#1754 - DadSpace: Increasing Community Support Resources for Perinatal Fathers

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Approved**	**Jan 31, 2022**	**--**

Expiration Date	Initial Approval Date	Initial Review Type
May 09, 2024	**May 10, 2021**	**Expedited**

Feedback

Approval Comment

Amendment [v 2] has been reviewed and granted approval by expedited review (§46.110(b)(2)) of minor changes on January 31, 2022. This protocol was previously assessed as qualifying for expedited review, category 7. This amendment includes updated procedures to expand the podcast satisfaction survey to include participants who are not enrolled in the DadSpace Intervention but who access the podcast through publicly available podcasting channels. Participants can submit their email addresses to enter to win a $25.00 Amazon gift card, with two gift cards being given out each month. The IRB has determined that the risk level remains no more than minimal and the safeguards for participants are appropriate. The study was assessed as being in accordance with 45 CFR 46.111 of the 2018 Requirements. This study is funded by Colorado Clinical and Translational Sciences Institute. Changes to the consent form were made resulting in a reconsent of all participants.

Protocol Amendment Form

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Protocol Amendment Form

Amendment

Amendment Instructions

1. Complete this Amendment overview.
2. Update the sections of your protocol that you are requesting to amend.
3. Upload any amended documentation (consent; assent; attachments)
4. When it is ready to go, click Submit in the menu on the right-hand side of this page.

Note: If you are amending a currently approved document, delete the file that is currently attached and add a Tracked Changes and updated Clean Version. The IRB will approve the project with only the clean version included. Previous versions are available in your protocol version history and do not need to be maintained on the current amendment.

Summarize the proposed changes to the protocol in lay terms.

We are proposing to expand our proposed podcast satisfaction survey to include participants who are not enrolled in the DadSpace Intervention but who find the podcast through publicly available podcasting channels. We had initially proposed to only collect podcast satisfaction data from participants who were in the DadSpace Intervention; however, the podcast episodes are going to be available to a wider audience than only intervention participants. Since podcasting is a relatively new option for disseminating educational information, we are interested in understanding how the wider audience of podcast listeners perceive the podcast's value. Podcast listeners will be invited on the podcast website and through the episode to complete a brief (1-5 minutes) anonymous online survey. The survey will ask about participant perceptions of the value of the podcast, basic demographics, and ideas for podcast topic suggestions. Podcast survey participants will be invited to submit their email address to be entered to win a $25 Amazon gift card, with two gift cards being given out each month. Two attachments have been added: The online consent document for the podcast survey and the podcast survey questions.

Indicate whether you think the level of risk increases, decreases, or does not change the risk determined by the IRB at initial review.

(If level of risk has changed, please update the section 'Risks' in the protocol information.)

No Change

Please document how many participants have been enrolled to date who may be impacted by your proposed changes.

0 - although participants in the DadSpace intervention may choose to listen to the podcast and participate in the podcast survey, their participation in the podcast survey will not have any affect on their participation in the DadSpace intervention study. They will need to complete the podcast survey online consent if they choose to participate in a podcast survey.

Will you re-consent subjects?

Yes

Will you reconsent all participants or a specific group (currently enrolled, still in research activity)?

All participants

General Information

Principal Investigator

Rieker, Julie Margaret

Lead Unit

Human Development + Family Studies (CO-1570)

Title

DadSpace: Increasing Community Support Resources for Perinatal Fathers

People

People

Person

Rieker, Julie Margaret

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

juliebraungart.rieker@colostate.edu

Phone

CSU Status

Faculty

Researcher Role

Principal Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

Rayburn, Stephanie Rebecca

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

stephanie.rayburn@colostate.edu

Phone

970-988-6306

CSU Status

Other

Researcher Role

Co-Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

MacPhee, David L

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

david.macphee@colostate.edu

Phone

0000000000

CSU Status

Faculty

Researcher Role

Co-Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Yes

External Personnel

Name

Kristin Glenn

Researcher Role

Co-Investigator

Email

glennk@fcwc.com

Name

Andrew Frisina

Researcher Role

Key Person

Email

andrew.frisina24@gmail.com

Name

Mike Sebald

Researcher Role

Key Person

Email

sebald.mike@gmail.com

Legacy eProtocol ID number

If applicable, enter the ID number this study was previously assigned in eProtocol.

General Questionnaire

Application Type

Expedited

Does this study include use of existing data or biospecimens?

No

Does this study include use of student educational records and data?

No

Does this study include the use of human blood, cells, tissues or body fluids?

No

Does this study include evaluation of medical equipment or devices?

No

Does this study include evaluation of drugs, biologics, reagents or chemicals?
No

Is this study a clinical trial?
Yes

Does this study include the use of Protected Health Information (PHI)?
No

Is this study a Graduate Level Thesis or Dissertation Project?
No

Is this study another type of class project?
No

Is the project funded?
Yes

Study Participants

Subjects Checklist (Select All that Apply)
Adults

Collaborators

Will Colorado State serve as the Single IRB for other collaborating institutions on this study?
No, Colorado State University is the only participating institution in this study.

Funding

Funding Sources

Funding Type
Federal Government

KP Proposal Number or OSP Reference Number
CE-JP-21-24

Title of Grant (if different from protocol title)

Period of Funding
May 1, 2021 - April 30, 2022

Is the study occurring at CSU?
Yes

Prime or Subawardee?
Prime

Funding was secured by:
CSU Office of Sponsored Programs

Please provide your IRB Approval documentation to Sponsored Programs upon receipt.

Expedited Review Categories

For research to qualify for an expedited category, all aspects of the study must present no more than minimal risk to participants and fit into one or more of the categories below. Using your judgment, please self-categorize the research activities. If you are unsure or none of the categories apply, you can leave this section blank. The IRB will make the final determination during the review.

Expedited 1

1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
2. Research on medical devices for which
    a. An investigational device exemption application (21 CFR Part 812) is not required; or
    b. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Expedited 2

1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
2. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited 3

Examples:

1. Hair and nail clippings in a non-disfiguring manner;
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
3. Permanent teeth if routine patient care indicates a need for extraction;
4. Excreta and external secretions (including sweat);
5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
6. Placenta removed at delivery;
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. Sputum collected after saline mist nebulization.

Expedited 4

Examples:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
2. Weighing or testing sensory acuity;
3. Magnetic resonance imaging;
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited 5

Expedited 6

Expedited 7

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects - 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Summary and Purpose

Proposed Start Date

July 15, 2021

Proposed End Date

July 30, 2022

Provide a brief summary or abstract of the project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

Our proposed project is aimed at meeting the support needs of community fathers who are expecting a baby or who have recently had a baby. This work is being conducted in conjunction with community partners through The Women's Clinic of Northern Colorado (WCNC). Researchers and WCNC staff will work together to develop and implement programs for prenatal and postpartum fathers. Participants will be invited to a group mentoring program and also will be provided access to supplementary educational podcasts focused on topics relevant to prenatal and postpartum fathers. We are seeking to understand what participants like and don't like about the program and how participation in the program affects participants' stress, well-being, and parenting.

Describe the purpose for the proposed project.

We are building on previous work to identify opportunities to meet the needs of perinatal fathers. The term perinatal encompasses the time leading up to and immediately following the birth of a child. Father involvement in child rearing is beneficial to mothers and children, but fathers are routinely overlooked by available support opportunities at the transition to parenthood. Our pilot project seeks to apply research evidence and best practices to address the disparity in socioemotional community support and education programs serving perinatal fathers. In a previous pilot study, we learned from fathers participating in focus groups that they are interested in opportunities to connect with other fathers in the same life stage to talk about their experiences and learn from each other. We also learned that fathers worry about meeting varied role expectations, that available resources tend to overlook the unique experiences of fathers, and that it can be challenging to find quality information in a digital world saturated with conflicting information about parenting. This project seeks to address these primary issues through community-based, father-centric support and educational programs. WCNC education staff will facilitate a discussion-based group mentoring program for fathers who are expecting or recently had a baby. This program seeks to increase connection with other fathers, reduce stress related to parenting a baby, and increase parenting confidence. We plan to evaluate the feasibility of the program through satisfaction surveys and other measures of the program's implementation. We also plan to evaluate the effectiveness of the program by providing participants with surveys asking about their well-being, knowledge, confidence in parenting, and their satisfaction with their social networks. We are additionally developing educational podcasts focused on topics relevant to prenatal and postpartum fathers, which will be evaluated as a supplementary component to the mentoring program. Our research objectives are the following: Study 1 Objective 1 (Primary): We seek to determine the feasibility and acceptability of a program targeting perinatal fathers offered in a community clinic setting. Study 1 Objective 2 (Primary): Examine whether participating in a discussion-based group mentoring program increases the likelihood of positive short-term outcomes for fathers. Study 1 Objective 3 (Secondary): Identify whether listening to brief, targeted educational podcasts predicts increased positive outcomes for fathers over and above the mentoring group alone. Study 2 Objective 1 (Primary): Identify whether participants who listen to brief,

targeted educational podcasts find them satisfactory and acceptable as a method of gaining information about perinatal fatherhood.

