Authors:

Brad E. Dicianno, MD
Andrea D. Fairman, PhD, OTR/L, CPRP
Michael McCue, PhD
Bambang Parmanto, PhD
Erika Yih, BS
Andrew McCoy, BS
Gede Pramana, MS
Daihua X. Yu, PhD
Justin McClelland, MS
Diane M. Collins, PhD, OT
David M. Brienza, PhD

Affiliations:

From the Department of Physical Medicine and Rehabilitation, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania (BED); MGH Institute of Health Professions, Boston, Massachusetts (ADF); Departments of Rehabilitation Science and Technology (MC), and Health Information Management and Biomedical Informatics (BP), University of Pittsburgh, Pittsburgh, Pennsylvania; University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania (EY); Drexel University College of Medicine, Philadelphia, Pennsylvania (AM); Department of Health Information Management, University of Pittsburgh, Pittsburgh, Pennsylvania (GP, DXY, JM); Department of Occupational Therapy, University of Texas Medical Branch, Galveston, Texas (DMC); and Department of Rehabilitation Science and Technology, University of Pittsburgh, Pittsburgh, Pennsylvania (DMB).

Correspondence:

All correspondence and requests for reprints should be addressed to: Brad E. Dicianno, MD, Department of Physical Medicine and Rehabilitation, Human Engineering Research Laboratories, University of Pittsburgh School of Medicine, 6425 Penn Ave, Suite 400, Pittsburgh, PA 15206.

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ORIGINAL RESEARCH ARTICLE

Feasibility of Using Mobile Health to Promote Self-Management in Spina Bifida

ABSTRACT

Dicianno BE, Fairman AD, McCue M, Parmanto B, Yih E, McCoy A, Pramana G, Yu DX, McClelland J, Collins DM, Brienza DM: Feasibility of using mobile health to promote self-management in spina bifida. Am J Phys Med Rehabil 2015;00:00–00.

Objective: To determine feasibility of using the interactive Mobile Health and Rehabilitation (iMHere) system in spina bifida and its effects on psychosocial and medical outcomes.

Design: In a randomized controlled trial, 13 intervention participants using the iMHere system and receiving usual care and 10 control participants receiving usual care were followed for 1 year.

Results: Feasibility of use of the system was demonstrated by participants using a customized smartphone system for reminders to conduct various self-care tasks, upload photos of wounds, manage medications, complete mood surveys, and for secure messaging. High usage of the system was associated with positive changes in the subscales of the Adolescent Self-Management and Independence Scale II.

Conclusion: Use of the iMHere system in spina bifida is feasible and was associated with short-term self-reported improvements in self-management skill. This system holds promise for use in many diverse chronic care models to support and increase self-management skills.

Key Words: Cellular Phone, Emergency Departments, Health Care Costs, Hospitalization, Mobile Applications, Pressure Ulcer, Rehabilitation, Self-Care, Spina Bifida, Spinal Dysraphism, Telemedicine, Urinary Tract Infections

Disclosures:

This manuscript has not been published and is not under consideration for publication elsewhere. Data from this manuscript were accepted as part of an abstract and were presented at the AAP 2015 Annual Assembly. Drs. Dicianno, Parmanto, McCue, Brienza, and Yu, and Mr. Pramana are all inventors of the iMHere system with no other financial interests in this technology. Dr. Fairman is an inventor of iMHere and also is CEO of UbiCue, Inc, which is a startup company that has licensed iMHere from the University of Pittsburgh. This study was funded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) grant 90DP5004-01-00 (RERC from Cloud to Smartphone: Empowering and Accessible ICT), grant 0DP0064-01-00 (DRRP Promoting Independence & Self-management using mHealth), and grant 90RE5004-01-00 (RERC on Telerehabilitation), the Verizon Foundation, and the National Institutes of Health (NIH) grants 1R21HD071810-01A1 and 5T35AT005933-02. Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

More than 166,000 Americans are living with spina bifida (SB), which is the most common permanently disabling congenitally acquired condition in the United States.[1] Most individuals with SB are adults who experience astounding rates of complications from neurogenic bladder, wounds, and sepsis.[2,3] More than one third of hospitalizations of adults with SB are due to preventable conditions,[2] and individuals with SB have higher rates of hospitalizations and 30-day re-admissions compared to the general population.[3] Over time, this leads to a cumulative negative impact on body structures, functions, activity, participation, quality of life, and psychological symptoms; extremely high costs of medical care; and increased risk for early mortality.[2,3] Yet, many of these secondary conditions are, in part, preventable with proactive self-management skills.[4] Strong evidence exists to support interventions to improve self-management skills as a way to improve health outcomes and independence in activities of daily living.[5–7]

Evidence is emerging that self-management could be improved by interventions delivered via mobile health (mHealth) tools like smartphones.[8] The Food and Drug Administration predicts that by 2016, more than 500 million smartphone users will use mobile medical applications.[9] It is clear that some technologies benefit people with intellectual disabilities in daily tasks.[10] In other populations, phone-based surveys and text messaging systems have been built for young adults with various chronic conditions to assess daily activities; concussion symptoms[11]; asthma symptoms[12]; and diabetes treatment.[13] Yet, feasibility studies evaluating the use of mHealth tools to promote acquisition of self-management skills and provide 2-way communication between a user and a clinician are lacking, particularly for individuals with conditions such as SB.

