45 minutes for 8 weeks. After completion of the program, there will be monthly sessions in the continuation phase (90 minutes per session) for 36 weeks.

Sample Size and Population

The sample will include 80 adolescent high school students with subsyndromal depression, defined as having symptoms of major depression that are not of sufficient severity to meet diagnostic criteria of major depression disorder (MDD).

1. STUDY OBJECTIVES

1.1: Primary Objective

The primary goal of this research project is to refine and test the feasibility of the "Making Friends with Yourself" program, as well as a credible attention control program, involving education and discussion on healthy behaviors, for 14-17 year-old adolescents with subsyndromal depression and to compare the feasibility of the two interventions[1].

The proposed study will randomize high school aged adolescents (aged 14-17, participants may turn 18 after enrollment) with subsyndromal depression to an eight-week program of the proposed prevention program, entitled "Making Friends with Yourself" (MFY), or an attention-control group that focuses on healthy behaviors.

Specific Aim 1

Refine and manualize the mindful self-compassion program, "Making Friends with Yourself" (MFY), and a credible attention control program among adolescents. Refinement of procedure manuals for adolescent participants and instructors will ensure that future interventions are delivered in a consistent and reproducible fashion.

Purpose 1

Refinement of procedure manuals for adolescent participants and instructors will ensure that future interventions are delivered in a consistent and reproducible fashion.

Our group has developed the MFY program as a developmentally-appropriate adaptation of Neff and Germer's Mindful Self-compassion program. The MFY program has been piloted with healthy adolescents and showed promise as an intervention for reducing depressive symptoms. Further adaptation will target an adolescent population with subsyndromal depression.

1.2: Secondary Objectives

Specific Aim 2

To test the feasibility of an exploratory clinical trial involving a mindful self-compassion intervention, the MFY program (treatment group), and a comparison attention-control among 14-17 year old adolescents (participants may turn 18 after enrollment) with subsyndomal depression. Study results will guide the development of an adequately powered clinical trial in terms of recruitment needs and logistics, equivalence of credibility of the two programs, and participants' willingness to complete assessment instruments, adhere to study protocols, and complete the study.

Purpose 2

Study results will guide the development of an adequately powered clinical trial in terms of recruitment needs and logistics; subjects' acceptance of the treatment and control programs;

equivalence of credibility of the two programs; and subjects' willingness to complete assessment instruments, adhere to study protocols, and complete the study.

Specific Aim 3

With feasibility being tested in Aim 2, we will explore primary and secondary outcomes and mediators in response to the MFY program in Aim 3, including time to incident depression by the time of the 36-week follow-up (i.e., MDD-major depressive disorder) (primary outcome); resilience, change in depressive symptoms (secondary outcomes); and rumination, negative cognitive style, and shame (potential mediators).

Purpose 3

This study intends to analyze, in an exploratory fashion, the following: incident depression (primary outcome); change in depressive symptoms and resilience (secondary outcomes); and rumination, negative cognitive style, and shame (potential mediators).

Measures are collected at baseline, halfway through the 8-week course, after completion of each 8-week program, at 22 weeks post-program, and at 36 weeks post-program. Analyses are conducted to inform the planning of an adequately powered randomized controlled trial.

2. BACKGROUND AND RATIONALE

2.1: Background on Condition, Primary Study Focus

The rate of depression increases markedly over the course of adolescence[3]. Currently 20-25% of adolescents experience a depressive episode before they graduate high school. In 2012 alone, 14% of girls and 5% of boys age 12-17 experienced a major depressive disorder, with only a third of those seeking treatment[28]. Due to the number of adolescents untreated for symptoms, and the ability of these symptoms to interfere with developmental processes[2] and lead to other clinical disorders[29], depression in adolescence increases the risk for maladaptive behaviors[5,6]. Since depression often first appears in adolescence and unsuccessful treatment of adolescent depression increases the risk of chronic or recurrent depression in adulthood, managing depression symptoms at this critical stage of development can benefit mental health and functioning throughout the lifespan[9].

2.2: Study Rationale

The Impact of Depression in Adolescence

Adolescents struggling with depression are often set on a maladaptive behavior trajectory which may lead to academic challenges, substance abuse, risky sexual behavior, impairment in relationship building, and suicidality[30-34]. They are also more likely to experience negative somatic health outcomes such as migraine headaches[35] and obesity[36]. Depressive symptoms are associated with sleep disturbances (e.g. insomnia and hypersomnia), exacerbating the negative impacts on health and social domains[37]. These difficulties often persist into adulthood[34,38,39]. Adolescent depression was shown to predict poorer health, higher health-care utilization, low levels of social support, and increased work impairment due to physical health over the subsequent decade[35,40]. Adolescent depression may also result in an altered educational trajectory (i.e., dropping out of high school, change of type of post-secondary school) [41]. Those who experienced even subsyndromal depression, defined as evidencing

symptoms of major depression, but not of the severity to meet a diagnosis of major depression[42], have a higher risk of developing major depressive disorder (MDD) as adolescents [43]and are two to three times more likely to experience depression as adults[39,44,45]; depression in adults has been associated with lower lifetime income and socioeconomic status, welfare dependency, and fewer occupation options[33,46-48].

Changes in Adolescence and the Onset of Depression

During adolescence, individuals undergo rapid physiological growth[49-51] including changes in both structure and function of the brain[52]. Coupled with these physiological changes are new cognitive abilities including the capacity for metacognition and the ability to think abstractly, which promote adolescents' increasingly complex and sophisticated ways of relating to their world[53]. Taken together, such changes often have dramatic effects on the ways in which adolescents perceive, understand, and interpret their daily experiences, particularly those that occur in social and emotional domains. Identity exploration, characteristic of this stage of development[54], may lead adolescents to self-reflect and to consider their relationship with others and their role in society. As they compare themselves with their peers, adolescents often engage in self-doubt and self-criticism[55], which may contribute to a negative self-image and self-consciousness[56,57]. Additionally, due to these physical and cognitive changes, reflected in peer evaluation and greater awareness of gender roles, adolescents often experience increased shame[58], as well as increased stress and poor coping skills.

Theoretical Explanations for Depression and Mechanisms of Change

Theoretical underpinnings of depression in adolescence explain that cognitive vulnerability, and specifically **negative cognitive style**, predicts depression through an interaction with stressful events. According to hopelessness theory[59], individuals with negative attribution styles perceive stressful events as due to persistent and immutable causes, as having further stressful consequences, and as being precipitated by their own lack of worthiness. Therefore, when an individual with a negative cognitive style experiences a painful or challenging event, he s/he tends to hold him/herself responsible for the cause, assumes that this negative experience will recur repeatedly, and that this same experience will generalize to multiple situations[60]. Numerous studies provide evidence that negative cognitive style predicts depression in adolescents[61-63]. Personality types prone to self-criticism or in need of others' approval are also predisposed to depression[64]. Additionally, self-critics have less of an ability to self-soothe in times of stress[65], and this inability has been linked to depression[66-69]. In addition, **shame** has been linked to depressive symptoms in various adolescent populations[58,70-75]. At times emerging from repeated self-criticism, shame is defined as a global negative evaluation of the self, resulting in a sense of a shrinking,

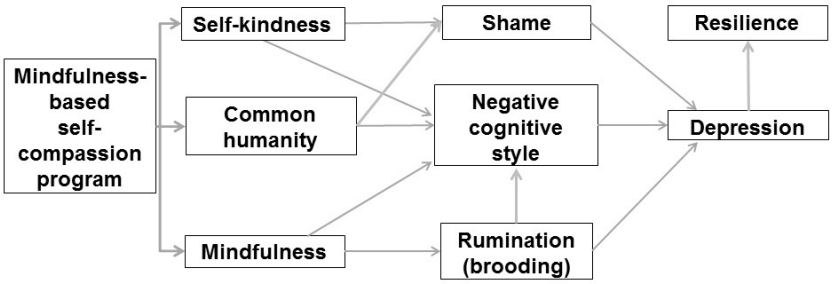


Figure 1. Components of a Mindfulness-Based Self-Compassion Program and Relationships with Depression

small, powerless and worthless self[75], and a concern that the self will be exposed as defective[76]. Shame is experienced as stable and unremitting over time, and shame-prone individuals often exhibit a negative cognitive style[70,77-79].

Rumination, a method of coping with negative mood, has been described as having two components: reflection and brooding. Brooding is characterized by repetitive focus on negative emotions and has been linked to depressive symptoms[80]. In addition, rumination, in general, has consistently predicted increases in depressive symptoms in children and adolescents[81-84]. Finally, **resilience,** or the ability to bounce back from stress[85], has been negatively associated with depression in numerous studies[85,86] and can serve as a protective factor from depression[87].

Behavioral Programs for Depression Prevention in Adolescents

Several depression-prevention programs have been developed for youth. These have included cognitive behavioral therapy (CBT)[88-98], psycho-educational interventions[99-101], problem solving[102,103], and behavioral skills training interventions (e.g., interpersonal relationship building and social skills)[94,99,104-106]. A meta-analysis of depression-prevention programs for youth reported that only 41% of the programs included in the study had significant reductions in depressive symptoms post intervention and the effect sizes were small (r = .15 pre to post; r = .11 pre to follow-up)[9]. Additionally, many of the trials had either waitlist or assessment-only control conditions, which are likely to overestimate effect sizes (e.g., one study that compared a CBT treatment group with four active control groups and a waitlist control found that all active controls and CBT outperformed the waitlist control[107]). Furthermore, only 4 of 47 trials produced significant reductions in future depression onset[9].

The lessons learned from these depression-prevention programs have implications for future program design. For example, the most effective programs utilized professional interventionists (rather than classroom teachers), assigned homework, and were relatively short in length[9]. Also, the developmental appropriateness of CBT for adolescents has been questioned, as these youth may not be able to fully grasp the concepts foundational to CBT. Third-wave therapies such as Acceptance and Commitment Therapy and Dialectical Behavior Therapy, although popular in clinical practice, have few well-controlled clinical trials[108]. Based on the mixed success of well-studied behavioral interventions, there is a need to investigate new approaches to depression prevention that are tailored to the developmental needs of the adolescent population.

Mindfulness-based Self-Compassion: An Antidote for Depression?

One promising approach is mindfulness-based self-compassion training. Mindfulness has been defined as paying attention to the present moment with nonjudgmental awareness[109]. It includes recognition of thoughts or emotions that are in one's momentary experience and subsequently "letting go" of those emotions or thoughts, acknowledging that they are transitory[110]. Mindfulness-training interventions, most notably Mindfulness-Based Stress Reduction (MBSR)[25],teaches skills that increase one's ability to be more mindful in everyday life. In adults, these studies are conclusively shown to lower depression[111-116] and in one meta-analysis, a robust effect size was reported for mindfulness interventions on improving mood in individuals with diagnosed depression (Hedges g = .95)[117].

Although mindfulness research with adolescents is nascent, studies show that greater mindfulness is indicative of improved psychological wellbeing. A recent meta-analysis on mindfulness interventions with youth reported a moderate effect size (Cohen's d=.37) for psychological symptoms, and a large

effect size for studies that used a clinical sample (Cohen's *d*=.50)[118]. Specifically, post-intervention, depression was shown to decrease in a clinical sample[17] and rumination decreased in 4th and 5th grade public school students[119]. Mindfulness was correlated negatively with perceived stress in one study[15], and mindfulness training resulted in decreased stress in clinic-referred adolescents in another study[17]. Other studies found significantly improved overall wellbeing[120] and decreased depressive symptoms[121].

Both mindfulness and self-compassion independently contribute to improvements in psychological health[122]. Self-compassion, as defined by Neff[26], is described as being open and present to one's own suffering, to actively heal oneself with kindness, and to understand that one's suffering is inherent in the human experience and as such is shared among others. Neff defines three components of self-compassion: mindfulness, or maintaining perspective amidst challenging circumstances; common humanity, or recognizing that one is integrally connected to a network of imperfect human beings, and self-kindness, or treating oneself with tenderness when one is suffering[26]. Greater self-compassion is associated with lower depression, anxiety, and stress in both adults[13,123-133] and adolescents[22-24] and self-compassion is lower in high school females than both high school males and middle school females[24]. Self-compassion has also been shown to predict lower depression symptomology over a 5-month interval[13], supporting the theory that "self-compassion represents a potentially important protective factor for emotional problems such as depression." (p. 33).

Neff and Germer developed the Mindful Self-compassion program (MSC) for both clinical and non-clinical applications[14]. MSC meets weekly for 8 weeks, and involves didactic instruction as well as practice of self-compassion exercises. A clinical trial of this program has demonstrated significant decreases in anxiety, depression (large effect size compared to wait-list control), and stress that were maintained at both 6 and 12 month follow-up[14]. A similar program, developed for patients with mood disorders, resulted in marked decreases in depression[134]. At UNC, in collaboration with our colleagues at University of California-San Diego (UCSD), we have developed a mindfulness-based self-compassion program for adolescents and tested it in a non-clinical, teen population.

Development of a Mindfulness-based Self-Compassion Program for Adolescents with Subsyndromal Depression: "Making Friends with Yourself"

This R-34 proposes to refine and test the feasibility of a mindfulness-based self-compassion training program for adolescents who are experiencing subsyndromal depression, comparing it with a "healthy lifestyles" group program, which is based on a program developed by our group as a control condition for mindfulness studies with adolescents, and which will be adapted in length and content as a comparison attention-control for the treatment intervention. Our mindfulness-based self-compassion program, "Making Friends with Yourself", adapts the MSC format and contains elements of it. It is guided by the three components of self-compassion[26]: self-kindness, common humanity, and mindfulness. It differs from the adult program in that classes will be shorter, developmentally appropriate (e.g., more activity-based such as games and role-plays), includes a component about the adolescent brain, a mindful movement segment halfway through each class, and shorter meditations. Treating oneself kindly and experiencing oneself as part of a common humanity is posited to shift negative cognitive style so that inferences related to self are less negative. Developing these qualities is also hypothesized to decrease shame. Keeping perspective in the midst of difficult moments (mindfulness) is posited to also shift negative cognitive style, as well as decrease brooding (negative rumination). Further, both shame and rumination are known to correlate with negative cognitive

style[70,77-79,135-137]. These changes in negative cognitive style, shame, and brooding are hypothesized to decrease depression and increase resilience.

Rationale for use of an active comparison group as an attention control

This healthy behaviors control group, identical to the mindful self-compassion group in form and structure, was first piloted in an adolescent mindfulness study by this group and was found to be both credible and acceptable among participants (see preliminary studies). It has been tested as a 6-session course with community adolescents, and results from the Borkovec and Nau credibility scale[138] indicated no difference in adolescents' perceived credibility between the control and intervention programs. We are now proposing to expand it to eight sessions and test it with a different population, specifically adolescents with subsyndromal depression. For this project, with our clinician coinvestigators, we will expand and refine this program, in order to develop a suitable control condition for a future RCT. The program is similar to lifestyle group programs offered to at-risk adolescents by Co-I April Harris-Britt, PhD.

Preliminary Studies

In the past two years, our group has investigated outcomes associated with mindfulness training for adolescents and has developed and piloted a prototype of a mindfulness-based self-compassion program for adolescents. In the first study, one aim was to determine how a self-report measure of self-compassion correlated with self-reported emotional wellbeing and impacted response to a lab social stressor. Male and female adolescents (n=28) ages 13 to 18 were randomized to a six-week mindfulness program adapted for teens entitled "Learning to Breathe" or an attention-control intervention, "Healthy Lifestyles", which involved education and discussion about ways in which they might make more healthy choices in relation to behavior (e.g. nutrition, sleep, exercise). Participants completed a teen-adapted Trier Social Stress Test (TSST) in a lab setting, with physiological stress assessed via salivary cortisol, heart rate, blood pressure, and heart rate variability at baseline, during the TSST, and during recovery along with measures of perceived stress, life satisfaction, positive and negative affect. We analyzed the TSST for induction of a significant stress response, and assessed meaningful differences (Hedges' g > .20) between the groups. Those in the high self-compassion group (equal to or above the median) self-reported greater emotional wellbeing across all measures than those in the low self-compassion group (below the median) (Table 1).

Table 1. Results for mean differences of low and high self-compassion on indicators of wellbeing

	Mean (SD)		
	LSC (*n* = 12)	HSC (*n* = 16)	Hedge's *g* (95% CI)
Anxiety	36.50 (8.25)	31.75 (6.38)	0.64 [-0.11, 1.38]
Perceived Stress	32.08 (5.66)	27.50 (7.76)	0.64 [0.11, 1.39]
Negative Affect	24.50 (7.72)	20.62 (6.67)	0.53 [0.21, 1.27]
Positive Affect	29.67 (6.02)	31.19 (8.19)	-0.20 [-0.91, 0.53]
Life Satisfaction	2.33 (0.38)	2.72 (0.65)	-1.18 [-0.93, 0.53]

Note. **CI = Confidence interval; LSC = Low Self-Compassion; HSC = High Self-Compassion * $p < 0.1$**

In addition, those in the high self-compassion group had a lower physiologic stress response when exposed to the TSST than those in the low self-compassion group. Figure 2 depicts differences between high and low self-compassion groups in change in systolic blood pressure in response to the TSST.

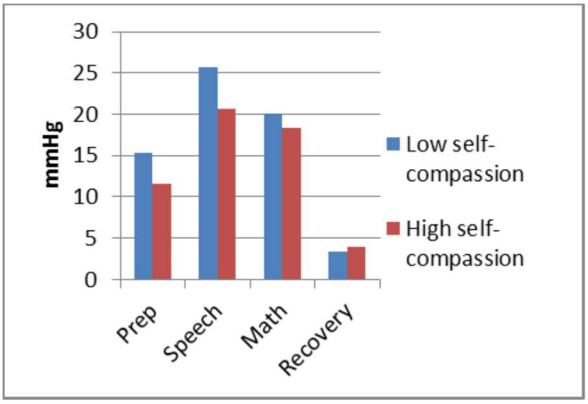


Figure 2. Change in Systolic Blood Pressure during Trier Tasks

In our second study**,** we developed and pilot-tested a prototype of Making Friends with Yourself, adapted from the Neff & Germer Mindful Self-Compassion program for adults. We used a mixed-methods wait-list control in which participants completed online measures of mindfulness, self-compassion, and dimensions of emotional wellbeing measures before and after the course. Most notably, we found a 25% decrease in depressive symptoms in the intervention group, in addition to statistically significant changes in all measures except life satisfaction, social connectedness, and positive affect. In the waitlist control condition, no significant pre-post differences were present in any of the measures (Figure 3). Together, changes in mindfulness and self-compassion significantly predicted changes in depression, perceived stress, anxiety, and life satisfaction post-intervention ($p<.05$).

Interestingly, at baseline, the link between stress and depression was stronger in those with low self-compassion compared to those with high self-compassion ($\beta = -.31$, $p = .02$), indicating that these low self-compassionate adolescents may more easily become depressed when faced with stress. This finding, linked with findings from the first study, indicate that adolescents with low self-compassion are likely to be more easily stressed and therefore more easily depressed.

Impact

Depression among adolescents is a prevalent and growing public health problem, the consequences of which have significant, long-term negative impacts for the individual, their families, and society. This innovative project, in a high-priority NCCIH area, will test the feasibility of a promising, novel, depression-prevention program adapted from a

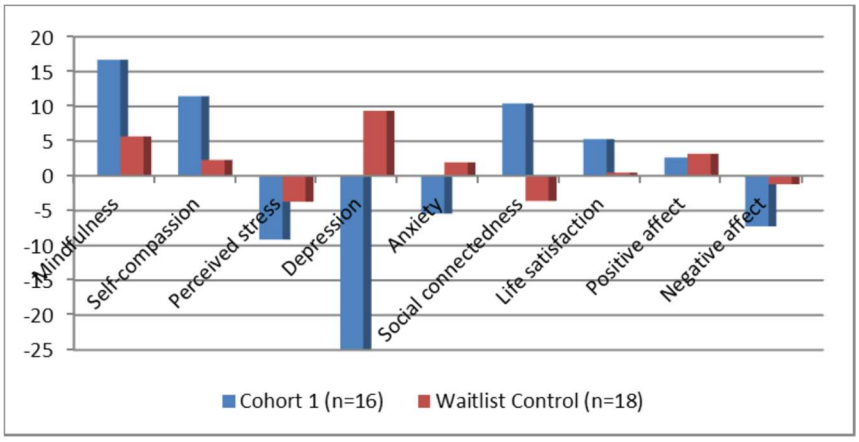


Figure 3. Change in Measures of Mindfulness, Self-compassion, and Dimensions of Emotional Wellbeing Measures

successful adult Mindful Self-Compassion program. "Making Friends with Yourself" (MFY) will be refined and manualized, as well as feasibility-tested in an exploratory clinical trial, in adolescents who experience subsyndromal depression. It will also refine and test the comparative feasibility of an attention-control condition, piloted by our team in a mindfulness intervention for adolescents, to be adapted as a control intervention for this study. The measures selected for feasibility testing are theoretically meaningful and likely able to elucidate mechanisms by which either program impacts depressive symptoms. This information can be used to plan a future randomized trial. Reinforcing the potential impact is the collective extensive experience of the investigative team, including their experience with this population and in designing, implementing, and evaluating similar studies, as well as the supportive research environment of the University of North Carolina at Chapel Hill. If this manualized program proves acceptable, feasible and efficacious, there is great potential for its use in schools and other adolescent settings, thus amplifying its potential impact on reducing depression by enhancing the lives of adolescents and those who care for them.

3. STUDY DESIGN

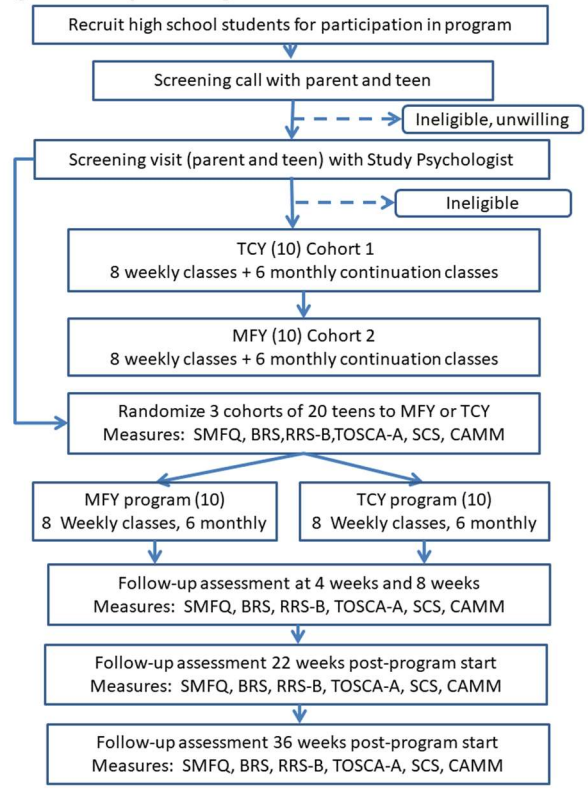
In this study, we will refine and feasibility-test our mindful self-compassion program and an attention control program with a focus on adolescents who are experiencing subsyndromal depression. Subsyndromal to mild depression is defined as a score of at least 6 and 10 on the Quick Inventory of Depressive Symptoms (QIDS). The intervention program, called "Making Friends with Yourself" (MFY), implements mindfulness and self-compassion training. The control condition is a healthy lifestyle program for high-school aged adolescents. The control condition was developed by our team as an attention control group for our pilot adolescent mindfulness program and will be adapted for comparison with the MFY intervention. The 8-week programs will be piloted with a total of 80 adolescents. After completion of the 8-week program, the teens will participate in a post-group meeting to give feedback about program contents. Feedback will take place in the form of a focus group. Following the 8-week program, adolescents will be invited to participate in 6 monthly continuation sessions, designed to strengthen understanding of the topics presented in the 8-week course. Measures of depression, resilience, brooding, shame, mindfulness, and self-compassion will be obtained before the 8-week program, halfway through the program, after the 8-week program (intervention phase), and 3 and 36 weeks after program completion (continuation phase). Feedback from program participants will inform modifications and refinement of both programs.

Our primary goal is to examine the feasibility of implementing the program. After feasibility, the primary outcome to be explored will be the occurrence of incident major depressive disorder (MDD) with a secondary outcome to be explored being the trajectory of depressive symptoms over time (measured at baseline, program end and at 3 and 36 weeks post program) using the Short Mood and Feelings Questionnaire (SMFQ) administered to both the adolescent and a parent. Studies indicate high predictive validity in adolescent self-report of depression[139,140]. The study psychologist will contact parents of teens with incident major depression, captured by the SMFQ at any of the scheduled time-points during the study, for referral to appropriate mental health care.

Randomization will be stratified by gender. As soon as 20 eligible adolescents qualify for enrollment, they will be allocated to either the MFY or healthy lifestyle groups, using a specially-designed computer program which utilizes a random number generator with a permuted block design to ensure that the

number of subjects allocated to the two arms over time are equal and to conceal the allocation. This will continue through 4 cohorts of adolescents (n=80). During participation, adolescents will keep a daily online diary, accessible from a cell phone, to document homework practice. Their engagement in the program will be captured by audiotaping program sessions. After each program's completion, adolescents will participate in a focus group to give feedback about program contents. The adolescents will be invited to participate in 6 monthly continuation sessions, designed to strengthen understanding of the topics presented in the 8-week course. After the first two cohorts, a post-participation interview and questionnaire will capture additional feedback about the program.

Figure 4. Study Flow Diagram



The research assistant will transcribe audio-taped data from sessions and focus groups. The team will combine this data with feedback provided in diaries, interviews, and post-participation questionnaires. This will be analyzed using qualitative methods to inform revision of specific program components and the revision of detailed program manuals for future programs.