What do the investigators hope to learn from the project?

We hope to learn the potential for supporting the well-being of perinatal fathers through targeted programs offered in an existing perinatal clinical setting. We also hope to learn whether listening to brief podcasts is a valuable supplement to mentoring programs and whether perinatal fathers find podcasts to be a useful way to gather information on topics relevant to them.

Describe how sharing results of this study could influence behavior, practice, theory, future research designs. Specifically, how will study results apply to a larger population than the studied participants?

We intend to use the results of this study to inform the practice of supporting perinatal fathers through the transition to fatherhood.

Background

Provide a brief overview of the relevant background. Discuss the present knowledge, appropriate literature and rationale for conducting the research.

Father involvement in child rearing is beneficial to mothers and children, but fathers are routinely overlooked by available support opportunities at the transition to parenthood. Our pilot project seeks to apply research evidence and best practices to address the disparity in socioemotional community support and education programs serving perinatal fathers. The term perinatal encompasses the time leading up to and immediately following the birth of a child. Fathers are providing increasing levels of care for their infants (Bakermans-Kranenburg et al., 2019), and experience many of the same stressors that mothers do. Fathers who are underinformed and who lack a supportive network are more likely to experience psychological distress (Boyce et al., 2007) which predicts decreased father engagement (Halme et al., 2006). Father involvement contributes to a variety of positive outcomes for children, including cognitive, social, and emotional well-being (Sarkadi et al., 2008) and couple relationship quality (McClain & Brown, 2017). Addressing information and support disparities at the beginning of fatherhood may serve to help fathers and their families have a healthy beginning and contribute to positive long-term outcomes. As part of another research study (Protocol # 20-9985H), we conducted focus groups with 14 expecting fathers and 15 postpartum fathers with a child less than 1 year of age, most of whom resided in the community (Rayburn et al., 2020). Eight participants also had older children. We asked fathers about their ideas of the father role, their experiences preparing for fatherhood, and about the resources they accessed or wish they had access to. Primary themes emerging from the data suggested fathers find available instrumental resources to be frequently targeted toward mothers and that fathers are not aware of the few available fathercentric resources. Participants additionally expressed frustration about the conflicting information and high social pressure around parenting decisions and reported being unsure how to find helpful and accurate information about best practices for birth and parenting. Non-White fathers also reported an increased likelihood to use informal social support resources such as friends or family but expressed interest in formal group support or mentoring over instructional resources. These findings are consistent with prior research indicating fathers report not being adequately included in perinatal support programs (Carlson et al., 2014) and wanting more guidance and support to prepare for fatherhood (Baldwin et al., 2018).

Paternal mental health over the transition to parenthood is an additional concern affecting family well-being (Paulson et al., 2016). Fathers in the U.S. have been found to experience perinatal depression at a rate of about 13% (Cameron, Sedhov, & Tomfohr-Madsen, 2016), and depressive symptoms have been found to increase over the first 5 years of the child's life by an average of 68% (Garfield et al., 2014). Depressive symptoms place men at an increased risk of suicide, and suicide rates for men in Colorado are rising (Colorado Department of Public Health and Environment, 2018), suggesting needs are not being met. Parent depression is also related to later interparental conflict, which has negative effects on children (Shelton & Harold, 2008). Paternal perinatal depression is frequently overlooked, and there has been a recent call for perinatal and pediatric health professionals to screen for depressive symptoms in fathers and provide resource referrals (Rayburn, 2020; Walsch et al., 2020). Available services have not yet caught up to this need. In Larimer County, a Department of Health and Environment coalition on postpartum depression, anxiety, and mood disorders focuses only on maternal mental health (LCDHE, n.d.). This project is grounded in bioecological theory, which proposes that development occurs through a process of interactions between individual characteristics and social contexts such as relationships, institutions, and policies across time (Bronfenbrenner & Morris, 2006). Since perinatal fathers are adjusting to fatherhood within families and communities, we seek to utilize the clinical, media, and social spaces perinatal fathers interact with to engage fathers in educational resources and intervention programs targeted to their needs.

Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training).

Julie Braungart-Rieker has worked for several decades on projects involving fathers, mothers, and infants. She has conducted studies assessing parenting behaviors, parental perceptions, infant behavior, couples' relationships, and other factors. She has also conducted intervention studies designed to enhance parenting, including fathering. David MacPhee has 35 years' experience in conducting basic and applied research on parenting, teaching graduate and undergraduate courses on parenting, and leading community workshops on parenting and child development. In addition, his decades of community-engaged collaborations typically focus on program evaluations of family-strengthening programs, parenting programs (e.g., Best Start for Babies), and human service/public health programs. Among the graduate service learning courses he teaches is Prevention Program Evaluation. Stephanie Rayburn has worked as a childbirth educator, doula, and therapist in the community and has experience working with expectant and postpartum families, including fathers. Stephanie Rayburn also has taken coursework in risk and resilience and program evaluation that is relevant to conducting community assessment. Stephanie has been involved in multiple research projects with perinatal fathers

Explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research.

The Women's Clinic serves a socioeconomically diverse population that is primarily English speaking. The focus groups we conducted helped us to understand the attitudes and needs of fathers local to the community. As such, the development of the mentoring program has been conducted in such a way as to be sensitive to the needs of community fathers. The discussion focus of the program will allow for fathers to explore their own experiences and support needs in the context of fathering. With this study, we hope to gain greater clarity around how this program works for different community populations so that future iterations of the program can be honed or adapted to meet the needs of specific cultural and socioeconomic groups.

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Please provide details.

Procedure Description
Recruitment

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Participants will be recruited from the pool of people who have signed up for the mentoring group through WCNC. WCNC will advertise the mentoring group through their website and marketing materials as they do for other education classes they offer. Fathers who sign up for or express interest in the group program will be provided information about the associated research study by information posted on the WCNC website or by WCNC staff through verbal interaction, emails and/or flyers handed out at the clinic. Social media (e.g., Instagram/Facebook) postings made by department and clinic accounts will also be used to promote the study. Participation in the study is not required for those attending the mentoring group. Fathers attending the mentoring groups will be provided with links to listen to podcast episodes. Podcast listeners who have consented to participate in the study will be invited through the podcast website to complete brief satisfaction surveys about each podcast episode using their study ID.

Who will conduct this procedure?

Personnel
Kristin Glenn

External User

Personnel
Andrew Frisina

External User

Personnel
Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

Describe how the data will be collected (i.e. in person or online).
Sign-ups for mentoring groups will occur online through the WCNC website.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
No

Procedure Description
Screening and Consent

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Where and when will this procedure take place?

All those who have decided to take part in the mentoring groups will be assigned an ID by WCNC staff. Potential participants will use this ID to complete an online screener survey. Those who are eligible will then be automatically provided consent information online through Qualtrics. Research staff will notify WCNC staff of the ID numbers of consented participants for management of survey distribution.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

Completing the online screening and consent procedure will take 5-15 minutes.

Describe how the data will be collected (i.e. in person or online).

Online

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Participation in the Mentoring Program

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Where and when will this procedure take place?
Program facilitation will be conducted by trained staff members (Frisina, Sebald) through WCNC – either in-person at clinic facilities or virtually by Zoom depending on health guidelines. Programs will start running in August, 2021, with a new group starting each month.

Who will conduct this procedure?

Personnel
Andrew Frisina

External User

Personnel
Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.
1.5 hours per session, with 8 total sessions. Total time: 12 hours.

Describe how the data will be collected (i.e. in person or online).
Facilitators will be asked to keep attendance data, rate participant engagement, and complete a checklist of program items completed for each week of the intervention. At the end of the mentoring program, facilitators will also be asked to provide their feedback about the supportiveness of the group dynamics.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
No

Procedure Description
Online Surveys

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Participants from the mentoring group or who are on a waiting list for the next mentoring group will be invited to complete electronic surveys at four time points over four months, with four weeks between each survey. A WCNC staff member (Frisina) will send out a survey link to consented participants at each time point. Surveys will be available through Stephanie Rayburn's CSU Qualtrics account. Participants will enter their unique ID number in each survey so surveys can be linked over time. Surveys will assess demographics and outcomes of interest, including stress, mental health symptoms, parenting knowledge, confidence in parenting, the coparenting relationship, and satisfaction with their social networks. Participants will also be asked about whether or not they listened to podcasts.

Who will conduct this procedure?

Personnel
Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

15-30 minutes for each electronic outcome survey over 4 surveys. Total time: 1-2 hours.

Describe how the data will be collected (i.e. in person or online).

Online through Qualtrics

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Mentoring Program Satisfaction Surveys

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Experimental

Where and when will this procedure take place?

