

Study Title

Culturally Modified Family Based Therapy for Haitian Youth in South Florida (CIFFTA).

Informed Consent Forms

NCT number: 03876171

Date: July 19, 2018



Parental Informed Consent

Study Title: Culturally Modified Family Based Therapy for Haitian Youth in South Florida

Dear Parent/Guardian:

Key Information: The following is a short summary of our study to help you decide if you want to take part. More specific information can be found later on in this form.

You are asked to take part in a study. You can choose to take part in the study or not. The goal of this study is to test a family therapy that could help families with stress associated with youth behavior problems. You will also be asked to take part in 4 interviews: an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview. Each interview will last about 1.5 to 2 hours, and will be audio or videotaped. After the first interview, you will be assigned to either a family therapy group (Group A) or one that will not receive family therapy but that attend other intervention services. Group A will receive therapy sessions that should last about 1 hour. You will also be asked to do brief surveys, lasting 10-20 minutes, before and after each group session.

There are no major risks in being in this study. During the interviews or group sessions, you could become upset when talking about your experience or other personal information.

No direct benefits are promised to you for being in this study. You may learn skills to better manage your mental health. Your time in this study may help us develop family-based therapies for other Haitian families experiencing the same problems like yours is facing.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

Why you are asked to allow your child to take part in this research study.

Your child has been asked to take part in this research study to examine a new, brief, treatment as follow-up to your child's visit to the diversion program. You and your child are invited because your child may have a need for services to help with alcohol/other drug use. We hope to learn more about how and why young people use drugs and alcohol. We want to support a healthier lifestyle for young people. This study is being conducted by staff members from the University of Miami. About 88 youths and their families will be invited to be in this study. This study is being done in Miami-Dade, Florida.

What should I know about this research study?

- Someone will explain this research study to you.
- Being in this study is not forced.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.



- We will not hold your decision against you.
- You may have questions this form does not answer. If you do, ask the person in charge of study or study staff as you go along.
- You don't have to guess at things you don't understand. Ask the people doing the study to explain things in a way you can understand.

You can ask questions:

If you have questions you can call Dr. Louis Herns Marcellin, at (305)284-2535.

You can also call University of Miami Human Subject Research Office at (305) 243-3195, for questions about your rights as a research participant.

What does consent involve?

By giving consent (permission), you agree to have your child share information about his or herself and to talk about his or her drug use with the researcher assigned to your child. You are also giving consent to participate in the parent counseling session if your child is assigned to that group. In addition to your consent, your child will be given a form to provide his or her permission to join in this study. If at any time during the study, you or your child wishes to stop, you and your child can do so without penalty. It will not affect any future relationship with the University of Miami; or with your child's school. Your signature shows that you understand the study, including its possible risks and benefits.

What will my child be asked to do?

Your child will be asked to spend about 12 months in this study. Your child's participation will involve:

- A minimum of 4 therapy sessions per month. Each service session will last about an hour.
- Four (4) interviews (an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview).
- A voluntary, confidential urine sample will also be collected after each of the 4 interviews. We will test for methamphetamines, opiates, cocaine, and marijuana.
- There are two groups to this study. Your child will only be put into ONE of these groups. Trained and clinically-supervised counselors will conduct all the intervention services at your home. The sessions will be taped with your permission.

Group A is for youths who will participate in the intervention services. We would like to meet (in your home) with you, the parent(s) or guardian(s) four time for about one hour. We will talk about your child's involvement in the juvenile justice. These sessions will be at least 3 months apart.

Group B is for youth who will be receiving mandatory services by the Juvenile Assessment



Center from community-based organizations in the context of the diversion program. Your child will be scheduled to attend four interviews within a 12-month period. If your child gets selected to be in Group B, we would like to meet (in your home) with you, the parent(s) or guardian(s) one time for about one hour to discuss your child's behavior.

Regardless of the group you and your child are in, you both will first be asked to complete a brief interview (initial) with a member of the research staff in your home. It will take about 1 hour to complete. This interview will be done separately with you and your child. You both will be asked about your child's history of involvement with the juvenile justice, reasons for this involvement, experiences with school, and the relationship with you and your child. Your child will also be asked to give a confidential urine specimen.

