Social/Behavioral
SECTION I

Therapeutic/Non-Therapeutic
Does your research involve a drug, medical device, technique or other intervention or strategy (including means like diet, cognitive therapy, behavioral therapy, exercise) to diagnose, treat or prevent a particular condition or disease: "THERAPEUTIC RESEARCH"?
Yes

1. Title of Protocol:
Using Mobile Technology to Address the Trauma Mental Health Treatment Gap: Developing Implementation Protocols for Primary Care

2. Responsible Personnel:
A. Principal Investigator (PI):
Emerson, Margaret (Maggie) Rose - CON-Omaha Division - 402-559-6625 - margaret.emerson@unmc.edu - alt #: 402-559-6625 - degree: DNP, APRN (PI) - address: CNS 40108 UNMC Midtown (Zip 5330) - phone: 9-6625

B. Secondary Investigator (SI):
Dinkel, Danae Melinda - HPER - 402.554.3259 - dmdinkel@unomaha.edu - alt #: 402-554-4843 - degree: PhD - address: HPER 207 (Zip 68182) - phone: 402-554-2670

Watanabe-Galloway, Shinobu - COPH Epidemiology - 402-559-5387 - swatanabe@unmc.edu - alt #: 402-559-5387 - degree: PhD - address: MCPH 3023 UNMC Midtown (Zip 4395) - phone: 9-5387

C. Participating Personnel:
Granger, Casey Shapiro - CON-Omaha Division - - casey.shapiro@unmc.edu - alt #: 402-559-6625 - degree: PMHNP APRN

Howland, Nathan Andrew - Primary Care Medical Home Support - 402-559-5031 - nahowland@nebraskamed.com - alt #: 402-559-5031 - degree: PCMH BHP

Kreuzberg, Daniel (Dan) Jacob - Primary Care Medical Home Support - - dkreuzberg@nebraskamed.com - alt #: 402-.55-9039 - degree: PLMHP, PCMSW - address:

Clarkson Family Medi (Zip 68102) - phone: 402-559-8075

Lash, Brenna - - - brenna.lash@huskers.unl.edu - alt #: 402-559-6625 - degree: Graduate Student

Wolnisty, Sarah E - Primary Care Medical Home Support - 402-559-0142 - swolnisty@nebraskamed.com - alt #: 402-559-5031 - degree: LICSW - address: Midtown Clinic (Zip 68131) - phone: 402-559-0142

Zheng, Cheng - COPH Biostatistics - 402-552-7613 - cheng.zheng@unmc.edu - alt #: 402-552-7613 - degree: Statistician - address: MCPH 3052 UNMC Midtown (Zip 4375) - phone: 2-7613

D. Lead Coordinator:

E. Coordinator(s):

F. Data/Administrative Personnel:
Thomas, Robbin - Student - Masters of Public Health - 208-789-7180 - robthomas@unmc.edu - alt #: 402-559-5387 - degree: COPH Student

G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
Cooperative Group:
Center for Clinical and Translational Research (CCTR)
Federal (e.g., NIH) Grant - Provide source:
♦ Other Grant: IDEA CTR-Pilot Team Building
Departmental funding
Commercial - Provide company name:
Department of Defense
Other - Provide source (e.g. personal funding):

4. Deadline for IRB Approval:
♦ Yes - Explain and provide date: ASAP. IDEA CTR would like final approval to be

submitted within 60 days from February 12th 2021
No

5. Contract:
Is there a contract associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
No

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
Nebraska Medicine Fontenelle, Midtown, and Old Market Clinics

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
Yes

List the sites.
UNL

Bluestem Health Lincoln, Main Clinic
1021 N 27th St. Lincoln, NE 68503

Bluestem Health Lincoln, Kreshel Clinic
3100 N 14th St Lincoln, Ne 68521

D. Does this study involve any international sites where the PI will either; 1) conduct 2) supervise or 3) receive / ship HBM or data to / from UNMC?
No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:
I certify that:

- **I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.**
- **I, and all listed research personnel, have the necessary qualifications, expertise, and hospital credentials to conduct this study in a manner which fully protects the rights and welfare of research subjects.**
- **There are, or will be, adequate resources and facilities to safely initiate, carry out and complete this research at the study sites specified in Section I.7. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address adverse events and any unanticipated problems involving risk to the subject or others. If the necessary resources become unavailable I will promptly notify the IRB.**
- **All listed research personnel, including external investigators, will be given a copy of the final IRB approved application and any other relevant study-related documents in accordance with their defined responsibilities.**
- **All listed research personnel, including external investigators, will be notified promptly of any changes in protocol, in accordance with their defined responsibilities.**
- **Research personnel, including data and administrative personnel who have access to protected health information (PHI) or subject identifiers will have adequate training in confidentiality and protection of PHI.**
- **The minimum amount of protected health information (PHI) or other identifiers necessary will be used and disclosed to conduct this research study (if applicable). I will implement reasonable safeguards to protect the PHI/identifiers at all times.**
- **I and all other personnel listed in Section I.3A-E of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the UNMC Conflict of Interest Policy #8010 and HRPP Policy. I further certify that all potential financial conflicts of interest are appropriately**

managed in order to ensure protection of the rights and welfare of subjects.

I recognize that:

- As the PI it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol (including all amendments), all applicable federal regulations, state laws, and HRPP policies.
- It is my responsibility to ensure that valid informed consent/assent will be obtained, as appropriate, from all research subjects or their legally authorized representative(LARs).

I will:

- Ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to federal regulations, state laws, and HRPP policies.
- Promptly inform the IRB of internal adverse events, as well as any unanticipated problems involving risk to the subjects or to others, as required within the time frame defined by HRPP policies. I will analyze each internal adverse event/reported problem to determine if it impacts the risk-benefit relationship of the study, the safety of the subjects, or informed consent.
- Analyze each MedWatch/safety report to determine if it impacts the risk/benefit relationship of the study, the safety of the subjects, or informed consent.
- Promptly submit external adverse event reports in accordance with HRPP policies.
- Promptly inform the IRB if I become aware of 1) any complaints from research subjects, LARs, or others about research participation, 2) violations of federal regulations or state law, 3) violations of the HIPAA Rule, or 4) violations of HRPP policies.
- Promptly inform the IRB of the results of external audits performed by sponsors, Contract Review Organizations (CROs), cooperative groups, FDA, or other external groups.
- Not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.
- Promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.
- Maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, FDA, and other Federal Departments or Agencies may inspect these records in accordance with granted authority.

I understand that:

- **Continuing review by the IRB is required at least annually, or as per Federal Regulations and HRPP Policy, in order to maintain approval status. I will maintain IRB approval as long as this study is active.**
- **I am responsible for appropriate research billing in accordance with UNMC Clinical Trial Professional and Technical Fee Billing Policy #8008 or applicable Children's Hospital & Medical Center policy.**

Failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, applicable FDA regulations, the HIPAA Rule, applicable state law, HRPP policies, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB Approval of my research project and/or other administrative or legal actions.
Emerson, Margaret (Maggie) Rose - 2025-02-28 08:15:30.953

9. Principal Investigator Financial Interest Disclosure
A. As the PI, I declare:
♦ I have no financial interest in this research.
I have a financial interest in this research.

B. As the PI, I understand
♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:
♦ No Responsible Personnel have a financial interest in this research.
The Responsible Personnel listed below have informed me that they have a financial interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.
Emerson, Margaret (Maggie) Rose - 2025-02-28 08:15:30.953

11. Scientific/Scholarly Merit and Resource Review Certification
Scientific Reviewer:
Schmaderer, Myra Sue - CON-Lincoln Division - 402-472-7335 - mschmade@unmc.edu - alt #: 402-432-8863 - degree: PhD, MSN, RN - address: HCCN 359 UNL City (68588-0046) - phone: 402-472-7335

As the Scientific Reviewer,
♦ I do not have a financial conflict of interest associated with this study.
I do have a financial conflict of interest associated with this study.

