Mobile Phone Support for Adults and Support Persons to Live Well with Diabetes

FAMS 2.0 RCT

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Version date: 10/24/2021

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1.0 Background

For adults with type 2 diabetes (T2D) performing recommended self-care improves glycemic management (hemoglobin A1c) and prevents disease-related complications and premature mortality. Achieving good self-care remains very challenging, and there may be significant benefits to involving close family and friends in patients' behavior change efforts. Family members and friends can either reinforce or undermine patients' self-care, and many experience distress about not knowing how to best support the patient's self-care efforts. Both in-home and out-of-home support directly affect patients' self-care, medication adherence, and glycemic control. Moreover, family/friend support indirectly affects diabetes outcomes through its benefits to diabetes distress and quality of life. The large international Diabetes Attitudes, Wishes, and Needs follow-up study (DAWN2) found that although patients' family members clearly want to help them, they lack basic knowledge about how to do this effectively. Additionally, many family members experience significant distress and other negative impacts themselves. Although engaging family/friend support persons may be a highly effective way to improve outcomes for adults with T2D and their support persons, this has rarely been investigated. There is a critical need for feasible interventions for adults with T2D to enhance supportive social environments for health behavior change and improve psychosocial wellness among patients and their support persons.

We developed a mobile phone-delivered diabetes self-care support intervention called FAMS (Family/friends Activation to Motivate Self-care) with and for racially diverse adults with T2D receiving care at Federally Qualified Health Centers. FAMS includes phone coaching for patient participants focused on improving family and friend involvement and setting and monitoring self-care goals. FAMS also includes text message support for patient participants and text message support for their adult support person. FAMS uses one-way informational text messages and interactive text messages, and patients’ and support persons’ text messages are tailored to the self-care goals patient participants set during monthly coaching. We completed usability testing and integrated users’ feedback before we evaluated FAMS in a pilot RCT. In the pilot RCT, FAMS established its acceptability and accurate delivery and demonstrated improvements in family/friend involvement in patients' self-care, and in patients' diabetes self-efficacy, eating behavior, and physical activity.

2.0 Rationale and Specific Aims

We built upon these promising initial findings by expanding and improving FAMS through usability testing and before evaluating FAMS 2.0 in a larger, 15-month randomized control trial (RCT) including support persons (SPs) in both the intervention and control condition. This project's focus aligns closely with the American Diabetes Association's new psychosocial standards and represents an advance in the use of technology to deliver patient and family-centered care. Moreover, this work has the potential to improve the social contexts in which adults live with T2D, key diabetes-related psychosocial outcomes for patients and their family/friends, and glycemic management.

The aims of this RCT are:

1. Among patient participants, to evaluate the effects of the expanded FAMS 2.0 intervention versus enhanced treatment as usual (print materials on T2D self-care and access to A1c results) on glycemic management (A1c; primary outcome) and psychosocial well-being (diabetes distress and global well-being; secondary outcomes). We examine effects during the 9-month intervention period and sustained effects after the intervention periods ends.
2. Among support person participants, to explore effects of the expanded FAMS 2.0 intervention versus enhanced treatment as usual (print materials) on psychosocial well-being (diabetes distress) and support burden.
3. To examine intervention effects on intervention targets including:
    a. Patient participants: family/friend helpful involvement, family/friend harmful involvement, diabetes self-efficacy, and diabetes self-care behaviors
    b. Support person participants: support person's own involvement in the self-management of the person with diabetes
4. To test hypothesized mediators and explore subgroups difference of intervention effects.

3.0 Inclusion/Exclusion Criteria

Patient participants:
Inclusion

- Speaks and reads in English
- 18-75 years old*
- Diagnosed with type 2 diabetes*
- Receiving outpatient care from a partnering clinic*
- Community-dwelling (e.g., not in a nursing facility)
- Prescribed at least one daily diabetes medication
- Owns a mobile phone

Exclusion

- Unable to communicate by phone
- Currently pregnant
- Currently undergoing treatment for cancer (e.g., radiation, chemotherapy)*
- Diagnosed with end-stage renal disease*
- Had a discharge disposition for hospice*
- Diagnosed with congestive heart failure*
- Diagnosed with dementia*
- Diagnosed with schizophrenia*
- Reported current abuse during screening
- Demonstrated an inability to receive and respond to a text
- Did not take medication on his/her own/medication administered by someone else

