STUDY TITLE:

Testing the impact of the PROACTIVE parent program with the caregivers of youth in the child welfare system

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1.0 Purpose and rationale of the study:

Over 650,000 children experience abuse each year in the U.S[1]. Approximately 1 in 2 children who experience abuse exhibit mental health symptoms, maladaptive behaviors, and psychiatric disorders[2]. Only about 25% of child abuse victims access mental health treatment; for those who do access treatment, the average time between the first episode of mental disorder and the first treatment contact is over 11 years[2]. Foster parents (referred to as parents below) may not know how to identify their foster child's mental health (MH) needs, find evidence-based MH treatment, or maintain an environment that supports their youth's mental health needs. This is particularly true for children who have special health care needs, as these additional needs increase the

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[1] U.S. Department of Health & Human Services, Administration for Children and Families, Administration on Children, Youth and Families, Children's Bureau. (2020). *Child Maltreatment 2018*. Available from https://www.acf.hhs.gov/cb/research-data-technology /statistics-research/child-maltreatment.

[2] Burns, B. J., Phillips, S. D., Wagner, H. R., Barth, R. P., Kolko, D. J., Campbell, Y., & Landsverk, J. (2004). Mental health need and access to mental health services by youths involved with child welfare: A national survey. *Journal of the American Academy of Child & Adolescent Psychiatry, 43*(8), 960-970. doi:https://doi.org/10.1097/01.chi.0000127590.95585.65
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complexity of mental health service delivery as well as of supporting the mental well-being of the child. For many parents, including foster parents, these skills and resources are not readily taught or accessible. As a result, our team is developing and testing PROACTIVE parent, a new model designed to increase access to, and effectiveness of, MH treatment for youth in care. By **PRO**viding **AC**cess **T**o **I**nno**V**ative & **E**vidence-Based Treatment (PROACTIVE), our research team aims to empower foster parents so they can (1) identify symptoms of mental illness in their foster youth; (2) locate appropriate MH evaluation and treatment; (3) promote mental wellness; (4) overcome barriers to accessing treatment; and (5) manage their child's MH treatment. Ultimately, PROACTIVE Parent serves to extend current mental health treatment by facilitating access to mental health services and equipping foster parents with the skills necessary to promote their child's mental well-being.

The purpose of this study is to develop and pilot test an educational intervention for foster parents of youth in foster care programs throughout the United States. This program involves a member of the research team serving as a parent coach who will help parents learn emotion regulation and behavior management skills that will help them create a more predictable environment for their youth in care, learn how to use publicly available resources to identify mental health treatments for themselves and their youth, and learn how to better understand their youth's mental health care needs. While this educational program is designed to create a better environment for the youth, the youth themselves will not be involved with any study interactions.

In addition to creating the infrastructure and content necessary to support PROACTIVE Parent, this study ultimately has two aims:

1. Does the PROACTIVE Parent Program improve foster parents' capacity for supporting their youth in care's mental wellbeing?
2. Does the PROACTIVE Parent Program improve youth in cares' mental health symptoms, as reported by the foster parents?

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

For the needs assessment, eligible participants are foster parents of youth with a special health care need (including disabilities, mental health needs, and/or complex medical needs). Participants must be over the age of 18 and be actively fostering a child through the Illinois Department of Children and Family Services.

For the pilot study, eligible participants are foster parents of youth with identified mental health needs. Foster parents must be over the age of 18 and be actively fostering a child ages 5-13 through a child welfare agency in the United States. All participants will also need to speak English, be a resident of Illinois, and be able to navigate virtual meeting technologies (e.g. Zoom).

3.0 Sample Size:

For our needs assessment, we anticipate that 1000 caregivers involved in the specialized foster care program will complete our survey. Given that over 3000 caregivers foster youth in care with special health care needs, we believe that this is a feasible number with recruitment support from DCFS.

For our initial pilot study, we will be recruiting 50 caregivers who will receive the pilot intervention. This pilot data will be used to inform a larger iteration of the study, but we believe that 50 caregivers is sufficient for our initial pilot.

4.0 Recruitment and Screening Methods:

For our needs assessment, we will obtain a list of caregivers involved with the specialized foster care program in DCFS as well as their contact information through the data sharing agreement in place between DCFS and Northwestern. We will attempt to recruit families through email first, then following up with a call, and then sending the survey and recruitment materials to the home. If we are not able to reach the caregivers, we will reach out to the youth's caseworker to facilitate our connection with the caregiver. For families we know do not easily engage with email, we will focus our recruitment efforts on calling and sending mail. Caregivers will be allowed to respond in any way that meets their needs.