3.1: Recruitment, screening and consent

Recruitment

We will recruit adolescents who are experiencing subsyndromal depression in three ways:

1) Discussions with local guidance counselors and school personnel;
2) University-wide emails to the University community; and
3) Flyers posted in local high schools/community boards (a successful strategy in our preliminary studies).

Members of our study team have established relationships with personnel in several of the local school systems. This has been successful in meeting targeted recruitment numbers in previous research studies.

Screening

If an adolescent or parent is interested in the study, they can begin the screening process through the following ways:

1) **Phone:** interested participants can initially contact the study team by calling the contact number directly;
2) **Email**: interested participants can initially contact the study team through the study's email (smartstudy@med.unc.edu);

3) **Study Website**: parents of interested participants can initially contact the study team through the study website (http://smartstudy.web.unc.edu/parent-survey/);

The study team will explain the study to interested parents and, with permission, arrange for the adolescent to complete the online screening, which includes the Quick Inventory for Depressive Symptomology (QIDS). Adolescents who meet pre-screen eligibility criteria (see Section 4. Selection and Enrollment of Participants) and their parent will then meet with a study team member to review study procedures in detail and provide informed consent and assent (see Section 4.3: Study Enrollment Procedures and Section 6.2: Description of Evaluations). Potentially eligible adolescents and a parent will then meet with the Study Psychologist for a clinical mental health assessment.

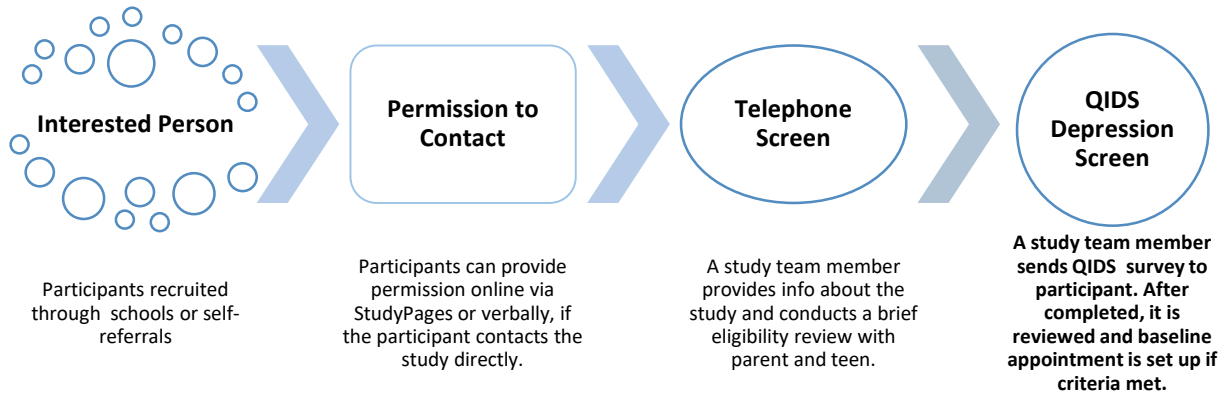
4. Selection and Enrollment of Participants

4.1: Inclusion Criteria

Participants must meet all of the inclusion criteria to participate in this study. Inclusion criteria for the study includes:

- Adolescents between ages 14-17. Adolescents may turn 18 after enrollment.

Figure 5. Flow of Interested Participants through the Screening Process



- Adolescents who are in high school.
- Adolescents with access to a smartphone or internet-enabled device.
- Adolescents and parent willing for their adolescent to be randomized to one of the two groups.
- Adolescent able to attend group sessions (8 weekly, 1.75 hour sessions; 6 monthly, 1.5 hour sessions) and complete study assessments.
- Adolescents experiencing subsyndromal depression assessed by:
    - Completion of screening questions by parent (see Parent Screening Survey and Telephone Consent);
    - Completion of QIDS by adolescent (see ;
    - Completion of clinical mental health assessment based on Diagnostic Interview Schedule for Children for Children (DISC-IV) by a study provider. The clinical mental health

assessment will screen for serious psychiatric illness, including major depression (MDD), suicidality, and other exclusion criteria.

Preliminary identification of subsyndromal depression will occur through screening questions completed by the parent (see Telephone Consent for details) and completion of QIDS by adolescent.
Adolescent and parent willing to receive a clinical mental health assessment, administered by a study provider, based on the Diagnostic Interview Schedule for Children-IV (DISC-IV) to screen for serious psychiatric illness, including major depression (MDD) and suicidality.

4.2: Exclusion Criteria

All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation. Exclusion Criteria include:

- Adolescent and parent unable to speak, write, and read in English.
- Adolescents who have received prior mindfulness training (such as a mindfulness course).
- Adolescent unable or unwilling to attend or participate in group sessions and/or self-report assessments.
- Adolescents with the presence of suicidality or MDD as determined by clinical exam. Adolescents who have experienced MDD in the past will not automatically be excluded from the study.
- Adolescents with active substance abuse, defined as active treatment for substance abuse, legal consequences/school suspensions associated with substance use, or ongoing family conflict associated with substance use.
- Adolescents with a history of bipolar disorder, schizophrenia, severe autism/intellectual disability, or psychiatric hospitalization within the past 36 weeks. Milder forms of mental health and/or developmental disorders will not automatically constitute exclusion. The Study Psychologist will recommend exclusion only if the disorder would lead to disruption of the group process.
- Adolescents who currently or previously participated in a research intervention to address depression or psychiatric conditions. Adolescents are allowed to see their mental health provider while participating in the study.

4.3: Study Enrollment Procedures

We will recruit teens, ages 14-17, who are in high school and have subsyndromal depression, in several ways including:

- Emails with study information sent to the University community;
- Local guidance counselors made aware of the study;
- Flyers posted in the community and at local schools;
- In-person recruitment at local teen community organizations, churches, and school events (such as parent-teacher associations or parent-teacher organizations).

4.3.1: Phone Screening and Psychological Exam

The study staff will contact interested parents and, with consent and assent, conduct an initial telephone screen with the adolescent. If still interested, materials will be sent to the parent to share with the adolescent, describing the study as two programs to help teens to reduce stress and feel more positive about themselves. Candidates will be given the QIDS assessment and if their score is at least 6, the teen and a parent will be eligible for a visit with the Study Psychologist for a clinical mental health assessment.

4.3.2: Consenting

If a teen is eligible to participate based on the QIDS, the parent and teen will meet with a study team member to review study procedures in detail and provide written informed consent and assent. Any questions asked by the parent and or teen will be answered accordingly. They may decline, sign, or take the consent home with them to be signed later. The adolescent will considered to be a subject after both the Informed consent is signed by the parent and the assent is signed by the teen.

At that time, if consented, the teen and parent will meet with the Study Psychologist for a psychological exam, including a face-to-face administration of the Diagnostic Interview Schedule for Children (DISC-IV). The clinical mental health assessment will determine continued eligibility.

4.3.3: Documentation

The study team will maintain a screening log on REDCap (a secure, web-based research database) throughout the study. This will include names, dates of contact, and outcomes of the recruiting effort for each candidate. At all stages of the recruitment process, the study team will store any written documentation securely in locked study cabinets.

4.3.4: Randomization

Although the study is not designed as an RCT, we do plan to test our randomization system. In all but the first two cohorts, as soon as 14-20 eligible adolescents qualify for enrollment, they will be allocated to one of the educational groups, using a specially-designed computer program (in REDCap). This program requires the operator to check off inclusion/exclusion criterion for each subject and confirm that subjects have been consented. The program utilizes a random-numbers generator with a permuted block design (blocks of 2 to 4) to ensure that the numbers of subjects allocated to the two arms over time are equal and to conceal the allocation. Randomization is stratified by gender.

5. STUDY INTERVENTIONS

5.1: Interventions, Administration, and Duration

5.1.1: Prevention Programs

Each program will be 8 weeks in length and meet weekly for 1.75 hours per session. The week before the programs begin, each subject and parent will complete baseline measures through an electronic interface (REDap survey). A trained instructor, assisted by a mental health provider (including mentored psychologist/social work interns or school counselors) who work with adolescents will lead each program. Mental health providers or their supervised students will identify any behaviors that may indicate deteriorating mental health status and confer with the Study Psychologist. Instructors of the

Making Friends with Yourself Program undergo extensive training through the Center for Mindful Self-Compassion and the University of California, San Diego. Instructors of the control program are experienced health behavior specialists, preventive medicine physicians, health teachers in the schools, or school counselors. Continuation sessions, 90-minutes in length, will occur monthly through the first six months to review the skills taught in the sessions and to encourage continued practice of techniques learned in the program. Each program session will be audio-recorded to ensure program fidelity and to enable assessment of the value of specific study components. The study curriculum will include in-class didactic training and exercises, group discussion, hands-on class activities that reinforce the ideas presented, and homework assignments designed to encourage participants to practice what they have learned.

Making Friends with Yourself Curriculum

The MFY program will be led by an experienced mindful self-compassion instructor trained in teaching the teen program and assisted by a mental health provider who works with teens. The curriculum will be adapted from the adult program in that it will be developmentally appropriate for adolescents. The team has developed a Chatbot for the study to reinforce concepts that are learned in class. For example, participants can choose emotion words to express how they are feeling in a given moment; the chatbot will then provide them with a short practice to help them be mindful and self-compassionate.
The MFY curriculum will contain the following:

- **Session 1**: Discovering Mindful Self-Compassion: Definitions of mindfulness and self-compassion will be provided. Guided meditation is presented. Through a hands-on exercise, students become familiar with the concept that we treat ourselves more harshly than we treat our friends in time of difficulty.
- **Session 2**: Paying Attention on Purpose: Mindfulness concept is presented. Sound meditation, eating meditation, and a body scan are introduced.
- **Session 3**: Lovingkindness: Concept of lovingkindness is introduced, along with lovingkindness practices. Included is how to tailor lovingkindness practices to meet one's own personal needs.
- **Session 4**: Self-Compassion: Definition of self-compassion is articulated through guided meditations and exercises. Music meditation is introduced.
- **Session 5**: Self-Compassion vs. Self-Esteem: The similarity and differences of these two ways of relating to oneself are presented.
- **Session 6**: Living Deeply: The compassionate voice is contrasted with the voice of the Inner Critic. An art and writing activity is incorporated into the lesson.
- **Session 7**: Managing Difficult Emotions: Adolescents are taught specific tools to deal with particularly emotionally challenging situations, i.e., those that potentially could increase anxiety or depression.
- **Session 8**: Embracing Your Life: Focus is on how to integrate gratitude and self-appreciation practices into daily life.

Continuation sessions, 90-minutes in length, will be held monthly and revisit aspects of the class content.

Healthy Lifestyles Group (HLG)

An experienced facilitator will lead the HLG curriculum and will be assisted by a mental health provider. The program focuses on the development of healthy lifestyles for adolescents. Each session involves the introduction of the weekly topic by the facilitator followed by hands-on activities and discussion. A mobile friendly website will be explored to help reinforce concepts learned in this class and participants will complete homework related to the class content. The HLG curriculum will contain the following topics, adjusted with feedback from the participants:

- **Session 1**: Sleep hygiene: The science behind sleep and its effects on the brain
- **Session 2**: Nutrition: Eating well for a healthy body and healthy mind
- **Session 3**: Exercise: Getting moving to feel better
- **Session 4**: Academic Stress: Overcoming School Stress
- **Session 5**: Social media—Instagram, Twitter and beyond: How to manage this in your life without it overtaking your life
- **Session 6**: Creativity: Shaping your Environment
- **Session 7**: Diversity: Exploring your Identity
- **Session 8**: Community service: Engaged Citizenship

Continuation sessions, 90-minutes in length, will be held monthly and revisit aspects of the class content.

5.1.2: Measurement Time Points

Adolescents will be evaluated at baseline (Visit 2), halfway through the intervention (Visit 6), after the intervention (Visit 10), in the middle of the continuation phase (Visit 13), and after the continuation phase (Visit 16). Parents complete the SMFQ-P evaluating their perception of their child's depressive symptoms at baseline (Visit 2), post-program (Visit 10), and the continuation visits (Visit 13 and Visit 16). The PROMIS Pediatric Depression Scale, originally designed as a safety measure, is employed as the time-to-event measure.

5.1.3: Measures

Several measures will be used for the study. Table 2 lists each measure, the construct(s) it assesses, and the timepoint it is administered in the study.

Measures Used For Pre-Screening

Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR)[141]: Adolescents will complete the QIDS self-report as a **screening** measure for depression. The sixteen-item QIDS is highly correlated with the full Inventory of Depressive Symptomatology and is limited to the nine DSM-IV domains: 1) sad mood; 2) concentration; 3) self-criticism; 4) suicidal ideation; 5) interest; 6) energy/fatigue; 7) sleep disturbance; 8) appetite change; 9) psychomotor changes. The QIDS is a reliable (α=.86) measure[141] that compares favorably with other depression measures[142] and has been investigated in adolescents[143]. A score of 6-10 is consistent with subsyndromal to mild depression. The QIDS will be completed following the telephone screen to determine eligibility to come in for an enrollment visit.

Diagnostic Interview Schedule for Children- Version IV (DISC-IV)[144]: The DISC-IV assesses psychiatric diagnoses of children and adolescents by eliciting the diagnostic criteria specified in the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV) and the WHO International Classification of Diseases, Version 10 (IDC-10). The DISC is a highly structured interview for children and

adolescents aged 6 to 18, or their parents. The DISC was designed to be administered by lay interviewers following a training manual. Questions are worded so that they can be answered "yes", "no", and "somewhat" or "sometimes". The DISC-IV is used as a guide by study clinicians to assess study eligibility at the enrollment (baseline) visit.

PROMIS Pediatric Depression Scale. The Patient Reported Outcomes Mesurement Information System was funded and promulgated by the National Institutes of Health as a way to harmonize across measures. They included measures specifically for pediatric populations, including adolescents. One such measure is the pediatric depression short form. The short form was chosen as a safety measure for this study because of its simplicity, its brevity (8 questions), and its ability to be administered and scored electronically using REDCap. Because it was administered weekly, it also serves as an excellent measure to use for a time-to-event analysis.

Short Mood and Feelings Questionnaire (SMFQ)[145]: The SMFQ is a depression scale created for children and adolescents. There is a 13-item youth version **(SMFQ-C)** and 13-item parent version **(SMFQ-P).** Items are symptoms of depression experienced over the past 2 weeks which the child or parent would endorse as "not true", "sometimes true" or "true". Internal reliability has been reported as α=.85 (SMFQ-C) and α=.87 (SMFQ-P)[146,147].

Brief Resiliency Scale (BRS)[85]: This scale defines resiliency as the ability to "bounce back" and recover from stress; the items reflect a sense of personal agency. Six items are rated on a scale from 1 (*strongly disagree*) to 5 (*strongly agree*). Convergent and discriminant validity have been established, and Cronbach's alpha is between .80 and .91. Test-retest reliability over one month has been reported as .69 and >22 weeks as .62.

Adolescent Cognitive Style Questionnaire (ACSQ)[148]: The ACSQ assesses the extent to which adolescents utilize a negative cognitive style. Twelve hypothetical negative event scenarios are presented that are relevant to teens, and the participant is asked to write down one potential cause for the event. Participants then rate the degree to which the cause is 1) internal, 2) stable, and 3) global, the likelihood for future negative consequences to occur as a result, and the degree to which the result implies that the self is flawed. Construct validity was supported through correlations with other attributional style measures and depressive symptoms, and the scale demonstrated internal consistency (α =.95) and test-retest reliability (.73 over 2 weeks). Reliability and validity remain consistent with using as few as four scenarios. This study uses six of the twelve scenarios (items 1, 2, 3, 6, 8, and 12) that are relevant to the study population. Items not as relevant (e.g. attending college, having a boss) or that were redundant (e.g. questions dealing with boyfriends/girlfriends or grades) were not included for this study to reduce participant burden with answering questions.

Ruminative Response Style scale – brooding factor (RRS-B)[80,149]: Five items from the 22 original items of the Ruminative Response Style questionnaire will be used in this study reflecting the tendency to dwell on negative emotions and potential consequences. Brooding is the component of rumination that correlates most strongly with depression. On a scale from 1 (never/almost never) to 4 (always/almost always), participants are asked to indicate how often they would initiate a specific response when they were upset. The 5-item scale has been used previously in a study with adolescents and correlate highly with the full rumination scale (*r*=.93); internal consistency for this shortened scale was good (α=.82) and test-retest reliability was good[150].

Test for Self-Conscious Affect for Adolescents (TOSCA-A)[151]: This scale was developed to assess proneness to shame, proneness to guilt, externalization of blame, detachment-unconcern, and pride in self and pride in behavior. The scale is comprised of 15 scenarios (10 negative, 5 positive) that might occur in the everyday life of an adolescent. Participants are asked to indicate on a 5-point scale their likelihood of reacting with each response. TOSCA is correlated with measures of anger, empathy, and psychological symptoms, and internal consistency was good (shame, α =.77; guilt, α =.81)

Self-Compassion Scale (SCS)[124] (26 items): The self-compassion subscales are self-kindness, common humanity, and mindfulness. Participants indicated their responses to each item using a 5-point scale ranging from 1 (*almost never)* to 5 (*almost always)*. Construct validity was established through expected correlations with the self-criticism subscale of the Depression Experience Questionnaire, the Social Connectedness scale, and the attention, clarity, and repair subscales of the Trait-Meta Mood Scale. Internal consistency for this scale was found to be excellent (α = .93).

Child and Adolescent Mindfulness Measure (CAMM)[16]: CAMM assesses mindful awareness and acceptance. Participants indicate their responses to 10 items using a 5-point scale ranging from 0 (*never true)* to 4 (*always true).* Construct validity was established through positive correlations with measures of quality of life, academic competence, and social skills and negative correlations with measures of somatic complaints, and internalizing and externalizing behavior problems; adequate internal consistency also was found (α = .80).

Expectations of Benefit / Credibility (CRED)[138,152]: This instrument, administered at the end of the first class, provides an assessment of expectation of benefit and credibility of each intervention using an adaptation of a validated scale previously developed for psychological studies for purposes of comparing two treatment arms. Participants respond to 6 items on a 9-point scale ranging from 1 (*not at all*) to 9 (*very much*). Psychometric testing supported high internal consistency within each factor (expectation, α = .90; credibility, α = .86) and good test-retest reliability (.83).

Feelings About the Class: This is a process questionnaire developed for Gregory Clarke's "Coping with Stress" program to assess subjects' feelings about the instructors and other class participants as well as satisfaction with the program. It will be administered at the end of the intervention phase (at the last class) for both programs with permission of the author.

Home Practice Completion (Daily Diary): Adolescents in the intervention program will be expected to practice concepts taught in the class. Each day, they will receive a text message (or email) from the study team. Embedded in the text or email will be a link to the diary website. The daily diary will consist of no more than 5 short questions about skills they practiced, number of minutes they practiced, and any barriers to practice.

Patient-Reported Outcomes Measurement Information System Pediatric Short Form (PROMIS Pediatric Short Form): The PROMIS Pediatric Short Form is a short 12-item survey designed to screen for depression. The PROMIS Pediatric Short Form will be used as a safety measure once participants are in the 8-week course to assess any changes in depressive symptoms. See 7. Safety Assessments for more details about the PROMIS Pediatric Short Form being used as a safety measure for the study. A T score of 70 on the PROMIS depression measure will generate a referral to the study psychologist.

Demographics: The study is limited to adolescents experiencing subsyndromal depression. The demographic survey, administered at baseline, will collect data about each teen's age, gender, race/ethnicity, years of education, and parental educational attainment.

Qualitative measures: We will collect two types of formal qualitative data: 1) Evaluation (focus) groups following each 8-week set of classes at the end of the last class; 2) Transcriptions of audio-recorded classes. The focus groups will address the following topics related to the teens' experience with the programs, including:

1) Most memorable aspects of program (e.g. most favorite and least favorite aspects);
2) Whether they would recommend it to a friend;
3) Usefulness, challenges and recommended changes including in-class and out-of-class assignments;
4) Usefulness of the program for management of stress, mood, and well-being in daily life;
5) Tools that might help them maintain practices; and
6) Unfulfilled expectations of the program.

Each focus group will be audio-recorded and transcribed.

Table 2. Study measures

MEASURE	CONSTRUCT	TIMING
Inclusion/Exclusion Criteria		
QIDS-SR	Depression screening	Pre-screening
Diagnostic Interview Schedule for Children (DISC-IV)	Screening for serious psychopathology	Screening visit
Primary Outcomes		
PROMIS Pediatric Depression Short Form v1.1	Incident major depression	Weekly from the beginning of the intervention
Secondary Outcomes		
Short Mood and Feelings Questionnaire (SMFQ-C)	Depression scores change	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Brief Resiliency Scale (BRS)	Resiliency	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Exploratory Mediating Measures		
Adolescent Cognitive Style Questionnaire (ASCSQ)	Cognitive Style	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Rumination Response Style-brooding factor (RRS-B)	Brooding	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Test of Self-conscious affect-adolescence (TOSCA-A)	Shame	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Process Measures		
Home-practice (HW)	Homework completion	Daily during program, then weekly
Pediatric Depressive Symptoms Short Form (PDS)	Safety assessment for depression	Weekly during program
Self-Compassion Scale (SCS)	Self-compassion	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Child and Adolescent Mindfulness Measure (CAMM)	Mindfulness	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16
Credibility Scale (CRED)	Expectation of benefit	Following first class
Feelings about the class	Post-participation evaluation	Visit 16
Post-participation focus group	Program evaluation	Visit 10, Visit 16

Parent Measures		
Demographics		Visit 2
Short Mood and Feelings Questionnaire (SMFQ-P)	Parent perception of adolescent's depression	Visit 2, Visit 6, Visit 10, Visit 13, Visit 16

5.1.3 Modifications to the interventions

After the programs, adolescents will participate in a focus group to give feedback about program contents. The adolescents will be invited to participate in 6 monthly continuation sessions, designed to strengthen understanding of the topics presented in the 8-week course. Measures of depression, resilience, brooding, shame, mindfulness, and self-compassion will be obtained before, halfway through, and after the program as well as at 22 weeks and 36 weeks after the program.

Feedback from program participants and their parents will inform modifications and refinement of both programs. Once this has been completed and program manuals updated, an additional 2 cohorts will be recruited.

5.2: Handling of Study Interventions

A Manual of Operations will be actively maintained to document subject participation in all aspects of the project including, for examples, attendance at weekly session visits, completion of homework and online assessments, and follow up questionnaires.

5.2.1: Masking

The nature of the interventions tested in this study does not allow for masking of subjects, instructors, or other personnel involved in program delivery. To preserve unbiased outcome assessments, study personnel involved in clinical assessments or data analysis will be masked with respect to group assignment. To minimize differences in subject expectancy, the programs will be described to participants as two programs, both of which have been previously found to be beneficial to teens. Participants will not know the name of the group: Making Friends with Yourself or Healthy Lifestyle Group. The intent is to prevent the participant from knowing which program the investigators believe is most likely to prevent depression. To verify that adolescents assigned to either group have the same expectation of benefit, participants will be asked to complete a Credibility Scale[138] at the end of Session 1.

5.3: Concomitant Interventions

5.3.1: Allowable Interventions

Participating adolescents may continue to receive medical care from their primary care provider.

5.3.2: Required Interventions

Participants are expected to attend baseline visits, 8 weekly classes, and 6 continuation classes. In addition, they are encouraged to complete homework diaries (daily during the intervention, then weekly during the continuation sessions), weekly depression screens, and questionnaires at Visits 2, 6, 10, 13, and 16.

5.3.3: Prohibited Interventions

Participants will be excluded from enrolling in the program if they have participated in a mindfulness-training program. They will be asked not to participate in any other mental health intervention study during their participation in this study, which includes a study on medications or other group interventions. Participants who do not develop major depression may follow the advice of their physicians and primary care providers and may take any prescribed medication. Participants who develop major depression during the study will be referred to a mental health provider.

5.4: Adherence Assessment

We will define study adherence as 80% compliance with the home practice and self-report assessments and attendance at 6 out of 8 weekly sessions and 4 out of 6 continuation sessions.

6. STUDY PROCEDURES

6.1: Schedule of Evaluations

Participants will follow the schedule in Table 3 to complete consenting and assessments:

Table 3. Schedule of Evaluations

Assessment	Visit 1 Screen and Baseline	Before Visit 2 (online)	Visit 2 (W0)	*Daily (W0-8)*	Visits 3-5 (W1-3)	Visit 6 (W4)	Visits 7-9 (W5-7)	Visit 10 (W8)	Visit 11-12 (W13, 17)	Visit 13 (W22)	Visit 14-15 (W27, 32)	Visit 16 FINAL (W36)
Informed Consent	X											
Demographics	X											
Enrollment	X											
Psychological	X											
Inclusion/Exclusio	X											
Questionnaires		X				X		X		X		X
Randomization		X										
Credibility			X									
Daily practice diary				X								
Weekly practice									X	X	X	X
Weekly depression			X		X	X	X	X	X	X	X	X
Focus Group								X				X
Parent measures		X						X		X		X

6.2: Description of Evaluations

6.2.1 Screening Evaluation

Screening

The screening process will consist of the following:

- Potentially eligible participants will be identified and referred to the study by guidance

counselors. Parents may also respond to study advertisements (e.g., UNC campus-wide email, posted flyers).