The current study uses the interactive Mobile Health and Rehabilitation (iMHere) system,[14] which was designed to support self-management of adults with disabilities (Fig. 1). iMHere consists of a suite of 6 Android smartphone modules for patients (B), a web-based clinician portal (E–F), and a 2-way communication system. "MyMeds" is a module that stores a list of medications along with a photo and description of each. Users can set reminders for medications and respond to them to indicate whether they have taken the medications. "Telecath" and "BMQs" modules remind users to conduct their catheterization and bowel management programs and report compliance and problems such as symptoms of a urinary tract infection or constipation. The "Skincare" module provides reminders to conduct inspections of insensate skin and report compliance and new wounds with photos and several wound descriptors. The "Mood" module reminds users to complete a periodic survey of depressive symptoms. The "Messages" module enables the patient and clinician to communicate with each other similar to text messaging. All modules use a secure Health Insurance Portability and Accountability Act (HIPAA)-compliant, 2-way communication system. The system triages patient problems clearly on a Web-based dashboard, providing a means for a clinician to address problems quickly. iMHere has undergone usability and accessibility testing[15,16] and enhancements to improve use by those with motor, sensory, and cognitive impairments.[15,16]

A receptivity study[17] of iMHere in 107 adults with SB, family members, caregivers, and clinicians who work with them was previously conducted. Of the 36 clinicians, 72% stated they would use the system in clinical practice. Of the 71 individuals with SB, family members, and caregivers, 79% felt that it would be easy to use by persons with SB, and 82% felt it would make a "strong positive impact" on health.

The primary aim of the present study was to determine whether use of the system would result in improved medical and psychosocial outcomes. Hypothesis 1A was that individuals with SB who

FIGURE 1 *A, Patient opens iMHere and accesses 6 modules. Skincare, for example, sends a reminder (B) to check the skin and provides a body diagram (C) to report location, description, and photo if problem is encountered. D, The portal viewed by a clinician allows quick triage of all modules for each user. E, Skin issue is reported by patient.*

used iMHere would have significantly improved physical independence, self-management skills, depressive symptoms, perception of patient-centered care, and quality of life over time. Hypothesis 1B was that those using the system would have better medical and health care usage outcomes over time. Hypothesis 1C was that high users of the system would have greater improvements in self-management skill than low users.

The secondary aim was to determine whether individuals with SB would consistently use the system to carry out their own self-management routines. Hypothesis 2A was that users would achieve average usage rates above minimum thresholds based on realistic self-management routines. Hypothesis 2B was that there would be a positive association between number of photos and messages sent and medical events because of reporting of new issues, but a negative association between number of responses to reminders and medical events due to proactive self-management.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of the University of Pittsburgh, and all participants signed written informed consent. Participants were recruited from a local adult SB clinic and local community organizations. Inclusion criteria were the following: age 18 to 40 years, primary diagnosis of myelomeningocele with hydrocephalus, passing a screening that demonstrated ability to use a smartphone, and living in a community setting within 100 miles of the testing site to allow for technical support. Exclusion criteria were the following: actively participating in a wellness pilot program,[18] a diagnosis of severe intellectual disability, a diagnosis of nonmyelomeningocele subtype of SB, and severe and persistent psychiatric illness and/or drug or alcohol addiction.

Participants were randomized into a control and intervention group by using a Microsoft Excel (Microsoft, 2010) file to generate odd and even values from a number table for random assignment to a group. The control group received usual care in the adult SB clinic. The intervention group received usual care and was provided an Android smartphone equipped with the iMHere system and a plan that included unlimited texting and data. Participants were asked to use the modules according to their own prescribed protocols and use secure messages or upload photos of skin issues as needed. An occupational therapist served as the wellness coordinator and monitored the intervention groups remotely. She helped patients meet goals for self-management, communicated with them through the portal about problems

reported and their compliance with self-management routines, and ensured patients had appropriate in-person follow-up for issues that required hands-on care.

Data on usage were extracted from the iMHere system electronically. Survey outcome measures were collected at baseline and approximately every 4 months for a total of 12 months (4 time points) via phone by an investigator blinded to participant group. Medical and usage outcome measures were collected by chart review for 1 year before the study and also for the 1-year duration of the study. In depth participant interviews and exit surveys were used to verify the data collected from the chart and resolve any discrepancies.

