Study Protocol

Official Title: Social Media Intervention for Online Victimized Youth (SMILEY)

Clinical Trials.gov ID (NCT number):

Protocol Date: 1/27/2025

<insert local department letter head>

Consent for Participation in a Research Study

PRINCIPAL INVESTIGATOR: <insert local PI information>

TITLE OF PROJECT: SMILEY R34-Aim 3

SOURCE OF SUPPORT: National Institute of Mental Health

Key Information:

This research is being done to test an intervention called SMILEY, a chatbot used by teens who have had negative online experiences (e.g., bullying, harassment, or discrimination). The goal of SMILEY is to reduce further exposure to negative online experiences and depression symptoms while increasing use of coping skills and healthier social media use.

Participation includes:

- Completing an onboarding session with the study clinician.
- Being randomly assigned to receive one of two study interventions.
- One study intervention involves a) engaging with a chatbot on Meta's Messenger app approximately 2-3 times a week for a duration of approximately 10-20 minutes at a time over the course of 4 weeks and b) receiving resources related to using social media effectively and responding to negative online experiences.
- The other study intervention involves only resources about using social media effectively and responding to negative online experiences.

We are inviting up to 75 participants in the ETUDES Center Primary Care Study who have experienced negative online interactions and depression symptoms and are aged 12-18.

The intervention will not replace any treatment your child would normally receive. This means your child can continue to participate in their current treatment program(s).

Risks include potential for breach in confidentiality, potential for worsening distress or suicidal thoughts and behaviors, and potential for continued or worsening cyberbullying. However, there is nothing about this study's intervention that suggests it would increase your child's risk level. We have careful plans in place to support your child and to protect their safety.

If your child experiences a crisis, the resources below are available 24/7, can be contacted anonymously, and have trained counselors who are available to talk.

- National resources include the 988 Suicide and Crisis Hotline at 988, the Crisis Text Line by texting HOME to 741741, or the Trevor Project, a crisis hotline specifically for LGBTQ+ youth at 1-866-488-7386.
- <enter local site crisis contact information here>

- Additional behavioral health resources can be found here: https://www.etudescenter.org/resources-for-families

Study Intervention

This study is a randomized controlled trial (RCT). That means that your child will be randomly assigned to either the intervention condition (called SMILEY) or the control condition. While both conditions are still being tested, they include best practices for response to negative online experiences and youth suicide prevention. Randomization means that we will essentially ask a computer to "flip a coin" to decide which group your child will be assigned to. About 50 of the teens will receive SMILEY and about 25 will receive the control condition.

The SMILEY Intervention: If your child is randomized to the SMILEY intervention, they will be asked to use their Messenger app to engage with the chatbot. If your child does not have Messenger, they will be provided information on how to download the app and create an account through Facebook to use during the initial onboarding session (see below). If you and your child do not want to keep this Facebook account, you can delete it after creation and still have access to Messenger. The chatbot only operates on Messenger and does not run in the background when your child is not actively chatting with it. The SMILEY chatbot is automated and will provide your child with messages, images, videos, and other resources to help them use social media in more positive ways and increase their ability to cope with stress. The chatbot in this study does NOT use artificial intelligence to generate the responses to the user. While the chatbot does not have a human on the other end communicating with your child, a section of the chatbot aims to foster communication with trusted adults and others who could provide support. Moreover, should your child type any word that implies risk, the chatbot will immediately notify our research team and we will contact you and your child. The research team will monitor alerts for these words once a day on both weekdays and weekends.

During an initial 30-minute onboarding session over the phone, video conference or other agreed upon method, a study clinician will ask your child questions about their background (e.g., preferred coping skills) and trusted contacts so that the chatbot can be better tailored to your child's personal experiences and what resources are best to connect them with in the event of a crisis. This onboarding session will also include questions that will ask your child to think about strategies that they can use to cope with distress from negative online interactions. Lastly, the study clinician will deliver brief psychoeducation to your child during this session. This will include resources to support using social media effectively and provide guidance on how to respond and cope with negative online interactions.

