



Published in final edited form as:

Clin Rehabil. 2016 May ; 30(5): 495–507. doi:10.1177/0269215515585134.

Comparing treatment fidelity between study arms of a randomized controlled clinical trial for stroke family caregivers

Susan M McLennon¹, Rebecca D Hancock¹, Kathleen Redelman¹, Lisa L Scarton¹, Elizabeth Riley¹, Bobbie Sweeney, RN, BSN¹, Barbara Habermann², Nnette M Jessup¹, and Tamilyn Bakas¹

Indiana University School of Nursing, Indiana University, United States

University of Delaware College of Health Sciences, United States

Abstract

Objective—To compare treatment fidelity among treatment arms in the Telephone Assessment and Skill-Building Kit study for stroke caregivers (TASK II) with respect to: 1) protocol adherence; 2) intervention dosage; and 3) nurse intervener perspectives.

Design—A randomized controlled clinical trial design.

Setting—Urban, community, midwestern United States.

Subjects—254 stroke caregivers (mean \pm SD age, 54.4 \pm 11.8 years), 55 (22.0%) males and 199 (78.4%) females) randomized to the TASK II intervention (n=123) or an Information, Support, and Referral (ISR) comparison group (n=131).

Interventions—TASK II participants received the TASK II Resource Guide; ISR participants received a standard caregiver brochure. At approximately 8 weeks after discharge, both groups received 8 weekly calls from a nurse, with a booster call 4 weeks later.

Measures—Protocol adherence was evaluated with the TASK II Checklist for Monitoring Adherence. Intervention dosage was measured by the number of minutes caregivers spent reading materials and talking with the nurse. Nurse intervener perspectives were obtained through focus groups.

Results—Protocol adherence was 80% for the TASK II and 92% for the ISR. As expected, intervention dosage differed between TASK II and ISR with respect to caregiver time spent reading materials (t=−6.49; p<.001) and talking with the nurse (t=−7.38; p<.001). Focus groups with nurses yielded further evidence for treatment fidelity and recommendations for future trials.

Conclusions—These findings substantiate treatment fidelity in both study arms of the TASK II stroke caregiver intervention trial [NIH R01NR010388; [ClinicalTrials.govNCT01275495](https://clinicaltrials.gov/NCT01275495)].

Corresponding author. Susan M McLennon, School of Nursing, Indiana University 1111, Middle Dr. NU E411, Indianapolis, Indiana 46202-5107, smclenno@iu.edu.

Competing interests

There are no other competing interests.

Keywords

family caregivers; stroke; behavioral research; telephone assessment

There is a need for greater attention to ensuring and reporting treatment fidelity in clinical trials.¹⁻³ Much of the limited literature on treatment fidelity in behavioral research has focused on adherence in the experimental group, with less attention given to the comparison group.⁴⁻⁷ Monitoring fidelity in both groups is essential to establish treatment differentiation⁸ and to ensure treatment components are delivered as designed, thus reducing the risk for Type I and Type II errors.^{4,9}

A subgroup of the National Institutes of Health (NIH), the Behavior Change Consortium (BCC), has developed guidelines to improve intervention adherence and protect the scientific rigor of behavioral research. The guidelines include a framework comprised of five elements: study design, personnel training, protocol delivery, participant receipt, and enactment.^{10, 11} *Design* ensures adequate hypothesis testing relative to the underlying theory and clinical processes. *Training* is assessed by evaluation of the research staff ability to deliver the intervention. *Delivery* is an evaluation of consistent protocol delivery. *Receipt* is an indication the protocol was received and understood by the participant. *Enactment* is an assessment of participant performance of behavioral skills or tasks outside of the study protocol.

Findings from recent systematic reviews of outcomes from clinical trials suggest that evidence for treatment fidelity is lacking.^{1,3} In the neuro-rehabilitation literature, although treatment fidelity has been recommended as a key component to intervention testing,¹¹ a review of aphasia treatment studies over the last decade indicated only 14% reported such data.¹² Among caregiver trials, only two studies offered evidence for treatment fidelity following the National Institutes of Health Behavior Change Consortium framework.^{7,12,14} Additionally, in the few studies where treatment fidelity was reported, most focused on protocol adherence in the experimental group and lacked evidence for treatment differentiation.^{6-8, 15}

To address this gap, researchers from the Telephone Assessment and Skill Building (TASK II) Intervention Study for Stroke Caregivers clinical trial used a novel approach of quantitative and qualitative methods to evaluate treatment fidelity following the NIH Behavior Change Consortium framework. In addition to comparing treatment fidelity in both study arms, the researchers held focus groups with the nurse interveners to determine their perspectives on treatment fidelity. Further information about the original TASK intervention [NIH K01NR008712; [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00264745) NCT00264745]¹⁶⁻¹⁸ and the TASK II trial [NIH R01NR010388; [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01275495) NCT01275495] has been published elsewhere.¹⁹⁻²¹ Analyses of the primary outcomes from the TASK II trial are ongoing.

The purposes of these analyses, were to compare the TASK II (experimental) and Information, Support, and Referral (ISR) (comparison) groups with respect to: 1) protocol adherence; 2) intervention dosage (i.e., nurse call time in minutes; time spent reading study materials; TASK II participant call ratings); and 3) nurse intervener perspectives on

treatment fidelity. It was hypothesized there would be: 1) no significant differences in protocol adherence between the two study arms; and 2) significant differences in intervention dosage between the two study arms.