Outcome Measures

- Usage: the number of times a participant responded to a reminder, corresponded through secure message, or uploaded a photo.
- Physical independence: Craig Handicap Assessment and Reporting Technique Short Form (CHART-SF), Physical independence domain.[19] The CHART-SF has 6 domains, each validated to be used independently. The physical independence domain represents the number of hours of paid and unpaid caregiver assistance needed per day and is converted to a score of 0 to 100, with higher scores indicating higher levels of physical independence.
- Self-management skill: Adolescent Self-Management and Independence Scale II (AMIS-II), which has been validated for use in adults with SB.[20] Seventeen questions are ranked from 1 to 7, summed and averaged to obtain a total score. The independent living subscale is an average of 10 items on topics such as ordering supplies and community living skills. The condition self-management subscale is an average of 7 items on topics such as medication management and complication prevention. Higher scores indicate higher self-management skill.
- Depressive symptoms: The Beck Depression Inventory-II (BDI-II)[21,22] is a screening questionnaire consisting of 21 questions with each answer assigned a point value on a scale from zero to 3, with zero indicating no active symptoms and 3 representing the most severe symptoms. Scores are totaled and range from a minimum of 0 to a maximum of 63. The BDI-II as a screening tool has been demonstrated to be particularly useful in populations at high risk for depression, such as those with chronic and complex medical conditions[23] and SB.[24]
- Perception of patient-centered care: Patient Assessment of Chronic Illness Care (PACIC),[25] a valid measure of perception of chronic care delivery. The average score of 20 questions, each scored 1 to 5, is reported, with higher scores indicating higher satisfaction with care.
- Quality of life: World Health Organization Quality of Life Brief Instrument,[26,27] a valid measure of quality of life within the context of culture, value systems, personal goals, standards, and concerns. This measure contains 4 domains, each scored zero to 100, with higher scores indicating higher quality of life.
- Number of UTIs: defined as the number of urinary tract infections diagnosed in any setting with documented symptoms, diagnostic urine culture, and subsequent treatment with antibiotics.
- Number of wounds: defined as the number of unique skin breakdown episodes that were at least stage II, either in different locations or as separate breakdowns in the same area but separated by a period of healing verified by history and documented physical examination findings.
- Number of emergency department (ED) visits: defined as the number of visits to an ED for any reason.
- Number of ED visits due to UTI or wound: defined as the number of visits to an ED with a resultant diagnosis of UTI or wound at discharge from the ED, with UTI and wound being defined previously.
- Number of planned hospitalizations: number of expected admissions to a hospital for a scheduled same-day surgery or hospital procedure.
- Number of unplanned hospitalizations: number of hospital admissions as a result of an ED visit.
- Number of hospitalizations due to UTI or wound: number of hospital admissions as a result of an ED visit and during which a UTI or wound as previously defined was a diagnosis during the hospitalization (excluding diagnoses verified in the ED).

Statistical Analysis

To reduce the probability of obtaining a type II error, an a priori power analysis was completed using the G*Power software program, version 3.1.9.2, to determine sample size. A moderate effect size of 0.30 was applied based on preliminary data gathered through an in-person wellness program for individuals with SB wherein the incidence of secondary conditions (ie, pressure ulcers and UTIs) were reduced by 30% to 50% in comparison to a similar population not receiving wellness services.[18] Using a one-way repeated-measures analysis of variance

approach with 4 data collection points, a total of 18 subjects yielded a power of 80%. Alpha levels were set at 0.05 a priori. SPSS Statistics version 22 was used for all analyses.

Hypothesis 1A: Mann-Whitney *U* tests (ordinal or nonparametric continuous variables), *t* tests (parametric continuous variables), and Fisher exact tests (categorical variables) were used to compare intervention and control groups with respect to baseline demographics and outcome measures. Repeated-measures analysis of variance (parametric continuous variables) and Friedman tests (nonparametric continuous variables) were used to evaluate whether scores changed significantly over time within each group.

Hypothesis 1B: Mann-Whitney *U* tests were run to compare the control and intervention groups at baseline with respect to medical event variables. Wilcoxon tests were run within each group to determine if statistically significant changes occurred in the number of events from the prestudy period to the intervention period. Effect sizes were calculated according to work by Lakens.[28] Cohen d_z was used because it estimates the effect size for the difference between 2 correlated measurements. Effect sizes were categorized as follows: small (0.2), medium (0.5), and large (0.8).[29]

Hypothesis 1C: Intervention participants were divided into high and low users of the system overall and within each component of the system (4 reminders, photo feature, and secure messaging) based on usage data. Friedman tests were run to evaluate for changes in each user group with respect to the AMIS-II condition self-management subscale for each of the components. Since the only component of the system that relates to the independent living subscale is myMeds, which can be used to order wound supplies, one Friedman test was run to evaluate for changes in this subscale in the usage groups.

Hypothesis 2A: usage data were reported descriptively and compared to benchmarks (myMeds, ≥1 use/day; Telecath, ≥2 uses/day; Skincare, ≥1 use/day; Mood survey, ≥1 use/2 weeks; BMQs, ≥2 uses/week; and secure messages and skin photos as needed) to determine feasibility of use of the system. Benchmarks were based on the minimal frequency that each self-management task is typically carried out in our population. Individuals are encouraged to check their skin once per day. The lowest frequency of medication usage is one medication dosed once per day. Typically, individuals catheterize the bladder and conduct a bowel program at least 3 times per day and 3 times per week, respectively. Additionally, mood surveys were scheduled every 2 weeks to mitigate overreporting of symptoms.

Hypothesis 2B: change scores for each medical event were calculated by subtracting the number of events in the year before the study from those in the study period for each intervention participant. Spearman correlations were then run to identify associations between each change score and usage for each component of the system.

