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**BRIEF REPORT**

## A Telerehabilitation Intervention for Persons with Spinal Cord Dysfunction

**ABSTRACT**

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Pressure ulcers and depression are common preventable conditions secondary to a spinal cord dysfunction. However, few successful, low-cost preventive approaches have been identified. We have developed a dynamic automated telephone calling system, termed *Care Call*, to empower and motivate people with spinal cord dysfunction to improve their skin care, seek treatment for depression, and appropriately use the healthcare system. Herein, we describe the design and development of *Care Call*, its novel features, and promising preliminary results of our pilot testing. Voice quality testing showed that *Care Call* was able to understand all voice characteristics except very soft-spoken speech. Importantly, pilot study subjects felt *Care Call* could be particularly useful for people who are depressed, those with acute injury, and those without access to quality care. The results of a randomized controlled trial currently underway to evaluate *Care Call* will be available in 2011.

**Key Words:** Spinal Cord Injuries, Telemedicine, Pressure Ulcer, Depression

**P**ressure ulcers and depression are common preventable secondary conditions for people with spinal cord dysfunction (SCD). Unfortunately, diagnosis and/or treatment of secondary conditions is often delayed.<sup>1–4</sup> This can undermine rehabilitation and have a significant impact on a person's quality-of-life and his/her healthcare costs.<sup>5–8</sup>

A patient's self-care behavior can impact the onset and severity of secondary conditions after an SCD. Pressure ulcers, for example, can be prevented through the use of patient education.<sup>9</sup> Depression can be improved and successfully managed if a patient receives treatment.<sup>10</sup> Nonetheless, persons with SCD do not generally receive the necessary follow-up care<sup>11</sup> that could promote self-management behaviors. Patients report various obstacles to complying with self-care management and annual follow-up evaluations, including cost, transportation, time, and reluctance to seek treatment,<sup>12</sup> such that they are not being successfully encouraged to prevent or seek treatment for pressure ulcers and depression.

Interventions to promote healthy behaviors, which can in turn prevent secondary conditions, are typically resource intensive.<sup>13,14</sup> Telerehabilitation and

related technologies are a promising strategy that, if successful, could improve the quality and reduce the cost of secondary prevention.<sup>15</sup> For persons with spinal cord injury (SCI), particular attention in telerehabilitation interventions has been paid to using telephone contact and video monitoring for the prevention and management of pressure ulcers.<sup>16,17</sup> However, because telerehabilitation interventions have not been evaluated, few successful, low-cost approaches that prevent secondary conditions have been identified<sup>18,19</sup>; such a system could bring not only substantial long-term cost savings but also enhanced quality-of-life of people with SCD.

With this goal in mind, we have developed *Care Call*—an innovative telerehabilitation intervention system designed to empower and motivate people with SCD to improve their skin care and mental health. The system does not replace face-to-face health care, rather, it supplements a clinician's role in long-term management after SCD. *Care Call* has the potential to help significant numbers of people after an SCD using a low-risk, low-cost approach that could be used for long-term patient monitoring and service provision. If efficacious, this intervention could be offered by clinicians to patients across multiple settings. Herein, we describe the design, development, and initial pilot testing of the *Care Call* intervention, with the ultimate goal of informing the final intervention protocol for an initial randomized controlled trial (RCT) now underway.

## METHODS

### Description of the Care Call Technology

The *Care Call* intervention is delivered from the Telephone-Linked Computer System (TLC),<sup>20</sup> an automated, interactive conversation system that speaks with a digitized human voice.<sup>21</sup> TLC, which functions as an at-home monitor, educator, and counselor for reinforcing or changing health-related behaviors, has been used to screen and monitor numerous diseases<sup>22-27</sup> and has been applied to important health-related behaviors.<sup>28</sup> Clinical trials show TLC to improve medication adherence,<sup>29</sup> increase exercise among the general<sup>13</sup> and elderly populations,<sup>30</sup> decrease the degree of dyspnea for people with chronic obstructive pulmonary disease,<sup>31</sup> and improve eating habits<sup>32</sup> and lower serum cholesterol levels through dietary changes.<sup>31</sup>