Methods

The primary purpose of the randomized controlled clinical trial was to determine the efficacy of the TASK II intervention (n=123) compared to the Information, Support, and Referral (ISR) (n=131) group. The study received approval from the University Institutional Review Board and informed consent was obtained from all participants. Caregivers were persons who considered themselves to be the main (non-paid) person providing most of the care for a stroke survivor. Caregivers were primarily family members (spouse/significant other, adult child, other relative or friend) and were randomly assigned to either the TASK II or Information Support and Referral group after baseline data was collected. Nurse interveners were hired and trained for either the TASK II or Information, Support, and Referral group. Because of the content of the telephone calls, nurses were required to have a registered nurses license. The trial consisted of nine nurse-led telephone calls to primary caregivers, beginning within 8 weeks after stroke survivors were discharged.

In the TASK II group, participants received the TASK II Resource guide, a pamphlet from the American Heart Association (AHA) entitled, "Caring for Stroke Survivors,"²² and calls from trained nurses who taught caregivers how to: a) assess their needs for providing care for the stroke survivor, b) assess their personal needs as a result of caregiving, and c) empower caregivers to independently address current and future needs using innovative skill-building strategies.^{16, 17} The TASK II Resource guide was the intervention toolkit that contained tips sheets and skill-building activities designed for stroke family caregivers and addressed commonly encountered caregiver needs and concerns. If randomized to the Information, Support, and Referral group, stroke caregivers were mailed an information packet about the study, the same AHA brochure²² and received calls from trained study nurses who used therapeutic communication techniques including active listening and referral to the brochure or their physician for additional resources or information.

Methods used to enhance and monitor treatment fidelity included the use of detailed training manuals and podcasts, training booster sessions, audio and video recordings and reviews, centralized access to intervention recordings, quality checklists, and frequent team meetings.^{4, 11, 14, 23} Specific details about the integration of the five elements from the Behavior Change Consortium can be found in Table 1.

Adherence to the protocol was assessed by members of the research team and study investigators using a 27-item Checklist for Monitoring Adherence created specifically to address the unique components of the TASK II study. See Table 2 for items addressed on the checklist. Items applicable to the Information, Support, and Referral group were selected, following recommended procedures,^{9, 10} to assess adherence (13-items; 1–4, 18–25, 27). All nurse intervener calls to stroke caregivers were audio-recorded. Adherence was monitored by self-evaluation (interveners) and compared with study investigator evaluations of audio-recorded calls at six to eight week intervals. Interveners listened to their audio-recordings

after the call to complete the self-evaluations. Allowing the interveners to self-evaluate their own calls prior to meeting with the study investigator enhanced the training process. Deviations from protocol, identified through negative responses on the adherence checklist, were addressed by additional training and monitoring.

Upon study completion, additional recorded calls were evaluated by one of the most experienced study intervention nurses to ensure a representative subset was evaluated in this analysis (i.e. inclusion of all nine calls, all interveners, and participants from early, middle, and later study time periods), and to ensure an adequate sample size for this study. In each group the adherence checklist reports, prospective and retrospective, purposively sampled, underwent ongoing analyses until an adequate sample size was reached. Adequacy was determined based on consistency in adherence ratings. Adherence on the checklist was scored with dichotomous (Y/N) responses for presence or absence of each item. Frequencies and percentages were calculated for each item. Two-way Chi-square tests of independence were calculated for applicable items to compare group differences.

The amount of time nurse interveners spent on the weekly calls was recorded upon completion of each call. Intervention dosage was calculated for nurse call duration (minutes) and time caregivers spent reading study materials (minutes) for the prior week. Study materials for the TASK II group were the TASK II Resource Guide and the American Heart Association (AHA) brochure.²² For the Information, Support, and Referral group it was the same brochure. Descriptive statistics were used to analyze duration of calls and time spent reading materials. Independent-samples t-tests were conducted to compare mean differences between the TASK II and Information, Support, and Referral groups on each of the nine calls (duration, time with materials) and total time. Additionally, participants in the TASK II group were asked to rate each call on the amount of information received (BCC framework “receipt”) as 1=too little; 2=just right; 3=too much. They were also asked to rate each call for data such as “usefulness of information used” (BCC framework “enactment”) as 1=not used; 2=little; 3=some; 4=a lot. Additional assessment questions with respective rating scales can be found in Table 4.

As a retrospective review of treatment fidelity, the nurse interveners participated in two focus groups with the investigators, one for the TASK II interveners and another for the Information, Support, and Referral interveners. Nurses recounted their experiences with the design, training, delivery, receipt, and enactment phases of the TASK II or Information, Support, and Referral intervention. Suggestions for improvement in treatment fidelity methods were also discussed. Results were transcribed, verified by a second researcher, and placed in an Excel spreadsheet. The spreadsheet was distributed to each nurse, who independently identified descriptive phrases (subcategories) under the categories of design, training, delivery, receipt, and enactment following methods for descriptive content analyses.^{24, 25} At a follow up meeting with each group, results were compared and discussed until agreement was reached.

Results

A total of five nurse interveners completed 858 TASK II calls to the 123 caregivers randomized to the TASK II intervention. A total of four nurse interveners completed 1013 calls to the 131 caregivers randomized to the Information, Support, and Referral intervention.

Protocol adherence

Detailed results of protocol adherence for each of the checklist items for both study arms can be found in Table 2. Overall within group (TASKII) adherence to the checklist was 80% (range=28%–100%). Overall within group (Information, Support, and Referral) adherence to the checklist was 92% (R=63%–100%). Results for comparing percentages for adherence across both groups for shared items on the checklist for the TASK II and Information, Support, and Referral groups were 90% and 92%, respectively. Results of the chi-squared tests to examine the relationships between each of applicable items on the checklist demonstrated no significant differences between the TASK II and Information, Support, and Referral groups ($p<.05$).