To estimate cost of care, cost estimations in previous literature were used. For patients with SB, the mean costs of an ED visit and inpatient admission have been estimated at $2,102 and $28,918, respectively.[30] The mean cost of UTIs treated in an outpatient setting is estimated to be $462 for 18- to 29-year-olds with SB and $511 for 30- to 44-year-olds with SB.[31] For cost savings calculations, $462 was used given that the participants in this study had a mean age of 29.6 years, and $462 was the more conservative estimate. The estimated mean cost to heal a wound in the outpatient setting is $3,927.[32] However, the most common wound for individuals with SB is a pressure ulcer, and the cost of outpatient treatment of pressure ulcers, particularly pressure ulcers in people with paralysis, is difficult to estimate but is thought to be much higher than the treatment of other types of wounds because of common comorbidities, as well as complications associated with loss of sensory input.[33,34] Therefore, $3,927 was used. Since these health care cost estimations were derived from reviewing data from prior years (2006–2010 for ED visits, 2004–2005 for inpatient admissions, 2003–2006 for UTIs, and 2005–2010 for wounds),[2,30] they were converted to current (2015) US dollars using the United States Department of Labor's Consumer Price Index Inflation Calculator.[35]

RESULTS

Twenty-seven participants enrolled. One participant was excluded based on not having a diagnosis of myelomeningocele, one was lost to follow-up, and 2 participants voluntarily withdrew (one in the intervention group could not acquire consistent wireless service, and one in the control group stated she was moving). The control group had 10 participants, and the intervention group had 13 participants. All 23 remained enrolled for the 1-year duration of the study. The wellness coordinator was able to manage all intervention participants in 1 hour per day or less on average, which was similar to time

TABLE 1 Baseline demographic comparisons between intervention and control groups

Demographic Variables		Intervention, N = 13	Control, N = 10	Statistical Test *P*
Age, mean (SD), yrs		29.7 (5.0)	29.5 (6.8)	*t* test 0.938
Sex	Male	8 (61.5%)	5 (50.0%)	Fisher exact 0.685
	Female	5 (38.5%)	5 (50.0%)	
Ethnic and racial origin	White	12 (92.3%)	10 (100%)	Fisher exact 1.000
	Hispanic	1 (7.7%)	0 (0.0%)	
Marital status	Single	12 (92.3%)	10 (100%)	Fisher exact 1.000
	Not single	1 (7.7%)	0 (0.0%)	
Highest level of education	High school diploma (only)	3 (23.1%)	4 (40.0%)	Fisher exact 0.650
	Higher education (college, trade, tech)	10 (76.9%)	6 (60.0%)	
Received special education services		11 (84.6%)	8 (80.0%)	Fisher exact 1.000
Level of lesion	L2 and above	9 (69.2%)	7 (70.0%)	Fisher exact 1.000
	L3-L5	4 (30.8%)	3 (30.0%)	
Uses paid personal assistance		4 (30.8%)	3 (30.0%)	Fisher exact 1.000
Hours of paid personal assistance used per week		8.6 (16.6)	5.7 (11.5)	Mann-Whitney 0.879
Living situation	Lives alone	1 (7.7%)	3 (30.0%)	Fisher exact 0.281
	Lives with others	12 (92.3%)	7 (70.0%)	
Assistive device used for mobility	Ambulates with or without an assistive device	1 (7.7%)	3 (30.0%)	Fisher exact 0.281
	Nonambulatory (uses wheelchair)	12 (92.3%)	7 (70.0%)	
Is a student		1 (7.7%)	3 (30.0%)	Fisher exact 0.281
Is a smoker		1 (7.7%)	0 (0.0%)	Fisher exact 1.000
Describes self as "tech savvy"		12 (92.3%)	9 (90.0%)	Fisher exact 1.000
Has problems with vision but uses glasses		1 (7.7%)	2 (20.0%)	Fisher exact 0.560
Has problems with fine motor skills		1 (7.7%)	1 (10.0%)	Fisher exact 1.000
Has previous experience with "Apps"		7 (53.8%)	7 (70.0%)	Fisher exact 0.669
Has previous experience using smartphones		9 (69.2%)	7 (70.0%)	Fisher exact 1.000

TABLE 2 Baseline survey outcome measure comparisons between intervention and control groups

	Intervention, n = 13	Control, n = 10	Statistical Test
Outcome Measure	Mean (SD)	Mean (SD)	*P*
AMIS-II	5.5 (1.3)	5.9 (1.3)	Mann-Whitney 0.186
Condition	5.6 (1.3)	6.2 (1.2)	Mann-Whitney 0.257
Independent living	5.3 (1.4)	5.7 (1.5)	Mann-Whitney 0.343
PACIC	3.3 (1.0)	2.9 (0.7)	*t* test, 0.311
BDI-II	6.6 (6.3)	3.9 (5.4)	*t* test, 0.286
WHOQOL-BREF			
Physical	76.6 (16.5)	78.2 (10.3)	*t* test, 0.796
Psychological	78.2 (14.3)	75.4 (11.0)	*t* test, 0.616
Social	75.0 (18.3)	72.5 (16.2)	*t* test, 0.737
Environment	82.2 (13.3)	79.7 (11.7)	*t* test, 0.635
CHART-SF			
Physical	83.7 (22.3)	93.6 (10.0)	Mann-Whitney 0.257
Cognition	71.5 (35.0)	73.8 (25.1)	*t* test, 0.864
Mobility	75.1 (21.8)	89.3 (13.7)	Mann-Whitney 0.057
Occupational	38.6 (34.4)	58.1 (36.9)	*t* test, 0.204
Social	91.2 (18.2)	98.0 (6.3)	Mann-Whitney 0.410
Economic	51.6 (32.8)	78.3 (29.0)	*t* test, 0.074

spent on phone calls by nurses for usual care of those in the control group.

