**Research Team Perspectives of Fidelity during a Stroke Caregiver Intervention Study**

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**Abstract**

**Background and Purpose:** Treatment fidelity is an essential process for randomized controlled clinical trials; however, there are a lack of studies that report treatment fidelity from the perspectives of research team members. Even fewer studies detail fidelity of recruitment, screening, and data collection procedures. The purpose of this study was toanalyze fidelity of recruitment and screening, data collection, intervention, and control group procedures from the perspectives of research team members in an ongoing randomized controlled clinical trial. The trial was aimed at testing feasibility of the Telephone Assessment and Skill-Building Kit (TASK III) program compared with an Information, Support, and Referral (ISR) program in 74 stroke family caregivers. **Methods:** Five separate focus groups were conducted with a total of 12 research team members to obtain perspectives regarding fidelity in 4 main areas: 1) Recruitment and screening; 2) data collection; 3) TASK III program; and 4) ISR program. Within each area, a structured interview guide was used to access fidelity (design, training, delivery, receipt, enactment). Data were analyzed using rigorous content analysis procedures with a predetermined code matrix to capture strengths and weaknesses of each type of fidelity within each area. **Results:** Strengths and weaknesses were found regarding fidelity in all four areas (recruitment and screening, data collection, TASK III program, and ISR program). Cultural implications were obtained as well. Findings informed valuable protocol refinements for each role in preparation for a future trial. **Conclusion:** Research team members have valuable perspectives regarding fidelity of procedures that can be used to enhance and refine protocols for future studies. Feasibility studies provide the optimal opportunity to assess research team perspectives regarding fidelity of procedures to ensure the success of future efficacy trials.

**Key words:** stroke, caregivers, treatment fidelity

**Introduction**

Treatment fidelity is an essential process for rigorous clinical trial management (Bellg et al., 2004; Borrelli et al., 2005). Treatment fidelity refers to the strategies employed to monitor the reliability and validity of study interventions (Borrelli et al., 2005), thereby enhancing the rigor of studies. The National Institutes of Health Behavior Change Consortium established guidelines for treatment fidelity consisting of five main elements: study design, personnel training, protocol delivery, participant receipt, and enactment (Bellg et al., 2004). Based on these five elements, a treatment fidelity checklist was designed to assess studies for treatment fidelity (Borrelli et al., 2005). Monitoring of treatment fidelity is essential to ensure interventions are implemented as designed, minimizing the risk of Type I and Type II errors, and increasing confidence that a study may be both replicated and generalized (Borrelli et al., 2005; Bellg et al., 2004). Monitoring treatment fidelity is important because it can help to explain study findings, provide useful information for revising future interventions, and help to ensure that the study is measuring what it is designed to measure and that is replicable (Morrison et al., 2017; Moncher & Prinz, 1991; Borrelli et al., 2005). In addition to focusing on treatment fidelity of the experimental group, attention should be given to comparison groups as well in order to establish treatment differentiation (Perepletchikova, Treat, & Kazdin, 2007). Although potential treatment fidelity threats should be identified and monitored in intervention studies, information on treatment fidelity is not frequently reported in the literature. A review of aphasia studies by Richardson et al. (2016) showed that only 57% of studies provided information about assessment fidelity. Areas of vulnerability during assessment and data collection can include lack of reliability, assessor qualifications, assessor blinding, assessor training, and inadequate information about assessment instruments (Richardson et al., 2016). Soliciting feedback from the research team through qualitative interviews may provide insight into the fidelity of the data collection and screening processes, as well as treatment fidelity for intervention and control procedures that is not easily evaluated through other methods.

***Treatment fidelity in family caregiver intervention studies***

Some articles have been published on treatment fidelity in caregiver intervention studies (Farran et al., 2011; O’Malley & Qualls, 2019; Spell et al., 2020), but only a few (Horne et al., 2015; McLennon et al., 2015) have evaluated treatment fidelity of interventions through qualitative focus groups with study staff. Additionally, fidelity of the data collection and screening process (assessment fidelity) is not often reported (Farran et al., 2011). While a number of intervention programs designed to address the unmet needs of stroke family caregivers have been reported in the literature (Bakas et al., 2014; Bakas et al., 2017; Minshall et al., 2019; Panzeri et al., 2019; Pucciarelli et al., 2020; Schwertfeger et al., 2020), most do not report on treatment or assessment fidelity (Inci & Temel, 2016; Robinson-Smith et al., 2016; Cameron et al., 2015; Cheng, Chair, & Chau, 2018).

***Treatment fidelity in the TASK II and ISR programs for stroke caregivers***

One stroke family caregiver program with a track record of monitoring and reporting treatment fidelity is the Telephone Assessment and Skill-Building Kit (TASK II) program (Bakas et al., 2015; McLennon et al., 2015). The TASK II program is a theoretically-based, nurse-led intervention designed to address stroke caregiver needs and concerns after discharge to the home setting (Bakas et al., 2009a, 2009b; Bakas et al., 2015). The TASK II program involved a mailed TASK II Resource Guide consisting of a tabbed binder with 35 tip sheets addressing caregiver needs and concerns in 5 main areas: 1) Finding information about stroke; 2) Managing emotions and behaviors; 3) Providing physical care; 4) providing instrumental care; and 5) Dealing with one’s own personal responses to caregiving. Six skill-building tip sheets were designed to enhance caregiver skills and to further individualize content in the 35 tip sheets. The 6 skill-building tip sheets included: 1) strengthening existing skills; 2) screening for depressive symptoms; 3) maintaining realistic expectations and schedules; 4) communicating with healthcare providers; 5) problem solving; and 6) stress management. Caregivers randomized to the TASK II program received 8 weekly telephone calls from a nurse, with a booster call a month later (Bakas et al., 2015). Nurses trained caregivers how to assess their needs and concerns, prioritize strategies found within the 35 TASK II content tip sheets, and how to use the 6 skill-building tip sheets. Caregivers also received a pamphlet entitled, “Caring for Stroke Survivors” (American Heart Association, American Stroke Association, 2015), as well as active listening from the nurse who suggested additional resources. Caregivers randomized to the ISR group just received the pamphlet (American Heart Association, American Stroke Association, 2015) and the 8 weekly calls from the nurse, with a booster call a month later for active listening and referral to the American Heart Association and the American Stroke Association for resources. Detailed treatment fidelity procedures for both the TASK II and ISR programs were reported by McLennon and colleagues (2015).