TLC uses an interactive voice response system to generate digitized speech over the telephone, a speech recognition software, a conversation control system that directs the content and flow of indi-

vidual TLC conversations with users, and a database management system for storing user information and call logs. It is a call-in and call-out system; that is, users can call (from any telephone) at any time and the system will also call the user according to an adaptive scheduling protocol that reflects how well a person is doing with his/her self-care. If the system initiates a call and no contact is made, it will leave a message for the person to call TLC and will call again according to a call schedule protocol. TLC automatically produces reports on utilization statistics to assist in system operation, intervention evaluation, and patient monitoring.

### Design of the Care Call Intervention

The target population for the *Care Call* intervention consists of persons with SCD who use a wheelchair at least 6 hrs a day. For the *Care Call* clinical trial, further exclusion criteria were developed, including having nontraumatic SCI diagnoses with fast progression (amyotrophic lateral sclerosis, postpolio, and metastatic disease of the spine), having severe major depression, and having a stage III or greater pressure ulcer. In practice, the appropriateness of *Care Call* for subgroups meeting these exclusion criteria would need to be evaluated on an individual basis.

We designed the *Care Call* intervention to (1) screen for pressure ulcers and depressive symptoms, (2) educate about the prevention of depression and pressure ulcers and the appropriate use of health care services, and (3) alert a nurse telerehabilitation coordinator (NTC), when appropriate, for direct medical or mental health attention. Furthermore, we hypothesized a secondary goal, that *Care Call* would improve community integration and quality-of-life. Each of these goals is being evaluated in the RCT. An interdisciplinary team of rehabilitation professionals developed the content, design, and overall functionality of the *Care Call* system.

The content of the *Care Call* intervention is based on the Transtheoretical Model<sup>33</sup> and Social Cognitive Theory,<sup>34</sup> as well as on the heuristics of experienced counselors. The Transtheoretical Model posits that people at different stages of readiness to make a desired behavioral change will respond to different counseling messages. A fundamental precept in the Social Cognitive Theory is that individuals use self-referent thought to mediate between knowledge and behavior, which allows them to evaluate their own experiences and thought processes.<sup>35</sup> Through the process of self-evaluation,

individuals may alter their own thinking about their abilities and the outcomes of their actions and subsequently alter their behavior.

Care Call targets pressure ulcers and depression, in particular, because of their prominence for people with SCD and their preventability through self-management. The prevalence of pressure ulcers in a community-based sample of individuals with SCD is estimated at 33%.<sup>36</sup> Patient education is generally considered paramount for proper prevention of pressure ulcers.<sup>36</sup> The percentage of adults with disabilities who reported that feelings of depression kept them from being active was three times that of the general population, 28% compared with 7%, respectively.<sup>15</sup> Research has shown that TLC technology has been able to successfully change health behavior and disease outcomes.<sup>13,20,23,32,37</sup> Although there is little research on using TLC to prevent or treat depression, screening for another sensitive mental health issue, substance use, has proven effective using TLC.<sup>25</sup> In addition, several randomized trials over the last decade have demonstrated that telehealth interventions can decrease depression severity.<sup>38,39</sup>

### General Description of Care Call

The Care Call scripts are organized into modules and integrate information relative to three targeted areas: skin care, depression and wellness, and healthcare utilization. Although most content is delivered by computer voice, the system also has recorded vignettes from people with SCD and recorded comments from healthcare professionals. Throughout each module, users are referred to local community and informational resources via the Care Call Resource Book (see below).