Hypothesis 1A: Tables 1 and 2 show comparisons of study groups at baseline. No significant differences between groups were found at baseline with regard to demographics or survey outcome measures. Table 3 shows variations in survey outcome measures over the study period. Adolescent Self-Management and Independence Scale II, BDI-II, Patient Assessment of Chronic Illness Care, and WHO Quality of Life Brief Instrument scores did not change significantly over the study period. The CHART-SF physical domain had a spike in score at time point 2 for the intervention group, which produced a significant change over time ($P = 0.044$). In the control group, the CHART-SF physical domain score did not change significantly; see Figures 2–4.

Hypothesis 1B: Table 4 shows comparisons of the outcome measures of the study groups at baseline with respect to medical events. These baseline differences were not statistically significant. Table 5 shows changes in the number of events for each outcome measure over time and effect sizes. A trend was seen in favor of decreased medical events and usage measures for the intervention group. Although this trend was not statistically significant, it was consistent across all 7 outcome measures.

Hypothesis 1C: Within the intervention group, AMIS-II total score significantly increased in high users of the system ($P = 0.020$). Significant improvements over time were seen in the condition self-management subscale for high users of Skincare photos ($P = 0.028$), Skincare reminders ($P = 0.029$), BMQs ($P = 0.038$), and Telecath reminders ($P = 0.038$). No significant associations were found for the

TABLE 3 Survey outcome measures

	Baseline	1st	2nd	3rd	Statistical Tests
Outcome Measure	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	*P**
AMIS -II					Friedman test
Intervention	5.5 (1.3)	5.5 (1.3)	5.6 (1.2)	5.7 (1.2)	0.062
Control	5.9 (1.3)	6.7 (0.3)	5.8 (1.5)	5.4 (1.4)	0.345
Condition					Friedman test
Intervention	5.6 (1.3)	5.6 (1.3)	5.8 (1.2)	5.9 (1.1)	0.151
Control	6.2 (1.2)	6.9 (0.1)	6.1 (1.4)	5.9 (1.4)	0.581
Independent living					Friedman test
Intervention	5.3 (1.4)	5.4 (1.5)	5.4 (1.3)	5.6 (1.3)	0.064
Control	5.7 (1.5)	6.5 (0.5)	5.7 (1.6)	5.4 (1.4)	0.054
PACIC					RM ANOVA
Intervention	3.3 (1.0)	3.4 (0.9)	3.3 (1.0)	3.1 (1.1)	0.354 (time)
Control	2.9 (0.7)	2.6 (0.9)	3.0 (0.6)	3.1 (0.5)	0.338 (time)
					0.432 (group)
					0.258 (time*group)
BDI-II					Friedman
Intervention	6.6 (6.3)	5.6 (6.9)	4.6 (5.7)	4.8 (6.4)	0.426
Control	3.9 (5.4)	6.0 (12.3)	6.3 (14.5)	9.4 (16.6)	0.776
WHOQOL-BREF					
Physical					Friedman
Intervention	76.6 (16.5)	78.9 (19.8)	76.4 (21.0)	76.5 (21.6)	0.433
Control	78.2 (10.3)	78.6 (22.6)	78.9 (17.7)	82.1 (13.5)	0.682
Psychological					Friedman
Intervention	78.2 (14.3)	78.0 (18.7)	76.9 (15.3)	80.9 (15.4)	0.172
Control	75.4 (11.0)	77.5 (22.9)	77.9 (19.7)	75.0 (19.5)	0.907
Social					RM ANOVA
Intervention	75.0 (18.3)	70.5 (19.1)	76.3 (18.3)	76.4 (16.6)	0.303 (time)
Control	72.5 (16.2)	75.0 (25.0)	85.8 (11.8)	79.8 (12.6)	0.202 (time)
					0.676 (group)
					0.064 (time*group)
Environment					Friedman
Intervention	82.2 (13.3)	81.3 (16.9)	79.3 (18.0)	80.7 (17.7)	0.755
Control	79.7 (11.7)	75.0 (24.8)	79.7 (19.7)	80.4 (19.1)	0.564
CHART-SF					
Physical					Friedman
Intervention	83.7 (22.3)	88.4 (15.0)	91.3 (12.6)	84.3 (16.6)	**0.044**
Control	93.6 (10.0)	95.2 (6.6)	94.4 (6.6)	96.6 (6.3)	0.392

RM indicates repeated measures; boldface, significance at 0.05 level.

