UNM IRB PROTOCOL

TITLE:	Developing a Brief Family-Involved Treatment for Alcohol Use Disorders: Phase II
VERSION DATE:	February 12, 2017
INVESTIGATOR/RESPONSIBLE FACULTY:	Barbara McCrady, Ph.D.
STUDENT INVESTIGATOR:	
FUNDING AGENCY:	National Institute on Alcohol Abuse and Alcoholism

BACKGROUND/SCIENTIFIC RATIONALE

The overall aim of this treatment development study is to develop an efficacious, brief, family-involved treatment that can be used flexibly in on-going alcohol treatment settings to advance the dissemination of evidence-based treatment. The PI and her colleagues have been developing a couple-based alcohol treatment, Alcohol Behavioral Couple Therapy (ABCT), and conducting research on this treatment since the late 1970s. The proposed research builds on our earlier NIAAA-supported efficacy trials and studies of mechanisms of change in ABCT.

Significant advances have been made in the treatment of Alcohol Use Disorders (AUDs), and several psychosocial and pharmacological approaches have good evidence for their efficacy. Despite these advances, only about 35-40% of patients complete a pre-defined length of treatment (e.g., Anton et al., 2006; Project MATCH Research Group, 1997), and only about 30% of patients sustain abstinence and 30-35% reduce their drinking to nonharmful levels over a year of follow-up (Miller, Walters, & Bennett, 2001). Sadly, then, between 30 and 35% of patients are consuming alcohol at pretreatment levels one-year after treatment. These figures suggest that there is considerable room to improve existing treatments to enhance adherence and improve outcomes. The goal of the proposed study is to develop an intervention to involve families in treatment to improve retention, adherence, and, ultimately, treatment outcomes.

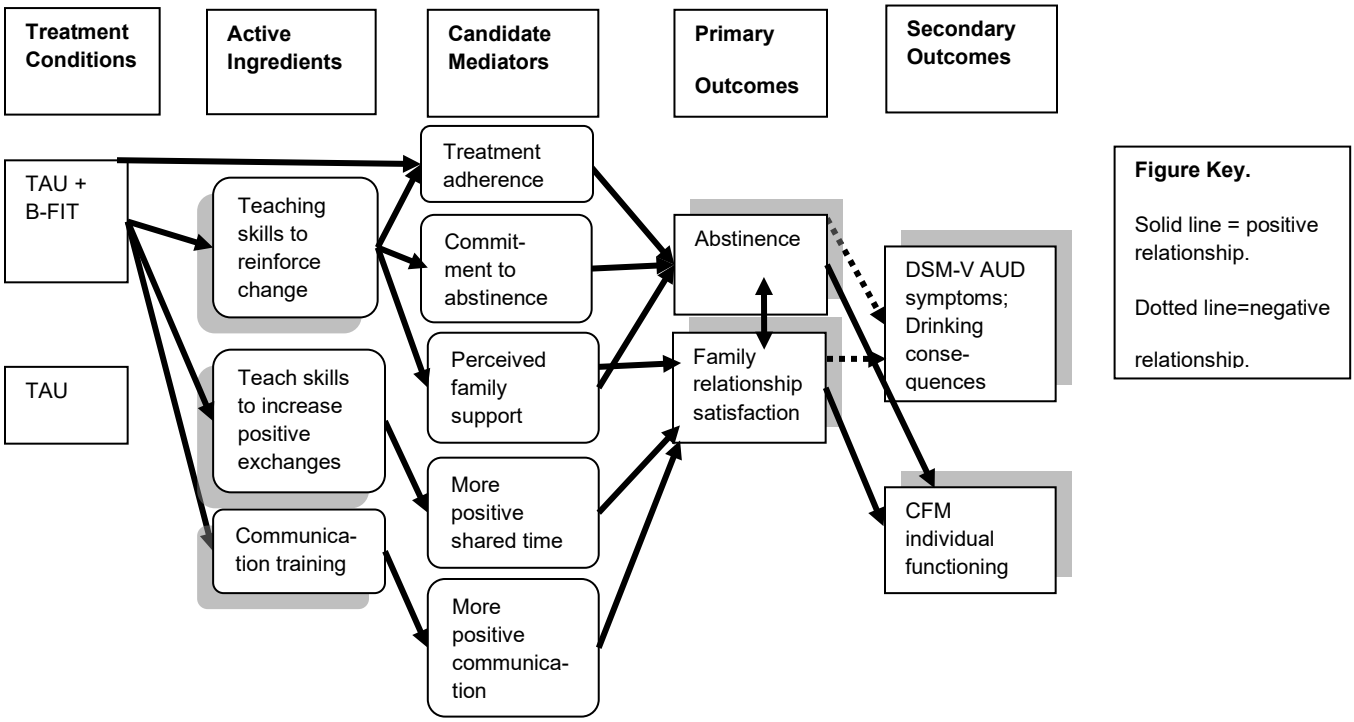
Family involvement leads to better treatment outcomes for individuals with alcohol and other substance use disorders (Carr, 2014; McCrady, Epstein, Cook, Jensen, & Hildebrandt, 2009; McCrady et al., 1986; O'Farrell, Choquette, & Cutter, 1998; Powers, Vedel, & Emmelkamp, 2008). Unfortunately, although national surveys suggest that 80% of substance abuse treatment programs provide some family-involved treatment (Forcehimes et al., 2010), very little of this treatment is evidence-based. Possible barriers to the use of evidence-based, family-involved alcohol treatment include: (a) the *length and complexity* of empirically supported family therapies (Haug, Shopshire, Tajima, Gruber, & Guydish, 2008); (b) *patient and family* factors such as patient reluctance to have their families involved, family concerns about feeling blamed or responsible for the patient's treatment, and pragmatic issues related to scheduling (McCrady, Epstein, Cook, Jensen, & Ladd, 2011); (c) *clinician* barriers such as disagreements with the models underlying evidence-based approaches, lack of appropriate training, and the perceived complexity of couple and family therapies (e.g. Haug et al., 2008); and (d) *institutional* barriers such as difficulties with third-party reimbursement for family treatment sessions.

In the past decade the alcohol field has moved towards briefer manual-guided interventions that can be learned and implemented fairly easily by healthcare providers. We believe there are several reasons to expand the brief intervention literature by developing a brief family-involved treatment

model. First, there is consistent evidence that family involvement helps to engage treatment-resistant alcohol and drug abusers into therapy (Manuel et al., 2012; Miller, Meyers, & Tonigan, 1999), enhances the probability that adults in detoxification units later enter formal treatment (Ino & Hayasida, 2000; O'Farrell, Murphy, Alter, & Fals-Stewart, 2008), and improves outcomes across a range of populations (McCrady et al., 2009; McCrady et al., 1986; O'Farrell et al., 1998; Powers et al., 2008). Second, although these findings are promising, few efforts have focused on the integration of efficacious elements of family-involved interventions *within* on-going community-based treatment.