The Skin Care Module assesses and monitors old and new skin problems, trains users in skin care, and assesses and monitors risk factors such as incontinence and equipment needs. Care Call reviews barriers to skin care adherence to offer specific encouragement and advice.<sup>34</sup> To provide individualized messages, the system is adapted based on data collected at baseline (e.g., history of pressure ulcers, consistency of sensation, and level of paralysis) and on responses in previous calls.

The Depression and Wellness Module screens, monitors, and educates users on depression and adjustment. For those with existing untreated depression, Care Call provides education and encouragement to improve their understanding and management of depression. The system assesses satisfaction with treatment and promotes adherence. Care Call also has a wellness track for de-

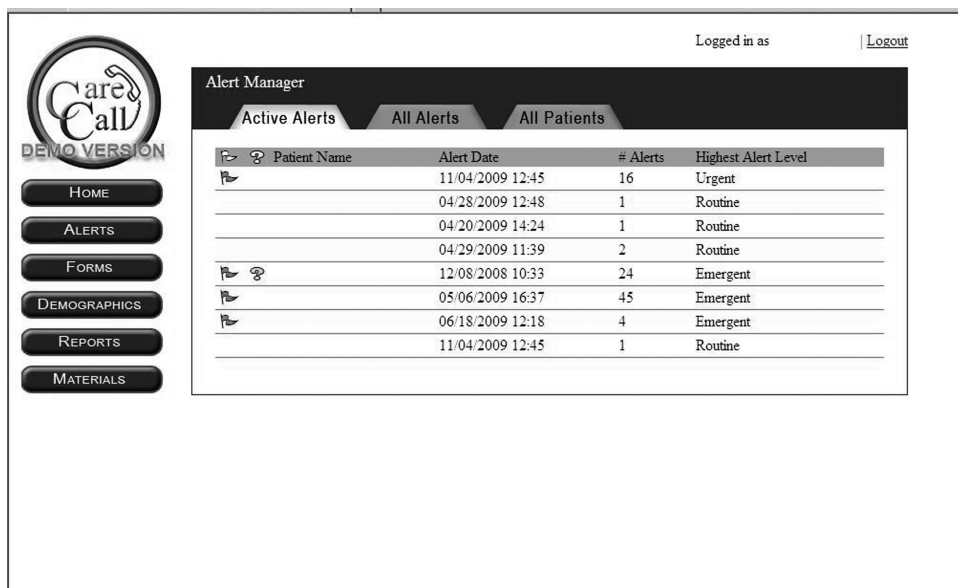
creasing depression in which participants are assessed; educated about exercise, sleep habits, and alcohol use; and offered a brief relaxation exercise that can be done at any time.

As part of the depression track, a “Self-harm Protocol” was developed for use when a subject endorsed thoughts of hurting himself/herself within the past 2 wks. When used, a follow-up script would be immediately implemented (by Care Call, the NTC, or field staff) to assess a subject’s risk of self-harm. If the subject was found to be at immediate risk of self-harm, the system or Care Call staff would page an on-call clinical psychologist with the subject’s status. The clinical psychologist would then reply within 1 hr to assess the situation and contract for safety, when appropriate. Otherwise, subjects would be counseled that if they ever began to feel like they could hurt themselves, they should go to the emergency department, and they would be provided with a national hotline number. In all cases, the NTC follows up within 48 hrs to see how a subject is doing.

The Health Care Utilization Module tracks each person’s medical and mental health appointments. Because seeking treatment to prevent these problems is paramount, Care Call both reviews with users logistical factors before a healthcare visit and coaches them in communicating with a provider during a visit. If users miss an appointment, Care Call assesses barriers and offers recommendations to overcome them.

Care Call integrates audiotaped vignettes from actual patients with SCD. We recorded interviews with nine key informants with SCD to illustrate tips and personal experiences on all three modular topics. The key informants represented a range of SCDs (including multiple sclerosis and SCI) and ethnic/racial backgrounds (seven white non-Hispanic, two black; five men, four women). Users hear at least one audio clip per call, with relevant audio clips embedded throughout. Additional vignettes provide advice from SCD clinicians.