The TASK II and ISR programs were monitored carefully for treatment fidelity following the National Institutes of Health Behavior Change Consortium guidelines and the Treatment Fidelity Checklist (Bellg et al., 2004; Borrelli et al., 2005; McLennon et al., 2015). Using both quantitative and qualitative methods, treatment fidelity was evaluated for both TASK II and ISR programs across five elements (design, training, delivery, receipt, and enactment) (McLennon et al., 2015). All TASK II and ISR calls were audio-recorded to assess protocol adherence using a structured checklist (McLennon et al., 2015). It was not feasible to address all skill-building tip sheets during each TASK II call; therefore, protocol adherence was 80% for TASK II and 92% for ISR. Comparing shared items on the checklist, TASK II and ISR showed similar adherence rates (TASK II 90% versus ISR 92%). Dosage was measured as the number of minutes spent on the calls with the nurse. As expected, TASK II calls were significantly longer than ISR calls (p<.001). Qualitative data were obtained through focus groups with the TASK II and ISR nurses to evaluate the 5 elements of treatment fidelity from their perspectives (design, training, delivery, receipt, and enactment). Qualitative analyses revealed valuable strengths, weaknesses, and opportunities for future research design and delivery for both TASK II and ISR programs (McLennon et al., 2015).

***Treatment fidelity in the TASK III and ISR programs for stroke caregivers***

The Telehealth Assessment and Skill-building Kit (TASK III) was optimized to deliver content through various types of telehealth technologies (Bakas et al., 2020a). Stroke caregivers now have the choice to access the TASK III Resource Guide through a TASK III mailed hard copy binder, TASK III website (<https://task3web.com>), TASK III eBook, or TASK III USB drive (Bakas et al., 2020a). TASK III calls with the nurse are provided based on caregiver preference by telephone, FaceTime, or online videoconferencing (Bakas et al., 2020a). A new skill-building tip sheet was added to promote caregiver self-management of their own health through goal setting (Bakas et al., 2020b). As in the TASK II trial (Bakas et al., 2015; McLennon et al., 2015), treatment fidelity (design, training, delivery, receipt, enactment) was closely monitored in the TASK III feasibility study involving 74 stroke family caregivers randomized to TASK III or ISR groups. Unlike existing studies, screening and data collection procedures were monitored for fidelity in 4 areas: design, training, delivery, and receipt. Because research team members are valuable front line workers of clinical trial implementation, their unique perspectives were obtained to assess and refine procedures for fidelity. The purpose of this study was toanalyze fidelity (design, training, delivery, receipt, enactment) from the perspectives of research team members involved in recruitment and screening, data collection, and the TASK III and ISR program procedures.

**Methods**

***Design and Sample***

Using a content analysis design (Miles et al., 2013), qualitative data were collected and analyzed from focus groups conducted with 12 research team members involved in a study testing feasibility of the TASK III program for stroke family caregivers (R21NR016992, Clinicaltrials.gov NCT03635151). Separate focus groups were conducted for research staff who provided recruitment and screening (n=4), data collection (n=4), TASK III nurse calls (n=4), and ISR nurse calls (n=4). Some research staff participated in multiple roles. For example, a few of the TASK III nurses also engaged in recruitment and screening of participants. Sample characteristics for the 12 research staff are provided in Table 1.

***Procedures***

The focus groups were conducted online using WebEx videoconferencing. Sessions ranged from 35 to 94 minutes. The sessions were audio-recorded and transcribed for analysis. Ground rules were established in an effort to stay within a structured agenda and time allotted. For each topic, every team member had the opportunity to participate. A constructivist paradigm was incorporated to allow participants to construct their own experience within the roles they served on the study. A structured interview guide using open ended questions for each role in the study (recruitment and screening, data collection, TASK III program, ISR program) was guided by the 5 elements of treatment fidelity (design, training, delivery, receipt, enactment) (Table 2).

***Data analysis***

Rigorous content analysis procedures were used to analyze qualitative data with a “prior list” of codes (Krueger & Casey, 2015; Miles et al., 2013; Royse et al., 2001) based on the structured interview guide (Table 2). The second author placed direct quotes into a coded matrix template based on the codes (Miles et al., 2013; Royce et al., 2001) utilizing Microsoft word. The matrix template was organized by role (recruitment and screening, data collection, TASK III program, ISR program) and fidelity elements (design, training, delivery, receipt, enactment). Strengths and weaknesses were identified for each fidelity element within each role. Each direct quote was independently reviewed within the matrix by the remaining 11 authors. Areas of disagreement were resolved with consensus reached. No additional themes or codes appeared during the process. Data saturation was achieved within each area (recruitment and screening, data collection, TASK III program, and ISR program) and type of fidelity (design, training, delivery, receipt, enactment).

The authors were instructed to select their favorite quotes within each category. The second author compiled all selected direct quotes into one document. Representative quotes were extracted from the matrix for the manuscript based on authors’ agreement. In order to ensure credibility and reliability, each author completed their grid independently and sent their selected quotes to the second author. Each step of the coding process was tracked in addition to decisions made during the process (Royse et al., 2001). Credibility was improved by lowering investigator bias by utilizing an audit trail that tracked each step of the coding process and decisions made during analyses (Royse et al., 2001). Throughout the duration of the coding process, consistency of procedures, analyses, and conclusions through the audit trail provided evidence of reliability (Davies & Dodd, 2002).

**Results**

 Within each study role (recruitment and screening, data collection, TASK III program, ISR program), perspectives from the 12 research staff illuminated the strengths and weaknesses regarding all aspects of fidelity (design, training, delivery, receipt, enactment). Table 3 provides a listing of procedures for each type of fidelity within each role. Qualitative results for fidelity within each role are presented below.