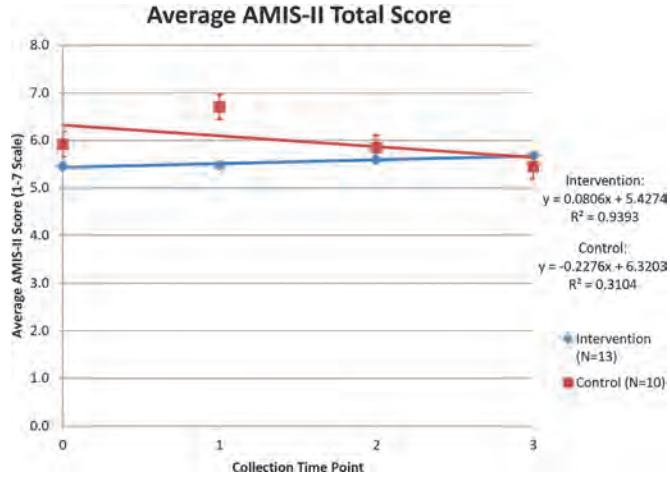

FIGURE 2 *Graph of AMIS-II scores in intervention and control groups. Error bars indicate standard error.*

condition self-management subscale for myMeds or secure messaging in high users. Significant improvements in the independent living subscale were seen for high users of the myMeds module ($P = 0.022$). No significant associations were seen in low users.

Hypothesis 2A: Table 6 shows usage of all components of the system in comparison to benchmarks. A total of 12 participants were on medications and using bladder catheterization, and 11 were on bowel programs, all of whom used the modules to some extent. Usage of myMeds, BMQs, and Mood survey exceeded benchmarks. Usage of Telecath and Skincare reminders fell below benchmarks. All participants used secure messaging. More than 69% of participants uploaded skin photos, with reported wounds ranging from stage I pressure ulcers and abrasions to stage IV pressure ulcers.

Hypothesis 2B: Significant positive associations were found between the use of both the secure messaging module ($P = 0.003$; $r = 0.720$) and skincare reminder function ($P = 0.013$; $r = 0.611$) with change in the number of wounds. Significant positive associations were also found between the use of the secure messaging module with change in both ED visits ($P = 0.007$; $r = 0.663$) and hospitalizations ($P = 0.012$; $r = 0.623$) because of UTIs. No other associations between usage and medical and usage outcomes were identified.

Estimated cost of care is presented in Table 7.

Four participants in the intervention group had no previous experience using smartphones. When the smartphones were removed at the end of the study, two of these participants purchased new smartphones. Of the 9 participants with smartphone experience, at the end of the study, one purchased the same phone used in this study, and one purchased an upgraded smartphone. These participants indicated that part of the decision to upgrade their phone was that they saw value to their health in using a smartphone.

DISCUSSION

A dearth of literature exists on outcomes of telehealth and mHealth in SB. Besides a pilot study

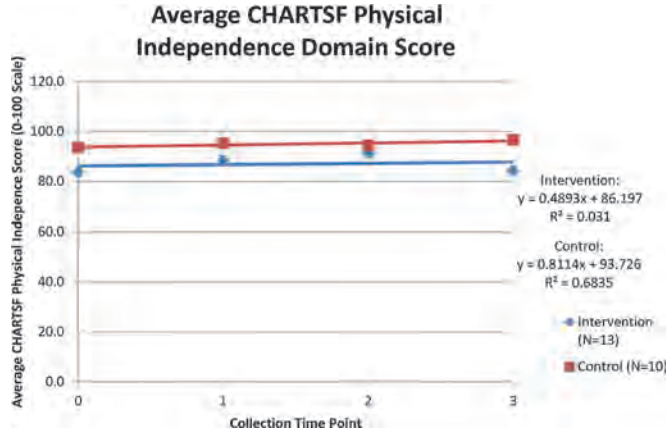

FIGURE 3 *Graph showing the average CHART-SF Physical Independence Domain Score in intervention and control groups. Error bars indicate standard error.*

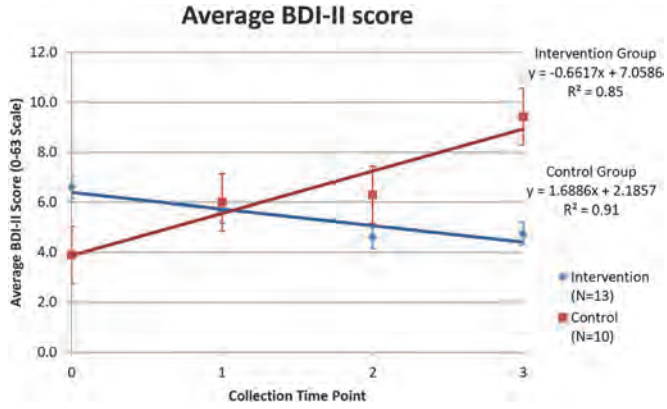

FIGURE 4 *Graph showing the average BDI-II score in intervention and control groups. Error bars indicate standard error.*

that used Skype effectively to provide a telehealth intervention to support continence care at home,[36] we know of no other studies evaluating efficacy of telehealth or mHealth technology interventions for individuals with SB.