For 4 weeks following the initial onboarding session, your child will be asked to engage with SMILEY. SMILEY is designed to be self-paced. We anticipate that using SMILEY 2-3 times a

week for 10-20 minutes at a time for 4 weeks will be sufficient to learn and engage with its content. However, the amount of time spent on SMILEY will vary from person to person and some may wish to use SMILEY more frequently or over a longer duration than others.

After 4 weeks of using the SMILEY chatbot, your child will receive a report that details their use of SMILEY and its helpfulness for them. This report will be shared with your child's primary care provider, and your child will have the option to share this report with a trusted adult such as you (their caregiver), their therapist, etc.

After 5-6 weeks of using the SMILEY chatbot, you and your child may be one of 10 people selected to participate in a final interview. During the interview, you and your child will be asked to provide feedback on your child's experience with SMILEY. The interview will take 25-45 minutes and will be recorded. Recordings will be transcribed for the study team to analyze. The feedback will be used to make adaptations to the SMILEY intervention for future research studies. You and your child will be paid $25 each for completing the interview. If you and your child are not selected to participate in the interview, these procedures will not apply to you.

The control condition: If your child is randomized to the control condition, they will receive a written list of resources that introduce basic concepts of using social media more positively (e.g., screen time guidance, technological coping skills, and encouragement of positive online interactions) and how to effectively respond and cope with negative online experiences when they occur. A study clinician will conduct an approximately 10-minute onboarding session over the phone, video conference or other agreed upon method with your child to deliver these resources. You as the caregiver will receive a similar written list of resources. The study clinician will also help your child identify their crisis and emergency contacts to reach out to if needed during the study.

Study Assessments: After 2 weeks of participating in the study, your child will complete a short survey that will ask them about their social media experiences and use of coping skills. This short survey is not part of the assessments that are described in the ETUDES Center Primary Care Study consent. Your child will receive $5 for completing this short survey.

After 4 weeks of participating in the study, your child will complete a questionnaire that will ask them to provide feedback about their experience using the chatbot (if they were randomized to the SMILEY intervention) and reflect on their ability to use social media and coping skills effectively. They will be asked to complete this questionnaire, minus providing feedback on the chatbot, again 3 months, 6 months, and 12 months after the time they began using SMILEY. All of these questionnaires are part of the assessments described in ETUDES Center Primary Care Study consent.

Payment for participating

Your child will receive $5 for completing the mid-intervention assessment. If you and your child are selected to participate in the final interview, you will each receive $25 for completing it.

Please refer to the ETUDES Center Primary Care Study consent for more information about payment.

There will be no costs to you or your insurance provider.

Medical Record Review

We are asking for you and your child's authorization to access your child's medical records. If you and your child agree, we will access diagnoses, use of medications, and the course of mental health treatment. This information will be used to learn whether our research interventions affect the mental health services a young person receives. Your and your child's permission to allow us to access these medical records will not expire, but you may cancel it at any time. Cancelling authorization does not impact your child's participation in the rest of the study activities.

All research assessments and interviews are confidential, however there are times when our research staff cannot keep certain information secret that you and your child tell us. These instances include:

A. If child abuse or neglect is suspected or reported, the research team is obligated to follow mandatory state reporting laws.

B. When our research staff assess your child's depression and suicidal risk, we may uncover the presence of suicidal thoughts or behaviors. We will review or develop a safety plan with your child and review concerns that came from the assessment with them. We will also place information about the assessment and the safety plan in your child's medical record so that their providers are aware of these concerns and can access the safety plan. We will follow up with your child to determine if they are engaged in care to ensure safety and provide referral recommendations if necessary.

Even after agreeing to participate in this study, if you or your child change your mind and want to cancel your authorization and permission, please let us know in writing. Write to the study's Principal Investigator: <insert local PI name & address>

If you and your child cancel your permission, no other health information about you and your child will be collected for this research. However, the health information that was received with your and your child's permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons.
- to verify the research data.
- if required by law.

