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A Substance Use Adaptation of Fathering Through Change

October 15, 2020

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Consent for Research Participation

Title:	An Adaptation of Fathering Through Change for Fathers receiving Treatment for Substance Use Disorders
Sponsor:	National Institute on Drug Abuse
Researcher(s):	Camille Cioffi, University of Oregon
	Dave DeGarmo, University of Oregon
Researcher Contact Info:	541-525-4886
	ccioffi@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to test the usefulness for improving parenting skills through the Fathering Through Change intervention for fathers in recovery for substance use disorders.
- **Duration.** It is expected that your participation will last 4 months. During the 4 months, you will be asked to participate in three surveys, the first survey lasting 95 minutes long, and the second and third survey lasting 90 minutes each, and may also be invited to participate in an intervention. If selected for the intervention, it would include watching a set of videos once per week (5-15 minutes each) for 6 weeks and talking on the phone with a parenting coach three times (20 minutes each time).
- **Procedures and Activities.** You will be asked to complete three surveys that include information about your parenting, your child, your mental health, and substance use, one at the beginning of the study, another 6 weeks later, and final survey at 4 months after the beginning of the study. You may be randomly assigned to receive computerized/cell phone-based intervention that will last for 6 weeks to improve your parenting practices. Being part of this intervention would include watching a set of videos for 5-15 minutes per week and talking with a coach on the phone three times for one-on-one coaching. A goal of the intervention is to see if this intervention, previously created for divorced and separated fathers, will improve parenting practices among fathers with substance use disorders.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include psychological and social discomfort as well as a risk of breach of confidentiality.

- **Benefits**. Some of the benefits that may be expected include are sharing your lived experiences and improving your parenting skills and relationship with your child. You will benefit research and humanity by being involved in research.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

Dr. Camille Cioffi, a faculty member at the University of Oregon is conducting this research with mentorship from Dr. Dave DeGarmo, a professor at the University of Oregon. Camille Cioffi is asking for your consent to participate in this study.

This study is one of many studies that is part of a large research project on parenting and substance use. This project is organized by the Center on Parenting and Opioids (CPO), and it involves researchers at both the University of Oregon (UO) and the Oregon Health & Sciences University (OHSU).

Why is this research being done?

The purpose of the research is to understand if a fathering intervention, Fathering Through Change, is suitable for fathers receiving or who have previously received substance use treatment. You are being asked to participate because you are a father who is in recovery from a substance use disorder. About 80 people will take part in this research.

What happens if I agree to participate in this research?

You will need to have access to a computer, tablet, or cell phone with texting/video viewing capabilities to participate. If you agree to be in this research, your participation will include completing responding to texts/emails from our study team and participation in three surveys, the first survey lasting 95 minutes and the second and third survey lasting 90 minutes each to complete. The first survey will happen after you consent to participate, the second survey will happen in 6-weeks, and the final survey will happen in 4-months. Surveys will include information about parenting, your child, your mental health and substance use. Surveys will be completed on your personal computer, tablet, or cell phone. You can decline to answer any questions. You may be randomly selected to participate in an intervention which will be 6 weeks of videos about parenting and lasting approximate 5-15 minutes per week. It will also include and 3 sessions with a parenting coach lasting no more than 20 minutes each. One coaching call will occur during week 1 as an introduction; one around week 3 of the intervention; and one around week 6 of the intervention. The parenting coach will be Dr. Jeremy Jones who is an experienced parent trainer and contracted by the University of Oregon to provide services.

You will be randomly selected for one of two groups- either you will take three surveys and will not receive the intervention or you will take three surveys and also be invited to participate in the intervention.

We will tell you about any new information that may affect your willingness to continue participation in this research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What happens to the information collected for this research?

Information collected for this research will be used to understand whether a fathering intervention may be effective for helping fathers improve their parenting skills among dads receiving in recovery from substance use disorders. Information may be published in scientific journals or shared with the organization you are or have received treatment from. Your personal information will never be shared. Only the PI for this project and research assistants who need to have your information to contact you will have on-going access to your personal information. Dr. Jeremy Jones may have temporary access to your de-identified information in order to collect data and provide services, respectively. There may be others that will have access to your identifiable data. These organizations are listed in this consent document.

You can discontinue participation at any time, and if after participation you decides that you want your information withdrawn from the study, and future studies, you can notify the research team and your wishes will be honored. However, once the code linking names and numeric identifies is destroyed, it may not be possible to remove specific information.

