The University of Texas Medical Branch at Galveston
Protocol

Protocol Title:	Applying a Family Caregiver Supports Needs Assessment Tool in Home-based Primary Care: An Approach to Elder Mistreatment Risk Reduction and Prevention
Principal Investigator:	Karen E. Schlag
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1. Introduction and Purpose:

Older adults receiving home-based medical care face a greater risk of elder mistreatment (EM) when they have greater functional and cognitive impairments and increased care dependency.[1-3] While family caregivers are crucial in safeguarding older adults living at home, the risk of abuse by caregivers remains high.[4] Research has consistently linked strain and distress from caregiving responsibilities to a greater risk of EM.[4,5] Caregiving-related strain may be especially high for family caretakers of older adults who are responsible for completing complex nursing-related tasks [6] or managing competing demands.[7] Family caregivers also often perform care-related tasks with little training and have unmet support needs[8], which can exacerbate experiences of strain[9] and negatively impact their health,[10,11] the latter of which has also been recognized as a factor in EM risk.[12] To improve efforts to mitigate EM risk and prevent EM occurrences in community environments, it is vitally important to develop strategies that address family caregiver support needs.[13,14]

To address this need, this study will apply and examine the impact of an intervention facilitated by use of the carer support needs assessment tool (CSNAT) with family caregivers of older adults receiving home-based primary care (HBPC) in Galveston, TX and surrounding areas. HBPC is a type of home medical care where a greater number of enrollees are likely to present with extensive care needs.[15] The CSNAT provides a brief, person-centered framework that guides caregivers in identifying and expressing their patient care and personal support needs with a healthcare professional who works with them to create a uniquely tailored support plan.[16] Specific objectives for this study include testing the feasibility and acceptability of using the CSNAT in a HBPC setting, and examining its potential influence on caregivers' perceived strain, health and acts of EM. We will pursue these objectives through the following aims:

AIM 1: Test the feasibility and acceptability of applying the CSNAT intervention in HBPC by conducting a two-arm trial (CSNAT group vs. control group) and collecting baseline and post-test data on measures of caregiving strain, caregiver physical and mental well-being, and EM (n = 80).

> 1.a. To assess intervention feasibility, we will use recruitment and adherence metrics.
> 1.b. To assess intervention acceptability, we will use qualitative interviews (n = 20) of caregivers who have participated in the CSNAT initiative.

AIM 2: Explore the impact of the CSNAT intervention on mechanistic variables of EM (caregiving strain, caregiver well-being and quality of life) by measuring statistical differences and variations in pre- and post-test changes between the intervention and control groups.

AIM 3: Conduct an exploratory analysis using correlational analyses to examine the relationships between mechanistic variables and EM.

Minimal risks are anticipated for individuals from participating in this study. They include potential discomfort for participants in discussing their experiences related to caring for a relative or their relative's condition. Considering that caregivers will be having these conversations mostly with practitioners they are already in contact with about their relative's health, the anticipated risk of discomfort is minimal. Additionally, participants randomly selected to either the CSNAT intervention or control group for this study, or recruited to be in a qualitative interview, will have the option to skip any survey item or question presented to them as well as end their participation at any time. Moreover, every effort will be made to keep participant information confidential. Potential benefits from participating in this study include family caregivers of patients in HBPC having focused time with practitioners who are treating a relative in HBPC and receiving information about desired support resources related to their caregiving responsibilities.