***Recruitment and Screening Fidelity***

 **Design.** Screeners emphasized the importance of being able to reach the next of kin. When making calls a screener mentioned “So, I think being able to reach the caregiver, I think it's more time efficient (Screening, pg. 2).” Another screener added, “I only try to reach the stroke survivor if I've tried multiple times to reach the caregiver and have been unsuccessful, because then it makes me think maybe the next of kin is not the caregiver, so then I try to reach the stroke survivor (Screening, pg. 2).” Another screener offered the difficulty of recruiting at one of the hospital sites due to lack of next of kin “I also feel like sometimes it's challenging, especially from IU Health Methodist, because we don't get the next of kin's contact information. So, recruiting from that side is kind of challenging” (Screening, pg. 1). Screeners liked the questionnaire “I think that the screening questionnaire has a nice smooth transmission to it (Screening, pg. 6)”.

Team members discussed the importance of the time gap between hospital discharge and when they were contacted for recruitment. They wondered, “is there a sweet spot with time from stroke? Because some people we got had had their stroke in November and it was March and some people were pretty fresh out and maybe they'd just been home a week or so” ((Screening, pg. 16). Also, the question was raised “is there a window that's best to reach them” ((Screening, pg. 16). Screeners used their own personal cell phones to conduct calls and a comment was made “I think having a cellphone that actually has the UC, Hi, you have reached the University of Cincinnati Stroke ..., you know, we are not available at this time. Please leave your message. And we can turn that on when we've finished and we've moved on” (Screening, pg. 4). Cultural perspectives were discussed. One team member expressed that she “…felt that the questions, that there was a cultural issue. Because when I ask the questions, I have actually had to go back and re-explain it to them because in certain cultures it's not considered a burden” (Screening, pg. 9).

 **Training**. Screeners generally felt the training was important. “I think that it speaks to how important the training is and it doesn't have to be long and elaborate, but just having the right tools in the right order (Screening, pg. 11).” A suggestion was made to hire more screeners for future studies, “…because, when I see how many calls it takes just to get one person in, I think hiring way more screeners would be real effective” (Screening, pg. 14). Diversity was discussed: “I feel like the variety or diversity of screeners is important because some of us hit sweet spots with different people. I think that rapport that you establish even in the screening call, even if they have someone different down the road, kind of sets their tone about what this is going to be like. So, I don't think you want all white screeners or all Black screeners, or all young ones or all old ones” (Screening, pg. 14).

 **Delivery.** Ascreener made the suggestion about editing the questionnaire to include ‘Not Applicable’ on the Oberst Caregiving Burden Scale (OCBS) form. As one team member reflected, “…there have been some people who have said, well, I don't have to do that. And so, they struggle with how to answer it. So, do we need to put in a ‘not applicable’” (Screening, pg. 11). The caregiver’s mood was briefly discussed, “(I) think it's the day that we actually get ahold of them. Because caregiving, it can be good one day or good one week and then boy, it can all fall apart (Screening, pg. 11).” Finding a good time to reach the caregiver was important “I'll call back and maybe they'll answer, I don't know. This is not a good time. Call back tomorrow.” (Screening, pg. 13). Cultural perspectives were discussed. “I felt like the African men who I talked to and there were a couple of them who were taking care of their family members, really felt the duty and felt like it's not even my place to complain” (Screening, pg. 11).

**Receipt**. A screener thought the (OCBS) was a bit confusing to some caregivers “The only thing that I've encountered when I'm doing a screening is sometimes people are a little confused when you go to the Burden Scale” (Screening pg. 10). The same screener added, “Someone will say, well, do you mean is it hard for them or is it hard for me? And so, then I have to clarify. I have to now kind of preface that with, this is about you and how difficult it is for you, not the stroke survivor getting in and out of the car, it's you. How difficult is it for you? And so, I clarify that now” (Screening, pg. 10).

***Data Collection Fidelity***

**Design.** Data collectors offered suggestions for improving the design of the data collection process. Their suggestions were to: 1. Have a centralized area for communication between nurses and data collectors. 2. Shorten questionnaires due to repetition. 3. Have a reminder call for caregivers that have an upcoming data collection call. 4. Have a connection to the rest of team as data collectors were blinded and didn’t interact with other team members. 5. Be mindful of the time was estimated for the calls as caregivers would sometime have other things on their plate. By having a centralized area for communication with nurses, information can be shared. For example, “I think it might be helpful to have like a centralized area for where the nurses can sort of communicate with us in terms of letting us know things like, oh, they prefer using their home phone number”(Data Collector, pg. 1).Team members brought up some issues with the questionnaire. One data collector felt it was repetitive, “I think there's two of them that seem almost repetitive in a way, because we ask if they are, the support groups and stuff and all the various resources that they might use. And most of them will say no to something like a visiting nurse or a home health aide. And then we get to the end and we ask them again if they've already said no” (Data Collector, pg. 13). Majority of the data collectors’ (n=3) stated they struggled with the dietary screener questionnaire, “So even if we can not necessarily remove the whole questionnaire but at least say shorten it in a way so that we are more targeted about their vegetable consumption, their food consumption overall, their whole grains consumption rather than being like, there’s this is one question with like the Danish pastry” (Data Collector, pg. 20).

Data collectors wanted a connection to the rest of the team “But having some kind of connection with the rest of the people who were also involved in this study, I think could be helpful, at least for myself” (Data Collector, pg. 16). Data Collectors were kept separate from the team for fidelity purposes. To prevent bias the data collectors were kept blinded and didn’t know whether participants randomized to TASK III or ISR group. They felt like the interviews could be too long “if there was a way that we could get the baseline to 45 minutes on average, we can get that 8-week at 30 minutes and the 12-week at like maybe 45 minute. If there's a way to shorten it (Data Collector, pg. 19). Another comment related to time was made “I do feel like the calls can get a bit long and I know that caregivers can sometimes get frustrated, especially if we're hitting the two-hour mark” (Data Collector, pg. 3).