NOTE: * indicates patient eligibility criteria identified with electronic medical record data via a validated phenotype algorithm

Support persons:
Inclusion

- Speaks and reads in English
- 18 years or older
- Owns a mobile phone

Exclusion

- Demonstrated inability to receive & respond to a text

4.0 Enrollment/Randomization

Potentially eligible participants were identified through a clinical data warehouse that queried electronic medical records (EMR). We mailed letters and a study brochure to potentially eligible participants, asking that they let research staff know of their interest or to request no further contact. After one week, study staff called potential participants who did not opt-out to explain the study and assess interest. Interested participants confirmed inclusion and exclusion via self-report by phone and then completed informed consent by phone. Enrolling participants were asked if they wish to invite a support person, but support person invitation and/or enrollment was not required. Research staff obtained contact information for a potential support person. Research staff then contacted potential support persons to confirm eligibility and obtain their verbal informed consent by phone. All participants were sent a copy of the consent document.

Consented patient participants were sent a survey and A1c kit and consented support person participants were sent a survey. Once patient participants completed the survey and put their A1c kit in the mail, they were randomized. Support persons were randomized with the patient participant.

Participants (or dyads) were randomized to intervention or control with a 1:1 ratio. As baseline data were available at randomization, the study statistician performed an adaptively stratified randomization process to ensure balance between treatment arms on support person enrollment status and baseline values of outcomes of interest for the patient participant. The randomization algorithm placed relative importance on balancing specific covariates through weighting, the balance of which shifted once during enrollment in response to an imbalance in baseline variables. The statistician gave study staff randomization assignments after participant enrollment and baseline data collection were complete, blinding allocation until randomization.

Then, study staff contacted participants to tell them what to expect during their participation. This includes an overview of study components specific to their assigned condition and collection of mobile phone information and preferences for the text messaging platform.

5.0 Study Procedures

Procedure/Activity	Frequency
Survey (patient participants and SPs)	Baseline, 6mo, 9mo, 15mo
A1c test (patient participants)	Baseline, 6mo, 9mo, 12mo, 15mo
Diabetes educational materials (patient participants and SPs)	Baseline and quarterly (4x per year)
FAMS 2.0 mobile phone intervention (patient participants)	Approx. 2 texts per day for 9 months
FAMS 2.0 mobile phone intervention (SPs)	Approx. 4-5 texts per week for 9 months
FAMS 2.0 phone coaching (patient participants)	Approx. 25-30 min. calls once a month for nine months

All data were stored in REDCap. Information collected as part of regular care was collected from patient participants' EMR (e.g., birthdate, gender, A1c test results, height, weight, BMI, medications, co-morbidities, etc.). Surveys were administered to all participants at baseline, 6, 9, and 15 months—online, mailed copy, or by telephone. A1c results were collected from persons with diabetes with each survey as well as at 12 months. Participants received mail-in HbA1c test kits provided by CoreMedica Laboratories. HbA1c values collected as part of clinical care were also extracted from the EMR.

Patient participants assigned to control group:
Text messages - Patient participants received a text message when their A1c result was ready (baseline, 6mo, 9mo, 12mo, 15mo).

Patient/SP dyads assigned to FAMS intervention:
Phone coaching - Patient participants completed a phone coaching session with a trained coach once a month for nine months (10 total sessions; 9 core sessions and a brief 10th wrap-up session). Coaching sessions lasted 25-30 minutes each. Coaching sessions included:

- Setting a behavioral goal that can be completed at least 4 days per week in the categories of dietary behavior, physical activity, or stress management (setting and/or adjusting the goal, check in on goal progress)
- Skill building around family/friend involvement in diabetes management, specific to the goal (discussion of helpful and/or harmful family involvement, coach-selected skill building to align with and address the patient participant's experiences, setting a verbal contract to practice the learnt skill with a specific identified person and – at subsequent sessions – check in on how that went).