My signature certifies that:

- **this application has been reviewed for scientific/scholarly merit and available resources. It has been determined that the application merits consideration by the IRB based upon the following:**
- **The proposal has an acceptable level of scientific/scholarly merit which justifies the involvement of human subjects.**
- **The proposal has a sound research design in consideration of the stated objectives,**
- **The PI has the necessary qualifications, experience and credentials to conduct this research.**
- **The PI has or will have the necessary funding to support this research**
- **There is or will be adequate physical space required for the research interventions at all study sites specified in Section I.7. In addition, there is or will be adequate laboratory and administrative support, data storage capability, and any other resources necessary to complete this research.**
- **At all study sites specified in Section I.7, there is or will be emergency equipment, personnel, or services necessary to respond promptly to adverse events or unanticipated problems involving risk to the subject or others.**
- **I will promptly notify the IRB if the necessary resources to support this research become unavailable.**

Schmaderer, Myra Sue - 2021-05-10 13:21:59.960

Do you have any additional comments that you wish the IRB to consider during the review of this application?
No

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief (less than 2500 characters) abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
BounceBack Now (BBN) is a self-help, trauma-focused mental health mobile app with automated assessment with treatment guidance and in-app evidence-based treatment support for depression, post-traumatic stress disorder (PTSD), sleep difficulties, and anxiety. BBN contains many of the necessary components to promote self-management of these conditions. We will evaluate the apps feasibility and acceptability among underserved patients (e.g., African Americans and patient with lower socioeconomic status) with trauma histories in an integrated primary care (IPC) setting. There are two specific aims: 1) to develop educational materials for patients and behavioral health providers for BBN in IPC, and 2) to conduct a pilot trial of BBN for patients with trauma histories in an IPC setting. To achieve Aim 1, we will conduct focus groups with behavioral health providers and patients to obtain feedback about BBN and training materials. For Aim 2, a feasibility study with 15 patients will be conducted to identify and address any procedural issues and to refine the protocol before conducting the full-scale study.

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
1. Develop educational materials for patients with trauma exposure and behavioral health providers for BBN in IPC emphasizing needs of two health disparity populations: African American and low-income patients.
2. Conduct a pilot trial of BBN for patients with trauma exposure in an IPC setting.

3. Background and Rationale
Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.
A majority of US residents (56.7%) with mental health needs do not receive care.[1] Racial/ethnic minority groups face significant gaps in care, with African Americans receiving care at 60% the rate of Whites. Within this context, primary care has become the de-facto mental health system, treating the largest share of those with common mental health conditions.[2] Integrated Primary Care (IPC) models of mental health care appear to reduce these disparities of access but face challenges in treating trauma-related mental health,

especially since the vast majority of patients attend two or fewer sessions.[3,4] Improving equity in trauma-focused outcomes is a critical public health need, particularly with the persistent disparities in traumatic event exposure and related mental health.[5] Unfortunately, efficacious treatments for trauma-related concerns in IPC require a minimum of eight weekly sessions.[6] Moreover, successful trauma-focused IPC interventions build on treatments that also face challenges in maintaining fidelity in traditional psychotherapy settings[7] that often treat even less clinical diversity than IPC. We hypothesize that trauma-focused clinician guides that can function in primary care, while also supporting patients who may be unable to attend the suggested several sessions, may hold substantial promise for improving outcomes and equity among racial/ethnic minority and/or low-income populations. Mobile health tools are well-positioned to serve as both clinician guides and patient self-management tools. Mobile in-session guides appear effective in increasing fidelity to trauma-focused care,[8,9]and similar self-management apps significantly reduce depression and post-traumatic stress disorder, even without clinician guidance.[10]The proposed project addresses critical knowledge gaps: 1) Lack of training materials for patients and providers to implement a mobile app intervention to treat trauma related disorders in integrated care settings; and 2) Lack of clinical protocol to use the mobile app intervention to treat trauma related disorders in integrated care settings.

CHARACTERISTICS OF THE SUBJECT POPULATION

4. Accrual

A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g. UNMC, Nebraska Medicine, CHMC, UNO)?

Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?

Aim 1: Total 14 - 10 patients and 4 behavioral health providers
Aim 2: Total 45 - Patients (15), BHPs (10), Clinical staff, providers and administration (20)

2. What is the statistical or other justification for the total number of subjects described above?

Because of the pilot nature of the study, it is not anticipated that quantitative results will achieve statistical significance. The data will primarily serve to demonstrate feasibility of our approach and success recruitment for a larger clinical trial. We aim for the number indicated in Section II 4 A 1, based on our ability to recruit patients at the clinic during the pilot funding period.

5. Gender of the Subjects

A. Are there any enrollment restrictions based on gender?
No

6. Age Range of Subjects
A. Will adults be enrolled ?
Yes

1. What is the age range of the adult subjects?
19 years and older

2. What is the rationale for selecting this age range?
This study aims to explore smartphone app technology in the adult population. We have determined in our previous work with this population that the adults being served at this clinic location have an interest in using mobile apps.

B. Will children (18 years of age or younger) be included in this research?
No

1. What is the justification for excluding children from participating in this research?
Research is irrelevant to children (e.g. disease or condition rarely encountered in children).
Knowledge being sought in the research is already available for children or will be obtained from another ongoing study.
♦ A separate study in children is warranted and preferable.
Insufficient data are available in adults to judge the potential risk in children.
Other. Explain.

7. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

8. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
Critically ill patients
Students of the investigator

Employees of the investigator
♦ Educationally disadvantaged individuals
♦ Socially or economically disadvantaged individuals
♦ Individuals with a stigmatizing illness or condition
♦ Individuals from a marginalized social or ethnic group
Other.
No vulnerable subjects will be specifically recruited

Describe the additional safeguards to protect the rights and welfare of the educationally disadvantaged individuals.
1. An informed consent detailing the procedure and purpose of the study will be implemented. The researchers will ensure that participants understand that participation is completely voluntary with option of withdrawal at any time.
2. In an effort to protect the rights and welfare of educationally disadvantaged individuals delayed consent will be offered. In the event that the study personnel and/or the potential participant appears to need additional time to process the information necessary to make an informed decision additional time will be allotted to do so. The potential participant will also be encouraged to contact a family member or significant other to assist them in making an informed decision about whether or not to participate. The consent document will be reviewed with the participant, the study personnel will answer their questions, ensure their understanding of the study, give them a copy of the informed consent and ask them to think over their potential participation.
3. For semi-structured interviews, participants will be mailed a copy of the consent form one-week prior to their participation or handed the consent at their baseline surveys. They will be encouraged to review the consent form, prior to the interview meeting and discuss their participation with a member of their family or a friend. At the interview, the consent form will be read aloud and they will have an opportunity to individually ask questions with research personnel. Participants will also be assured that their participation (or not) will not impact their relationship with clinic staff.

Describe the additional safeguards to protect the rights and welfare of the socially or economically disadvantaged individuals.
1. An informed consent detailing the procedure and purpose of the study will be implemented. The researchers will ensure that participants understand that participation is completely voluntary with option of withdrawal at any time.
2. In an effort to protect the rights and welfare of socially or economically disadvantaged individuals delayed consent will be offered. In the event that the study personnel and/or the potential participant appears to need additional time to process the information necessary to make an informed decision additional time will be allotted to do so. The potential participant

will also be encouraged to contact a family member or significant other to assist them in making an informed decision about whether or not to participate. The consent document will be reviewed with the participant, the study personnel will answer their questions, ensure their understanding of the study, give them a copy of the informed consent and ask them to think over their potential participation.

Describe the additional safeguards to protect the rights and welfare of the individuals with a stigmatizing illness or condition.
1. Previously, when we conducted a focus group (approved by UNMC IRB), we explained to the patient participants ahead of time that the data will be collected in a group setting with individuals who have a diagnosis of depression. For this study, we will use the same approach, and highlight with the patients during the consent process that the study will be conducted in a group setting and be comprised of individuals who have diagnosis of a mental health condition to participate in the focus group.

2. The focus group will be conducted only by Dr. Dinkel and student research assistants so that other project team members will not know the identity of the patients.

3. For semi-structured interviews/focus groups participants will be mailed a copy of the consent form one-week prior to their participation or handed the consent at their baseline surveys. They will be encouraged to review the consent form, prior to the interview meeting and discuss their participation with a member of their family or a friend. At the interview, the consent form will be read aloud and they will have an opportunity to individually ask questions with research personnel. Participants will also be assured that their participation (or not) will not impact their relationship with clinic staff.