For our pilot study, we will work with the Medical Director and the Psychology & Psychiatry Assistant Program Administrator at DCFS to identify caregivers who they believe could benefit from this program as well as organizations that serve foster parents who could connect us to interested families. Once these families have been identified and their contact information has been received by DCFS staff, we will reach out to the caregivers via phone, email, or text to see if they would be interested in participating in this pilot program. If they are interested, a member of the research team will meet with the family via phone or video-based conferencing to discuss the program and to obtain consent. This meeting will also be used to ensure that the family can participate in the intervention. If any of the initial families do not want to participate, or if they are found to be ineligible, we will work with DCFS staff to identify additional families who meet the criteria until we have achieved our desired sample size. Additionally, we will post recruitment information on social media online platforms (Facebook, Reddit, Craigslist, etc.). Potential subjects will be asked to complete a screening questionnaire via REDCap survey that goes over the eligibility criteria for our study. Potential subjects will also be asked to provide us with their contact information at the end of the screening questionnaire (name, email address/phone number).

5.0 Research Locations:

All study interventions will take place virtually. Study staff will meet with participants via Zoom, all data will be collected via REDCap, and data will be converted into reports to share with caregivers. All software used will be part of Northwestern's resources.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

All research interventions will be conducted by Northwestern employees and students. However, DCFS staff will assist with recruitment of participants. Since they will only be referring participants to us and will not be participating in any research processes, including collecting consent, the research team believes that IRB approval within DCFS is not warranted.

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

This section is not applicable.

8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:

☒One-on-one interviews
☐Focus Groups
☒Questionnaires/surveys
☐Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)
☐Ethnographic observation
☐Physiological measurements (e.g., EEG, EKG, MRI)
☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)
☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)
☐Behavioral decisionmaking tasks (e.g., puzzles, interactive games, etc.)
☐Physical activities such as walking and other forms of exercise
☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above): ____

This current study has two components that will happen concurrently to iteratively inform the development of the PROACTIVE Parent intervention.

First, the research team will conduct a needs assessment with caregivers of youth in the DCFS specialized foster care program. We will disseminate this 10-15 minute needs assessment using email, online communications, connections with caseworkers, and mailing hard copies of the survey to families to complete on their own time. This assessment will inform content development for PROACTIVE Parent. It is intended to identify any gaps in services, particularly in regards to mental health services, that will be important for informing the work of future iterations of the PROACTIVE Parent educational program. Parents will be recruited through DCFS and will not be compensated for their time. However, in order to make sure that the assessment is accessible to a wide array of foster parents, we will first pilot the needs assessment with 10 parents in an interview format. These 10 parents will be compensated $20 for their time.

At the same time, the research team will pilot the initial iteration of the PROACTIVE parent model with foster parents of youth in the foster care programs. After foster parents complete an initial screening via REDCap survey, a member of the research team will contact the foster parent to confirm eligibility. The research team member will then obtain informed consent. After consent has been given, the foster parents will be asked to complete an initial and final assessment. Initial assessment is completed prior to attendance of parent coach sessions and the final assessment is completed after the last session.

The subjects will complete a demographics questionnaire (i.e. name, age, sex, gender, race, ethnicity, education, employment, socioeconomic status, address (for mailing payment, confirmation of state residency, and mailing consent form if requested), caseworker contact information) as part of their initial assessment. We will also ask subjects questions regarding their own parenting needs, their youth's mental health needs, and the parents' ability for engaging with mental health services.

During this initial and final assessment, the parent will complete the following measures:

- Parent-Patient Activation Measure – Mental Health
- PROMIS Parent Proxy Measure – Anxiety
- PROMIS Parent Proxy Measure – Depression
- Pediatric Symptom Checklist-17 (Parent Proxy)
- Barriers to Treatment Participation Scale
- Client Satisfaction Questionnaire (final assessment only)

Data will be collected through a REDCap survey.

Parent involvement in the intervention is anticipated to be 30-60 minutes each session (up to 10 sessions) which may occur over the course of up to 12 weeks.

Foster parents will be compensated $20 after completing the initial assessment *and* attending the initial session. Foster parents will also be compensated $20 after completing the final assessment. In addition, foster parents will have the ability to earn continuing education credits necessary for foster parent licensure for completing this program.

Following the initial assessment, the caregiver will meet with a parent coach, who is an internal member of the NU research team, for 30-60 minutes each session. The content of the sessions will consist of one or more of the following:
1) introducing the program
2) identifying and setting goals
3) discussing results of the assessment
4) helping parents develop literacy regarding their child(ren)'s mental health needs
5) developing skills on locating mental health services using publicly available resources
6) developing skills related to Dialectical Behavioral Therapy, Cognitive Behavioral Therapy, and Parent-Child Interaction Therapy.

