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ORIGINAL ARTICLE

Michigan Stroke Transitions Trial

A Clinical Trial to Improve Stroke Transitions

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BACKGROUND: To test whether access to home-based social worker–led case management (SWCM) program or SWCM program combined with a website providing stroke-related information improves patient-reported outcomes in patients with stroke, relative to usual care.

METHODS AND RESULTS: The MISTT (Michigan Stroke Transitions Trial), an open (unblinded) 3-group parallel-design clinical trial, randomized 265 acute patients with stroke to 3 treatment groups: Usual Care (group-1), SWCM (group-2), and SWCM+MISTT website (group-3). Patients were discharged directly home or returned home within 4 weeks of discharge to a rehabilitation facility. The SWCM program provided in-home and phone-based case management services. The website provided patient-orientated information covering stroke education, prevention, recovery, and community resources. Both interventions were provided for up to 90 days. Outcomes data were collected by telephone at 7 and 90 days. Primary patient-reported outcomes included Patient-Reported Outcomes Measurement Information System Global-10 Quality-of-Life (Physical and Mental Health subscales) and the Patient Activation Measure. Treatment efficacy was determined by comparing the change in mean response (90 days minus 7 days) between the 3 treatment groups using a group-by-time interaction. Subjects were aged 66 years on average, 49% were female, 21% nonwhite, and 86% had ischemic stroke. There were statistically significant changes in Patient-Reported Outcomes Measurement Information System Physical Health (P=0.003) and Patient Activation Measure (P=0.042), but not Patient-Reported Outcomes Measurement Information System Mental Health (P=0.56). The mean change in Patient-Reported Outcomes Measurement Information System Physical Health scores for group-3 (SWCM+MISTT Website) was significantly higher than both group-2 (SWCM; difference, +2.4; 95% CI, 0.46–4.34; P=0.02) and group-1 (usual care; difference, +3.4; 95% CI, 1.41–5.33; P<0.001). The mean change in Patient Activation Measure scores for group-3 was significantly higher than group-2 (+6.7; 95% CI, 1.26–12.08; P=0.02) and marginally higher than group-1 (+5.0; 95% CI, −0.47 to 10.52; P=0.07).

CONCLUSIONS: An intervention that combined SWCM with access to online stroke-related information produced greater gains in patient-reported physical health and activation compared with usual care or case management alone. There was no intervention effect on mental health.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT02653170.

Key Words: case management ■ clinical trial ■ patient reported outcomes ■ social worker ■ stroke ■ transitional care

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WHAT IS KNOWN

- Acute stroke survivors and their caregivers often report health-related, social, and emotional challenges after returning home after hospitalization.
- There is a substantial need to develop effective, practical, evidence-based interventions that can assist and support patients during this transition period.

WHAT THE STUDY ADDS

- The MISTT (Michigan Stroke Transitions Trial) was undertaken to determine whether delivering a home-based social worker–led case management program or a social worker–led case management program combined with a website providing stroke-related information to acute stroke patients, improved patient-reported outcomes relative to usual care.
- The combination of social worker–led case management with access to the website resulted in clinically meaningful increases in physical-health quality-of-life and patient activation but no changes in mental-health quality-of-life.
- The MISTT results demonstrate that it is possible for transitional care interventions to produce meaningful improvements in patient-reported outcomes; further work is required to determine the independent effects of online information to improve patient outcomes during the transition period.

For many patients with stroke, navigating the transition between hospital and home is associated with substantial emotional, social, and health-related challenges. Patients with stroke commonly encounter high readmission rates,[1] limited access to rehabilitation care,[2,3] or community-based resources.[4–6] The emphasis on minimizing hospital length-of-stay and the complex care system that patients encounter following discharge exacerbate these challenges.[4,5,7]

One strategy for improving care during the hospital-to-home transition period is to provide a case manager or coach, often a nurse or para-professional,[8,9] but most transition-based intervention studies to date have included few patients with stroke.[10,11] There are a handful of transition-related studies, conducted in other patient populations, that have utilized social workers.[12–14] Social workers play a vital role in healthcare by advocating for clients, providing counseling, and coordinating services; by evaluating the complex social, medical, and mental health needs of patients, social workers can play an important role in improving transitional care.

Other strategies used to improve transitional care include patient engagement and education.[15] Stroke survivors and caregivers often report dissatisfaction with information provided to them.[6,16,17] Although interventions have been designed to educate patients during hospitalization,[18] this is often not the optimal time to comprehend and retain information effectively.[19] Moreover, many of the challenges patients face after returning home cannot be anticipated and thus cannot be addressed before discharge.

To address these challenges, the MISTT (Michigan Stroke Transitions Trial) was designed to test whether case management led by a social worker either alone or in combination with a curated website providing stroke-related information could improve patient-reported outcomes in stroke survivors who return home, compared with usual care (UC).

METHODS

The data that support the findings of this study are available upon request from the corresponding author.