Participants who have attended the mentoring program will be invited to complete an electronic satisfaction survey through Rayburn's CSU Qualtrics account following completion of the group program. Surveys will ask about demographics, what participants liked or didn't like about the program, their perceptions of the group environment, and supportive group dynamics. Participants will also be given a brief (1-2 minute) electronic questionnaire at the beginning of each week of the program assessing their engagement in homework. Survey links will be sent by a member of the WCNC staff (Frisina) to maintain separation of participant contact information from data. Rayburn will manage the data on the research side.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

10-20 minutes for the mentoring group satisfaction survey, 1-2 minutes for each weekly homework survey. Total time commitment: 18-36 minutes

Describe how the data will be collected (i.e. in person or online).

Online through Qualtrics

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?
No

Procedure Description
Podcast creation

This procedure is:
Other Procedure

Please explain:
Approximately 10-20 podcasts will be created by Sebald and Rayburn and released during the study time-period. Each podcast will be approximately 15 minutes in duration. Podcasts will contain interviews from content experts related to fathering as well as interviews with fathers interested in being guests. Interviewees will be asked questions about their area of expertise or about their experiences in becoming fathers.

Procedure Description
Podcast dissemination and satisfaction

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?

Podcasts will be made available to mentoring group participants through a dedicated website maintained by Rayburn and Sebald. DadSpace intervention participants will be invited by their mentoring group facilitator (Sebald, Frisina) to listen to the podcasts as supplementary material to the group program. Podcasts will also be available through public channels (e.g., Apple iTunes, Spotify, etc.) and may be listened to by people who find them spontaneously. Podcast engagement metrics will be evaluated. A link to a brief podcast satisfaction survey through Qualtrics (Rayburn) will be available on the web page for each podcast episode. Since podcast episodes will be publicly available, a separate online consent form will be used to consent podcast survey participants. Podcast survey participants will be able to complete podcast surveys anonymously and will be invited to enter an email address to be entered into a drawing for an Amazon gift card.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Personnel

Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

~15 minutes for each podcast, up to 20 podcasts. Total possible time for listening: 5 hours The podcast survey will take approximately 1-5 minutes.

Describe how the data will be collected (i.e. in person or online).

Podcast engagement metrics will be collected online through the podcast website. Podcast satisfaction surveys will occur online through Qualtrics.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

Yes

Procedure Description

Data Analysis

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Experimental

Where and when will this procedure take place?

Analysis of study data will occur at CSU by members of the research team. Data will be monitored throughout the study collection period to monitor for any adverse events. Data analysis will occur at the end of the study collection period. Only aggregated data outcomes without identifiers will be provided to staff at the women's clinic.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Rieker, Julie Margaret

Personnel

MacPhee, David L

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

N/A

Describe how the data will be collected (i.e. in person or online).

N/A

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Following up with participants about potentially concerning survey responses

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Standard of Care or Established Practice

Where and when will this procedure take place?

Should participants list high scores on measures of depression or anxiety or indicate in survey responses ideation about self harm, research staff (Rayburn) will contact staff at WCNC (Glenn) to notify them of a participant who may need additional support. WCNC staff will reach out to the participant to provide referral resources as needed.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Kristin Glenn

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

N/A

Describe how the data will be collected (i.e. in person or online).

Any contact with participants to provide referrals will be noted and tracked by the staff member.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Privacy and Confidentiality

Explain how the established data management plan along with consent processes and other elements of the research design address the following.

Privacy is considered from the perspective of the participant and is a right to be protected. Privacy refers to an individual's interest in controlling others' access to themselves. Based on their privacy interests, participants may want to control:

- The time and place where they give information
- The nature of the information they give
- Who receives and can use the information

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center identified as such by signs on the front of the building.

Describe how you will protect subject's privacy.

Participants will be able to complete electronic surveys in locations they are comfortable with, as chosen by the participant. Participants who attend the small-group mentoring program will be associating with a business they have already chosen to be affiliated with prior to being recruited for the study. If a participant is not comfortable attending the program due to its location or the other group participants, they may choose to stop attending the mentoring program at any time. Participants who complete the podcast survey will be able to provide their responses anonymously.

Confidentiality is about data. Confidentiality pertains to protecting information from disclosure based on an agreement between the participant and the researcher. When an individual shares information in a relationship of trust and expects it to be kept private or will be disclosed only with specific permissions, researchers must uphold this agreement and maintain data appropriately.

Describe how you will maintain the confidentiality of subjects' information.

Identifiable information will only be accessible to WCNC staff. WCNC staff will provide ID numbers to each participant to use for completing their surveys. Research staff will only have access to participant ID numbers paired with survey data, not participant names or contact information. Survey responses will be aggregated for the purposes of reporting to community partners, stakeholders, publications, and grant reports. Given the small sample size, it is possible a person's data could be linked to their demographic information. To mitigate this risk, any data reported by demographic will be withheld if the demographic subgrouping contains a population of 3 or fewer people.

Clinical Trial

Will participants will be prospectively assigned to one or more interventions (including placebo or other control)?
Yes

Will the study evaluate the effects of the intervention on health-related outcomes (biomedical or behavioral)?
Yes

Does this study involve an FDA-regulated drug or device?
No

Will the study be conducted as a
Single-Site Clinical Trial

Will this study be posted on ClinicalTrials.gov?
Yes

ClinicalTrials.gov Registration# (or pending)
Pending

Additional information and support available through CSU Quality Assurance:
RICRO_QA@colostate.edu

Participant Population

Are you interacting or intervening with participants?
Yes

Provide an estimate of the anticipated participant total.
56

Are you analyzing existing data records or biospecimens?

No

Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

Please list all inclusion criteria

Participants must be expecting a baby or have a baby less than one year of age and have signed up to participate in the DadSpace mentoring program at WCNC

Please list all exclusion criteria

Less than 18 years of age, non-English-speaking.

What is the rationale for studying the requested group(s) of participants?

These participants comprise the target population of people served by the clinic and the primary focus of the intervention.

Will you use a screening procedure, instruments, tools, questionnaires etc.?

Yes

Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire), if applicable at then end of the form.

Participants will be screened for inclusion and exclusion criteria as listed above. Screening questions are attached.

Recruitment Process

Describe the procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

Participant Group Descriptor

DadSpace Mentoring Group members and wait-listed members

Please describe the recruitment process:

Marketing for the mentoring group will occur through traditional means, such as internet ads/postings, flyers/posters, face-to-face interactions, and email to clinicians and educators in related fields (e.g., pediatricians, OBGYNs, general practice, childbirth educators, doulas). Mentoring group information and sign-up will be available on the WCNC website alongside other class offerings WCNC provides. WCNC will assist in identifying potential subjects through their list of people who have signed up for the mentoring program. Recruitment information will also be available on the WCNC group website. Participants may also be recruited through emails or face-to-face interactions with WCNC staff.

Planned Subject Identification Methods

Direct advertising
Class participants
Referrals

Will a specific agency or institution provide access to prospective subjects?

Yes

Identify Agency

The Women's Clinic of Northern Colorado

Please select the recruitment personnel

Rayburn, Stephanie Rebecca

Yes

Please list the external person(s) who will contact prospective students.

Prospective participants will be contacted by Glenn, Frisina, and/or Sebald.

Planned Recruitment Materials/Methods
*(All advertising must be submitted for review in its final printed/recorded form)
Note: Attach copies of ALL recruitment materials in the attachment Section

Flyers/posters
Internet ads/postings
Email
Face to face interactions

Is there any possibility that potential participants may feel coerced to participate?
No

Is there any possibility that potential participants may feel undue influence to participate?
No

Participant Compensation/Costs

Will participants be compensated?
Yes

Form of Compensation

Gift Card/Certificate/Voucher

What is the approximate monetary value?
$44 for the Intervention surveys, possibility to win $25 for completing a podcast survey

Describe the remuneration plan.
Subjects will be paid for each survey they complete according to the following payment plan: $8 outcome survey 1 $10 outcome survey 2 $10 outcome survey 3 $10 outcome survey 4 $6 mentoring group satisfaction survey Subjects who complete podcast satisfaction surveys will be entered into a drawing each month to win one of two $25 Amazon gift cards.

Will a 1099 be issued?
No

Will participants incur any costs to participate in this research?
Yes

Explain. This should be clearly outlined in the consent form.
Study participants will all have signed up to participate in the DadSpace mentoring program at the Women's Clinic of Northern Colorado. As with other classes WCNC offers, there is a fee to participate in the program. Class fees have not yet been set, but classes of similar length at The Women's Clinic run $90.

Risks and Benefits

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [Department of Health and Human Services 45 CFR 46.102(j)]

Please indicate the researchers' evaluation of the overall risk level, and describe all known risks or discomforts associated with the study procedures, as prompted below. Note that any risks identified here should be consistent with risks you will disclose to participants in the consent process.
Minimal Risk

Are there risks associated with physical well-being?
No

Are there risks associated with psychological well-being?
Yes

Please describe.
While the level of risk is minimal, participants may become uncomfortable with some questions related to their experiences. They are allowed to decline to answer any question they feel uncomfortable with.