We will also ask for addresses and phone numbers where you and your child can be reached as well as the names and phone numbers of other people who might know how to reach you. We want to make sure to schedule the intervention sessions with us. If we contact any other people in order to locate you or your child, we will not tell them about your child's involvement in this study. We will only tell them that you and/or your child have agreed to participate in a survey and that you have given us permission to contact you.

After completing the initial interview, your child will be randomly assigned one of the groups discussed above. Random assignment is like rolling dice and means that each person has an equal chance of being in Group A or Group B.

The interviews will be conducted again at 3 months, 6 months and 12 months following the initial interview. Your child will also be asked to give urine samples at those interviews. During interviews, your child will be asked about their experiences of the counseling sessions they received.

We shall also like to obtain information on your child's diversion program visit, your child's school behavior and performance; and information on his/her contact with the justice system. This information will not be shared with anyone outside of the research team.

What will I be asked to do?

Parents/guardians will be asked to spend about 12 months in this study. Participation will involve: (a) participation in two or three intervention/service referral sessions, and (b) the completion of four interviews (an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview. Each interview is expected to last about an hour-for a total of about 4 hours over 12 months. The interviews will be conducted in your home.

What other choices do you have if you decide not let your child to take part?

If you decide not to let your child take part in this study, that is okay. You will still be able to choose other alternative services for your child in your community.



Will you and your child be paid for taking part in this study?

We will pay you \$25 for each interview you complete (initial, 3 months, 6 months and 12 months) for a total of \$100.00.

We will pay your child \$20 for each completed interview/urine specimen (initial, 3 months, 6 months and 12 months) for a total of \$80.00.

Hence, each youth and parent/guardian who completes all of the interviews will receive \$180.00.

What will it cost you to let your child participate in the study?

It will not cost you or your child anything to take part in the study.

What are the potential benefits to your child if you let him/her take part in this study?

Your child will receive a brief intervention that may help to lower or stop his/her problem behaviors that cause him or her to be in contact with the juvenile justice. If you or your child ask for assistance for any mental health or chemical health problem, we will gladly help you connect with these services. However, we will not be able to pay for any additional services outside of this research study.

The youths who participate in this study (Group A) may learn new skills to help them reduce or stop their problem behaviors and improve their family and peer relationships. Group B youths may find it interesting to answer questions about themselves, and there are no restrictions on them receiving service referrals to community-based agencies.

What are the risks if your child takes part in this study?

Some of the questions in the interview are sensitive and may be uncomfortable to answer. While these questions may cause mild discomfort, they are routine questions that are asked in doctor's visits.

Analysis of the urine samples from your child may reveal drug use. However, this information will be kept confidential as explained below.

Once assignment to a diversion program has been made, participation by the youth, and in many cases also by a parent, becomes a mandatory condition of the program. A case manager is assigned to monitor program compliance. If either fails to participate the program will not be completed and the youth may then be referred to the juvenile justice and may face further sanctions.

What we do to provide protection against these risks?



We will take the following steps to help protect your privacy:

1. We will separate the research data from identifying information to prevent any breach of confidentiality. All participants will be given a study identification number, which will be used instead of names or other personal identifiers on all questionnaires, other written material, data sets for analysis and other project material. The code linking the identification number with participant personal identifiers will be kept in a separate locked, secure file. Also, we will report study results only at a group level.

The interview, urine specimen, justice system contact and school data we plan to collect will be used for research purposes only. The data files will contain unique IDs for each youth/family participant. We will maintain a name-ID number matching list in secure storage. The PI will maintain a central data file in which it will not be possible to identify any participating youth or family member. All persons working on the project will sign a pledge of confidentiality, which will serve as a condition of employment.

All baseline, follow-up interview and related information will be stripped of identifying information assigned a code number and entered electronically into data files at the University of Miami. These files will be sent to us to help us evaluate this project. Voluntary urine specimens will be obtained from the youth at the baseline and follow-up interviews, in order to validate self-reported use of illegal drugs. All specimens collected will have labels containing the youth's unique ID number only. Following their being coded into the youth's data file, the specimen results will be placed in secure storage for the duration of the project, and then destroyed. Similar confidentiality safeguards will be used in collecting, processing, coding, and storing official reports of youth contacts with the justice system and school data. Coded official agency information will be identified only by project case number, and the official reports from which information was coded will be maintained in a locked file for the duration of the project, then destroyed.