2. Background:

This study seeks to evaluate the feasibility and acceptability of applying an existing CSNAT intervention with family caregivers of older adults receiving HBPC in Galveston, TX and surrounding areas. The CSNAT is a comprehensive, evidence-based tool that helps caregivers identify their patient care and personal support needs across 15 domains, and, based on these responses, develop an action support plan with a healthcare professional.[16] The CSNAT has been successfully administered in multiple countries within palliative and end-of-life care settings [17-19] as well as in the context of caregiving for patients with specific medical diagnoses, such as cancer [20] and chronic obstructive pulmonary disease [21]. Outcomes of this intervention applied in home settings have included reduced family caregiver strain[17] and improved physical and mental well-being.[18,19] The present study will extend prior research by exploring the influence of the CSNAT on perceived caregiving strain and well-being of family caregivers of older HBPC patients one month after the intervention's implementation. Moreover, considering that research has underscored the utility of family caregiver support interventions in mitigating risk of EM of older adults,[14] this study will also examine associations between changes in potential mechanistic variables (i.e., caregiving strain and caregiver well-being) and measures of EM. Needs-based and caregiver-driven support interventions can play an important role in addressing EM in home settings by managing caregiver stress and enhancing well-being.[17, 22, 23] In HBPC specifically, family caregivers frequently provide ongoing assistance to older patients who often receive treatment for comorbidities and have extensive in-home support needs.[15] These family members can experience increased caregiving stress when faced with their own unmet support needs,[8] which can result in adverse clinical outcomes for patients.[24]

Support offered by professionals to family caregivers in home healthcare settings frequently occurs on an ad hoc basis, such as through informal, impromptu, patient-care focused conversations. Caregiver support in this context is also typically delivered using a provider-led approach, which can result in specific carer needs being overlooked.[16] In contrast, the CSNAT creates a systematic caregiver-driven approach wherein family members identify their most important and pressing care-related and personal support needs from a provided list of support domains (e.g., need help talking to a relative about their disease, need help establishing personal time).[16] In doing so, caregivers reflect on multiple aspects of support, including emotional, informational, and practical needs. This caregiver reflection creates a basis for a needs assessment conversation with a home healthcare provider, with both individuals ultimately working together to develop an action plan that addresses identified caregiver support needs. Providers and caregivers also participate in a follow-up discussion to assess progress made in relation to implementing the action plan as well as needed adjustments. The present study will extend previous research on the CSNAT by testing the feasibility and acceptability of implementing it specifically within HBPC as well as explore the intervention's potential to mitigate risk for EM through addressing family members' caregiving strain and physical and mental well-being. Currently, there are no studies examining the impacts of caregiver strain and well-being on EM in HBPC settings. Ultimately, outcomes from this study will address a research gap in understanding specific mechanisms through which actions to resolve caregiver needs may also mitigate and prevent EM.

3. Concise Summary of Project:

Design: We will implement the CSNAT intervention with family caregivers of patients in Galveston-area HBPC. To assess the intervention implementation feasibility (AIM 1.a.) we will collect data on recruitment, retention, and adherence metrics. To examine the impact of the CSNAT intervention on family caregiver outcomes and how these outcomes are associated with EM (AIMs 2 & 3), we will also collect survey data completed by family caregivers randomly assigned to the CSNAT intervention (n = 40) and those randomly assigned to a control group (n = 40). This data will encompass HBPC family

caregivers' perceived caregiving strain, physical and mental well-being, quality of life, alcohol use, social connection, and instances of EM. This survey data collection will occur with participants in both study arms before the implementation of the CSNAT intervention and after the one-month follow-up. Additionally, we will collect qualitative data from family caregivers who participated in the CSNAT intervention (*n* = 20) to explore their experiences and perspectives with the program as a measure of intervention acceptability (AIM 1.b.).

Through the collection of survey data, we will assess primary and secondary outcomes using previously established and validated scales for our measurements of interest. For caregiving strain, we will use the eight-item strain subscale from the Family Appraisal of Caregiving Questionnaire for Palliative Care.[25] We will assess caregiver physical and mental well-being using the 12-Item Short-Form Health Survey (SF-12v2), [26] the Patient Health Questionnaire (PHQ9).[27] We will use two measures to capture our secondary outcome of elder mistreatment. These include using items from the Potentially Harmful Behavior Scale (PHBS)[28] and adapting items from the Neglect Scale.[29] Additional outcome measures we will assess include: the WHOQOL-BREF,[30] the Alcohol Use Disorders Identification Test (AUDIT),[31] the NIH PROMIS Social Isolation Scale,[32] and the Lubben Social Network Scale.[33] Caregivers will indicate the extent to which they have experienced measures of interest over the past month by responding to items presented via Likert-type scales (e.g., strongly agree – strongly disagree, never - frequently). We will also collect information on caregiver demographics and use NP-provided information on care recipient health and condition being treated in HBPC to describe study sample characteristics and assess potential confounding influences on findings.

