PROTOCOL TITLE:

Promote Healthy Lifestyle Behaviors for Adolescents with Mental Health Conditions

PRINCIPAL INVESTIGATOR:

Rachel Sharp, BSN, RN, CPN

FSU DNP-FNP Student

850-865-4443

rls14c@my.fsu.edu

VERSION NUMBER/DATE:

Version 1 – 06/24/22

Version 2 – 07/08/22

Version 3 – 08/08/22

Version 4 – 08/10/22

Version 5 – 10/31/22

Version 6- 11/4/22

Version 7- 11/15/22 (Modification approved by IRB 11/26/22)

REVISION HISTORY

Revision #	**Version Date**	**Summary of Changes**	**Consent Change?**
1	7/8/22	Updated: • **Section 6.2** – Provide a list of what information and data element headers will be collected from the medical records for study purposes. • Clarified that PHI will not be obtained from the EHR. The only PHI information for this study will be provided through the REDCap survey. • **Section 13.1** – Provide information about the partially waiver • See Appendix G for HIPAA Authorization form.	Yes- HRP 502 Consent Provided.

		• **Section 13.2/13.3**– List the data element headers that will be collected form medical records for recruitment purposes. • Clarified that PHI will not be obtained from the EHR. The only PHI information for this study will be provided through the REDCap survey. • In the REDCap survey, participants will be asked to provide name of diagnosis, diagnosis date, name of medications, date of birth. • **Section 18** – Needs to provide Data and Safety Monitoring Plan • Attached Data and Safety Monitoring Plan. • **Section 17/19** – In accordance with 45 CFR 164.514(d)(3)(iii)(D) your need for disclosure of PHI must include a statement to the effect that the requested disclosure of PHI is the minimum necessary for research purposes. Provide a statement to this effect in section 17 or 19 of your protocol. • Updated statement for PHI disclosure. • **Section 20** – Complete section 20 • This study will not engage in any activities that may lead to potential injury for participants. • **Section 22/23** – Indicate that consent will be obtained and documented electronically; describe how you will explain the study and/or otherwise be available (email, telephone, other remote interaction) to answer prospective subjects' questions given that study staff and prospective subjects are not interacting in-person; describe how prospective subjects should electronically affix their	

		signatures and date, as well as print/sign/scan the consent form and return the signed and dated consent to the study team; and describe how the study team will subsequently counter-sign, return the counter-signed copy to the subject for subjects' records; how subjects may maintain a copy of their signed consent; and how the study team will document and/or maintain a record of the executed consent form. • Updated consent to reflect how PI will be available for questions during the study.	
2	8/8/22	Requested Clarification: • **Will the participants names be on the electronic survey?** o Participants names will not be on the electronic survey. • **The protocol suggests that you will not collect identifiable data on the survey. That is, you will not have a way to link the participants names to the responses on the survey as they are taking the survey anonymously. Is that accurate? There is no mention of any codes linking participant names to survey responses in the protocol.** o Participant names will not be used to link the participants to their survey responses. Participants will be linked via the email they provide on their REDCap survey. o This is stated in general, adolescent, and children consent. • **During recruitment, are you not asking anyone at the Wolfson Children's Hospital for the names**	Yes- Child, Adolescent, and General Consent

		of clients with identified an mental health disorder. Is that accurate? Are you solely recruiting through flyers sent via email by staff and posted in the facility? o I will not be asking anyone at Wolfson Children's Hospital for names of clients with identified mental health disorders. o I will solely be recruiting through flyers sent via email and staff, posted flyers in the facility, and providers and staff have agreed to provide possible clients meeting the project criteria with the information for the study.	
3	8/10/22	Requested Clarification: • **Please change regarding the information below:** o Parents/legal guardians will be sent the survey via email before the adolescent is sent the survey. During the parent/legal guardian survey, they will be asked to provide assent for their adolescent to participate in the study and assent for HIPAA authorization for their adolescent. If parents/legal guardians do not provide assent for the study, the dyad will be removed from the study. Once parents/legal guardians provide assent and finish their survey, the survey will then be sent to the email address provided for the adolescent.	No- Clarification on the consenting/ assenting process. No change to consenting documents.

		• **To explain the process of consenting parents and obtaining assent from adolescents. For example:** ○ Parents can consent for their children to participate, but you still want to obtain child assent. So, when the parent/legal guardian are sent the survey, they will be asked to provide consent for their child to participate in the study. If the parent/legal guardian does not provide consent, the dyad will be removed from the study. Once parents/guardians provide consent, a survey will be sent to the email of the child and the child/adolescent will be asked to assent. • Updating recruitment process to include posting approved study flyers on social media platforms. Including the Bridge program at Wolfson Childrens Hospital for study flyer placement. • Updated estimated project timeline. • Update Inclusion/Exclusion criteria. Modifications to exclusion/inclusion criteria include: "If pt scores <13 on WHO-5 criteria, they MUST currently be enrolled in therapy services to participate." • Incentive change: A $30.00 Amazon E-Gift Card will be emailed to each adolescent-parent dyad after completing the post-survey.	