Lastly, Care Call offers users the opportunity throughout to speak with the NTC and alerts the NTC to contact the user for follow-up on important issues that are identified. The main role of the NTC is to respond to Care Call alerts in a timely manner, providing appropriate referral, resources, and/or action steps for users. Care Call does not act as an emergency responder to medical situations or dispense medical advice; the NTC provides an important triage role to further ascertain the needs of each Care Call user beyond the limitations of automated technology. The NTC uses a Web-based

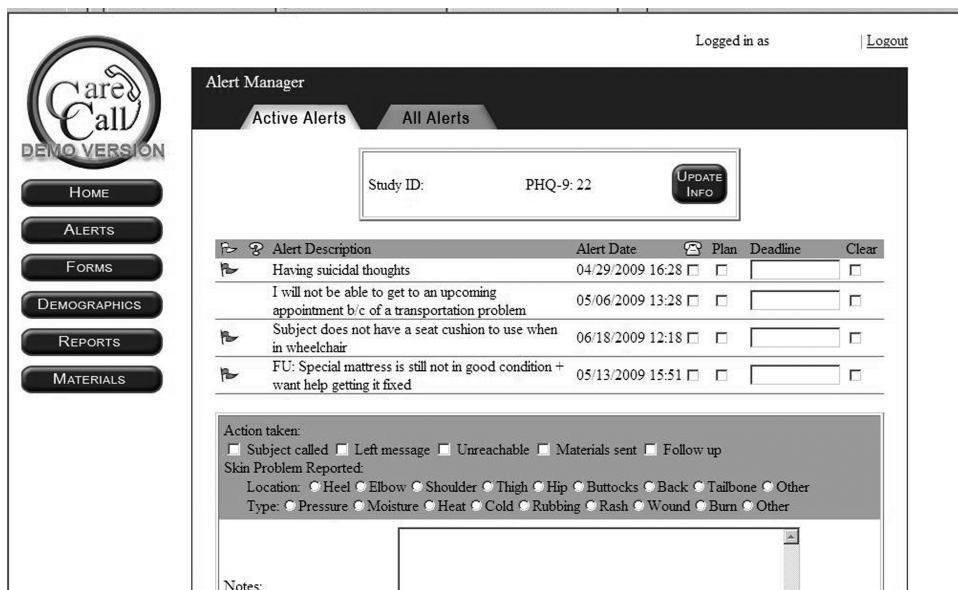


**FIGURE 1** Screenshot of the demo version of the Alert Manager, a Web-based tool for the nurse telerehabilitation coordinator, showing all active alerts (using mock data; mock names have been deleted).

tracking form to document the length, content, and outcome of each contact with a user. We developed three levels of alerts for problems identified in Care Call: emergent (e.g., new skin problem), urgent (e.g., equipment problem), and routine (e.g., old problem that user wants to discuss with NTC). When an emergent medical problem is identified, Care Call directs users to contact their physician immediately or go to the emergency department or call 911. For urgent matters, Care Call tells users to see their physician as soon as possible and to ask

for proper contact information for urgent medical problems at their next office visit (Figs. 1 and 2).

One of the major companions to Care Call is a Resource Book that all users receive at enrollment. Care Call and the NTC use this book in each encounter with participants. The Resource Book includes both local resources and informational resources for topics like medical supplies, mental and physical health providers, and personal care assistants. Included within the Resource Book is a set of user-friendly forms created by the research



**FIGURE 2** Screenshot of active alerts for an individual mock subject in the demo version of the Alert Manager.

team which Care Call reviews to help a user prepare for upcoming office visits to a health provider.

### A Care Call Encounter

A Care Call user typically engages with Care Call weekly by receiving a call from TLC at an appointed time. Alternatively, a user may call into the system at any time to do their regular weekly call, report a new problem, hear the relaxation exercise, or leave a message for the NTC or technical staff. A typical conversation lasts 5 to 20 mins, depending on the patient's condition. After a unique password is entered, Care Call greets a user and a predetermined sequence of modules is delivered, as illustrated in Figure 3.