Intervention dosage

A full description of the analyses for protocol dosage can be found in Table 3. Results of the independent samples t-tests indicated total mean scores from the two groups were significantly different ($t=-7.38$; $p<.001$). Mean scores between groups, for time spent on each call, were also significantly different for each weekly call, when analyzed individually. Results of the independent samples t-tests demonstrated total mean scores for the two groups on time spent reading materials were significantly different ($t=-6.49$; $p<.001$). Mean scores between groups were also significantly different for time spent reading materials at each weekly call, when analyzed individually.

Detailed results for participants randomized to the TASKII group on calls 1–9 overall evaluation ratings for receipt and enactment can be found in Table 4. The average across all nine calls for the amount of information (receipt) was “just right” (96%). Overall, 61% rated the call information as used (enactment) “some” or “a lot.” On average, most caregivers found the TASK II intervention to be useful, found strategies to be moderately helpful, and most made progress on resolving problems (Table 4).

Focus groups

The categories and subcategories derived for the two groups are depicted in Figure 1.

Representative quotes for each of the subcategories can be found in the supplementary Table found online.

For the TASK II nurse intervener group, there were 112 qualitative descriptions of the nurses’ experiences coded into subcategories based on the five NIH Behavior Care Consortium categories of design, training, delivery, receipt, and enactment. For the Information, Support, and Referral nurse intervener group, there were a total of 60

descriptive phrases coded similarly. Their comments provided a general evaluation of both the TASK II and ISR interventions.

Design—When asking nurses about their perception of the design component of treatment fidelity, they responded with comments about the TASK II Resource Guide. Several nurses thought it was well-designed and valuable for the caregivers and made several suggestions for improvements that included reorganization of the materials, addressing content gaps, addressing flexibility to allow for more tailoring to individual needs. Nurses noted that educational level of the nurse did not matter as much as quality of communication skills and the ability to follow the caregiver’s lead. The Information, Support, and Referral nurses reported the AHA brochure was helpful but needed additional information about financial issues. The weekly calls were generally acceptable as scheduled but some nurses suggested greater flexibility in the timing of the calls. Information, Support, and Referral nurses thought their experience was helpful in using effective communication skills, active listening techniques, and being able to pick up on clues provided by the caregivers. They offered suggestions for future design modifications to include instructions to address concerns for basic needs and safety and also documenting call summaries.

Training—The TASK II nurses suggested training improvements in these areas: : 1) knowledge of how to differentiate between stress and depression, so as to not overemphasize depressive symptoms; 2) listening to actual calls with experienced TASK II nurses; and 3) including audio-taped calls as exemplars for how to handle specific difficult situations (suicidal, depressed, overly talkative). They also expressed the need for more training on the skill-building tip sheets. The Information, Support, and Referral nurse interveners noted that active listening was particularly challenging “I felt extremely uncomfortable...and with repeated practice was able to overcome the teaching role.” A nurse said she was reassured that sometimes “conversations would be short and it’s okay, it was helpful to get that information that they [caregivers] may have more or less to talk about.”

Delivery—Nurses thought communicating with caregivers was an important aspect of the intervention. The skill-building tip sheets were considered to be key features of the TASK II Resource Guide. Weekly team meetings were considered integral to effective delivery of the TASK II intervention for learning and support. With respect to telephone delivery, they agreed that delivering the TASK II intervention by telephone was “quite feasible.” The caregiver needs assessment was important yet challenging, particularly on subsequent calls when they were asked to assess helpfulness of the previous call. One of the nurses offered the following as a suggested way to begin each call: “First I’m going to ask you about how our conversation went last week, then I’m going to ask you about this week, then I’m going to ask about future needs and concerns.” Information, Support, and Referral group nurses discussed the importance of using effective communication including establishing rapport, using opening statements, and asking open-ended questions. Study nurses expressed difficulty with the protocol restrictions in offering advice, education, and other information not found in the AHA brochure. The importance of documenting the content of the calls was also discussed. For example, “if I went back and looked at my notes, I could find out what to follow up on.”

Receipt—The TASK II nurses offered suggestions for using Resource Guide for the weekly calls. For example, a nurse said “[for a person] to sit and read the TASK II Resource Guide, there is no emotion... but to have it delivered by a nurse... have that investment in them, nurses were the hope in the kit.” Differences in caregiver education level, life experiences, and motivation levels were thought to influence caregiver receipt. The nurses agreed they had to “adapt their teaching style for each of those situations to make it work.” Information, Support, and Referral nurse interveners, reported that most caregivers thought the AHA brochure was helpful and cited the topics of reflex crying, depression, and signs of a stroke as discussed frequently. The nurses also noted variations in caregiver responses to the AHA brochure, primarily related to reading ability and educational levels.

Enactment—TASK II nurses reported the process of asking about the use and number of minutes spent reading study materials was “cumbersome.” They also noted examples of caregiver use of study information such as using the tip sheet about how to talk with health care professionals. The Information, Support, and Referral nurses reported caregivers used information from the AHA brochure such as taking time for themselves, attending an aphasia support group, and feeling more at ease about what to do when specific issues arose.

Discussion

These findings provide evidence for treatment fidelity in the TASK II stroke caregiver intervention trial. As expected, there were no differences across the two study arms when comparing protocol adherence, supporting minimal protocol drift. Also as expected, there were significant differences protocol dosage in call duration and time spent reading study materials between the TASK II and Information, Support, and Referral groups. Finally, focus groups with nurse interveners demonstrated evidence for treatment fidelity following the NIH Behavior Change Consortium in the areas of design, training, delivery, receipt, and enactment. They also offered suggestions for improvements that will be used in future trials.