4. Prior to the start of the focus group/interview, all participants will be reminded the following of the inclusion criteria and the importance of protecting one another's privacy. Prior to the group starting the research team will instruct the participants that the members of the group and information that is shared within the group should not be shared outside the group to protect one another's privacy and confidentiality. We will reinforce the importance of not putting private information into the apps during mobile app exploration.

6. Any study related materials will be locked in the cabinet of the PI or stored in the password-protected project folder in the server, which can be only accessible by the team member.

Describe the additional safeguards to protect the rights and welfare of the individuals from a marginalized social or ethnic group.
1. An informed consent detailing the procedure and purpose of the study will be

implemented. The researchers will ensure that participants understand that participation is completely voluntary with option of withdrawal at any time.

2. In an effort to protect the rights and welfare of individuals from a marginalized social or ethnic group delayed consent will be offered. In the event that the study personnel and/or the potential participant appears to need additional time to process the information necessary to make an informed decision additional time will be allotted to do so. The potential participant will also be encouraged to contact a family member or significant other to assist them in making an informed decision about whether or not to participate. The consent document will be reviewed with the participant, the study personnel will answer their questions, ensure their understanding of the study, give them a copy of the informed consent and ask them to think over their potential participation.

9. Inclusion Criteria
What are the specific inclusion criteria?
Behavioral Health Providers, Clinical staff, providers and administration
- 19 years and older

For Patients: Aim 1
- 19 years and older
- Being referred to a behavioral health provider at the Fontanelle or Midtown Clinic or receiving care at Fontanelle or Midtown clinic and contacting the research team through clinical trials registry
- Own a smart phone
For Patients: Aim 2
- 19 years and older
- Being referred to a behavioral health provider at the Fontanelle, Midtown or Old Market Clinics or receiving care at Fontanelle, Midtown Or Old Market clinics and contacting the research team through clinical trials registry

For Aim 2: Bluestem clinic location recruitment will only take place for Aim 2. So inclusion criteria for Aim 2 will include:
Patient is 19 years of age or older
Being referred to a behavioral health provider at the Fontanelle, Midtown, Old Market or Bluestem Clinic
Presence of Trauma Related Disorder or Trauma Related Symptoms as identified by BHPs or member of the research team.

10. Exclusion Criteria
What are the specific exclusion criteria?

Behavioral Health Providers, Clinical staff, providers and administration :
- 18 years and younger

Patients:
- 18 years and younger
- Does not own a smart phone
- No presence of Trauma Related Disorder or Trauma Related Symptoms as identified by the BHP or research team for Aim 2
- High suicidality based on a clinical assessment by the behavioral health provider
- Having neurocognitive conditions either assessed by a primary care provider or diagnostic code for neurocognitive condition found in the patient note or E.H.R.

11. Pregnancy and Contraception Requirements
A. Are women of child bearing potential (WOCBP) included in this research?
Yes

a. Are there any specific contraception requirements for subjects?
No

1. Provide justification for absence of contraception requirements
♦ There are no interventions that are likely to be of risk to a fetus
Investigational drug(s) is (are) not systemically absorbed
Investigational drug(s) is (are) systemically absorbed, but there is no evidence from human studies, or from clinical experience, that there is risk to a fetus
Other

B. Are pregnant women included in this research?
Yes

C. Are breast feeding women included in this research?
Yes

Provide justification
None of the study interventions pose a risk to pregnant women or breastfeeding mothers. We will ensure that IRB compliance and protection standards will be met.

METHODS AND PROCEDURES

12. Methods and Procedures Applied to Human Subjects

A. Are there any evaluations or tests that will be performed for the purpose of determining subject eligibility which would not be routinely conducted as part of standard clinical care of the prospective subject?
No

B. Describe the research plan, including all procedures, interventions, evaluations and tests.
BounceBack Now:

BBN was developed at the Medical University of South Carolina and Dr. Andrews participated in the app development. UNMC does not have anything to do with the app development.
After consent has been completed a BHP will assist the participant in downloading BBN onto their smartphone device for Aim 2. The current BBN structure contains a brief assessment and multiple treatment components for disorders that are frequently associated with traumatic event exposure. A brief assessment based on the Kessler 6 will be completed, based on this assessment the participants are then guided to treatment recommendations with an interactive rationale for each treatment. Education/explanations are provided in written, spoken, and animated video formats. Given that each of these treatments may be beneficial for patients with subsyndromal or very minor symptoms, all patients are able to see and interact with all treatment components, but it is anticipated that BHPs will provide recommendations for the sections that will be most beneficial. The treatment components are each based on effective in-person interventions. These include behavioral activation (depression), Written Exposure Therapy, and Expressive Writing (PTSD), Cognitive Behavioral Therapy for Sleep, and Relaxation/Mindfulness (stress/anxiety). The corresponding app sections are titled Activate, Write, Sleep, and Coping Tools, respectively. Each of these sections contains education components and there is a separate education component for the app overall that can be found through the coping tools page. An overview of each treatment component and its designed target is included below in table format.

***BBN* Component**	**Function**
Initial Assessment	Identify symptoms, direct to appropriate intervention
Relaxation/Mindfulness	Reduce mild symptoms of anxiety
Behavioral Activation	Reduce depression symptoms
CBT for Sleep	Increase sleep duration and efficiency
Writing Exposures	Decrease trauma-related anxiety and avoidance
Psychoeducation	Basic and disorder-specific mental health education

Aim 1: Participants will be recruited in one of two ways for aim one. The first is patients who present to their behavioral health care provider (Nathan Howland or Sarah Wolinsky), will be offered the opportunity to participate in focus groups/one on one semi-structured interviews to review the BBN (Bounce Back Now) trauma app. The behavioral health providers (BHPs) will discuss the study and refer interested participants. For interested participants, the BHP will provide them with a QR code that links directly to a Redcap survey that first presents the description of the study and initial screening eligibility assessment. If requested, BHPs will assist participants in scanning the QR code to obtain the link to the study. Basic information about the study will be shown first and state that we are interested in learning about how to better use mobile apps to benefit care for trauma-related mental health concerns (phrased to participants as emotional or mental health problems related to extremely stressful or traumatic events). Eligible participants will be directed to a page where they can electronically complete the IRB-approved consent form via Redcap. On this page, participants will affirm that they have read and understood the consent form and agree to participate in order to proceed. If they indicate that they decline to participate, they will be directed to a page that thanks them for their time. Once they complete the consent form, the redcap survey will ask for contact information and their preferred method of being contacted by the research team (IE phone call, text message or email.)

The second way participants may volunteer for the study is through promotional materials placed within the clinic and via clinicaltrials.gov registry or UNMC research database. These approaches help ensure inclusive opportunities for interested participants who may have or may have previously had experienced trauma-related mental health concerns who are not actively receiving care from a BHP, as their perspectives on the use of the app would still help inform any future adaptations. The in-clinic promotional materials will contain basic information about the study (i.e., that they can help us improve mental health apps), contain the QR code that links to the Redcap information and screening page (which asks their age and if they are receiving care from the approved Fontenelle or Midtown locations), and contact information for the study team where they can reach out for any additional questions.
If the interested participant reaches out to a member of the research team through the clinical trials registry or UNMC research database via email as opposed to scanning a QR code the participant will be emailed the Redcap link which will contain the above described content in addition to resource materials.. The QR code and link for the participants recruited via flyers and trials registry will differ from the ones that BHPs will use to recruit. . This is done because these participants may not have an existing relationship with a BHP and may not currently be engaged in BH services. We therefore will present different information at the end of the screening and consent process to inform them that they may request BH services from their clinic and we will provide a list of BH resources that they may access if they would like to seek services for mental health. For all of the above recruitment methods, using the QR code and screening/consent/download link in this manner, helps reduce barriers to participation and simplifies the process of completing measures and accessing the application.