 **Training.** Data Collectors offered suggestions to improve training: 1. Do more practice calls. 2. Add more script to each survey asked during the calls. 3. Pace out the practice call. 4. View the TASK III tip sheets so that they can be more familiar in case questions come up during the interview.Regarding the practice calls, a team member said, “I think that there needs to be more practice calls. Not necessarily maybe not even the entire length of the call. Just maybe tackling certain parts over and over again.” (Data Collector, pg. 5). Another data collector wanted more of a script added to each survey “I think something else that could help in general is just adding some more script to like the introductions of each survey” (Data Collector, pg. 6). Data Collectors agreed that viewing the TASK III tip sheets would be helpful “…one thing I thought is that I wanted to add about the training is just that I think that it might be helpful for us to go through what the Task tip sheets look like and also what that pamphlet looks like” (Data Collector, pg. 6).

 **Delivery**. Data Collectors thought that caregivers enjoyed connecting with them during the calls. They agreed that delivering the TASK III data collection calls by telephone was efficient. Data collectors were instructed to call up to 10 calls during baseline, week 8 and 12 week calls.Data Collectors thought it was a good idea to have a standardized protocol with number of calls, “I guess I was wondering if there could be some kind of standardized procedure moving forward, as far as the number of times that we decide that we're going to call them. Maybe it can be even some kind of conditional logic” (Data Collector, pg. 9 &10**).** When asked about their favorite part of the process “I think one of my favorite parts personally is just the 12-week calls when we get to that caregiver satisfaction section of the questions. And I get to really hear like how this program has really impacted them so positively. I think that's one of the most incredible parts ever” (Data Collector, pg. 14). Time was a concern, “And I always try to monitor the time. I don't rush anyone, but I just look at the time just to see how long are we spending on the section? You know, could I do something to help move it along?” (Data Collector, pg. 15). When probed about noticing any differences amongst caregivers, gender was mentioned, “Gender-wise, sometimes with the men it's like hurry up, let's get through it. So there's not a lot of chit chat” (Data Collector, pg. 15). .

 **Receipt.** A data collector mentioned difficulty with delivering the Oberest Caregiving Burden scale (OCBS) “…once we get to questions regarding how they felt about giving care and stuff, especially like the OCBS, they'll be like, oh I found it a little difficult in the beginning but now things are kind of better. That they're just different. So what should I base that off of? And so I think normally I've been saying just let it be an average of that or something closer to where you are at right now” (Data Collection, pg. 11). The OCBS uses two different scales. The first is related to the time it takes a caregiver to assist the stroke survivor with tasks (identify what the scale is) and then how difficult it is to complete them (explain this scale). A data collector suggested “...if you could combine that into one single table that might be more helpful for them or just even helpful for maybe me personally” (Data Collector, pg. 11 & 12).

***TASK III Intervention Fidelity***

**Design.** Nurses discussed their perception of the TASK III intervention design. Several nurses made comments about how well the TASK III resource guide was designed. A TASK nurse commented “…every person that I have worked with, even from the onset, have just absolutely loved the binder and felt that it was so essential as a caregiver and often wished they had had it even earlier when the stroke survivor actually had the stroke” (TASK III, pg. 1, 2). Another nurse mentioned how essential the weekly caregiver calls were, in addition to the binder, “…the calls from the nurse, I think that is such an essential piece” (TASK III, pg. 2).

A few of the nurses thought some of the tip sheets could have gone into more depth. “…there were a couple of tip sheets that I thought could have gone a little bit more in depth that it kind of introduced them to an idea, but for some people they need a little bit more guidance into it. In particular, it’s related around the goals and the wellness of the caregiver. I kind of feel like it just kind of took them to the edge, but that was it” (TASK III, pg. 2). A few of the nurses thought they could have used more guidance with having conversations related to spirituality. “…could have used is a little bit more of a tip sheet about the spiritual aspect of taking care of yourself” (TASK III, pg. 2). Religiosity was brought up, “I’m wondering if we need to develop the questions a little bit more about coping because some people might use prayer or their religious affiliation, or others may not be believers and see the relevance” (TASK III, pg. 2).

 Nurses perceived that caregivers generally looked forward to the calls, “They just really look forward to the calls, and they express that by saying I’m so glad that you called, and I have somebody to vent and run things through and really are complementary of the binder (TASK III, pg.2). Technology was discussed, “I think an app would work better than the eBook” (TASK III, p. 8). Another suggestion was made about using iWatches instead of the pedometer as technology is moving fast enough. “The pedometers, I think technology is moving fast enough that a lot of people have iWatches now, and so that was a bit of a struggle because they can just put that watch on and track their steps” (TASK III, pg. 8).

 **Training.** Suggestions were made to improve training. “…maybe it’s better to do the roleplaying on a typical caregiver until you kind of get the hang of it and then get into those more difficult or challenging scenarios” (TASK III, pg. 14). A nurse discussed the benefits of the practice sessions, “I thought that the practice sessions were excellent, and being able to listen to yourself back” (TASK III, pg. 13). The orientation was described as “smooth” (TASK III, pg. 14). A nurse discussed using WebEx “I was a nervous wreck thinking how am I going to do this and negotiate through this whole WebEx conference and sharing a screen, but thanks to her patience and then just getting in there and the patience of the caregivers too that did do their calls that way, I became a lot more comfortable with it” (TASK III, pg. 10). Another nurse mentioned wanting a checklist “The only thing I wanted for myself was more of a checklist so I could remember to do everything that was required, follow this step, and then you do this, and then you put it in REDCap and stuff like that” (TASK III, pg. 12).

 **Delivery.** When asked about how they conduct their calls “For me, I’m kind of always guided by the concerns and needs checklist”(TASK III, pg. 15).Calls were conducted from the nurse’s personal cell phone. One nurse inquired about receiving cell phones in future related studies “That actually brought me to a question I was going to ask, and that is, will the next phase have cell phones that will be issued and cell phones that will cut off like at a certain time? (TASK III, pg. 17). After nurse call 9, the nurse and caregiver weekly calls end. The nurse’s discussed the challenges of having nurse call 9 call with the caregiver “So, it was like letting go of a friend” (TASK III, pg. 18).