Protocol adherence

For the TASK II group, there was a high level of overall adherence to the protocol. For items in which adherence rates were noted to be lower than 60%, the investigators noted opportunities for improvement with the nurse and provided retraining and re-evaluation. In addition, a general discussion of the item was held in the weekly team meetings for the benefit of all the intervention nurses. For example, in reference to item 11, when stress was present, the protocol led the nurse to assess for depressive symptoms and other emotions using skill-building tip sheets. Addressing the level of stress for each problem led some caregivers to believe that they should be experiencing more stress, and resulted in some nurses overemphasizing depressive symptoms and other negative emotions. During the early team meetings and protocol updates, this problem was discussed and the protocol was modified so that depressive symptoms were not always assessed in caregivers who were stressed, particularly if depressive symptoms had been assessed during prior calls. Eliminating the repeated assessments and discussions of stress and depression levels within the skill building tip sheets did not detract from the design of the protocol; nor did the nurses

ignore symptoms, and the alteration allowed the nurses to deliver the intervention in a less mechanistic manner when stress or depressive symptoms were not predominant.

Decisions to alter delivery methods such as stress and depression assessments were purposeful and data based operational decisions. Beck and colleagues²⁶ suggested that tailored interventions may have greater efficacy than standardized interventions, thus resulting in greater adherence, improved outcomes, and cost savings. With evidence-based decisions, the context of a behavioral intervention (training, format, setting, patient population or evaluations) can be modified without actually altering the content or effectiveness of the intervention.²⁷

Adherence rates for items 14 through 17 were low because they were always addressed towards the end of the phone call and there was often not enough time for further skill-building. In addition, if they had been covered in an earlier call, the nurse did not always address them again, a factor that may have affected the lower rates for these items.

Item 7 on the checklist required the caregiver to assess amount of help needed with all tip sheets of interest and had an adherence rate of 28%. Following a discussion in the weekly meetings, it was approved for the caregiver to select the tip sheet of highest interest or need rather than to rate the amount of help needed for each tip sheet of interest, and this created an artificially lower adherence.

In the Information, Support, and Referral group, there were no individual items less than 60%. The only item at 63% adherence was item 25 “thanking the participant.” Some of the nurses reported that they often did thank the participant after the recording was turned off at the very end of the conversation and may have been missed. This item, and other protocol recommendations, was also addressed at weekly team meetings as a reminder, included in the protocol update tracking sheet, and made available via electronic file format for all study team members to access and review. The use of ongoing “protocol updates” electronic tracking files during weekly team meetings greatly enhanced momentum, augmented training, and helped maintain treatment fidelity. The files provided documentation on issues that were discussed during the weekly team meetings for both the TASK II and Information, Support, and Referral nurses. The TASK II and Information, Support, and Referral protocol updates were referenced regularly and provided an enhanced orientation to new nurses that were hired later during course of the study. While the initial protocols contained detailed procedures, the protocol updates helped nurses “put these procedures into action” with actual caregivers. Putting the procedures into action is consistent with recommendations for implementation strategies that advocate for operationalizing interventions within the framework of the actor [nurse], action [TASK II or Information, Support, and Referral intervention], action targets [caregivers] and dose implementation outcomes [delivery of content as intended].²⁸ The protocol updates also documented what was modified, type of modification, and nature of the content changes in a tailored intervention.²⁷

Finally, these findings suggest there were no differences in protocol adherence as assessed by the Checklist for Monitoring Adherence when comparing the TASK II intervention group

nurses to the Information, Support, and Referral intervention group nurses. This contributes evidence to support minimal protocol drift within and across study arms over time.

Protocol dosage

As expected, there were significant differences in call duration and time spent reading study materials between the TASK II and Information, Support, and Referral groups. The TASK II calls took longer, and caregivers spent more time reading the TASK II Resource Guide than the AHA pamphlet. There was a surprising amount of variability in the duration of the calls for both groups that can be attributed to individual variability among the participants as evidenced by some of the wide standard deviations found in Table 4. The amount of time spent reading study materials also varied widely within and between groups with the Information, Support, and Referral group spending much less time reading the AHA brochure compared to the much larger and more in-depth TASK II Resource Guide.

Focus groups

No studies were found in the literature to document the qualitative experiences of nurses while delivering behavioral interventions. The NIH Behavior Change Consortium framework was embedded a priori into the study design to ensure study nurses were naïve to the concept of treatment fidelity until the study was completed. By doing so, strengths, weaknesses, and opportunities for future research design and delivery were identified in the focus groups. Findings demonstrated consistent support of the treatment fidelity framework. The nurses provided valuable feedback on the design of the TASK II and Information, Support, and Referral interventions for future implementation that will be used to guide future implementation of the TASK II Intervention for Stroke Caregivers.

Nurses offered suggestions for future training to include listening to experienced nurses deliver the intervention rather than practicing with a fellow novice nurse. They noted with surprise their ability to deliver the protocols completely by telephone and believed telephone delivery sharpened their listening skills. These findings were consistent with those of Pettinari and Jessopp²⁹ who stated that “your ears become your eyes” in a telephonic intervention. The nurses listened intently to nonvisual cues to effectively build rapport and tailor their interactions with caregivers, similar to interveners in Pettinari and Jessopp’s study²⁹ who developed different skills to “compensate for the absence of visibility.”