This study demonstrated feasibility of using several components of an mHealth system in the SB population. Participants met or exceeded set benchmarks for use and were more likely to use modules that reminded them to conduct activities that occurred on a less than daily basis (bowel management, which is typically done 2–3 times per week) and to remind them to take medications, which often changed during the period of the study. They were also more likely to communicate new information or symptoms to a wellness coordinator by secure message, survey, or photograph. They were less likely to use modules to remind them to conduct activities that occur on a daily or more frequent basis (catheterizing bladder or checking the skin), as evidenced by benchmarks not met. Some participants had already incorporated these activities into their daily routine and felt they did not need such frequent reminders, but some also had difficulty checking the skin and catheterizing at the frequency recommended by their physiatrist. Additionally, some disliked receiving too many reminders. Feasibility was also demonstrated by the fact that several participants attributed health value to smartphones and purchased their own phones at the end of the study.

We anticipated that individuals would use the photo and secure messaging features more when experiencing new events. This held true for the secure messaging feature. A surprising but encouraging finding was that the photo feature was used more than anticipated, for even minor skin issues that did not require treatment. Higher usage of reminders was not associated with decreased events, as expected, and in fact, the opposite was true for Skincare reminders. This is likely because participants responded to Skincare alerts more often when they had concerns about their skin, rather than using it to remind them to check the skin as a way to detect new problems.

The hypothesis that use of iMHere would result in improvements in self-management skill was supported only for high users. High usage of the system was associated with a gain in independence in some self-management skills. High users began the study at a "supervision level" and then approached or exceeded a level of "modified independence" by the end of the study. Low users began the study at a statistically similar level but did not change. High

TABLE 4 Baseline medical event comparisons between intervention and control groups

	Intervention, n = 13	Control, n = 10	Statistical Test
Outcome Measure	Mean (SD)	Mean (SD)	*P*
UTIs	0.6 (0.8)	0.2 (0.6)	Mann-Whitney, 0.186
Wounds	0.6 (0.5)	0.4 (0.5)	Mann-Whitney, 0.410
ED visits	0.6 (1.0)	0.1 (0.3)	Mann-Whitney, 0.232
ED visits due to UTI/wound	0.4 (0.7)	0.1 (0.3)	Mann-Whitney, 0.410
Planned hospitalizations	0.3 (0.6)	0 (0)	Mann-Whitney, 0.376
Unplanned hospitalizations	0.4 (0.8)	0 (0)	Mann-Whitney, 0.376
Hospitalizations due to UTI/wound	0.2 (0.4)	0 (0)	Mann-Whitney, 0.376

TABLE 5 Occurrences of medical events in participant groups over time

Outcome Measure	Prestudy Period		Study Period		Change Score	Wilcoxon *P*	Cohen d_z Effect Size
	Events	Events per Person	Events	Events per Person			
No. UTIs							
Intervention	8	0.6	4	0.3	−0.3	0.271	0.30
Control	2	0.2	5	0.5	+0.3	0.408	
No. wounds							
Intervention	8	0.6	4	0.3	−0.3	0.206	0.36
Control	4	0.4	7	0.7	+0.3	0.317	
Total no. ED visits							
Intervention	8	0.6	3	0.2	−0.4	0.301	0.31
Control	1	0.1	2	0.2	+0.1	0.564	
No. ED visits due to UTI/wound							
Intervention	5	0.4	1	0.1	−0.3	0.157	0.41
Control	1	0.1	1	0.1	0	1.000	
No. planned hospitalizations							
Intervention	4	0.3	3	0.2	−0.1	0.564	0.16
Control	0	0	1	0.1	+0.1	0.317	
No. unplanned hospitalizations							
Intervention	5	0.4	1	0.1	−0.3	0.194	0.36
Control	0	0	2	0.2	+0.2	0.157	
No. hospitalizations due to UTI/wound							
Intervention	3	0.2	2	0.2	−0.1	0.655	0.12
Control	0	0	1	0.1	+0.1	0.317	

Intervention, n = 13; control n = 10.

users may therefore have perceived a greater benefit to using the system than low users and thus used the system more. Skill improvements were seen in those who used components of the system to manage skincare, neurogenic bowel and bladder, and to order wound supplies.

Depressive symptoms trended down in the intervention group and up in the control group. The average total BDI-II scores at all time points fell within the normal range of symptoms, but these scores began to approach the threshold of mild depressive symptoms for the control group at the conclusion of the study. More work using a population with higher levels of depressive symptoms is needed to determine whether the use of iMHere could have a larger impact on scores.