- Study staff will contact the candidate's parents and, with permission, conduct an initial telephone screen with the adolescent.
- Information describing the study will be sent to the parent for sharing with the adolescent.
- Adolescents will be sent a link to the QIDS-SR assessment through REDCap. Study staff will review QIDS-SR scores. Participants with scores of at least 6 are considered eligible for a baseline psychological evaluation.
- A baseline psychological evaluation will occur within 5 weeks of screening. If the baseline psychological evaluation cannot be scheduled within this timeframe, the adolescent should retake the screening questionnaire to assure continued eligibility.
- After consenting, a parent and the adolescent will meet with the study psychologist for the baseline psychological evaluation using the in-person Diagnostic Interview Schedule for Children (DISC-IV), including assessment of eligibility criteria.
- The Study Psychologist notifies the study team of the adolescent's eligibility for the class. Eligible participants will start the class within 6 weeks of the baseline visit. If the adolescent cannot start the class prior to the six weeks, the adolescent will participate in a review of eligibility criteria with the Study Psychologist.

6.2.2: Enrollment, Baseline, and/or Randomization

The enrollment procedures and baseline assessments will constitute Visit 1.

Enrollment

Study enrollment will occur at the time the parent signs the informed consent and the adolescent signs the assent form. Section 4.3.2 describes the consenting procedure.

Baseline Assessments

The adolescent and a parent participate in the baseline visit. At this visit, the adolescent and parent review the study consents and study procedures in detail with designated study personnel. If the parent signs the parental permission form and the adolescent signs the assent, they will see the Study Psychologist or a member of her staff that has been trained in administering the DISC-IV. The Study Psychologist will evaluate the adolescent's eligibility for the program and notify study team personnel of eligibility.

Randomization

After the first two groups (one each of MFY and HLG), randomization occurs one week before the first class. A designated study team member will use the randomization feature of REDCap to randomize participants. The procedure involves a review of eligibility followed by an assignment to one of the groups.

6.2.3: Follow-up Visits

Following the eight-week program, participants will have self-report assessments 22 weeks after the program (Visit 13) and 36 weeks after the program (Visit 16, final evaluation).

Visit 1

Section 6.2.2, *Enrollment* and *Baseline Assessments*, provides a description of Visit 1.

Visit 2

Study staff will send the study questionnaires via a link to parents and adolescents one week before the start of classes. Parents and adolescents will complete the online measures. Once measures are completed, study staff will notify the participants of their group assignment and logistics of participation (time, place, etc.)

Visits 3-10 (8 weeks of Classes)

Adolescents attend the 8 weeks of classes. Classes will be audio recorded to evaluate the fidelity of the instructor to the program.

Visit 6 (Week 4 of Classes)

At week 4 of the intervention (Visit 6), adolescents complete a set of questionnaires online.

Visit 10 (Week 8 of Classes)

At week 8, adolescents participate in a focus group designed to obtain feedback about the program. The focus group will be audio recorded.

In addition, adolescents complete another set of online questionnaires. Study staff will send a link to the study questionnaires to the adolescents and parent one week following completion of the 8-week class. See schedule of evaluations and list of measures above.

Visits 11-16 (Continuation Classes—see 6.2.5 for final visit)

At each continuation class, adolescents will review and practice what they learned in the 8-week classes. Both the adolescents and their parents will complete questionnaires 22 weeks post-intervention (Visit 13) and 36 weeks post-intervention (Visit 16). At Visit 16, adolescents will participate in a brief post-participation interview. See schedule of evaluations and list of measures above.

6.2.5: Completion/Final Evaluation

At the end of the continuation phase, participants will complete the final on-line questionnaires.

Early Discontinuation from Study Intervention

Potential reasons for early termination include:

1) Subject no longer interested
2) Adverse events
3) Subject not able or willing to follow the protocol
4) Subject moved away from the area.

If subjects withdraw early, the PI or a designee will follow-up by telephone to inquire about health status as it relates to adverse events experienced by the subject leading to early discontinuation of participation.

7. SAFETY ASSESSMENTS

Participant safety is monitored through daily diaries (monitored by study staff), weekly depression assessments (PROMIS Pediatric Depression short form), and contact with program instructors (weekly during program, monthly during continuation phase). Participants exhibiting increased symptoms of depression are evaluated by the Study Psychologist and referred for further evaluation. Further details on safety are found in the study's Data Safety Monitoring Plan (DSMP, Appendix IV).

7.1: Specification of Safety Parameters

Combined SMFQ-C / SMFQ-P scores of 12 is the recommended cut-off value for MDD; this value or greater will generate follow-up with the study psychologist. In addition, a T score of 70 or an increase of 3 standard deviations from the baseline score on the PROMIS depression measure will generate a referral to the study psychologist.

7.2: Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

1) Timing: every contact with the participant will be an opportunity to capture adverse events.
2) Recording: each incidence of an adverse event will be recorded in REDCap.
3) Analyzing: the PI will be informed of all adverse events and will forward the information to the IRB and the Independent Safety Monitoring Committee (ISMC) (See DSMP).

7.3: Adverse Events and Serious Adverse Events

Adherence to current definitions and submission guidelines for identification and reporting to the IRB of Adverse Events (AEs), including Serious AEs (SAEs), and Unanticipated Problems (UPs) is planned. Reporting of all adverse events will be the responsibility of the PI (Dr. Susan Gaylord). The project manager and research assistant will assist the PI with summarizing, recording, and reporting all AEs. The PI will be informed of each AE by direct subject communication or by members of the research team. Subjects will be encouraged to report, in a timely fashion, any incidents of discomfort, or a change in health status for any reason, to the research personnel.

It will be the responsibility of the PI, with assistance from the project manager and research assistant, to respond to IRB directives growing out of adverse events, including but not limited to, development and implementation of corrective action plans. The reporting process has recently been streamlined and made available online to investigators. It is also the responsibility of the PI to implement corrective action for SAEs, at times, in advance of IRB review of the incident.

7.3.1: Definitions

An adverse event (AE) is any untoward medical occurrence in a subject during participation in a clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these regardless of relationship to participation in the study.

A serious adverse event (SAE) is any AE that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- An important medical event based upon appropriate medical judgment

7.3.2: Classification of AE Severity

Classification of AEs will be based on the Common Terminology Criteria for Adverse Events (CTCAE) Version 4, 2009. AEs will be described by symptom or condition/diagnosis, and graded for severity (mild, moderate, or severe) — depending on the intensity of the event. Two additional categories will be used based on the CTCAE system, "life threatening" and "death".

Grade 1. Mild: asymptomatic or mild symptoms; clinical or diagnostic observations only; minimal impact on subject's life; intervention not indicated.

Grade 2. Moderate: medical care sought; significant but limited inconvenience on Activities of Daily Living (ADL) or lifestyle; local or noninvasive intervention indicated.

Grade 3. Severe: medically significant but not immediately life-threatening; disabling; limiting self-care; substantial disruption to the subject's well-being; hospitalization or prolongation of hospitalization indicated.

Grade 4. SAE. Life-threatening consequences; urgent medical intervention indicated.

Grade 5. SAE. Death: related to AE.

An AE that is graded as severe (Grade 3) can be distinct from an SAE (Grades 4 and 5). A subject could experience a severe AE (Grade 3) that does not meet the definition of an SAE (see above). Alternatively, a subject could experience a moderate AE (fever, mild confusion) that meets the SAE definition (example - need for antibiotics to combat a life threatening infection).

7.3.3: AE Attribution Scale

AEs will also be classified on an assessment of relatedness to the study intervention. AEs will be categorized according to the likelihood that they are related to the study intervention. They will be labeled as: 1) definitely related, 2) definitely unrelated, 3) probably related, or 4) possibly related to the study intervention in the opinion of the PI and Study Psychologist after review of the circumstances and relevant records.

7.4: Reporting Procedures

No events will be solicited. Unsolicited events will be captured by query at each subject contact after enrollment and through the diaries.

A dated log of AEs, UPs, and SAEs will be kept in the study database. Data captured will include a detailed description of each incident, experience, or outcome. In addition, staff will include an explanation of why the AE, incident, experience, or outcome is considered a UP. The PI will determine and the project manager will document any changes to the protocol or corrective action taken or

proposed in response to a UP.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to NCCIH within 7 days of the investigator becoming aware of the event.
- The PI, within 24 hours, will report all related or possibly-related AND serious adverse events (SAE) occurring in subjects to the IRB. This will be accomplished by submitting an adverse event report to the IRB and to the ISMC. Serious adverse events will be reported even if the PIs and Study Psychologist believe that the adverse events are unrelated to the protocol.

- Unexpected (but not serious) adverse events occurring in subjects which, in the opinion of the Study Psychologist, are possibly related to participation AND place subjects or others at a greater risk of harm than was previously known or recognized in the protocol will be reported by the PI within 24 hours of discovery by email or phone to the IRB and the ISMC. A follow-up written report within 5 business days to the IRB and the ISMC will be submitted by the PI.

- Unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported to the IRB and DSMB via email or telephone within 24 hours of discovery and a written follow up report within 5 business days.

- Any other unanticipated problem will be reported to the IRB, Independent Safety Monitor(s), and NCCIH within 14 days of the investigator becoming aware of the problem.

- When a protocol deviation occurs, the investigator will report the occurrence to the IRB. The investigator will make the determination whether the deviation meets the criteria for an unanticipated problem involving risks to subjects or others. The IRB Chair or IRB staff member will also make the determination if the protocol deviation meets the definition of an unanticipated problem involving risks to participants or others.

All unanticipated problems will be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Independent Safety Monitor(s), IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Office, and ISMC within 3 days of the investigator becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Safety Monitor(s), IRB, and other oversight organizations in accordance with their requirements and will be reported to NCCIH on an annual basis.

- All other AEs documented during the course of the trial will be reported to NCCIH on an annual basis by way of inclusion in the annual report and in the annual AE summary which will be provided to NCCIH and to the Independent Monitors. The Independent Safety Monitor(s) Report will state that all AEs have been reviewed.
- All AEs documented during the course of the trial will be reviewed by the Independent Safety Monitoring Committee (ISMC) on a regular basis. The ISMC will meet initially after the first cohort (20) subjects have completed the intervention and are in the continuation phase of the study. The ISMC will meet every 36 weeks thereafter.

Detection of increased depression.

A major activity of the Board will be to determine if subjects are developing depression at an unusual rate during their time in the project. Removal of subjects from the study is included in the responsibilities of the PI. Study continuation is the duty of the ISMC and rests, in part, on the collected data pertaining to incidence of new depression in this subject population.

7.5: Follow-up for Adverse Events

The Study Psychologist will investigate AEs related to participant mental health and make appropriate referrals for further care. The Study Psychologist will follow-up with the parent to assess follow-through within one week of the reported event. The Project Manager will investigate all other AEs and follow up with the participant until stable.

7.6: Safety Monitoring (See DSMP)

An Independent Safety Monitoring Committee (ISMC) will be constituted with a charter describing membership, meeting frequency, review process, report generation, liaison with the PI and research team, range of recommendations and criteria for subject removal and program suspension.

ISMC membership should include: a psychologist with expertise in depression, a psychologist/psychiatrist with a research/statistical background, and an individual with expertise in mindfulness. None of these individuals will be directly associated with the study other than through the ISMC.

7.6.1: Frequency of Review

The ISMC will meet prior to the first group trainings, and within one month after the first full cohort of 20 subjects (10 in each group) have completed the 8 week training period. They will meet every six months thereafter or whenever the PI requests a review outside of those times. Meetings will be facilitated by the PI and project manager by providing a private meeting location and all requested materials on the day of the review. The PI and project manager will also provide a summary of the project dating from the time of the last review. The PI and other research personnel will be available to meet with the Board as requested. The ISMC will continue to meet through data collection.

7.6.2: Review Materials

The ISMC will review all available data sets, AEs, SAEs and UPs, operational manuals, focus group reports, IRB submissions and renewal documentation, IRB notifications and all other materials generated by the study.

7.6.3: Summary report

A member of the ISMC will be designated by consensus as chairperson and will be responsible for conducting the meetings and for preparing a report after each meeting, summarizing the review along with recommendations for changes, if any, and continuation of the project. The report will be transmitted to the PI within 2 weeks of the meeting unless there is urgency, as determined by the Board, requiring action.

8. INTERVENTION DISCONTINUATION

8.1: Discontinuation of Intervention for a Participant

Subject may stop their participation for any reason, e.g., the subject is non-compliant with the protocol; subject develops unacceptable side effects; or psychosocial circumstances prevent continuation.

8.2: Possible reasons for discontinuation of the whole study

Possible reasons for discontinuation of the whole study include the following:

- Study closure by NIH institute
- Research environment is no longer supportive
- Multiple Unexpected Problems (UP)
- Insufficient recruitment
- ISMC or Study Monitor find evidence of serious safety issues. If greater than 3 enrolled and randomized subjects develop a grade 3 or greater adverse event due to the intervention, the entire study would be stopped and the ISMC will reevaluate.

8.3: Early discontinuation

Participants will continue to be followed, with their permission, for another 6 weeks if study interventions are discontinued for reasons other than the normal end of the study. Permission will be sought for questionnaire completion at stopping.

8.4: Normal end to the study

At the end of the 8-week intervention, subjects completing that part of the study will be followed for another 36 weeks with encouragement to maintain their assigned home practice. Questionnaires will be completed at 22 weeks post-intervention (Visit 13) and 36 weeks post intervention (Visit 16).

9. STATISTICAL CONSIDERATIONS

9.1: General Design Issues

This study is a planning grant for development of an adequately powered clinical trial. Statistical hypotheses are not considered relevant to this mechanism. Randomization is designed to assess feasibility of our randomization plan, in addition to general feasibility issues of the delivery of the educational programs.

In our third aim, we proposed exploratory analysis of clinical outcomes (see below).

9.2: Sample Size and Randomization

9.2.1: Treatment Assignment Procedures

Participants are randomized to treatment assignments to test the acceptability of randomization in the population. Random allocation, stratified by gender, is assured by a computer-generated assignment accessible to the REDCap administrator, but group assignment cannot be masked, except to quantitative data analysts.

Power and sample size. Untreated, >30% of adolescents are expected to develop incident depression. Power is calculated for time to incident MDD. With a sample size of 80, we expect to have 80% power to detect a hazard ratio of 0.52 for time to MDD between the groups. It is anticipated that we will screen 160 with the QIDS and 120 with the DISC to achieve a sample of 80 eligible teens (with 80 parents). Our target recruitment estimate is 53 females and 27 males, based on research demonstrating that there are twice as many female teens with subsyndromal depression as males. ***Note that all enrollment figures refer to teens***. Each will have the involvement of one parent.

9.3: Definition of Populations

The ITT (Intent to treat) population is any participant randomized to an intervention group, whether or not he/she participates. “Per protocol” populations (“Completers”) are participants who do not formally withdraw.

9.4: Interim Analyses and Stopping Rules

9.4.1: Study-wide stopping rules

These include the occurrence of a serious adverse event, CTCAE Grade 3 or higher, possibly related to the study protocol, occurring in 5 or more randomized adolescents. If these conditions occur, the ISMC will review and make recommendations on the advisability of continuing the study

9.4.2: Individual stopping rules

If a participant scores above 12 on the combined parent and child SMFQ at any point in the study, s/he will be referred to the study psychologist (Dr. Harris-Britt) within 24 hours. The study psychologist will then contact the parent of the teen (within 24 hours) to inform the parent of the depression status of the teen. Dr. Harris-Britt will make an evaluation to determine if s/he can continue in the study and will refer the family for appropriate psychological care.

We have added a safety depression screening measure, the PROMIS pediatric depression scale, which will be administered weekly via REDCap. The Assessment Center at NIH provides a scoring algorithm with REDCap software, enabling use of the measure for safety monitoring. The Project Manager or trained designee will monitor these measures weekly and will alert the team (including the Study Psychologist) to sharp increases in depressive symptoms and depressive symptoms meeting criteria for major depression. If the Study Psychologist confirms the development of major depression, the adolescent will be withdrawn from the study and referred for further care.

9.4.3: Additional Reasons for Withdrawal of a Participant

Additional reasons a participant may withdraw from the study include:

- The adolescent wishes to withdraw from the study;
- Loss of study eligibility (development of major depression);
- Intervening illness or injury making participation difficult;
- The adolescent develops any condition that, in the opinion of the study psychologist, would make continued participation unsafe.

In the unlikely event that a participant is unable to participate in a group setting, s/he may be withdrawn from the study.

9.5: Outcomes

Our primary goal is to develop a depression-prevention program based on mindfulness and self-compassion and to establish the feasibility of its implementation as compared with an active attention-control comparator. Hence, the establishment of quality assurance processes and complete data documentation assume even greater importance than data analysis. Data of multiple types from multiple sources will be captured. For questionnaire assessments, secure internet-based data collection instruments will be used, accessible by internet-capable device.

Quality assurance of these measures will include review of study instruments for range and consistency checks, and descriptive analyses to assess distributions of study variables. Quality assurance of qualitative measures include 1) maintaining a spreadsheet to log scheduled, completed, transcribed, and analyzed focus groups and interviews; 2) establishing a transcription template to ensure data is uniform in appearance; 3) arranging for secure storage of recordings and transcripts on REDCap; 4) review of consistency of styles across interviewers; and 5) review of recordings to assess accuracy of transcriptions.

All statistical analyses will utilize all adolescents who were randomized to one of the intervention arms and who attended at least one class. Individuals who were unable to attend a class are excluded. Complete case analyses are planned (without imputations).

9.5.1: Primary Outcome

For the primary outcome, (to be explored as described in Specific Aim 3, once feasibility is examined in Specific Aim 2), a score of 70 on the PROMIS Pediatric Depression Scale short form t-score. To assess incident depression, we will use exploratory nonparametric (Kaplan-Meier plots) and semi-parametric analyses (Cox proportional hazards models) to examine the trends in incident depression within and between treatment arms. If too few students reach the target of 70 (2 standard deviations above the population mean), we will explore outcomes using a target of 65 (1.5 standard deviations above the population mean). We had originally planned to use the SMFQ, but the SMFQ was collected only 5 times for those with complete data and the PROMIS Depression score was collected weekly, making it a much more reasonable measure for a time-to-event analysis.

9.5.2: Secondary Outcomes

For the secondary outcome, assuming feasibility is established, change in the Short Mood and Feelings Questionnaire (child and parent versions) will be examined in a linear regression in each condition, to test for any effect of either program. Then we will examine the change in depression scores through an

ANCOVA model controlling for baseline depression score and cohort to control for group specific effects. Subsequently, an exploratory analysis will examine the trajectory of changes over time by program arm, using graphical representations of outcomes at each time point by subject, cohort, and program arm as well as a longitudinal random effects model.

Hence, a within-group model would include terms for the follow-up depression score, the overall intercept, the cohort effect, the time effect, and a cohort*time interaction—to allow the trajectory to vary by cohort—as well as random effects for individual subjects and subjects nested within cohorts. Between program arms, we would add terms for the program arm and its interaction with time.

9.6: Data Analyses

9.6.1 Exploratory analyses of outcomes and mediators.

Exploratory analyses will involve first examining variable distributions and missing data patterns. Next, we will conduct exploratory analyses to assess patterns of change associated with participation in the programs. The study is not expected to produce a quantity of data large enough to have adequate power to detect significant effects of the MFY program compared to the TFY control program. However, trends in incident depression (primary outcome, PROMIS Pediatric Depression Scale), change in depression scores (combined SMFQ-C, PROMIS Pediatric Depression Score) resilience (secondary outcome), and potential mediators will be examined by program arm.

To assess incident depression, we will use exploratory nonparametric (Kaplan-Meier plots) to examine the trends in incident depression within and between treatment arms using the PROMIS Pediatric Depression Scale short-form..

To address the change in depressive symptoms (secondary outcome), we will examine the paired t-test in each condition, to test for any effect of either program. Subsequently, an exploratory analysis will examine the trajectory of changes over time by program arm, using graphical representations of outcomes at each time point by subject, cohort, and program arm as well as longitudinal random effects models. Hence, a within-group model would include terms for the follow-up depression score, the overall intercept, the cohort effect, the time effect, and a cohort*time interaction—to allow the trajectory to vary by cohort—as well as random effects for individual subjects and subjects nested within cohorts.

Additional explorations will include bivariable associations (correlation, simple regressions) between the process measures and the outcome, between intervention assignment and process measures, between intervention assignment and potential mediators, and between process measures and outcomes. If indicated, mediation analyses will be conducted to investigate possible mechanisms; strength of mediation (indirect effect) will be calculated as the product of the association of the causal variable on the mediator and the association of the mediator on the outcome variable.

9.6.2: Feasibility Analyses

Feasibility will be measured by the following:

1. Acceptance of the treatment and control programs as measured by attendance in 6 of 8 active intervention sessions and 4 of 6 continuation sessions;
2. Equivalence of the credibility of the two programs as measured with the credibility questionnaire;

3. Identification of recruitment challenges and their remedies as measured by:
    a. the number of individuals screened;
    b. the proportion of screened adolescents who qualify;
    c. the number of qualifiers who enroll; and d) the number of enrollees who complete the program—80% completion defined by the acceptance criteria above defines a feasible program;
4. Identification of factors associated with subjects' willingness to adhere to the study protocol such as:
    a. Location or timing of program classes, or lack of transportation;
    b. Those not completing the program will be contacted for a telephone interview to evaluate factors leading to dropout.
5. Identification of study components fostering engagement in the study groups and materials.

Subject Engagement

In addition to attendance data, engagement will be measured by:

1. Subjective class participation as rated by the instructor;
2. Adherence to recommended homework practice as measured in the daily diary;
3. Barriers for practice as captured in the diary;
4. Participant comments about the degree to which these practices have enabled them to adopt an attitude of mindfulness and self-compassion (as captured in the audio-taped class sessions). At the end of participation in the study, at month 8-9, subjects will be invited to give their impressions about the study in a brief, post-participation focus group or interview (see Section 5.1.3, Qualitative Measures).

Program Fidelity

All program sessions will be audio-recorded. The purpose of the recording is two-fold:

1. To identify any systematic variations in instructors' attitude, communication, or behavior between treatment groups; to assess adherence to the protocol; and to screen for any group-dependent differences in communication in content or style between the instructors and subjects;
2. To capture participants' input and comments during the classes (see qualitative analysis).

An evaluation matrix will be developed based on the program manuals and other written protocols. Two members of the study staff will listen to selected program sessions independently to rate adherence to the protocol.

Program Credibility

Credibility is measured by both the Borkovec and Nau questionnaire and qualitative data.

Acceptance of randomization is measured by a comparison of drop-out rates by intervention arm.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1: Data Collection: Data Type, Personnel Collecting Data

Project Manager and Research assistants:

- Entering screening data.
- Prompting questionnaire completion by both parents and teens.
- Reminding teens to complete daily/weekly homework assignment assessments and depression screens.

The study psychologist or a member of her practice will collect eligibility data.

10.2: Data Management

Data resulting from telephone screening is housed in a screening database on REDCap. The research assistant will enter screening data directly into REDCap.

After consenting, the participant is added to the study REDCap database as an enrolled subject. The study psychologist will notify study staff if the participant remains eligible for the study after evaluation. This information will be added to the study database as eligible or ineligible at baseline (to protect participant privacy).

Online data collection forms are developed by the PIs and the Project Manager. Participants and their parents enter this questionnaire data directly into REDCap.

10.3: Quality Assurance

10.3.1: Training

Current HIPAA and CITI training (Human Research Ethics, Good Clinical Practice) certificates are required of all study personnel who will be recruiting subjects, evaluating subjects, collecting or analyzing data.

Before participant data is collected, the PI or Project Manager will ensure that staff has completed training for applicable tasks. A log including dates and type of training will be kept in section 10 of the Study Regulatory Binder.

The Study Manual of Operating Procedures (MOP) will include detailed procedures for each of the following:

- Consent forms:
  - Telephone/screening (with detailed script and instructions included)
  - Full Consent (parental permissions and assents)
  - HIPAA Consent
  - Social Security Collection for Payments
- Study visit procedures including advising participants in collection of questionnaire and diary data

- Advising participants on use of the study app

10.3.2: Quality Control Committee

The quality control committee consists of the project manager, the internal QA Reviewer (Faurot), and the study statistician (Suchindran). Monthly reports are made to the committee and PI by the project manager.

10.3.3: Metrics

Diary Data

Participants will complete daily diaries during the 8 weeks of classes. The adolescents will receive a text prompt from the study team if they have not completed their diaries by 4:00 PM.

Self-report Questionnaires

Questionnaires will be completed at baseline (Visit 2) and at weeks 4 (Visit 6), 8 (Visit 10), 22 (about 22 weeks after the intervention; Visit 13), and 36 (about 36 weeks after the intervention ends; Visit 16). Participants will complete the questionnaires via a link to the survey mechanism on REDCap, accessing the site through a password-protected interface. The questionnaires prompt participants to complete skipped items and they must confirm that they wish to skip an item. After the participant completes the questionnaire, study team personnel will access the REDCap site and check the entries for completeness to ascertain any computer or questionnaire malfunction. Study team will keep paper copies of the questionnaires for use in the event of site malfunction.

Questionnaires designed to be completed on paper (Expectation of Benefit/Credibility), will be made available to participants at the first class, collected by the research assistant, and entered (twice) into REDCap. The paper copy will be saved in the participant's study folder to be used for corrections as needed. An error rate of greater than 1% will generate additional training.

10.3.4: Protocol Deviations

Staff will be trained to record any protocol deviation that may occur while performing their specific research related activities. Many of the data collection forms include comment sections where protocol deviation information will be captured on the source documents. Deviations will also be documented in the Study Regulatory Binder, section 12, and on REDCap. Training of the research staff will include practices of double checking all demographics, inclusion/exclusion criteria, data collection procedures including capture and secure storage, intervention procedures and data management activities.

Deviations will be documented as a written report submitted to the UNC IRB by the PI or Project Manager. New deviations will be presented by the Project Manager at the monthly Project Team meeting and reviewed by the research team at that time. Corrective action plans will be developed and submitted to the IRB as part of that reporting process.