2. Youths in Group A or Group B may begin or continue any of the usual health services they might typically obtain, including drug treatment and mental health care. In the event that either: (1) the youth and/or their parent requests services; or (2) the interventionist or interviewer believes based on their judgment that a subject needs additional care, the family will be informed and provided with referral phone numbers for local mental health care.

3. If, in the course of an assessment or intervention with a youth, concerns emerge about imminent threat of harm to self or others, an appropriate social service agency will be contacted.

4. However, certain people may need to see your child's study records. By law, anyone who looks at your child's records must keep them confidential. The only people who will be allowed to see these records are:

- The study staff.
- People who make sure that we are doing the study in the right way. They also make sure that we protect your rights and safety:



- The UM Institutional Review Board (IRB), and its staff and other individuals acting on behalf of the IRB;
- The United States Department of Health and Human Services (DHHS).
- We may publish what we find out from this study. If we do, we will not use your child's name or anything else that would let people know who your child is.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers 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 to this use. Information, documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; see below); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Clinical trial information for this study is posted at ClinicalTrials.gov in accordance with NIH guidance.

You can get the answers to your questions.

If you have any questions about this study, call Dr. Louis Herns Marcellin, at (305)284-2535.

If you have questions about your rights as a research participant, call University of Miami Human Subject Research Office at (305) 243-3195.



Consent for Child to Take Part in this Research Study

It's up to you. You can decide if you want your child to take part in this study.

I, _____, agree to participate in this research study and agree for my family to be audio or videotaped as part of the study.

I understand that the researcher(s) in this study will audio or videotape us in order to record interviews and intervention sessions and that the tapes will be used solely for the purposes of ensuring that me/my family are provided with quality services. I, further, understand that each audio or videotape will be erased/destroyed when the study is completed.

Signature of Subject

Date

Signature of Investigator

Date

I freely give my consent to let my child take part in this study. I understand that this is a study. I have received a copy of this consent form.

Name of Child

Signature of Parent/Guardian Participant
of child taking part in study

Printed Name of Parent/Guardian

Date

Signature of Person Obtaining Consent
or Authorized Research Investigator
Designated by the Principal Investigator

Printed Name of Person Obtaining Consent

Date



Youth Consent to Participate in a Research Study

Study Title: Culturally Modified Family Based Therapy for Haitian Youth in South Florida

Dear Potential Study Participant:

Key Information: The following is a short summary of our study to help you decide if you want to take part. More specific information can be found later on in this form.

You are asked to take part in a study. You can choose to take part in the study or not. The goal of this study is to test a family therapy that could help families with stress associated with youth behavior problems. You will also be asked to take part in 4 interviews: an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview. Each interview will last about 1.5 to 2 hours, and will be audio or videotaped. After the first interview, you will be assigned to either a family therapy group (Group A) or one that will not receive family therapy but that attend other intervention services. Group A will receive therapy sessions that should last about 1 hour. You will also be asked to do brief surveys, lasting 10-20 minutes, before and after each group session.

There are no major risks in being in this study. During the interviews or group sessions, you could become upset when talking about your experience or other personal information.

No direct benefits are promised to you for being in this study. You may learn skills to better manage your mental health. Your time in this study may help us develop family-based therapies for other Haitian families experiencing the same problems like yours is facing.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

What should I know about this research study.

You are being asked to take part in this research study to examine a new, brief, treatment as part of your involvement in the Juvenile Services Department's (JSD) diversion program. You are invited because you may have a need for services to help with alcohol/other drug use. We hope to learn more about how and why young people use drugs and alcohol. We want to support a healthier lifestyle for young people. This study is being conducted by staff members from the University of Miami. About 88 youths and their families will be invited to be in this study. This study is being done in Miami-Dade, Florida.

What should I know about this research study?

- Someone will explain this research study to you.
- Being in this study is not forced.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.