Educational materials for patients and Behavioral Health Providers (BHPs) for BBN in IPC will be developed.
Dr. Dinkel and her research assistants will present the educational materials and BBN in focus groups. We will conduct one focus group for behavioral health providers and one to two focus groups for patients or offer individual virtual meetings (in order to accommodate their schedule, we may need to have two separate focus group for patients or individual times to participants). Upon semi-structured interview or focus group, a member of the research team will review the consent form contained in the

Redcap survey and reconfirm that patient understands and wishes to proceed. The re-verification of this information will serve as verification of consent. (Electronic Consent). These focus groups may be conducted virtually (i.e., zoom call) or in-person. The focus group will last 30 - 60 minutes. Focus groups will focus on acceptability, feasibility, and usability of the materials and the education materials and the app.
At the beginning of the focus group the patients will be asked to download BBN on their smartphone device with the assistance of the research team, if they have not already done so. A basic tutorial of the BBN and the developed educational materials will be conducted/reviewed with the participants. After the tutorial and education has been provided the participants will be asked to try some of major features of the app. Then, they will be asked to review the patient education materials. They will be asked to discuss strengths and weaknesses of the materials. They will be also asked whether there is any content missing from the education material. Finally, they will be asked to assess usability of the material. At the completion of the focus group the research team will assist the participants in removing BBN from their phones.
As for the provider focus group, a similar process will be used to ask about the provider educational materials and patient educational materials. We will also collect the following information including gender, age, job, years in practice, and years at the clinic.
Focus groups will be audio recorded and a transcript will be prepared. Information obtained from the focus groups will be used to refine the patient and provider educational materials before we implement Aim 2 activities.

Aim 2: Conduct a pilot trial of BBN for patients with trauma histories in an IPC setting
Trey Andrews, UNL Faculty will be the PI of record for the Bluestem Health Clinics, He currently provides patient care services at these locations in addition to overseeing the work of other BHPs at the identified Bluestem sites.
Margaret Emerson, UNMC faculty, will be the PI for the other sites.

Recruitment will take place in two ways:

<u>1.) Baseline</u>
Prior to engagement with the BBN application and as part of standard care at the clinic, a primary care provider at one of the specified Fontenelle, Downtown, Midtown or Bluestem Clinic locations will do a standard "warm handoff" referral to a behavioral health provider (BHP) if the patient is determined to have a behavioral health issue. All participants under Aim 2 will have gone through this process and have discussed identified mental health needs with both the BHP and their primary care provider. They will therefore already be receiving behavioral health services. In this context, BHPs will advertise BBN and the study to participants they believe may benefit, which mimics naturalistic app recommendations in this setting. For such patients, the BHP will provide the patient with a QR code that directs participants to where they can download BBN, which is publicly available. Continuing further with standard care when using apps, BHPs will have discretion as to whom they will recommend BBN. All BHPs have been trained in its use and have viewed its functionality. They will then guide patients through the sections that they perceive as relevant for that patient. Any patient may be directed through these procedures regardless of whether they elect to participate in the research phase. Thus, all Aim 2 procedures to this point are for standard of care. However, they must have had BBN recommended to them by the BHP in order to be eligible for Aim 2 research. For any adult participants (i.e., 19+ years of age) to whom they introduce BBN, BHPs will be asked to advertise a research study on the use, perceptions and initial effectiveness of BBN. To do so, they will use flyers with a QR code that links to a Redcap survey. The BHP will inform the patient that participation in the

study is voluntary and does not affect their care or access to BBN. The BHP will also assist the patient with the QR code, if necessary, but it is anticipated that participants will interact with this link after the session has ended, which will reduce both patient and provider burden by minimizing disruption to services. The BHP will be trained to problem solve QR code usage with the patient to ensure they can access the link before leaving. The Redcap survey will begin with a modified consent form (it is modified in accordance with the prior waiver of written consent we received previously where participant will confirm the consent electronically). If participants agree to participate in the study, they will then complete a series of questionnaires. All questionnaires are standard in survey research and do not contain any items that identify risk or result in significant distress. They are listed under Research Assessment below. The measures do contain an assessment of stressful event exposure, but prior studies indicate that such measures do not significantly increase participant distress and more frequently report research studies involving such measure as a positive experience overall (Jaffe et al., 2015). Further, the consent procedures will explicitly suggest that participants complete the survey in a private setting and inform the participants that the study will contain questions about stressful life experiences. Additionally, participants will be afforded the opportunity to complete the study in a private setting at the clinic, though we anticipate some participants may choose to complete the survey after. They will be advised that they should complete the consent form and survey within two days of their appointment. At the end of the survey, they will be given information that they should reach out to their BHP if they would like to further discuss any symptoms or topics discussed during the assessment and that they may contact the research team with any questions about the study. The Redcap will also automatically redirect to a separate survey where participants can provide contact information for compensation and follow-up phone surveys (see Follow-up Phone surveys below). Participants will be able to provide contact information for compensation and still decline participation in follow-up phone surveys. Participants will also be able to indicate a preference for completing follow-up surveys electronically and receiving the link via email or text or completing the survey over the phone. They will be asked to provide the contact information corresponding with their preference.

The patient will continue to meet with their BHP as determined by the standard of care interactions. And, if deemed appropriate the BHP will highlight features contained in BBN for patient to use in between appointments.

2.) Recruitment for the study will occur in the manner described above in addition to this advertising opportunity to participate using Opt-in registry email which is described below.
The opt in registry will be used to identify patients who meet the inclusion criteria and who have had an appointment with the BHP at one of the participating sites within the last three to six months. The Opt in email will provide basic information about the study and include a link which will take the interested participants to the same redcap survey described above which contains the informed consent, contact information for research team members for any questions prior to selecting to proceed, followed by research related questionnaires.
Participants choosing to participate with the Opt-in format will have already an established relationship with the BHP, documented trauma condition within the electronic health record and expressed interest in participating by proceeding from the opt-in initial inquiry. Upon completion of the initial baseline data collection from the participants, BHPs will made aware of the patients expressed interest through the opt-in recruitment process in order to incorporate the app use into subsequent standard of care appointments with the patient. This process will mimic the in-person appointments.

<u>Follow-Up Phone Calls</u>

The follow-up phone calls will be scheduled for 2 week and 6 weeks after the initial baseline data collection. Participants will be notified of these surveys through the mode of communication they indicated at baseline. If they indicated a preference for online surveys, they will be sent a link to the surveys. If they elected to complete them by phone, the participant will be contacted by a member of the research team to complete follow-up surveys. Similar to the baseline data collection, they survey may be completed online or administered by the research assistant over the phone. The two-week follow-up surveys will be identical to the baseline surveys.

The 6-week follow-up survey will be completed in the same fashion as the two-week survey. It will contain the same measures as the 2-week survey including that patient usability of the app will be assessed using the 18-item mHealth App Usability Questionnaire (MAUQ). Patient acceptability will be measured using the 20-item User Burden Scale. Additionally, participants will be invited to complete semi-structured interviews about their use experience to be completed at a later date and will be prompted to provide their preferred contact information for scheduling that interview.

<u>The Use of BBN</u>
Usage of the app is entirely self-paced. While some features do have recommended intervals for use (e.g., weekly writing), users are able to schedule these at any interval they choose. The app will be introduced to the participant by the behavioral health provider using a shared decision-making framework where providers and participants collaborate to discuss how to best use the application. The app will only capture data pertaining to utilization, which will include initial login date, last use date, number of logins, and number of times each component is accessed.

<u>Focus Group and Semi-Structured Interviews for Aim 2</u>
Dr. Dinkel and her research assistants will conduct semi-structured with BHPs, Clinical Staff, Providers and Administration and individual video or semi-structures phone interviews with patients. They will ask questions to BHPs,, Clinical Staff, Providers and Administration and patients about feasibility, acceptability, and usability of BBN and overall clinical protocol. The BHPs will complete a 5-item questionnaire about their comfort-level with integrating mental health apps into clinic care.

The semi-structured interviews with BHPs, Clinical Staff, Providers and Administration will be guided by the
Tailored Implementation for Chronic Diseases Checklist (Flottrop, 2013). The interviews will occur in a private location at the clinic or via Zoom, be audio recorded, and last no longer than 1 hour. Specifically, the BHPs, Clinical staff, providers and administration will be asked about the Implementation Topics derived from the guideline checklist which includes: Recommendations, Individual and Health professional factors. Professional behaviors, Patient Factors, Professional Interactions, Incentives and Resources, Capacity for Organizational Change, Social, Political, and Legal Factors which relate to the feasibility and implementation efforts of mobile app integration within the clinical setting. The interviews will be audio-recorded and transcribed.