The proposed study takes this next step. Specifically, the treatment to be developed and tested in this grant, "B-FIT" (Brief Family-Involved Treatment), is designed as an add-on to community-based substance abuse treatment-as-usual (TAU). B-FIT uses family involvement to enhance patient treatment adherence and outcomes by improving family functioning and increasing family-provided incentives for treatment adherence and abstinence. Study aims are carefully sequenced to develop the B-FIT treatment and judge its merits.

Figure 1. Proposed relations among B-FIT active ingredients, mediators, and outcomes



OBJECTIVES/AIMS/HYPOTHESES

The overall study has three specific aims:

Aim 1. To modify our existing ABCT model to make it (a) appropriate for any concerned family member, (b) shorter, (c) focused on key mechanisms of change identified in prior research, (d) appropriate for use as part of an on-going alcohol treatment program, and (e) more efficacious by incorporating behavioral contracting procedures (O'Farrell & Fals-Stewart, 2000; Smith & Meyers, 2004).

Aim 2. To conduct a small-scale clinical trial of B-FIT to: ***Aim 2a.*** Obtain preliminary effect-size estimates of the impact of B-FIT on (a) patient treatment adherence; (b) drinking outcomes; (c) family functioning; and (d) functioning of the concerned family member. ***Aim 2b.*** Obtain estimates of the disseminability of the protocol by assessing: (a) clinicians' ability to learn and implement the

intervention; (b) clinician evaluations of the ease of protocol implementation; (c) patient and family member feedback about B-FIT; and (d) the proportion of patients and concerned family members willing to participate in the intervention. ***Aim 2c***. Develop and conduct a preliminary test of a methodology to study the active ingredients in the B-FIT treatment and purported mechanisms by which it works. ***Aim 2d.*** Test major moderators of the treatment effect: (a) demographic variables and severity of AUD; (b) individual psychological variables; and (c) familial distress/support.

Aim 3. Finalize materials for a larger-scale RCT, including: (a) treatment manual; (b) patient and family manuals; (c) clinician training materials; (d) a treatment integrity rating system; (e) all measures.

The focus of this IRB application is the pilot study and randomized clinical trial. We were previously approved for the focus group portion of the study in IRB application 01815.

STUDY DESIGN AND PROCEDURES

I. *Study Design*

Feedback from the initial focus groups (IRB application 01815) will be used to modify the therapist and patient materials prior to implementation of the B-FIT protocol. After materials are ready, therapists will receive a short, intensive training that will include didactic material and role-play rehearsal of each intervention. Following this training, six patients with alcohol use disorders (AUDs) and their concerned family members (CFMs) will be recruited to pilot test the treatment. A short debriefing questionnaire will be administered to the therapist, patient, and CFM after each session that will query several aspects of the session: (a) length and timing; (b) ease or difficulty in delivering or understanding material; (c) relevance to the patient and family member; and (d) open-ended comments about the intervention. Based on the experience with the first six patients and family members, additional adjustments will be made to the therapist manual and handouts. A second set of focus groups will be used to obtain feedback on the revised materials using the same procedures detailed in IRB application 01815. Adjustments to the materials will be completed in response to this feedback. These revised materials will then be used for a small clinical trial to evaluate the B-FIT intervention compared to treatment-as-usual (TAU).

II. *Study Procedures*

Table 1. Study Measures for Patients (PT) and Concerned Family Members (CFM)

PURPOSE	MEASURE	TYPE OF MEASURE	TIME TO ADMINISTER (MINUTES)	WHEN ADMINISTERED?							
				Screening		Baseline		Within-Treatment		Follow-Up	
				PT	CFM	PT	CFM	PT	CFM	PT	CFM
Patient and Concerned Family Member measures											
Patient Eligibility	B-FIT Screening Interview - Patient. Includes:										
	• Important People Interview (importance item only)	Self-report	2	X							
	• AUDIT	Interview	10	X							
	• Drug Abuse Screening Test (DAST-10)	Interview	5	X							
	• SCID Psychotic screener	Interview	5	X							
	• Partner Violence Screen	Interview	2	X							

	SCID-Substance Abuse Module	Self-report	15	X							X
CFM Eligibility	B-FIT Screening Interview – Family. Includes:										
	• AUDIT	Interview	10		X						
	• Drug Abuse Screening Test (DAST-10)	Interview	5		X						
	• SCID Psychotic screener	Interview	5		X						
	• Partner Violence Screen	Interview	2		X						
Descriptive and Moderators	B-FIT Demographic Interview	Self-report	12			X	X				
	Confidential Information Form (CASAA locator form)	Self-report	10			X	X				
	SCID-5 screener with PCL-5	Interview	10			X				X	
Pre-post patient substance use measures	Form-90	Interview	45			X					
	Form-90 follow-up	Interview	25							X	
	Drinker Inventory of Consequences (DrINC)	Self-report	10			X					
	Short Inventory of Problems (SIP)		5							X	
	Inventory of Drug Use Consequences (INDUC)		10			X				X	
CFM functioning measures	Beck Depression Inventory	Self-report	8				X				X
	Beck Anxiety Inventory	Self-report	8				X				X
Biological measures	Breathalyzer	Self-report	5			X				X	
Mediators	Treatment Services Review (TSR: treatment attendance, use of medication, self-help group involvement)	Self-report	5					X		X	
	Commitment to Sobriety Scale	Self-report	5			X		X		X	
	Perceived Social Support – Family	Self-report	15			X				X	
	Family Environment Scale	Self-report	15			X	X			X	X
	Pleasant Events Schedule - adapted	Self-report	15			X	X	X	X	X	X
	FACES-IV	Self-report	5			X	X	X	X	X	X
B-FIT evaluation	Helping Alliance Questionnaire	Self-report	8					X	X		
	Client Satisfaction Questionnaire	Self-report	8					X	X	X	X
Therapist measures (all within treatment)											

Active ingredients	Clinician use of each B-FIT interventions	Self-report	5	
	Brief C-TIRS	Coders	60	
Mediators	B-FIT Session attendance	Self-report	2	
	Patient homework compliance	Self-report	2	
	CFM homework compliance	Self-report	2	
B-FIT evaluation	Helping Alliance Questionnaire	Self-report	8	
	Clinician feedback on B-FIT	Self-report	5	

Initial screening. Patients will be screened in person or over the phone by study personnel. A simple checklist will be used to determine eligibility criteria related to date of treatment entry, age, and methadone maintenance status. AUD diagnosis will be assessed using the substance abuse module of the SCID interview (First et al., 2002). Psychotic symptoms will be assessed using the psychotic screening questions from the SCID (http://www.scid4.org). Presence of domestic violence will be assessed using the Partner Violence Screen (Feldhaus et al., 1997). These measures are all included in the B-FIT Screening interview. If eligible, the patient will be provided with a brief description of the study, will be asked to provide the name of an eligible CFM and verify frequency of contact and perceived importance (using one item from the Important People Interview, Longabaugh & Zywiak (1999), and will sign a release of information to allow study personnel to contact the family member and will be asked to mention study participation to the family member.