10.3.5: Monitoring

The PI and Project Manager are responsible for scheduling any clinical site monitoring visits at the direction of NCCIH. The logs and reports of these visits are kept in the Study Regulatory Binder.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1: Institutional Review Board (IRB) Review

This protocol and the informed consent document (Appendix I) and any subsequent modifications will be reviewed and approved by the UNC IRB responsible for oversight of the study. The IRB application, modification and renewal procedures will be adhered to throughout the study.

11.2: Informed Consent Forms

A signed parental informed consent form and a signed participant assent form will be obtained for each participant if the teen participant is under 18, and a consent form from the teen participant if the participant turns 18.

The consent form will describe the purpose of the study, the procedures to be followed, reasons not to be in the study, the risks and benefits of participation, responsibilities of the participant, incentives and remunerations, privacy and confidentiality measures, and the name and contact information for the PI and the study staff. The participant will be given the opportunity to read the Informed Consent and ask questions regarding the study. If they have their questions answered and are willing to participate, the informed consent and informed assent will be signed at this meeting and also signed by the study staff that is obtaining the consent. A copy of the IFC and the IFA will be given to each participant.

11.3: Participant Confidentiality

Participant confidentiality will be maintained according to the Health Insurance Portability and Accountability Act (HIPAA). All records will be kept in a locked file cabinet. All data will be stored on password-protected computers in an encrypted database.

11.4: Study Discontinuation

The study may be discontinued at any time by the IRB, the NCCIH, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

12. COMMITTEES

An Independent Safety Monitoring Committee (ISMC) will be formed. Refer to Section 7.6: Safety Monitoring and Appendix IV for details about the ISMC.

13. PUBLICATION OF RESEARCH FINDINGS

Research findings will be published in ClinicalTrials.gov and in the scientific literature. A poster documenting the development of the Healthy Lifestyles Group has already been presented at the American Public Health Association Meeting in 2019.

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Appendices

A. Informed Consent Forms (Telephone consent, Parental Consent, Child Assent, Adult Consent)
   a. Telephone Consent
   b. Parental Consent
   c. Child Assent (ages 14-17)
   d. Adult Consent (age 18)

B. Measures
   a. Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR)
   b. Diagnostic Interview Schedule for Children- Version IV (DISC-IV)
   c. Adolescent Survey
      i. Short Mood and Feelings Questionnaire (SMFQ-C)
      ii. Brief Resiliency Scale (BRS)
      iii. Adolescent Cognitive Style Questionnaire (ACSQ)
      iv. Ruminative Response Style scale – brooding factor (RRS-B)
      v. Test for Self-Conscious Affect for Adolescents (TOSCA-A)
      vi. Self-Compassion Scale (SCS)
      vii. Child and Adolescent Mindfulness Measure (CAMM)
      viii. Demographics
   d. Parent Survey
      i. Short Mood and Feelings Questionnaire (SMFQ-P)
      ii. Demographics
   e. PROMIS Pediatric Short Form (version 1.1)
   f. Expectation of Benefit / Credibility
   g. Daily Diary

C. Recruitment Materials
   a. Flyer
   b. Email Announcement

D. Data Safety Monitoring Plan (without Appendices)

Appendix A.a: Telephone Consent (version 0.3, 7 June 2017)

Screening ID: _____

University of North Carolina-Chapel Hill
Telephone Consent and Screening Form

Consent Form Version Date: 7 June 2017
IRB Study # 16-1864
Title of Study: The S.M.A.R.T. Project: Stress Management and Resilience Training for Teens
Principal Investigator: Susan Gaylord, PhD
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: 919-966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Co-Investigators: Karen Bluth, PhD; April Harris-Britt, PhD; Kim Faurot, PhD; Chirayath Suchindran, PhD
Funding Source and/or Sponsor: NIH National Center for Complementary and Integrative Health (NCCIH).

********** (NOTE: Personal identifiers are NOT to be written on this sheet) **********

Instructions for screening staff: Logon to REDcap website, select screening project and enter data directly into REDcap.

Leaving voicemail message:

Hello, this call is for _____ (*parent of child*). My name is_____. I am a (researcher/research assistant) from the University of North Carolina at Chapel Hill working with Dr. Gaylord on a research on the S.M.A.R.T project, which is a study to learn about mood in teens and to find out if emotional well-being can be improved with an 8-week class. I am calling because you or your child indicated that you would like to be contacted for more information about our study. I'm sorry I missed you. I'd like to speak with you about the study in more detail. We will try to reach you again later or if you'd like, you may call our office at 919-966-8586 and ask for the S.M.A.R.T. project. If you reach our voice mail, please leave a message as to the best time to return your call. Thank you for interest and we hope to talk with you soon.

Incoming study inquiry calls—if the youth calls, ask for the parent or guardian first

Hello, this is _____, (researcher/research assistant) with the S.M.A.R.T. project at UNC, which is a study to improve well-being in teens. Thank you for your interest in our study.

If not already known: **First, could I ask you how you found out about the study?**

_____UNC All User e-mail broadcast
_____Newspaper Ad: If yes, Name of newspaper: _____
_____Friend/Acquaintance
_____Flyer/Poster
_____MD; Name of MD or Clinic_____
_____Clinical trials.gov
_____Other, specify _____

Okay, great. Next, I'd like to tell you about the study. The purpose of this study is to learn about mood in teens and whether emotional well-being can be improved with an 8-week, stress management and resilience training program. We have two programs that we are studying, and if eligible, we will ask your child to participate in one of them. Overall, the course is designed to last 8 months and consists of 8 weekly sessions followed by monthly booster sessions for 6 months.

If your child qualifies for the study after answering the screening questions, we will ask you to come in for a visit to review and sign a separate informed consent form for the main study. If you and your child agree to join the study during this visit, we will ask you and your child to attend a visit with our study psychologist for an evaluation to determine your child's eligibility to participate based on the study's requirements. If your child is eligible, we will randomize your child to one of two programs. To randomize means that the choice of curricula your child will receive is decided by a computer and not by you or us. Your child will come to a 1 ¾ hour class once per week for 8 weeks to learn strategies to improve his or her emotional well-being. After the first 8 weeks, your child will return for a 90-minute follow-up "booster session" once per month for six months. In addition to the sessions, we will ask your child to complete 5 online surveys at different time points during the study that take no longer than 30 minutes. Also, during the 8-week course, we will ask your child to complete 5-15 minutes of home practice each day, complete a daily diary, and complete brief (<5 minutes) weekly surveys to assess mood.

Along with the child's assessment, we will also ask you, their parent, to complete brief online surveys on 5 different occasions during the study.

If this still sounds like something you would like your child to participate in, I'll just need to ask you some questions to see if your child may be eligible to complete the enrollment visit. You can stop me at any time and you may refuse to answer any question you do not wish to answer. Do I have your permission to ask some general questions?

Parent response: No_____ Yes _____ (*If no thank them for their time and end the call).*
(If they answer yes, proceed)

Thank you for agreeing to talk with me at this time. First, I will ask you some general questions:

1. What is your full name? _____
2. What is your child's name? _____
3. How are you related to the child? ___Mother ___father ____grandparent ____other guardian
4. How old is your child? ___ __ years (*If less than 14 or greater than 17, stop and thank the parent for their interest. Explain that only individuals 14-17 are eligible to participate.*
5. What is your child's gender? ____Male or _____Female
6. How would you describe your child's race? ____White ___Black OR African American ___African ___ American Indian or Alaskan Native ___Asian ___Native Hawaiian or other Pacific Islander ___More than one race ___Unknown or Not Reported
7. Do you consider your child to be Hispanic or Latino? _____ Yes ____ No
8. Is your child able to read and communicate in English? ____ No (***STOP****, ineligible*) ____Yes (*continue)*
9. Have you been concerned about your child's mood? ____ No ____Yes
10. Are you willing to allow your child to have a clinical mental health assessment with our study psychologist? ____ No (***STOP****, ineligible*) ____Yes (*continue)*

11. Are you willing to allow your child to be randomized to one of the two programs? ____ No (***STOP,*** *ineligible*) ____Yes (*continue)*

12. Are you willing and able to transport your child (as needed) to enable your child to attend the class sessions and complete assessments?
____ No (***STOP,*** *person is ineligible*) ____Yes (*continue*)

13. Does your child have regular internet access by at least one device? ____ No (***STOP,*** *person is ineligible*) ____Yes (*continue*)

14. Has your child had any prior formal training in mindfulness, such as a mindfulness course? ____ No (*continue*) ____Yes (***STOP,*** *person is ineligible*)

Next, I would like to read off a list of questions to determine your child's eligibility to continue to participate in the study. In order to protect your privacy, I do not want you to answer each question, individually. Instead, wait until I have finished reading from the entire list, and if your answer would be "yes" to any of them, say "yes" when I am finished. Do I have your permission to ask these questions?

Parent response: No_____ Yes _____ *(If no, let them know that there is the option to go over these questions in the first visit with Dr. Harris-Britt. If they answer yes, proceed)*

(1) Has your child been diagnosed with a severe mental illness like bipolar disorder or schizophrenia?
(2) Does your child currently have an active substance abuse problem?
(3) Does your child have severe autism?
(4) Has your child been hospitalized for mental illness in the past 2 years?

Would your response to any of these questions be "yes?"
Parent response: No_____ Yes _____ *(If they have any yes responses, thank them for their time and end the call). (If they answer no, proceed)*

I will need to speak with your child to describe the study and see if your child is interested in participating. If so, I will send you and your child a link to our screening survey for your child to complete. This survey will ask your child about his or her feelings at present. If the score on this screening survey meets the criteria for the study, the next step is the enrollment, or baseline, study visit. We will contact you again, and, with your permission, we'll make an appointment for you and your child to see our study psychologist, Dr. April Harris-Britt, at her office in Durham. We will send you detailed information by mail or email (as you prefer) about the study procedures prior to the visit. Your child will receive a $25 Amazon gift card for attending this visit and you will receive a $25 gas card.

Obtain contact information for parent/guardian:

Phone number: _____

Email address: _____

*Preferred Dates/Times for Follow-up call*_____

Great! I have just a couple additional things to tell you before I ask to speak with your child. First, this study is funded by the National Institutes of Health. Dr. Karen Bluth, one of the researchers, is an author/owner of one of the curricula and receives compensation for training teachers.

Also, all research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights or your child's rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Could I speak with your child to describe the study?

Participant response: No_____ Yes _____ *(If they answer yes, and the youth is available, ask for the child's name proceed to the next section. If the youth is unavailable, ask for the youth's name and contact information and a preferred time for the call). (If they answer no, thank them for their time and end the call)*

Describe study to youth

Hello, this is _____, (researcher/research assistant) with the S.M.A.R.T. project at UNC, which is a study to improve well-being in teens. Thank you for your interest in our study. Your parent (or guardian) has given me permission to tell you about the study.

Do you have time to hear a bit about the study now?

Youth response: No_____ Yes _____ *(If no thank them for their time and ask if you may call them back. Request contact information and a preferred time for the call)*

Phone number_____ Carrier, if youth prefers to be texted first: _____

Good times to call: _____
(If they answer yes, proceed)

This is an 8-month study to find out if participating in one of two 8-week classes and monthly booster sessions for 6 months can promote health and well-being in youth. We are looking for teens who are already feeling some stress. If you qualify for the study after completing the screening questions online, we will ask you and your parent or guardian to attend a visit with our Psychologist for an evaluation. At that time, we will review all of the study requirements with you both and determine if you are eligible to participate in the study. If you are eligible, we will randomly assign you to one of two sets of classes. This means that the choice of classes is decided by a computer and not by you or us. You will come to a 1 ¾ hour class once per week for 8 weeks to learn strategies to improve your well-being. After the first 8 weeks, you will return for a follow-up booster class once per month for six months. You will complete 5 on-line surveys no longer than 30 minutes as well as brief (<5 minutes) weekly surveys to assess mood. You will also be asked to practice what you learn in the classes for 5-15 minutes each day with help from an app that you can download to your phone, tablet, or computer. To compensate you for your time, you will receive Amazon gift cards for completing the baseline visit, the five longer on-line surveys, and your home practice. If you complete all of these, you will receive gift cards worth $175. You will sign a separate informed assent form prior to the start of the main study.

If this sounds like something you would like to participate in, we would like for you to complete the screening survey. I can send you a link to the survey either by email or by text. Is this something you think you might like to do?

Youth response: No_____ Yes _____ *(If no thank them for their time.)*

(If they answer yes or maybe, proceed)

Phone number **WITH CARRIER**, if youth prefers to be texted: _____

Email, if youth prefers: _____

Thank you very much for your willingness to consider our study. We will look forward to reviewing your responses on the survey and speaking with you again!

During the telephone call, participants are also assessed for impaired cognition. Impaired cognition is determined by assessing if the participant has the ability to follow and respond appropriately to screening questions. Cognition will continue to be assessed throughout the study enrollment; continued participation will be at the discretion of the study personnel and study physician.

During this telephone call, has the participant been able to follow and respond appropriately to screening questions?

No_____ Yes_____

Please provide further information below to describe why you think this participant has impaired cognition and should not be considered to participate further in this study.

_____	_____	_____
Signature of Study Staff Member Obtaining Telephone Consent	Printed name of person obtaining consent	Date

Appendix A.b: Parent Consent (version 0.3, 1 June 2017)

University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: 1 June 2017
IRB Study # 16-1864
Title of Study: The S.M.A.R.T Project: Stress Management and Resilience Training for Teens
Principal Investigator: Susan Gaylord, PhD
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: 919-966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Co-Investigators: Karen Bluth, PhD; April Harris-Britt, PhD; Kim Faurot, PhD; Chirayath Suchindran, PhD
Funding Source and/or Sponsor: NIH National Center for Complementary and Integrative Health (NCCIH).

What are some general things you and you child should know about research studies? You and your child are being asked to take part in a research study. To join the study is voluntary. You may refuse to join and give permission for your child, or you may withdraw your permission for you and your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early. Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher, the health care provider, or the University of North Carolina-Chapel Hill. Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study. You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study? The purpose of this research study is to learn about mood in teens, and whether emotional wellbeing can be improved with an 8-week class. Your child is being asked to be in the study because he or she is between the ages of 14 and 17.

How many people will take part in this study? There will be approximately 80 teens and 80 parents in this research study.

What will happen if you and your child take part in the study?

If you and your child decide to participate in this study, you and your child will have a meeting with the study psychologist, who will determine eligibility. If your child is eligible to participate, your child will be placed in one of two programs with 8-week classes. While enrolled in the classes, your child may have some skills practice to do at home each day, but this should take no longer than 15 minutes. Your child will receive a text reminder daily asking a few questions about his or her home practice and a brief survey each week. If an instructor of the class or the results of a survey indicate that your child may be experiencing depression, we will refer your child to the study psychologist who will contact you to arrange for evaluation of your child. All classes will be audiotaped.

You will be asked to complete a short online assessment at four separate time points: prior to the beginning of your child's 8-week course, after the course is over, 3 months after the course is over, and 6 months after the course is over.

As part of the study, your child will be required to download and use an app. This app may monitor your child's usage. Before your child downloads the app, we will provide you with a link to their Privacy Policy. You are encouraged to review the policy and decide if you want your child to continue in this study.

How long will you and your child's part in this study last? Your child will attend 8 weekly 1 3/4 hour sessions followed by 6 monthly 90-minute 'booster' sessions. Your child will take 5 online surveys that will take no longer than 30 minutes each to complete; one survey will be taken prior to the course, one will be taken halfway through the course, one will be taken at the conclusion of the course, one will be taken 3 months after the end of the class, and the last will be taken 6 months after the class is over. Your child will also take a very brief survey each week to monitor depression symptoms. You will complete a brief (5-minute) assessment of your child's depression symptoms before and after the 8-week class and at 3 and 6 months after the class.

Your child is asked to complete 5 – 15 minutes of home practice each day. Also, your child will be asked to participate in a 30 minute focus group at the conclusion of the class. You and your child's entire involvement with the study will extend over approximately 8 months.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. You may benefit from your child learning tools to deal with challenges in adolescence. Your child may benefit from learning tools to deal with challenges in adolescence.

What are the possible risks or discomforts involved from being in this study? There is a slight possibility the questions may make you feel uncomfortable. Please remember that you don't have to answer any questions that you don't want to. There is also the possibility the questionnaires may cause your child to feel distressed or uncomfortable. S/he does not have to answer any questions that s/he does not want to. Your child may not like participating in the course or doing the at-home practice. S/he can decide at any time that s/he does not want to go to a class, withdraw from the course, or that s/he doesn't want to do the at-home practice. Additionally, if we suspect that your child is experiencing any emotional challenges, you will be contacted by Dr. April Harris-Britt, a licensed clinical psychologist who works with adolescents. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study? You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about you and your child be protected? Every effort will be taken to protect you and your child's identity in this study. We will use a special number to identify you and your child rather than using you or your child's name in all our paperwork. We will keep personal identifying information needed to contact you separate from all information collected as part of this study, in a password protected computer file.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, you or your child's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What if you or your child wants to stop before your child's part in the study is complete? You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because your child has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

Will your child receive anything for being in this study? Your child will receive Amazon gift cards: $25 for the baseline visit with the study psychologist, $25 for each of 5 online surveys, and $25 for completing 80% of the homework. In addition, you (the parent) will receive up to $175 in gas cards for travel expenses; parking vouchers will also be provided.

Will it cost you anything for your child to be in this study? It will probably not cost your family anything to be in this study. However, since your child will receive text messages as reminders and the

homework apps may require an internet connection, if you have limited cell phone or internet service, you may incur some charges.

Who is sponsoring this study? This research is funded by the NIH National Center for Complementary and Integrative Health (NCCIH) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. Karen Bluth, a co-investigator on this study, has an authorship /ownership interest in an educational curriculum which will be used and evaluated in this study. In addition, Karen Bluth receives money for training teachers related to this program. If this program or training approach is successful at some point in the future, Karen Bluth may receive financial benefits.

A committee at the University of North Carolina at Chapel Hill has reviewed these financial arrangements. They concluded that the possible benefit to the person(s) listed above is not likely to affect your safety or the scientific quality of the study. If you would like more information, please ask the researchers listed on the first page of this form.

What if you or your child has questions about this study? You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form.

What if there are questions about your child's rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Parent's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study and give permission to allow my child to participate in this research study.

_____
Printed Name of Child Research Subject

_____
Printed Name of Parent Research Subject

_____ _____
Signature of Parent Research Subject Date

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

Appendix A.c: Child Assent (ages 14-17) (version 0.3, 1 June 2017)

University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Adolescent Participants age 14-17

Consent Form Version Date: 1 June 2017
IRB Study # 16-1864
Title of Study: The S.M.A.R.T. Project: Stress Management and Resilience Training for Teens
Principal Investigator: Dr. Susan Gaylord
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: 919-966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Co-Investigators: Drs. Karen Bluth, April Harris-Britt, Kim Faurot, Chirayath Suchindran
Funding Source and/or Sponsor: NIH National Center for Complementary and Integrative Health (NCCIH)

What are some general things you should know about research studies? You are being asked to take part in a research study. Your parent, or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study? The purpose of this research study is to learn about mood in teens, and whether emotional wellbeing can be improved with an 8 week class. You are being asked to participate in this study because you are between the ages of 14 and 17.

How many people will take part in this study? There will be approximately 80 teens in this research study.

What will happen if you take part in the study? If you decide to participate in this study, you and your parent or guardian will meet with a study psychologist who will determine eligibility. You will then be placed in one of two programs of 8-week classes. The choice of programs is decided by a random process in a computer. We are not able to choose who is assigned to which group.

While enrolled in the class, you may have some skills practice to do at home each day, but this should take no longer than 15 minutes. You will receive a text reminder daily asking a few questions about your home practice. Once a week, you will complete a short survey about your feelings. If an instructor of the class or the results of the survey indicate that you may be

experiencing depression, we will refer you to the study psychologist for evaluation. All classes will be audiotaped.

How long will your part in this study last? You will attend 8 weekly 1 3/4 hour classes, and then 6 monthly 90-minute classes—one time a month for 6 months. There will be 5 online surveys that will take no more than 30 minutes each to complete; one survey will be taken immediately prior to the class, one will take place halfway through the class, one will be taken at the conclusion of the class, one will be taken 3 months after the end of the class, and the last will be taken 6 months after the class is over. Once every week you will complete a brief survey asking about your feelings. This survey should take no more than 5 minutes to complete.

In addition, there will be 5-15 minutes of at-home practice each day. You will be asked to download an app on your smartphone or computer to help reinforce what you've learned in class. Also, you will be asked to participate in a 30-minute focus group after the class is over. Your entire involvement with the study will extend over approximately 8 months.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. You may benefit from learning tools to deal with challenges in adolescence.

What are the possible risks or discomforts involved from being in this study? There is the possibility the questions may make you feel uncomfortable. Please remember that you don't have to answer any questions that you don't want to. If you decide that you don't like the course or doing the at-home practice, you can withdraw from the course, or skip a class. Also, there may be uncommon or previously unknown risks. You should report any problems to a member of the research team.

How will information about you be protected? Every effort will be taken to protect your identity in this study. We will use a special number to identify you rather than using your name in all our paperwork.

No subjects will be identified in any report or publication about this study. However, in some cases, representatives of the University, research sponsors, or government agencies could review your information in this research study for various reasons.

What if you want to stop before your part in the study is complete? You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study? You will receive Amazon gift cards for participating in the study: $25 for the baseline visit with the study psychologist, $25 for each of 5 online surveys, and $25 for completing 80% of the homework, for a possible total of $175 in gift cards.

Will it cost you anything to be in this study? It will probably not cost you anything to be in this study. However, since you will be reminded to do your homework through text messages and the homework apps may require connection to the internet, if you have limited cell phone service or limited internet, you and your family may incur charges.

Who is sponsoring this study?
This research is funded by the NIH National Center for Complementary and Integrative Health (NCCIH) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. In addition, Karen Bluth, a co-investigator on this study, is the author and owner of one of the programs, which you will learn about as part of this study, and also receives money for training teachers.

A committee at the University of North Carolina at Chapel Hill has reviewed these financial arrangements. They concluded that the possible benefit to the person(s) listed above is not likely to affect your safety or the scientific quality of the study. If you would like more information, please ask the researchers listed on the first page of this form.

What if you have questions about this study? You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Your signature if you agree to be in this study	Date
Your printed name if you agree to be in this study	
Signature of person obtaining assent	Date
Printed name of person obtaining assent	

Appendix A.d: Adult Consent (version 0.3, 1 June 2017)

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants (For subjects who turn 18 years old)

Consent Form Version Date: 1 June 2017
IRB Study # 16-1864
Title of Study: The S.M.A.R.T Project: Stress Management and Resilience Training for Teens
Principal Investigator: Dr. Susan Gaylord
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: 919-966-8586
Principal Investigator Email Address: gaylords@med.unc.edu
Co-Investigators: Drs. Karen Bluth, April Harris-Britt, Kim Faurot, Chirayath Suchindran
Funding Source and/or Sponsor: NIH National Center for Complementary and Integrative Health (NCCIH)

What are some general things you should know about research studies? You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study? The purpose of this research study is to learn about mood in teens, and whether emotional wellbeing can be improved with an 8 week class. You are being asked to participate in this study because you are 18 years old.

How many people will take part in this study? There will be approximately 80 teens in this research study.

What will happen if you take part in the study? If you decide to participate in this study, you and your parent or guardian will meet with a study psychologist who will determine eligibility. You will then be placed in one of two programs with 8-week classes. The choice of programs is decided by a random process in a computer. We are not able to choose who is assigned to which group.

While enrolled in the class, you may have some skills practice to do at home each day, but this should take no longer than 15 minutes. You will receive a text reminder daily asking a few questions about your home practice and a short survey each week. If an instructor of the class or

the results of the survey indicate that you may be experiencing depression, we will refer you to the study psychologist for evaluation. All classes will be audiotaped.

You will be required to download and use an app. This app may monitor your usage and track your device using your IP address,. Before you download the apps, we will provide you with a link to their Privacy Policy. We will ask you to read their Privacy Policy before deciding if you want to remain in this study.

How long will your part in this study last? You will attend 8 weekly 1 3/4 hour classes, and then 6 monthly 90-minute classes—one time a month for 6 months. There will be 5 online surveys that will take no longer than 90 minutes each to complete; one survey will be taken immediately prior to the class, one will be taken halfway through the class, one will be taken at the conclusion of the class, one will be taken 3 months after the end of the class, and the last will be taken 6 months after the class is over. Once every week you will complete a brief survey asking about your feelings. This survey should take no more than 5 minutes to complete.

In addition, there will be 5-15 minutes of at-home practice each day. Also, you will be asked to participate in a 30 minute focus group after the class is over. Your entire involvement with the study will extend over approximately 8 months.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. You may benefit from learning tools to deal with challenges in adolescence.

What are the possible risks or discomforts involved from being in this study? There is the possibility the questions may make you feel uncomfortable. Please remember that you don't have to answer any questions that you don't want to. If you decide that you don't like the course or doing the at-home practice, you can withdraw from the course, or skip a class. Also, there may be uncommon or previously unknown risks. You should report any problems to a member of the research team.

How will information about you be protected? Every effort will be taken to protect your identity in this study. We will use a special number to identify you rather than using your name in all our paperwork. No subjects will be identified in any report or publication about this study. However, in some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for various reasons.

What if you want to stop before your part in the study is complete? You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study? You will receive Amazon gift cards for participating in the study: $25 for the baseline visit with the study psychologist, $25 for each of 5 online surveys, and $25 for completing 80% of the homework, for a possible total of $175 in gift cards.

Will it cost you anything to be in this study? It will probably not cost you anything to be in this study. However, since you will be reminded to do your homework through text messages

and the homework apps may require connection to the internet, if you have limited cell phone service or limited internet, you and your family may incur charges.