Are there risks associated with economic well-being, including employability?
No

Are there risks associated with social well-being, including reputational risks?
Yes

Please describe.
In a group setting, it is possible people in the group will know each other. If participants are not comfortable sharing their experiences during the group, they can choose not to say anything or remove themselves from the group.

Describe how the benefits of the research justify the likely risks to participants.
The group program and podcasts are research-informed to promote well-being and social support. Though psychological and social risks are possible, the risk is minimal compared to the potential benefits of participating in a program aimed at supporting fathers' successful adjustment before and after having a baby.

Describe direct research benefits to the participants, if any.
Risks in this study are minimal. The mentoring program and podcasts are designed to support positive outcomes in well-being and parenting for participants and their families. It is likely that any potential distress caused by surveys or social well-being will be outweighed by the benefits of the intervention and the supportive social environment.

Describe the indirect research benefits to society.
At the community level, the research may help refine the DadSpace mentoring program such that it becomes a sustainable and ongoing program to increase support resources for fathers. If the program is found to be feasible and efficacious, it may also help to inform future research for supportive fathering interventions. It is also possible the mentoring program could be adopted by other communities. Since podcasts are easily disseminated to a wide audience, podcasts may be useful to a variety of listeners, including perinatal fathers and those who help support them.

Data Management

Data management plans, including plans for data sharing, are integral to project development. How you decide to collect, store, share and/or destroy data impacts your consent process, research procedures, data analysis, and publication.

Responses in this section constitute your plan. For guidance on how to answer these questions and plan for the data lifecycle, reference the resources and tools listed here.

Data Management Services at CSU Libraries
General guidance and unfunded projects (DMPTool)
Funder-specific guidance and templates (DMPTool)

If you choose to create a standalone data management plan (DMP) for your own purposes or at the direction of a funding agency, please attach that document to your protocol, also.
A DMP fillable template is available from CSU Libraries.

How will the data be stored and backed up during the research?

Initially, data will be managed and stored on Co-PI Rayburn's password-protected Qualtrics account. Data will be downloaded from Qualtrics to a password-protected file folder in a secure HDFS research drive for statistical analyses (e.g., SPSS, Mplus). Access to this folder will only be granted to study personnel. Both Qualtrics and the PI's personal account are secure storage systems that are backed up regularly. A metadata repository will be developed for each study that describes the source of the data, a codebook for the demographic questions, syntax for computation of scale scores, and types of data files available (e.g., Excel, SPSS).

Who will be responsible for data and access management, and security?

Data Access Responsibility

Rayburn, Stephanie Rebecca

Data Access Responsibility

Rieker, Julie Margaret

Data Access Responsibility

MacPhee, David L

Who will have access to study records or specimens?

Personnel

Rayburn, Stephanie Rebecca

Personnel

MacPhee, David L

Personnel

Rieker, Julie Margaret

Will any external personnel have access to study records or specimens?

Yes

Please identify the external personnel with access to study records/data

WCNC staff (Glenn, Frisina, and Sebald) will have access to participants' contact information and associated participant ID numbers. They will not have access to research data (survey data) associated with each participant ID.

How will you share the data?

Data outcomes will be reported in aggregate through reports to stakeholders and manuscripts. The availability of the data sets will be communicated to research peers and at conferences, and referenced in publications. The embargo period for the data sets restricting public access will be for two years from completion of the studies, and will be implemented in CSU's Digital Repository. Afterward, materials will be made available via persistent URLs configured for discovery by all major web crawlers.

Will identifiable data collected as part of the research be released in identifiable form? (e.g., pictures, recordings, responses to research questions, quotes)

No

Will the identifying information be destroyed at a specific date? For guidance, please reference any associated contract or grant (if applicable) and/or the CSU Research Data Policy.

Yes

Destruction Date

August 1, 2031

What is the long-term preservation plan for the dataset?

After 2 years from completion of our study, we will archive the data in CSU's digital repository. We have no plans to submit data for open source access because as a CCTSI-funded project, the expectation is that we will use our findings to secure a larger extramural grant.

Do you intend to deposit your research data/specimens into a repository for future use?

Yes

If you already have a plan, please describe. Otherwise, you can enter N/A.

The data and related materials will be stored and preserved in CSU's open access digital institutional repository, a service jointly provided, operated, and managed by the CSU Libraries and the Department of Academic Computing and Networking Services. Because the total materials are <=1 TB in size, they will be stored, preserved, and made accessible at no cost to the project. The PIs will evaluate, distill, and select the data for preservation, and supply traditional and contextual metadata that will be reviewed and augmented as appropriate by librarians who are experts in digital repositories, including data and metadata organization and management. The CSU Digital Repository provides an exceptionally high-quality environment for data discovery, accessibility, transmissibility, and preservation. The CSU Libraries faculty and staff are experts in operating, managing, and sustaining digital data in formal repositories, possessing experience with multiple metadata schemes, harvesting of metadata and crawling of digital objects, digital rights management, and preservation.

Consent/Assent

Consent

The informed consent process involves presenting potential research participants with the key elements of a research study and what their participation will involve before they decide whether to participate. Please visit the IRB website for templates and guidelines on what information to include.

The default process for gaining consent is to use a signed form. Knowing that this does not always make sense, the IRB can approve alterations to what information is included, waive the requirement to get a signature or waive the requirement to obtain consent altogether when the request meets specific criteria.

Follow the prompts below to describe all consent processes and provide justification for any requested alterations or waivers.

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

Yes

CSU Consent Personnel

Rayburn, Stephanie Rebecca

No

Are you requesting a waiver of documentation of consent?

No

Consent

You do not have any procedures that include deception. If you are going to deceive or incompletely inform any subjects about any aspect of this study describe in the procedures section.

List each consent process

Who will obtain subjects consent?

Personnel

Rayburn, Stephanie Rebecca

Which participant group is this consent process for?

All participants who agree to be involved in the mentoring program

How is consent being obtained?

WCNC staff will send a link to the electronic screener and study consent form to those who have signed up to participate in the mentoring group. Rayburn will confirm eligibility and receipt of consent and provide consent data to The Women's Clinic to house with participant identifiers.

Will non-English speaking participants be enrolled?

No

Program facilitation is being provided in English as with other programs WCNC offers, so it stands to reason that all participants will be able to understand and speak English.

Are any subjects unable to legally provide consent?

No

Conflict of Interests

For guidance on how to answer these questions and information please visit the CSU Conflict of Interest page.

Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

No

Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

No

Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

No

Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

No

Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

No

Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

No

Significant Financial Interest: Please check Yes or No for each item below.

Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

No

Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

No

Minimizing Risks and Disclosure to Subjects

Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

Yes

By submitting this form, you are attesting that you have read Colorado State University's policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

Attachment Type

Data Management Plan

Attachment

DATA MANAGEMENT PLAN DADSPACE.DOCX

Name

Data Management Plan

Attachment Type

Recruitment Materials

Attachment

DADSPACE STUDY FLYER.PNG

Name

Study Flyer

Attachment Type

Recruitment Materials

Attachment

DADSPACE STUDY SOCIAL MEDIA IMAGE.PNG

Name

Social Media recruitment image

Attachment Type

Recruitment Materials

Attachment

RECRUITMENT COPY_UPDATED.DOCX

Name

Recruitment wording

Attachment Type

Screening Tool or Procedure

Attachment

SCREENER QUESTIONS.DOCX

Name

Screening questions

Attachment Type

Other

Attachment

DADSPACE MEASURES_FINAL.DOC

Name

Survey measures

Attachment Type

Other

Attachment

DADSPACE RESOURCE GUIDE.PDF

Name

Referral resource guide

Attachment Type

Grant or Contract

Attachment

NOS_CE-JP-21-24_BRAUNGART-RIEKER AND GLENN_2021 CE PILOT GRANT AWARD.PDF

Name

Notice of selection

Attachment Type

Grant or Contract

Attachment

GLENN-BRAUNGART RIEKER 2021 CE PILOT GRANT PROPOSAL.PDF

Name

Grant proposal

Attachment Type

Other

Attachment

FRISINA_20210408_CITI_GROUP2_SOCIAL_FRISINA_COMPCERT (1).PDF

Name

Frisina Human Subjects training certificate - social and behavioral

Attachment Type

Other

Attachment

FRISINA_20210408_CITI_GROUP1_BIOMEDICAL_FRISINA_COMPCERT.PDF

Name

Frisina Human Subjects training certificate renewal - biomedical

Attachment Type

Consent

Attachment

DADSPACE MENTORING GROUP CONSENT FORM_REVISEDFORIRB.DOC

Name

Attachment Type

Other

Attachment

RAYBURN_SBM_GCP_CERTIFICATE.PDF

Name

Rayburn GCP Certificate

Attachment Type

Consent

Attachment

PODCAST SURVEY ONLINE CONSENT.DOC

Name

Anonymous Podcast Survey Online Consent Form

Attachment Type

Other

Attachment

DADSPACE PODCAST SURVEY QUESTIONS_EDITED.DOCX

Name

Podcast Survey Questions

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

- Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.
- Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.
- Ensure that personnel training status remains current.
- Provide all subjects a copy of the signed consent form, when applicable.
- Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.
- Maintain current protocol approval by submitting renewals, as required.
- Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.
- Notify the IRB when the study is complete and take steps to close the protocol.