- We will not hold your decision against you.
- You may have questions this form does not answer. If you do, ask the person in charge of study or study staff as you go along.
- You don't have to guess at things you don't understand. Ask the people doing the study to explain things in a way you can understand.

You can ask questions:

If you have questions you can call Dr. Louis Herns Marcellin, at (305)284-2535.

You can also call University of Miami Human Subject Research Office at (305) 243-3195, for questions about your rights as a research participant.

What does consent involve?

By giving consent (permission), you agree to share information about yourself and to talk about your drug use with the researcher assigned to you. If at any time during the study, you wish to stop, you can do so without penalty. It will not affect any future relationship with the University of Miami; or with your school. Your signature shows that you understand the study, including its possible risks and benefits.

What will I be asked to do?

You will be asked to spend about 12 months in this study. Your participation will involve:

- A minimum of 4 therapy sessions per month. Each service session will last about an hour.
- Four (4) interviews (an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview).
- A voluntary, confidential urine sample will also be collected after each of the 4 interviews. We will test for methamphetamines, opiates, cocaine, and marijuana.
- There are two groups to this study. You will only be put into ONE of these groups. Trained and clinically-supervised counselors will conduct all the intervention services at your home. The sessions will be taped with your permission.

Group A is for youths who will participate in the intervention services. We would like to meet (in your home) with you, the parent(s) or guardian(s) four time for about one hour. We will talk about your child's involvement in the juvenile justice. These sessions will be at least 3 months apart.

Group B is for youth who will be receiving mandatory services by the Juvenile Assessment Center from community-based organizations in the context of the diversion program. You will be scheduled to attend four interviews within a 12-month period. If you get selected to be in Group B, we would like to meet (in your home) with you one time for about one hour to discuss your behavior.



Regardless of the group you are in, you will first be asked to complete a brief interview (initial) with a member of the research staff in your home. It will take about 1 hour to complete. This interview will be done separately with you and your parent. You both will be asked about your history of involvement with the juvenile justice system, reasons for this involvement, experiences with school, and the relationship with you and your parent. You will also be asked to give a confidential urine specimen.

We will also ask for addresses and phone numbers where you can be reached as well as the names and phone numbers of other people who might know how to reach you. We want to make sure to schedule the intervention sessions with us. If we contact any other people in order to locate you, we will not tell them about your involvement in this study. We will only tell them that you and have agreed to participate in a survey and that you have given us permission to contact you.

After completing the initial interview, you will be randomly assigned one of the groups discussed above. Random assignment is like rolling dice and means that each person has an equal chance of being in Group A or Group B.

The interviews will be conducted again at 3 months, 6 months and 12 months following the initial interview. You will also be asked to give urine samples at those interviews. During interviews, you will be asked about their experiences of the counseling sessions received.

We shall also like to obtain information on your diversion program visit, your school behavior and performance; and information on your contact with the justice system. This information will not be shared with anyone outside of the research team.

What will my parent/guardian be asked to do?

Parents/guardians will be asked to spend about 12 months in this study. Participation will involve: (a) participation in two or three intervention/service referral sessions, and (b) the completion of four interviews (an initial interview, and interviews at 3 months, 6 months and 12 months following the initial interview. Each interview is expected to last about an hour-for a total of about 4 hours over 12 months. The interviews will be conducted in your home.

What other choices do you have if you decide not to take part?

If you decide not to take part in this study, that is okay. You will still be able to choose other alternative services in your community.

Will you be paid for taking part in this study?

We will pay you \$20 for each interview/urine specimen you complete (initial, 3 months, 6 months and 12 months) for a total of \$80.00.

We will pay your parent/guardian \$25 for each completed interview (initial, 3 months, 6



months and 12 months) for a total of \$100.00.

Hence, each you and your parent/guardian who completes all of the interviews will receive \$180.00.

What will it cost you or your parent to participate in the study?

It will not cost you or your parent anything to take part in the study.

What are the potential benefits to you if you take part in this study?

You will receive a brief intervention that may help to lower or stop your problem behaviors that cause you to be in contact with the juvenile justice. If you ask for assistance for any mental health or chemical health problem, we will gladly help you connect with these services. However, we will not be able to pay for any additional services outside of this research study.