Who is sponsoring this study? This research is funded by *the* NIH National Center for Complementary and Integrative Health (NCCIH) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. Karen Bluth, a co-investigator on this study, has an authorship /ownership interest in an educational curriculum which will be used and evaluated in this study. In addition, Karen Bluth receives money for training teachers related to this program. If this program or training approach is successful at some point in the future, Karen Bluth may receive financial benefits.

A committee at the University of North Carolina at Chapel Hill has reviewed these financial arrangements. They concluded that the possible benefit to the person(s) listed above is not likely to affect your safety or the scientific quality of the study. If you would like more information, please ask the researchers listed on the first page of this form.

What if you have questions about this study? You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

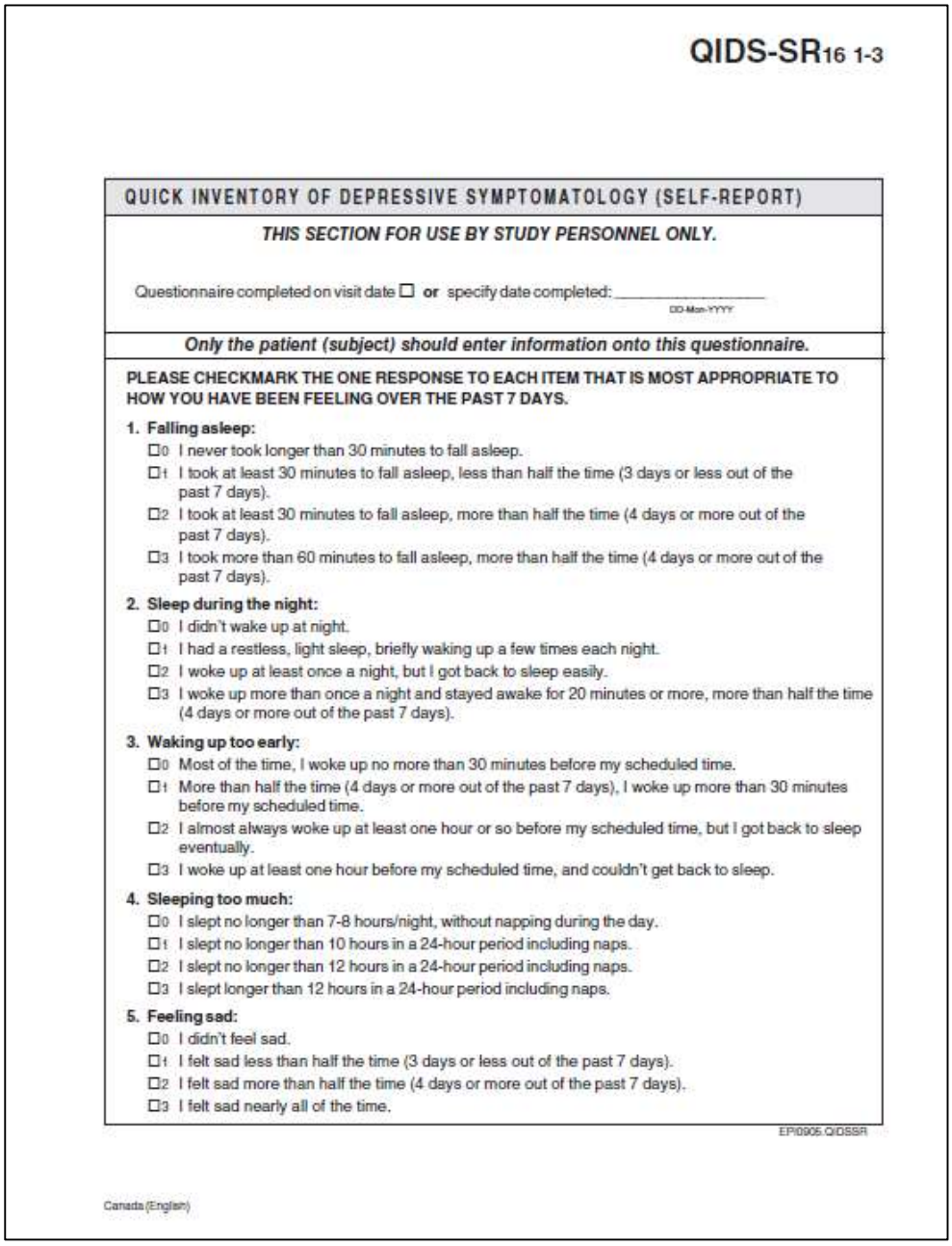
What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Your signature if you agree to be in this study	Date
Your printed name if you agree to be in this study	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Appendix B.a: QIDS-SR



QIDS-SR16 1-3

QUICK INVENTORY OF DEPRESSIVE SYMPTOMATOLOGY (SELF-REPORT)

THIS SECTION FOR USE BY STUDY PERSONNEL ONLY.

Questionnaire completed on visit date ☐ **or** specify date completed: _____
DD-Mon-YYYY

Only the patient (subject) should enter information onto this questionnaire.

PLEASE CHECKMARK THE ONE RESPONSE TO EACH ITEM THAT IS MOST APPROPRIATE TO HOW YOU HAVE BEEN FEELING OVER THE PAST 7 DAYS.

1. **Falling asleep:**
   - ☐0 I never took longer than 30 minutes to fall asleep.
   - ☐1 I took at least 30 minutes to fall asleep, less than half the time (3 days or less out of the past 7 days).
   - ☐2 I took at least 30 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days).
   - ☐3 I took more than 60 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days).
2. **Sleep during the night:**
   - ☐0 I didn't wake up at night.
   - ☐1 I had a restless, light sleep, briefly waking up a few times each night.
   - ☐2 I woke up at least once a night, but I got back to sleep easily.
   - ☐3 I woke up more than once a night and stayed awake for 20 minutes or more, more than half the time (4 days or more out of the past 7 days).
3. **Waking up too early:**
   - ☐0 Most of the time, I woke up no more than 30 minutes before my scheduled time.
   - ☐1 More than half the time (4 days or more out of the past 7 days), I woke up more than 30 minutes before my scheduled time.
   - ☐2 I almost always woke up at least one hour or so before my scheduled time, but I got back to sleep eventually.
   - ☐3 I woke up at least one hour before my scheduled time, and couldn't get back to sleep.
4. **Sleeping too much:**
   - ☐0 I slept no longer than 7-8 hours/night, without napping during the day.
   - ☐1 I slept no longer than 10 hours in a 24-hour period including naps.
   - ☐2 I slept no longer than 12 hours in a 24-hour period including naps.
   - ☐3 I slept longer than 12 hours in a 24-hour period including naps.
5. **Feeling sad:**
   - ☐0 I didn't feel sad.
   - ☐1 I felt sad less than half the time (3 days or less out of the past 7 days).
   - ☐2 I felt sad more than half the time (4 days or more out of the past 7 days).
   - ☐3 I felt sad nearly all of the time.

EPI0905.QIDSSR

Canada (English)

QIDS-SR16 2-3

QUICK INVENTORY OF DEPRESSIVE SYMPTOMATOLOGY (SELF-REPORT)

PLEASE CHECKMARK THE ONE RESPONSE TO EACH ITEM THAT IS MOST APPROPRIATE TO HOW YOU HAVE BEEN FEELING OVER THE PAST 7 DAYS.

Please complete either 6 or 7 (not both)

6. Decreased appetite:

- ☐0 There was no change in my usual appetite.
- ☐1 I ate somewhat less often or smaller amounts of food than usual.
- ☐2 I ate much less than usual and only by forcing myself to eat.
- ☐3 I rarely ate within a 24-hour period, and only by really forcing myself to eat or when others persuaded me to eat.

7. Increased appetite:

- ☐0 There was no change in my usual appetite.
- ☐1 I felt a need to eat more frequently than usual.
- ☐2 I regularly ate more often and/or greater amounts of food than usual.
- ☐3 I felt driven to overeat both at mealtime and between meals.

Please complete either 8 or 9 (not both)

8. Decreased weight (within the last 14 days):

- ☐0 My weight has not changed.
- ☐1 I feel as if I've had a slight weight loss.
- ☐2 I've lost 2 pounds (about 1 kilo) or more.
- ☐3 I've lost 5 pounds (about 2 kilos) or more.

9. Increased weight (within the last 14 days):

- ☐0 My weight has not changed.
- ☐1 I feel as if I've had a slight weight gain.
- ☐2 I've gained 2 pounds (about 1 kilo) or more.
- ☐3 I've gained 5 pounds (about 2 kilos) or more.

10. Concentration/decision-making:

- ☐0 There was no change in my usual ability to concentrate or make decisions.
- ☐1 I occasionally felt indecisive or found that my attention wandered.
- ☐2 Most of the time, I found it hard to focus or to make decisions.
- ☐3 I couldn't concentrate well enough to read or I couldn't make even minor decisions.

11. Perception of myself:

- ☐0 I saw myself as equally worthwhile and deserving as other people.
- ☐1 I put the blame on myself more than usual.
- ☐2 For the most part, I believed that I caused problems for others.
- ☐3 I thought almost constantly about major and minor defects in myself.

12. Thoughts of my own death or suicide:

- ☐0 I didn't think of suicide or death.
- ☐1 I felt that life was empty or wondered if it was worth living.
- ☐2 I thought of suicide or death several times for several minutes over the past 7 days.
- ☐3 I thought of suicide or death several times a day in some detail, or I made specific plans for suicide or actually tried to take my life.

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Canada (English)

QUICK INVENTORY OF DEPRESSIVE SYMPTOMATOLOGY (SELF-REPORT)

PLEASE CHECKMARK THE ONE RESPONSE TO EACH ITEM THAT IS MOST APPROPRIATE TO HOW YOU HAVE BEEN FEELING OVER THE PAST 7 DAYS.

13. General interest:

- ☐0 There was no change from usual in how interested I was in other people or activities.
- ☐1 I noticed that I was less interested in other people or activities.
- ☐2 I found I had interest in only one or two of the activities I used to do.
- ☐3 I had virtually no interest in the activities I used to do.

14. Energy level:

- ☐0 There was no change in my usual level of energy.
- ☐1 I got tired more easily than usual.
- ☐2 I had to make a big effort to start or finish my usual daily activities (for example: shopping, homework, cooking or going to work).
- ☐3 I really couldn't carry out most of my usual daily activities because I just didn't have the energy.

15. Feeling more sluggish than usual:

- ☐0 I thought, spoke, and moved at my usual pace.
- ☐1 I found that my thinking was more sluggish than usual or my voice sounded dull or flat.
- ☐2 It took me several seconds to respond to most questions and I was sure my thinking was more sluggish than usual.
- ☐3 I was often unable to respond to questions without forcing myself.

16. Feeling restless (agitated, not relaxed, fidgety):

- ☐0 I didn't feel restless.
- ☐1 I was often fidgety, wringing my hands, or needed to change my sitting position.
- ☐2 I had sudden urges to move about and was quite restless.
- ☐3 At times, I was unable to stay seated and needed to pace around.

Rush et al, Biol Psychiatry (2003) 54: 573-83.

EPI0905.QIDSSR

I confirm this information is accurate.	Patient's/Subject's initials:	Date:

Canada (English)

QIDS-SS

QUICK INVENTORY OF DEPRESSIVE SYMPTOMATOLOGY (SCORE SHEET)

NOTE: THIS SECTION IS TO BE COMPLETED BY THE STUDY PERSONNEL ONLY.

_____ Enter the highest score on any 1 of the 4 sleep items (1-4)

_____ Item 5

_____ Enter the highest score on any 1 of the appetite/weight items (6-9)

_____ Item 10

_____ Item 11

_____ Item 12

_____ Item 13

_____ Item 14

_____ Enter the highest score on either of the 2 psychomotor items (15 and 16)

_____ **Total Score (Range: 0-27)**

Rush et al, Biol Psychiatry (2003) 54: 573-83.

EPI0905.QIDSSR

Canada (English)

Appendix B.b: Diagnostic Interview Schedule for Children- Version IV (DISC-IV)

Only the Depression Section of DISC-IV shown.

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

START NEW CARD
DUP COL 1 - 10

MOD. C 1 [11 - 12]

CARD NO. 0 1 [13 - 14]
b [15]

MDD

I'm now going to ask you some questions about feeling sad and unhappy.

1.	In the last year – that is, since [[NAME EVENT]/[NAME CURRENT MONTH] of last year] – was there a time when you often felt sad or depressed?	0	2	7	9	[16]
	IF YES, A. Was there a time in the last year when you felt sad or depressed for a long time each day?	0	2	7	9	[17]
	IF NO, GO TO Q 2					
	B. Would you say that you felt that way for most of the day?	0	2	7	9	[18]
	C. Was there a time when you felt sad or depressed almost every day?	0	2	7	9	[19]
	IF NO, GO TO Q 2					
	IF YES, D. In the last year, were there two weeks in a row when you felt sad or depressed almost every day?	0	**2***	7	9	[20]
	IF NO, GO TO Q 2					
	E. When you were sad or depressed, did you feel better if something good happened or was about to happen to you?	0	2	7	9	[21]
	F. Now, what about the last four weeks? Since [[NAME EVENT]//the beginning of/the middle of/the end of [LAST MONTH]], have you felt sad or depressed?	0	2	7	9	[22]
2.	In the last year – that is, since [NAME CURRENT MONTH] of last year – was there a time when nothing was fun for you and you just weren't interested in anything?	0	2	7	9	[23]
	IF YES, A. Was there a time when nothing was fun for you almost every day?	0	2	7	9	[24]
	IF NO, GO TO Q 3					
	B. In the last year, were there two weeks in a row when you felt nothing was fun almost every day?	0	[2]	7	9	[25]
	IF NO, GO TO Q 3					
	C. Now, what about the last four weeks? *(Since [[NAME EVENT]//the beginning of/the middle of/the end of [LAST MONTH]])*, has there been a time when nothing was fun for you?	0	2	7	9	[26]

Module C: Mood Disorders
Major Depression/Dysthymic Disorder
DISC IV-Y, past year

Page 1

[10/09/03]

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9, 99=DON'T KNOW	

3.	In the last year (*that is, since [NAME CURRENT MONTH] of last year*), was there a time when you often felt grouchy or irritable and often in a bad mood, when even little things would make you mad?	0	2	7	9	[27]
IF YES,	A. Was there a time in the last year when you felt grouchy or irritable for a long time each day?	0	2	7	9	[28]
	IF NO, GO TO NOTE 1					
	B. Would you say that you felt that way for most of the day?	0	2	7	9	[29]
	C. Was there a time when you felt grouchy or irritable almost every day?	0	2	7	9	[30]
	IF NO, GO TO NOTE 1					
IF YES,	D. In the last year, were there two weeks in a row when you felt grouchy or irritable almost every day?	0	**2***	7	9	[31]
	IF NO, GO TO NOTE 1					
	E. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you often felt grouchy or irritable and in a bad mood?	0	2	7	9	[32]

NOTE 1:	**WERE ANY * OR [ ] RESPONSES CODED IN Q 1 - 3?**	0	2	[33]
	IF YES: **ASK BOXED CONTINGENT QUESTIONS FOR Q 4 - 22 IF CORRESPONDING STEM QUESTION IS POSITIVE** ***Use first * or [ ] response coded in Q 1 - 3 as "keyword" in [ ] when asking these questions***			
	IF NO: **DO NOT ASK BOXED CONTINGENT QUESTIONS**			

NOTE 2:	**WAS THERE A * RESPONSE CODED IN Q 1 OR 3?**	0	**[2]**	[34]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

4.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you lost weight?	0	2	7	9	[35]
	IF NO, GO TO Q 5					
	A. Were you on a diet or trying to lose weight?	0	2	7	9	[36]
	IF YES, B. In the last year, did you ever lose weight when you weren't trying?	0	2	7	9	[37]
	IF NO, GO TO Q 5					
	C. Did you lose so much weight that other people noticed?	0	2	7	9	[38]
	IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:					
	D. You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]. Did you lose weight during that time?	0	**2*#**	7	9	[39]
	E. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you lost weight?	0	2	7	9	[40]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

5.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you lost your appetite or often felt less like eating?	0	2	7	9	[41]

IF NO, GO TO Q 6

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

A.	You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]. Did you lose your appetite or often feel less like eating during that time?	0	**2***	7	9	[42]
IF YES, B.	Did you lose your appetite or feel less like eating nearly every day for two weeks or longer?	0	**2#**	7	9	[43]
C.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you lost your appetite or often felt less like eating?	0	2	7	9	[44]
6.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you gained a lot of weight?	0	2	7	9	[45]

IF NO, GO TO Q 7

A.	Did you gain so much weight that other people noticed?	0	2	7	9	[46]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B.	You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]. Did you gain a lot of weight during that time?	0	**2*#**	7	9	[47]
C.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you gained weight?	0	2	7	9	[48]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

7.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you felt much hungrier than usual or when you ate a lot more than usual?	0	2	7	9	[49]

IF NO, GO TO NOTE 3

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

A.	You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]. Were you much hungrier or did you eat a lot more than usual during that time?	0	**2***	7	9	[50]
IF YES, B.	Did you feel much hungrier or eat a lot more than usual nearly every day for two weeks or longer?	0	**2#**	7	9	[51]
C.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you felt much hungrier or often eaten a lot more than usual?	0	2	7	9	[52]

NOTE 3:	**WAS THERE A * RESPONSE CODED IN Q 4 - 7?**	0	**[2]**	[53]
	WAS THERE A # RESPONSE CODED IN Q 4 - 7?	0	**‹2›**	[54]

8.	In the last year – that is, since [NAME CURRENT MONTH] of last year – was there a time when you had trouble sleeping, that is, trouble falling asleep, staying asleep, or waking up too early?	0	2	7	9	[55]

IF NO, GO TO Q 9

A.	When you had trouble sleeping, was that different from how you usually sleep?	0	2	7	9	[56]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B.	*(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you have trouble sleeping during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]?	0	**2***	7	9	[57]
IF YES, C.	Did you have trouble sleeping nearly every night for two weeks or longer?	0	**2#**	7	9	[58]
D.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you had trouble sleeping?	0	2	7	9	[59]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

9. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you slept more during the day than you usually do? 0 2 7 9 [60]

IF NO, GO TO NOTE 4

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

A. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you sleep more during the day during [the time you felt [sad or depressed/like nothing was fun/ grouchy]/that time]? 0 **2*** 7 9 [61]

IF YES, B. Did you sleep more during the day nearly every day for two weeks or longer? 0 **2#** 7 9 [62]

C. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you slept more during the day than you usually do? 0 2 7 9 [63]

NOTE 4: WAS THERE A * RESPONSE CODED IN Q 8 - 9? 0 **[2]** [64]

WAS THERE A # RESPONSE CODED IN Q 8 - 9? 0 **-2-** [65]

10. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you often felt slowed down ... like you walked or talked much slower than you usually do? 0 2 7 9 [66]

IF NO, GO TO Q 11

A. Did other people notice that you were slowed down? 0 2 7 9 [67]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you often feel slowed down during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]? 0 **2*** 7 9 [68]

IF YES, C. Did you feel slowed down like this nearly every day for two weeks or longer? 0 **2#** 7 9 [69]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you felt slowed down? 0 2 7 9 [70]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

11.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you often felt restless … like you just had to keep walking around?	0	2	7	9	[71]
	IF NO, GO TO NOTE 5					
	A. When you felt restless like that, was that different from how you usually feel?	0	2	7	9	[72]
	B. Did other people notice that you were restless?	0	2	7	9	[73]
	IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:					
	C. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you often feel restless during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]?	0	2*	7	9	[74]
	IF YES, D. Did you feel restless like this nearly every day for two weeks or longer?	0	2#	7	9	[75]
	E. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you often felt restless?	0	2	7	9	[76]

NOTE 5:	**WAS THERE A * RESPONSE CODED IN Q 10 - 11?**	0	[2]	[77]
	WAS THERE A # RESPONSE CODED IN Q 10 - 11?	0	2	[78]

START NEW CARD
DUP COL 1 - 12

CARD NO. 0 2 [13 - 14]
b [15]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

12.	In the last year – that is, since [NAME CURRENT MONTH] of last year] – was there a time when you had less energy than you usually do?	0	2	7	9	[16]

IF NO, GO TO Q 13

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

A.	*(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you have less energy during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]?	0	**2***	7	9	[17]
	IF YES, B. Did you have less energy than usual nearly every day for two weeks or longer?	0	**2#**	7	9	[18]
C.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you had less energy than you usually do?	0	2	7	9	[19]
13.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when doing even little things made you feel really tired?	0	2	7	9	[20]

IF NO, GO TO NOTE 6

A.	When you felt tired like this, was that different from how you usually feel?	0	2	7	9	[21]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B.	*(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you feel really tired during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]?	0	**2***	7	9	[22]
	IF YES, C. Did you feel really tired like this nearly every day for two weeks or longer?	0	**2#**	7	9	[23]
D.	Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you felt really tired?	0	2	7	9	[24]

NOTE 6:	**WAS THERE A * RESPONSE CODED IN Q 12 - 13?**	0	**[2]**	[25]
	WAS THERE A # RESPONSE CODED IN Q 12 - 13?	0	**2**	[26]

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9,99=DON'T KNOW	

14. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when your arms and legs felt heavy, like you were weighed down by them? 0 2 7 9 [27]

IF NO, GO TO Q 15

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

A. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did your arms and legs feel heavy during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]? 0 2 7 9 [28]

IF YES, B. Did your arms and legs feel heavy like this nearly every day for two weeks or longer? 0 2 7 9 [29]

C. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have your arms and legs felt heavy? 0 2 7 9 [30]

15. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you often blamed yourself for bad things that happened? 0 2 7 9 [31]

IF NO, GO TO Q 16

A. Was blaming yourself in that way different from how you usually feel about yourself? 0 2 7 9 [32]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you blame yourself like that during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]? 0 **2*** 7 9 [33]

IF YES, C. Did you blame yourself nearly every day for two weeks or longer? 0 **2#** 7 9 [34]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you often blamed yourself for bad things that happened? 0 2 7 9 [35]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

16.	In the last year – that is, since [NAME CURRENT MONTH] of last year] – was there a time when you felt you couldn't do anything well or that you weren't as good-looking or as smart as other people?	0	2	7	9	[36]
	IF NO, GO TO NOTE 7					
	A. When you felt bad about yourself, was that different from how you usually feel about yourself?	0	2	7	9	[37]
	IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:					
	B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did you feel bad about yourself during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]?	0	2*	7	9	[38]
	IF YES, C. Did you feel like this nearly every day for two weeks or longer?	0	2#	7	9	[39]
	D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you felt like you couldn't do anything well or that you weren't as good looking or as smart as other people?	0	2	7	9	[40]
	NOTE 7: WAS THERE A * RESPONSE CODED IN Q 15 - 16?	0	[2]			[41]
	WAS THERE A # RESPONSE CODED IN Q 15 - 16?	0	<2>			[42]
17.	In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you couldn't think as clearly or as fast as usual?	0	2	7	9	[43]
	IF NO, GO TO Q 18					
	IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:					
	A. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Did it seem like you couldn't think as clearly or as fast as usual during [the time you felt [sad or depressed/ like nothing was fun/grouchy]/that time]?	0	2*	7	9	[44]
	IF YES, B. Did it seem like you couldn't think as clearly or as fast as usual nearly every day for two weeks or longer?	0	2#	7	9	[45]
	C. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, has it seemed like you couldn't think as clearly or as fast as usual?	0	2	7	9	[46]

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9,99=DON'T KNOW	

18. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when you often had trouble keeping your mind on (your [schoolwork/work] or other) things? — 0 | 2 | 7 | 9 | [47]

IF NO, GO TO Q 19

A. When you had trouble keeping your mind on (your [schoolwork/work] or other) things, was that different from how you usually are when you're doing things? — 0 | 2 | 7 | 9 | [48]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]).* Did you often have trouble keeping your mind on (your [schoolwork/work] or other) things during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]? — 0 | **2*** | 7 | 9 | [49]

IF YES, C. Did you have trouble keeping your mind on your [schoolwork/work] or other things nearly every day for two weeks or longer? — 0 | **2#** | 7 | 9 | [50]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you often had trouble keeping your mind on (your [schoolwork/work] or other) things? — 0 | 2 | 7 | 9 | [51]

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9,99=DON'T KNOW	

19. In the last year *(that is, since [NAME CURRENT MONTH] of last year)*, was there a time when it was often hard for you to make up your mind or to make decisions? 0 2 7 9 [52]

IF NO, GO TO NOTE 8

A. When it was hard for you to make up your mind or to make decisions, was that different from how you usually are? 0 2 7 9 [53]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy].)* Was it hard for you to make up your mind or to make decisions during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]? 0 2* 7 9 [54]

IF YES, C. Was it hard for you to make up your mind or to make decisions nearly every day for two weeks or longer? 0 2# 7 9 [55]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, has it often been hard for you to make up your mind or to make decisions? 0 2 7 9 [56]

NOTE 8: WAS THERE A * RESPONSE CODED IN Q 17 - 19? 0 [2] [57]

WAS THERE A # RESPONSE CODED IN Q 17 - 19? 0 <2> [58]

20. In the last year – that is, since [NAME CURRENT MONTH] of last year] – was there a time when you often thought about death or about people who had died or about being dead yourself? 0 2 7 9 [59]

IF NO, GO TO Q 21

A. Did you think about death or dying a lot more than you usually do? 0 2 7 9 [60]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

B. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]).* Did you think a lot about death or dying during [the time you felt [sad or depressed/like nothing was fun/grouchy]/that time]? 0 2* 7 9 [61]

IF YES, C. Did you think about death or dying nearly every day for two weeks or longer? 0 2# 7 9 [62]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you often thought about death or about people who have died or about being dead yourself? 0 2 7 9 [63]

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9,99=DON'T KNOW	

21. In the last year, *(that is since [NAME CURRENT MONTH] of last year)*, was there a time when you thought seriously about killing yourself? 0 2 7 9 [64]

IF NO, GO TO Q 22

A. Did you think about killing yourself many times in the last year? 0 2 7 9 [65]

B. In the last year, did you have a plan for exactly how you would kill yourself? 0 2 7 9 [66]

IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:

C. *(You told me that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]).* Did you think about suicide during [the time you felt [sad or depressed/like nothing was fun/grouchy]/ that time]? 0 **2*#** 7 9 [67]

D. Now, what about the last four weeks? *(Since [[NAME EVENT]//the beginning of/the middle of/the end of [LAST MONTH]])*, have you thought seriously about killing yourself? 0 2 7 9 [68]

IF YES, E. Did you think about killing yourself many times in the last four weeks? 0 2 7 9 [69]

F. Did you plan exactly how you would kill yourself? 0 2 7 9 [70]

START NEW CARD
DUP COL 1 - 12

CARD NO. 0 3 [13 - 14]
b [15]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

22. For the next question, I would like you to think about your whole life.

Have you ever, in your whole life, tried to kill yourself or made a suicide attempt?	0	2	7	9	[16]
IF NO, GO TO NOTE 9					
A. How many times have you tried to kill yourself?					
CODE NUMBER OF TIMES ---------->	|___ ___|				[17-18]
B. Now thinking about the whole last year – that is, since [[NAME EVENT]/[NAME CURRENT MONTH] of last year] – have you tried to kill yourself?	0	2	7	9	[19]
IF YES, C. How many times did you try to kill yourself in the last year?					
CODE NUMBER OF TIMES ---------->	|___ ___|				[20-21]
D. How did you try to kill yourself (the last time you tried)? What did you do?					
_____	|___ ___|				[22-23]
_____					
E. Did you go to see a doctor, go to an emergency room, or go into the hospital because of trying to kill yourself?	0	2	7	9	[24]
IF A * OR [ ] RESPONSE WAS CODED IN Q 1 - 3, ASK:					
F. You told me earlier that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy]. Did you try to kill yourself during that time?	0	2*#	7	9	[25]
G. Now, what about the last four weeks? *(Since [[NAME EVENT]/the beginning of/the middle of/the end of [LAST MONTH]])*, have you tried to kill yourself?	0	2	7	9	[26]

NOTE 9: WAS THERE A * RESPONSE CODED IN Q 20 - 22?	0	**[2]**	[27]
WAS THERE A # RESPONSE CODED IN Q 20 - 22?	0	2	[28]

b [29]

NOTE 10: WERE THREE OR MORE [ ] RESPONSES CODED IN Q 2 AND NOTES 2 - 9?	0	2	[30]
IF YES: CONTINUE **IF NO: GO TO Q 35, P. 21**			

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

23. You said that in the last year there was a time when you felt [sad or depressed/like nothing was fun/grouchy] and that during that time you [NAME [ ] SYMPTOMS IN NOTES 3 - 9].