We aim to consent a maximum of 80 participants to test application of the CSNAT in HBPC, which includes 40 participants randomly selected for the intervention arm and 40 for the control group. This sample size is based on an assumption of having a retention rate of 80% in both arms. To examine the acceptability of applying the CSNAT in HBPC settings, we also aim to recruit 20 participants from the intervention arm to participate in semi-structured interviews about their experiences and perceptions of support tool and planning sessions. Conditions that would result in participants ending their participation in the intervention, collection of survey data, or qualitative interviews include non-compliance and their withdrawal of consent.

4. Study Procedures:

To test the feasibility and acceptability of applying the CSNAT intervention in HBPC, we will use purposeful sampling to recruit family caregivers (*n* = 80) who live with homebound adults (age 65+) enrolled in UTMB Health Geriatrics Home Based Primary Care. Caregivers will be recruited after being identified by NPs based on meeting eligibility criteria and providing permission to be contacted by the research team. Consenting caregivers will be randomly assigned to either the intervention or control group.

Initiating the intervention implementation: The PI and/or research coordinator will meet individually with caregivers in both the intervention and control groups to screen participants and obtain their verbal consent after reviewing the Fast Fact sheet and enroll those who are eligible and interested in participating. At this time, a second meeting will be scheduled to collect participant baseline data, although if caregivers prefer, they can continue at that time with the baseline meeting once officially enrolled. Caregivers will have the option to have these introductory and baseline meetings with the research team members in person, over Zoom, or over the phone. During the baseline meetings, caregivers will be given a unique study ID and PIN # to log in and complete baseline study surveys online through REDCap®. The PI or research coordinator will help them as needed with logging into REDCap® to complete surveys. Upon completion of the baseline measures, participants will be randomized into an intervention or control group. This will be done through a REDCap feature using a computer-generated sequence established by the study statistician and triggered once participants

complete all baseline measures. *For the intervention group only*, research team members will also introduce the CSNAT intervention to caregivers, who will be instructed to complete the CSNAT questionnaire (referred to as the About You Booklet) at least one day prior to a scheduled HBPC visit for their family member. On this questionnaire, participants indicate the degree of need they have for different types of support. Caregivers can access this questionnaire on REDCap via a link sent to them by a research coordinator or PI. Once completed, a research coordinator or PI will send caregivers a copy of their online responses via email and/or physical mail. (These will be discussed during their intervention visit with the NP). The PI or research coordinator will also email or deliver a physical copy of caregivers' CSNAT questionnaire responses to the NP at least one day prior to the first intervention visit between the NP and a caregiver. Research team members will send reminders to participants over the phone or through email to complete the CSNAT questionnaire prior to their a care recipient's next scheduled HBPC visit.

Intervention Group: Following the introductory meeting between study participants and the research team members, CSNAT-trained NPs will meet with caregivers in the intervention group during a regularly scheduled home visit for their care recipient in HBPC. During the visit, the NP will discuss the caregiver's responses to the CSNAT questionnaire, and based on those answers, develop mutually agreed-upon strategies and a shared plan to increase caregiver support in the desired areas. This plan will be documented in writing, with both the NP and caregiver receiving a copy. This action plan will also be recorded on REDCap by a research team member and stored in a participant folder on a secure Utmb server

One month later, during a subsequent patient visit or follow-up phone call to the caregiver, the NP will conduct a brief follow-up with the caregiver to discuss progress on the support plan and make any necessary adjustments.

Control Group: For caregivers in the control group, following the introductory meeting with research team members and collection of baseline data, these participants will receive standard practice, which consists of informal ad hoc conversations with the visiting NP about caregiver needs.