Design

Details regarding the MISTT study design have been previously published.[20] This article follows the CONSORT-SPI (Consolidated Standards of Reporting Trials for Social and Psychological Interventions) extension for reporting social and psychological intervention studies.[21] MISTT was an open (nonblinded), randomized, parallel, 3-group clinical trial. Participants were recruited from 3 Michigan hospitals and randomized on the day they discharged home either directly from the hospital or after a 4-week or shorter stay in a rehabilitation facility. Treatment groups were allocated (1:1:1) to

1. Group-1: UC.
2. Group-2: Home-based social worker–led case management (SWCM) program.
3. Group-3: SWCM program plus access to the MISTT website, a curated patient-orientated information resource (SWCM+MISTT Website).

The randomization scheme was generated centrally using a concealed, computer generated, randomized block design (block size=6 or 9) stratified by hospital site. Treatment group allocation was communicated by the project manager (M.C. Fritz) to social work team members who then informed the patient and caregiver. Study personnel were not blinded to the final treatment group assignments.

Participants

Patients were enrolled by study coordinators at 3 stroke centers in 2 Michigan cities (Lansing, Ann Arbor). The target population was adult acute patients with stroke returning home within 1 month of hospital discharge.[20] Eligible patients had a confirmed diagnosis of acute ischemic or hemorrhagic stroke, were living at home before admission, and were discharged either directly home or to an acute or subacute rehabilitation facility with an expectation of returning home within 1 month. Patients discharged directly home had to exhibit functional deficits (modified Rankin Score [mRS] ≥1) or have rehabilitative therapy recommended at discharge (see Methods in the Data Supplement). Proxy consent was obtained for patients who failed cognitive screening (defined

as a score of ≤4 on the 6-item cognitive screen[22]) or had significant stroke-related communication deficits as determined by study coordinators.[20]

Although not required for participation, patients had the option of identifying a caregiver (defined as the person most likely to be helping them at home) to be enrolled in the trial.[20] Caregiver results will be described in subsequent publications.

The MISTT study was approved by Institutional Review Boards at Michigan State University and each study site.[20] Written informed consent was obtained from all enrolled participants. Recruitment occurred between January 2016 and July 2017; data collection was completed by November 2017.

Interventions

The theoretical underpinnings of the MISTT interventions were guided by core principles of SWCM which were integrated with 3 components of the Chronic Care Model,[23] specifically, self-management support, community resources, and decision support (Figure 1). The organization and content of the SWCM program and MISTT website were developed following input from focus groups conducted with patients with stroke, caregivers, and health providers during the pretrial planning phase.[20] Hypothesized mechanisms of action for the MISTT interventions included increased self-management, care coordination, information access, and patient engagement (Figure 1).

The 90-day intervention period began when patients returned home. Subjects in the UC group received the hospitals' standard postdischarge instructions, services, and recommendations, which included medication lists, education materials, follow-up instructions, and referrals to medical appointments, and postacute services. We did not document which specific components individuals assigned to UC received, but we monitored hospitals throughout the study to ensure there were no major changes in discharge practices. None of the hospitals had active case management or online programs that targeted patients with stroke after discharge. To promote study retention, letters with stroke- and health-related brochures were mailed to UC subjects at 1, 4, and 8 weeks.

Subjects in group-2 and group-3 both received the SWCM program which was delivered by 4 masters-level trained social workers (SWs) through a combination of in-home visits and follow-up phone calls.[24] The goal was to provide services for 60 days (±8 days) after return to home unless patient needs or preferences dictated a shorter or longer duration (up to 90 days). Services were stopped early if subjects became noncompliant or withdrew or were unable to continue due to health reasons (eg, nursing home or hospice admission). The SWCM program started with a comprehensive biopsychosocial assessment[25] conducted by the social workers during the first home visit. The biopsychosocial assessment was used to identify unmet needs in 8 domains: health, social support, finances, health insurance, housing, stroke education, mental health,