Qualitative comments from the TASK II nurses during the focus group revealed additional considerations for intervention delivery. For example, the needs assessment process was challenging. Nurses initially had trouble finding time to cover the skill-building tip sheets, but learned to create time after gaining a greater understanding that providing information alone (i.e. content tip sheets) often results in little to no impact on caregiver outcomes; whereas, studies that use information combined with skill building strategies (e.g., problem solving) are much more effective.^{30,31} In the Information, Support, and Referral nurse group, communication skills including active listening was a priority. Validating caregivers’ emotions and “just being there” for them was considered important. During the three years of the intervention phase of the protocol, the weekly team meetings greatly enhanced team

member's camaraderie and study engagement, and, as a result, they felt they were better able to implement the protocol.

The TASK II nurses suggested strategies to enhance the treatment fidelity components of receipt and enactment such as: (a) adapting their teaching style based on certain caregiver characteristics (e.g., education); (b) providing a summarization at the end of each call; and (c) pointing out skill-building tip sheets when caregivers mentioned strategies that they were using. The Information, Support, and Referral nurses suggested offering options for caregivers with limited reading ability and reinforcing information in the AHA brochure that was particularly helpful to the caregivers.

The use of the NIH Behavior Change Consortium framework for behavioral intervention research to address the areas of design, training, delivery, receipt, and enactment has been recommended.^{2, 4,9,10} This framework, as adapted by Resnick and colleagues,³² provided a replicable and reliable context for the TASK II Intervention for Stroke Caregivers. In this paper, we employed a novel and comprehensive approach to assessing treatment fidelity in both the experimental (TASK II) and Information, Support, and Referral comparison groups with respect to: 1) protocol adherence; 2) protocol dosage; and 3) nurse interveners' perspectives regarding treatment fidelity. These findings are unique because they fill a gap in the literature about the importance of monitoring, comparing, and reporting treatment fidelity in both study arms of a stroke caregiver behavioral trial. With the known tendency to drift from a defined intervention in behavioral research, these findings offer novel strategies to evaluate treatment fidelity by comparing protocol adherence and dosage in the study arms that may be applicable for the design of future behavioral intervention research studies

Limitations

Although adherence to protocol was carefully monitored and assessed in this clinical trial, when implemented in a real world setting adherence may vary, thus potentially limiting the intervention effects. Regarding protocol dosage, participant reports of time spent reading study materials were self-reported, thus there may have been error from over- or under-reporting. Regarding outcomes from the focus groups, there may have been personal biases expressed by nurse participants about their experiences as study nurses.

Clinical Messages

The maintenance of protocol adherence among each study arm is a key component of intervention testing in clinical trials. Monitoring and reporting of treatment fidelity is important to substantiate study outcomes prior to implementation in a real-world setting.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors would like to acknowledge the assistance of Pam Brake, RN and Kim Hadler RN, Indiana University School of Nursing.

Funding for this study was provided by the National Institutes of Health, National Institute of Nursing Research, R01NR010388 (Tamilyn Bakas, PI).

References

1. Avery L, Flynn D, Van Wersch A, et al. Changing physical activity behavior in type 2 diabetes: A systematic review and meta-analysis of behavioral interventions. *Diabetes Care*. 2012; 35:2681–2689. [PubMed: 23173137]
2. Borrelli B, Sepinwall D, Bellg A, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol*. 2005; 73:852–860. [PubMed: 16287385]
3. Cummings GG, Olivo SA, Biondo PD, et al. Effectiveness of knowledge translation interventions to improve cancer pain management. *J Pain Symptom Manage*. 2011; 41:915–939. [PubMed: 21398088]
4. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent*. 2011; 71:S52–S63.
5. Breitenstein SM, Gross D, Garvey C, et al. Implementation fidelity in community-based interventions. *Res Nurs Health*. 2010; 33:164–173. [PubMed: 20198637]
6. Eaton LH, Doorenbos AZ, Schmitz KL, et al. Establishing treatment fidelity in a Web-based behavioral intervention study. *Nurs Res*. 2011; 60:430–435. [PubMed: 22048559]
7. Resnick B, Michael K, Shaughnessy M, et al. Exercise intervention research in stroke: Optimizing outcomes through treatment fidelity. *Top Stroke Rehabil*. 2011; 18:611–619. [PubMed: 22120030]
8. Perepletchikova F, Treat TA, Kazdin A. Treatment integrity in psychotherapy research: Analysis of the studies and examination of the associated factors. *J Consult Clin Psychol*. 2007; 75:829–841. [PubMed: 18085901]
9. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: Best practice and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004; 23:445–451.
10. Resnick B, Bellg AJ, Borrelli B, et al. Examples of implementation and evaluation of treatment fidelity in the BCC studies: where we are and where we need to go. *Ann Behav Med*. 2005; 29(Special Supplement):46–54. [PubMed: 15921489]
11. Resnick B, Galik E, Pretzer-Aboff I, et al. Treatment fidelity in nursing home research: The res-care intervention study. *Res Gerontol Nurs*. 2009; 2:30–38. [PubMed: 20077991]
12. Behrman AL, Bowden MG, Rose DK. Clinical trials in neurorehabilitation. *Handb Clin Neurol*. 2013; 110:61–66. [PubMed: 23312630]
13. Hinckley JJ, Douglas NF. Treatment fidelity: its importance and reported frequency in aphasia treatment studies. *Am J Speech Lang Pathol*. 2013; 22:S279–S284. [PubMed: 23695904]
14. Farran CJ, Etkin CD, McCann JJ, et al. Role of technology in supporting quality control and treatment fidelity in a family caregiver clinical trial. *West J Nurs Res*. 2011; 33:953–978. [PubMed: 21245285]
15. Perepletchikova F, Kazdin A. Treatment integrity and therapeutic change: Issues and research recommendations. *Clin Psychol Sci Prac*. 2005; 12:365–383.
16. Bakas T, Farran CJ, Austin JK, et al. Stroke caregiver outcomes from the telephone assessment and skill building kit (TASK). *Top Stroke Rehabil*. 2009; 16:105–121. [PubMed: 19581197]
17. Bakas T, Farran CJ, Austin JK, et al. Content validity and satisfaction with a stroke caregiver intervention program. *J Nurs Scholarsh*. 2009; 41:368–375. [PubMed: 19941582]
18. Bakas, T.; Austin, J.; Buelow, JM., et al. Preliminary efficacy of a stroke caregiver intervention program for reducing depressive symptoms. *Stroke; American Stroke Association International Stroke Conference; San Antonio, Texas, United States. February 24–26, 2010; 2010. p. e104*
19. Jessup NM, Bakas T, McLennon SM, et al. Are there gender, racial, or relationship differences in caregiver task difficulty, depressive symptoms, and life changes among family caregivers of stroke survivors? *Brain Injury*. 2014 Aug 20. Epub ahead of print <http://informahealthcare.com/doi/abs/10.3109/02699052.2014.947631>.