4	10/31/22	• Incentive change: A $30.00 Amazon E-Gift Card will be emailed to the first 30 adolescent-parent dyads that complete the post-intervention survey (Change reflected on flyer). • Adding statistician to project team. • Goal Number of parent-adolescent dyads in study. • Clarified zoom session meeting dates. • Updated final question on the post-intervention survey to assess the impact of the moderator (Rachel Sharp) on the receptiveness of the educational presentation (Reflected on updated questionnaires).	
5	11/15/22		

Study Summary

Study Title	Promote Healthy Lifestyle Behaviors for Adolescents with Mental Health Conditions
Study Design	Quasi-experimental study with a one group pretest-posttest design
Primary Objective	To evaluate the impact of an online educational program on improving healthy lifestyle knowledge and behaviors (nutrition, physical activity, screen time, and sleep) among adolescents diagnosed with a mental health condition(s) and their parent(s)/ legal guardian(s).
Secondary Objective(s)	1. Educate adolescents with mental health conditions and their family members about ways to improve healthy lifestyle behaviors. 2. Evaluate an increase in knowledge on healthy lifestyle behaviors after a 45-minute online education session. 3. Evaluate an increase in healthy lifestyle behaviors after the intervention.
Research Intervention(s)/ Investigational Agent(s)	This project utilizes a one-group pretest-posttest design study for 30 (Goal) adolescents (aged 12-17 years) diagnosed with a mental health condition(s) and their parent(s)/legal guardian(s). This project will implement best practices to promote healthy lifestyle knowledge and behaviors to adolescents and their parent(s)/legal guardian(s). An online educational program will be delivered via a 45-minute Zoom meeting. We will compare the effects of an educational program on healthy lifestyle knowledge and behaviors pre-and post-program (after one month) via a REDCap survey for the adolescent and their parent/legal guardian. The survey will utilize an adapted version of the 2021 National Youth Risk Behavior Survey (YRBS) and the 2020 National Survey of Children's Health (NSCH-T3). The analysis of this project will compare changes in healthy lifestyle knowledge and using a paired t-test.
IND/IDE #	N/A

Study Population	- Adolescents, 12-17 years old, with a clinical diagnosis of a mental health condition(s) - Adolescent's parent(s)/legal guardian(s) ages 18 or older
Sample Size	Goal: 30 adolescent-parent dyads
Study Duration for individual participants	One month
Study Specific Abbreviations/ Definitions	PA- Physical Activity

1.0 Objectives*

Purpose:

The purpose of this project is to improve healthy lifestyle knowledge and behaviors among adolescents with a mental health condition(s) through preventative and detailed nutritional, physical activity, screen time, and sleep education.

Clinical Question:

Among adolescents 12-17 years old who are diagnosed with a mental health condition(s), does an educational intervention improve healthy lifestyle knowledge and behaviors including nutrition, physical activity, screen time, and sleep?

Aims

We will accomplish three aims using a one group pretest-posttest design:

1. Educate adolescents with mental health conditions and their family members about ways to improve healthy lifestyle behaviors.

2. Evaluate an increase in knowledge on healthy lifestyle behaviors after a 45-minute online education session.

3. Evaluate an increase in healthy lifestyle behaviors after the intervention.

Background*

Background and Significance

The pediatric population faces a public health crisis involving children and adolescents with overweight or obesity. Childhood obesity has become the most disconcerting and predominant pediatric nutritional disorder worldwide (Centers for Disease Control and Prevention [CDC], 2020a). From 2017 to 2018, 19.3% of the children and adolescents in the United States (US) were diagnosed with obesity (CDC, 2020b). Childhood obesity has been linked to psychological conditions such as depression and anxiety (CDC, 2020b). Children that are overweight or obese are more commonly diagnosed with depression than children with a healthy weight (Lindberg et al., 2020). In 2019, 13.6% of children five to seventeen years old received mental health treatment in twelve months, and 8.4% of that population had taken psychotropic medication for their mental health condition (CDC, 2020c).

Healthy lifestyle behaviors impact short and long-term health and quality of life among children with depression. Physical activity (PA), healthy nutritional habits, and maintaining a healthy weight can improve children's quality of life with depression and overweight or obesity (Rippe, 2018). Parents have the most significant influence on their children's health. Thus, family-based intervention studies have been conducted to

promote children's healthy lifestyle behaviors. Behavioral interventions that combine nutritional, physical, and behavioral components and parental involvement have proven to be the best and most effective practice for treating and preventing childhood obesity among adolescents 12-17 years old (Al-Khudairy et al., 2017).