 **Receipt.** Caregivers had a choice on which technologies they wanted to utilize during their calls with the nurse (i.e, phone, online video conferencing WebEx, FaceTime). Nurses discussed technology as it relates to the caregiver’s age. “What I found was there was sort of an age thing. Even the one gentleman that I had that was very good at the computer, he was in his 80s. He preferred not to use the computer. So, I just think it’s more the older, the 85, 87-year-old, and these people were very busy, the two that I’m thinking of” (TASK III, pg. 16). This underscores the importance of having a flexible program where technology is available according to the needs and preferences of the caregivers.

 **Enactment.** Nurses thought caregivers would use the resource guide in the future, “…for the most part, I’d say 85% to 90% are reading it, and I’m telling you they know this as well as we do. So, I think they will continue with it” (TASK III, pg. 16). Another stated, “So, I do find that most of them will use it, and then they mention that they went back and read it, or they went to stroke.org and got some more information. So, I think they are using the interventions” (TASK III, pg. 16).

***ISR Intervention Fidelity***

**Design.** ISR nurses were asked about their thoughts on the design of the ISR program. They were equipped with a pamphlet from the American Stroke Association to reference during calls with stroke family caregivers. ISR nurses felt like the pamphlet was a nice point of reference for initiating conversations. It contained excellent information for caregivers and was useful during the calls. A number of stroke family caregivers mentioned it was a shame that they did not get this information in the beginning upon diagnosis of the stroke or discharge from the hospital. ISR calls occurred weekly. The nurses felt the cadence of the weekly calls was nice and they could see progression toward the end of the program. ISR nurses reported that most caregivers felt that the 8 weekly calls, with a 12 week booster a month later, were sufficient; however, there were a few caregivers who wished the program went beyond the 12 week booster for ongoing support. The biggest challenge for the nurses was resisting the temptation to go outside of the parameters of their role as an Information, Support, and Referral Nurse. It was difficult to listen and not give advice or recommendations. ISR nurses had mixed feelings about the use of technology with caregivers. Initially the nurses focused on the traditional phone calls and the hard copy of the ASA pamphlet. As the study moved along, they made an effort to encourage more use of the Task III website, the ISR link, and the ASA websites. The majority of caregivers elected to communicate by the telephone and did not opt for videoconferencing. More in depth ISR nurse training on the technology up front might have contributed to increased uptake of technology with caregivers.

 **Training.** ISR nurses received in depth training on the calling protocol and documentation and were provided with the opportunity to do practice phone calls prior to calling caregivers. They were required to participate in a few self-evaluations and were evaluated by a study team member who listened to the recorded calls. The nurses indicate that listening to recordings of calls and doing self-evaluations were helpful. Nurses were able to make adjustments to improve future calls. One nurse stated, “I was really happy with how much training I got because then I could practice and re-practice…” (ISR, p. 10) The nurses agreed that the face-to-face training calls were very helpful, and they could have benefited from doing mock documentation as well. One nurse stated, “…this is the first time I’ve gotten what I would call training and orientation…and it was very helpful.” (ISR, p. 10 & 11)

 **Delivery.** The nurses felt like they were able to build a rapport with the caregivers. The calls allowed the stroke family caregivers to talk about things they are going through or things that were important to them. Weekly ISR nurse team meetings allowed the nurses to learn from each other and explore any issues that arose. There was discussion about the study protocol and the nurses shared their experiences and advice for documentation or communication techniques to facilitate conversation with caregivers. Some examples of communication techniques discussed included asking open-ended questions and establishing rapport. One nurse stated, “I always open the conversation with ‘this is an opportunity for you to talk about things that you’re going through or things that are important to you.” ISR nurses shared some frustration with protocol restrictions. As one ISR nurse stated, “…as nurses we’re fixers and some of the solutions are so obvious.” It was difficult to not be able to offer solutions.

 **Receipt.** ISR nurses felt that the calls were well appreciated. A portion of the study took place during COVID. One nurse stated “…the calls were appreciated because so many people felt isolated, especially people that were retired, that they were by themselves…especially with COVID.” Nurses felt like individual circumstances impacted how calls were received. “…it’s daunting to see how many different things they’re (caregivers) juggling.” Some caregivers were very chatty, and others were more reserved.

 **Enactment.** Some of the caregivers remarked that they would go back to the ASA pamphlet to review information when they had issues come up with the stroke survivor. Caregivers would refer to the pamphlet and either find reassurance that they were doing what they should be doing or find reminders of things to try or consider when caregiving. Caregivers remarked that it was helpful to talk about their situation with someone. Some caregivers would report back one week on something they did that may have been discussed the week before. For example, one caregiver talked about how he did not like to ask for help. The following week, he reported that he talked to people at his church about his situation and found someone who had gone through something similar.

**Discussion**

***Recruitment and Screening Fidelity***

Screeners overwhelmingly felt that reaching the next of kin was crucial for recruitment even though after a few tries, they would contact the stroke survivor. The questionnaire used during the screening process was well-liked and one screener felt it had a smooth transition. In addition to reaching the caregiver, finding a good time post discharge was important. If they’ve been caregiving for a while, the caregiver didn’t view it as difficult. Screeners thought the time you reached the caregiver played a role in whether they wanted to participate or not. A screener noted that there may be some cultural differences and some caregivers may not view tasks as a burden. The training was viewed as an essential part of the screening process.

***Data Collection Fidelity***

A few of the data collectors agreed that having a centralized area for communication between nurses and data collectors would be helpful. The data collectors were kept blinded and were unaware of the group the caregiver randomized to in order to minimize bias. As a result, the data collectors didn’t interact with the rest of the team other than the Principal Investigator and Project Manager. Having a centralized area for communication could help form a connection to other team members and learn important information about the caregiver (i.e., preferred telephone number).