Text messages - Patient participants received a text message when their A1c result was ready (Baseline, 6mo, 9mo, 12mo, 15mo). They also received approximately 2 texts per day for 9 months:

- 3 to 4 one-way texts per week pertaining to goal set in the patient participant's most recent coaching session; sent randomly within a window of time identified as convenient by the patient participant
- 3 to 4 one-way texts per week pertaining to medication adherence barriers identified as relevant by the patient participant during the baseline survey; sent randomly within a window of time identified as convenient by the patient participant
- 1 daily interactive medication assessment messages sent shortly before the patient participants' bedtime (e.g., "Did you take all of your diabetes medications as directed today, Tues, Jan 18, 2022? Please reply Yes or No.")
- 1 weekly interactive text asking about goal progress to be followed by feedback text from coach within the next few days (e.g., "This week is done! Your SMART goal was to walk 20 mins each day for 6 days. What went well or got in your way? Reply with the number of days you met your goal and a brief reflection.")

Support persons received approximately 4-5 texts per week for 9 months:

- 3 to 4 one-way texts per week pertaining to supporting the patients' self-care efforts and increasing dialogue about diabetes and health behaviors with the patient participant; tailored to the goal "type" set in the patient participant's most recent coaching session; sent randomly within a window of time identified as convenient by the support person participant.
- 1 interactive text per week about supporting the patient participant in their diabetes self-care; sent at a time of day identified as convenient by the support person participant. Responses received an automated message. (e.g., "This week is done! Reflect on how you supported [patient participant name] this week. Reply with what went well or what could go better next week"; "How confident do you feel supporting [patient participant name] with her health goals? Please provide a rating from 1 to 5 where 1=not so confident and 5=very confident")

Summary of Measures:

Construct	**Instrument or Source**
Patient Participants	
Outcomes	
Hemoglobin A1c (primary outcome)	Venipuncture or point-of-care device used in regular clinical care collected from the electronic medical record or collected via mail-in kit from CoreMedica
Psychosocial Well-being (secondary outcome)	
Diabetes Distress	Problem Areas in Diabetes (PAID) with scores ranging 0 to 100 where higher scores indicate more emotional, psychological and social distress related to diabetes management (worse)
Global Well-Being	World Health Organization – Five Well-Being Index (WHO-5) with scores ranging 0 to 100 where higher scores indicate better global mental wellbeing (better)
Intervention Targets/Hypothesized Mediators	
Diabetes Self-	Perceived Diabetes Self-Management Scale (PDSMS) with scores

efficacy	ranging 8 to 40 with higher scores indicating more self-efficacy (better)
Diabetes Self-care	
Dietary Behavior	Personal Diabetes Questionnaire (PDQ) scales: Problem Eating Behavior with scores ranging 1-6 where higher scores indicate more problem eating behaviors (worse) Use of Information for Dietary Decision Making with scores ranging 1-6 where higher scores indicate more use of dietary information for decision making (better)
Physical Activity	Modified version of the Rapid Assessment of Physical Activity (RAPA) with scores ranging 0 to 6533 with higher scores indicating more physical activity (better)
Medication Adherence	Adherence to Refills and Medications Scale for Diabetes (ARMS-D) with scores ranging 11-44 with higher scores indicating more problems with adherence (worse) Summary of Diabetes Self-Care Activities medications subscale (SDSCA-MS) with scores ranging 0 to 7 representing days in the prior week with perfect adherence (higher better)
Diabetes-specific Family/friend Involvement	
Helpful Involvement	Family/friend Involvement in Adults' Diabetes (FIAD) helpful scale assessing helpful behaviors over the past month with scores ranging 1 to 5 with higher scores indicating more helpful behaviors from family/friends (better) Important Others Climate Questionnaire specific to diabetes management, with scores ranging 1 to 5 with higher scores indicating more autonomy supportive communication (better)
Harmful Involvement	Family/friend Involvement in Adults' Diabetes (FIAD) harmful scale assessing harmful behaviors over the past month with scores ranging 1 to 5 with higher scores indicating more harmful behaviors from family/friends (worse) Perceived Criticism specific to diabetes management assessed with items from the Family Emotional Involvement and Criticism Scale with scores ranging 0 to 16 with higher scores indicating more perceived criticism related to diabetes management (worse)
Potential Moderators	
Race and ethnicity	Participants self-report Hispanic ethnicity and race(s)
Socioeconomic disadvantage	Indicator variable calculated based on self-reported education (<12 years), health insurance (uninsured or public insurance only), or annual household income (<$50,000 USD)
Gender	Male, Female, Other self-reported gender
Cohabitating with support person	Whether or not the patient participant and support person life together
Support Person (SP)	
Outcomes	
Diabetes Distress	Family Members Problem Areas in Diabetes (PAID-FM) from the Diabetes Attitudes, Wishes, and Needs Second study (DAWN2)