Research team members will collect post-test data from participants in the intervention and control groups within seven days of the NP follow-up visit (or the second patient visit for the control group). In case of extenuating circumstances (e.g., severe weather, patient hospitalization) an allowable window to collect posttest data will be within 20 days of the NP follow-up visit. The same procedures and surveys used to collect baseline data will be used for collecting post-test data. After collecting post-test data, participants provide information (i.e., preferred email address or physical address) to be sent/mailed a $40 gift card (e.g., Amazon, Walmart) as compensation. While each participant will be involved in this study for slightly over a one-month period, the entire implementation period encompassing baseline/post-test data collection and intervention implementation is planned for 17 months.

Intervention Fidelity Assessment. Throughout the implementation period, NPs who serve as study interventionists will take notes and address questions related to the extent to which specific elements of the intervention were completed as well as provide details on how each caregiver meeting was conducted and, if necessary, explain any deviations from the prescribed intervention components. Additionally, with the caregiver participant's consent, intervention sessions (i.e., the support planning conversations) and control group sessions (i.e., NP-caregiver communication of care instructions only) will be audio-recorded and reviewed at least monthly by the PI to ensure fidelity to the implementation process. The research team will seek participants' consent to have intervention or control group sessions recorded prior to enrollment. Their consent to be recorded will also be captured on the recording. For participants who decline having the sessions recorded, they will be informed that they can still participate with the NP taking notes as described above.

Intervention Acceptability: Three months into the implementation period, we will initiate recruitment for and begin conducting qualitative interviews to assess the acceptability of the CSNAT intervention. Specifically, we will use purposeful sampling to recruit 20 caregivers who completed the CSNAT intervention to participate in semi-structured interviews about their experiences and perceptions of the support tool and planning session. Interviews will be conducted in English by a research team member. Interviews will take place in person or via a phone call or Zoom, depending on the participants' preference, and will last between 45-60 minutes. With participants' consent, interviews will be recorded and transcribed for analysis. For interviews where participants do not consent to being recorded, a member of the research team will take notes of the interview for the purpose of data analysis. Participants receive a $40 gift card as compensation. Interview questions will cover four domains: 1) general caregiving experiences and stressors, 2) caregiving support needs, 3) caregivers' experiences and perspectives on participating in the CSNAT intervention, and 4) barriers and facilitators to using the CSNAT or implementing a support plan. Qualitative responses will be transcribed verbatim using transcription software (e.g., Trint.com, Rev.com).

Table 1: Study Timeline

Project Activity	**Year 1 2026 - 2027**				**Year 2 2027 - 2028**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Finalize IRB approval, hire research coordinator								
Conduct CSNAT trainings								
Recruit family caregivers for intervention study								
Intervention implementation (CSNAT, action plan, 1mo follow-up)								
Analyze findings (Aim 1a, 2, 3), write up and dissemination of findings								
Recruit caregivers for qualitative study (Aim 1b)								
Conduct qualitative interviews								
Analyze findings (Aim 1b), write up and dissemination of findings								

5. Sub-Study Procedures: NA

6. Criteria for Inclusion of Subjects:

To be eligible, caregivers must be 18 years of age or older and self-report as providing consistent home care to a patient 65 years of age or older who is enrolled in the UTMB Health HBPC program. This patient should also be receiving clinical visits from an NP associated with the program. Consistent home care includes tasks such as assistance with activities of daily living, medication management, or medical nursing tasks. Caregivers must be able to read and speak English to participate.

7. Criteria for Exclusion of Subjects:

We will exclude caregivers who do not provide consistent home care (as described above) to adults age 65 or older who are enrolled in the UTMB Health HBPC program and receiving monthly medical visits in their home from an NP. Caregivers will also be excluded if they are not at least 18 years old and cannot communicate in English. We will also not include a caregiver if they have an obvious

neurological or psychiatric condition or communication deficits affecting their participation as conservatively interpreted by the nurse practitioner.