I understand that as the Principal Investigator I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.

Administrative Details Form

Determinations

Review Type

Study Status

Amendment

Amendment Instructions

1. Complete this Amendment overview.
2. Update the sections of your protocol that you are requesting to amend.
3. Upload any amended documentation (consent; assent; attachments)
4. When it is ready to go, click Submit in the menu on the right-hand side of this page.

Note: If you are amending a currently approved document, delete the file that is currently attached and add a Tracked Changes and updated Clean Version. The IRB will approve the project with only the clean version included. Previous versions are available in your protocol version history and do not need to be maintained on the current amendment.

Summarize the proposed changes to the protocol in lay terms.

We are proposing to expand our proposed podcast satisfaction survey to include participants who are not enrolled in the DadSpace Intervention but who find the podcast through publicly available podcasting channels. We had initially proposed to only collect podcast satisfaction data from participants who were in the DadSpace Intervention; however, the podcast episodes are going to be available to a wider audience than only intervention participants. Since podcasting is a relatively new option for disseminating educational information, we are interested in understanding how the wider audience of podcast listeners perceive the podcast's value. Podcast listeners will be invited on the podcast website and through the episode to complete a brief (1-5 minutes) anonymous online survey. The survey will ask about participant perceptions of the value of the podcast, basic demographics, and ideas for podcast topic suggestions. Podcast survey participants will be invited to submit their email address to be entered to win a $25 Amazon gift card, with two gift cards being given out each month. Two attachments have been added: The online consent document for the podcast survey and the podcast survey questions.

Indicate whether you think the level of risk increases, decreases, or does not change the risk determined by the IRB at initial review.

(If level of risk has changed, please update the section 'Risks' in the protocol information.)

No Change

Please document how many participants have been enrolled to date who may be impacted by your proposed changes.

0 - although participants in the DadSpace intervention may choose to listen to the podcast and participate in the podcast survey, their participation in the podcast survey will not have any affect on their participation in the DadSpace intervention study. They will need to complete the podcast survey online consent if they choose to participate in a podcast survey.

Will you re-consent subjects?

Yes

Will you reconsent all participants or a specific group (currently enrolled, still in research activity)?

All participants

General Information

Principal Investigator

Rieker, Julie Margaret

Lead Unit

Human Development + Family Studies (CO-1570)

Title

DadSpace: Increasing Community Support Resources for Perinatal Fathers

People

People

Person

Rieker, Julie Margaret

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

juliebraungart.rieker@colostate.edu

Phone

CSU Status

Faculty

Researcher Role

Principal Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

Rayburn, Stephanie Rebecca

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

stephanie.rayburn@colostate.edu

Phone

970-988-6306

CSU Status

Other

Researcher Role

Co-Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Person

MacPhee, David L

Home Unit

Human Development + Family Studies (CO-1570)

Email Address

david.macphee@colostate.edu

Phone

0000000000

CSU Status

Faculty

Researcher Role

Co-Investigator

Contact Roles

Admin

Permissions

Full Access

People Attachments

Yes

External Personnel

Name

Kristin Glenn

Researcher Role

Co-Investigator

Email

glennk@fcwc.com

Name

Andrew Frisina

Researcher Role

Key Person

Email

andrew.frisina24@gmail.com

Name

Mike Sebald

Researcher Role

Key Person

Email

sebald.mike@gmail.com

Legacy eProtocol ID number

If applicable, enter the ID number this study was previously assigned in eProtocol.

General Questionnaire

Application Type

Expedited

Does this study include use of existing data or biospecimens?

No

Does this study include use of student educational records and data?

No

Does this study include the use of human blood, cells, tissues or body fluids?

No

Does this study include evaluation of medical equipment or devices?

No

Does this study include evaluation of drugs, biologics, reagents or chemicals?
No

Is this study a clinical trial?
Yes

Does this study include the use of Protected Health Information (PHI)?
No

Is this study a Graduate Level Thesis or Dissertation Project?
No

Is this study another type of class project?
No

Is the project funded?
Yes

Study Participants

Subjects Checklist (Select All that Apply)
Adults

Collaborators

Will Colorado State serve as the Single IRB for other collaborating institutions on this study?
No, Colorado State University is the only participating institution in this study.

Funding

Funding Sources

Funding Type
Federal Government

KP Proposal Number or OSP Reference Number
CE-JP-21-24

Title of Grant (if different from protocol title)

Period of Funding
May 1, 2021 - April 30, 2022

Is the study occurring at CSU?
Yes

Prime or Subawardee?
Prime

Funding was secured by:
CSU Office of Sponsored Programs

Please provide your IRB Approval documentation to Sponsored Programs upon receipt.

Expedited Review Categories

For research to qualify for an expedited category, all aspects of the study must present no more than minimal risk to participants and fit into one or more of the categories below. Using your judgment, please self-categorize the research activities. If you are unsure or none of the categories apply, you can leave this section blank. The IRB will make the final determination during the review.

Expedited 1

1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
2. Research on medical devices for which
    a. An investigational device exemption application (21 CFR Part 812) is not required; or
    b. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Expedited 2

1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
2. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited 3

Examples:

1. Hair and nail clippings in a non-disfiguring manner;
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
3. Permanent teeth if routine patient care indicates a need for extraction;
4. Excreta and external secretions (including sweat);
5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
6. Placenta removed at delivery;
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. Sputum collected after saline mist nebulization.

Expedited 4

Examples:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
2. Weighing or testing sensory acuity;
3. Magnetic resonance imaging;
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited 5

Expedited 6

Expedited 7

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects - 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Summary and Purpose

Proposed Start Date

July 15, 2021

Proposed End Date

July 30, 2022

Provide a brief summary or abstract of the project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

Our proposed project is aimed at meeting the support needs of community fathers who are expecting a baby or who have recently had a baby. This work is being conducted in conjunction with community partners through The Women's Clinic of Northern Colorado (WCNC). Researchers and WCNC staff will work together to develop and implement programs for prenatal and postpartum fathers. Participants will be invited to a group mentoring program and also will be provided access to supplementary educational podcasts focused on topics relevant to prenatal and postpartum fathers. We are seeking to understand what participants like and don't like about the program and how participation in the program affects participants' stress, well-being, and parenting.

Describe the purpose for the proposed project.

We are building on previous work to identify opportunities to meet the needs of perinatal fathers. The term perinatal encompasses the time leading up to and immediately following the birth of a child. Father involvement in child rearing is beneficial to mothers and children, but fathers are routinely overlooked by available support opportunities at the transition to parenthood. Our pilot project seeks to apply research evidence and best practices to address the disparity in socioemotional community support and education programs serving perinatal fathers. In a previous pilot study, we learned from fathers participating in focus groups that they are interested in opportunities to connect with other fathers in the same life stage to talk about their experiences and learn from each other. We also learned that fathers worry about meeting varied role expectations, that available resources tend to overlook the unique experiences of fathers, and that it can be challenging to find quality information in a digital world saturated with conflicting information about parenting. This project seeks to address these primary issues through community-based, father-centric support and educational programs. WCNC education staff will facilitate a discussion-based group mentoring program for fathers who are expecting or recently had a baby. This program seeks to increase connection with other fathers, reduce stress related to parenting a baby, and increase parenting confidence. We plan to evaluate the feasibility of the program through satisfaction surveys and other measures of the program's implementation. We also plan to evaluate the effectiveness of the program by providing participants with surveys asking about their well-being, knowledge, confidence in parenting, and their satisfaction with their social networks. We are additionally developing educational podcasts focused on topics relevant to prenatal and postpartum fathers, which will be evaluated as a supplementary component to the mentoring program. Our research objectives are the following: Study 1 Objective 1 (Primary): We seek to determine the feasibility and acceptability of a program targeting perinatal fathers offered in a community clinic setting. Study 1 Objective 2 (Primary): Examine whether participating in a discussion-based group mentoring program increases the likelihood of positive short-term outcomes for fathers. Study 1 Objective 3 (Secondary): Identify whether listening to brief, targeted educational podcasts predicts increased positive outcomes for fathers over and above the mentoring group alone. Study 2 Objective 1 (Primary): Identify whether participants who listen to brief,

targeted educational podcasts find them satisfactory and acceptable as a method of gaining information about perinatal fatherhood.

What do the investigators hope to learn from the project?

We hope to learn the potential for supporting the well-being of perinatal fathers through targeted programs offered in an existing perinatal clinical setting. We also hope to learn whether listening to brief podcasts is a valuable supplement to mentoring programs and whether perinatal fathers find podcasts to be a useful way to gather information on topics relevant to them.

Describe how sharing results of this study could influence behavior, practice, theory, future research designs. Specifically, how will study results apply to a larger population than the studied participants?

We intend to use the results of this study to inform the practice of supporting perinatal fathers through the transition to fatherhood.