Risks of Volunteering

- As the study is enrolling individuals who have recently experienced depression symptoms or suicidal thoughts, <u>there is always a risk for worsening suicidal thoughts and behavior</u>. However, there is nothing being done as part of this study that suggests your child's participation will increase their risk level. Our research team is trained in assessment and management of youth suicide risk, and we will incorporate best practices for suicide prevention within our study procedures. We will work with your child to establish a list of personal contacts including trusted adults and professional resources

your child can contact in the event of a crisis. If our study team becomes aware that your child is at acute risk, we have standard procedures in place to manage this, which include notifying a parent/guardian or an emergency contact, providing referrals for mental health evaluation and treatment, and connecting them with crisis resources. Additionally, youth who endorse suicidal risk at the time of their ETUDES Center assessment visits or other study communications will complete a safety plan with a study clinician if they do not already have one in place. A safety plan is a structured tool for preventing suicidal risk, which includes identifying coping strategies and sources of support for youth.

- As this study is enrolling youth who recently had negative online experiences, such as cyberbullying, there is always a risk for continued or worsening cyberbullying. However, there is nothing to suggest that your child's participation in this study will change or increase the risk they experience within online environments. In fact, we anticipate our intervention may improve teens' experiences following cyberbullying by offering resources that support coping and seeking support. Our research team is trained in assessing and responding to cyberbullying events, including severe events such as physical or sexual harassment. If our study team becomes aware of a severe incidence of cyberbullying, we will evaluate any potential risks to your child's safety. In the event that there is a potential risk to your child's safety, we will activate our standard procedures, which include contacting you and your child to offer educational and support resources that are in line with your child's experiences as well as referrals for mental health treatment if needed.
- There is potential for a breach in confidentiality if your child's answers were somehow to become available to non-study personnel. We may use text messaging through a study staff phone to schedule appointments for interviews. No personal information other than scheduling will be asked of your child through texting. Any information passed through text messaging is not encrypted and can be accessed by an outside party. Someone not associated with the research study may see the messages on your phone. Feel free to let research staff know if your child is not comfortable receiving texts at any time. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. The information we receive from you and your child will be labeled with a code number that we assign and not with anything that directly identifies your child. Electronic records will be kept on secure servers behind <insert local site information> firewall.
- Calls, emails, text messages, and messages from the chatbot that you or your child send from your personal devices may not be encrypted or secure & copies of messages may be stored in multiple places depending on your phone plan. The text services in this study

  follow privacy laws (HIPAA, Health Insurance Portability & Accountability Act) and messages will be deleted after processing. We suggest you check for and delete any

sensitive information that may be in these messages on your phones. Messenger may not be secure, and we suggest that your child only uses their personal device to talk with the chatbot rather than interacting with the chatbot on public computers (e.g., at the library or an internet café).

- <insert local communication language or keep Pitt info>

Emergencies. In the event of a clinical emergency not related to this study, the research team may not be able to respond immediately to your child's calls, text messages, or emails. In case of emergencies, your child should stop contacting research staff, and immediately call 911.

Benefits of Volunteering

Your child will be randomly assigned to one of two intervention conditions. For participants who are randomized to receive SMILEY, there may be some benefit to their ability to use social media and coping skills effectively. However, we cannot guarantee that your child will benefit directly from participating in this study. The information we get from those who participate may help researchers find ways to help adolescents who have negative online experiences.

Sharing and Retention of Research Data

This research study is supported by the National Institute of Mental Health (NIMH) and representatives of NIMH may review the information we collect. Authorized representatives from the <insert local HRPO and site reviewers> may review our research records for the purpose of monitoring the conduct of this study. Information will be de-identified before it is shared by removing identifiable information about you and your child (e.g., your name, date of birth, or other private information).

Identifiable information collected from this study may be shared with other investigators at the University of Pittsburgh, which is another site participating in this multi-site study; however, this information will not include identifiers like your name but may include zip codes, dates, and other data that are essential to our study's research aims. Deidentified information may be shared with collaborators at the University of Oregon and Columbia University.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.