The semi-structured interviews with patients will be guided by the Integrated Promoting Action on Research Implementation in Health Services framework. The interviews will occur in a private location at the clinic or via Zoom, be audio recorded, and last no longer than 1 hour. Specifically, with the patient interviews, patients will be asked about the following: 1) the overall usability of of BBN, 2) the overall acceptability of BBN, 3) each major components of BBN, 4) the feasibility of incorporating BBN into the clinical practice, 5) the ease of using BBN to complete the surveys, and 6) strengths and

weaknesses of BBN for treatment of their mental health condition. The focus group and interviews will be audio-recorded and transcribed.

Data Analysis
Qualitative data will be tabulated and summarized using frequencies and percentages and will be analyzed using a direct content analysis approach. Focus group data will be transcribed and uploaded to QSR NVivo 12. As for qualitative data, a linear mixed effect model will be fitted to analyze each continuous outcome measured at different time points to estimate the potential intervention effect size for the future design of larger trials. A generalized linear mixed effect model with cumulative logistic link will be fitted to analyze ordinal outcome. Analysis will be performed using SAS.

EHR/Clinical Notes Data Collection:
In addition, we will collect basic demographic and clinical information about the patient by abstracting information from the clinical notes and E.H.R. The information will be abstracted by the BHP who will participate in the study. The information collected will be: race/ethnicity, age, gender, health insurance status, educational level, employment status, physical health conditions, BMI, and mental health diagnoses. The information will be saved in the Excel file with unique patient study IDs.

Data Storage:
The patient data for Aim 2 will be kept electronically in the project folder in the College of Nursing server, which will be password protected. The patient database will only contain the study IDs. BBN usage data will be downloaded by Trey Andrews PhD through an online portal to which he only has access. This portal does not contain identifiers and linkages will occur through download dates and times. Trey Andrews PhD will share this via a secure shared drive to which only the research team will have access. Nebraska Medicine BHPs, who have ethical access to patients, will keep a list of patient names and the study ID electronically in a password protected folder.

Measurement:

All assessments will be scored using tools validated

<u>Standard Clinical Assessment for Patients:</u>

- Patient Health Questionnaire 9 items (PHQ-9): Baseline and two follow-up visits
  - The PHQ-9 is an assessment tool validated for provisional diagnosis and grading symptom severity of Major Depressive Disorder.
- 7-item Generalized Anxiety Disorder Scale (GAD-7): Baseline and two follow-up visits
  - GAD-7 screens for Generalized Anxiety Disorder and assesses severity.

<u>Research Assessment for Patients</u>

- Trauma History Questionnaire-
  - The Trauma History Questionnaire (THQ) is a 24-item self-report measure that examines experiences with potentially traumatic events such as crime,

general disaster, and sexual and physical assault using a yes/no format. For each event endorsed, respondents are asked to provide the frequency of the event as well as their age at the time of the event. The THQ can be used in both clinical and research settings, and is available in English, Will be assessed at Baseline

- Promis-Emotional Distress Depression Short Form 8a
  - is an 8 item self-report measure and this is not a diagnostic screening., Baseline and follow-ups
- Post-Traumatic Stress Disorder Checklist for DSM-5 (PCL-5): Baseline and two follow-up visits
  - 20 item report assesses for the 20 DSM-5 symptoms of PTSD.
- Pittsburgh Sleep Quality Index: Baseline and two follow-up visits
  - 19 questions rated by the participant and 5 by a bed partner (if available). Used to assess sleep quality and broken down into 7 components.
- mHealth App Usability Questionnaire (MAUQ): After the 2nd visit
  - A reliable and validated tool assessing the usability of mHealth apps. Will be used to evaluate BounceBack Now
- User Burden Scale: After the 2nd visit
  - Evaluates the difficulty of use and burden the app may place on participants.

Research Assessment for BHP

- Self-Management Support in Behavioral Health Organizational Assessment Tool (SMS): Baseline
  - Designed to assist behavioral health organizations in delivering self-management support to clients managing serious mental illness.

Addressing Needs of African American and Low-Income Patients
The participating clinics Fontenelle, Downtown, Midtown and Bluestem Health Clinics primarily serve African American or low-income patients. Thus, almost all of the patients who will be recruited for Aims 1 and 2 are expected to come from these two population groups. Race/ethnicity and income information will be collected through E.H.R. data. The needs of these two patient population groups will be met by recruiting the patients primarily from these two population groups for Aim 1 to ensure that their perspectives will be reflected in the patient education materials. Similarly, the needs of these patients' groups will be met by conducting a pilot for Aim 2 and obtaining feedback through the individual interviews we conduct at the end of the study.

C. Select any of the following that apply to the research:

Phase I study
Randomization
Placebo (or non-treatment arm)
Washout
Sensitive surveys or questionnaires

♦ None of the above

D. Identify:
1. All procedures, interventions, evaluations and tests performed solely for research purposes (eg, administration of an investigational drug or a new psychological assessment instrument; randomization)
BBN is being used for the purposes of research.

The focus groups conducted for Aim 1 are for the purpose of research.

We will ask the patients to complete the following instruments for the purpose of research for Aim 2:
-THQ
-Promis 8a
-Pittsburgh Sleep Quality Index
-PCL-5
- MAUQ
- User Burden Scale

We will ask the BHP to complete Self-Management Support in Behavioral Health Organizational Assessment Tool (SMS) and a 5-item comfort level questionnaire.

2. All procedures, interventions, evaluations and tests performed for clinical indication but more frequently than they would be if the subject was not participating in the research (eg, extra blood tests; additional radiology exams)
Not Applied.

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).
Aim 1: Qualitative data will be analyzed using a directed content analysis approach. Peer debriefing and member checking will be utilized to validate the data.

Aim 2: Quantitative data regarding usability, acceptability and feasibility will be tabulated and summarized using frequencies and percentages. Qualitative data will be analyzed using a directed content analysis approach.23 Interviews will be transcribed verbatim and uploaded to QSR NVivo 12.23 Data will be validated through the process of peer debriefing and thick description.24 Additionally, for usability, acceptability, and feasibility, both quantitative and qualitative data will be integrated and analyzed collectively. A linear mixed effect model (LMM) will be fitted to analyze each continuous outcome measured at different time points

to estimate the potential intervention effect size for future design of larger clinical trial. Transformation of continuous outcome will be performed as needed to satisfy distribution assumption. A generalized linear mixed effect model (GLMM) with cumulative logistic link will be fitted to analyze ordinal outcome. Analysis will be performed using SAS version 9.4 (SAS Institute, Cary, NC).

F. Does this study involve the collection of blood, urine, saliva or other human biological material (HBM)?
No

DRUGS, BIOLOGIC DRUGS AND DEVICES

13. Drugs and Biologic Drugs
1. Does this research involve the use of drugs or biologics?
No

14. Devices
1. Does this research involve a medical device(s)?
Yes

A. Are any of the medical devices used in this study FDA approved?
No

B. Are any of the medical devices used in this study not approved by the FDA?
Yes

(i) Describe the device(s)
BBN is a trauma-focused technology tool to enhance equity and outcomes of trauma-related disorders in primary care settings. BBN is a self-help, trauma-focused mental health guide with automated assessment with treatment guidance and in-app guidance through evidence-based treatments for depression, PTSD, sleep difficulties, and anxiety.

(ii) Specify the sponsor of the device(s)
The research team is the sponsor of the device. The app is copyrighted under MUSC (primary) and UNL (secondary). The app is publicly available and free. The app is available to anybody who is interested in using.

(iii) Do any of the devices have an IDE number?
No

(iv) Are any of the device(s) a Non-significant Risk Device (NSRD)?
Yes

a. Provide rationale.
Under 21 CFR 812.3(m), a Significant Risk device is defined as an investigational device that:
1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

C. Indicate the stage or type of the investigation
♦ Stage I
Stage II
Nonclinical study
Other

D. Describe oversight procedures in place for departments, clinical units, or operating rooms where devices are used which provide for independent monitoring of the storage and dispensing of devices, and for required record-keeping.
The patients will use their own smartphone to download and use the BNN app. Therefore, there is no need to monitor the devices. They will be provided directions on how to delete the app at anytime.