Background

Provide a brief overview of the relevant background. Discuss the present knowledge, appropriate literature and rationale for conducting the research.

Father involvement in child rearing is beneficial to mothers and children, but fathers are routinely overlooked by available support opportunities at the transition to parenthood. Our pilot project seeks to apply research evidence and best practices to address the disparity in socioemotional community support and education programs serving perinatal fathers. The term perinatal encompasses the time leading up to and immediately following the birth of a child. Fathers are providing increasing levels of care for their infants (Bakermans-Kranenburg et al., 2019), and experience many of the same stressors that mothers do. Fathers who are underinformed and who lack a supportive network are more likely to experience psychological distress (Boyce et al., 2007) which predicts decreased father engagement (Halme et al., 2006). Father involvement contributes to a variety of positive outcomes for children, including cognitive, social, and emotional well-being (Sarkadi et al., 2008) and couple relationship quality (McClain & Brown, 2017). Addressing information and support disparities at the beginning of fatherhood may serve to help fathers and their families have a healthy beginning and contribute to positive long-term outcomes. As part of another research study (Protocol # 20-9985H), we conducted focus groups with 14 expecting fathers and 15 postpartum fathers with a child less than 1 year of age, most of whom resided in the community (Rayburn et al., 2020). Eight participants also had older children. We asked fathers about their ideas of the father role, their experiences preparing for fatherhood, and about the resources they accessed or wish they had access to. Primary themes emerging from the data suggested fathers find available instrumental resources to be frequently targeted toward mothers and that fathers are not aware of the few available fathercentric resources. Participants additionally expressed frustration about the conflicting information and high social pressure around parenting decisions and reported being unsure how to find helpful and accurate information about best practices for birth and parenting. Non-White fathers also reported an increased likelihood to use informal social support resources such as friends or family but expressed interest in formal group support or mentoring over instructional resources. These findings are consistent with prior research indicating fathers report not being adequately included in perinatal support programs (Carlson et al., 2014) and wanting more guidance and support to prepare for fatherhood (Baldwin et al., 2018).

Paternal mental health over the transition to parenthood is an additional concern affecting family well-being (Paulson et al., 2016). Fathers in the U.S. have been found to experience perinatal depression at a rate of about 13% (Cameron, Sedhov, & Tomfohr-Madsen, 2016), and depressive symptoms have been found to increase over the first 5 years of the child's life by an average of 68% (Garfield et al., 2014). Depressive symptoms place men at an increased risk of suicide, and suicide rates for men in Colorado are rising (Colorado Department of Public Health and Environment, 2018), suggesting needs are not being met. Parent depression is also related to later interparental conflict, which has negative effects on children (Shelton & Harold, 2008). Paternal perinatal depression is frequently overlooked, and there has been a recent call for perinatal and pediatric health professionals to screen for depressive symptoms in fathers and provide resource referrals (Rayburn, 2020; Walsch et al., 2020). Available services have not yet caught up to this need. In Larimer County, a Department of Health and Environment coalition on postpartum depression, anxiety, and mood disorders focuses only on maternal mental health (LCDHE, n.d.). This project is grounded in bioecological theory, which proposes that development occurs through a process of interactions between individual characteristics and social contexts such as relationships, institutions, and policies across time (Bronfenbrenner & Morris, 2006). Since perinatal fathers are adjusting to fatherhood within families and communities, we seek to utilize the clinical, media, and social spaces perinatal fathers interact with to engage fathers in educational resources and intervention programs targeted to their needs.

Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training).

Julie Braungart-Rieker has worked for several decades on projects involving fathers, mothers, and infants. She has conducted studies assessing parenting behaviors, parental perceptions, infant behavior, couples' relationships, and other factors. She has also conducted intervention studies designed to enhance parenting, including fathering. David MacPhee has 35 years' experience in conducting basic and applied research on parenting, teaching graduate and undergraduate courses on parenting, and leading community workshops on parenting and child development. In addition, his decades of community-engaged collaborations typically focus on program evaluations of family-strengthening programs, parenting programs (e.g., Best Start for Babies), and human service/public health programs. Among the graduate service learning courses he teaches is Prevention Program Evaluation. Stephanie Rayburn has worked as a childbirth educator, doula, and therapist in the community and has experience working with expectant and postpartum families, including fathers. Stephanie Rayburn also has taken coursework in risk and resilience and program evaluation that is relevant to conducting community assessment. Stephanie has been involved in multiple research projects with perinatal fathers

Explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research.

The Women's Clinic serves a socioeconomically diverse population that is primarily English speaking. The focus groups we conducted helped us to understand the attitudes and needs of fathers local to the community. As such, the development of the mentoring program has been conducted in such a way as to be sensitive to the needs of community fathers. The discussion focus of the program will allow for fathers to explore their own experiences and support needs in the context of fathering. With this study, we hope to gain greater clarity around how this program works for different community populations so that future iterations of the program can be honed or adapted to meet the needs of specific cultural and socioeconomic groups.

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Please provide details.

Procedure Description
Recruitment

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Participants will be recruited from the pool of people who have signed up for the mentoring group through WCNC. WCNC will advertise the mentoring group through their website and marketing materials as they do for other education classes they offer. Fathers who sign up for or express interest in the group program will be provided information about the associated research study by information posted on the WCNC website or by WCNC staff through verbal interaction, emails and/or flyers handed out at the clinic. Social media (e.g., Instagram/Facebook) postings made by department and clinic accounts will also be used to promote the study. Participation in the study is not required for those attending the mentoring group. Fathers attending the mentoring groups will be provided with links to listen to podcast episodes. Podcast listeners who have consented to participate in the study will be invited through the podcast website to complete brief satisfaction surveys about each podcast episode using their study ID.

Who will conduct this procedure?

Personnel
Kristin Glenn

External User

Personnel
Andrew Frisina

External User

Personnel
Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

Describe how the data will be collected (i.e. in person or online).
Sign-ups for mentoring groups will occur online through the WCNC website.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
No

Procedure Description
Screening and Consent

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Where and when will this procedure take place?

All those who have decided to take part in the mentoring groups will be assigned an ID by WCNC staff. Potential participants will use this ID to complete an online screener survey. Those who are eligible will then be automatically provided consent information online through Qualtrics. Research staff will notify WCNC staff of the ID numbers of consented participants for management of survey distribution.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

Completing the online screening and consent procedure will take 5-15 minutes.

Describe how the data will be collected (i.e. in person or online).

Online

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Participation in the Mentoring Program

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Where and when will this procedure take place?
Program facilitation will be conducted by trained staff members (Frisina, Sebald) through WCNC – either in-person at clinic facilities or virtually by Zoom depending on health guidelines. Programs will start running in August, 2021, with a new group starting each month.

Who will conduct this procedure?

Personnel
Andrew Frisina

External User

Personnel
Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.
1.5 hours per session, with 8 total sessions. Total time: 12 hours.

Describe how the data will be collected (i.e. in person or online).
Facilitators will be asked to keep attendance data, rate participant engagement, and complete a checklist of program items completed for each week of the intervention. At the end of the mentoring program, facilitators will also be asked to provide their feedback about the supportiveness of the group dynamics.

Will any video, photography, or audio be recorded as part of this procedure?
No

Will data be collected anonymously?
No

Procedure Description
Online Surveys

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Participants from the mentoring group or who are on a waiting list for the next mentoring group will be invited to complete electronic surveys at four time points over four months, with four weeks between each survey. A WCNC staff member (Frisina) will send out a survey link to consented participants at each time point. Surveys will be available through Stephanie Rayburn's CSU Qualtrics account. Participants will enter their unique ID number in each survey so surveys can be linked over time. Surveys will assess demographics and outcomes of interest, including stress, mental health symptoms, parenting knowledge, confidence in parenting, the coparenting relationship, and satisfaction with their social networks. Participants will also be asked about whether or not they listened to podcasts.

Who will conduct this procedure?

Personnel
Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

15-30 minutes for each electronic outcome survey over 4 surveys. Total time: 1-2 hours.

Describe how the data will be collected (i.e. in person or online).

Online through Qualtrics

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Mentoring Program Satisfaction Surveys

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Experimental

Where and when will this procedure take place?

Participants who have attended the mentoring program will be invited to complete an electronic satisfaction survey through Rayburn's CSU Qualtrics account following completion of the group program. Surveys will ask about demographics, what participants liked or didn't like about the program, their perceptions of the group environment, and supportive group dynamics. Participants will also be given a brief (1-2 minute) electronic questionnaire at the beginning of each week of the program assessing their engagement in homework. Survey links will be sent by a member of the WCNC staff (Frisina) to maintain separation of participant contact information from data. Rayburn will manage the data on the research side.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

10-20 minutes for the mentoring group satisfaction survey, 1-2 minutes for each weekly homework survey. Total time commitment: 18-36 minutes

Describe how the data will be collected (i.e. in person or online).