Research records will be maintained for at least 7 years following final reporting or publication of a project. Research records for children will be maintained until the child reaches the age of 25, or at least 7 years following the final reporting or publication of a project, whichever is longest.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you and your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you and your child has consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you and your child have consented to the disclosure, including for your child's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIMH. You and your child should understand that a Certificate of Confidentiality does not prevent you and your child from voluntarily releasing information about your involvement in this research. If you and your child want your research information released to an insurer, medical care provider, or any other person not connected with the research, you and your child must provide consent to allow the researchers to release it.

You and your child will be promptly notified if any new information develops during the conduct of this research study which may cause your child to change their mind about their continued participation.

Alternatives to the SMILEY intervention

Your child's alternative to being in this study is to simply not participate. Your child has the choice to ignore reminders to use SMILEY or stop using SMILEY at any time.

Your Rights

If you have any questions about your rights as a research subject, please contact the <insert local HRPO site name and phone number/contact information>

<insert coordinator contact information>

If you have any questions for the research staff, please reach out to:

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PARENTAL CERTIFICATION

The above information has been explained to me and all my current questions have been answered. To indicate my agreement for my child to participate in this research study, and to allow the use and disclosure of my child's medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box(es) and by completing the fields below.

q I agree

Child's name _____ (first, middle, last name):

Child's DOB __/___/____ (mm/dd/year)

Parents's name _____ (first, middle, last name):

Parent's DOB __/___/____ (mm/dd/year)

Signature line (if available in survey software) Please

answer ONE of the following questions:

1. What is your mother's maiden name?
2. In what city were you born?
3. What high school did you attend?

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Child Assent

The above information has been explained to me and my current questions have been answered. To indicate my agreement to participating in the study, I assent to participate in the study by clicking the 'I agree' box(es) and by completing the fields below.

q I agree

Child's name _____ (first, middle, last name):

Child's DOB __/___/____ (mm/dd/year)

Signature line (if available in survey software) Please

answer ONE of the following questions:

1. What is your mother's maiden name?
2. In what city were you born?
3. What high school did you attend?

<insert local department letter head>

Consent for Participation in a Research Study

PRINCIPAL INVESTIGATOR: <insert local PI information>

TITLE OF PROJECT: SMILEY R34-Aim 3

SOURCE OF SUPPORT: National Institute of Mental Health

Key Information:

This research is being done to test an intervention called SMILEY, a chatbot used by teens who have had negative online experiences (e.g., bullying, harassment, or discrimination). The goal of SMILEY is to reduce further exposure to negative online experiences and depression symptoms while increasing use of coping skills and healthier social media use.
Participation includes: • Completing an onboarding session with a study clinician. • Being randomly assigned to receive one of two study interventions. • One study intervention involves a) engaging with a chatbot on Meta's Messenger app approximately 2-3 times a week for a duration of approximately 10-20 minutes at a time over the course of 4 weeks and b) receiving resources related to using social media effectively and responding to negative online experiences. • The other study intervention involves only resources about using social media effectively and responding to negative online experiences
We are inviting up to 75 participants in the ETUDES Center Primary Care Study who have experienced negative online interactions and depression symptoms and are aged 12-18.
The intervention will not replace any treatment you would normally receive. This means you can continue to participate in your current treatment program(s).
Risks include potential for breach in confidentiality, potential for worsening distress or suicidal thoughts and behaviors, and potential for continued or worsening cyberbullying. However, there is nothing about this study's intervention that suggests it would increase your risk level. We have careful plans in place to support you and to protect your safety.
If you experience a crisis, the resources below are available 24/7, can be contacted anonymously, and have trained counselors who are available to talk. □ National resources include the 988 Suicide and Crisis Hotline at 988, the Crisis Text Line by texting HOME to 741741, or the Trevor Project, a crisis hotline specifically for LGBTQ+ youth at 1-866-488-7386. □ <enter local site crisis contact information here>

- Additional behavioral health resources can be found here: https://www.etudescenter.org/resources-for-families

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This study is a randomized controlled trial (RCT). That means that you will be randomly assigned to either the intervention condition (called SMILEY) or the control condition. While both conditions are still being tested, they include best practices for response to negative online experiences and youth suicide prevention. Randomization means that we will essentially ask a computer to "flip a coin" to decide which group you will be assigned to. About 50 of the teens will receive SMILEY and about 25 will receive the control condition.