Quality of life did not seem to change in either group. Previous work[37] has suggested that individuals with SB report a high overall quality of life even when they have clear challenges such as

TABLE 6 Usage of components of iMHere system and comparison to benchmarks

	Response to MyMeds Reminder	Response to Telecath Reminder	Response to BMQ Reminder	Response to Skincare Reminder	Uploaded Skincare Photo	Response to Mood Reminder	Corresponded Through Secure Message
Total number	8,104	3,944	1,794	1,743	112	506	870
Average per user over 1 yr	623.4	303.4	138.0	134.1	8.6	38.9	66.9
SD	1,386.5	312.4	129.7	136.8	12.4	60.8	79.7
Minimum	0	0	0	4	0	1	4
Maximum	5,176	950	346	496	35	180	273
Average per user per month	51.9	25.3	11.5	11.2	0.7	3.2	5.6
Average per user per week	12.0	5.8	2.7	2.6	0.2	0.7	1.3
Average per user per day	1.7	0.8	0.4	0.4	0.0	0.1	0.2
Benchmark	≥1 use/d	≥2 uses/d	≥2 uses/wk	≥1 use/d	As needed	≥0.5 use/wk	As needed

TABLE 7 Estimated cost of care

	Intervention Group		Control Group	
Cost	Before Study	After Study	Before Study	After Study
Outpatient UTIs	$274.19	$91.40	$118.81	$297.04
Outpatient wounds	$2,294.35	$1,311.06	$1,704.38	$2,556.56
Total ED Visits	$1,403.54	$526.33	$228.08	$456.15
Total hospitalizations	$24,253.71	$10,779.42	$0.00	$10,509.94
Total	$28,225.78	$12,708.21	$2,051.27	$13,819.69

mobility impairments or incontinence. This may be due to individuals perceiving that they are doing "as well as possible" despite their limitations. We are currently conducting a clinical trial in individuals with spinal cord injury. Results will inform whether differences exist in quality-of-life outcomes for individuals with adult onset injuries versus congenitally acquired conditions such as SB.

Whereas participants' perception of patient-centered care did not improve through use of iMHere, retrospective analysis of the data revealed opportunities to make changes to our practice. The lowest scores were reported for the item "Encouraged to go to a specific group or class to help me cope with my chronic condition," which is consistent with findings from a prior study.[6] It is not clear whether clinic patients would actually attend group classes given geographic and transportation barriers. However, opportunities for telemedicine or mHealth to play a role in deploying group activities should be explored.

With regard to medical events, the intervention group showed improvement in all outcome measures from the prestudy period to the study period. In comparison, the control group had slightly worsening scores for 6 outcomes and no change for one outcome. However, these were not statistically significant. Since consistent trends were seen across all 7 measures, it is possible that there is a measurable effect of iMHere, which could be detected with a larger sample size. Our a priori sample size calculation was based on expected changes in survey outcome variables. To detect changes in medical events, using a Wilcoxon signed rank test design with only 2 collection points, a total of 74 subjects yield power of 80%. Therefore, although the study was powered to detect changes in the primary psychosocial outcomes of interest, one limitation of this study was that it was underpowered to detect changes in the types of medical events measured. The trends of worsened outcomes in the control group may also be due to chance or regression to the mean. Finally, although the control and intervention groups were not significantly different at baseline with respect to medical event data, a ceiling effect may have prevented significant improvements from occurring. The average number of inpatient admissions per person per year for individuals with SB in the United States ranges from 0.28 to 2.0.[38] Therefore, the rates of hospitalization seen for both the control and intervention groups in this study are lower overall than what has been reported in other areas and may be due to the clinic being particularly attuned to wellness care.

Other limitations to this study deserve discussion. We had initially planned on collecting outcomes every 3 months for 1 year, which would have yielded more data collection points and may have increased power to detect differences in outcome measures that approached significance or which trended according to expectations. However, for practical reasons, problems with scheduling interviews with participants made this difficult to achieve. Furthermore, provision of a smartphone may have been a strong incentive for the intervention group, but this incentive was minimized by 2 factors. First, we financially compensated the control participants ($100) but not the intervention participants; and second, only 3 of the control participants had no previous experience using smartphones (Table 1).

Additional refinements of the system are currently undergoing development to improve outcomes by increasing usage of each of the modules. Educational material on medical conditions is being added to the modules. Usability and accessibility features of the system are being improved in an iterative fashion with ongoing studies. A new alarm bundling system was added so that when several self-management tasks are scheduled at one time, the user will receive only one alarm but can respond to each task individually. A new "badge" feature was also added to allow users to easily see when they have received a new secure message or reminder. Work is also being conducted to add gamification features to motivate and reward users. We are also expanding the suite of modules available so that other self-management and psychosocial outcomes can be addressed and the system can be piloted in

individuals with other chronic conditions. Finally, cross-platform functionality will be added to allow use of the system on iOS (Apple) platforms.

The impact of chronic illness and disability on self-management is a critical barrier to health and wellness. More than half of all Americans have at least one chronic illness,[39] and approximately one fourth of people with chronic conditions have a disability that limits one or more activities of daily living.[40] We are planning future studies that examine the specific type, quantity, and frequency of mHealth interventions that are optimal within various age groups and abilities. The ultimate goal will be to develop a "smart" mHealth system that provides the most effective intervention techniques to keep individuals motivated and engaged. Sustaining interest and engagement is challenging. Yet, the opportunities to discover new ways to lessen the negative impact of secondary conditions are vast.

CONCLUSIONS

To our knowledge, use of the iMHere System is the first application of mHealth to the SB population. This study demonstrates feasibility of use of the iMHere system through participant use of mobile reminders, messages, and photos. High usage of the system was associated with positive changes in self-management skills. This system holds promise for use in many diverse chronic care models to develop and maintain increased self-management skills.

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