	with scores ranging 0-100 where higher scores indicate more distress about the PWDs' diabetes experienced by the support person (worse)
Support Burden	DAWN2 Family Burden Item which asks how much of a burden it is to help the PWD manage their diabetes, with responses on a scale from 0 (no burden) to 4 (a very large burden; worse)
Intervention Targets	
Support Person Involvement	
Helpful Involvement	Family member version of the Family/friend Involvement in Adults' Diabetes (FIAD-FM) helpful scale assessing the support person's own performance of helpful behaviors over the past month with scores ranging 1 to 5 with higher scores indicating more helpful behaviors (better)
Harmful Involvement	Family member version of the Family/friend Involvement in Adults' Diabetes (FIAD-FM) harmful scale assessing the support person's own performance of harmful behaviors over the past month with scores ranging 1 to 5 with higher scores indicating more harmful behaviors (worse)
Alignment between desired and actual involvement	Items from the DAWN2 Family Experience of Patient Involvement measure. Scores range 0 to 4 where a score of 2 indicates alignment between the support person's current level of involvement and their desired level of involvement
Potential Moderators	
Race and ethnicity	Participants self-report Hispanic ethnicity and race(s)
Gender	Male, Female, Other self-reported gender
Cohabitating with patient participant	Whether or not the patient participant and support person live together

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

We have a Data and Safety Monitoring Board (DSMB) comprised of physicians and scientists who do related research among adults with diabetes. The PI and study coordinator are responsible for reviewing study components for data completeness and protocol compliance. The PI is responsible for meeting regularly with the study team throughout the RCT to discuss the study timeline, recruitment and enrollment, and any participant concerns. The PI and study coordinator are responsible for reviewing study components for data completeness and protocol compliance, evaluating patient concerns, and if applicable, reporting any serious adverse events or unanticipated problems involving risks to participants to the DSMB, IRB, and NIH. The PI would report any serious adverse events or unanticipated problems involving risks to participants to the DSMB, IRB, and NIH per IRB policy. If changes were made to the protocol, an amendment was submitted to the IRB. An annual progress report is submitted annually to the NIH.

The PI also provides the DSMB with reporting on recruitment and enrollment, recruitment, intervention engagement, study timeline and milestones, and any adverse events or protocol deviations via a written report every 6 months, and a meeting as

needed to discuss challenges or an adverse event. The DSMB reviewed reporting, made recommendations if needed, and signed a letter affirming their review and itemizing recommendations (if any).

7.0 Study Withdrawal/Discontinuation

During the enrollment phase, persons with diabetes who did not return their baseline survey after 5 weeks and were unresponsive to research staff communication were administratively withdrawn. If persons with diabetes were not reached for their condition assignment call within one month, then they and their support person (if applicable) were administratively withdrawn.

If a participant expressed wishes to withdrawal from the study, study staff would contact the participant. Study staff followed a protocol to determine which levels of participation the patient does/does not want:

(1) limited intervention (e.g., no text messages but willing to complete coaching if so assigned) but will complete study assessments
(2) no intervention (opt out of all assigned study components) but will complete study assessments
(3) no surveys but okay with completing A1c kits or vice versa and receiving assigned components
(4) no surveys nor A1c tests but will allow study staff to review and extract relevant data to the study from their EMR
(5) no further participation

If a SP expressed that they did not want to participate in the study, study staff followed a protocol to determine what level of participation they do/do not want:

(1) limited intervention – no text messages but will complete study assessments
(2) no surveys but okay with receiving text messages
(3) no further participation

Patients can still engage with all aspects of the study if their SPs withdraws. If the patient withdraws to the level of no further participation, their SP would be administratively withdrawn. If a SP withdraws to the level of no further participation, we would contact their patient partner to let them know their SP has withdrawn completely from the study. If a support person withdraws for any reason, the patient participant could identify another support person to participate in the study with them.

If a participant expressed wishes to withdrawal and could not be reached by study staff to confirm their level of withdrawal, the participant was treated as a full withdrawal with no further participation (option 5 from the list above.)