CFMs will be screened in person or over the phone by study personnel. A simple checklist will be used to assess family member age, frequency of contact with the patient, and current help-seeking status. Presence of domestic violence will be assessed using the Partner Violence Screen (Feldhaus et al., 1997). Psychotic symptoms will be assessed using the psychotic screening questions from the SCID (http://www.scid4.org). Severity of alcohol use will be assessed with the AUDIT (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993); a score of 8 or greater will exclude the CFM from the study. Severity of drug dependence will be assessed with the DAST-10 (Skinner, 1982); a score of 3 or greater will exclude the CFM. If eligible, the family member will be provided with a brief description of the study, and asked about willingness to participate.

Baseline assessment. Baseline assessments with patients and CFMs will be conducted by staff from the CASAA Program Evaluation Service (PES). Screening and baseline measures assess inclusion/exclusion criteria; locator and tracking information, sociodemographic descriptors, potential moderator variables; alcohol and other drug use, consequences, and diagnosis; CFM functioning and baseline measurement of hypothesized mediators of response to treatment (see Table 1). Each individual will be interviewed separately, and the patient and CFM may be scheduled at different or the same times for their baseline interviews. Patient baseline data collection will take approximately 2.5 hours; CFM baseline data collection will take approximately 1.25 hours. Patients will be compensated $50; CFMs will be paid $30.

Randomization. After the baseline interview, couples will be randomly assigned to TAU or TAU+B-FIT using urn randomization (Stout, Wirtz, Carbonari, & Del Boca, 1994) to balance groups on patient gender, severity of alcohol dependence, and type of CFM (parent versus partner versus other).

Treatment Conditions

Treatment as usual (TAU). Turquoise Lodge Hospital (TLH) provides detoxification services and residential treatment to adults with substance use disorders. The average residential stay is 18-21 days. TLH is currently developing an intensive outpatient program from which we also plan to recruit. TAU at TLH consists of mainly group and some individual therapy. Families do not typically participate in treatment but are allowed to visit patients during designated weekend hours.

TAU + B-FIT. Patients randomized to the TAU + B-FIT condition will receive standard TAU at TLH, a combination of individual and group CBT. In addition, the patient and CFM will participate together in three B-FIT sessions of 60 minutes duration. The sessions typically will be scheduled at weekly intervals. The B-FIT protocol is designed to be manual-guided. *Session 1* includes*:* (a) rationale for CFM involvement and psychoeducation about alcohol problems; (b) interventions to identify ways that the patient and CFM can be supportive to each other; (c) interventions to identify a shared positive activity for the patient and CFM; (c) introduction to effective communication, and a communication handout. *Session 2* includes*:* (a) brief review of the results of the supportive behaviors and shared positive activity and discussion of problems encountered; (b) selection of a second activity with implementation plans that address any problems encountered in implementing the first activity; (c) review of the communication handout; (d) therapist coaching of the patient and CFM to try out one effective communication skill and then therapist helping the patient and CFM to use better communication skills for the balance of the session; (e) introduction to the recovery contract, including identification of specific patient behavior for the CFM to reinforce (treatment attendance or medication), and what CFM behavior will be used as the reinforcer; (f) development of a written recovery contract and discussion of potential problems in implementation of the contract. *Session 3* includes*:* (a) review of the supportive behaviors, shared positive activity, and recovery contract; (b) review of the second communication handout; and (c) role play rehearsal to apply communication skills to discussion of a specific topic. The three sessions will follow a similar *structure,* regardless of the relationship status of the CFM and whether or not the patient and CFM live together. The *content* of the sessions will be tailored to the specific relationship. For example, an intimate other might provide a backrub to a patient as a reinforcer; a sibling might take the patient out for dinner as a reinforcer. Consistent with a behavioral approach, the therapist will help the patient and CFM develop a concrete plan for the implementation of each intervention that is tailored to their relationship and living situation. Each implementation plan will specify the day(s) and time(s) that skills will be practiced, and also identify barriers to implementation.

Treatment fidelity. To measure treatment fidelity to ABCT, the PI and colleagues developed the 37-item Couples Treatment Integrity Rating Scale (C-TIRS (Hallgren et al., under review). Because ABCT includes interventions not relevant to B-FIT, the C-TIRS will be shortened to eliminate CBT items; other items will be reworded to assess interventions with family member rather than just an intimate partner. Sessions will be digitally recorded and rated for fidelity by graduate students trained to use the modified C-TIRS, using training and reliability procedures used previously in our lab.

Therapist selection, training, and supervision. B-FIT therapy sessions will be provided by a TLH clinician. Clinician training will include four elements: (a) didactic material on the rationale for B-FIT and each B-FIT intervention as well as a detailed description of each intervention; (b) role play rehearsal of each intervention; (c) supervised practice with the B-FIT manual with the first six patients/CFMs in which each audio-taped session will be reviewed by Dr. McCrady Fink, or Epstein and feedback provided to the clinician; (d) additional didactic training and role play rehearsal with the modified B-FIT protocol after the pilot testing and second round of focus groups. Treatment delivery will be monitored throughout the small clinical trial and Drs. McCrady, Fink, and Epstein will continue to listen to session tapes and give feedback to study clinicians.

Within treatment data collection. At TLH, patients and CFMs will complete measures of patient drinking since the last session, CFM level of distress, patient and CFM use of B-FIT interventions, and satisfaction with the treatment session (see Table 1). Patients and CFMs will each be compensated $10 for completing within-treatment forms after each session.

Follow-up. Patients and CFMs in the randomized clinical trial will be re-assessed at CASAA four months after baseline data collection (approximately 3 months after the last B-FIT session if all three sessions are completed). Persons with alcohol and other substance use disorders often have unstable lives, inconsistent living arrangements, and telephones that are turned off at times. To assist in keeping track of participants, a study locator form (Confidential Information Form) will be used. This is standard procedure in substance abuse research, and has been used in clinical trials at CASAA and elsewhere for 20 years. The form asks participants to provide personal contact information as well as contact information for relatives or friends who could assist the researchers in finding participants who cannot be located through their initial contact information. Participants give signed consent on the locator form for research staff to use the contact information (see bottom of pages 1 & 3). Specifically, on page 1, the consent reads, "I hereby grant my permission for the above information to be used to locate me if I cannot be found, for the purpose of completing a research interview. I understand that I may withdraw this permission at any time." At the bottom of page 3, participants give separate consent for the research team to contact individuals listed on the form: "I hereby grant my permission for the people I have named above to be contacted in the event that I cannot be found. I understand that the only purpose of such contact would be to locate me, and that the individuals need not be given any information about the nature of the research in which I am participating, unless I grant permission. I may at any time change these names or withdraw my permission for one of more of them to be contacted." This form is used only for participants who are continuing in the research but difficult to locate; it is not used for participants who have formally withdrawn from the study.

Patients and CFMs in the pilot study will not provide follow-up assessments. Patients and CFMs in the clinical trial each will be compensated $40 for completion of follow-up data collection. See Table 1 for list of assessments. Some patients may still be receiving treatment services at the time of research follow-up; this information will be tracked on the Treatment Services Review (McLellan, Alterman, Cacciloa, Metzger, & O'Brien, 1992).