Although there is evidence to support that adolescents benefit from peer and family support and group education, there are few in-depth studies documenting lifestyle modifications that can improve this population's overall physical and mental health. Given this lack of implementation into practice, this project aims to improve healthy lifestyle knowledge and behaviors among adolescents with a mental health condition(s) through preventative and detailed nutritional, physical activity, screen time, and sleep education.

This study's purpose is to identify factors that may aid in answering the clinical question: Among adolescents 12-17 years old who are diagnosed with a mental health condition(s), does a family-based educational intervention improve healthy lifestyle knowledge and behaviors, including nutrition, PA, screen time, and sleep? The specific aims are to: Aim 1: To educate adolescents with mental health conditions and their family members about ways to improve healthy lifestyle behaviors. Aim 2: To evaluate an increase in knowledge on healthy lifestyle behaviors after a 45-minute online education session. Aim 3: To evaluate an increase in healthy lifestyle behaviors after the intervention.

Study Endpoints*

Study Endpoints*

This study will be completed by May 2023**.**

Study Intervention/Investigational Agent

1.1 *Description:*

This project utilizes a one-group pretest-posttest design study for 30 adolescents (aged 12-17 years) diagnosed with a mental health condition(s) and their parent/legal guardian. This project will implement best practices to promote healthy lifestyle knowledge and behaviors to adolescents and their parent(s)/legal guardian(s). This will be a 45-minute educational presentation delivered via Zoom. Participants can select between multiple dates/times (over a 3-week period) for the educational session. We will compare the effects of an educational program on healthy lifestyle knowledge and behaviors pre- and post-program (after one month) via a REDCap survey for the adolescent and their parent/legal guardian. The survey will utilize an adapted version of the 2021 National Youth Risk Behavior Survey (YRBS) and the 2020 National Survey of Children's Health (NSCH-T3). The analysis of this project will compare changes in healthy lifestyle knowledge and behaviors using a paired t-test. The educational presentation will be recorded and emailed to participants within 1 week of intervention to re-watch/review.

The educational program will promote a healthy lifestyle knowledge and behaviors through education established by the Centers for Disease Control and Prevention, the World Health Organization, and the American Academy of Pediatrics. Educational sessions will include the importance of healthy lifestyle modifications in the adolescent population with a mental health condition(s), lifestyle recommendations versus reality, nutrition, physical activity, screen time, and sleep recommendations and guidelines. The educational presentation via Zoom will include: 5-10 minutes of education regarding recommendations versus reality for nutrition, PA, screen time, and sleep, 20-25 minutes of education regarding ways to improve healthy lifestyle knowledge and behaviors. Potential obstacles to consider for this project include the recruitment of thirty applicants for this study and maintaining participant and family involvement in the study from pre-intervention to post-intervention.

1.2 Drug/Device Handling: N/A
1.3 N/A

Procedures Involved*

1.4 Describe and explain the study design.

Interventions will be evaluated through a pre- and post-intervention survey regarding parental/adolescent's healthy lifestyle knowledge and behaviors developed from nationally approved health surveys including the National Survey of Children's Health (NSCH), the WHO (Five) Well-Being Index, the Patient Health Questionnaire- 9 (PHQ-9), and the Youth Risk Behavior Surveillance System (YRBSS) (Bureau, n.d.; Kroenke et al., 2001; *CDC*, 2021; *WHO-5 Questionnaires*, n.d.). The World Health Organization (Five) Well-Being Index questions will appear in the REDCap survey as a screening prior to the project survey. This survey is suitable for children nine years and above. If the raw score is below 13 or if the patient has answered 0 to 1 to any of the five items, they will not be allowed to complete the REDCap survey or participate in the project (*The World Health Organisation- Five Well-Being Index (WHO-5)*, n.d.; World Health Organization. Regional Office for Europe, 1998).

The pre- and post-intervention survey will be the same, except the post-intervention survey will not include demographic questions. The adolescent survey will include 61 questions total: 6 WHO-5 mental health screening, 7 demographics, 2 weight/self-image, 16 nutrition, 10 PA, 12 sleep, 5 screen time, 4 home environment, and 1 comment box for questions regarding nutrition, PA, screen time, and sleep. The parent/legal guardian(s) survey will include 70 questions total: 4 adolescent mental health screening, 11 demographics, 7 evaluating adolescent overall health, 16 nutrition, 10 PA, 12 sleep, 5 screen time, 4 home environment, 1 comment box for questions regarding nutrition, PA, screen time, and sleep. 1 question will be added to the end of the post-intervention survey (for both adolescent and parent/legal guardian surveys) to assess the impact of the Zoom moderator on the educational intervention. See Appendix.