8.0 Statistical Considerations

Power estimates were conservatively calculated based on a two-sample unequal variance *t*-test of 9-month A1c for a minimum detectible difference of 0.5%; we targeted enrollment of 334 dyads to obtain sufficient effective sample size to detect this effect. Allowing for a dropout rate of ~15%, an effective sample size of 284 (~142 per condition) provides 80% power to detect this minimum difference at a 5% significance

level assuming a standard deviation of 1.5%. For secondary outcomes and mediators, assuming skewness similar to A1c (in general it will be less) and retention of 80–90%, we will be able to detect standardized effect sizes of 0.32–0.34. Estimates of detectable effect were made via 40,000 simulations with a Beta distribution calibrated to approximate skewness similar to that observed in our prior work.

Our power will be greater than estimates, given our plans to use data imputation methods for missing data, and adjust for baseline values of the outcome(s) of interest and other covariates as needed per analysis, which should increase power by reducing the effective standard deviation of the outcome.

9.0 Privacy/Confidentiality Issues

Only key study personnel (KSP) approved by the IRB have access to research information. Participant survey and phone coaching data was entered and stored electronically in REDCap. KSP assigned participants a unique subject ID associated with their identifiable information in REDCap. Original paper copies of any surveys or coaching notes were deidentified and filed in a locked file cabinet. Participant contact information is password protected in a REDCap database and on a secure VUMC server. Patient information collected for payment purposes is stored separately from research data in a locked file cabinet. Only select participant data from REDCap was securely and automatically transferred to CareWire, whose platform delivers the mobile phone intervention, to initiate and tailor the intervention (e.g., name, cell phone number, birthdate, preferred time of day to receive text messages, patient's self-care goal set during coaching, study A1c). Individual participant responses to text messages were only accessible by KSP through a secure password-protected portal.

10.0 Follow-up and Record Retention

The study duration is 3 years (recruitment start through last follow-up assessment for all participants). KSP assigned participants a unique subject ID associated with their identifiable information in REDCap. De-identified data is stored on a secure VUMC server and retained for at least ten years after the close of the study. CareWire provided de-identified reports to KSP to monitor the content and delivery of text messages and participant engagement, which are retained on a secure VUMC server for at least ten years after the close of the study. Participant contact information is password protected and stored separately, without any health information, on a secure VUMC server for one year following the close of the study, at which point it will be destroyed. Patient information collected for payment purposes is stored separately from research data in a locked file cabinet and destroyed upon study closure. Participant contact information for those participants who want to be contacted for future research studies is stored on a secure VUMC server and password protected.

15.0 Background

In November 2020 – less than half-way through recruitment for the FAMS 2.0 RCT, we applied for a competing revision to NIH to support expanding the aims of the original R01 to include secondary data analyses from the FAMS 2.0 RCT and exit interviews.

Using cluster analysis with data from a large cohort of adults with T2DM, we identified 4 types of diabetes-specific family functioning. Type was independently associated with diabetes outcomes, including glycemic control (primary outcome of FAMS 2.0 RCT) and psychosocial wellbeing (diabetes distress and global well-being, secondary outcomes of FAMS 2.0 RCT). Because this evidence suggests effects of the FAMS 2.0 intervention may vary by type of diabetes-specific family functioning, we added the typology assessment measures to the RCT surveys. This addition will allow us to explore type as a moderator of intervention engagement and effects. The addition of exit interviews will help inform future intervention efforts by type.

The aims of the FAMS 2.0 RCT are unchanged.

16.0 Rationale and Specific Aims

Aim 1. Validate the diabetes-specific family functioning typology longitudinally in a diverse sample to:
1a. Determine if similar types emerge in the more diverse RCT sample at baseline.
1b. Examine type stability over time in the control group.
1c. Examine associations between type and outcomes prospectively in the control group. Findings will enhance the utility of the typology in diverse samples and the clinical validity of the typology.

Aim 2. Explore diabetes-specific family functioning type as an effect modifier of FAMS 2.0. We will use mixed methods to understand how efficacy of the FAMS 2.0 intervention was moderated by baseline type.
2a. Examine effect modification by type over the 15-month RCT and explore which components of the intervention were/were not engaging for each type.
2b. Complete exit interviews with n=80 intervention participants using rolling purposive sampling to ensure representation of each type.

Upon completion of these aims, we will know how to identify patients for whom the FAMS 2.0 intervention will be maximally effective to inform future implementation efforts and we will have hypotheses about what intervention components may maximize effects for other patients in the future.