We anticipate participation in the intervention or qualitative interviews would be ended upon hospitalization or other serious health change in the caregiver or patient receiving HBPC. This would include the patient being assisted by the caregiver participant becoming disenrolled from the HBPC program.

8. Sources of Research Material:

We will collect data directly from participants through their survey responses provided on REDCap® and information they share during qualitative interviews. Information obtained from participants will be collected specifically for research purposes and de-identified.

9. Recruitment Methods and Consenting Process:

Eligible participants for this intervention study will be identified for recruitment by NPs from the UTMB HBPC program based on the NP's knowledge and experience working with patients in the program and their family caregivers. NPs will share contact information (e.g., phone numbers and/or email addresses) with the research team of potential participants who have agreed to be contacted (according to their preferences of phone, email, or either). Contact information as described will be shared with the research team by NPs during regularly scheduled weekly implementation check-in meetings between research team members and NPs during the course of the implementation period. NPs may also email the study PI or research coordinator with contact information of caregivers who have consented to be contacted. To minimize the potential for undue influence, NPs will initially describe the study to caregivers as, "We have a research study at UTMB testing a support program for family members who are caring for patients in homebased primary care such as yourself. This program is designed to be easily done in the home, and I feel you may qualify for it. Would you be okay if the researcher called you at a convenient time to share more information?" (See Scripts in the attachments for additional information). At this time, the NP will also share a study flyer and Fast Fact sheet with the caregiver to provide further information about the study (see attachments).

To facilitate recruitment, the research coordinator with assistance from the NPs will also generate a monthly list of HBPC patients scheduled to be seen by the study NPs. The study PI, research coordinator, and NPs will review this list weekly to biweekly to identify patients who are likely to have caregivers potentially eligible for the study. The NPs will introduce the study to these caregivers during routine HBPC patient visits or through a phone call. If a caregiver expresses interest and agrees to be contacted, the research coordinator or PI will use the caregiver's contact information, as available in the patient record, to follow up, provide additional study information, and proceed with screening and enrollment.

Final determination of a caregiver's eligibility and interest in participating in the study will occur through a screening conversation between the research team and the potential participant. Only English-speaking subjects will be consented (see Consenting Process)

For the qualitative interviews, participants who have completed the CSNAT intervention arm of the trial will be asked by members of the research team if they would like to participate in a qualitative interview to learn about their experiences and perceptions of participating in the intervention. Researchers will introduce information about qualitative study during a time when they are meeting with participants to collect post-test data for the intervention trial. Participants who express interest in participating will be provided with a Fast Fact sheet and scheduled for an interview at a time and modality (e.g., in person, zoom, phone) of their convenience.

Consenting process

Intervention: Participants will be provided a copy of the Fast Fact sheet by their care recipient's NP prior to meeting with a research team member to be screened as well as a second meeting to initiate the trial and collect baseline data (for both the CSNAT and control groups). This Fast Fact sheet will be reviewed with participants prior to enrollment, and verbal consent to participate will be obtained. After a participant is enrolled and prior to collecting baseline measures, the researcher will review the Fast Fact sheet with them a second time and confirm verbal consent for participation The research team is requesting a Waiver of Documented Consent for participation in the trial as they pose no more than minimal risk. We will only use a Fast Fact sheet for this study. For individuals that identify as deaf or hard of hearing they will give consent through the interpreter on the VRS. When reviewing the Fast Fact sheet with participants and seeking their verbal consent for participation, researchers will also seek their consent to audio record both of the intervention or control group sessions for the purpose of intervention fidelity checking. For the intervention group, this would involve the support-planning conversations, and for the control group, this would involve care instructions discussed between NPs and caregivers. At this time, participants will also be informed that if they do not consent to audio recording, they may still participate in the support-planning or control group sessions. Participants' consent to participate and be audio recorded (for those that agree) will also be captured on the study audio recording.