1.5 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

- This project utilizes a one-group pretest-posttest design study for 30 adolescents (aged 12-17 years) diagnosed with a mental health condition(s) and their parent/legal guardian.
- This will be an educational program delivered via a 45-minute presentation delivered via Zoom.
- Participants can select between multiple dates/times (over a 3-week period) for educational session.
- The educational presentation will be recorded and emailed to participants within 1 week of intervention to re-watch/review.
- The educational program will promote a healthy lifestyle knowledge and behaviors through education evidenced by the CDC, WHO, and the American Academy of Pediatrics. Educational sessions will include the importance of healthy lifestyle modifications in the adolescent population with a mental health condition(s), lifestyle recommendations versus reality, nutrition, physical activity, screen time, and sleep recommendations and guidelines. The educational presentation will

include: 5-10 minutes of education regarding recommendations versus reality for nutrition, PA, screen time, and sleep, 20-25 minutes of education regarding ways to improve healthy lifestyle knowledge and behaviors, 10 minutes for questions and discussion.

- We will compare the effects of an educational program on healthy lifestyle knowledge and behaviors pre-and post-program (after one month) via a REDCap survey for the adolescent and their parent/legal guardian.
    - The survey will utilize an adapted version of the 2021 National Youth Risk Behavior Survey (YRBS) and the 2020 National Survey of Children's Health (NSCH-T3). The analysis of this project will compare changes in healthy lifestyle knowledge and behaviors and knowledge using a paired t-test.
- Information required for this study will be provided through the pre-and post-intervention survey.
- PHI will not be obtained from the EHR. The only PHI information for this study will be provided voluntarily through the REDCap survey.
    a. The PHI information provided through REDCap includes:
        i. Name of current mental health diagnoses
        ii. Mental health diagnosis date
        iii. Name of medications
        iv. Date of birth
    b. Participants names will not be on the electronic survey.

1.6 The pre- and post-intervention survey will be the same, except the post-intervention survey will not include demographic questions. The adolescent survey will include 61 questions total:6 WHO-5 mental health screening, 7 demographics, 2 weight/self-image, 16 nutrition, 10 PA, 12 sleep, 5 screen time, 4 home environment, and 1 comment box for questions regarding nutrition, PA, screen time, and sleep. The parent/legal guardian(s) survey will include 70 questions total: 4 adolescent mental health screening, 11 demographics, 7 evaluating adolescent overall health, 16 nutrition, 10 PA, 12 sleep, 5 screen time, 4 home environment, and 1 comment box for questions regarding nutrition, PA, screen time, and sleep. 1 question will be added to the end of the post-intervention survey (for both adolescent and parent/legal guardian surveys) to assess the impact of the Zoom moderator on the educational intervention.

1.7 *Describe:*

- Procedures performed to lessen the probability or magnitude of risks.
    - Parental Consent and Adolescent Assent
    - Parental Involvement in educational intervention
    - Adolescent mental health screening- The World Health Organization (Five) Well-Being Index questions
        a. If the raw score is below 13 or if the adolescent has answered 0 to 1 to any of the five items, they will not be allowed to complete the REDCap survey or participate in

the project, unless they are currently enrolled in outpatient mental health services (Ex: counseling, therapy, partial hospitalization).

- All drugs and devices used in the research and the purpose of their use, and their regulatory approval status. N/A
- The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
    - See Appendix A and B

1.8 What data will be collected during the study and how that data will be obtained.

- The data collected will compare the effects of an educational program on healthy lifestyle knowledge and behaviors pre-and post-program (after one month) via a REDCap survey for the adolescent and their parent/legal guardian.
- The data will be obtained through a REDCap survey.

1.9 N/A

Data and Specimen Banking* N/A

Sharing of Results with Subjects* N/A

Study Timelines*

1.10 Describe:

- Project recruitment will be begin in early October 2022.
- Project recruitment will end November 2022.
- Project pre-survey survey will be sent out the middle to end of November 2022.
- Participants will have 2 weeks to complete pre-survey prior to Zoom educational session. A reminder email will be sent to complete pre-survey.
- An online educational session will be held middle to end of November 2022. Participants can select between multiple dates/times (over a 3-week period) for educational session.
- Participants will be emailed the recorded educational presentation within 1 week of intervention.
- Participants will then receive a post-survey 1 month after educational session.
- Study will be completed by middle/end of December 2022-Early January 2023.