Online through Qualtrics

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?
No

Procedure Description
Podcast creation

This procedure is:
Other Procedure

Please explain:
Approximately 10-20 podcasts will be created by Sebald and Rayburn and released during the study time-period. Each podcast will be approximately 15 minutes in duration. Podcasts will contain interviews from content experts related to fathering as well as interviews with fathers interested in being guests. Interviewees will be asked questions about their area of expertise or about their experiences in becoming fathers.

Procedure Description
Podcast dissemination and satisfaction

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?

Podcasts will be made available to mentoring group participants through a dedicated website maintained by Rayburn and Sebald. DadSpace intervention participants will be invited by their mentoring group facilitator (Sebald, Frisina) to listen to the podcasts as supplementary material to the group program. Podcasts will also be available through public channels (e.g., Apple iTunes, Spotify, etc.) and may be listened to by people who find them spontaneously. Podcast engagement metrics will be evaluated. A link to a brief podcast satisfaction survey through Qualtrics (Rayburn) will be available on the web page for each podcast episode. Since podcast episodes will be publicly available, a separate online consent form will be used to consent podcast survey participants. Podcast survey participants will be able to complete podcast surveys anonymously and will be invited to enter an email address to be entered into a drawing for an Amazon gift card.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Andrew Frisina

External User

Personnel

Mike Sebald

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

~15 minutes for each podcast, up to 20 podcasts. Total possible time for listening: 5 hours The podcast survey will take approximately 1-5 minutes.

Describe how the data will be collected (i.e. in person or online).

Podcast engagement metrics will be collected online through the podcast website. Podcast satisfaction surveys will occur online through Qualtrics.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

Yes

Procedure Description

Data Analysis

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Experimental

Where and when will this procedure take place?

Analysis of study data will occur at CSU by members of the research team. Data will be monitored throughout the study collection period to monitor for any adverse events. Data analysis will occur at the end of the study collection period. Only aggregated data outcomes without identifiers will be provided to staff at the women's clinic.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Rieker, Julie Margaret

Personnel

MacPhee, David L

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

N/A

Describe how the data will be collected (i.e. in person or online).

N/A

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Procedure Description

Following up with participants about potentially concerning survey responses

This procedure is:

Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:

Standard of Care or Established Practice

Where and when will this procedure take place?

Should participants list high scores on measures of depression or anxiety or indicate in survey responses ideation about self harm, research staff (Rayburn) will contact staff at WCNC (Glenn) to notify them of a participant who may need additional support. WCNC staff will reach out to the participant to provide referral resources as needed.

Who will conduct this procedure?

Personnel

Rayburn, Stephanie Rebecca

Personnel

Kristin Glenn

External User

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.

N/A

Describe how the data will be collected (i.e. in person or online).

Any contact with participants to provide referrals will be noted and tracked by the staff member.

Will any video, photography, or audio be recorded as part of this procedure?

No

Will data be collected anonymously?

No

Privacy and Confidentiality

Explain how the established data management plan along with consent processes and other elements of the research design address the following.

Privacy is considered from the perspective of the participant and is a right to be protected. Privacy refers to an individual's interest in controlling others' access to themselves. Based on their privacy interests, participants may want to control:

- The time and place where they give information
- The nature of the information they give
- Who receives and can use the information

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center identified as such by signs on the front of the building.

Describe how you will protect subject's privacy.

Participants will be able to complete electronic surveys in locations they are comfortable with, as chosen by the participant. Participants who attend the small-group mentoring program will be associating with a business they have already chosen to be affiliated with prior to being recruited for the study. If a participant is not comfortable attending the program due to its location or the other group participants, they may choose to stop attending the mentoring program at any time. Participants who complete the podcast survey will be able to provide their responses anonymously.

Confidentiality is about data. Confidentiality pertains to protecting information from disclosure based on an agreement between the participant and the researcher. When an individual shares information in a relationship of trust and expects it to be kept private or will be disclosed only with specific permissions, researchers must uphold this agreement and maintain data appropriately.

Describe how you will maintain the confidentiality of subjects' information.

Identifiable information will only be accessible to WCNC staff. WCNC staff will provide ID numbers to each participant to use for completing their surveys. Research staff will only have access to participant ID numbers paired with survey data, not participant names or contact information. Survey responses will be aggregated for the purposes of reporting to community partners, stakeholders, publications, and grant reports. Given the small sample size, it is possible a person's data could be linked to their demographic information. To mitigate this risk, any data reported by demographic will be withheld if the demographic subgrouping contains a population of 3 or fewer people.

Clinical Trial

Will participants will be prospectively assigned to one or more interventions (including placebo or other control)?
Yes

Will the study evaluate the effects of the intervention on health-related outcomes (biomedical or behavioral)?
Yes

Does this study involve an FDA-regulated drug or device?
No

Will the study be conducted as a
Single-Site Clinical Trial

Will this study be posted on ClinicalTrials.gov?
Yes

ClinicalTrials.gov Registration# (or pending)
Pending

Additional information and support available through CSU Quality Assurance:
RICRO_QA@colostate.edu

Participant Population

Are you interacting or intervening with participants?
Yes

Provide an estimate of the anticipated participant total.
56

Are you analyzing existing data records or biospecimens?

No

Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

Please list all inclusion criteria

Participants must be expecting a baby or have a baby less than one year of age and have signed up to participate in the DadSpace mentoring program at WCNC

Please list all exclusion criteria

Less than 18 years of age, non-English-speaking.

What is the rationale for studying the requested group(s) of participants?

These participants comprise the target population of people served by the clinic and the primary focus of the intervention.

Will you use a screening procedure, instruments, tools, questionnaires etc.?

Yes

Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire), if applicable at then end of the form.

Participants will be screened for inclusion and exclusion criteria as listed above. Screening questions are attached.

Recruitment Process

Describe the procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

Participant Group Descriptor

DadSpace Mentoring Group members and wait-listed members

Please describe the recruitment process:

Marketing for the mentoring group will occur through traditional means, such as internet ads/postings, flyers/posters, face-to-face interactions, and email to clinicians and educators in related fields (e.g., pediatricians, OBGYNs, general practice, childbirth educators, doulas). Mentoring group information and sign-up will be available on the WCNC website alongside other class offerings WCNC provides. WCNC will assist in identifying potential subjects through their list of people who have signed up for the mentoring program. Recruitment information will also be available on the WCNC group website. Participants may also be recruited through emails or face-to-face interactions with WCNC staff.

Planned Subject Identification Methods

Direct advertising
Class participants
Referrals

Will a specific agency or institution provide access to prospective subjects?

Yes

Identify Agency

The Women's Clinic of Northern Colorado

Please select the recruitment personnel

Rayburn, Stephanie Rebecca

Yes

Please list the external person(s) who will contact prospective students.

Prospective participants will be contacted by Glenn, Frisina, and/or Sebald.

Planned Recruitment Materials/Methods
*(All advertising must be submitted for review in its final printed/recorded form)
Note: Attach copies of ALL recruitment materials in the attachment Section

Flyers/posters
Internet ads/postings
Email
Face to face interactions

Is there any possibility that potential participants may feel coerced to participate?
No

Is there any possibility that potential participants may feel undue influence to participate?
No

Participant Compensation/Costs

Will participants be compensated?
Yes

Form of Compensation

Gift Card/Certificate/Voucher

What is the approximate monetary value?
$44 for the Intervention surveys, possibility to win $25 for completing a podcast survey

Describe the remuneration plan.
Subjects will be paid for each survey they complete according to the following payment plan: $8 outcome survey 1 $10 outcome survey 2 $10 outcome survey 3 $10 outcome survey 4 $6 mentoring group satisfaction survey Subjects who complete podcast satisfaction surveys will be entered into a drawing each month to win one of two $25 Amazon gift cards.

Will a 1099 be issued?
No

Will participants incur any costs to participate in this research?
Yes

Explain. This should be clearly outlined in the consent form.
Study participants will all have signed up to participate in the DadSpace mentoring program at the Women's Clinic of Northern Colorado. As with other classes WCNC offers, there is a fee to participate in the program. Class fees have not yet been set, but classes of similar length at The Women's Clinic run $90.

Risks and Benefits

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [Department of Health and Human Services 45 CFR 46.102(j)]

Please indicate the researchers' evaluation of the overall risk level, and describe all known risks or discomforts associated with the study procedures, as prompted below. Note that any risks identified here should be consistent with risks you will disclose to participants in the consent process.
Minimal Risk

Are there risks associated with physical well-being?
No

Are there risks associated with psychological well-being?
Yes

Please describe.
While the level of risk is minimal, participants may become uncomfortable with some questions related to their experiences. They are allowed to decline to answer any question they feel uncomfortable with.

Are there risks associated with economic well-being, including employability?
No

Are there risks associated with social well-being, including reputational risks?
Yes

Please describe.
In a group setting, it is possible people in the group will know each other. If participants are not comfortable sharing their experiences during the group, they can choose not to say anything or remove themselves from the group.

Describe how the benefits of the research justify the likely risks to participants.
The group program and podcasts are research-informed to promote well-being and social support. Though psychological and social risks are possible, the risk is minimal compared to the potential benefits of participating in a program aimed at supporting fathers' successful adjustment before and after having a baby.