20. McLennon SM, Bakas T, Jessup NM, et al. Task difficulty and life changes among stroke family caregivers: Relationship to depressive symptoms. *Archives of Physical Medicine and Rehabilitation*. 2014; 95(12):2484–2490. [PubMed: 24858447]
21. Bakas, T.; Austin, JK.; Habermann, B., et al. Telephone Assessment and Skill-Building Kit for Stroke Caregivers (TASK II): A Randomized Controlled Clinical Trial. Late Breaking Abstracts Poster Presentation at the American Heart Association/American Stroke Association International Stroke Conference; Nashville, Tennessee, United States. February 1–13, 2015;
22. American Heart Association. *Caring for stroke survivors*. Dallas: Krames; 2010.
23. Radziewicz R, Rose JH, Bowman KF, et al. Establishing treatment fidelity in a coping and communication support telephone intervention for aging patients with advanced cancer and their family caregivers. *Cancer Nurs*. 2009; 32:193–202. [PubMed: 19295420]
24. Berg, BL. *Qualitative research methods for the social sciences*. 5th. Boston: Pearson Education; 2004.
25. Miles, MB.; Huberman, AM. *Qualitative data analysis: an expanded sourcebook*. 2nd. Thousand Oaks, CA: Sage; 1994.
26. Beck C, McSweeney JC, Richards KC, et al. Challenges in tailored intervention research. *Nurs Outlook*. 2010; 58:104–110. [PubMed: 20362779]
27. Stirman S, Miller C, Toder K, et al. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci*. 2013; 8:1–12. [PubMed: 23279972]
28. Proctor E, Powell B, McMillen C. Implementation strategies: Recommendations for specifying and reporting. *Implement Sci*. 2013; 8
29. Pettinari C, Jessopp L. ‘Your ears become your eyes’: Managing the absence of visibility in NHS Direct. *Issues and innovations in nursing practice. J Adv Nur*. 2001; 36:668–675.
30. Smith J, Forster A, House A, et al. Information provision for stroke patients and their caregivers. *Cochrane Database Syst Rev*. 2008:CD001919. [PubMed: 18425877]
31. Bakas T, Clark PC, Kelly-Hayes M, et al. on behalf of the American Heart Association Council on Cardiovascular and Stroke Nursing and the Stroke Council. Evidence for stroke family caregiver and dyad interventions: A statement for healthcare professionals from the American Heart Association. *Stroke*. 2014 Jul 17; 45(9):2836–2852. Epub ahead of print <http://stroke.ahajournals.org/content/early/2014/07/17/STR.0000000000000033>. [PubMed: 25034718]
32. Resnick B, Inguito P, Orewig D, et al. Treatment fidelity in behavior change research: a case example. *Nurs Res*. 2005; 54:139–143. [PubMed: 15778656]