III. *Consent Procedures*

PES staff will obtain full informed consent at TLH in a one-on-one, private meeting. Prospective research participants will be apprised of all requirements of the study, including the sessions, the type of therapy, who will provide that therapy, the nature of the assessments, follow-up requirements, official records that will be reviewed, who is responsible for the study, and to whom the subject should go if they need information or help. The Consent Form also states that participating in the study will neither help nor hurt the participant's standing in any legal matters. Standard Consent form assurances are included, for example that the subject may withdraw from the study at any time with no harm to them or loss of services to which they are otherwise entitled. Consent forms will be signed by the prospective research participants (patients and CFM), and a research staff person and dated. In addition, a Federal Certificate of Confidentiality (FCC) has been obtained to ensure a higher level of protection for participant research data. Participants will be provided a copy of the consent form (see appended patient and CFM consent forms for both the pilot and RCT).

It is possible that patients or family members could be under the influence of alcohol or drugs during the consent process and therefore at diminished decisional capacity. Research staff obtaining consent will have the discretion to terminate the consent procedure if they have clear reason to believe the

person is intoxicated, either through positive breathalyzer results or overt behavior, as reliable biological assessment of acute non-alcohol drug intoxication is unavailable.

As an additional safeguard to ensure understanding during the consent process, the patient and family member consent forms will end with a brief quiz containing the following True/False questions: (1) I will be in 3 therapy sessions that include a family member and myself (True); (2) I will not be paid for my participation (False); and (3) My conversations during the therapy sessions will be recorded (True). The person obtaining consent will verbally address any incorrect responses with the participant and re-verify if the person understands the consent and wishes to participate.

HIPAA identifiers being collected will include name, date of birth, physical address, phone number, appointment dates, and e-mail address. This information will be necessary for tracking and scheduling participants from baseline through treatment and follow-up. We will also be collecting date of birth in order to describe the age of the sample. We will be using a HIPAA form (see appended).

IV. *Study Timelines*

Clinicians will be trained in the B-FIT intervention during September 2015 in preparation for the pilot study. The six pilot participants will be recruited, treated, and debriefed October through December, 2015. From January to March 2016, treatment manuals will be modified based on pilot outcomes. The new manuals will be distributed to focus groups of patients, CFMs, and clinicians in April and the focus group data will be analyzed in May. The manuals will be modified in June and July, and all materialized finalized in August, 2016. Clinicians will be trained in the revised B-FIT intervention in September 2016. RCT participants will be recruited starting in October 2016 and ending in June 2017, with the final participants completing the study intervention in July 2017. Follow-up assessments will take place between January and November 2017. Finally, data will be analyzed and interpreted between December 2017 and March 2018.

V. *Study Location(s)*

The study will be conducted through the Center on Alcoholism, Substance Abuse, and Addictions (CASAA), a UNM research center with a 25-year history of conducting clinical trials of innovative treatments for alcohol and other substance use disorders. Participants will be recruited and treated at Turquoise Lodge Hospital (TLH), which is run by the New Mexico Department of Health and located in Albuquerque. TLH offers a range of substance use disorder treatment services including psychosocial and medical interventions. CASAA researchers have conducted multiple clinical studies at TLH and the CASAA Program Evaluation Service (PES) staff, who will assist in recruitment and data collection, has established procedures for recruiting and assessing research participants at TLH.

VI. *Participant Compensation*

Participants will be compensated for providing research data at a rate of approximately $20/hour. Patient baseline data collection will take approximately 2.5 hours; CFM baseline data collection will take approximately 1.25 hours. Patients will be compensated $50; CFMs will be paid $30. During treatment, patients and CFMs will complete measures of patient drinking since the last session, CFM level of distress, patient and CFM use of B-FIT interventions, and satisfaction with the treatment

session. Patients and CFMs will each be compensated $10 for completing within-treatment forms after each session. Finally, patients and CFMs in the clinical trial each will be compensated $40 for completion of follow-up data collection. Patients and CFMs in the pilot study will not provide follow-up assessments. All payments will be in the form of Walmart gift cards. During inpatient treatment, gift cards will be securely stored with patients' personal belongings and available for retrieval upon the patient's discharge.

VII. *Study Resources*

Most patients with AUDs seeking treatment have at least one family member (Copello et al., 2010); analyses of the Project MATCH outpatient sample recruited in Albuquerque, NM (conducted for this proposal) reveal that 85.8% of patients in the sample named a family member or significant other as a collateral who would be willing to provide data. It should be noted that only 7% of New Mexico Hispanics are not English-speaking, so few potential patients will be excluded because of language barriers. In Project COMBINE 26.9% of clients had a concerned family member attend at least one treatment session (Hunter-Reel et al., 2012), so even if our recruitment rate for families is similar to COMBINE we will should have sufficient patient flow. Recruitment, intervention and data collection will take place at TLH and CASAA (for follow-up).

Three PES staff will be available for recruitment, data collection, and data entry. Four psychology doctoral students will be available to assist with recruitment, data collection, and data entry as needed. PES has provided participant recruitment, assessment, tracking, and follow-up services to investigators at CASAA for the past 20 years, and for approximately 75 different clinical trials. PES has collected data for studies of vulnerable populations including incarcerated juveniles and adults, opiate dependent adolescents, homeless and pregnant women, and persons receiving substance abuse treatment in residential and ambulatory treatment settings. PES has worked regularly with TLH staff for several previous studies. Thus they are knowledgeable about the data collection process and understand how to work with patients and also how to identify difficulties requiring intervention.

In addition to the availability of on-site Master's-level clinicians and medical staff at TLH, the CASAA research team includes licensed clinical psychologists who will provide backup consultation. There will be no need to utilize outside emergency resources, as our sites will fully cover these needs.

Clinicians will utilize CASAA's existing digital audio recorders to record in-session interactions. Hard copy data will transported daily from TLH to CASAA and stored in locked filing cabinets, and consent forms will be securely stored in a separate locked cabinet. All computerized data (including audio recordings) will be backed up on the CASAA server, which is firewall protected and accessible only through individual authorization and passwords. Data will be analyzed and integrated into B-FIT materials by core research staff including the PI.

VIII. *Unanticipated Problems*

The ongoing interaction between TLH clinicians and medical staff, patients and their families, and CASAA research staff will help to ensure that if there are any adverse clinical events they will be identified and dealt with swiftly. It will be made clear during training that any adverse events need to be dealt with locally and quickly and that the PI (a licensed clinical psychologist) should be notified during the event if need be, or the same day if it is not an emergency. Any unanticipated adverse events will be recorded, and an adverse event form will be completed and submitted to the UNM IRB within seven days.

EXPECTED RISKS/BENEFITS

I. *Risks*

We believe the risks in this research are minimal. We foresee no physical risks as a result of participating in the research project. Similarly we foresee no direct financial or legal risks as a result of participating in the research study. Clients may be involved with the criminal justice system, but that involvement is overseen by other entities and is not a part of the research project. If we find the participant is intoxicated at baseline or follow-up assessment they will be voluntarily retained at the site until they are legally sober. There are three potential areas of risk: (1) perceived coercion to participate in the study; (2) a risk of some psychological harm in carrying out treatment studies. Participants may find answering some of the questions causes discomfort, or that participating in treatment with a family member contributes to relationship distress; (3) potential breaches of confidentiality. Methods for managing these potential risks are outlined below.