After each session, parent coaches will also briefly ask parents questions about their experience with the session to further improve the program (i.e. Post Session Evaluation Questionnaire).

Communication between sessions - to remind foster parents of upcoming sessions or to pass along relevant information in between sessions – will be conducted by email and/or by text. All text communication will happen through personal cell phone or Google Voice number. Google Voice number would provide study staff the option to not use their personal cell numbers to communicate with study participants if they are not comfortable doing so.

9.0 Research with Vulnerable Populations (if children are the ONLY vulnerable population you plan to enroll, do NOT complete this section -- instead fill out Appendix A)

This study will work with foster parents of children with special health care needs, including mental health needs. Since this intervention focuses on the foster parents, we do not believe our population of interest would be considered a vulnerable population.

10.0 Incomplete Disclosure or Deception:

This project does not involve incomplete disclosure or deception.

11.0 Consent Process:

For the needs assessment interview, parents will complete the REDCap e-consent process after a research staff member explains the purpose of the interview, the structure of the survey interview, all benefits and risks, as well as security measures, such as privacy protections and resources, if there is a concern. Since this intervention will be taking place virtually, an e-consent process will be used, where record of consent is stored via REDCap, and a copy of the consent form is emailed or mailed to the participants.

For the needs assessment, parents will complete an online consent form before accessing the survey since we will not be requiring parents provide identifying information (in other words, parents have the option to opt into providing identifiable information but are not required to). This consent form will detail the focus of the study, the length it will take to answer the survey, data security measures, and information on who to contact in case there is an issue or concern. Consenting parents will then select “I agree” after reading through the consent form if they would like to participate. Consenting parents will also have the ability to print or save the consent form from the survey if they would like a copy.

For the parents interested in participating in the PROACTIVE Parent pilot study, they will first meet with a research staff member who has been approved to consent participants over the phone or via video-based conferencing. The research staff member will explain the purpose of the study, the structure of the intervention, all benefits and risks, as well as security measures, such as privacy protections and resources if there is a concern. Since this intervention will be taking place virtually, an e-consent process will be used, where record of consent is stored via REDCap, and a copy of the consent form is emailed or mailed to the participants. The member of the research team who is obtaining consent will e-sign on a separate REDCap form to confirm consent was obtained.

12.0 Waiver of Participant Signature on Consent Form:

The initial 10 parents who will be piloting the needs assessment, a waiver of consent is not being requested. Parents will provide an e-signature for consent, using REDCap’s e-consent process, since we will be interviewing them to test the usability of the survey. This consent form can be found under “Needs Assessment Interview Consent.” For the actual needs assessment, though, parents will complete an online consent form. We felt this was appropriate since parents do not have to provide identifying information. This consent form can be found under “Needs Assessment Consent.”

For the pilot component of the study, a waiver of participant signature is not being requested.

13.0 Waivers and Alterations of Consent Information:

Waivers and alterations of consent information are not being requested.

14.0 Financial Compensation:

The first 10 parents who complete the initial needs assessment interview will receive $20 for their time. Parents who complete the finalized needs assessment will not be compensated.

Parents who participate in the pilot study will receive $20 after initial assessment is completed *and* attendance of initial session. Participants will also receive $20 after completing the final assessment. Participants will have the opportunity to earn $40.

Parents will also be able to receive continuing education credits to maintain their foster parent licensure after completing the PROACTIVE Parent intervention.

Participants will either receive payment in the form of a $20 gift card or a stored e-gift card.

Participants will be responsible to cover the costs of accessing the needs assessment, talking on the phone or Zoom with research staff either both project, and/or any online resources utilized during the pilot study.

15.0 Audio/Video Recording/Photography

For the needs assessment, we will not be recording participants in any form.

For the pilot study, we will audio and video recordings of zoom conversations between the parent coach and the participants. These recordings will be used for quality assurance and training purposes as well as to refine interactions between the parent coach and the participants. Data will be stored on FSM secure servers and not on the Zoom cloud. If a parent does not agree to being recorded, their sessions will not be recorded. Instead, the parent coach will take notes during the session to gather insight on how the session went.

16.0 Potential Benefits of this Research:

The needs assessment has multiple potential benefits for participants. First, it will allow participants to share their experiences and contribute to efforts to improve the fostering experience. Second, they will be able to contribute to research and inform practices to better support youth with special health care needs, particularly those with mental health needs.