Describe direct research benefits to the participants, if any.
Risks in this study are minimal. The mentoring program and podcasts are designed to support positive outcomes in well-being and parenting for participants and their families. It is likely that any potential distress caused by surveys or social well-being will be outweighed by the benefits of the intervention and the supportive social environment.

Describe the indirect research benefits to society.
At the community level, the research may help refine the DadSpace mentoring program such that it becomes a sustainable and ongoing program to increase support resources for fathers. If the program is found to be feasible and efficacious, it may also help to inform future research for supportive fathering interventions. It is also possible the mentoring program could be adopted by other communities. Since podcasts are easily disseminated to a wide audience, podcasts may be useful to a variety of listeners, including perinatal fathers and those who help support them.

Data Management

Data management plans, including plans for data sharing, are integral to project development. How you decide to collect, store, share and/or destroy data impacts your consent process, research procedures, data analysis, and publication.

Responses in this section constitute your plan. For guidance on how to answer these questions and plan for the data lifecycle, reference the resources and tools listed here.

Data Management Services at CSU Libraries
General guidance and unfunded projects (DMPTool)
Funder-specific guidance and templates (DMPTool)

If you choose to create a standalone data management plan (DMP) for your own purposes or at the direction of a funding agency, please attach that document to your protocol, also.
A DMP fillable template is available from CSU Libraries.

How will the data be stored and backed up during the research?

Initially, data will be managed and stored on Co-PI Rayburn's password-protected Qualtrics account. Data will be downloaded from Qualtrics to a password-protected file folder in a secure HDFS research drive for statistical analyses (e.g., SPSS, Mplus). Access to this folder will only be granted to study personnel. Both Qualtrics and the PI's personal account are secure storage systems that are backed up regularly. A metadata repository will be developed for each study that describes the source of the data, a codebook for the demographic questions, syntax for computation of scale scores, and types of data files available (e.g., Excel, SPSS).

Who will be responsible for data and access management, and security?

Data Access Responsibility

Rayburn, Stephanie Rebecca

Data Access Responsibility

Rieker, Julie Margaret

Data Access Responsibility

MacPhee, David L

Who will have access to study records or specimens?

Personnel

Rayburn, Stephanie Rebecca

Personnel

MacPhee, David L

Personnel

Rieker, Julie Margaret

Will any external personnel have access to study records or specimens?

Yes

Please identify the external personnel with access to study records/data

WCNC staff (Glenn, Frisina, and Sebald) will have access to participants' contact information and associated participant ID numbers. They will not have access to research data (survey data) associated with each participant ID.

How will you share the data?

Data outcomes will be reported in aggregate through reports to stakeholders and manuscripts. The availability of the data sets will be communicated to research peers and at conferences, and referenced in publications. The embargo period for the data sets restricting public access will be for two years from completion of the studies, and will be implemented in CSU's Digital Repository. Afterward, materials will be made available via persistent URLs configured for discovery by all major web crawlers.

Will identifiable data collected as part of the research be released in identifiable form? (e.g., pictures, recordings, responses to research questions, quotes)

No

Will the identifying information be destroyed at a specific date? For guidance, please reference any associated contract or grant (if applicable) and/or the CSU Research Data Policy.

Yes

Destruction Date

August 1, 2031

What is the long-term preservation plan for the dataset?

After 2 years from completion of our study, we will archive the data in CSU's digital repository. We have no plans to submit data for open source access because as a CCTSI-funded project, the expectation is that we will use our findings to secure a larger extramural grant.

Do you intend to deposit your research data/specimens into a repository for future use?

Yes

If you already have a plan, please describe. Otherwise, you can enter N/A.

The data and related materials will be stored and preserved in CSU's open access digital institutional repository, a service jointly provided, operated, and managed by the CSU Libraries and the Department of Academic Computing and Networking Services. Because the total materials are <=1 TB in size, they will be stored, preserved, and made accessible at no cost to the project. The PIs will evaluate, distill, and select the data for preservation, and supply traditional and contextual metadata that will be reviewed and augmented as appropriate by librarians who are experts in digital repositories, including data and metadata organization and management. The CSU Digital Repository provides an exceptionally high-quality environment for data discovery, accessibility, transmissibility, and preservation. The CSU Libraries faculty and staff are experts in operating, managing, and sustaining digital data in formal repositories, possessing experience with multiple metadata schemes, harvesting of metadata and crawling of digital objects, digital rights management, and preservation.

Consent/Assent

Consent

The informed consent process involves presenting potential research participants with the key elements of a research study and what their participation will involve before they decide whether to participate. Please visit the IRB website for templates and guidelines on what information to include.

The default process for gaining consent is to use a signed form. Knowing that this does not always make sense, the IRB can approve alterations to what information is included, waive the requirement to get a signature or waive the requirement to obtain consent altogether when the request meets specific criteria.

Follow the prompts below to describe all consent processes and provide justification for any requested alterations or waivers.

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

Yes

CSU Consent Personnel

Rayburn, Stephanie Rebecca

No

Are you requesting a waiver of documentation of consent?

No

Consent

You do not have any procedures that include deception. If you are going to deceive or incompletely inform any subjects about any aspect of this study describe in the procedures section.

List each consent process

Who will obtain subjects consent?

Personnel

Rayburn, Stephanie Rebecca

Which participant group is this consent process for?
All participants who agree to be involved in the mentoring program

How is consent being obtained?
WCNC staff will send a link to the electronic screener and study consent form to those who have signed up to participate in the mentoring group. Rayburn will confirm eligibility and receipt of consent and provide consent data to The Women's Clinic to house with participant identifiers.

Will non-English speaking participants be enrolled?
No

Program facilitation is being provided in English as with other programs WCNC offers, so it stands to reason that all participants will be able to understand and speak English.

Are any subjects unable to legally provide consent?
No

Conflict of Interests

For guidance on how to answer these questions and information please visit the CSU Conflict of Interest page.

Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?
No

Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

No

Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

No

Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

No

Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

No

Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

No

Significant Financial Interest: Please check Yes or No for each item below.

Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

No

Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

No

Minimizing Risks and Disclosure to Subjects

Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

Yes

By submitting this form, you are attesting that you have read Colorado State University's policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

Attachment Type

Data Management Plan

Attachment

DATA MANAGEMENT PLAN DADSPACE.DOCX

Name

Data Management Plan

Attachment Type

Recruitment Materials

Attachment

DADSPACE STUDY FLYER.PNG

Name

Study Flyer

Attachment Type

Recruitment Materials

Attachment

DADSPACE STUDY SOCIAL MEDIA IMAGE.PNG

Name

Social Media recruitment image

Attachment Type

Recruitment Materials

Attachment

RECRUITMENT COPY_UPDATED.DOCX

Name

Recruitment wording

Attachment Type

Screening Tool or Procedure

Attachment

SCREENER QUESTIONS.DOCX

Name

Screening questions

Attachment Type

Other

Attachment

DADSPACE MEASURES_FINAL.DOC

Name

Survey measures

Attachment Type

Other

Attachment

DADSPACE RESOURCE GUIDE.PDF

Name

Referral resource guide

Attachment Type

Grant or Contract

Attachment

NOS_CE-JP-21-24_BRAUNGART-RIEKER AND GLENN_2021 CE PILOT GRANT AWARD.PDF

Name

Notice of selection

Attachment Type

Grant or Contract

Attachment

GLENN-BRAUNGART RIEKER 2021 CE PILOT GRANT PROPOSAL.PDF

Name

Grant proposal

Attachment Type

Other

Attachment

FRISINA_20210408_CITI_GROUP2_SOCIAL_FRISINA_COMPCERT (1).PDF

Name

Frisina Human Subjects training certificate - social and behavioral

Attachment Type

Other

Attachment

FRISINA_20210408_CITI_GROUP1_BIOMEDICAL_FRISINA_COMPCERT.PDF

Name

Frisina Human Subjects training certificate renewal - biomedical

Attachment Type

Consent

Attachment

DADSPACE MENTORING GROUP CONSENT FORM_REVISEDFORIRB.DOC

Name

Attachment Type

Other

Attachment

RAYBURN_SBM_GCP_CERTIFICATE.PDF

Name

Rayburn GCP Certificate

Attachment Type

Consent

Attachment

PODCAST SURVEY ONLINE CONSENT.DOC

Name

Anonymous Podcast Survey Online Consent Form

Attachment Type

Other

Attachment

DADSPACE PODCAST SURVEY QUESTIONS_EDITED.DOCX

Name

Podcast Survey Questions

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

- Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.
- Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.
- Ensure that personnel training status remains current.
- Provide all subjects a copy of the signed consent form, when applicable.
- Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.
- Maintain current protocol approval by submitting renewals, as required.
- Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.
- Notify the IRB when the study is complete and take steps to close the protocol.

I understand that as the Principal Investigator I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.

Administrative Details Form

Determinations

Review Type

Study Status