Perceived coercion: We are working with clients who may have been convicted of DWI or otherwise are involved in the criminal justice system. However, the treatment they receive as part of this research study has no bearing on the requirements they need to fulfill obligations with the court. We will make it clear both verbally and in the Informed Consent form that participation in the treatment study will neither help nor hinder their standing with the courts. Further, only clients who have voluntarily admitted themselves (i.e., are not court-mandated) to treatment at TLH will be eligible for study participation.

Although participants in this study are not prisoners, they may be involved in the criminal justice system insofar as they have been convicted for an alcohol related offense. We will make it very plain that data collected as part of the research study will not be available to the courts and will have no bearing on their status with the courts. Because they are not prisoners they will not require special protections, but we still need to be mindful that simply being involved in the criminal justice system makes them more vulnerable than a group not involved in the criminal justice system.

More generally, it is possible that patients may believe they should participate to maintain good standing with their treatment providers. The recruitment and informed consent processes will clearly state that participation in the study intervention or subsequent withdrawal will have no impact whatsoever on their course of treatment.

Potential psychological harm: There is always a risk of some psychological harm in carrying out treatment studies. First, some of the questions in the assessment instruments may cause discomfort in some people. We have administered these measures in previous research studies and have found that they cause minimal distress to most people. If time needs to be taken so the person can compose themselves the interviewers will allow them to do so. In the unlikely case that a question causes severe discomfort, senior clinical staff from TLH will be called in and the PI will be contacted by phone. All data collection will be completed by experienced interviewers from the CASAA Program Evaluation Services (PES), who have had training in how to deal with crises, such as giving respite time, calling a clinician, and when to call a crisis center. The second potential source of psychological harm is that the provision of family-involved treatment could increase conflict in the family. Families in which there is domestic violence will be screened out of the study, so the risk of actual physical violence will be decreased substantially. One of the most consistent findings for family-involved treatment for alcohol and other substance use disorders is an increase in couples or family satisfaction and a decrease in domestic violence, and the B-FIT treatment protocol is designed to teach better communication skills,

thus mitigating the chance of increased conflict. The therapy will be given by licensed and trained counselors who have experience working with people with substance use disorders, and they will receive formal training and on-going supervision in the B-FIT protocol. If a participant (patient or CFM) finds some of the issues difficult the counselor can help them work through those issues. Furthermore, the research staff includes licensed clinical psychologists who will provide backup consultation to the therapists.

Potential breaches of confidentiality: The third risk is the possibility of a breach of confidentiality. Several steps will be taken to minimize the risk of breaches of confidentiality:

(1) Data will be labeled only with participant identification number. Participant names and study identification numbers will be recorded and stored separately from the research data files.

(2) All research data collected by a research assistant on site at will be transported from TLH to the CASAA research offices in a briefcase or similar closed storage medium - loose papers or papers in open folders will not be allowed. After returning to the research office, assessment instruments and audio recordings will be logged in on our firewall-protected network and the hard copy data stored in a locked file cabinet.

(3) Data collected from this project will be available only to selected research staff. Data will be collected by research staff and shared with treatment staff only if there is a need in order to protect client or CFM safety. For example, if during the baseline measures research staff find out that a participant has current suicidal ideation we would share this with the therapist because this could have material effect on the participant's well being. CASAA has a standard procedure for following up on reports of suicidal ideation (see CASAA Participant Emergency Procedure in the Appendices). During the assessment, research personnel review the self-report Beck Depression Inventory (BDI), which includes a suicidal ideation item, and implement the CASAA Participant Emergency Procedure if the participant has endorsed suicidal ideation on this form or has reported suicidal ideation at any point during the research interview.

If a participant reports possible child abuse or neglect, study personnel will inform the Principal Investigator or Dr. Fink if Dr. McCrady is unavailable. Dr. McCrady or Dr. Fink will make a determination of whether there is a possibility of child abuse or neglect and, if so, will make a report to the New Mexico Children, Youth and Families Department (CYFD) within one business day. Other than those contingencies only the research staff composed of the PI, research assistants who will be administering the measures, and co-investigators will have continuing access to identified client data. Other research staff will also have access on an as-needed basis. For example, if the data analyst needs to access a particular client record he would have that access.

(4) We have applied for and received a Federal Confidentiality Certificate from the Office of Research Protection.

(5) For screening, we will create separate Excel spreadsheet logs of screens for patients and CFMs. All screens will be logged into the spreadsheets with a yes/no for whether the individual meets each inclusion/exclusion criterion. Individuals will be identified on the spreadsheet by screen participant number. The screening spreadsheet will not contain names or contact information. Screens for ineligible individuals will be filed in a locked file cabinet in a locked room without names or other identifying information on the forms. If both the patient and CFM meet initial eligibility criteria and are interested in the study they will be assigned a study number, a file will be created for them, and their screens will be filed in their study file. A second spreadsheet with study ID numbers and participant names for individuals who meet initial screening criteria and are interested in the study will include a field for screen participant number. Because the screens and spreadsheet for ineligible potential

participants will never have identifying information we plan to retain these data on the same schedule as other data (five years post publication). The data from the screens will be used to report the number of individuals screened, and reasons for ineligibility.

Benefits

We expect that participation in the B-FIT and Treatment as Usual (TAU) conditions will offer substantial help to both the client and their CFM in helping them reduce alcohol consumption and subsequent risky behaviors. We anticipate that the advice that CFMs receive in the B-FIT program will give them new knowledge and tools to work with family members who have had an alcohol use disorder. B-FIT is an add-on to a community based substance abuse treatment program and will use family involvement to enhance patient treatment adherence and outcomes by improving family function and increasing family-provided incentives for treatment adherence and abstinence. By beginning to improve their family interactions during their inpatient stay, patients may be more likely to enter a social environment that promotes sobriety following discharge. There also is research evidence suggesting that participating in research evaluations as part of alcohol treatment studies has positive benefits, so even those in the TAU condition may receive additional benefit by completing the research measures. As stated above, we believe the risks of being involved in this research as very minimal. Therefore, we believe that the benefits will outweigh the risks.

We believe that the enhanced therapy we propose in this application will add substantial original knowledge to the addictions field. As mentioned in the beginning of this proposal, substance use disorders are a continuing and relatively intransigent problem. AUD treatment outcomes are suboptimal; we hope to improve outcomes by focusing on ways to support adherence and reinforce change outside of therapeutic settings. If the enhanced therapy proves to be efficacious, we think that the minimal risks to clients are outweighed by the knowledge to be gained.

Human Subjects Interactions

I. *Target Population*

Participants will be: (a) patients with AUDs receiving services at TLH, and (c) family members of patients with AUDs who are receiving services at TLH.

Given that our target population is substance abuse treatment patients and their family members, it is likely that many participants will be ethnic minorities, economically or educationally disadvantaged, or with trauma histories. Because we want our sample to be representative, it is justified that we include participants who may come from these groups, although such characteristics will not affect study inclusion or exclusion. There is the potential that pregnant women could participate in the intervention, although this will not be a concern given the non-invasive, low-risk nature of the study.