E. Does this research involve an investigational in-vitro diagnostic device (IVD)?
No

CONFIDENTIALITY AND PRIVACY

15. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
♦ On a secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO (including REDCap)
♦ On a secure cloud server - Specify the secured cloud serve: OneDrive

On a firewall protected database accessible through the internet - Specify who has administrative responsibility for maintenance of the server:
On an encrypted, password protected local hard drive
On an encrypted, password protected portable computer
On an encrypted, password protected flash drive
♦ In hard copy
Other

a. Please provide justification for use of hard copies
BHPs have the option of providing face to face or virtual visits with the patients. In the event that a patient presents face to face then a hard copy consent would be used.

b. Will hard copies will be transported from one site to another, on or off campus?
Yes

c. Describe how they will be secured during transport
locked briefcase.

B. Will any of the following subject identifiers be recorded (at any time) in association with the research data?
Yes

1) Indicate the subject identifiers that will be recorded. Check all that apply.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
♦ Postal address information: street address, city, county, precinct, ZIP code
♦ Telephone numbers
Fax numbers
♦ Electronic mail addresses
Social Security numbers
Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice print
Full face photographic images [and any comparable images]

No Identifier

2) Will a unique subject identifying number (e.g., S1, S2, S3), characteristic or code be used to link data to any of the identifiers listed above?
Yes

a. Where will the key (that links the unique subject identification code to the subject's name or other identifier) be stored?
The BHP's will keep a list of patient names and study IDs electronically in their own project folder that can be accessible only by them using the password.

Participants who contact the research team through clinical trial registry will only receive emails or telephone calls from UNMC researchers/investigators associated with this IRB for the purposes of discussing potential participation with the potential recruitment. A log with unique identifiers associated with the patients subject identifiers will only be accessible by members of the UNMC researchers/investigators associated with this IRB

Dr. Dinkel will keep the list of BHP names, Clinical Staff, Providers and Administration and study IDs electronically in her own project folder which only she will be able to access. Identifiable information which will be collected from the BHPs, Clinical Staff, Providers and Administration and include, name, gender, years of employment, number of years at the clinic, and clinic location.

b. Does the code number include the subject's initials or other subject identifier as part of the code?
No

3) What is the justification for recording the specific subject identifiers listed above? Check all that apply.
Schedule appointments
Collect continuous clinical information from the medical records
♦ Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
♦ Compensation
Other. Explain.

4) How long will the subject identifiers be maintained in association with the research data?
Once the study data has been collected and analyzed the subject identifiers will be

destroyed according to UNMC IRB policy and procedures (7 years following completion of the study).

5) How will all of the identifiable research data be destroyed (e.g., all identifiers stripped from the data and destroyed, hard copies shredded etc) when the identifiable data is no longer required?
All identifiable research data will be destroyed once the study data has been collected and analyzed. The subject identifiers will be destroyed according to UNMC IRB policy and procedures. The PI will work with UNMC IT to ensure all data is stripped and destroyed according to UNMC IRB policy guidelines. Study materials that do not contain patient identifiers will be retained for the designated 7-year timeframe. After which the PI will work with UNMC IT to ensure all data is stripped and destroyed according to UNMC IRB policy guidelines. Audio files from focus groups will be deleted per UNO IT policy after data analysis is complete.

C. Will research data that contain subject identifiers be disclosed to:
Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

2. Investigators outside of UNMC, NM, UNO or CHMC?
No

3. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization or entity (e.g., NCI cooperative groups)?
No

D. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

E. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future

research that is not related to this study?
No

RISK/BENEFIT ASSESSMENT

16. Potential Risks
What are the potential risks associated with each research procedure, intervention, evaluation and/or test? If data are available, estimate the probability that a given harm may occur and its potential reversibility.
We anticipate the minimal risk associated with the use of BBN. BBN has been studied extensively and found to produce no known harms to the patients. However, it is possible that the use of some features of the app may trigger some negative psychological response. In case, the patient experiences any negative consequences from using the app, the patient will directed to contact the clinic BHP.

The potential risks to subjects associated with the study interactions are deemed to be minimal. We do not anticipate any physical risks. The psychological, social, cultural, financial, and legal risks are breach of confidentiality which may result in negative psychological experience. Risks to privacy and/or confidentiality are minimal as the focus group participants will not be asked to provide personal health information and we will adhere to IRB privacy and confidentiality standards for each aim of the study. We will however review all risks and ensure informed consent is completed with each participant prior to the start of the study. In order to protect patient privacy, we will use assign unique study IDs to the patients. The BHPs, who have ethical access to the participants, will keep the spreadsheet that contains the participants name and medical record number as well as the study ID.

17. Risk Classification
What is the overall risk classification of the research?
♦ Minimal risk
Greater than minimal risk

18. Minimization of Risk
A. Describe how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety.
Members of the focus groups will be informed that individuals who recruited for the purpose of the study have been Identified through their involvement with their BHP as a result of being referred due to a mental health condition.

Participants who contact the UNMC research team through clinical trial registry will be

assessed during the initial contact to describe the study and potential participation and will also be monitored for any signs of distress during the interviews. Notably the recruitment which occurs from the clinical registry will only be used to get feedback for AIM 1 of the study which focuses on providing feedback for the app itself. Therefore monitoring needs are minimal.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis. If there is an independent Data and Safety Monitoring Board (DSMB) provide the charter, or describe (1) the composition of the DSMB membership, (2) the frequency of DSMB meetings and reports.
With regard to data safety issues, Health Information Technology Solutions (HITS), the company that manages BBN on servers at the Medical University of South Carolina (MUSC) utilizes secure, confidential, user-friendly digital spaces. These are an n-tier architecture with responsive multichannel capability such that participating clinical staff, which we refer to as advocates, can access the components via a HIPAA compliant website or mobile application on smartphone or tablet (IOS, Android, Windows, etc.). HITS has proven software development architecture that allows for seamless delivery of content in a consistent, customized experience regardless of device, media form, or operating system. Respondent confidentiality will be masked by the use of participant ID numbers rather than personal information. Moreover, all data will be stored using resources located in the HITS facilities in the School of Nursing at Medical University of South Carolina (MUSC) until de-identification is complete. Electronic data will be stored on secure, password-protected computers/servers on site. De-identified use data will be transferred to investigators at UNL via secure, cloud-base storage. These data will be linked with interview data via cross-linking of app initiation dates and times, which will prevent even HITS staff from ever having access to identifiable information of users. The interview data and combined interview data will be stored at UNL facilities through secure servers at the Rural Drug Addiction Research Center (RDAR). When processed data are ready for data analyses, those analyses will be performed through protected storage at UNL.

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
Either Dr. Emerson or Dr. Watanabe will audit the study at the 6-month point.

D. Describe the specific subject withdrawal criteria.
Participants will be withdrawn if he/she voluntarily withdraws his or her consent to participate in a study at any time for any reason. Participants will also be withdrawn if any time they are experiencing any indication of suicidality and/or experiencing difficulty, either physically or mentally, with the study. Should this occur these events will follow the current

standard of care within their respective treatment facility.

E. Describe the stopping rules for the research (e.g., the specific criteria for halting or early termination of the study).
If for some reason the participant becomes upset during the interview, the qualitative researcher will bring the interview to the end, thank the participant for his/her participation and be available afterward to discuss any concerns participants may have. If 2 or more subjects become upset and require withdrawal from the trial, the trial will be halted.

F. Describe plans and resources available to promptly address any subject injury.
This research involves mobile app use and survey/interview-based primary data collection in a safe indoor environment. There is no intervention or any other physical or medical procedure that may pose a risk of a research-related injury to the subjects. However, if any subject expresses distress related to questions asked or discussed, they will be referred to their primary care provider for follow-up, either through self-referral or referral made by an investigator.

19. Potential Benefits to the Subject
Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?
No

20. Potential Benefits to Society
Describe the potential benefits to society that may reasonably be expected to result from this research.
The project can potentially generate information to improve the trauma informed access to care among vulnerable patients. While there is a minimal risk involving the breach of information, such risk is deemed reasonable given the potential for the benefit of the research.