After an initial inquiry into any new skin problems, users hear different contents and questions in each call. User responses from previous encounters and the current encounter shape ensuing questions and feedback, such that content varies for each user and within each encounter. Throughout the entire conversation, Care Call alerts the NTC as needed and offers relevant patient audio clips, as well as tips from Care Call.

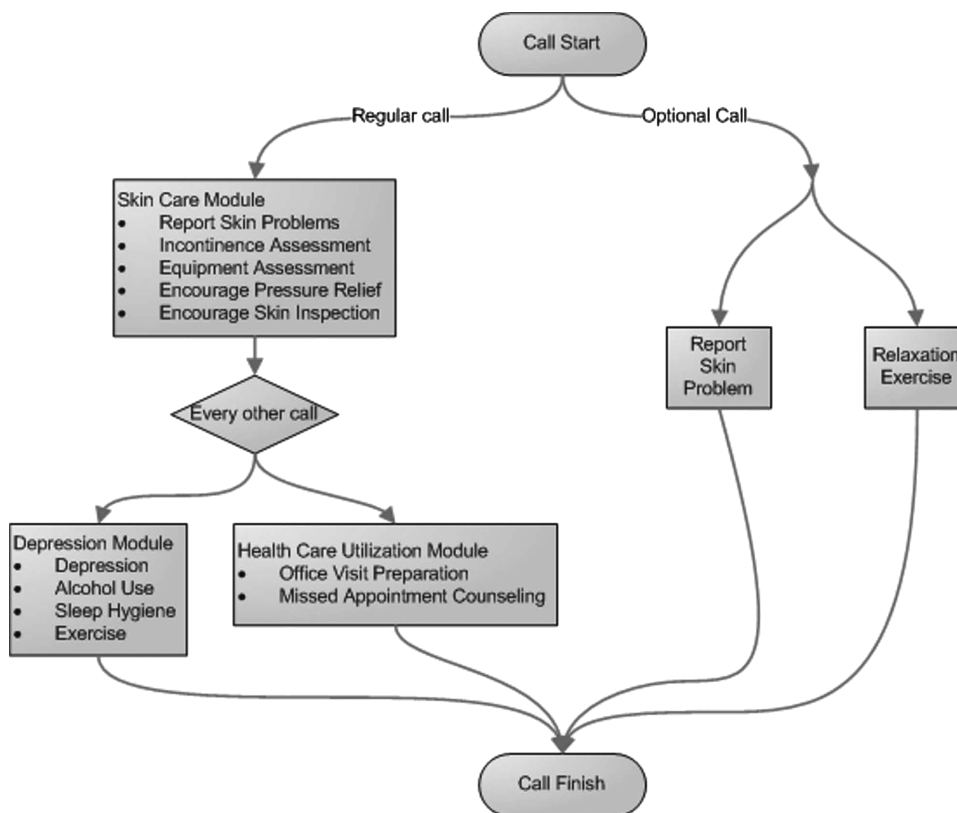
### Pilot Testing

We used three types of testing in Care Call's development, the results of which have shaped both

the final intervention and the clinical trial research protocol. The first was voice quality testing, which evaluates Care Call's ability to process various voice characteristics specific to our target population. Participants in the voice quality testing included five people with notable voice characteristics (ventilator use, pseudobulbar affect, dysarthria, soft-spoken speech, and stuffy nose) and one person with no notable voice characteristics. Testing the feasibility of Care Call for differing voice qualities was crucial for informing the criteria for participation in the clinical trial.

The second approach was pilot testing a beta version of the Care Call system with nine people with SCD to garner consumer feedback on content and to uncover any logic errors or technical difficulties. The Care Call team then revised the beta version of the Care Call system to create a final version for the trial. Subjects participated in six calls focusing on different scripts of the Care Call system and provided feedback during an in-depth interview.