Qualitative interviews: We will follow a similar process as outlined above. Prior to the interview, participants will be given a copy of the Fast Fact sheet. At the start of the interview, the researcher will review the Fast Fact sheet with them. The research team is requesting a Waiver of Documented Consent for these interviews as they pose no more than minimal risk. We will only use a Fast Fact sheet for this study. During the interviews, participants will be asked to give their consent to audio recording that we will transcribe for the purposes of research. If they do not consent to audio recording, they may still participate in the interview. For individuals that identify as deaf or hard of hearing they will give consent through the interpreter on the VRS.

10. Potential Risks:

The risk for participating in this study is believed to be minimal. The risks for participation include potential discomfort in describing or discussing experiences of caregiving strain or the health and/or condition of their care recipient. There may also be potential discomfort of participants in reflecting on actions they might take to address their support needs or manage stress.

Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep information confidential (e.g., not revealing identified information in study analysis or outside of the research team); however, this cannot be guaranteed. Additionally, there is a potential risk of loss of confidentiality when a disclosure of elder abuse and/or neglect during the study reaches the threshold of mandatory reporting by the PI. Mandatory reporting to agencies including the Texas Department of Family and Protective Services (TFPS) applies to individuals who have reasonable cause to believe an adult age 65 or older is being physically or psychologically abused, financially exploited, or neglected.

11. Subject Safety and Data Monitoring:

Subject Safety

To minimize risk or discomfort or loss of confidentiality to participants, the following will be implemented:

a. All participation in this study is voluntary including the CSNAT intervention (i.e., completing baseline/post-test measures, answering the support needs CSNAT questionnaire, creating an action

plan with a UTMB Health NP, participating in follow-up discussion) and qualitative interviews. Participants can choose to skip any survey or interview question or inquiry from an NP at any time. They can also stop any intervention component or qualitative interview at any time. Additionally, researchers and NPs administering data collection or the intervention will be mindful of cues of discomfort. If someone becomes distressed during the intervention or during data collection periods (i.e., completing surveys or qualitative interviews), the researcher or NP involved will remind the participant that all questions are voluntary and that they can stop at any time. They will also ask the participant if they would like to take a break and resume at a later period.

b. Participants will have the option to complete baseline/post-test measures and qualitative interviews in person, over the phone or over Zoom, for their convenience. Regarding the CSNAT questionnaire document, where caregivers rank different types of desired support, and the support planning documentation, these will only be shared between a participant, their care recipient's regularly visiting NP in HBPC, and members of the research team

c. Participants will be asked to undergo the consent process, preparing them for the types of questions to expect during the intervention and data collection periods. There is no known risk to social standing or employability with subject participation. Participants will also be informed during the consent process that the study PI will be required to report any disclosures of elder abuse and/or neglect that present safety concerns reaching the threshold of mandatory reporting to agencies including the Texas Department of Family and Protective Services (TFPS). Participants will be made aware that this could risk a loss of confidentiality.

d. No knowingly identifiable information from a participants' participation in this study will be shared with individuals outside of the PI and core study team (i.e., research coordinator, NPs). Audio recordings of action planning sessions between participants and NPs will be destroyed upon completion of the study analyses. Audio recordings of qualitative interviews will be destroyed once transcriptions are created and verified.

e. Resources and contact information for support services, including national hotlines, will be provided to all participants if needed. See attachments for types of support resource information to be provided.

f. While not expected, in the event of participant disclosures of elder abuse or suicidal ideation, members of the study team or the NPs will contact grant PIs from UTHealth Houston (i.e., Dr. Ron Acierno and Dr. Carolyn Pickering), who are trained in crisis response, and will reach out to the participant within 24 hours of the initial report and establish appropriate support for the caregiver or HBPC care recipient (e.g., referral to a qualified mental health or other professional). The study PI will also monitor the case disposition weekly for two weeks. Upon identification of elder abuse determined by professionals from UTHealth Houston to meet criteria of mandatory reporting, Dr. Schlag will report a disclosure to TFPS. A protocol for identifying reportable disclosures of abuse or suicidal ideation has been included as a protocol attachment.

In addition to the above, the format and flow for all data collection tools were reviewed by researchers that have experience working with family caregivers of older adults and elder mistreatment survivors.