FINANCIAL OBLIGATIONS AND COMPENSATION

22. Financial Obligations of the Subject
A. Who will pay for research procedures, interventions, evaluations and tests? Check all that apply.
Sponsor
♦ Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
Department/Section funds

Other. Explain

B. Will any of these procedures, interventions, evaluations and tests will be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
No

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
No

23. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
Yes

1. Describe the form of compensation, dollar amount (if applicable) and the prorated compensation plan (if applicable).
For Aim 1, the patient will receive a $25 gift card. For Aim 2, the patient will receive a $25 gift card for baseline participation and a $25 gift card at each of two follow-ups (total $75). They will also receive an additional $25 gift card for completion of the semi-structured interviews which may take place at the second follow-up phone call or at a separate time of the patients choosing..
The BHP, will receive a $25 gift card for completion of each focus group for Aim 1. The BHP, Clinical Staff, Providers and Administration will receive a $25 gift card for focus group participation for Aim 2

PRIOR REVIEW

24. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
No

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and disapproved?
No

SUBJECT IDENTIFICATION & RECRUITMENT

25. Method of Subject Identification and Recruitment
A. Will prospective subjects be identified through initial contact by the investigator?

Yes

1. Identified through: Check all that apply.
♦ Clinic
Hospital inpatient units
Previous research participants
♦ Investigator or clinic databases or registries
♦ Hospital Opt-In Database (thru Nebraska Medicine, BMC or CHMC Conditions of Treatment)
School records
Support groups, or other Interest Groups
Other. Explain.

2. Describe how the research staff has ethical access to the potential subjects?
Dr. Howland practices at Midtown clinic and Sarah Wolinski practices at the Fontenelle Clinic as behavioral health providers.
Daniel Kreuzberg practices at the Midtown, and Downtown NMC Clinics
Dr. Trey Andrews along with his two psychology interns, Hannah Coffey and AnneLiss Sartin-Tarm all practice at Bluestem Health at the specified locations.
BHPs

If a participant expresses interest in the study through the clinical registry option then a member of the UNMC Research Team will reach out the patient to determine interest and eligibility for participation.

3. Who will initially screen potential subjects to determine eligibility?
♦ Investigator with an existing clinical relationship
♦ Investigator with other legitimate access
Investigator whose professional responsibilities that require access to names of potential subjects
Honest broker (thru Nebraska Medicine or Bellevue Medical Center COT Opt-in database)
Research coordinator or other person without ethical access

B. Will prospective subjects make the initial contact with the research personnel to inquire about the study?
Yes

1. Potential Subjects learn about the research through: Check all that apply.
♦ Referral by clinician or other parties specifically for the research

♦ Printed advertisements (including bulletins, newsletters, posters, fliers, and magazine or newspaper ads)
Radio and Television advertisements
Electronic advertisements (including social media or other on-line venue)
Word of mouth
♦ Public UNMC study database
Other. Explain.

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?
Yes

1. Provide the NCT#.
NCT05374408

2. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

26. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

27. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
Yes

1. Identify the type of waiver requested:
Waiver of signed consent where the principal risk would be associated with a breach of confidentiality (45 CFR 46.117(C)(1)(i))
♦ Waiver of signed consent where written consent is normally not required outside the research context (45 CFR 46.117(c)(1)(ii); 21 CFR 56.109(c))
Waiver of signed consent if the subjects are members of a distinct cultural group or community in which signing forms is not the norm (45 CFR 46.117(c)(1)(iii)

WAIVER OF SIGNED CONSENT WHERE WRITTEN CONSENT IS NORMALLY NOT REQUIRED OUTSIDE THE RESEARCH CONTEXT (45 CFR 46.117(c)(1)(ii); 21 CFR 56.109(c)

1. Do any of the research tests and procedures involve more than minimal risk to subjects?
No

2. Does the waiver apply to:
All subjects
♦ A subset of subjects - describe the characteristics of these subjects Patients who are not established with BHP at either clinic or those who prefer to review the material in an electronic format

3. Does the research involve any procedures for which written consent would normally be required outside of the research context?
No

29. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
For Aim 1 participants will be recruited with 2 methods. For Aim 1, patients who are interested as identified through clinical trial registry will be contacted by a member of the research team to review participation in the study and determine eligibility criteria and if eligible will complete the informed consent process for the semi-structured focus groups.

For Aim 1 only the BHPs (Nathan Howland and Sarah Wolinski) who are listed on this IRB application with ethical access will identify any participants that may be interested in the study.

For Aim 2, Participants will be identified using two strategies 1.) BHPs at any of the study sites will identify participants who are interested in the study and 2.) Participants who meet the opt in criteria will be sent an email communication which provides brief summations of the study. BHP will advertise the opportunity to participant in the research study during their standard of care appointment. Any participant who wishes to participate and meets eligibility criteria, will complete the informed consent process with one of the study site research staff or if preferred by the patient, through the QR code/survey link for consent completion.

In either instance participants will then have time to ask questions. Participants, at this time, will decide whether they wish to participate or not. It is estimated that the provider reading the informed consent document, answering participants' questions, and assuring understanding of the study will take 5-10 minutes, but additional time will be used if needed for delayed consent or discussion with family/friends if the patient desires and/or the BHP or research investigator believes they need more time to decide.

Approved methods pertaining to UNMC E-Consents will be used in the instance that the participant is presenting virtually for participation.

Additionally for those who wish to participate through the use of the QR code then consent will be presented in this format for the patient to review and sign electronically with the research staff being available to answer any questions. Prior to starting the focus group or interview a member of the research team will review the interview portion of the study to ensure that the participant clearly understands and consents to participate in this portion of the study.

For Aim 2, the BHP will approach his/her patient during the clinic visit.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
All eligible patient participants will be made aware of the study through communications provided via approved opt-in communication or by the behavioral health provider during their standard of care appointment in a private confidential office or zoom setting or from access to research registry related information.

If the patient is interested in hearing more about participating in the study during a standard of care appointment the behavioral health care provider will review the informed consent content and details if they are approved for this IRB application.
In the instance the patient wishes to hear more about the study based on clinical trial registry a member of the research team will complete phone communication using the same procedures. If the patient wishes to participate after understanding of the informed consent is demonstrated the patient will be asked to sign electronic consent with an UNMC

organizational approved method that adheres to grant signature requirements, or will provide written consent if the visit is taking place in a face to face format or mailed (electronic or postal mail) the consent for patient to sign and return one. A copy of the consent will be provided to the participant if the visit is conducted in person and mailed or emailed to the patient for virtual visits.
In the event that the participant wishes to use the QR code to begin study then the participant will be directed to a member of the research team to get informed consent when present at the clinic site or contact information for any questions or concerns related to the consent process using the QR will be provided before they proceed further in the study.

C. Who will be involved in the process of consent and what are their responsibilities?
For Aim 1, patients who are interested as identified through clinical trial registry will be contacted by a member of the research team to review participation in the study and determine eligibility criteria and if eligible will complete the informed consent process for the semi-structured focus groups.

In the instance where the participant is identified by any BHP and wishes to participate in the study using the QR code contact information to a member of the research team will be provided to the participant to review any questions they may have pertaining to the consent prior to starting any survey questions.

Dr. Dinkel will be consenting BHP's, Clinical Staff, Providers and Administration

D. How much time will be allotted to the process of consent?
The consent process is likely to take between 5-10 minutes. However, more time will be provided if needed. We will follow up with the BHP, Clinical Staff, Providers and Administration's manager to determine BHP, Clinical Staff, Providers and Administration interest and invite those interested in participating to complete the informed consent. BHPs at the participating clinic site will identify patients who meet the eligibility criteria and determine interest in participation.

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
Informed consent will be completed in the office of the BHP or with UNMC research Team member on this IRB approved who is identified via clinical trial registry or during their standard of care appointment. Consent will be completed virtually or in written format for in person visits, as such, it will be read aloud to participants. Participants will have additional time, if needed, for delayed consent and encouraged to discuss their participation with family/friends. Only Citi trained and UNMC IRB approved members of this IRB application will be performing consent.