As previously stated, TLH patients may be involved in the criminal justice system insofar as they have been convicted for an alcohol related offense. We will make it very plain during informed consent that data collected as part of the research study will not be available to the courts and will have no bearing on their status with the courts. Because they are not prisoners they will not require special protections, but we still need to be mindful that simply being involved in the criminal justice system makes them more vulnerable than a group not involved in the criminal justice system. Further, only clients who have voluntarily admitted themselves (i.e., are not court-mandated) to treatment at TLH will be eligible for study participation.

Individuals receiving inpatient services may perceive decreased autonomy in their decision to participate in the study. As a precaution against this, we will recruit only patients who admitted themselves voluntarily to TLH's inpatient unit. More generally, it is possible that patients may believe they should participate to maintain good standing with their treatment providers. The recruitment and informed consent processes will clearly state that participation in the study intervention or subsequent withdrawal will have no impact whatsoever on their access to or course of treatment.

There is also a risk that patients or family members could be under the influence of alcohol or drugs and therefore at diminished decision-making capacity. It will be at the discretion of staff obtaining consent or collecting assessments to use a breathalyzer on a patient or family member showing signs of intoxication; as there is no reliable method for assessing acute drug intoxication, staff will have the discretion to preclude participation based on visible impairment regardless of breathalyzer results. Clinicians conducting therapy sessions will use the same discretion. This information will be made clear in the informed consent forms. The informed consent forms will also include a short quiz to help ensure that patients and family members fully understand the nature of study participation (see appended).

II. *Inclusion and Exclusion Criteria*

Participants will include patients receiving services at TLH and a CFM who is willing to participate in the treatment and research. To be included, patients must: (a) have voluntarily initiated treatment (not been court-mandated) and had at least one alcohol treatment session in the last 30 days; (b) meet DSM-5 criteria for an AUD; (c) have an adult family member who is willing to participate; (d) be at least 18 years of age; (e) able to speak and read English at a 6th grade level; (f) not show current psychotic symptoms; and (g) not meet criteria for a severe non-alcohol substance use disorder. Family members will be included if they: (a) are at least 18 years of age; (b) able to speak and read English at a 6th grade level; (c) have in-person and/or telephone/text/email contact with the patient at least 4 days per week; (d) are rated as "important" by the patient on the Important People Interview (Longabaugh & Zywiak, 1999); (e) are willing to participate in treatment by coming to family visiting hours; (f) are not seeking treatment for an alcohol or drug problem of their own; (g) do not show current psychotic symptoms; and (h) do not meet screening criteria for a current alcohol or other drug problem. Patients and family members also will be excluded from the clinical trial if either partner reports domestic violence in the past 12 months serious enough to warrant medical attention, or if either reports concerns about participating in treatment with the patient/family member.

III. *Participant Enrollment*

Our goal is to enroll 12 pilot participants (6 patients, 6 CFMs) who complete the three session treatment and 120 RCT participants (60 patients, 60 CFMs) who complete the three session treatment. We anticipate that approximately 20% of patient-family member dyads will not complete the full three sessions, so it may be necessary to recruit up to 16 pilot participants and 150 RCT participants to achieve the final targeted sample sizes.

IV. *Recruitment and Screening Procedures*

At study initiation, the PI and members of the research team will meet with TLH clinicians to describe study goals and procedures, inclusion/exclusion criteria, and study incentives. A simple

checklist of study inclusion/exclusion criteria and referral cards will be provided to TLH clinicians. The clinician will complete the card and obtain patient consent for CASAA PES staff to contact potentially eligible patients. The study recruitment specialist will collect referral cards from TLH staff to identify potential study participants and track patients who refuse participation.

Patients will be screened in person or over the phone by research staff for eligibility and interest in study participation. At the beginning of the screening, the staff member will clarify, “Now I am going to ask you a few short questions about your alcohol and drug use, your relationship to your family member, and your own psychological state to see if you and your family member are eligible for this study. If you do not want to answer a question that is fine and we can end our conversation at that point." A simple checklist will be used to determine eligibility criteria related to date of treatment entry, age, and methadone maintenance status. AUD diagnosis will be assessed using the substance abuse module of the CIDI interview (Robins et al., 1988). Psychotic symptoms will be assessed using the psychotic screening questions from the SCID (http://www.scid4.org). Presence of domestic violence will be assessed using the physical violence items from the Partner Violence Screen (Feldhaus et al., 1997). If eligible, the patient will be provided with a brief description of the study, will be asked to provide the name of an eligible CFM and verify frequency of contact and perceived importance (using one item from the Important People Interview, Longabaugh & Zywiak (1999), and will sign a release of information to allow study personnel to contact the family member and will be asked to mention study participation to the family member.

Research staff will obtain study informed consent and consent to contact the CFM. After informed consent, research staff will contact the CFM to describe the study and conduct an initial screening. CFMs will be screened in person or over the phone by study personnel. At the beginning of the screening, the staff member will clarify, “Now I am going to ask you a few short questions about your alcohol and drug use, your relationship to your family member, and your own psychological state to see if you and your family member are eligible for this study. If you do not want to answer a question that is fine and we can end our conversation at that point." A simple checklist will be used to assess family member age, frequency of contact with the patient, and current help-seeking status. Presence of domestic violence will be assessed using the Partner Violence Screen (Feldhaus et al., 1997). Psychotic symptoms will be assessed using the psychotic screening questions from the SCID (http://www.scid4.org). Severity of alcohol use will be assessed with the AUDIT (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993); a score of 8 or greater will exclude the CFM from the study. Severity of drug dependence will be assessed with the DAST-10 (Skinner, 1982); a score of 3 or greater will exclude the CFM. If eligible, the family member will be provided with a brief description of the study, and asked about willingness to participate. If ineligible, the family member will be offered referrals for other treatment programs (we will only do this with family, as the patients will already be in treatment).

If the family member is willing to participate and meets all screening criteria, the research staff member will meet with the family member, complete the informed consent, and collect baseline study data. After the CFM has provided informed consent, the research staff member will collect baseline data from the patient.

We will create separate Excel spreadsheet logs of screens for patients and CFMs. All screens will be logged into the spreadsheets with a yes/no for whether the individual meets each inclusion/exclusion criterion. Individuals will be identified on the spreadsheet by screen participant number. The screening spreadsheet will not contain names or contact information. Screens for ineligible individuals will be filed in a locked file cabinet in a locked room without names or other identifying information on the forms. If both the patient and CFM meet initial eligibility criteria and are interested in the study they will be assigned a study number, a file will be created for them, and their screens will be filed in their study file. A second spreadsheet with study ID numbers and participant names for individuals who meet initial screening criteria and are interested in the study will include a

field for screen participant number. Because the screens and spreadsheet for ineligible potential participants will never have identifying information we plan to retain these data on the same schedule as other data (five years post publication). The data from the screens will be used to report the number of individuals screened, and reasons for ineligibility.