How old were you the first time you ever felt like that?

CODE AGE (66 = WHOLE LIFE, ALWAYS) ----------> |___ ___| YRS. [31-32]

IF AGE NOT KNOWN, ASK: What grade were you in?
CODE GRADE (44 = PRE-K, 55 = KINDERGARTEN, 13 = COLLEGE FRESHMAN, 14 = SOPHOMORE, 15 = JUNIOR, 16 = SENIOR, 17 = POST B.A.) ----------> |___ ___| GRADE [33-34]

a: IF [AGE/GRADE] GIVEN WAS CHILD'S CURRENT [AGE/GRADE], GO TO Q 24

IF [AGE/GRADE] GIVEN WAS CHILD'S CURRENT [AGE/GRADE] MINUS ONE, GO TO A

ALL OTHERS, GO TO B

A. Was that more than a year ago – that is, before [NAME CURRENT MONTH] of last year]? 0 2 7 9 [35]

IF NO, GO TO Q 24

B. Since that first time, was there ever a time when you were not [sad or depressed/like nothing was fun/grouchy]? 0 2 7 9 [36]

IF NO, GO TO Q 24

C. Did that time when you weren't [sad or depressed/like nothing was fun/grouchy] last for two months or more? 0 2 7 9 [37]

IF NO, GO TO Q 24

D. You said that you were [sad or depressed/like nothing was fun/grouchy] in the last year. How old were you when these feelings began this time?

CODE AGE (88 = NEVER STARTED AGAIN) ----------> |___ ___| YRS. [38-39]

IF AGE NOT KNOWN, ASK: What grade were you in?
CODE GRADE (44 = PRE-K, 55 = KINDERGARTEN, 13 = COLLEGE FRESHMAN, 14 = SOPHOMORE, 15 = JUNIOR, 16 = SENIOR, 17 = POST B.A., 88 = NEVER STARTED AGAIN) ----------> |___ ___| GRADE [40-41]

b: IF [AGE/GRADE] GIVEN IS CURRENT [AGE/GRADE] MINUS ONE, GO TO E

ALL OTHERS, GO TO Q 24

E. Did you start to feel [sad or depressed/like nothing was fun/grouchy] again more than a year ago – that is, before [NAME CURRENT MONTH] of last year? 0 2 7 9 [42]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

24. You told me that in the last year you had problems with feeling [sad or depressed/ like nothing was fun/grouchy].

Did you start feeling this way soon after someone you were close to died?	0	2	7	9	[43]
IF YES, A. Who died?					
_____	|__ __|				[44-45]
_____					
B. When did [he/she/they] die? **(RECORD MONTH AND YEAR:)**					
_____	|__ __|__ __|				[46-49]
C. After [NAME PERSON IN A] died, did you feel [sad or depressed/ like nothing was fun/grouchy] for two months or longer?	0	2	7	9	[50]
IF NO, D. Did you ever feel [sad or depressed/like nothing was fun/grouchy] before [NAME PERSON IN A] died?	0	2	7	9	[51]
IF YES, E. Was that in the last year?	0	2	7	9	[52]
IF YES, F. When you were feeling [sad or depressed/like nothing was fun/grouchy] that time, did it last for two weeks or longer?	0	2	7	9	[53]

c: **IF ONSET (USING AGE OR GRADE) NAMED IN Q 23 WAS LESS THAN 2 YEARS AGO, GO TO Q 26, P. 18**

ALL OTHERS, CONTINUE

0=NO	1=SOMETIMES/SOMEWHAT	2=YES	7, 77=REFUSE TO ANSWER	8, 88=NOT APPLICABLE	9,99=DON'T KNOW	

25. In the last two years, did you [become sad or depressed/feel like nothing was fun/become grouchy], and then get better and then [become sad or depressed/feel like nothing was fun/become grouchy] again? 0 2 7 9 [54]

IF NO, GO TO Q 26

A. Did you start to [become sad or depressed/feel like nothing was fun/become grouchy] around the same time each year? 0 2 7 9 [55]

IF YES, B. Was this in Winter or Fall? 0 2 7 9 [56]

IF NO, GO TO H

C. Did you stay [sad or depressed/feeling like nothing was fun/grouchy] until Spring or Summer? 0 2 7 9 [57]

D. Did you start to get better in Spring or Summer? 0 2 7 9 [58]

E. Did you ever get very hyper or excited in Spring or Summer? 0 2 7 9 [59]

F. In the last two years, did you ever [become sad or depressed/feel like nothing was fun/become grouchy] at other times of the year, say in Spring or Summer? 0 2 7 9 [60]

IF NO, GO TO Q 26

G. Did these times ever last for as long as two weeks or more? 0 2 7 9 [61]

GO TO Q 26

H. Was this in Spring or Summer? 0 2 7 9 [62]

IF YES, I. Did you stay [sad or depressed/feeling like nothing was fun/grouchy] until Fall or Winter? 0 2 7 9 [63]

J. Did you start to get better in the Fall or Winter? 0 2 7 9 [64]

K. Did you ever get very hyper or excited in Fall and Winter? 0 2 7 9 [65]

L. In the last two years, did you [become sad or depressed/feel like nothing was fun/become grouchy] at any other times of the year, say in Fall or Winter? 0 2 7 9 [66]

M. Did these times ever last for as long as two weeks or more? 0 2 7 9 [67]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

26. You said that in the last year you felt [sad or depressed/like nothing was fun/ grouchy] and you also [NAME [ ] SYMPTOMS IN NOTES 3 - 9].

Now I'd like you to think back to the time in the last year when feeling this way caused the most problems.

At that time, did your [CARETAKERS] seem annoyed or upset with you because you were feeling [sad or depressed/like nothing was fun/grouchy]? 0 1 2 7 9 [68]

IF YES, A. How often did your [CARETAKERS] seem annoyed or upset with you because you felt this way? Would you say: a lot of the time, some of the time, or hardly ever? [69]

A lot of the time	3
Some of the time	2
Hardly ever	1
Refuse to answer	7
Don't know	9

27. At that time, did feeling [sad or depressed/like nothing was fun/grouchy] keep you from doing things or going places with your family? 0 1 2 7 9 [70]

IF YES, A. How often did feeling this way keep you from doing things or going places with your family? Would you say: a lot of the time, some of the time, or hardly ever? [71]

A lot of the time	3
Some of the time	2
Hardly ever	1
Refuse to answer	7
Don't know	9

28. At that time, did feeling [sad or depressed/like nothing was fun/grouchy] keep you from doing things or going places with other [children/people your age]? 0 1 2 7 9 [72]

IF YES, A. How often did feeling this way keep you from doing things or going places with other [children/people your age]? Would you say: a lot of the time, some of the time, or hardly ever? [73]

A lot of the time	3
Some of the time	2
Hardly ever	1
Refuse to answer	7
Don't know	9

START NEW CARD
DUP COL 1 - 12

CARD NO. 0 4 [13 - 14]
b [15]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

d: IF CHILD DID NOT ATTEND SCHOOL OR WORK IN LAST YEAR, CODE "8" IN Q 29 - 30 AND THEN GO TO Q 31

29. When the problems were worst, did feeling [sad or depressed/like nothing was fun/grouchy] [make it difficult for you to do your schoolwork or cause problems with your grades/make it difficult for you to do your work]? 0 1 2 7 8 9 [16]

IF YES, A. How bad were the problems you had with your [schoolwork/work] because you felt this way? Would you say: very bad, bad, or not too bad?

Very bad	3	[17]
Bad	2	
Not too bad	1	
Refuse to answer	7	
Don't know	9	

30. At that time, did feeling [sad or depressed/like nothing was fun/grouchy], cause your [teachers/boss] to be annoyed or upset with you? 0 1 2 7 8 9 [18]

IF YES, A. How often [were/was] your [teachers/boss] annoyed or upset with you because you felt this way? Would you say: a lot of the time, some of the time, or hardly ever?

A lot of the time	3	[19]
Some of the time	2	
Hardly ever	1	
Refuse to answer	7	
Don't know	9	

31. When the problems were worst, did feeling [sad or depressed/like nothing was fun/grouchy] make you feel bad or make you feel upset? 0 1 2 7 9 [20]

IF YES, A. How bad did this make you feel? Would you say: very bad, bad, or not too bad?

Very bad	3	[21]
Bad	2	
Not too bad	1	
Refuse to answer	7	
Don't know	9	

32. In the last year – that is, since [NAME CURRENT MONTH] of last year – have you been to see someone at a hospital or a clinic or at their office because you were feeling [sad or depressed/like nothing was fun/grouchy]? 0 2 7 9 [22]

IF YES, GO TO OPTIONAL DETAILS, NEXT PAGE

IF NO, A. Do you have an appointment set up to see someone because you feel this way? 0 2 7 9 [23]

IF YES, GO TO OPTIONAL DETAILS, NEXT PAGE

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

OPTIONAL DETAILS:

33. Who [did you/are you going to] see? **(WRITE IN:)**

Name: _____ |__ __| [24-25]

Profession: _____

Address: _____

_____

A. What did the person you saw say was the matter?

_____ |__ __| [26-27]

_____

e: IF CHILD IS AGE 7 OR OLDER, CONTINUE

ALL OTHERS, GO TO Q 35

Whole Life Screen

34. You told me that in the last year you felt [sad or depressed/like nothing was fun/grouchy] and you also [NAME [ ] SYMPTOMS IN NOTES 3 - 9].

Now I want you to think back to before the last year ... since the time you turned five years old up until the last twelve months.
(INTERVIEWER: point out age five on whole life chart.)

Since you turned five years old, was there ever a time when you felt more [sad or depressed/like nothing was fun/grouchy] than you have in the last year? 0 2 7 9 [28]

IF YES, A. How old were you when feeling this way was worse than in the last year?
(INTERVIEWER: IF MORE THAN ONE YEAR IS REPORTED, ASK: "During which single year of age were you the worst?" IF MORE THAN ONE YEAR STILL REPORTED, ENTER YOUNGEST AGE.)

CODE AGE ----------> |__ __| [29-30]

IF AGE NOT KNOWN, ASK: What grade were you in?
CODE GRADE (44 = PRE-K, 55 = KINDERGARTEN, 13 = COLLEGE FRESHMAN, 14 = SOPHOMORE, 15 = JUNIOR, 16 = SENIOR, 17 = POST B.A.) ----------> |__ __| [31-32]

f: IF FIVE OR MORE ‹› RESPONSES WERE CODED IN Q 2 AND NOTES 2 - 9, GO TO Q 60, P. 27

ALL OTHERS, CONTINUE

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

START NEW CARD
DUP COL 1 - 12

CARD NO. 0 5 [13 - 14]
b [15]

DD

35.	During the last year – that is, since [[NAME EVENT]/[NAME CURRENT MONTH] of last year] – has there been a time when you felt sad or depressed a lot of the time?	0	2	7	9	[16]
IF YES, A.	Did you feel sad or depressed for at least a whole year – that is, for twelve months or longer?	0	2	7	9	[17]
IF YES, B.	During these twelve months, were there more days when you felt sad or depressed than days when you felt okay?	0	**2***	7	9	[18]
IF YES, C.	Did you feel this way for as long as two years?	0	2	7	9	[19]
D.	On the days when you felt sad or depressed, did you feel like this for most of the day?	0	2	7	9	[20]
E.	When you were sad or depressed, did you feel better if something good happened or was about to happen to you?	0	2	7	9	[21]
F.	Have you felt sad or depressed like this in the last four weeks – that is, since [[NAME EVENT]//the beginning of/the middle of/the end of [LAST MONTH]]?	0	2	7	9	[22]

g: IF A * RESPONSE WAS CODED IN Q 35B, GO TO Q 37

ALL OTHERS, CONTINUE

36.	During the last year – that is, since [NAME CURRENT MONTH] of last year – has there been a time when you felt grouchy or irritable a lot of the time?	0	2	7	9	[23]
IF YES, A.	Did you feel grouchy or irritable for at least a whole year – that is, for twelve months or longer?	0	2	7	9	[24]
IF YES, B.	During those twelve months, were there more days when you felt grouchy or irritable than days when you felt okay?	0	**2***	7	9	[25]
IF YES, C.	Did you feel this way for as long as two years?	0	2	7	9	[26]
D.	On the days when you felt grouchy or irritable, did you feel like that for most of the day?	0	2	7	9	[27]
E.	Have you felt grouchy or irritable like that in the last four weeks – that is, since [[NAME EVENT]//the beginning of/the middle of/the end of [LAST MONTH]]?	0	2	7	9	[28]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

h: IF A * RESPONSE WAS CODED IN Q 36B, CONTINUE

ALL OTHERS, GO TO MAN/HYPOMAN, P. 29

37. You just said that there were twelve months when you were [sad or depressed/grouchy or irritable] most of the time. Now I want to ask you about some other things that may happen when you feel this way.

When you feel [sad or depressed/grouchy or irritable], do you eat less or lose your appetite?	0	[1]	[2]	7	9	[29]
IF NO, A. When you feel [sad or depressed/grouchy or irritable], do you feel more hungry or eat too much?	0	[1]	[2]	7	9	[30]
38. When you feel [sad or depressed/grouchy or irritable], do you have trouble falling asleep or do you wake up too early?	0	[1]	[2]	7	9	[31]
IF NO, A. When you feel [sad or depressed/grouchy or irritable], do you sleep too much?	0	[1]	[2]	7	9	[32]
39. When you feel [sad or depressed/grouchy or irritable], do you feel you don't have any energy and that it takes a big effort to do anything?	0	[1]	[2]	7	9	[33]
40. When you feel [sad or depressed/grouchy or irritable], do you feel bad about yourself … that you are no good at anything or that other people don't like you?	0	[1]	[2]	7	9	[34]
41. When you feel [sad or depressed/grouchy or irritable], is it more difficult for you to pay attention to your [schoolwork/work] or to other things you do?	0	[1]	[2]	7	9	[35]
IF NO, A. When you feel [sad or depressed/grouchy or irritable], is it more difficult for you to make up your mind or to make decisions?	0	[1]	[2]	7	9	[36]
42. When you feel [sad or depressed/grouchy or irritable], do you feel that life is hopeless or do you feel full of despair?	0	[1]	[2]	7	9	[37]
IF NO, A. When you feel [sad or depressed/grouchy or irritable], do you feel like nothing good is ever going to happen to you?	0	[1]	[2]	7	9	[38]
43. When you feel [sad or depressed/grouchy or irritable], do you often feel like you are about to cry or are you tearful?	0	[1]	[2]	7	9	[39]
44. When you feel [sad or depressed/grouchy or irritable], does it seem like nothing is fun for you, even things you usually enjoy?	0	[1]	[2]	7	9	[40]
45. When you feel [sad or depressed/grouchy or irritable], do you feel bored or just not interested in anything?	0	[1]	[2]	7	9	[41]
46. When you feel [sad or depressed/grouchy or irritable], is it hard for you to do ordinary, everyday things?	0	[1]	[2]	7	9	[42]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

47. When you feel [sad or depressed/grouchy or irritable], do you think a lot about bad things that happened to you in the past? 0 [1] [2] 7 9 [43]

48. When you feel [sad or depressed/grouchy or irritable], do you want to be alone or away from other people? 0 [1] [2] 7 9 [44]

49. When you feel [sad or depressed/grouchy or irritable], do you talk a lot less? 0 [1] [2] 7 9 [45]

i: IF 1 OR MORE [ ] RESPONSES WERE CODED IN Q 37 - 49, CONTINUE

ALL OTHERS, GO TO MAN/HYPOMAN, P. 29

50. You have just told me that you have felt [sad or depressed/grouchy or irritable] a lot of the time for at least twelve months, and that when you feel [sad or depressed/grouchy or irritable] you also [NAME [ ] SYMPTOMS IN Q 37 - 49].

During that twelve months, were there times that you felt better, more like your normal self again? 0 2 7 9 [46]

IF YES, A. Did you feel better or more like your normal self for two months in a row or longer? 0 2 7 9 [47]

IF YES, GO TO MAN/HYPOMAN, P. 29

51. Thinking about your whole life, how old were you the first time you had twelve months of feeling [sad or depressed/grouchy or irritable] most of the time?

CODE AGE (66 = WHOLE LIFE, ALWAYS) ----------> |____ ____| YRS. [48-49]

IF AGE NOT KNOWN, ASK: What grade were you in?
CODE GRADE (44 = PRE-K, 55 = KINDERGARTEN, 13 = COLLEGE FRESHMAN, 14 = SOPHOMORE, 15 = JUNIOR, 16 = SENIOR, 17 = POST B.A.) ----------> |____ ____| GRADE [50-51]

j: IF [AGE/GRADE] GIVEN WAS CHILD'S CURRENT [AGE/GRADE], GO TO INSTRUCTION BOX "I"

IF [AGE/GRADE] GIVEN WAS CHILD'S CURRENT [AGE/GRADE] MINUS ONE, GO TO A

ALL OTHERS, GO TO B

A. Was that more than a year ago – that is, before [NAME CURRENT MONTH] of last year? 0 2 7 9 [52]

IF NO, GO TO INSTRUCTION BOX "I"

B. Since that first time, was there ever a time when these feelings of being [sad or depressed/grouchy or irritable] went away completely? 0 2 7 9 [53]

IF NO, GO TO INSTRUCTION BOX "I"

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

C. Did these feelings of being [sad or depressed/grouchy or irritable] go away completely for two months in a row or longer? 0 2 7 9 [54]

IF NO, GO TO INSTRUCTION BOX "I"

D. You said you were [sad or depressed/grouchy or irritable] and you [NAME [ ] SYMPTOMS IN Q 37 - 49] in the last year.

How old were you when these feelings began this time?

CODE AGE (88 = NEVER STARTED AGAIN) ----------> |___ ___| YRS. [55-56]

IF AGE NOT KNOWN, ASK: What grade were you in?
CODE GRADE (44 = PRE-K, 55 = KINDERGARTEN, 13 = COLLEGE FRESHMAN, 14 = SOPHOMORE, 15 = JUNIOR, 16 = SENIOR, 17 = POST B.A., 88 = NEVER STARTED AGAIN) ----------> |___ ___| GRADE [57-58]

k: IF [AGE/GRADE] GIVEN WAS CHILD'S CURRENT [AGE/GRADE] MINUS ONE, GO TO E

ALL OTHERS, GO TO INSTRUCTION BOX "I"

E. Did you start to feel [sad or depressed/grouchy or irritable] again more than a year ago – that is, before [NAME CURRENT MONTH] of last year? 0 2 7 9 [59]

I: IF THREE OR MORE [ ] RESPONSES WERE CODED IN Q 2 AND NOTES 2 - 9 IN MDD *(see tally sheet)* (i.e. impairment and treatment history (Q 26 - 33) were asked), GO TO Q 60, P. 27

ALL OTHERS, CONTINUE

52. You said that in the last year you felt [sad or depressed/grouchy or irritable] and you [NAME [ ] SYMPTOMS IN Q 37 - 49].

Now, I'd like you to think back to the time in the last year when feeling this way caused the most problems.

At that time, did your [CARETAKERS] seem annoyed or upset with you because you were feeling [sad or depressed/grouchy or irritable]? 0 1 2 7 9 [60]

IF YES, A. How often did your [CARETAKERS] seem annoyed or upset with you because you felt this way? Would you say: a lot of the time, some of the time, or hardly ever?

A lot of the time	3	[61]
Some of the time	2	
Hardly ever	1	
Refuse to answer	7	
Don't know	9	

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9, 99=DON'T KNOW

53. At that time, did feeling [sad or depressed/grouchy or irritable] keep you from doing things or going places with your family? 0 1 2 7 9 [62]

IF YES, A. How often did feeling this way keep you from doing things or going places with your family? Would you say: a lot of the time, some of the time, or hardly ever?

A lot of the time	3	[63]
Some of the time	2	
Hardly ever	1	
Refuse to answer	7	
Don't know	9	

54. At that time, did feeling [sad or depressed/grouchy or irritable] keep you from doing things or going places with other [children/people your age]? 0 1 2 7 9 [64]

IF YES, A. How often did feeling this way keep you from doing things or going places with other [children/people your age]? Would you say: a lot of the time, some of the time, or hardly ever?

A lot of the time	3	[65]
Some of the time	2	
Hardly ever	1	
Refuse to answer	7	
Don't know	9	

m: IF CHILD DID NOT ATTEND SCHOOL OR WORK IN LAST YEAR, CODE "8" IN Q 55 AND Q 56, AND THEN GO TO Q 57

55. When the problems were worst, did feeling [sad or depressed/grouchy or irritable] [make it difficult for you to do your schoolwork or cause problems with your grades/make it difficult for you to do your work]? 0 1 2 7 8 9 [66]

IF YES, A. How bad were the problems with your [schoolwork/work]? Would you say: very bad, bad, or not too bad?

Very bad	3	[67]
Bad	2	
Not too bad	1	
Refuse to answer	7	
Don't know	9	

56. At that time, did feeling [sad or depressed/grouchy or irritable] cause your [teachers/boss] to be annoyed or upset with you? 0 1 2 7 8 9 [68]

IF YES, A. How often [were/was] your [teachers/boss] annoyed or upset with you because you felt this way? Would you say: a lot of the time, some of the time, or hardly ever?

A lot of the time	3	[69]
Some of the time	2	
Hardly ever	1	
Refuse to answer	7	
Don't know	9	

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'T KNOW

57. When the problems were worst, did feeling [sad or depressed/grouchy or irritable] make you feel bad or make you feel upset? 0 1 2 7 9 [70]

IF YES, A. How bad did this make you feel? Would you say: very bad, bad, or not too bad? [71]

Very bad	3
Bad	2
Not too bad	1
Refuse to answer	7
Don't know	9

58. In the last year – that is, since [NAME CURRENT MONTH] of last year – have you been to see someone at a hospital or a clinic or at their office because you were feeling [sad or depressed/grouchy or irritable]? 0 2 7 9 [72]

IF YES, GO TO OPTIONAL DETAILS

IF NO, A. Do you have an appointment set up to see someone because you feel this way? 0 2 7 9 [73]

IF YES, GO TO OPTIONAL DETAILS

START NEW CARD
DUP COL 1 - 12

CARD NO. 0 6 [13 - 14]
b [15]

OPTIONAL DETAILS:

59. Who [did you/are you going to] see? **(WRITE IN:)**

Name: _____ |__ __| [16-17]

Profession: _____

Address: _____

_____

A. **IF SOMEONE WAS SEEN, ASK:**
What did the person you saw say was the matter?

_____ |__ __| [18-19]

_____

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'TKNOW

60. Some people feel very hurt if they are not invited to a party or if they are left off a team or a project.

Do you feel very bad or get upset if you are left out of something?	0	2	7	9	[20]
IF YES, A. Do you stay feeling upset for more than a day?	0	2	7	9	[21]
B. Have you ever dropped a friend completely because they left you out of something?	0	2	7	9	[22]
IF YES, C. Has that happened with more than two friends?	0	2	7	9	[23]

0=NO 1=SOMETIMES/SOMEWHAT 2=YES 7, 77=REFUSE TO ANSWER 8, 88=NOT APPLICABLE 9,99=DON'TKNOW

INTENTIONALLY LEFT BLANK

Appendix B.c: Adolescent Survey Measures

Short Mood and Feelings Questionnaire (SMFQ-C)

Self Report Version - SMFQ

SHORT MOOD AND FEELINGS QUESTIONNAIRE

This form is about how you might have been feeling or acting recently.