F. Will non-English speaking subjects be enrolled in this research?
No

Provide justification for exclusion of non-English speaking subjects
Because of limited funding, we will focus on recruiting English speaking subjects only. When we expand the study in the future, we will translate all the materials in Spanish to recruit Spanish-speaking subjects as well.

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
The participants will be asked about their understanding of the elements of informed consent prior to determining if the information presented was understood. The BHP and designated research staff will use open-ended questions to assess if participants understand what they believe need to do to participate in the study. If they do not communicate understanding, the study and aspects of their potential participation will be described to them again.

30. Documentation of Informed Consent and Assent
Select who will obtain consent from the subject/parent(s)/LAR.
Dinkel, Danae Melinda

Emerson, Maggie R

Howland, Nathan Andrew

Kreuzberg, Daniel Jacob

Thomas, Robbin K

Wolnisty, Sarah E

31. Consent Forms and Study Information Sheets
Indicate the type of consent forms and study information sheets to be used in this research. Check all that apply.
♦ Adult consent form
Legally authorized representative (LAR) consent form
Parental/Guardian consent form
Youth study information sheet
Child study information sheet

Adult study information sheet (decisionally-impaired)
Screening consent form
Addendum consent form
Other. Explain.

32. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

RESOURCES

33. Describe the resources available to safely conduct this study at <u>each</u> study sites specified in Section I.7.
We will use funding from Great Plains IDeA-CTR grant to hire study personnel to help to conduct research activities. Also, the Nebraska Medical Center Clinics approved our request to conduct the study at their sites and are in support of their health care providers participating in and supporting our study. The BHPs at the Nebraska Medicine Clinics and Bluestem Clinics will recruit patients and implement the app intervention. We have received verification of additional support for adding this site from the Director of the Bluestem Health system. Additionally, a member of our research team, Trey Andrews, provides direct patient care services for Bluestem.

LITERATURE REVIEW

34. References
Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.
1. Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the united states: Results from the 2018 national survey on drug use and health. 2019;HHS Publication No. PEP19-5068, NSDUH Series H-54.
2. National Institute of Mental Health. Integrated care: Overview. https://www.nimh.nih.gov/health/topics/integrated-care/index.shtml. Updated 2017. Accessed 08/12, 2018.
3. Bridges AJ, Gregus SJ, Rodriguez JH, et al. Diagnoses, intervention strategies, and rates of functional improvement in integrated behavioral health care patients. J Consult Clin Psychol. 2015;83(3):590-601.
4. Andrews AR, Gomez D, Larey A, et al. Comparison of integrated behavioral health treatment for internalizing psychiatric disorders in patients with and without type 2 diabetes. Fam Syst Health. 2016;34(4):367-377.

5. Andrews AR, Lopez CM, Snyder A, Saunders B, G Kilpatrick D. Polyvictimization, related symptoms, and familial and neighborhood contexts as longitudinal mediators of racial/ethnic disparities in violence exposure across adolescence. J Immigr Minor Health. 2019;21(4):679-692.
6. Cigrang JA, Rauch SA, Mintz J, et al. Moving effective treatment for posttraumatic stress disorder to primary care: A randomized controlled trial with active duty military. Fam Syst Health. 2017;35(4):450-462.
7. Holder N, Holliday R, Williams R, Mullen K, Suris A. A preliminary examination of the role of psychotherapist fidelity on outcomes of cognitive processing therapy during an RCT for military sexual trauma-related PTSD. Cogn Behav Ther. 2018;47(1):76-89.
8. Davidson TM, Bunnell BE, Saunders BE, et al. Pilot evaluation of a tablet-based application to improve quality of care in child mental health treatment. Behav Ther. 2019;50(2):367-379.
9. Ruggiero KJ, Bunnell BE, Andrews Iii AR, et al. Development and pilot evaluation of a tablet-based application to improve quality of care in child mental health treatment. JMIR Res Protoc. 2015;4(4):e143.
10. Yuen EK, Gros K, Welsh KE, et al. Development and preliminary testing of a web-based, self-help application for disaster-affected families. Health Informatics J. 2016;22(3):659-675.
11. Kilpatrick, D. G., Resnick, H. S., Milanak, M. E., Miller, M. W., Keyes, K. M., & Friedman, M. J. (2013). National estimates of exposure to traumatic events and PTSD prevalence using DSM‐IV and DSM‐5 criteria.*Journal of traumatic stress*,*26*(5), 537-547.

Flottorp, S.A., Oxman, A.D., Krause, J.*et al.*A checklist for identifying determinants of practice: A systematic review and synthesis of frameworks and taxonomies of factors that prevent or enable improvements in healthcare professional practice.*Implementation Sci***8**, 35 (2013). https://doi.org/10.1186/1748-5908-8-35

SECTION III

SUBMISSION DEADLINE

A. Full Board Review:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (e.g., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. Expedited Review
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)
Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
Investigational Device Review Committee (IDRC) Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
Sponsored Programs Administration (SPA)/UNeHealth grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
Other Review
♦ **None of the above organizational requirements apply to this study**

SECTION IV

COVID-19

Human Subjects Research Safety Plan
You have indicated in section I that this study involves face to face contact with subjects. Before final approval and release of this study will be issued, a Human Subjects Research Safety Plan found at unmcredcap.unmc.edu/redcap must be completed and submitted to the Human Subject Research Safety Review Committee (HSRSRC) for review and approval.
♦ I acknowledge this requirement.

ADDENDUM B
Research Involving Pregnant Women, Fetuses and Neonates of Uncertain Viability or Non-Viable

Title of Protocol
Using Mobile Technology to Address the Trauma Mental Health Treatment Gap: Developing Implementation Protocols for Primary Care

Principal Investigator
Emerson, Margaret (Maggie) Rose - CON-Omaha Division - 402-559-6625 - margaret.emerson@unmc.edu

1. Preclinical Studies and Studies on Non-Pregnant Women [45 CFR 46.204(A)]
A. Will Pregnant women/fetuses be included in the research?
Yes

B. Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted?
No

C. Do these studies provide data for assessing potential risks to pregnant women and fetuses?
No

2. Risks and Benefits to the Pregnant Woman or Fetus which are Associated with the Research [45 CFR 46.204(B)]
A. Is there *any prospect* of direct benefit for the woman or the fetus?
No

1) Describe any risks to the fetus.
Pregnant women are not being exclusively targeted for this research but they may be a part of the data and are not being specifically excluded as they may also suffer from mental illnesses. As the study involves the use of mobile apps in addition to surveys and semi-structured interviews for primary data collection, there is no research-based risk to the fetus or the woman herself.

2) Describe how the research could lead to the development of important biomedical knowledge.

Our results will directly inform how technology-based strategies may improve trauma-focused care for underserved populations and shape procedures for a larger clinical trial that may be conducted with the fully- developed and refined educational materials and procedures based on analyses from these data.

3) Could the research be conducted without involvement of pregnant women?
Yes

3. Minimization of Risks to the Pregnant Woman and Fetus [45 CFR 46.204(C)]
A. Describe how the risks to the pregnant woman and fetus are minimized to the greatest extent possible consistent with the objectives of the research.
The methods employed for this study with voluntary participation itself minimizes the risks to the pregnant woman and fetus. There is no clinical or behavioral intervention involved in the study. Pregnant women are not being specifically targeted but may participate. Excluding them will limit the generalizability of the findings as irrespective of their pregnancy, they are as likely to be affected by mental illnesses as the general adult population.

4. Pregnancy Termination and Determination of Viability [45 CFR 46.204(H-J)]
A. Will the research involve termination of a pregnancy?
No

5. Consent of the Pregnant Woman and Father [46.204(B), 205(B), 205(C)]
Information Only

	BENEFITS				
RISK TO FETUS		**NONE**	**TO MOTHER ONLY**	**TO MOTHER & FETUS**	**TO FETUS ONLY**
	MINIMAL	**Consent of mother**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***
	GREATER THAN MINIMAL	**Not allowable**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***

***Except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity or the pregnancy**

resulted from rape or incest.

6. Research Involving Neonates of Uncertain Viability [45 CFR 46.205]
A. Will the research involve neonates of uncertain viability?
No

7. Research Involvng Nonviable Neonates [45 CFR 46.205(c)]
A. Will the research involve nonviable neonates?
No