Several of the data collectors agreed that having a reminder call for the caregiver could be helpful. Data collectors felt it was important to monitor the length of calls, keeping caregivers at the forefront. Shortening the questionnaires was mentioned in order to help with the length of call with suggestions on cutting down the Dietary Screener questionnaire. In regards to training, data collectors suggested more practice calls and reviewing of the TASK III tip sheets to become more familiar with other parts of the study,

***TASK III Intervention Fidelity***

Overall, TASK III nurses thought the TASK III resource guide was well designed mentioning how much the caregivers loved the binder. Although, the resource guide was well designed a few of the nurses thought some of the tip sheets could have gone more in depth, specifically sleep, goals and wellness of caregiver. A suggestion was made to have guidance around discussion about spirituality with caregivers. Nurses recalled that caregivers generally looked forward to the calls and the challenges after the final weekly call with the caregivers. Conducting training through role-playing was highly favored among nurses as well as having practice sessions.

***ISR Intervention Fidelity***

ISR nurses found the American Stroke Association pamphlet useful as a starting point for conversations with caregivers. Many caregivers indicated they wished they had been given the pamphlet sooner or at discharge from the hospital. ISR nurses sometimes found it challenging to stay within their role and just listen and provide support, and not provide suggestions or tips to the caregivers. Some ISR nurses felt they could have benefited from having the opportunity to practice documentation in REDCap. Despite the struggle to just listen to the caregivers and not intervene, the nurses felt like they were well trained for their role and said the mock training calls were instrumental to their preparation. The nurses agreed that they were able to quickly establish rapport with the caregivers and perceived that the calls were beneficial and appreciated by the caregivers.

***Limitations***

Adherence to protocol was carefully monitored in this pilot study, but when implemented in the real world, adherence to a structured protocol may not be feasible. Generalizability is limited in that it was focused on a single stroke family caregiver intervention feasibility study, and the sample of research team members was small (N=12). While research team members were from diverse backgrounds, the majority were female.

***Implications for Future Research and Practice***

Although this study looked at treatment fidelity from the research team perspective, including research team members serving in recruitment and screening and data collector roles provided a unique perspective that is not often represented in the literature. More research is needed that documents fidelity for multiple roles in larger randomized control trials. This study provided valuable input from research team members regarding fidelity that may be even more important when implementing programs into practice settings.

**Conclusion**

Treatment fidelity remains an integral part of clinical trial management. Gaining the perspectives of research staff regarding treatment fidelity provides valuable implications for improvement in protocols. Research staff perspectives regarding fidelity of recruitment, screening, and data collection procedures are rarely presented in the literature, yet are important for study implementation. This study provided unique research team perspectives regarding detailed procedures for monitoring fidelity across several study roles (recruitment and screening, data collection, TASK III program, ISR program). Findings will be used to enhance the TASK III feasibility study in preparation for a future well-powered randomized controlled clinical trial. Researchers are urged to study research team perspectives regarding fidelity of procedures across all study roles, not only to improve the rigor of randomized controlled trials, but to also enhance future implementation of programs into practice.

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**Table 1. Sample Characteristics.**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **f** | **%** |
| **Type of Participant a** |  |  |
|  Screener | **4** | **33%** |
| Data Collector | **4** | **33%** |
| TASK III Nurse  | **2** | **17%** |
|  ISR Nurse | **3** | **25%** |
| Other Team Member (i.e., PI, Co-I,  Collaborator, Project Manager) | **4** | **33%** |
| **Gender**  |  |  |
| Male | **1** | **8%** |
|  Female | **11** | **92%** |
| **Race** |  |  |
|  Black or African American  | **4** | **33%** |
|  Asian  | **1** | **8%** |
|  White or Caucasian | **7** | **58%** |
| **Ethnicity** |  |  |
|  Hispanic or Latino | **0** | **0%** |
| **Current Students** |  |  |
|  Undergraduate | **1** | **8%** |
|  Masters | **0** | **0%** |
|  Doctoral | **4** | **33%** |
| **Highest Degree Obtained** |  |  |
| High school | **1** | **8%** |
| Undergraduate | **4** | **33%** |
|  Masters | **3** | **25%** |
|  Doctoral | **4** | **33%** |
| **Employment** |  |  |
|  Full time | **5** | **42%** |
|  Part time | **7** | **58%** |
|  Retired |  |  |