The SMILEY Intervention: If you're randomized to the SMILEY intervention, you will be asked to use your Messenger app to engage with the chatbot. If you do not have Messenger, you will be provided information on how to download the app and create an account through Facebook to use during the initial onboarding session (see below). If you do not want to keep this Facebook account, you can delete it after creation and still have access to Messenger. The chatbot only operates on Messenger and does not run in the background when you are not actively chatting with it. The SMILEY chatbot is automated and will provide you with messages, images, videos, and other resources to help you use social media in more positive ways and increase your ability to cope with stress. The chatbot in this study does NOT use artificial intelligence to generate the responses to the user. While the chatbot does not have a human on the other end communicating with you, a section of the chatbot aims to foster communication with trusted adults and others who could provide support. Moreover, should you type any word that implies risk, the chatbot will immediately notify our research team and we will contact you. The research team will monitor alerts for these words once a day on both weekdays and weekends.

During an initial 30-minute onboarding session over the phone, video conference or other agreed upon method, a study clinician will ask you questions about your background (e.g., preferred coping skills) and trusted contacts so that the chatbot can be better tailored to your personal experience and know what resources are best to connect you to in the event of a crisis. This onboarding session will also include questions that will ask you to think about strategies that you can use to cope with distress from negative online interactions. Lastly, the study clinician will deliver brief psychoeducation to you during this session. This will include resources to support using social media effectively and provide guidance on how to respond and cope with negative online interactions.

For 4 weeks following the initial onboarding session, you will be asked to engage with SMILEY. SMILEY is designed to be self-paced. We anticipate that using the SMILEY chatbot 2-3 times a week for 10-20 minutes at a time for 4 weeks will be sufficient to learn and engage with its content. However, the amount of time spent on SMILEY will vary from person to person and some may wish to use SMILEY more frequently or over a longer duration than others.

After 4 weeks of using the SMILEY chatbot, you will receive a report that details your use of SMILEY and its helpfulness to you. This report will be shared with your primary care provider, and you will have the option to share this report with a trusted adult such as your caregiver, your therapist, etc.

After 5-6 weeks of using the SMILEY chatbot, you may be one of 10 people selected to participate in a final interview. During the interview, you will be asked to provide feedback on your experience using SMILEY. The interview will take 25 to 45 minutes and will be recorded. Recordings will be transcribed for the study team to analyze. The feedback will be used to make adaptations to the SMILEY intervention for future research studies. You will be paid $25 for completing the interview. If you are not selected to participate in the interview, these procedures will not apply to you.

The control condition: If you're randomized to the control condition, you will receive a written list of resources that introduce basic concepts of using social media more positively (e.g., screen time guidance, technological coping skills, and encouragement of positive online interactions) and how to effectively respond and cope with negative online experiences when they occur. A study clinician will conduct an approximately 10-minute onboarding session over the phone, video conference or other agreed upon method with you to deliver these resources. The study clinician will also help you identify your crisis and emergency contacts to reach out to if needed during the study.

Study Assessments: After 2 weeks of participating in the study, you will complete a short survey that will ask you about your social media experiences and use of coping skills. This short survey is not part of the assessments that are described in the ETUDES Center Primary Care Study consent. You will receive $5 for completing this short survey.

After 4 weeks of participating in the study, you will complete a questionnaire that will ask you to provide feedback about your experience using the chatbot (if you were randomized to the SMILEY intervention) and reflect on your ability to use social media and coping skills effectively. You will be asked to complete this questionnaire, minus providing feedback on the chatbot, again 3 months, 6 months, and 12 months after the time you began using SMILEY. All of these questionnaires are part of the assessments described in ETUDES Center Primary Care Study consent.

Payment for participating

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All research assessments and interviews are confidential, however there are times when our research staff cannot keep certain information secret that you tell us. These instances include:

A. If child abuse or neglect is suspected or reported, the research team is obligated to follow mandatory state reporting laws.