17.0 Study Procedures

Procedure/Activity	Frequency
Survey (patient participants)	Baseline, 6mo, 9mo, 15mo – same as for

	the FAMS 2.0 RCT
Exit Interviews	Upon completion of the study (15mo) participants assigned to intervention were invited to participate in an exit interview

Each patient participant survey for the FAMS 2.0 RCT included measures of the typology dimensions.

Measures of Dimensions for Typology	
For these items, respondents are asked to "*think about the person who is most involved in your diabetes on a regular basis."*	
Collaborative Coping (3 dimensions): Cognitive Compensation, Interpersonal Enjoyment, & Frequency	Perceptions of Collaboration Questionnaire (PCQ) assesses Cognitive Compensation (degree to which collaboration is needed to overcome cognitive deficits or decline; α=0.80), Interpersonal Enjoyment (degree to which collaboration provides encouragement and closeness; α=0.64), and Frequency of Collaboration (α=0.79)
For these items, *"think about the people closest to you in your everyday life - it doesn't matter if they live with you."*	
Received support (2 dimensions): helpful & harmful	Family/Friend Involvement in Adults' Diabetes (FIAD) assesses the helpful and harmful aspects of received support for diabetes self-care activities in the past 30 days. 9-items assess helpful (e.g. "How often do your family members exercise with you or ask you to exercise with them?"; α=0.87) and 7-items assess harmful (e.g. "How often do your family members bring foods around that you shouldn't be eating?"; α=0.72). Harmful items query frequency of undermining/ sabotaging behaviors and nagging/arguing about self-care
Perceived support: Autonomy Support	Important Other Climate Questionnaire (IOCQ) assesses perception of the degree to which others support the individual's personal agency. We adapted the 6-item IOCQ to be specific to diabetes as the developers recommend and to reference more than one important other (e.g. "My important others try to understand how I see my diabetes before suggesting any changes"; α=0.89)
Perceived support: Criticism	The criticism scale from the Family Emotional Involvement and Criticism Scale, adapted to be specific to diabetes (e.g. "My important others find fault with the things I do to manage my diabetes"; α=0.71)
Match (2 dimensions): Effectiveness & Satisfaction	Single items: "How effective are your friends and family at dealing with troubles or issues related to your diabetes management?"; "How satisfied are you with your friends and family members' involvement in dealing with troubles or issues related to your diabetes management?"

Only patient participants assigned to the intervention are recruited for exit interviews.

Following the 15-month follow-up period, some intervention participants will be asked to participate in an exit interview to collect feedback about the intervention and learn about their experience. We will use baseline data from the RCT to purposively sample n=80 participants to complete interviews, such that n=15-20 represent each of the four typology types. Exit interviews are completed over the telephone, last ~30-45 minutes, and participants will provide verbal informed consent before any interview data is collected. Questions focus on (a) diabetes-specific family functioning prior to, during and after the intervention, (b) which intervention components they felt worked best/least for them, and (c) desirability and acceptability of alternative intervention formats and content.

Participants who complete an interview are compensated $40. Interviews are audio recorded and transcribed for analysis.

18.0 Statistical Considerations

This analysis leverages the outcomes measures data already collected during the RCT, including: hemoglobin A1c, diabetes distress, global well-being, self-efficacy, self-care behaviors (dietary behavior, physical activity, medication adherence) and helpful and harmful family/friend involvement.

This analysis leverages engagement data already collected during the RCT, including: enrollment of a support person, text message response rates, coaching session completion rates, elements of coaching protocol including completing rates of goals set, completion of verbal contract to engage friends/family.

The FAMS 2.0 RCT was not designed to test effect modification or moderation by type. Tests of effect modification are exploratory and intended for hypothesis generation, therefore we will interpret patterns of effects and use $p<.10$ as our threshold to discern potentially meaningful differences in intervention effects.

19.0 Privacy/Confidentiality Issues

Informed consent for patient participant exit interviews is obtained verbally over the phone before completing the exit interview. Exit interviews are recorded following participants' consent and the audio files and transcripts are stored using the subject's unique ID on a secure VUMC server. The transcripts are de-identified and will be stored separately from other participant data for at least ten years after the close of the study. Recorded exit interviews will be stored separately, on a secure VUMC until the close of the study, at which point they will be destroyed.