- The duration of an individual subject's participation in the study.
    - 1 month duration
- The duration anticipated to enroll all study subjects.
    - 1 month

- The estimated date for the investigators to complete this study (complete primary analyses)
    - Study will be completed by Middle/End of December 2022- Early January 2023

Inclusion and Exclusion Criteria*

1.11 Describe how individuals will be screened for eligibility.

- Adolescents, 12-17 years old, with a clinical diagnosis of a mental health condition(s) and their parent/legal guardian.
- Examples of eligible diagnosed mental health conditions include major depressive disorder (MDD), generalized anxiety disorder (GAD), attention-deficit disorder (ADD)/ attention deficit hyperactivity disorder (ADHD), bipolar disorder (BPD).
- Adolescents that score below 13 on the World Health Organization (Five) Well-Being Index survey or if the adolescent has answered 0 to 1 to any of the five items, they will not be allowed to complete the REDCap survey or participate in the project unless they are currently enrolled in outpatient mental health services (Ex: counseling, therapy, partial hospitalization).

Parent(s)/legal guardian(s), 18 years old or order, live with adolescents diagnosed with mental health condition(s)

1.12 Describe the criteria that define who will be included or excluded in your final study sample.

- Inclusion Criteria:
    - Individuals who are not yet adults (Adolescents 12-17 years old)
    - With diagnosed mental health condition (ex: Depression, Anxiety, ADD/ADHD) more than one year ago.
    - Adolescent eligibility determined with WHO-5 screening prior to pre-intervention survey.
    - Parent(s)/legal guardian(s), 18 years old or order, live with adolescents diagnosed with mental health condition(s)
    - Be able to read/write in English.
- Exclusion Criteria:
    - Children <12 years old or >18 years old
    - Children 12-17 that are wards of the state or any other agency, institution, or entity
    - Adolescent scoring <13 and not currently enrolled in mental health services, or if the adolescent has answered 0 to 1 to any of the five items, on the WHO-5, and not currently enrolled in mental health services.
    - Female participants that report they are pregnant before or after the start of the study will be excluded from the study.

- Parent(s)/legal guardian(s) < 18 years old
- Non-legal guardians

1.13 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent N/A*

2.0 Individuals who are not yet adults (infants, children, teenagers): Adolescents, 12-17 years old, with a clinical diagnosis of a mental health condition(s).

- *Pregnant women N/A*
- *Prisoners N/A*

Vulnerable Populations*

2.2 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.*: See attached checklist.

Local Number of Subjects N/A

Recruitment Methods

2.3 Describe when, where, and how potential subjects will be recruited. If recruitment will involve a non-FSU site, describe whether site approval for recruitment is required, and attach documentation of site approval.

- When: Project recruitment will be begin in early October 2022.
- Where:
  - The setting will be the Intensive Outpatient Behavioral Health Program (IOP) and the Partial Hospitalization Program (PHP) and Bridge Program at Wolfson Children's Hospital in Jacksonville, Florida.
  - Study flyers will also be posted on social media platforms (ex: Facebook and Instagram).
- Baptist Health IRB approval will be obtained.
- Attached is Wolfson Children's Hospital's Nursing Scientific Review Committee's approval letter.
- How:
  - Contact nurse and program manager in IOP/PHP/Bridge clinic and obtain permission to reach eligible participants.

    - Request that IOP/PHP/Bridge manager emails study flyers with monthly clinic email. Request placement of flyers in IOP/PHP/Bridge clinic. See Appendix C for project flyer.
    - I will not be asking anyone at Wolfson Children's Hospital for names of clients with identified mental health disorders.
- I will be recruiting through flyers sent via email and staff, posted flyers in the facility, and through flyers posted on social media platforms.
- Providers and staff within IOP, PHP, Bridge have agreed to provide possible clients meeting the project criteria with the information for the study.
- See Appendix G for HIPAA Authorization form. Refer to section 17.4 for information regarding how PHI will be protected during this project.

2.4 Describe the source of subjects.

- Intensive Outpatient Behavioral Health Program (IOP), the Partial Hospitalization Program (PHP), and Bridge Program at Wolfson Children's Hospital
- As previously mentioned, PHI will not be obtained from the EHR.
- Study flyers will be posted on various social media platforms.

2.5 Describe the methods that will be used to identify potential subjects.

- Request that IOP/PHP/ Bridge manager emails study flyers with monthly clinic email.
- Request placement of flyers in IOP/PHP/Bridge clinic. See Appendix C for project flyer.
- Study flyers will be posted on various social media platforms.
- This is the eligibility criteria used in the research flyer to recruit the potential participants in this study. Parents/Legal guardians will be asked and screened for eligibility. They are to complete the screening and provide permission for the adolescent prior to the adolescent's completion of the screening.

Adolescents, 12-17 years old, with a clinical diagnosis of a mental health condition(s) and their parent/legal guardian.

Examples of eligible diagnosed mental health conditions include major depressive disorder (MDD), generalized anxiety disorder (GAD), attention-deficit disorder (ADD)/ attention deficit hyperactivity disorder (ADHD), bipolar disorder (BPD).