V. *Privacy of Participants*

Eligibility screening and informed consent will occur one-on-one between research staff and potential participants in a discrete environment. Treatment sessions will take place in closed offices at TLH. Because patients and family members will already be familiar with the treatment setting, we expect that they will feel comfortable and unconcerned with potential stigma associated with participating in an on-site study. As detailed elsewhere, session audio recordings and all hard copy data will be stored securely and accessible only to the research team. Audio recordings will be reviewed in closed rooms at the lowest reasonable volume or with headphones.

HIPAA identifiers being collected will include name, physical address, phone number, appointment dates, and e-mail address. This information will be necessary for tracking and scheduling participants from baseline through treatment and follow-up. We will also be collecting date of birth in order to describe the age of the sample. We will be using a HIPAA form (see appended).

STUDY DATA

I. *Data Management Procedures*

All data collected by a research assistant on site will be transported from TLH to the CASAA research offices in a briefcase or similar closed storage medium—loose papers or papers in open folders will not be allowed. After returning to the research office, all hard copy data will be stored in a locked file cabinet. Audio recordings will immediately be transferred onto a computer and deleted from the digital recorder. All computerized data (including audio recordings) will be stored on the CASAA server, which is firewall protected, and accessible only through individual authorization and passwords. Audio recordings will be reviewed in closed rooms at the lowest reasonable volume or with headphones. Data will be retained for publication purposes for five years following the last study publication, per usual data retention standards.

Data collected from this project will be available only to selected research staff. Data will be collected by research staff and shared with treatment staff only if there is a need in order to protect patient or family member safety. For example, if during the baseline assessment a research staff member finds out that a participant has current suicidal ideation, we would share this with a clinician because this could have material effect on the participant's well being. Other than those contingencies only the research staff composed of the research assistants, co-investigators and the PI will have continuing access to participant data. Similarly, disclosures of child abuse or neglect will, by law, be reported to the CYFD.

II. *Data Analysis/Statistical Considerations*

Statistical power. The R34 mechanism is developmental in nature and for this reason substantial emphasis in this application is placed upon both inferential testing and the estimation and evaluation of effect sizes. Our test of the efficacy of the B-FIT intervention after anticipated attrition (15%; Aim 2a) will include 34 participants in the B-FIT group and 17 in TAU and test outcomes both for

percentage of days abstinent (PDA) and percentage of days of heavy drinking (PDH). We believe that this is a conservative estimate given the method in which the planned HLM handles missing data. In a two-tailed test adjusted for conducting correlated tests of drinking behavior over time (α = .05/2 = .025), the baseline dependent measure entered as a fixed covariate and 1 *df* for the between-group term, we estimate that we will have .703 power to reject the null hypothesis of no difference between TAU and TAU + B-FIT with 51 participants and an effect size of .20 (d = .25 to achieve power of .80).

Statistical analyses. An extensive set of analyses is proposed that includes the assessment of treatment fidelity, document CFM and patient satisfaction with the B-FIT intervention, and examine outcomes in general, mechanisms of change, and potential moderators of treatment response. Initial attention will be directed to investigating overall and between-group attrition rates and distributions of key measures prior to conducting primary analyses. Although quantitative support will be provided in the achievement of all study Aims, the described statistical analyses will focus on the stated objectives in study Aim 2a, 2c, and 2d, which are central to the proposed model (Figure 1).

Aim 2a. Obtain estimates of the relative impact of B-FIT on patient treatment adherence, drinking outcomes, family functioning, and functioning of the CFM. Treatment adherence will be defined as the total number of TAU sessions attended between randomization and the 4-month follow-up interview (measured by the TSR and Form-90). Two primary alcohol use measures will be considered and aggregated into four monthly values: proportion abstinent days from alcohol (PDA: days abstinent/ 30 days) and percentage of days of heavy drinking (PDH). Family functioning will be assessed using the Cohesion and Conflict subscales of the Family Environment scale, and the Family Communication scale total score. CFM functioning will be defined as total scores on the Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI).

Generalized linear models (GLM) will assess the relative benefit of the B-FIT intervention to TAU alone on treatment adherence, family, and CFM functioning. Parameter estimates will be derived using maximum likelihood with robust estimators. In the treatment adherence GLM, two covariates are planned: number of TAU sessions attended *prior* to randomization and baseline PDA. The dependent measure will be the total number of TAU sessions attended from randomization to the 4-month follow-up and treatment assignment will be entered as a between-subject factor. A two-tailed test will be done with Type I error set at α = .05. Four GLMs will be used to assess the relative benefit of B-FIT on family functioning; two using the patient 4-month report of family Cohesion and Conflict and two based upon CFM 4-month report of family Cohesion and Conflict. Baseline values of the two scales will be used as covariates. Treatment group will be entered into the model as a between-subject factor and Type I error will be adjusted to α = .05/2 = .025 in the two-tailed tests. The relative benefit of B-FIT on CFM functioning will be determined using two GLMs. The first GLM will use 4-month BDI scores as the dependent measure and baseline values of the BDI will be entered as a covariate. Baseline values of PDA for the CFM also will be entered as a covariate to negate any influence of drinking on self-reported depression. Treatment assignment will be entered as a between-subject factor. A second GLM following the same strategy then will use the 4-month BAI score as the dependent measure. These tests of CFM functioning will be adjusted by α = .05/2 = .025 to control for inflated Type I error.

The relative benefit of adding the B-FIT sessions to TAU on drinking over four months will be determined using two longitudinal hierarchical linear models, one for PDA and a second for PDH (Raudenbush & Bryk, 2002). Modeling of change in alcohol use will be restricted to the linear effect given the limited number of time points. The random intercept in the unconditional models will be examined first, followed by fitting the conditional models, which will introduce baseline value of the respective drinking measure (PDA or PDH) as a fixed covariate and the random linear time term. Treatment group will then be entered in level two of the model and will be tested via the *t*-statistic.

Cross-level interactions will be tested via the *t*-statistic to identify potential time by group interactions in changes in alcohol use. Type I error will be adjusted to α = .05/2 = .025 to account for the correlation between PDA and PDH.

Aim 2c. This aim will investigate whether the relative benefit of B-FIT occurred for the presumed reasons. As such, this aim will focus only on participants assigned to the B-FIT group (*n* = 40 at baseline). Tests of mediation will use a product-of-coefficients approach with a bootstrapping procedure (Hayes, 2009). This choice provides the most powerful test of mediation with smaller samples and does not assume normality in the distribution of (a'b') product terms (Preacher and Hayes, 2008; Hayes, 2009). Three active ingredients of B-FIT will be investigated separately: (1) teaching skills to reinforce change, (2) teaching skills to increase positive exchanges, and (3) teaching skills to improve communication, all of which are measured within treatment by the modified C-TIRS. Baseline values of mediators will be entered into all planned analyses as covariates. Overall, we will conduct six meditational tests. First, we will conduct 3 mediational tests to evaluate our prediction that teaching skills to reinforce change will increase 4-month abstinence (PDA) by mobilizing three mediators during the treatment phase of the study (TAU treatment adherence, commitment to abstinence, and perceived family support). The fourth test will examine if teaching skills to reinforce change increases family satisfaction (month 4) through enhanced impressions of perceived family support (within treatment). Our fifth test will examine if teaching skills to enhance positive family exchanges produces increased family satisfaction (month 4) by increasing positive shared time (within treatment). Finally, we will assess if teaching skills to improve communication increases 4-month family relationship satisfaction by mobilizing more positive partner communications within treatment. No adjustment for inflated Type I error is planned for these six tests.