All pilot testing procedures followed the approved protocol of the Boston University Medical Campus Institutional Review Board, conducted in accordance with the Declaration of the World Medical Association. Informed consent was obtained from all pilot participants.



**FIGURE 3** Flow diagram depicting the architecture of Care Call.

The final stage involved quality control testing to evaluate the final version of the Care Call intervention being deployed for the randomized controlled clinical trial, primarily for wording changes or technical errors. Three members of the development team assumed the identities of mock subjects with differing baseline characteristics. A report of unexplored areas of the system was distributed several times as the testing continued to guide testers in which untested pathways to follow with their responses. Pilot testing allowed the development team to address any possible issues before starting the trial.

## RESULTS

The results of the voice quality testing showed that Care Call was able to understand all voice characteristics except very soft-spoken speech. In particular, the TLC system had difficulty hearing and understanding the responses of a soft-spoken user. After inquiring twice without being able to understand one of the response options provided, the system stated that there were technical difficulties and discontinued the call, per protocol. Voice quality results confirmed that the study could enroll subjects with a wide range of voice quality.

In the beta test, pilot study subjects found Care Call to be an acceptable intervention overall. They felt that Care Call could be useful particularly for people who were depressed, those with a new injury (SCI), and those without access to quality care. Several subjects mentioned repetition of information but recognized at the same time how this could be helpful for those with limited education in, for example, the topic of skin breakdown. Because of their feedback, we staggered content from week to week to shorten call times and modified content to acknowledge individual differences in perceived need for various recommendations. For instance, one pilot study subject felt that heel protectors did not apply to him/her and thus did not like that Care Call would continue to suggest use of them and inquire about obtaining them. Care Call was modified to include shoes as heel protectors while in the wheelchair and to have the nurse follow up with a user rather than having Care Call repeatedly promote the use of heel protectors.

Lastly, our quality control testing uncovered some logic problems in the scripts and identified content sequences that needed modification to maintain the utmost sensitivity to the varying circumstances of individuals in the clinical trial. For instance, a member of our research team first re-

ported having two new skin problems and was then asked about the location of each. She imagined one on either side of her buttocks, yet Care Call did not specifically probe for this. When asking more about each skin problem, Care Call referred to each as being on the buttocks without differentiation between the right or the left buttock cheek. This line of questioning was confusing to the user, who did not know which problem to report on first.

Clinical experience suggested that most likely, skin problems on the same area of the body would be similar in cause and nature. Barring a total rewrite of this script and its logic, this issue was resolved most efficiently by adding a question with some instruction to users as follows: "Are you having a skin problem in just one area or in more than one area? If you're having problems on both sides of your body, for example both knees, count that as one area." Care Call was also revised to subsequently ask users if they had more than one skin problem in a particular area (in this case, the buttocks) to report on the worst skin problem, thus relieving any confusion or need for differentiation.

In terms of modifying content for sensitivity to individual differences, there was consensus that language needed to be softened related to feedback and education on adherence to skin care. Test callers felt that the weekly repetition of this content was reinforcement enough, such that the language itself should be less forceful, asking users if they would be willing to try to do more in the week ahead, rather than stating that they should. This change also allowed Care Call to be sensitive to the potential individual circumstances that might prevent a user from proper skin care, such as illness or a death in the family.