Adolescents that score below 13 on the World Health Organization (Five) Well-Being Index questionnaire or if the adolescent has answered 0 to 1 to any of the five items, they will not be allowed to complete the REDCap survey or participate in the project

Parent(s)/legal guardian(s), 18 years old or order, live with adolescents diagnosed with mental health condition(s)

- PHI will not be obtained from the EHR. The only PHI information for this study will be provided voluntarily through the REDCap survey.
    a. The PHI information provided through REDCap includes:
        i. Name of current mental health diagnoses
        ii. Mental health diagnosis date
        iii. Name of medications
        iv. Date of birth
    - The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals.
    - Participant names will not be used to link the participants to their survey responses. Participants will be linked via the email they provide on their REDCap survey.

2.6 *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

- See Appendix C

2.7 *Describe as applicable whether and how subjects will be paid, earn course or other credits, reimbursed or provided with any financial or other incentive, token or gift for taking part in the research. Include a description and schedule of the total amount or value as well as the timing of any payments, credits, reimbursement or other incentive, token or gift. Indicate how if at all any amount is pro-rated for research visit or activity completion, and whether and how subjects' refusal to answer any question or subjects' withdrawal from or discontinuing taking part in the study or any study activity will reduce or preclude subjects from earning part or all of such any payment, credit, reimbursement or other incentive, token or gift.*

Also describe the proposed method (how, by whom, form etc.) of payment/disbursement. While payment should not be contingent upon

completion of the entire study, a proportion or progressive partial payment as an incentive for completion of the study is acceptable.

Refer to this FSU link regarding use of gift cards:

https://procurement.fsu.edu/vendors/NationalGiftCard.

Refer to this FSU Controller link regarding use of cash payments for human subject incentive payments: https://controller.vpfa.fsu.edu/services/accounts-payable/unencumbered-payments/employee-cash-advance-requests.

- A $30.00 Amazon E-Gift Card will be emailed to the first 30 adolescent-parent dyads that complete the post-intervention survey.
- This will be offered as an incentive to adolescents and their parent(s)/legal guardian(s) to complete the education intervention and pre-and post-survey.
- Amazon E-Gift Card will be purchased through the SpearMart catalog under the supplier National Gift Cards (NGC)

13.6 N/A

Withdrawal of Subjects*

2.8 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

- Children <12 years old or >18 years old
- Children 12-17 that are wards of the state or any other agency, institution, or entity
- Adolescent scoring <13 and not currently enrolled in mental health services, or if the adolescent has answered 0 to 1 to any of the five items, on the WHO-5, and not currently enrolled in mental health services.
- Parent(s)/legal guardian(s) < 18 years old
- Non-legal guardians

2.9 N/A

2.10 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

- Subject may withdraw from the study at any time. If subjects withdraw from the research, any of their data will be destroyed and their collected data will not be included in the final data analysis.

Risks to Subjects*

2.11 Participants in this project will be at Minimal risk- means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and

of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Participants may feel embarrassed with some of the questions that I will ask
- Taking the survey and joining the educational presentation may make participants tired.

2.12 N/A

2.13 N/A

2.14 N/A

Potential Benefits to Subjects*

2.15 Improved nutrition, physical activity, screen time, and sleep education influenced by healthy lifestyle knowledge and behaviors. This project intends to improve healthy lifestyle knowledge and behaviors among adolescents with a mental health condition(s) through preventative and detailed nutritional, physical activity, screen time, and sleep education.

2.16 N/A

Data Management* and Confidentiality

2.17 Data will then be analyzed using SPSS version 27.0. Descriptive statistics for adolescent and their parent/legal guardian's demographic characteristics will be computed. The analysis of this project will compare changes in healthy lifestyle knowledge and behaviors and knowledge using a paired t-test.

2.18 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

- Data will be collected through REDCap survey
- REDCap allows users to export any and all data from their REDCap projects, supposing they have been given full data export privileges.
- The Data Export Tool also has advanced export features that allow one to implement data deidentification methods, such as being able to automatically remove free-form text fields, remove dates, perform date shifting, and remove fields tagged as identifiers (e.g. PHI) from the data file being exported by the user.

2.19 Describe any procedures that will be used for quality control of collected data.

- REDCap stores its data and all system and project information in various relational database tables (i.e. utilizing foreign keys and indexes) within a single MySQL database, which is an open source RDBMS (relational database management system).
- To help protect and secure the data stored in REDCap's back end database, the software application employs various methods to protect

against malicious users who may attempt to identify and exploit any security vulnerabilities in the system.

- In REDCap, all incoming data gets intentionally filtered, sanitized, and escaped. This includes all data submitted in an HTTP Post request and all query string data found in every URL while accessing REDCap, among other modes through which user-defined data gets submitted in the application. Server environment variables that are vulnerable to forgery by users are also checked and sanitized. All user-submitted data is properly filtered for any possibly harmful markup tags (e.g. <script>) and is then escaped before ever being displayed on a web page within the application.