For each question, please check how much you have felt or acted this way *in the past two weeks.*

If a sentence was true about you most of the time, check TRUE.

If it was only sometimes true, check SOMETIMES.

If a sentence was not true about you, check NOT TRUE.

		TRUE	SOME TIMES	NOT TRUE
1.	I felt miserable or unhappy	☐	☐	☐
2.	I didn't enjoy anything at all	☐	☐	☐
3.	I felt so tired I just sat around and did nothing	☐	☐	☐
4.	I was very restless	☐	☐	☐
5.	I felt I was no good any more	☐	☐	☐
6.	I cried a lot	☐	☐	☐
7.	I found it hard to think properly or concentrate	☐	☐	☐
8.	I hated myself	☐	☐	☐
9.	I was a bad person	☐	☐	☐
10.	I felt lonely	☐	☐	☐
11.	I thought nobody really loved me	☐	☐	☐
12.	I thought I could never be as good as other kids	☐	☐	☐
13.	I did everything wrong	☐	☐	☐

62

Brief Resiliency Scale (BRS)

The Brief Resilience Scale

Bruce W. Smith, University of New Mexico, bwsmith@unm.edu

Instructions: Use the following scale and **circle** one number for each statement to indicate how much you disagree or agree with each of the statements.

1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree

---

1. I tend to bounce back quickly after hard times..	1	2	3	4	5
2. I have a hard time making it through stressful events.....	1	2	3	4	5
3. It does not take me long to recover from a stressful event.....	1	2	3	4	5
4. It is hard for me to snap back when something bad happens.....	1	2	3	4	5
5. I usually come through difficult times with little trouble.....	1	2	3	4	5
6. I tend to take a long time to get over set-backs in my life.....	1	2	3	4	5

Adolescent Cognitive Style Questionnaire (ACSQ)

Questions 1, 2, 3, 6, 8, and 12 used for study.

1. You take a test and get a bad grade.

a. Write down why you think you got a bad grade.

_____

b. Did you get a bad grade because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason for getting a bad grade will cause you to get bad grades in the future? (Circle one number).

Will never again cause me to get a bad test grade	1	2	3	4	5	6	7	Will also cause me to get bad test grades in the future

d. Do you think the reason for your bad grade will cause problems in other parts of your life? (Circle one number).

Will only cause problems with my test grades	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because of your bad test grade? (Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because you got a bad test grade? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

2. You want a boyfriend/ girlfriend but you don't have one.

a. Write down why you think you don't have a boyfriend/ girlfriend.

_____

b. Do you not have a boyfriend/ girlfriend because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason you don't have a boyfriend/ girlfriend will cause you to not have a boyfriend/ girlfriend in the future? (Circle one number).

Will never again cause me not to have a boyfriend/ girlfriend	1	2	3	4	5	6	7	Will also cause me not to have a boyfriend girlfriend in the future

d. Do you think the reason you don't have a boyfriend/ girlfriend will cause problems in other parts of your life? (Circle one number).

Will only cause problems in my love life	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because you don't have a boyfriend/ girlfriend? (Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because you don't have a boyfriend/ girlfriend? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

3. You want to go to a big party, but nobody invites you.

a. Write down why you think you weren't invited to the party.

_____

b. Were you not invited to the party because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason you weren't invited to the party will also cause you not to be invited to parties in the future? (Circle one number).

Will never again cause me to not get invited to parties	1	2	3	4	5	6	7	Will also cause me to not get invited to parties in the future

d. Do you think the reason you weren't invited to the party will cause problems in other parts of your life? (Circle one number).

Will only cause problems in my social life	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because you weren't invited to the party? (Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because you weren't invited to the party? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

6. **You get in a big fight with your parents.**

a. Write down why you think you got in a big fight with your parents.

_____

b. Did you get in the fight with your parents because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason you got in the fight will also cause you to get in fights with your parents in the future? (Circle one number).

Will never again cause me to get in a fight with my parents	1	2	3	4	5	6	7	Will also cause me to get in fights with my parents in future

d. Do you think the reason you got in the fight with your parents will cause problems in other parts of your life? (Circle one number).

Will only cause problems with my parents	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because you got in the fight with your parents?
(Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because you got in the fight with your parents? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

8. You don't get chosen for an extracurricular activity (such as sports team, club, play) that you want to be a part of.

a. Write down why you think you were not chosen for the extracurricular activity.

_____

b. Did you not get chosen for the activity because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason you didn't get chosen for the activity will also cause you to not get chosen for activities in the future? (Circle one number).

Will never again cause me to not be chosen for activities	1	2	3	4	5	6	7	Will also cause me to not get chosen for future activities

d. Do you think the reason you didn't get chosen for the activity will cause problems in other parts of your life? (Circle one number).

Will only cause problems with my activities	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because you didn't get chosen for the activity? (Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because you didn't get chosen for the activity? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

12. Someone says something bad about how you look.

a. Write down why you think they said something bad about your looks.

_____

b. Did someone say something bad about your looks because of something about you or because of something else? (Circle on number).

Totally caused by something else	1	2	3	4	5	6	7	Totally caused by something about me

c. Do you think the reason someone said something bad about your looks will cause people to say bad things about your looks in the future? (Circle one number).

Will never again cause people to say bad things about my looks	1	2	3	4	5	6	7	Will also cause people to say bad things about my looks in the future

d. Do you think the reason someone said something bad about your looks will cause problems in other parts of your life? (Circle one number).

Will only cause problems with what people say about my looks	1	2	3	4	5	6	7	Will cause problems in all areas of my life

e. Do you think other bad things will happen to you because someone said something bad about your looks? (Circle one number).

Nothing bad will happen	1	2	3	4	5	6	7	Very bad things will happen

f. Do you think there is something wrong with you because someone said something bad about your looks? (Circle one number).

Doesn't mean anything is wrong with me	1	2	3	4	5	6	7	Definitely means something is wrong with me

Ruminative Response Style scale-brooding factor (RRS-B)

Items 5, 10, 13, 15, 16 assess the brooding factor and are the only items used in this study.

Rumination Scale

People think and do many different things when they feel depressed. Please read each of the items below and indicate whether you almost never, sometimes, often, or almost always think or do each one when you feel down, sad, or depressed. Please indicate what you *generally* do, not what you think you should do.

1 almost never 2 sometimes 3 often 4 almost always

1. think about how alone you feel
2. think "I won't be able to do my job if I don't snap out of this"
3. think about your feelings of fatigue and achiness
4. think about how hard it is to concentrate
5. think "What am I doing to deserve this?"
6. think about how passive and unmotivated you feel.
7. analyze recent events to try to understand why you are depressed
8. think about how you don't seem to feel anything anymore
9. think "Why can't I get going?"
10. think "Why do I always react this way?"
11. go away by yourself and think about why you feel this way
12. write down what you are thinking about and analyze it
13. think about a recent situation, wishing it had gone better
14. think "I won't be able to concentrate if I keep feeling this way."
15. think "Why do I have problems other people don't have?"
16. think "Why can't I handle things better?"
17. think about how sad you feel.
18. think about all your shortcomings, failings, faults, mistakes
19. think about how you don't feel up to doing anything
20. analyze your personality to try to understand why you are depressed
21. go someplace alone to think about your feelings
22. think about how angry you are with yourself

Test for Self-Conscious Affect for Adolescents (TOSCA-A)

1. *You trip in the cafeteria and spill your friend's drink.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would be thinking that everyone is watching me and laughing.	①	②	③	④	⑤
b) I would feel very sorry. I should have watched where I was going.	①	②	③	④	⑤
c) I wouldn't feel bad because it didn't cost very much.	①	②	③	④	⑤
d) I would think: "I couldn't help it. The floor was slippery."	①	②	③	④	⑤

2. *For several days you put off talking to a teacher about a missed assignment. At the last minute you talk to the teacher about it, and all goes well.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "I guess I'm more convincing than I thought."	①	②	③	④	⑤
b) I would regret that I put it off.	①	②	③	④	⑤
c) I would feel like a coward.	①	②	③	④	⑤
d) I would think: "I handled that well."	①	②	③	④	⑤
e) I would think: "The teacher should have asked me about it first. It's her job."	①	②	③	④	⑤

3. *While playing around, you throw a ball and it hits your friend in the face.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would feel stupid that I can't even throw a ball.	①	②	③	④	⑤
b) I would think: "Maybe my friend needs more practice catching."	①	②	③	④	⑤

c) I would think: "It was just an accident." ① - - - ② - - - ③ - - - ④ - - - ⑤

d) I would apologize and make sure my friend feels better. ① - - - ② - - - ③ - - - ④ - - - ⑤

4. *You and a group of classmates worked very hard on a project. Your teacher singles you out for a better grade than anyone else.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "The teacher is playing favorites."	①	②	③	④	⑤
b) I would feel alone and apart from my classmates.	①	②	③	④	⑤
c) I would feel that my hard work had paid off.	①	②	③	④	⑤
d) I would feel competent and proud of myself.	①	②	③	④	⑤
e) I would tell the teacher that everyone should get the same grade.	①	②	③	④	⑤

5. *You break something at a friend's house and then hide it.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "This is making me anxious. I need to either fix it or replace it."	①	②	③	④	⑤
b) I would avoid seeing that friend for a while.	①	②	③	④	⑤
c) I would think: "A lot of things aren't made very well."	①	②	③	④	⑤
d) I would think: "It was only an accident."	①	②	③	④	⑤

6. *At school, you wait until the last minute to plan a project, and it turns out badly.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would feel useless and incompetent.	①	②	③	④	⑤
b) I would think: "There are never enough hours in the day."	①	②	③	④	⑤
c) I would feel that I deserve a bad grade.	①	②	③	④	⑤
d) I would think: "What's done is done."	①	②	③	④	⑤

7. *You wake up one morning and remember it's your mother's birthday. You forgot to get her something.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "It's not the gift that matters. All that really matters is that I care."	①	②	③	④	⑤
b) I would think: "After everything she's done for me, how could I forget her birthday?"	①	②	③	④	⑤
c) I would feel irresponsible and thoughtless.	①	②	③	④	⑤
d) I would think: "Someone should have reminded me."	①	②	③	④	⑤

8. *You walk out of a test thinking you did extremely well. Then you find out you did poorly.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would feel that I should have done better. I should have studied more.	①	②	③	④	⑤

b) I would feel stupid. ① - - - ② - - - ③ - - - ④ - - - ⑤

c) I would think: "It's only a test." ① - - - ② - - - ③ - - - ④ - - - ⑤

d) I would think: "The teacher must have graded it wrong." ① - - - ② - - - ③ - - - ④ - - - ⑤

9. *You make a mistake at school and find out a classmate is blamed for the error.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "The teacher does not like the classmate."	①	②	③	④	⑤
b) I would think: "Life is not fair."	①	②	③	④	⑤
c) I would keep quiet and avoid the classmate.	①	②	③	④	⑤
d) I would feel unhappy and eager to correct the situation.	①	②	③	④	⑤

10. *You were talking in class, and your friend got blamed. You go to the teacher and tell him the truth.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "The teacher should have gotten the facts straight before he blamed my friend."	①	②	③	④	⑤
b) I would feel like I always get people in trouble.	①	②	③	④	⑤
c) I would feel good about setting the record straight.	①	②	③	④	⑤
d) I would be proud of myself for being an honest person.	①	②	③	④	⑤
e) I would think: "I'm the one who should get in trouble. I shouldn't have been talking in the first place."	①	②	③	④	⑤

11. *You and your friend are talking in class, and you get in trouble.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "I should know better. I deserve to get in trouble."	①	②	③	④	⑤
b) I would think: "We were only whispering."	①	②	③	④	⑤
c) I would think: "The teacher is unfair."	①	②	③	④	⑤
d) I would feel like everyone in the class was looking at me and they were about to laugh.	①	②	③	④	⑤

12. *You make plans to meet a friend. Later you realize you stood your friend up.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "I'm inconsiderate."	①	②	③	④	⑤
b) I would think: "Well, my friend will understand."	①	②	③	④	⑤
c) I would try to make it up to my friend as soon as possible.	①	②	③	④	⑤
d) I would think: "Someone distracted me just before I was supposed to meet my friend."	①	②	③	④	⑤

13. *You volunteer to help raise money for a good cause. Later you want to quit, but you know your help is important.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would feel selfish, and I'd think I am basically lazy.	①	②	③	④	⑤
b) I would think: "I was pressured into helping."	①	②	③	④	⑤

c) I would think: "I should be more concerned about doing whatever I can to help." ① - - - ② - - - ③ - - - ④ - - - ⑤

d) I would feel great that I had helped. ① - - - ② - - - ③ - - - ④ - - - ⑤

e) I would feel very satisfied with myself. ① - - - ② - - - ③ - - - ④ - - - ⑤

14. *Your report card isn't as good as you wanted. You show it to your parents when you get home.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would think: "Everyone gets bad grades once in a while."	①	②	③	④	⑤
b) I would think: "I really didn't deserve the grades, it wasn't my fault."	①	②	③	④	⑤
c) Now that I got a bad report card, I would feel worthless.	①	②	③	④	⑤
d) I would think: "I should listen to everything the teacher says and study harder."	①	②	③	④	⑤

15. *You have recently moved to a new school, and everyone has been very helpful. A few times you had to ask some big favors, but you returned the favors as soon as you could.*

	not at all likely	unlikely	maybe (half & half)	likely	very likely
a) I would feel like a failure.	①	②	③	④	⑤
b) I would think: "Maybe this school doesn't do enough to help new students."	①	②	③	④	⑤
c) I would be especially nice to the people who had helped me.	①	②	③	④	⑤
d) I would think: "I am smart to ask for help when I need it."	①	②	③	④	⑤
e) I would be proud that I returned the favors.	①	②	③	④	⑤

Self-Compassion Scale (SCS)

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				Almost always
1	2	3	4	5

_____ 1. I'm disapproving and judgmental about my own flaws and inadequacies.

_____ 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____ 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.

_____ 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.

_____ 5. I try to be loving towards myself when I'm feeling emotional pain.

_____ 6. When I fail at something important to me I become consumed by feelings of inadequacy.

_____ 7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.

_____ 8. When times are really difficult, I tend to be tough on myself.

_____ 9. When something upsets me I try to keep my emotions in balance.

_____ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____ 11. I'm intolerant and impatient towards those aspects of my personality I don't like.

_____ 12. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____ 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____ 14. When something painful happens I try to take a balanced view of the situation.

_____ 15. I try to see my failings as part of the human condition.

_____ 16. When I see aspects of myself that I don't like, I get down on myself.

_____ 17. When I fail at something important to me I try to keep things in perspective.

_____ 18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.

_____ 19. I'm kind to myself when I'm experiencing suffering.

_____ 20. When something upsets me I get carried away with my feelings.

_____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.

_____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.

_____ 23. I'm tolerant of my own flaws and inadequacies.

_____ 24. When something painful happens I tend to blow the incident out of proportion.

_____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.

_____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Child and Adolescent Mindfulness Measure (CAMM)

We want to know more about what you think, how you feel, and what you do. **Read** each sentence. Then, circle the number that tells **how often each sentence is true for you.**

	Never True	Rarely True	Some-times True	Often True	Always True
1. I get upset with myself for having feelings that don't make sense.	0	1	2	3	4
2. At school, I walk from class to class without noticing what I'm doing.	0	1	2	3	4
3. I keep myself busy so I don't notice my thoughts or feelings.	0	1	2	3	4
4. I tell myself that I shouldn't feel the way I'm feeling.	0	1	2	3	4
5. I push away thoughts that I don't like.	0	1	2	3	4
6. It's hard for me to pay attention to only one thing at a time.	0	1	2	3	4
7. I get upset with myself for having certain thoughts.	0	1	2	3	4
8. I think about things that have happened in the past instead of thinking about things that are happening right now.	0	1	2	3	4
9. I think that some of my feelings are bad and that I shouldn't have them.	0	1	2	3	4
10. I stop myself from having feelings that I don't like.	0	1	2	3	4

Adolescent Demographic Questions

Demographic questionnaire

Please circle the appropriate response to each question:

1. Your age:

14 15 16 17 18 19

2. Gender:

Male

Female

Male transitioning to female

Female transitioning to male

Unsure at this time

3. The race/ethnicity that you consider yourself:

Black White Asian East Indian American Indian Pacific Islander Latino/Hispanic African Other

Appendix B.d: Parent Survey

Short Mood and Feelings Questionnaire (SMFQ-P)

Parent Report Version - SMFQ

SHORT MOOD AND FEELINGS QUESTIONNAIRE

This form is about how your child may have been feeling or acting recently.

For each question, please check how much she or he has felt or acted this way *in the past two weeks.*

If a sentence was true about your child most of the time, check TRUE.

If it was only sometimes true, check SOMETIMES.

If a sentence was not true about your child, check NOT TRUE.

		TRUE	SOME TIMES	NOT TRUE
1.	S/he felt miserable or unhappy	☐	☐	☐
2.	S/he didn't enjoy anything at all	☐	☐	☐
3.	S/he felt so tired that s/he just sat around and did nothing.	☐	☐	☐
4.	S/he was very restless	☐	☐	☐
5.	S/he felt s/he was no good any more	☐	☐	☐
6.	S/he cried a lot	☐	☐	☐
7.	S/he found it hard to think properly or concentrate	☐	☐	☐
8.	S/he hated him/herself	☐	☐	☐
9.	S/he felt s/he was a bad person	☐	☐	☐
10.	S/he felt lonely	☐	☐	☐
11.	S/he thought nobody really loved him/her	☐	☐	☐
12.	S/he thought s/he could never be as good as other kids	☐	☐	☐
13.	S/he felt s/he did everything wrong	☐	☐	☐

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Parent Demographics Questions

Parent Demographics

What is your gender?

- ☐ Male
- ☐ Female

What best describes the highest level of your education?

- ☐ Less than high school
- ☐ High School graduate
- ☐ Some college
- ☐ College graduate
- ☐ Master's degree
- ☐ Doctorate or professional degree

What is the annual household income?

- ☐ Under $50,000
- ☐ $50,000 - $100,000
- ☐ $100,000 - $150,000
- ☐ $150,000 - $200,000
- ☐ Over $200,000

What is your age?

- ☐ 20-30
- ☐ 30-40
- ☐ 40-50
- ☐ 50-60
- ☐ 60-70

What is your employment status?

- ☐ Unemployed
- ☐ Part-time employed
- ☐ Full-time employed
- ☐ Retired
- ☐ Full-time caretaker at home

Is there another parent in the home?

- ☐ Yes
- ☐ No

What is their gender?

- ☐ Male
- ☐ Female

What best describes the highest level of his/her education?

- ☐ Less than high school
- ☐ High School graduate
- ☐ Some college
- ☐ College graduate
- ☐ Masters degree
- ☐ Doctorate or professional degree

What is their age?

- ☐ 20-30
- ☐ 30-40
- ☐ 40-50
- ☐ 50-60
- ☐ 60-70

What is their employment status?

- ☐ Unemployed
- ☐ Part-time employed
- ☐ Full-time employed
- ☐ Retired
- ☐ Full-time caretaker at home

Appendix B.e: PROMIS Pediatric Short Form (version 1.1)

Weekly measure for participants during 8-week intervention

PROMIS® Pediatric Item Bank v.1.1 - Depressive Symptoms - Short Form 8b

Pediatric Depressive Symptoms - Short Form

Please respond to each item by marking one box per row.

In the past 7 days.....	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
I could not stop feeling sad.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt alone.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt everything in my life went wrong.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt like I couldn't do anything right.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt lonely.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt sad.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
I felt unhappy.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
It was hard for me to have fun.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Appendix B.f: Expectation of Benefit / Credibility

Evaluation Participant ID Number: _____ Date: _____ Class #: ___

INSTRUCTIONS

You've had one class so far, and we are interested in getting your impressions of your experience of the course thus far.

1. How much does what's being taught in this course make sense to you in helping to you deal with teen issues?

Makes no sense — Makes a lot of sense

0	1	2	3	4	5	6	7	8	9
○	○	○	○	○	○	○	○	○	○

2. How confident are you that this class will help you have a healthier lifestyle?

Not at all confident — Very confident

0	1	2	3	4	5	6	7	8	9
○	○	○	○	○	○	○	○	○	○

3. How confident are you in recommending this course to a friend?

Not at all confident — Very confident

0	1	2	3	4	5	6	7	8	9
○	○	○	○	○	○	○	○	○	○

4. How important do you think it is that we make this class available to other teens?

Not at all important — Very important

0	1	2	3	4	5	6	7	8	9
○	○	○	○	○	○	○	○	○	○

5. How successful do you believe this class would be in decreasing problems or issues that teens have?

Not at all successful — Very successful

0	1	2	3	4	5	6	7	8	9
○	○	○	○	○	○	○	○	○	○

Appendix B.g: Daily Diary

Daily Diary Questions:

Please remember that we want you to be HONEST in your response. This is not school, and there are no grades!

1. Did you practice yesterday?
2. If so, about how many minutes?
3. What practice(s) did you do?

Thanks, and have a GREAT day!

Appendix IC: Recruitment

Flyer

Email Announcement

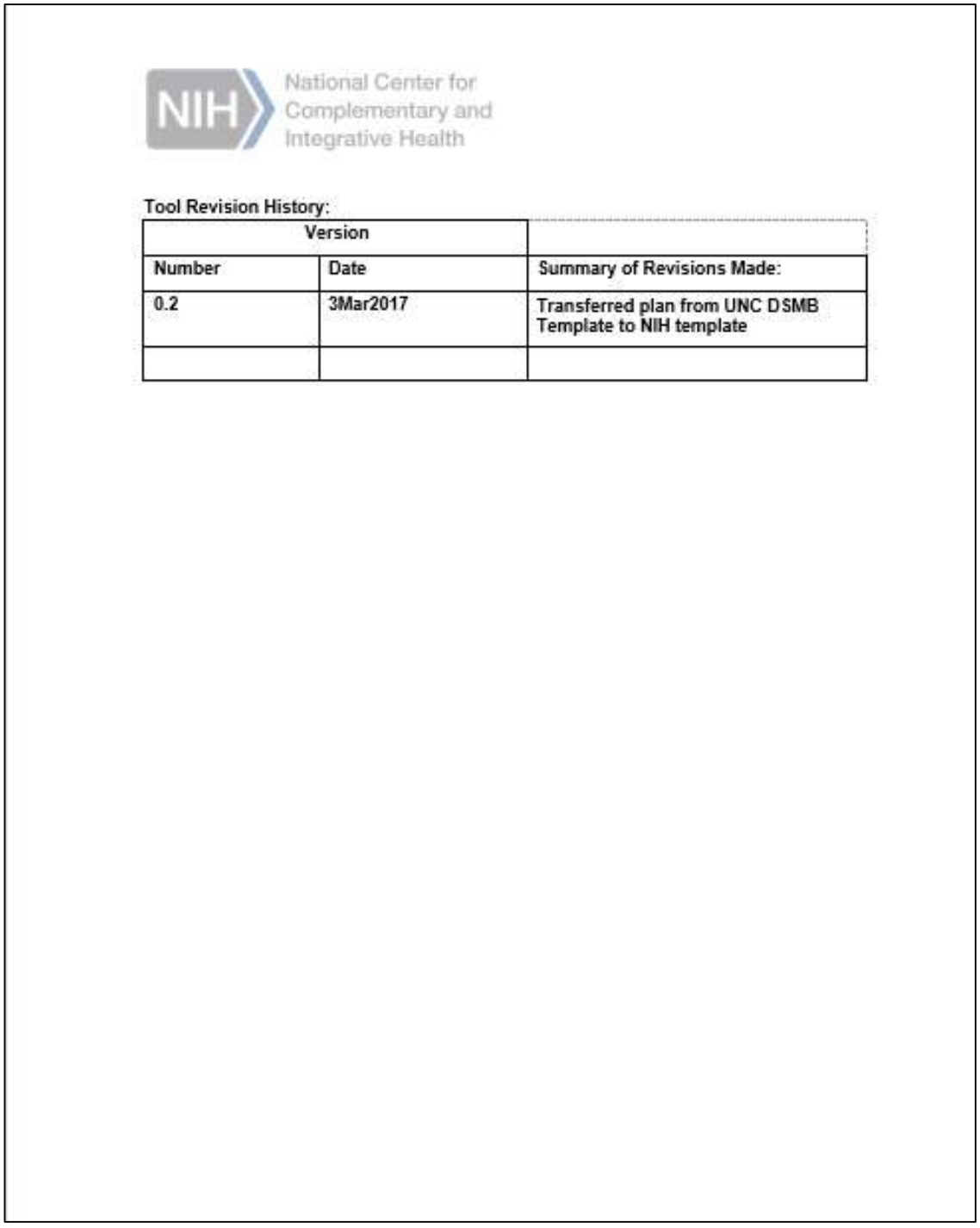
Attention all teens!

Got stress? Having any struggles with school, family, or friends? We are recruiting teens age 14-17 to participate in a research study to test two different courses for lowering stress and improving health and wellbeing in teens. Courses meet once a week for 8 weeks, and then once a month for 6 months after that. Refreshments will be served at classes and teens will receive up to $175 in Amazon gift cards for participating in this study.

Please contact: S.M.A.R.T. Project, UNC Program on Integrative Medicine, smartstudy@med.unc.edu, 919-966-8586 to see if you're eligible.