## DISCUSSION

The Care Call telerehabilitation approach described in this article uses a ubiquitous instrument (the telephone) and, if shown to be efficacious, has the potential for widespread dissemination at low cost. Although automated, TLC programs can successfully emulate the educational and behavioral content, support, and conversational style of a human professional.<sup>20,21,40</sup> Research to date has shown that TLC technology in other disease areas has been able to successfully change health behavior and disease outcomes.<sup>31</sup> The preliminary results of our pilot testing are encouraging. The results of the voice quality testing showed that Care Call was able to understand all voice characteristics except very soft-spoken speech. This problem could, in some

cases, be alleviated with coaching via three-way calling on required voice volume levels. Ventilator use was not a problem, and the TLC system was able to appropriately confirm responses for the user with a stuffy nose and cough. And, importantly, pilot study subjects felt that Care Call could be useful particularly for people who are depressed, those with a new SCI, and those without access to quality care.

The results of an RCT evaluating the Care Call intervention will be available in 2011. The final intervention protocol was shaped in important ways by pilot testing the results. In the trial, intervention subjects receive weekly calls for 6 mos. Because of pilot testing, we were able to decrease the length of calls by removing some marginal content and staggering modules across calls. For instance, we removed most of a script that attempted to assess possible bowel leakage problems in detail because we found that this problem is so individualized that it is better to ask generally about whether the problem exists and then let the NTC follow up to further assess and make appropriate recommendations and referrals. We also ended up staggering modules to decrease call length from 30 mins to 15 mins, on average, with some individual variation based on choosing to hear optional content and/or need for follow-up from previously identified issues.

Different types of follow-up care have been developed to fill the gap in the continuum of rehabilitative care, especially for people with lifelong health needs, such as people with SCD. A systematic review of the literature in 2005 on follow-up care for people with SCI in the community showed that the most important methods have been telemedicine, outpatient consulting hours, home visits, or a combination of methods.<sup>16</sup> Because the quality of these studies was generally low, the authors were not able to draw conclusions as to the effect of these follow-up interventions on secondary conditions or long-term costs of care. Another systematic review of the literature in 2006 on preventing pressure ulcers showed that there were few well-designed RCTs following standardized criteria and providing data on cost-effectiveness,<sup>41</sup> suggesting that more need to be developed. As technology continues to advance, experts and clinicians are looking to the field of telehealth to fill this gap.<sup>14</sup> These technologies offer accessibility to potentially highly effective behavior change interventions at low cost. For instance, the TLC-Hypertension trial was the first telehealth chronic disease application to be evaluated in a randomized clinical trial, involving 267 elderly, poorly controlled hypertensive patients. Mean adjusted diastolic blood pressure decreased signifi-

cantly; 69% of TLC users rated TLC in the upper quartile of satisfaction on a visual analog scale, whereas the cost per patient user for 6 mos of use was \$32.50.<sup>29</sup>

There are limitations to TLC technology and the Care Call intervention that must be noted. First, because TLC is an automated system, technical errors of varying kinds can occur (e.g., the system does not always recognize the user's responses or accept responses that it is not prepared to hear). To address this, technical staff needs to be available to assist users, and all calls should be logged line by line on a server to record any errors in detail for proper follow-up. In addition, the system is limited to the conversational pathways that were designed; it cannot truly take each individual user's situation into account or discuss any topic that the user is interested in pursuing. This means that Care Call may be advocating for a certain behavior that is not appropriate or not perceived to be relevant to a particular user. The system includes statements to explain these limitations, but users may still ultimately be frustrated at times. The extent to which this limits the impact of the system is an empirical question about which we will learn from our clinical trial.

## CONCLUSION

Care Call is designed to reduce the incidence and severity of secondary conditions such as pressure ulcers and depression, to be relevant across multiple consumer settings, and to facilitate long-term monitoring. The system is a low-risk, inexpensive intervention that could be widely disseminated. Results of pilot testing of Care Call demonstrated the intervention's feasibility for a wide variety of voice qualities and its general acceptability by consumers, with some minor content and logic changes. Pilot testing also allowed the team to uncover important content and logic changes that improved the system. These findings resulted in a stronger intervention and protocol for the clinical trial of Care Call.

Experience from the RCT will establish if people with SCD will use the Care Call system and if the intervention will successfully promote self-management in a cost-effective manner.

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