2.20 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
    - *REDCap will store pre- and post-intervention survey responses.*
- *Where and how data or specimens will be stored?*
    - REDCap stores its data and all system and project information in various relational database tables (i.e. utilizing foreign keys and indexes) within a single MySQL database.
- *How long the data or specimens will be stored?*
    - The data will be destroyed approximately five years after the study ends.
- *Who will have access to the data or specimens?*
    - *Rachel Sharp, Dr. Geneva Scott-King, Insu Paek, Ph.D*
- *Who is responsible for receipt or transmission of the data or specimens?*
    - *Data will be automatically uploaded into REDCap.*
- *How data or specimens will be transported?*
    - *All project data is stored and hosted there at the local institution, and no project data is ever transmitted at any time by REDCap from that institution to another institution or organization.*
- The requested disclosure of PHI is the minimum necessary for research purposes. PHI will not be reused or disclosed to any other person or entity, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 Study data will be sent to the Research Electronic Data Capture (REDCap) program, a secure, web-based application stored on a secure server at the Florida State University College of Medicine. Only de-identified information will be maintained on the PI's password-protected computer. The data will be accessed only by the PI using a password known only to her. The data will be destroyed approximately five years after the study ends.

2.21 Describe:

- This study is considered a clinical trial because it involves human participant that are assigned an intervention (there is no control). This study is designed to evaluate the effect of the intervention on behavioral outcomes.
- The PI will periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
- This study will not engage in any activities that may lead to potential injury for participants.
    - The data will be reviewed through REDCap questionnaire.
    - The project intervention includes a 45-minute educational presentation via Zoom will include: 5-10 minutes of education regarding recommendations versus reality for nutrition, PA, screen time, and sleep, 20-25 minutes of education regarding ways to improve healthy lifestyle knowledge and behaviors.
- Data from this study will be collected through REDCap survey.
- Data collection will only occur during September – November 2022. There will be a pre- and post-intervention survey.
- The PI and Major Professor will review the data.
- Since there is no risk for harm during this study, there will not be statistical tests for analyzing the safety data to determine whether harm is occurring.
- No conditions that trigger an immediate suspension of the research.

Provisions to Protect the Privacy Interests of Subjects

2.22 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

- Participants can refuse to answer any question on the survey.
- Adolescent refusal to answer screening questions regarding mental health screening will lead to withdrawal from the study.
- The requested disclosure of PHI is the minimum necessary for research purposes.

2.23 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

- Participants will be told that this survey is about health and lifestyle behaviors. It has been developed so you can tell us what you do that may affect your health. The information you give will be used to develop better health education for adolescents and their parent(s)/legal guardian(s).
- DO NOT include your name on this survey. The answers you give will be kept private. No one will know your responses. Answer the questions based on what you really do.
- Completing the survey is voluntary. If you are not comfortable answering a question, just leave it blank.
- The questions that ask about your background will be used only to describe the types of students completing this survey. The information will not be used to find out your name. No names will ever be reported.

2.24 *Indicate how the research team is permitted to access any sources of information about the subjects.*

- The research team is only allowed access to the information provided by the participants in the REDCap pre-and post-intervention survey.

Compensation for Research-Related Injury

- This study will not engage in any activities that may lead to potential injury for participants.

Economic Burden to Subjects N/A

Consent Process

2.25 *Indicate whether you will you be obtaining consent, and if so describe:*

- *Where will the consent process take place?*
  - Parent(s)/Legal Guardian(s) and adolescent consent will take place online through REDCap survey
  - Consent for parent(s)/legal guardian(s)
    a. Appendix D
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
  - No
- *Any process to ensure ongoing consent.*
  - Continued participation in the project. If participants do not continue to provide consent, they simply can refuse to complete the project.
- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)."*
  - Yes, parent(s)/legal guardian(s) will be provided with Informed Consent.

Non-English Speaking Subjects N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) N/A

Subjects who are not yet adults (infants, children, teenagers)

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
    - Adolescent participants will be asked to provide month, day, and year they were born.
    - *Parent(s)/legal guardian(s) will be asked to confirm their child's age in their survey.*
    - If ages provided by Adolescent and Parent/Legal Guardian(s) do not match, the adolescent-parent/legal guardian dyad will be withdrawn from the study.
- *Describe whether parental permission will be obtained from:*
    - One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
    - Parents/legal guardians will be sent the survey via email before the adolescent is sent the survey. When parent/legal guardians are sent the survey, they will be asked to provide consent for their child to participate in the study. If the parent/legal guardian does not provide consent, the dyad will be removed from the study. Once parents/guardians provide consent, a survey will be sent to the email of the child and the child/adolescent will be asked to assent.
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
    - Permission can be obtained from an adolescent's legal guardian.
    - The process to determine the authority to consent to the project will be determined by the first question on the parent/legal guardian survey
        a. *"Are you the parent of legal guardian of the adolescent participating in this project?"*
    - The survey will then determine the relationship of the parent/legal guardian again in the demographic questions.
        a. EX: How are you related to this child?