Data Monitoring

All data collected through participant surveys or interviews will be stored in a secure server or cloud-based storage such as REDCap® and the University's password-protected OneDrive study folder. Support action-planning meetings and interviews may be audio-recorded, only if participant consent is given. If individuals do not agree to be audio recorded, they may still participate in the study. In this case, NPs/researchers will take detailed notes of the planning session/interview on paper or via computer. Audio files of the interviews will be transcribed and destroyed upon transcription verification. Any identifying information in transcripts will be deleted and destroyed. Audio files from

the intervention and control group meetings collected to assess intervention fidelity will be destroyed upon completion of all study analyses. Only members of the research team will have access to these support action planning audio files for the purpose of taking notes to assess the fidelity of the intervention implementation.

I. Data will be securely stored at all times during and after the study.
   a. Electronic data collected through REDCap® or similar software and notes taken by NPs or researchers will be stored on secure servers, protected by The University of Texas Medical Branch.
   b. Audio recordings from support planning sessions or interviews will be labeled with the project name and date of recording and subsequently stored on secure servers. For the interviews, these recordings will be removed and destroyed once transcriptions are created and verified. Identifying information will be removed from transcription. For support action planning recordings, these files will be removed and destroyed upon completion of all study analyses.
   c. Although no data will ever be stored directly on a computer hard drive, any project computers used to access data secured on the server will be password protected. Hard copies of data, interview transcriptions, or any other data in physical form, will be securely stored in the researcher's locked office during and after study.

II. Data will be kept for the length of time specified below:
   a. Electronic data collected through REDCap® or similar software and researcher notes will be kept indefinitely at the discretion of the PI. They will be stored on secure servers protected by UTMB Health for the life of the data.
   b. Audio recordings from qualitative interviews will be kept and stored on secure servers protected by UTMB Health until recording transcripts are created and verified. At that time, audio files will be purged from the secure server and no back-ups will be created. Audio recordings of the support action planning sessions (intervention) will also be kept and stored on secure servers protected by UTMB Health. These will be removed from the secure server, with no back-ups created, upon completion of all study analyses.
   c. Transcriptions and notes taken from the recorded support planning meetings will be kept and stored indefinitely, which is at the discretion of the PI. They will be stored on secure servers protected by UTMB Health for the life of the data. Neither the transcriptions or research notes on planning meetings will contain identifying information.

Data will be kept confidential. Data will be coded so that individual answers to questions cannot be attributed to a specific participant or agency/organization. If a participant requests that particular information be kept confidential, the researchers will honor that request. Agency / organization names and contacts will be kept separate from all other information. The master key of organizations will be stored on secure servers, protected by UTMB Health. It will be kept for a minimum of five years and subsequently destroyed.

12. Procedures to Maintain Confidentiality:

All data collection activities for this study will be confidential and no personally identifying information will be used during any report of the study results. No identifying information will be stored with the survey or interview data. Instead, participants will be assigned an ID number to be used on surveys or interview transcripts for the purpose of study analyses. Any documents linking ID numbers to participants' names and other identifying information (e.g., email addresses) will be kept on secure servers protected by UTMB Health. Participants will be asked to provide identifying information such as their email or phone number to receive compensation. This contact information will be kept separate from other data and will not be able to be connected to individual data collected for study assessment. Email addresses collected through REDCap for study administration purposes (e.g., sending survey links) will be maintained separately from screening, survey, and interview data and will not be linked to study assessment data used for analysis. Any contact information stored separately

from interview data will be on OneDrive, a cloud-based server previously approved by UTMB Health IRB, under password protection. Only this study's PI and research coordinator will have access to the linked ID numbers and identifying information, which will be kept for a minimum of five years and subsequently destroyed.

13. Potential Benefits:

Participants will potentially benefit from this study in gaining access to new and/or supplemental support for their caregiving responsibilities through using the CSNAT questionnaire to assess their needs and subsequently making an action plan with trained NP to acquire needed support. In that this study trial will access the feasibility and acceptability of this intervention, there is potential benefit of reducing caregiving strain among other caregivers through the this study's refinement of the CSNAT in HBPC and its future use in larger groups of HBPC family caregivers.