**a Some participants served in multiple roles (Total participants N=12)**

**Table 2. Interview Guide for each Focus Group.**

|  |
| --- |
| **Recruitment and Screening** |
| **Design**How the program was designed, including the use of technology. | 1. What are your thoughts about how the recruitment process was designed (questionnaires, calling stroke survivors and their next of kin)?
2. What are your thoughts about the screening questionnaire (REDCap, etc.)?
3. Describe cultural perspectives regarding the design of the screening process. Cultural perspectives from caregivers?
4. Cultural perspectives from research staff?
 |
| **Training**Orientation, role playing, training, team meetings. | 1. What did you like about your training and orientation?
2. What improvements would you make?
3. What are your thoughts about discussing screening during weekly team meetings?
4. Cultural perspectives regarding these meetings (from research staff perspective)?
 |
| **Delivery**What it is like to deliver the calls.  | 1. What is it like to deliver the screening calls?
2. What do you like most about delivering the screening calls?
3. What improvements would you make?
4. Cultural perspectives regarding delivery (from research staff perspective?)
 |
| **Receipt**How participants received the calls.  | 1. How well do you think caregivers understood the TASK III study? (Were there any questions that caregivers had trouble with?)
2. What do you think caregivers liked best about the screening calls?
3. What do you think caregivers liked least about the screening calls?
4. Cultural perspectives regarding receipt of the program (from caregiver perspective?)
 |
| **Closing Remarks** | 1. What further thoughts do you have that we have not covered?
2. What did you think of this process of this focus group?
3. What did you like best?
4. How can we improve this process?
5. What other topics should we have covered?
 |
| **Data Collection** |
| **Design**How the program was designed, including the use of technology. | 1. What are your thoughts about how the Data collection process was designed (questionnaires, calls from the data collectors)?
2. What are your thoughts about how the data collection technologies were designed (pedometers, recorders, OneDrive, REDCap, etc.)?
3. Describe cultural perspectives regarding the design of the Data collection process. Cultural perspectives from caregivers? Cultural perspectives from research staff?
 |
| **Training**Orientation, role playing, training, team meetings. | 1. What did you like about your training and orientation?
2. What improvements would you make?
3. What are your thoughts about the Data Collection meetings with the program manager?
4. Cultural perspectives regarding these meetings (from research staff perspective)?
 |
| **Delivery**What it is like to deliver the calls.  | 1. What is it like to deliver the Data collection calls?
2. What do you like most about delivering the Data collection calls?
3. What improvements would you make?
4. Cultural perspectives regarding delivery (from research staff perspective?)
 |
| **Receipt**How participants received the calls.  | 1. How well do you think caregivers understood the Data collection questions? (Were there any questions that caregivers had trouble with?)
2. What do you think caregivers liked best about the Data collection calls?
3. What do you think caregivers liked least about the Data collection calls?
4. Cultural perspectives regarding receipt of the program (from caregiver perspective?)
 |
| **Closing Remarks** | 1. What further thoughts do you have that we have not covered?
2. What did you think of this process of this focus group?
3. What did you like best?
4. How can we improve this process?
5. What other topics should we have covered?
 |
| **TASK III Program** |
| **Design**How the program was designed, including the use of technology. | 1. What are your thoughts about how the TASK III intervention was designed (TASK III Resource Guide tip sheets, calls from the nurse)?
2. What are your thoughts about how the TASK III intervention technologies were designed (pedometers, mailed hard copy, website, ebook, USB, telephone, facetime, videoconferencing)? What about documentation processes? (Recorders, OneDrive, REDCap, etc.)?
3. Describe cultural perspectives regarding the design of TASK III. Cultural perspectives from caregivers? Cultural perspectives from research staff?
 |
| **Training**Orientation, role playing, training, team meetings. | 1. What did you like about your training and orientation?
2. What improvements would you make?
3. What are your thoughts about the weekly TASK III meetings?
4. Cultural perspectives regarding these meetings (from research staff perspective)?
 |
| **Delivery**What it is like to deliver the calls.  | 1. What is it like to deliver the TASK III intervention?
2. What do you like most about delivering the TASK III intervention?
3. What improvements would you make?
4. Cultural perspectives regarding delivery of the intervention (from research staff perspective?)
 |
| **Receipt**How participants received the calls.  | 1. How well do you think caregivers understood the TASK III intervention?
2. What do you think caregivers liked best about the TASK III intervention?
3. What do you think caregivers liked least about the TASK III intervention?
4. Cultural perspectives regarding receipt of the intervention (from caregiver perspective?)
 |
| **Enactment**How participants used what they learned in everyday life. | 1. How well do you think that caregivers used the TASK III intervention in their everyday lives? Provide examples from your interactions with caregivers.
2. What parts of the TASK III intervention were most used in their everyday lives?
3. What parts of the TASK III intervention were not used in their everyday lives?
4. Cultural perspectives regarding enactment of the intervention (from caregiver perspective?)
 |
| **Closing Remarks** | 1. What further thoughts do you have that we have not covered?
2. What did you think of this process of this focus group?
3. What did you like best?
4. How can we improve this process?
5. What other topics should we have covered?
 |
| **ISR Program** |
| **Design**How the program was designed, including the use of technology. | 1. What are your thoughts about how the ISR program was designed (ASA pamphlet, calls from the nurse)?
2. What are your thoughts about how the ISR program technologies were designed (pedometers, mailed hard copy ASA pamphlet, websites, telephone, thoughts about using facetime, videoconferencing)? What about documentation processes? (Recorders, OneDrive, REDCap, etc.)?
3. Describe cultural perspectives regarding the design of the ISR program. Cultural perspectives from caregivers? Cultural perspectives from research staff?
 |
| **Training**Orientation, role playing, training, team meetings. | 1. What did you like about your training and orientation?
2. What improvements would you make?
3. What are your thoughts about the weekly ISR meetings?
4. Cultural perspectives regarding these meetings (from research staff perspective)?
 |
| **Delivery**What it is like to deliver the calls.  | 1. What is it like to deliver the ISR program?
2. What do you like most about delivering the ISR program?
3. What improvements would you make?
4. Cultural perspectives regarding delivery (from research staff perspective?)
 |
| **Receipt**How participants received the calls.  | 1. How well do you think caregivers understood the ISR program?
2. What do you think caregivers liked best about the ISR program?
3. What do you think caregivers liked least about the ISR program?
4. Cultural perspectives regarding receipt of the program (from caregiver perspective?)
 |
| **Enactment**How participants used what they learned in everyday life. | 1. How well do you think that caregivers used the ISR program in their everyday lives? Provide examples from your interactions with caregivers.
2. What parts of the ISR program were most used in their everyday lives?
3. What parts of the ISR Program were not used in their everyday lives?
4. Cultural perspectives regarding enactment of the program (from caregiver perspective?)
 |
| **Closing Remarks** | 1. What further thoughts do you have that we have not covered?
2. What did you think of this process of this focus group?
3. What did you like best?
4. How can we improve this process?
5. What other topics should we have covered?
 |