Biological Parent

Stepparent

Grandparent

Legal Guardian

Other: Relative

Other: Non-Relative

- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
    - Assent will be obtained from all adolescents participating in the study.
    - Assent for adolescents 12-13
        - *a.* Appendix E
    - Assent for adolescents 14-17
        - *a.* Appendix F
- *When assent of children is obtained describe whether and how it will be documented.*
    - Assent will be obtained and documented as the first section of the REDCap survey.
    - PI will be available via email to answer any questions/concerns participants may have regarding the study.

Prospective subjects should electronically affix their agreement to consent by checking "yes" to, "Do you agree to participate in this study," and providing the date on their consent through the REDCap survey.

The REDCap survey will ask:

a. Do you agree to participate in this study? If they answer yes, it will populate the following prompts:
    i. Today's date
        1. All the following questions will be marked in REDCap as "identifiers" which will limit access to PHI when exporting your data.
        2. To maintain privacy, I will not require participants to enter their name for informed consent. If they check "yes" to, "Do you agree to participate in this study," that will be used in lieu of formal name/signature.

Subjects may maintain a copy of their signed, IRB Stamped, consent by downloading a copy of the signed consent from REDCap.

REDCap survey will state, "Copy of informed consent document for download. Please click on PDF document below to download and save to your computer.

Participants will be able to download their survey responses prior to completing the survey.

b. Consent will be affirmed through REDCap
    i. The REDCap survey will include a signature of person obtaining authorization (PI) and today's date.
c. Investigator accesses the informed consent form (ICF) to affirm informed consent, and e-signs their portion.
d. Participant and investigator each keep a copy of ICF for their research.

- For those who decline the study, REDCap will provide a message for those who decline.
    a. The message as follows: Thank you for your interest. If you agree to participate in the future, please let us know. You can close this window or click on submit below."
    b. They will still have the opportunity to download copy of informed consent.
    c. A PDF copy of the e-Consent will be automatically saved in the project's file suppository (not in the record), which can be accessed and downloaded by authorized users as needed.
    d. E-Consent Framework will be enabled which:
        i. Includes a certification page at the end of the survey
        ii. Requires respondents to review and confirm information an inline PDF copy of the survey to be marked as complete.
        iii. Allows versioning of a form.

Cognitively Impaired Adults N/A

Adults Unable to Consent N/A

Adults Unable to Consent N/A

Process to Document Consent in Writing
Please check attached consents.

Setting

2.26 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
  - The setting will be the Intensive Outpatient Behavioral Health Program (IOP) the Partial Hospitalization Program (PHP) and Bridge Program at Wolfson Children's Hospital in Jacksonville, Florida.
  - Study flyers will be posted on various social media platforms.
- *Identify where research procedures will be performed.*
  - Online via REDCap Survey and Zoom-based educational intervention.
- *Describe the composition and involvement of any community advisory board.*
  - *N/A*
- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization. N/A*
  - *Local scientific and ethical review structure outside the organization. N/A*
- *Describe non-FSU site approval to conduct research at any non-FSU site or location and attach approval documentation. If no such approval was required, so state and be prepared to provide documentation. Studies involving non-FSU sites, institutions, or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require those sites' IRB, research review or other approvals. Before submitting your studies for FSU IRB review, you must contact such sites to ascertain their review requirements and comply accordingly. The FSU IRB may require documentation of such site contact. Collaborations involving TMH are subject to specific requirements; click here for more information.*
  - Please see Appendix G: Baptist Health NSRC support letter.

Resources Available

2.27 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
  - Nurse and program manager in IOP/PHP/ Bridge clinic will help to recruit eligible participants.
  - Goal: 30 adolescent- parent/legal guardian dyads total

- *Describe the time that you will devote to conducting and completing the research.*
    - Early October 2022- Late December 2022/January 2023
- *Describe your facilities.*
    - Intensive Outpatient Behavioral Health Program (IOP) ,the Partial Hospitalization Program (PHP), and Bridge Program at Wolfson Children's Hospital in Jacksonville, Florida.
    - Social media platforms such as Facebook and Instagram.
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
    - Site liaisons at the Intensive Outpatient Behavioral Health Program (IOP), the Partial Hospitalization Program (PHP), and Bridge Program at Wolfson Children's Hospital will be available for psychological resources during the project.
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
    - Site liaisons will be informed of their role in helping to recruit participants for the project. Any other roles and responsibilities will be discussed prior to the recruitment process for the project via email. Protocol standards will be established via Baptist Health NSRC/IRB.

Multi-Site Research* N/A