The youths who participate in this study (Group A) may learn new skills to help them reduce or stop their problem behaviors and improve their family and peer relationships. Group B youths may find it interesting to answer questions about themselves, and there are no restrictions on them receiving service referrals to community-based agencies.

What are the risks if you take part in this study?

Some of the questions in the interview are sensitive and may be uncomfortable to answer. While these questions may cause mild discomfort, they are routine questions that are asked in doctor's visits.

Analysis of your urine samples may reveal drug use. However, this information will be kept confidential as explained below.

Once assignment to a diversion program has been made, your participation becomes a mandatory condition of the program. A case manager is assigned to monitor program compliance. If you fail to participate the program will not be completed and you may then be referred to the juvenile justice system and may face further sanctions.

What we do to provide protection against these risks?

We will take the following steps to help protect your privacy:

1. We will separate the research data from identifying information to prevent any breach of confidentiality. All participants will be given a study identification number, which will be used instead of names or other personal identifiers on all questionnaires, other written material, data sets for analysis and other project material. The code linking the identification number with participant personal identifiers will be kept in a separate locked, secure file. Also, we will report study results only at a group level.



The interview, urine specimen, justice system contact and school data we plan to collect will be used for research purposes only. The data files will contain unique IDs for each youth/family participant. We will maintain a name-ID number matching list in secure storage. The PI will maintain a central data file in which it will not be possible to identify any participating youth or family member. All persons working on the project will sign a pledge of confidentiality, which will serve as a condition of employment.

All baseline, follow-up interview and related information will be stripped of identifying information assigned a code number and entered electronically into data files at the University of Miami. These files will be sent to us to help us evaluate this project. Voluntary urine specimens will be obtained from the youth at the baseline and follow-up interviews, in order to validate self-reported use of illegal drugs. All specimens collected will have labels containing the youth's unique ID number only. Following their being coded into the youth's data file, the specimen results will be placed in secure storage for the duration of the project, and then destroyed. Similar confidentiality safeguards will be used in collecting, processing, coding, and storing official reports of youth contacts with the justice system and school data. Coded official agency information will be identified only by project case number, and the official reports from which information was coded will be maintained in a locked file for the duration of the project, then destroyed.

2. Youths in Group A or Group B may begin or continue any of the usual health services they might typically obtain, including drug treatment and mental health care. In the event that either: (1) the youth requests services; or (2) the interventionist or interviewer believes based on their judgment that a subject needs additional care, the youth will be informed and provided with referral phone numbers for local mental health care.

3. If, in the course of an assessment or intervention with a youth, concerns emerge about imminent threat of harm to self or others, an appropriate social service agency will be contacted.

4. However, certain people may need to see your study records. By law, anyone who looks at your records must keep them confidential. The only people who will be allowed to see these records are:

- The study staff.
- People who make sure that we are doing the study in the right way. They also make sure that we protect your rights and safety:
 - The UM Institutional Review Board (IRB), and its staff and other individuals acting on behalf of the IRB;
 - The United States Department of Health and Human Services (DHHS).
 - We may publish what we find out from this study. If we do, we will not use your child's name or anything else that would let people know who your child is.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers 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 to this use. Information, documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; see below); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Clinical trial information for this study is posted at ClinicalTrials.gov in accordance with NIH guidance.

You can get the answers to your questions.

If you have any questions about this study, call Dr. Louis Herns Marcellin, at (305)284-2535.

If you have questions about your rights as a research participant, call University of Miami Human Subject Research Office at (305) 243-3195.



Consent to Take Part in this Research Study

It's up to you. You can decide if you want to take part in this study.

I, _____, agree to participate in this research study and agree for to be audio or videotaped as part of the study.

I understand that the researcher(s) in this study will audio or videotape me and my family in order to record interviews and intervention sessions and that the tapes will be used solely for the purposes of ensuring that I am provided with quality services. I, further, understand that each audio or videotape will be erased/destroyed when the study is completed.

Signature of Subject

Printed Name of Subject

Date

Signature of Person Obtaining Consent
or Authorized Research Investigator
Designated by the Principal Investigator

Printed Name of Person Obtaining Consent

Date