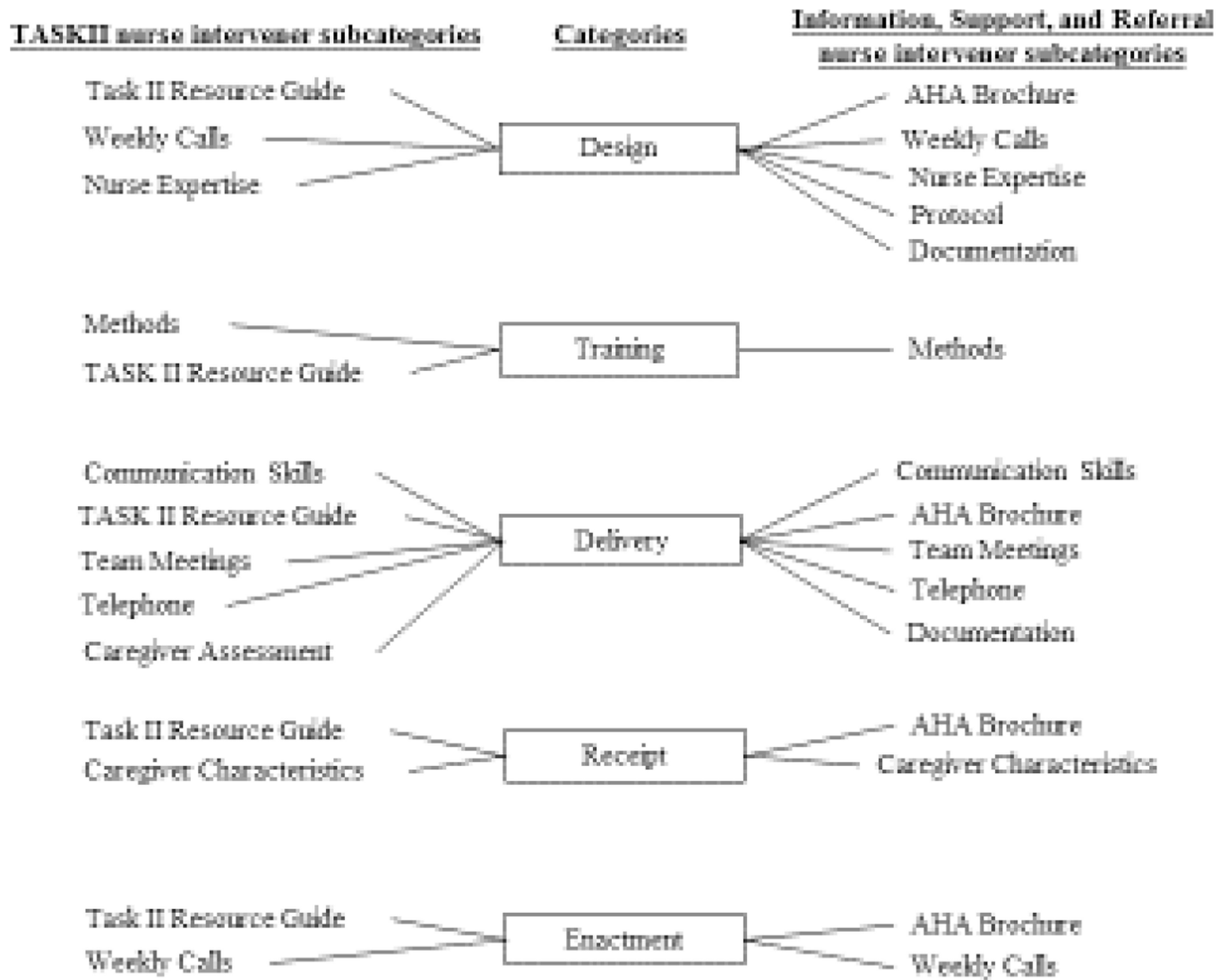


Figure 1. Results from focus groups with TASKII and Information, Support, and Referral nurse interveners

Table 1
Monitoring treatment fidelity in the Task II Intervention Study for Stroke Caregivers following National Institute of Health Behavior Change Consortium guidelines

Method	Design	Training	Delivery	Receipt	Enactment
1. Protocol development and review					
2. Checklist for Monitoring Adherence development					
3. Content validity verification of intervention tip sheets					
4. Hiring of qualified, engaged nurses					
5. TASKII Resource Guide (caregiver manual for TASKII group)					
6. Videotaped staff training modules					
7. Training <ul style="list-style-type: none"> TASKII nurses: use of TASKII Resource Guide - assessment checklist, tip sheets, skill-building, active listening, American Heart Association (AHA) brochure, mock interviews, training audiotapes for key experiences (e.g. suicidality, depression) Information, Support, Referral nurses: support and active listening techniques, AHA brochure, referrals, avoidance of advice, education, or other information, mock interviews 					
8. Weekly team meetings					
9. Maintenance of "Key Protocol Updates" log for review and documentation of weekly meeting comments and decisions					
10. Evaluations of audiotapes					
11. Weekly assessments <ul style="list-style-type: none"> TASKII group: (a) amount, use, and helpfulness of information and strategies; (b) whether problems or needs were resolved; and (c) minutes caregivers spent reviewing the TASK II Resource Guide Information, Support, Referral group: minutes spent reading and information used in the AHA brochure 					
12. Retrospective review with nurse interveners (focus groups)					

Table 2
 Comparing TASK II (N=123) and ISR (N=131) intervention groups on the Checklist for Monitoring Adherence

Item	TASK II Adherence <i>f</i> (%), Range = R (%)	TASK II Applicable Responses ^a N = 47	ISR Adherence <i>f</i> (%), Range = R (%)	ISR Applicable Responses ^d N = 48	χ^2
1. Completed call as scheduled. If no, explain.	46 (98)	47	44 (92)	48	.7
2. Call recorded with good quality. If no, explain.	45 (96)	47	43 (90)	48	.21
3. Reminder that call was being recorded	37 (79)	47	34 (77)	44 ^c	1.4
4. Gift card received? (calls 1, 9)	7 (70)	10	5 (100)	5	1.9
5. Evaluated previous week tip sheets	35 (97)	36	NA	NA	NA
6. Reviewed CNCC for new problems, ask caregiver to check	41 (87)	47	NA	NA	NA
7. Help needed for new problems?	13 (28)	47	NA	NA	NA
8. Reviewed BCOS (calls 5–9).	20 (95)	21	NA	NA	NA
9. Identify priority problem (calls 5–9, addressed life changes, other)	47 (100)	47	NA	NA	NA
10. Addressed problem with tip sheet	40 (95)	42 ^b	NA	NA	NA
11. Identified stress level for each problem addressed	24 (57)	42 ^b	NA	NA	NA
12. If issue was a benefit or benign, strengthened skills (Tip Sheet SB1)	9 (100)	9	NA	NA	NA
13. If stressed, screened for depressive symptoms, other emotions (Tip Sheet SB2), then to Stress Management workbook if needed (Tip Sheet SB6)	14 (93)	15	NA	NA	NA
14. Assessed for trouble finding time for skill. If so, to Tip Sheet SB3.	15 (36)	42 ^b	NA	NA	NA
15. Assessed for unrealistic expectations. If so, to Tip Sheet SB3.	14 (33)	42 ^b	NA	NA	NA
16. Assessed need for problem solving. If so, to Tip Sheet SB4.	14 (33)	42 ^b	NA	NA	NA
17. Assessed need for communicating with health professionals. If so, to Tip Sheet SB5.	13 (31)	42 ^b	NA	NA	NA
18. Active listening techniques used	47 (100)	47	48 (100)	48	0
19. Pace and understanding level matched caregivers. Easy for caregiver to hear and understand.	45 (96)	47	47 (98)	48	0
20. No use inappropriate feedback	39 (83)	47	37 (79)	47 ^c	.1
21. Did not use incorrect probes	43 (91)	47	46 (96)	48	1.4
22. Attended to caregiver needs/concerns	47 (100)	47	48 (100)	48	0
23. Reminders for next calls	45 (96)	45	46 (98)	47 ^c	1
24. Reminder next call would be data collection (calls 8, 9)	7 (100)	7	10 (100)	10	0