B. When our research staff assess your depression and suicidal risk, we may uncover the presence of suicidal thoughts or behaviors. We will review or develop a safety plan with you and review concerns that came from the assessment with you. We will also place information about the assessment and the safety plan in your medical record so that your providers are aware of these concerns and can access the safety plan. We will follow up with you to determine if you are engaged in care to ensure safety and provide referral recommendations if necessary.

Even after agreeing to participate in this study, if you change your mind and want to cancel your authorization and permission, please let us know in writing. Write to the study's Principal Investigator: <insert local PI name & address>.

If you cancel your permission, no other health information about you will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons.
- to verify the research data.
- if required by law.

Risks of Volunteering

- As this study is enrolling individuals who have recently experienced depression symptoms or suicidal thoughts, <u>there is always a risk for worsening suicidal thoughts and behavior</u>. However, there is nothing being done as part of this study that suggests your participation will increase your risk level. Our research team is trained in assessment and management of youth suicide risk, and we will incorporate best practices for suicide prevention within our study procedures. We will work with you to establish a list of personal contacts including trusted adults and professional resources you can contact in the event of a crisis. If our study team becomes aware that you are at acute risk, we have standard procedures in place to manage this, which include notifying a parent/guardian or

an emergency contact, providing referrals for mental health evaluation and treatment, and connecting you with crisis resources. Additionally, youth who endorse suicidal risk at the time of their ETUDES Center assessment visits or other study communications will complete a safety plan with a study clinician if they do not already have one in place. A safety plan is a structured tool for preventing suicidal risk, which includes identifying coping strategies and sources of support for youth.

- As this study is enrolling youth who recently had negative online experiences, such as cyberbullying, there is always a risk for continued or worsening cyberbullying. However, there is nothing to suggest that your participation in this study will change or increase the risk you experience within online environments. In fact, we anticipate our intervention may improve teens' experiences following cyberbullying by offering resources that support coping and seeking support. Our research team is trained in assessing and responding to cyberbullying events, including severe events such as physical or sexual harassment. If our study team becomes aware of a severe incidence of cyberbullying, we will evaluate any potential risks to your safety. In the event that there is a potential risk to your safety, we will activate our standard procedures, which include contacting you to offer educational and support resources that are in line with your experiences as well as referrals for mental health treatment if needed.
- There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel. We may use text messaging through a study staff phone to schedule appointments for interviews. No personal information other than scheduling will be asked of you through texting. Any information passed through text messaging is not encrypted and can be accessed by an outside party. Someone not associated with the research study may see the messages on your phone. Feel free to let research staff know if you are not comfortable receiving texts at any time. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. The information we receive from you will be labeled with a code number that we assign and not with anything that directly identifies you. Electronic records will be kept on secure servers behind <insert local site information> firewall.
- Calls, emails, text messages, and messages to the chatbot that you send from your personal devices may not be encrypted or secure & copies of messages may be stored in multiple places depending on your phone plan. The text services in this study follow privacy laws (HIPAA, Health Insurance Portability & Accountability Act) and messages will be deleted after processing. We suggest you check for and delete any sensitive information that may be in these messages on your phone. Messenger may not be secure, and we suggest that you only use your personal device to talk with the chatbot rather than interacting with the chatbot using public computers (e.g., at the library or an internet café).

<insert local communication language or keep Pitt language>

Emergencies. In the event of a clinical emergency not related to this study, the research team may not be able to respond immediately to your calls, text messages, or emails. In case of emergencies, you should stop contacting research staff, and immediately call 911.

Benefits of Volunteering

You will be randomly assigned to one of two intervention conditions. For participants who are randomized to receive SMILEY, there may be some benefit to their ability to use social media and coping skills effectively. However, we cannot guarantee that you will benefit directly from participating in this study. The information we get from those who participate may help researchers find ways to help adolescents who have negative online experiences.

Sharing and Retention of Research Data

This research study is supported by the National Institute of Mental Health (NIMH) and representatives of NIMH may review the information we collect. Authorized representatives from the <insert local HRPO and site reviewers> may review our research records for the purpose of monitoring the conduct of this study. Information will be de-identified before it is shared by removing identifiable information about you (e.g., your name, date of birth, or other private information).