Appendix IV: Data Safety Monitoring Plan (version 0.3, 23 May 2017)

Appendices of Data Safety Monitoring Plan (DSMP) not included. The DSMP appendices include CVs for ISMC members, which goes from page 17-148 of the DSMP.



National Center for Complementary and Integrative Health

Tool Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
0.2	3Mar2017	Transferred plan from UNC DSMB Template to NIH template

Data and Safety Monitoring Plan (DSMP)

Independent Monitoring Committee

Making Friends with Yourself: A Depression Prevention Program for Adolescents

Name of Sponsor:	National Center for Complementary and Integrative Health
Grant Number:	**1 R34 AT008822-01A1**
Version Date:	23 May 2017
Version Number:	0.3

1 STUDY OVERVIEW

1.1 Purpose of Study

This study was originally conceived of as a protocol development study. Since the original conception, the programs have been developed further and the funder (NIH) has asked that the study be conducted as a pilot/feasibility randomized trial, recognizing that between-cohort changes in the interventions may be made. The study randomizes 14-17 year old adolescents with sub-syndromal depression to one of two group educational interventions: a mindfulness-based self-compassion program and a healthy behavior education program. The latter is expected to have less impact on depressive symptoms in adolescents. In our previous studies of similar interventions for a general population of adolescents, we have encountered few adverse events, and no serious adverse events.

1.2 Adherence Statement

The Data Safety Monitoring Plan (DSMP) outlined below for 1 R34 AT008822-01A1 will adhere to the protocol approved by the University of North Carolina IRB (16-1864).

2 PROTOCOL AMENDMENTS

All protocol amendments, other than minor administrative changes as defined by the NCCIH Guidance on Changes in Clinical Studies in Active Awards will be submitted in a prospective manner to NCCIH except when necessary to protect the safety, rights, or welfare of subjects. Prior to submission to NCCIH the proposed changes will be reviewed and approved by the Independent Monitor(s). IRB-approval will not be sought until after NCCIH approval of the protocol amendment has been obtained.

3 MULTI-SITE STUDIES

THIS IS A SINGLE SITE STUDY.

4 CONFIDENTIALITY

4.1 Protection of Subject Privacy

Screening will be conducted in a private setting (closed-door office for both telephone contacts and direct contact with the potential participants and participants). All materials generated in the screening process will be stored in locked cabinets under the control of the PI. Electronic materials will be encrypted and password-protected under the control of the PI or designated project personnel. If potential subjects do not meet criteria, personal identifiers (name, contact information) generated in the screening process related to that subject will be deleted, but demographic information (age, grade in school, gender, race, ethnicity, city/town, school) will be kept. The screening database will be maintained separately from the study database.

Materials arising out of the research will consist of paper records, audio recordings of the sessions (no participants will be videotaped) and computer files. No biological materials will be collected. All data will be de-identified and given a research number to be used for all analysis. Audio-files will be deleted once transcribed. Written materials will be stored in locked storage cabinets under the control and scrutiny of the PIs. This space is outside of the normal

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pattern of human traffic at UNC. Most of the research data for this project includes surveys and testing instruments filled out on-line by the participants and stored electronically.

Electronic data will be stored in an encrypted and password-protected online database (REDCap). Access to written and electronic data will be limited to the PI, the project manager, research assistant, and the Co-Investigator responsible for data management/quality assurance. The Study Psychologist will have access to a single form to file reports of psychological evaluations. All data – audio recordings, hard copy and electronic files– necessary for analysis will be de-identified and the resulting data files assigned a research number specific for each participant for purposes of analysis. A file linking personal identifiers with participant data, will be maintained in REDCap in a separate file from the main data sets with access limited to the PI and study staff with access needs. No participants will be identified in any presentation or publication.

All data will be collected by the PI, project manager (Lynch) and research assistant as appropriate to their function. Data storage and retrieval will be under the direction of the Internal Quality Assurance Reviewer and the PI. Data will be collected and stored, whenever possible, on a secure server (REDCap).

Subject confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study subjects. The clinical study site will permit access to such records.

4.2 Confidentiality During Adverse Event (AE) Reporting

AE reports and annual summaries will not include subject or group-identifiable material. Each report will only include the identification code. All AEs and UPs are recorded in a password-protected, encrypted database (REDCap).

5 EXPECTED RISKS

Expected risks to the subject are as follows:

- Risk of depression. The study population, adolescents aged 14 through 18, is considered at risk for developing MDD based on their baseline subsyndromal depression (6 or higher on QIDS). It is unknown whether the study itself may contribute directly to the development of MDD in the participants. Since development of MDD is a risk based on the selection criteria for participation, staff will be trained by the project psychologist in the detection of worsening depressive symptoms and reporting of same to the PI for intervention if necessary. Monitoring will also take place with a) the PROMIS Pediatric Depression Short Form (weekly) and b) the short Mood and Feelings Questionnaire (SMFQ-C and SMFQ-P), completed by both the adolescent and a parent before and after the intervention, and 3, 6 months after the intervention. Adolescents will be asked to complete the PROMIS Pediatric Depression Measure through a survey interface on REDCap that provides immediate scoring. The project manager will monitor the PROMIS Depression short form scores weekly and scores on the Mood and Feelings Questionnaire (MFQ) after each administration. A T score of 70 or

greater on the PROMIS Depression short form or a combined child and parent score of 12 or greater on the MFQ will trigger an evaluation by the Study Psychologist.

- Participants will be encouraged to report any change in health status, including mood, to research personnel, instructors, and parents. Reports of increasing depressive symptoms will be reviewed by the Study Psychologist for consideration of appropriate action, including 1) direct confrontation, 2) informing parents, 3) referral to outpatient health care resources in the community, and 4) escorting the participant to emergency facilities for psychological assessment and treatment. Documentation of these events will be reported to the IRB and entered into the case report form for review by the Independent Safety Monitoring Committee (ISMC).

- Suicide risk. Suicide is a potential risk and will be screened for, when the level of reporting depressive symptoms or observed behavior consistent with significant depression is high. The instrument used to detect risk is the *Protocol to Screen for the Imminent Risk of Self Harm* . This instrument was developed locally at UNC for providing a triage-level of evaluation of patients with suspected self-harm thoughts. It is a 20-item, 3-step instrument for assessment of self-harm risk with an action plan detailed for each of four levels of risk. This instrument will be used by the Study Psychologist for assessment of risk and development of an action plan in participants reporting increasing depressive symptoms. A list of community mental health resources will be made available to all study personnel for referral purposes. The Study Psychologist will be immediately available to the research staff and group instructors when questions of self-harm arise.

- When individuals have been self-critical for some time, and then begin to engage in self-compassion practices, some individuals experience a phenomena called "backdraft"; a realization that they have suffered for some time by being self-critical. In teens, this phenomena is less prevalent and usually "weaker" because they have not been self-critical for as long (since they are younger). However, in the MFY course, we explain this phenomena, and how to deal with it if it arises. We provide a number of specific tools to manage it. All classes will be attended by an individual trained in mental health (school counselor, clinical social worker (LCSW), psychologist or a trainee supervised by a psychologist or LCSW) These individuals, along with the instructors, will monitor adolescents closely during the program and will report any concerns to the Study Psychologist, Dr. April Harris-Britt. Dr. Harris-Britt will follow up with the parent and, with permission, the adolescent, and will make referrals for further care as needed. All adolescents and their parents will receive contact information for Dr. Harris-Britt upon enrollment and will be encouraged to contact her directly, should they have an urgent need. Again, Dr. Harris-Britt will evaluate the adolescent and make referrals for care as needed.

- Individuals who develop severe distress during classes or who have a marked increase in symptoms (or reach the threshold for major depression) on the PROMIS pediatric depression short form will be referred immediately to the Study Psychologist, Dr. Harris-Britt. She will call the parent and assess the adolescent and provide the family with appropriate referrals.

- In the first class and periodically in other classes, instructors stress the importance of confidentiality, i.e., what is discussed in the room does not go beyond the room.

- Because of the inherent risk in this population, participants will be monitored at frequent intervals and will be followed for a sufficient period of time after the intervention to ensure stabilization of depressive symptoms. The educational programs to be tested are not commonly associated with increased risk of depression, but participants will be monitored weekly over 6 months for expected and unexpected AEs related to the programs.

- Participants may experience discomfort in answering some of the questionnaire questions or in making disclosures in the classes. Participants will be told that they may skip questions that they do not wish to answer and that disclosures in class are also entirely voluntary.

6 ADVERSE EVENT/ UNANTICIPATED PROBLEMS

6.1 Definitions

6.1.1 *Adverse Event (AE)*

An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these regardless of relationship to participation in the study.

6.1.2 *Unanticipated Problems (UP)*

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

6.1.3 *Serious Adverse Event (SAE)*

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)

- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

6.2 Time Period and Frequency for Event Assessment and Follow-Up

Unanticipated problems will be recorded in the data collection system (REDCap) throughout the study.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

6.3 Characteristics of an Adverse Event

6.3.1 *Relationship to Study Intervention*

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

6.3.2 *Expectedness of SAEs*

The Study PI and Independent Safety Monitoring Committee will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

6.3.3 *Severity of Event*

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)

2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL

3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

6.4 Reporting Procedures

6.4.1 *Reporting for Multi-Center Trials*

Not applicable.

6.4.2 *Unanticipated Problem Reporting*

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to NCCIH within 7 days of the investigator becoming aware of the event.
- The PI, within 24 hours, will report all related or possibly-related AND serious adverse events (SAE) occurring in subjects to the IRB. This will be accomplished by submitting an adverse event report to the IRB and to the ISMC. Serious adverse events will be reported even if the PIs and Study Psychologist believe that the adverse events are unrelated to the protocol.

- Unexpected (but not serious) adverse events occurring in subjects which, in the opinion of the Study Psychologist, are possibly related to participation AND places subjects or others at a greater risk of harm that was previously known or recognized in the protocol will be reported by the PI within 24 hours of discovery by email or phone to the IRB and the ISMC. A follow-up written report within 5 business days to the IRB and the ISMC will be submitted by the PI.

- Unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported to the IRB and DSMB via email or telephone within 24 hours of discovery and a written follow up report within 5 business days.

- Any other unanticipated problem will be reported to the IRB, Independent Safety Monitor(s), and NCCIH within 14 days of the investigator becoming aware of the problem.

- When a protocol deviation occurs, the investigator will report the occurrence to the IRB. The investigator will make the determination whether the deviation meets the criteria for an unanticipated problem involving risks to subjects or others. The IRB Chair or IRB staff member will also make the determination if the protocol deviation meets the definition of an unanticipated problem involving risks to participants or others.

All unanticipated problems will be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

6.4.3 *Adverse Event Reporting of Non-IND Studies*

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Independent Safety Monitor(s), IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Office, and ISMC within 3 days of the investigator becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Safety Monitor(s), IRB, and other oversight organizations in accordance with their requirements and will be reported to NCCIH on an annual basis.
- All other AEs documented during the course of the trial will be reported to NCCIH on an annual basis by way of inclusion in the annual report and in the annual AE summary which will be provided to NCCIH and to the Independent Monitors. The Independent Safety Monitor(s) Report will state that all AEs have been reviewed.

- All AEs documented during the course of the trial will be reviewed by the Independent Safety Monitoring Committee (ISMC) on a regular basis. The ISMC will meet initially after the first cohort (10) subjects have completed the intervention and are in the continuation phase of the study. The ISMC will meet every 6 months thereafter.

6.4.4 *Adverse Event Reporting for IND Studies*

Not applicable.

6.4.5 *Events of Special Interest (if applicable)*

6.4.6 *Reporting of Pregnancy*

There are no plans to withdraw or follow subjects who become pregnant during the intervention. Neither of the educational interventions affords any increased risk in pregnancy or childbirth.

6.5 Halting Rules

Study-wide stopping rules include the occurrence of a serious adverse event, CTCAE Grade 3 or higher, possibly related to the study protocol, occurring in 5 or more randomized adolescents. If these conditions occur, the ISMC will review and make recommendations on the advisability of continuing the study.

7 QUALITY CONTROL AND QUALITY ASSURANCE

Quality Management

The quality control committee consists of Dr. Faurot and Statistician Dr. Suchindran. Monthly reports are made to the committee and PIs by the project manager.

All study staff will complete and maintain the standard training requirements of the University of North Carolina at Chapel Hill for staff in clinical trials. This includes Good Clinical Practice training, Human Research Ethics training, and HIPAA. Staff will also engage in annual training in study procedures. Training activities will be led and documented by the Project Manager. Training of the research staff will include practices of double checking all demographics, inclusion/exclusion criteria, data collection procedures including capture and secure storage, intervention procedures and data management activities.

The Internal QA Reviewer (Faurot) will be responsible for reviewing questionnaires, documentation of video recordings, and eligibility criteria documents monthly and will conduct a quarterly data audit. She will report any errors in data entry and these will be addressed by the project manager.

7.1 Subject Accrual and Compliance

7.1.1 *Measurement and Reporting of Subject Accrual*

Review of the rate of subject accrual and compliance with inclusion/exclusion criteria will occur monthly during the recruitment phase to ensure that a sufficient number of participants are being enrolled, in keeping with proposed recruitment projections, and that they meet eligibility criteria and fulfill the targeted ethnic diversity goals outlined in the grant proposal (Targeted/Planned Enrollment Table).

7.1.2 *Measurement and Reporting of Participant Adherence to Treatment Protocol*

Data on adherence to the treatment protocol will be collected twice weekly by research staff and reviewed monthly by the Internal QA Reviewer (Co-I Faurot). Adherence of participants will be evaluated by diary completion, class attendance, and completion of questionnaires. Available data on the use of mindfulness interventions suggests an overall compliance rate of about 80%. If adherence falls below 75%, which might inhibit the ability of the study to test its primary hypotheses, the Internal QA Reviewer will suggest a meeting with study investigators to discuss methods for improving adherence.

7.2 Justification of Sample Size

Our primary goal is to refine our programs based on mindfulness and self-compassion to prevent MDD among adolescents and to establish the feasibility of its implementation as compared with an active attention-control comparator. Data of multiple types (focus group

recordings, questionnaires) will be captured with attention to complete data capture through frequent participant contact.

Power and sample size. Untreated, >30% of adolescents are expected to develop incident depression. Power is calculated for time to incident MDD and change in depressive symptoms. With a sample size of 80, we expect to have 80% power to detect a hazard ratio of 0.52 for time to MDD between the groups as well as >80% power to detect a mean difference of 4 (SD 6) in SMFQ-C + SMFQ-P. It is anticipated that we will screen 160 with the QIDS and 120 with the DISC to achieve a sample of 80 eligible teens (with 80 parents). Our target recruitment estimate is 53 females and 27 males-based on research demonstrating that there are twice as many female teens with subsyndromal depression as males. ***Note that all enrollment figures refer to teens***. Each will have the involvement of one parent.

7.3 Stopping Rules

The study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

Individual stopping rules. If a participant scores above 12 on the combined parent and child SMFQ at any point in the study, s/he will be referred to the study psychologist (Dr. Harris-Britt) within 24 hours who will then contact the parent of the teen (within 24 hours) to inform the parent of the depression status of the teen. Dr. Harris-Britt will make an evaluation to determine if s/he can continue in the study and will refer the family for appropriate psychological care.

We have added a safety depression screening measure, the PROMIS pediatric depression scale, which will be administered weekly via REDCap. The Assessment Center at NIH provides a scoring algorithm with REDCap software, enabling use of the measure for safety monitoring. The Project Manager will monitor these measures weekly and will alert the team (including the Study Psychologist) to sharp increases in depressive symptoms and depressive symptoms meeting criteria for major depression (T score of 70). If the Study Psychologist confirms the development of major depression, the adolescent will be withdrawn from the study and referred for further care.
Additional reasons for withdrawal of a participant include:
1. The adolescent wishes to withdraw from the study;
2. Loss of study eligibility;
3. Intervening illness or injury making participation difficult;
4. The adolescent develops any condition that, in the opinion of the Study Psychologist would make continued participation unsafe.

In the unlikely event that a participant is unable to participate in a group setting, s/he may be withdrawn from the study.

7.4 Designation of a Monitoring Committee

Three mental health professionals will make up the Independent Safety Monitoring Committee: a child and adolescent clinical psychologist and statistician experienced in research (Eric

Youngstrom, PhD, Professor of Psychology and Psychiatry at UNC-CH), a Clinical Professor and Director of Psychological Services at UNC-CH (Jennifer Youngstrom, PhD), and a mindfulness practitioner and clinician at Duke University (Cynthia D. Jones, Licensed Professional Counselor).These individuals are not associated with this research project and work independently of the PI, Dr. Susan Gaylord and the Co-Investigators. They are not part of the key personnel involved in this grant. No member of the Committee has collaborated or co-published with the PI or Co-I Karen Bluth within the past three years. They are qualified to review the patient safety data generated by this study because of their unique expertise. The CVs of all members of the IMC are attached.

7.5 Safety Review Plan

Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the Independent Monitor(s) semi-annually (every six months). An Annual Report will be compiled and will include a list and summary of AEs. In addition, the Annual Report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The Annual Report will be sent to the Independent Monitor(s) and will be forwarded to the IRB and NCCIH within 2 weeks of receipt. The IRB and other applicable recipients will review progress of this study on an annual basis

7.6 Study Report Outline for the Independent Monitors(s) (Interim or Annual Reports)

The study team will generate Study Reports for the Independent Monitor and will provide information on the following study parameters: accrual targets, accrual rates, UP, SAE, and AE occurrences, number of subjects with a UP, SAE, or AE, protocol deviations
Study Report tables will be generated only from aggregate (not by group assignment) baseline and aggregate safety data for the study population.

Data type	Frequency of review	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	Monthly	PI, Internal QA Reviewer, Study Statistician, Study Team
	Semi-annually	Independent Monitor(s)
Status of all enrolled subjects, as of date of reporting	Monthly	PI, Internal QA Reviewer, Study Statistician, Study Team
	Semi-annually	Independent Monitor(s)
Data entry quality control checks on 10% of charts	Monthly	Project Manager, Internal QA Reviewer, Study Statistician
Adherence data regarding study visits and intervention	Monthly	PI, Internal QA Reviewer, Study Team
	Semi-annually	Independent Monitor(s)

AEs and rates	Monthly	PI, Internal QA Reviewer, Study Team
	Semi-annually	Independent Monitor(s)
	Annually	NCCIH
SAEs (unexpected and related)	Per occurrence	PI, Independent Monitor (s) NIH/NCCIH, IRB
SAEs (expected or unrelated)	Per Occurrence	PI, Internal QA Reviewer, Independent Monitors
	Annually	Independent Monitor (s), NIH/NCCIH
Unanticipated Problems	Monthly	PI, Internal QA Reviewer, Study Statistician, Study Team
	Per Policy	IRB, Independent Safety Monitors

7.7 Submission of On-Site Monitoring/Audit and Inspection Reports

The IRB, ISMC, and NCCIH Program Officials will receive copies of all study monitoring/audit or inspection reports within 14 day of PI receipt. For example, the NCCIH (Westat) monitoring report will be submitted to the IRB and ISMC (NCCIH does not require copies of Westat monitoring reports).

7.8 Table A

Study Team consists of Co-Is, Consultants, Project Manager, and Research Assistants. Monthly data audits will commence once the interventions have started.

8 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain accurate case report forms (CRFs) and source documentation.

Collection of all data is detailed in each visit-specific Manual of Procedures. Electronic direct entry is planned for all questionnaires. Psychological evaluation documents will be completed on paper and maintained in the office of the Study Psychologist. Her staff will complete a study eligibility report to be provided to the study staff. The eligibility report (identified with study number only) data will be entered into REDCap and the report will be kept in a folder identified by the study id number in a locked file cabinet. The Internal QA Reviewer will review all eligibility documents as well as conduct a 10% audit of eligibility document entries.

Our primary goal is to develop a depression-prevention program based on mindfulness and self-compassion and to establish the feasibility of its implementation as compared with an active attention-control comparator. Hence, the establishment of quality assurance processes and complete data documentation assume even greater importance than data analysis. Data of

multiple types from multiple sources will be captured. For questionnaire assessments, secure internet-based data collection instruments will be used, accessible by internet-capable device. Quality assurance of these measures will include review of study instruments for range and consistency checks, and descriptive analyses to assess distributions of study variables. Quality assurance of qualitative measures include 1) maintaining a spreadsheet to log scheduled, completed, transcribed, and analyzed focus groups and interviews; 2) establishing a transcription template to ensure data is uniform in appearance; 3) arranging for secure storage of recordings and transcripts; 4) review of consistency of styles across interviewers; and 5) review of recordings to assess accuracy of transcriptions.

A majority of the aims of this study relate to the capture of refinements to the intervention and collection of feasibility data. A manual will be created for both interventions. The study database will capture versions of the manual with dates of completion of each version, sources of input for changes, and any needs for additional input. The study database will also document inputs from multiple sources, including:

1) Post-participation program group evaluations (audio-file);
2) Post- participation process questionnaires ('Feelings about the Class');
3) Transcriptions of classes (audio-files); and
4) Informal contributions by subjects or their parents to any member of the study team (written study notes).

After capture in the study database, all text data will be entered into qualitative analysis software (ATLAS.TI), to identify and organize main themes that will be used for program refinement. Briefly, for each cohort, 2 members of the study team will code each transcription and other data. The two coders will meet with the remaining member of the analysis team to compare codes and agree on final codes for each of the transcriptions. Each member of the team will reread all qualitative data to identify themes across interviews and other comments using a *qualitative description* approach, remaining as faithful to the words of the participants as possible. Qualitative data will inform the refinement of both programs and creation of the program manuals.

Feasibility will be measured by the following descriptive measures, also captured in the database:

1. Acceptance of the treatment and control programs as measured by attendance in 6 of 8 active intervention sessions and 4 of 6 continuation sessions;
2. Equivalence of the credibility of the two programs as measured by the CRED questionnaire (double-entered);
3. Identification of recruitment challenges and their remedies as measured in the screening database by:
    a. Number of individuals screened;
    b. Proportion of screened adolescents who qualify;
    c. Number of qualifiers who enroll (criterion 75%); and
    d. Number of enrollees who complete the program (criterion 80%);
4. Identification of factors associated with subjects' willingness to adhere to the study protocol (entered in the study database) such as:
    a. Location or timing of program classes, transportation challenges;
    b. Factors leading to dropout;
5. Identification of individual study components fostering engagement in the study.

Subject engagement. In addition to attendance data, engagement will be measured by:

1. Subjective class participation as rated by the instructor on a paper case report form, entered into REDCap by the research assistant;
2. Adherence to recommended home practice as measured in the daily diary (participant rating);
3. Barriers to practice as captured in the diary (text data);
4. Participant comments about the degree to which these practices have enabled them to adopt an attitude of mindfulness and self-compassion (as captured in the audio-taped class sessions).

Program Fidelity. All program sessions will be audio-recorded. The purpose of the recording is two-fold:

1. to identify any systematic variations in instructors' attitude, communication, or behavior between treatment groups; to assess adherence to the protocol; and to screen for any group-dependent differences in communication in content or style between the instructors and participants, and
2. to capture participants' input and comments during the classes (for qualitative analysis). An evaluation matrix will be developed (housed in REDCap) based on the program manuals and other written protocols. A member of the study staff will listen to each program session to rate adherence to the manual/protocol. Deviations will be discussed with the program instructor to assess barriers to program protocol adherence.

8.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff (project manager and research assistants) under the supervision of the investigator. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee.

8.2 Database Protection

This study will use a Real time Electromagnetic /digitally Controlled Analyzer and Processor (REDCap) database managed by the Translational and Clinical Sciences Institute of the University of North Carolina at Chapel Hill. The database will be secured with password protection. The informatics manager will receive only coded information that is entered into the database under those identification numbers. Electronic communication with outside collaborators will involve only unidentifiable information. The database incorporates an electronic audit trail to show change(s) to data after original entry including the date/time and user making the change.

8.3 Source Document Protection

All paper case report forms (other than the psychological evaluation) will be identified with a study id number and kept locked in a subject file within a cabinet controlled by the PI. All electronic records are maintained on REDCap, including study questionnaires. REDCap is password-protected and encrypted and enables personnel-specific access. Evaluation documents specific to classes will also be captured on REDCap.

8.4 Schedule and Content of Reports

Recruitment, accrual, drop-out, and data quality evaluations are conducted prior to monthly Study Team Meetings. A report is given to each member of the study team. Reports are made to the ISMC after the first 20 subjects have completed the interventions and every six months thereafter. Accrual reports are made to NCCIH every 3-4 months and a comprehensive annual report is submitted annually.

Treatment assignment is arranged through a randomization protocol (stratified by gender) implemented by the study statistician in REDCap. Due to the nature of the interventions, it is unlikely that the research assistant or qualitative analysis will remain masked to assignment. However, the quantitative analysts should be able to remain masked and will analyze the data as two groups—group one and group 2.

The study database will be locked as soon as it is deemed to be completed. No interim analysis of quantitative data is planned. Qualitative data will be reviewed and coded as soon as it is available for use in improving the interventions.

9 INFORMED CONSENT

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their parents or legal guardians. An assent form describing in detail the study procedures and risks will be given to the subject with a parental permission form for his/her parent. Consent and assent forms will be IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and parent and answer any questions that may arise. The subject will sign the assent document and the parent will sign the permission document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent documents will be given to subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. Subjects who have their 18th birthday during the study will be re-consented using a consent form applicable to an adult.

The consent process will be documented in the research record.

To complete the informed consent/assent process at the end of study participation, study staff will inform the subject when his/her participation has come to an end and will document the discussion in the study record.

10 REPORTING CHANGES IN STUDY STATUS

During the funding of this study, any action by the IRB, the Independent Safety Monitoring Committee, or one of the study investigators that results in a temporary or permanent suspension of the study will be reported to the NCCIH Program Official within 3 business days of notification.