The pilot study offers many potential benefits to participants. First, participants will be provided with the results of screenings that will give them insight into their youth's mental health needs. Second, they will be provided with personalized supports to find appropriate services and strategies to support their youth's needs. Third, foster parents will have opportunities to learn and practice skills and strategies with research staff that will allow them to better support their youth's mental health needs as well as their own emotional regulation. Fifth, foster parents will have access to a research-based curriculum regarding skills that can improve their ability to support their child's needs.

17.0 Potential Risks to Participants:

A potential risk for participants in both studies is that they might misconstrue our services to be comprehensive mental health services. However, our needs assessment is simply aimed at identifying needs to create recommendations to improve services while PROACTIVE Parent is only an educational program designed to support parents in learning new skills, learning how to locate services for their child, and obtaining referrals to providers through a publicly accessible databases. Thus, while this program fills in gaps in traditional mental health services, it does not constitute comprehensive mental health treatment, a fact that will be consistently emphasized to participants throughout both parts of the study. We will explicitly include this in the consent form and check in with participants regularly to ensure that this is understood and that participants have access to complete services. In addition, parents might feel uncomfortable sharing personal information with research study staff. In order to mitigate this risk, we will emphasize that participants do not have to answer any question they do not want to or participate in any activity that makes them uncomfortable. If they continue to feel uncomfortable, they can choose to opt out of the remainder of the needs assessment or pilot study, depending on which they are enrolled in.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

In terms of data storage, all data will be stored on secure Northwestern servers and only accessed by members of the research team. While the data will be stored with identifiers, since the research staff will need to contact participants, data will be de-identified when downloaded. When the data is being transferred from REDCap to the M drive, it will be downloaded on an FSM computer and immediately transferred to the appropriate M drive location. The data will be stored indefinitely on the M drive and on NU's REDCap server.

In terms of delivering the pilot intervention, all coach - participant check-ins will be held using confidential video-based software (e.g. Zoom) and will be conducted in a private setting where others not involved in the research project cannot hear the advocates' conversations with participants.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

Given that the pilot study will be working with caregivers of children with mental health issues and who are involved with the child welfare system, we will be monitoring the responses caregivers provide for potentially harmful situations during every interaction with research staff. Research staff will immediately make note of any potential issues during and after their interactions with participants, responding appropriately given the situation. Protocols have been developed for managing disclosures of child abuse or neglect as well as responding to indications of suicidality by the caregiver or youth. If research staff identify a need for more comprehensive mental health services, caregivers will be referred to the Service Provider IDententification & Exploration Resource (SPIDER) through DCFS to identify additional resources. In addition, the family's case worker will be notified of the increased need. If there is a direct risk to the child or caregiver's wellbeing, the proper authorities will be alerted. In addition, if the risk for or perpetration of abuse or neglect is suspected, research staff will immediately report relevant information to DCFS. If parents reveal any level of suicide risk, the youth's case worker and, if necessary, emergency services will be immediately contacted. To promote full transparency, these potential breaches of confidentiality will be included in the consent form.

20.0 Long-term Data and Specimen Storage and Sharing:

All data collected from this study will be stored on FSM-approved drives. These include the REDCap server, as REDCap will be used to collect the data, and the FSM M-drive under the MHSPP folder. Because the participants are being hand-picked for this study and will be monitored over a period of time, data will have identifiers attached. However, only study staff will have access to identifiable data.

21.0 Qualifications of Research Team to Conduct the Research:

Dr. Heather Risser is an Assistant Professor and Associate Director of the Mental Health Services and Policy Program at Northwestern University Feinberg School of Medicine. Dr. Risser's research focuses on violence prevention, child welfare, parenting, and access to parenting and mental health promotion services for underserved children and families. Dr. Risser studies parenting interventions designed to promote positive parenting and prevent child physical abuse (CPA) through the use of innovative technologies.

Ashley Murphy is a Research Project Manager in the Mental Health Services and Policy Program. She manages all projects related to the wellbeing of children with special health care needs on the DCFS contract. She has a master's degrees in special education and clinical psychology and has worked with individuals with special health care needs in various capacities for over a decade. She also has designed and managed multiple studies focused on understanding disparities in service delivery for children with disabilities and other complex medical needs.

Alexandra Morford is a fourth year clinical psychology doctoral student in MHSPP. She has worked extensively with parents and children in clinical settings. Her research interests also focus on improving parenting skills.

Doctoral and master's students in MHSPP will assist with delivering study interventions and with conducting assessments. These students have been trained in research methods, ethics, and assessment delivery. In addition, doctoral students have clinical experience working with families.