Item	TASK II Adherence <i>f</i> (%), Range = R (%)	TASK II Applicable Responses ^a N = 47	ISR Adherence <i>f</i> (%), Range = R (%)	ISR Applicable Responses ^d N = 48	χ^2
25. Thanked participant	30 (64)	47	29 (63)	46 ^c	.01
26. Completed tracking form	47 (100)	47	NA	NA	NA
27. Completed call notes	47 (100)	47	18 (100)	18	0
Total (all items)	(80) R=(28–100)		(92) R=(63–100)		
Total (shared items)	(90) R=(70–100)		(92) R=(63–100)		

^aSome responses were not applicable to each call. Percent adherence was computed based on applicable responses.

^bNot all caregivers identified a problem with each call; therefore, there were only 42 applicable responses for these items, rather than 47.

^cNot all responses were evaluated due to technical difficulties with recordings.

© Tamilyn Bakas, 2010. Reprinted with permission. Requests for the Checklist for Monitoring Adherence to the TASK II Protocol (CMATP) can be made to Tamilyn Bakas, Indiana University School of Nursing, 1111 Middle Dr., NU 413, Indianapolis, IN, 46202-5107. tbakas@iu.edu.

Table 3
Independent samples t-tests comparing dosage of the TASK II (n=123) and Information, Support, and Referral (ISR) interventions (n=131)

Weekly Calls	TASK II group	TASK II group	TASK II group	ISR group	ISR group	ISR group	Call	Reading
	Call Minutes	Resource Guide Reading Minutes	Call Minutes	Call Minutes	AHA Brochure Reading Minutes	Call Minutes	Minutes	Minutes
	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>M (SD)</i>	<i>t</i>	<i>t</i>
1	35.6 (13.7)	30.3 (64.3)	23.8 (14.5)	23.8 (14.5)	9.7 (23.1)	-6.65	***	-3.41
2	27.3 (16.6)	28.9 (51.0)	14.6 (12.9)	14.6 (12.9)	5.2 (14.6)	-6.84	***	-5.08
3	26.5 (16.7)	21.8 (42.1)	14.1 (13.2)	14.1 (13.2)	7.8 (20.7)	-6.60	***	-3.37
4	22.1 (16.4)	23.2 (40.1)	12.5 (12.2)	12.5 (12.2)	4.8 (13.7)	-5.34	***	-4.94
5	23.5 (17.4)	19.6 (52.5)	12.0 (12.1)	12.0 (12.1)	2.6 (9.3)	-6.14	***	-3.63
6	22.1 (17.1)	21.3 (46.2)	12.1 (12.2)	12.1 (12.2)	2.3 (12.3)	-5.36	***	-4.52
7	21.1 (16.8)	11.8 (22.3)	11.9 (13.1)	11.9 (13.1)	1.7 (9.2)	-4.91	***	-4.78
8	18.1 (15.6)	14.5 (27.7)	13.9 (15.9)	13.9 (15.9)	.9 (4.9)	-2.15	*	-5.53
9	18.7 (15.6)	36.9 (115.1)	13.3 (14.9)	13.3 (14.9)	1.9 (13.3)	-2.82	**	-3.44
Total	215.2 (100.8)	208.4 (285.1)	128.1 (85.8)	128.1 (85.8)	37.0 (69.1)	-7.38	***	-6.49

* p<.05;
** p<.01;
*** p<.001

Table 4

TASK II intervention group (N=123) evaluation of nurse calls

	Mean (SD)	Median (range)	% per response category
Receipt			
Amount of information	1.99 (.21)	2.0 (1–3)	2.5% too little (1) 95.7% just right (2) 1.8% too much (3)
Enactment			
Usefulness of information	2.73 (.96)	3.0 (1–4)	12.2% not used (1) 27.2% used it a little (2) 36.3% used it some (3) 24.3% used it a lot (4)
Strategies tried	2.65 (1.01)	3.0 (1–4)	12.0% didn't try strategies (1) 23.9% tried a little (2) 36.5% tried some (3) 22.6% tried a lot (4)
Helpfulness of strategies	3.188 (1.04)	3.0 (1–5)	7.1% no help (1) 17.1% little help (2) 33.5% moderately helpful (3) 34.7% very helpful (4) 7.6% extremely helpful (5)
Were problems resolved	1.992 (.49)	2.0 (1–4)	11.6% not resolved (1) 78.6% making progress (2) 8.8% fully resolved (3) 1.0% resolved on own (4)