Two post hoc strategies will be used to assess the confidence we can place on the results of our unprotected tests. First, we will employ a multiple meditational model (Hayes, 2009) to examine the actions of one B-FIT active ingredient, teaching skills to reinforce change. Here, if two or more of the mediators linked with this active ingredient are found to be significant in the primary analyses we will enter those mediators into a single multiple meditation model. Although this approach lacks the precision of the primary analyses, it does address the concern of potential mediator multicolinearity and the likely erroneous rejections of null hypotheses. Second, we will descriptively asses the magnitude and consistency of *a* and *b* path estimates generated in our primary meditational analyses. Using meta-analytic techniques, for example, we will determine if the *a* (n= 5) and *b* (n=6) path parameter estimate distributions are homogeneous or not using the Q statistic (Borenstein, Hedges, Higgins, & Rothstein, 2009). We believe that the rejection of the assumption of homogeneity will provide important descriptive information in the identification of "key signals" or actions among the active ingredients and presumed mediators.

Aim 2d. Moderators of B-FIT Response. Three classes of moderators will be collected at the intake interview and examined in these exploratory analyses: (1) demographic variables, (2) psychological variables, and (3) familial distress/support, such as perceived social support from family. Primary interest will focus on the moderating effect of these variables on monthly PDA and PDH while secondary analyses will assess the extent to which these moderators influence family relationship satisfaction. All moderators will be binary, and we will use median splits on continuous moderator variables to generate groups with equal number of patients, e.g., patient age. Two longitudinal HLM growth models will assess potential moderating effects of patient characteristics on treatment effectiveness using PDA and PDH. Baseline value of the dependent measure will be entered as a covariate and monthly PDA and PDH will be the dependent measure in the hierarchical linear model. The time effect will be restricted to the linear term and a given moderator variable will be entered in level two of the model. Additional terms entered in level 2 of these models will include a dummy coded

variable representing treatment assignment and a product term reflecting the group assignment by moderator interaction. *We acknowledge that the exploratory analyses in Aim 2d are statistically underpowered and involve substantial inflated Type I error.* In this light we are especially interested in the "pattern" of statistically significant findings in our moderator analyses rather than in a single inferential test.

III. *Quality Control and Quality Assurance*

Treatment fidelity. To measure treatment fidelity to ABCT, the PI and colleagues developed the 37-item Couples Treatment Integrity Rating Scale (C-TIRS (Hallgren et al., under review). Because ABCT includes interventions not relevant to B-FIT, the C-TIRS will be shortened to eliminate CBT items; other items will be reworded to assess interventions with family member rather than just an intimate partner. Sessions will be digitally recorded and rated for fidelity by graduate students trained to use the modified C-TIRS, using training and reliability procedures used previously in our lab.

Therapist selection, training, and supervision. B-FIT therapy sessions will be provided by a TLH clinician. Clinician training will include four elements: (a) didactic material on the rationale for B-FIT and each B-FIT intervention as well as a detailed description of each intervention; (b) role play rehearsal of each intervention; (c) supervised practice with the B-FIT manual with the first six patients/CFMs in which each audio-taped session will be reviewed by Dr. McCrady Fink, or Epstein and feedback provided to the clinician; (d) additional didactic training and role play rehearsal with the modified B-FIT protocol after the pilot testing and second round of focus groups. Treatment delivery will be monitored throughout the small clinical trial and Drs. McCrady, Fink, and Epstein will continue to listen to session tapes and give feedback to study clinicians.

Data quality assurance. PES has established standards for tracking data collection and quality. PES staff will review a checklist for each participant, verifying that they have completed all appropriate assessments and procedures. Regulatory binders will be created as a reference and updated on an ongoing basis to reflect any revised measures and consent forms. Assessments will be entered into the database twice by separate individuals, and the PES director will do monthly checks to identify and resolve any discrepancies in data entry.

IV. *Participant Confidentiality*

Several steps will be taken to minimize the risk of breaches of confidentiality:

(1) All research data collected by a research assistant on site at TLH will be logged in and taken back to the CASAA research offices in a briefcase or similar closed storage medium for transport - loose papers or papers in open folders will not be allowed. After returning to the research office, the assessment instruments will be logged in and the hard copy data stored in a locked file cabinet. Audio recordings will immediately be transferred onto a computer and deleted from the digital recorder. Consent forms will be stored separately from the research data files in a locked file cabinet. All computerized data (including audio recordings) will be stored on the CASAA server, which is firewall protected, and accessible only through individual authorization and passwords. Audio recordings will be reviewed in closed rooms at the lowest reasonable volume.

(2) Data collected from this project will be available only to selected research staff. Data will be collected by research staff and shared with treatment staff only if there is a need in order to protect

client or CFM safety or the safety of a child. Other than those contingencies only the research staff composed of the PI, research assistants who will be administering the measures, and co-investigators will have continuing access to identified client data. Other research staff will also have access on an as-needed basis. For example, if the data analyst needs to access a particular client record he would have that access. Data will be retained for publication purposes for five years following the last study publication, per usual data retention standards.

(3) We have applied for and received a Federal Confidentiality Certificate from the Office of Research Protection.

(4) We will create separate Excel spreadsheet logs of screens for patients and CFMs. All screens will be logged into the spreadsheets with a yes/no for whether the individual meets each inclusion/exclusion criterion. Individuals will be identified on the spreadsheet by screen participant number. The screening spreadsheet will not contain names or contact information. Screens for ineligible individuals will be filed in a locked file cabinet in a locked room without names or other identifying information on the forms. If both the patient and CFM meet initial eligibility criteria and are interested in the study they will be assigned a study number, a file will be created for them, and their screens will be filed in their study file. A second spreadsheet with study ID numbers and participant names for individuals who meet initial screening criteria and are interested in the study will include a field for screen participant number. Because the screens and spreadsheet for ineligible potential participants will never have identifying information we plan to retain these data on the same schedule as other data (five years post publication). The data from the screens will be used to report the number of individuals screened, and reasons for ineligibility.

V. *Participant Withdrawal*

Consent forms (see appended) will clearly state that participants may withdraw from the study intervention at any time for any reason and that this will not affect their course of treatment or standing in the criminal justice system (if applicable). The research team will withdraw participants in the event that evidence of domestic violence or severe psychopathology is detected after the initial screening, as these factors could interfere with treatment. Participants who withdraw from treatment will continue to be tracked for follow-up data collection. Participants who withdraw completely from the study will no longer be tracked, although their data will be retained unless they request otherwise.

PRIOR APPROVALS/REVIEWED AT OTHER IRBS

This project will not be reviewed at another IRB.

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APPENDICES

1) Consent Form(s)
2) Assessment(s)
3) Other Documents:
    - Therapy manual
    - CASAA Emergency Procedures