14. Biostatistics and other Analyses:

General Design:
It is anticipated that conducting the CSNAT-guided conversations in HBPC will be feasible as indicated by meeting specified recruitment, retention and adherence benchmarks. It is also expected that intervention participants will show greater variation in caregiver strain, physical and mental well being, and reduced elder mistreatment scores over time, both within the intervention group and relative to the control group.

In using a two-arm (parallel) study design, the research team will be able to examine feasibility metrics in both intervention and control groups. This design will also provide an opportunity for researchers to collect data on variability of outcomes between the intervention and control group, allowing for the estimation of a necessary sample size for a future, fully powered RCT.

For AIM 1 (feasibility):
For our primary feasibility outcomes, we will summarize recruitment, retention, and adherence using descriptive statistics and 95% confidence intervals. Recruitment will be assessed by recording the average time between screening and enrollment, the average time required to recruit a sufficient number of caregivers for each trial arm, and the refusal rate (the proportion of screened caregivers who decline participation). Retention will be evaluated by calculating the proportion of enrolled participants who complete both baseline and post-test assessments, regardless of their level of engagement with the CSNAT questionnaire or support planning. Adherence will be assessed within the intervention arm by determining the proportion of caregivers who complete the CSNAT questionnaire and support plan, as well as the number who report taking action on at least one identified planning item.

For AIM 2 (intervention differences among mechanistic variables of EM):
For secondary continuous outcomes (i.e., caregiving strain, physical and mental well-being, and elder mistreatment measures, caregiver depression, quality of life, alcohol use and problems, social isolation and connection; specific measures listed on p. 4), we will compute means, standard deviations, quantiles, and 95% confidence intervals at baseline and post intervention. Pre–post changes within each arm will be calculated, and between group differences in change scores will be summarized with 95% confidence intervals. Linear models may be used descriptively to estimate effect sizes and variability, recognizing that the study is not powered for inferential hypothesis testing.

For AIM 3 (exploratory relationships between mechanistic variables and EM):
Caregiver strain, well-being, and quality of life and EM outcomes will be examined using Pearson or Spearman correlation coefficients, depending on distributional assumptions. Correlations will be

estimated separately within each arm, and associations between pre–post changes in the intervention group will also be explored.

Given the feasibility focus and the modest sample size, formal multivariable adjustment is not planned. However, descriptive comparisons will consider potential confounders such as caregiver age, relationship to the care recipient, and baseline levels of strain or well-being. If substantial imbalance between arms is observed on key baseline characteristics, sensitivity analyses using linear models with covariate adjustment may be conducted to explore the robustness of observed trends.

In accordance with NIH policy, we will examine the intervention effect descriptively across sex and racial/ethnic subgroups to the extent possible. However, based on the demographic characteristics of the study region and prior experience with similar caregiver populations, we anticipate that the enrolled sample will be relatively homogeneous (predominantly non-Hispanic white women). As a result, subgroup analyses will be limited by small cell sizes and will not be powered to detect clinically meaningful differences. Any subgroup summaries will therefore be exploratory, descriptive, and interpreted cautiously.

For Intervention Acceptability (AIM 1b, qualitative interviews):
Interview responses will be transcribed verbatim using transcription software (e.g., Trint.com), and analysis will follow a mixed inductive-deductive thematic approach. Following steps prescribed through codebook thematic analysis approaches, members of the research team will initially code the verbatim transcripts, creating a preliminary codebook with initial themes. The study PI and other team members will then code the data line-by-line using qualitative analysis software, meeting regularly to discuss analytical progress and resolve discrepancies. Once coding is complete, the research team will meet to discuss coding development and proceed to identify and define themes. We will organize the final coded dataset according to themes reflecting codebook inclusion, exclusion, and example data. To ensure transparency, we will maintain an audit trail of analytical decisions.

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