**Table 3. Strategies for Monitoring Fidelity across Research Staff Roles.**

|  |
| --- |
| **Recruitment and Screening** |
| **Design** | -Structured protocol for telephone recruitment and screening using a script-Recruitment lists obtained from clinical sites; flyers distributed with postcards-Packets mailed: letter signed by healthcare providers, 2 copies of informed consent, postage paid return envelope for signed informed consent -Up to 10 calls made to survivors and caregivers various times of the day-Scheduling and documentation in REDCap |
| **Training** | -Structured training manual for screeners-Face to face session lasting 1 hour -Role playing until checked off-Weekly meetings with project manager reporting on assigned caregivers |
| **Delivery** | -Documentation in REDCap included scheduling, mailings, informed consent, responses to questions in the screening script, and narrative notes.  |
| **Receipt** | - Packets mailed: letter signed by healthcare providers, 2 copies of informed consent, postage paid return envelope for signed informed consent-Reviewed packets with caregivers during recruitment and screening calls to enhance caregiver understanding of the study.  |
| **Data Collection** |
| **Design** | -Structured protocol for telephone data collection using an interview guide-Packets mailed: Extra copy of informed consent, list of scheduled sessions, and response forms for data collection interviews -Calls at baseline, 8 weeks (end of intervention), and 12 weeks (after booster)-Calls audio-recorded and monitored for adherence to protocol-Pedometer used to track number of steps in past week at 8 and 12 weeks-Scheduling and documentation in REDCap; audio-recordings in OneDrive  |
| **Training** | -Structured training manual for data collectors-Face to face session lasting 2 hours-Audio-recorded role playing until checked off-Audio-recorded session with first caregiver, then checked periodically-Weekly meetings with project manager reporting on assigned caregivers |
| **Delivery** | -Structured protocol checklist used to measure protocol adherence-Calls audio-recorded and monitored for adherence to protocol-Documentation in REDCap included scheduling, mailings, informed consent, number of minutes on calls with the data collector, responses to instruments in the interview guide, pedometer readings 8 and 12 weeks, and narrative notes.  |
| **Receipt** | -Packets mailed: Extra copy of informed consent, list of scheduled sessions, and response forms for data collection interviews -Reviewed packets with caregivers during data collection calls to enhance caregiver understanding of the study and the questions being asked.  |
| **TASK III Program** |
| **Design** | -Structured TASK III needs and concerns framework with skill-building-TASK III Resource Guide with 35 content and 7 skill-building tip sheets -American Heart Association/American Stroke Association pamphlet-Packets mailed: Extra copy of informed consent, list of scheduled sessions, TASK III Resource Guide binder, TASK III USB drive, instructions for TASK III Website, instructions for TASK III eBook, American Heart Association/American Stroke Association pamphlet, and Pedometer.-8 weekly calls from a nurse (RN) with booster call a month later-Dose monitored by tracking number of minutes on calls with the nurse-Calls audio-recorded and monitored for adherence to protocol-Choice of telehealth technology for TASK III Resource Guide-Choice of telehealth technology for TASK III calls from the nurse-Pedometer used to track number of steps taken between each call-Scheduling and documentation in REDCap; audio-recordings in OneDrive |
| **Training** | -Structured training manual for the TASK III program -Face to face session lasting 8 hours-Audio-recorded role playing until checked off-Audio-recorded session with first caregiver, then checked periodically-Weekly research team meetings with PI reporting on assigned caregivers |
| **Delivery** | -Structured protocol checklist used to measure protocol adherence-Calls audio-recorded and monitored for adherence to protocol-Dose monitored by tracking number of minutes on calls with the nurse-Documentation in REDCap included scheduling, number of minutes on calls with the nurse, specific content and skill-building tip sheets used during each call, goals set based on goal setting tip sheet, types of telehealth technologies used, pedometer readings, and narrative notes.  |
| **Receipt** | -Packets mailed: Extra copy of informed consent, list of scheduled sessions, TASK III Resource Guide binder, TASK III USB drive, instructions for TASK III Website, instructions for TASK III eBook, American Heart Association/American Stroke Association pamphlet, and Pedometer.-Reviewed packets with caregivers during TASK III calls to enhance caregiver understanding of the study and the questions being asked. -Active listening strategies to assess caregiver understanding during call-Asked caregivers about amount of information from prior call (too little, just right, too much)-Asked caregivers about how many minutes they viewed materials since the last call (TASK III binder, TASK III Website, TASK III eBook, TASK III USB drive, American Heart Association/American Stroke Association pamphlet, American Heart Association/American Stroke Association website) |
| **Enactment** | -Asked caregivers about each prior call the following questions: -The strategies you tried (no strategies, tried a little, tried some, tried a lot) -How helpful (no help, little helpful, moderately helpful, very helpful, extremely helpful) -Whether problems discussed were resolved (not resolved, making progress, fully resolved, resolved on it’s own)-Reviewed progress on goals and action plans during each call-Active listening strategies to assess caregiver progress during each call |
| **ISR Program** |
| **Design** | -Structured ISR procedures for information, support, and referral-American Heart Association/American Stroke Association pamphlet-Packets mailed: Extra copy of informed consent, list of scheduled sessions, American Heart Association/American Stroke Association pamphlet, and Pedometer.-8 weekly calls from a nurse (RN) with booster call a month later-Dose monitored by tracking number of minutes on calls with the nurse-Calls audio-recorded and monitored for adherence to protocol-Choice of telehealth technology for calls from the nurse-Pedometer used to track number of steps taken between each call-Scheduling and documentation in REDCap; audio-recordings in OneDrive |
| **Training** | -Structured training manual for the ISR program-Face to face session lasting 4 hours-Audio-recorded role playing until checked off-Audio-recorded session with first caregiver, then checked periodically-Weekly research team meetings with PI reporting on assigned caregivers |
| **Delivery** | -Structured protocol checklist used to measure protocol adherence-Calls audio-recorded and monitored for adherence to protocol-Dose monitored by tracking number of minutes on calls with the nurse-Documentation in REDCap included scheduling, number of minutes on calls with the nurse, types of telehealth technologies used, pedometer readings, and narrative notes.  |
| **Receipt** | -Packets mailed: Extra copy of informed consent, list of scheduled sessions, American Heart Association/American Stroke Association pamphlet, and Pedometer.-Reviewed packets with caregivers during TASK III calls to enhance caregiver understanding of the study and the questions being asked. -Active listening strategies to assess caregiver understanding during call-Asked caregivers about amount of information from prior call (too little, just right, too much)-Asked caregivers about how many minutes they viewed materials since the last call (American Heart Association/American Stroke Association pamphlet, American Heart Association/American Stroke Association website) |
| **Enactment** | -Active listening strategies to assess caregiver progress during each call |