Identifiable information collected from this study may be shared with other investigators at the University of Pittsburgh, which is another site participating in this multi-site study; however, this information will not include identifiers like your name but may include zip codes, dates, and other data that are essential to our study's research aims. Deidentified information may be shared with collaborators at the University of Oregon and Columbia University.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.

Research records will be maintained for at least 7 years following final reporting or publication of a project.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical

treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIMH. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

You will be promptly notified if any new information develops during the conduct of this research study which may cause you to change your mind about your continued participation.

Alternatives to the SMILEY intervention

Your alternative to being in this study is to simply not participate. You have the choice to ignore reminders to use SMILEY or stop using SMILEY at any time.

Your Rights

If you have any questions about your rights as a research subject, please contact the <insert local HRPO site name and phone number/contact information>

<insert coordinator contact information>
If you have any questions for the research staff, please reach out to:

☐

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CERTIFICATION

The above information has been explained to me and all my current questions have been answered. To indicate my agreement to participate in this research study, and to allow the use and disclosure of my medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box(es) and by completing the fields below.

❑ I agree

Adult's name _____ (first, middle, last name):

Adult's DOB __/___/____ (mm/dd/year)

Signature line (if available in survey software) Please

answer ONE of the following questions:

1. What is your mother's maiden name?
2. In what city were you born?
3. What high school did you attend?

VERBAL CONSENT SCRIPT FOR SMILEY EXIT INTERVIEWS

Hello! My name is XX and I am the XX of the SMILEY study at the <insert local institution>. We are collaborating with researchers at <insert partner institution> to conduct a study sponsored by the National Institute of Mental Health (NIMH) that tests the feasibility of a social mediabased chatbot to teach effective social media use and increase coping skills among youth who have symptoms of depression and have had a negative social media experience in the past three months. Today, we are asking you to participate in an interview for our research study. We would like to ask questions to better understand your thoughts on how we can best design the chatbot for integration into primary care. We are grateful that you are here today!

If you agree to participate, I will be using an audio recorder and will inform you of when I am recording. This interview should last no longer than 45 minutes. You may not perceive any direct benefit from participating in today's interview. However, you may feel a sense of accomplishment in helping us enhance an intervention that aims to support teen mental health. Risks of taking part in this interview include loss of confidentiality (privacy). Further, your participation today is voluntary, meaning you do not have to answer anything you do not want, and you can take a break at any time.

We guard your confidentiality by storing information gathered from today's visit on a secure server without your name or other identifiable information. Your data will be stored separately from your identifiable information. Only our research team, who includes investigators at <insert local institution> and <insert partner institution> will have access to the information you have shared. Additionally, authorized representatives from the <insert local institution>, the University of Pittsburgh Office of Research Protections, and our sponsor, NIMH, may review your data solely for the purpose of monitoring the conduct of this study. <Insert partner institutions> is our research partner in this study, and they may have access to de-identified transcripts of your interview. Deidentified transcripts may also be shared with collaborators at the University of Oregon and Columbia University. Research records will be maintained for at least 7 years following final reporting or publication of a project.

You can, at any time withdraw from this research study. Withdrawing means you will be withdrawn from further participation in this research study. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will remain. To formally withdraw from this research study, provide a written and dated notice of this decision to the principal investigator, <insert local PI name>.

<insert local PI name, title, address>

In the letter, state that you changed your mind and do not want any more of your information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected.

Your decision to participate or to withdraw from this study will have no effect on your current or future relationship with <insert local institution> or <insert partner institution>.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

You will receive $75 for participating in the interview. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment.

Do you have any questions? If you have questions at any time, you may contact <insert local PI name and phone number>. Additionally, you may contact the Human Subjects Protection Advocate of the Human Research Protection Office, University of Pittsburgh (1-866-212-2668) or the < in addition to Pitt IRB insert local IRB information, if applicable>.

Do you agree to participate in this research study?

Do you agree to being audio recorded?