We will store any information about your personal identity (e.g., names, dates of birth) separate from the other information you provide during this study. We will keep your identifiable information until the study ends, and then we will destroy it. We will only keep your identifiable information if you sign the Consent to Recontact form, in which case we will keep the information stated on that form. Your identifiable information will not be used in our analyzed, publications, presentations, or other reports.

Data from this study, with all personally identifiable information removed ("de-identified data"), will also be stored in a secure, web-based data library called the CPO Data Repository. This library will also have de-identified data from all research studies that are part of the CPO. Data in this library will be preserved indefinitely. Other researchers outside of our research team may ask the CPO to access data in this library for scientific, educational, or instructional purposes. The CPO will make sure that only researchers who have training in human research ethics and are given access to the data in the CPO Data Repository. You cannot have your data removed from the repository since there may not be a way to identify you after it has been provided.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy including using a secure server to store data and a secure wifi connection. However, we can only secure the wifi we are using so your wifi will also need to be secure to ensure your information is protected when you are sharing it with us. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. We will take measures to protect the security of all your personal information including your name, date of birth, and diagnoses. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information.

- Identifiers will be removed from identifiable private information collected in this research. After removal of identifiers, the information will be used for future research and may be distributed to another investigator for future research without obtaining additional consent.
- Each participant will be assigned a unique numeric identifier, so your name does not appear anywhere with the information that they provide.

There is an exception to maintaining confidentiality, due to learning the participant is in danger of being hurt or hurting someone else.

Researchers are mandatory reporters and which means, they must report suspected abuse or neglect of children to the State of Oregon Department of Human Services or a law enforcement agency.

The project investigator and other study investigators and research assistants have access to the data collected for research purposes. In addition, individuals that conduct or monitor this research, such as the UO and the IRB, may access and inspect the research records but that names will not be associated with the questionnaire responses or other data. Individuals and organization that conduct or monitor this research maybe permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: The Institutional Review Board (IRB) that reviewed this research; The National Institute on Drug Abuse, and the National Institutes of Health. If any of these agencies have access to identifiable personal information, they are required to adhere to confidentiality procedures.

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

What are the risks if I participate in this research?

The risks or discomforts of participating in this research include psychological risks such as feeling uncomfortable with the questions asked or self-esteem about your fathering and social risks such as feeling uncomfortable watching videos about parenting or participating in coaching calls if others are around. Additionally, there are risks to privacy and confidentiality previously mentioned.

If staff will contact you by phone, text, email, or postal mail to set up meetings, remind you of meetings, or send you compensation for participating, there is a risk that people around you will learn that you are in the study because of this communication. Please let us know if we should not contact you using in a particular way to minimize this risk.

What are the benefits of participating in this research?

You may or may not benefit from participating in this research. However, there are potential benefits. You may enjoy the opportunity to reflect on your life experiences. You may see improvements in your parenting skills and in your relationship with your child and you child's other parent. You will also be contributing to

research on providing fathering supports to individuals in recovery from substance use disorders. There may be risks that are currently unforeseeable.

What are my responsibilities if I choose to participate in this research?

If you take part in this research, you will be responsible for: completing surveys, and, if selected for the intervention, engaging in a 6 week, weekly parenting videos as well as weekly knowledge checks and 3 coaching calls.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon or at the treatment center where you have or are currently receiving services.

You can inform a staff member at any time that you no longer want to participate in the study and you can request a staff member to remove any information already collected. You have the right to choose not to participate in any aspect of the study or to completely withdraw from continued participation.

Not participating or withdrawing your participation will not affect your relationship with any treatment centers you have or are currently receiving services from. This research is not a service of a treatment center and participating or not participating will not be taken into consideration with respect to treatment plans or other services offered by any treatment center. Coaching sessions are led by a clinician who is a member of the research team and not affiliated with any treatment center.

Will it cost me money to take part in this research?

It will not cost you money to take part in this research. You may be referred to additional support/services. Any services you are referred to are not part of this research and may have a cost. These costs would be your responsibility.

Will I be paid for participating in this research?

You will be compensated incrementally for each survey completed. You will receive $25 for the first survey, $50 for the second survey, and $75 for the final survey. You may also receive an additional $30 ($5 for each weekly video watch and take a knowledge quiz for) if you are selected for the intervention. If you are selected for the intervention you will also receive a certificate of completion indicating the number of video session completed (as indicated by the number of knowledge tests completed) and the number of coaching calls you participated in.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Camille Cioffi
541-525-4886

ccioffi@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

- I consent to participate in this study. (continue survey)
- I do not consent to participate in this study. (end survey)