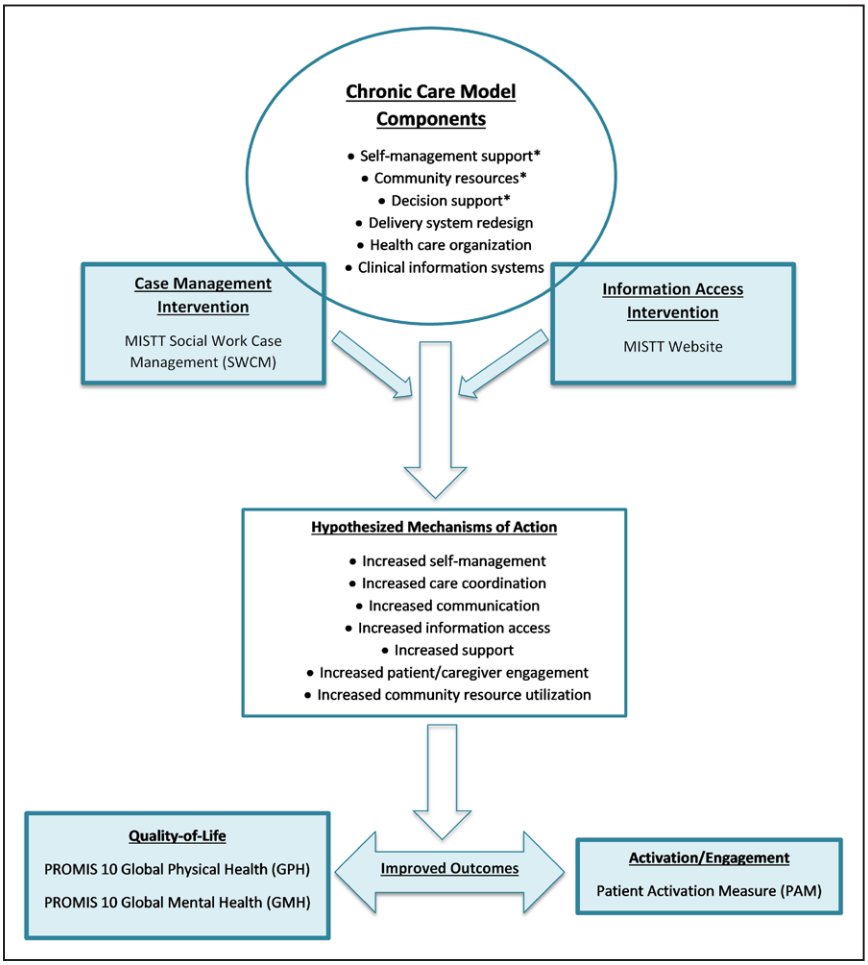

Figure 1. MISTT (Michigan Stroke Transitions Trial) intervention logic model: hypothesized relationships between intervention components, mechanisms of action, and patient outcomes.
GMH indicates global mental health; GPH, global physical health; PAM, Patient Activation Measure; PROMIS, Patient-Reported Outcomes Measurement Information System; and SWCM, social worker–led case management. *MISTT interventions were designed to address these 3 specific Chronic Care Model components.

and substance use. These unmet needs were used to develop a service plan that established patient-driven goals and priorities along with actions designed to address them. To address the service plan goals, SWs assessed safety issues, facilitated medical appointments, initiated social- and community-service referrals, promoted medication adherence, and offered practical and emotional support.[24] Consistent with the study's patient-centered approach, the number and intensity of the interactions and activities provided by the SWs were matched to each patient's ability and level of self-management. All interactions (home visits, phone, email, text messages), activities, and referrals were documented by the SWs. To foster consistency in the delivery of services, weekly group meetings were conducted by Dr Hughes to review activity logs and discuss challenges.

In addition to the SWCM program, subjects in group-3 also received access to the MISTT website, a curated patient-orientated information and support resource designed to complement the SWCM program. The MISTT website was developed following input from focus groups and user-experience evaluations.[20] Content was organized around 7 topics: stroke-related education, medication information, provider contact lists, patient portals, social and community services, stroke support groups, and caregiver resources. The MISTT website included original content (text, video), as well as links to established stroke-related websites.[26,27] MISTT website access required a username and password, which allowed Google Analytics (google.com/analytics) to track website utilization over the 90-day period. The SWs provided an orientation to the website during the first home visit and throughout the intervention period encouraged participants to utilize it to accomplish service plan tasks. A tablet with internet access was supplied to those who needed it.

Outcomes and Data Collection

Trained telephone interviewers collected outcomes data 7 days and 90 days after patients returned home.[20] An extensive list of candidate outcome measures and instruments, including Patient-Reported Outcomes Measurement Information System (PROMIS) measures,[28] Neuro-QOL (quality-of-life in Neurological Disorders) measures,[29] and other sources,[30] were assembled during the pretrial phase. As described in more detail in the study's published protocol,[20] following input from our focus group stakeholders, we chose to use 2 primary outcome measures: PROMIS Global-10, a generic QOL measure, and the Patient Activation Measure (PAM). PROMIS Global-10 produces 2 component scores or subscales—global physical health (GPH) and global mental health (GMH).[31,32] Each subscale includes 4 questions with a 5-point scale; the GPH subscale includes questions on physical health, fatigue, pain, and physical functioning, whereas GMH includes questions on overall QOL, mental health, emotional problems, and satisfaction with social activities and relationships. The subscales are reported as *T* scores with standardized mean=50 (SD=10); higher *T* scores indicate better QOL. PAM is a 13-item measure of global activation that measures the patient's knowledge, skills, and confidence in self-management; higher scores indicate greater activation (range, 0–100).[33] Secondary patient-reported outcomes included depression symptoms (Patient Health Questionnaire-9),[34] Neuro-QOL anxiety, simplified mRS (s-mRS; range, 0–5),[35] and activities of daily living (ADL) and instrumental ADLs (IADLs).[36] Neuro-QOL anxiety measures thoughts and feelings related to fear, helplessness, and worry; higher *T* scores indicate higher levels of anxiety.[37] Responses to each of 12 questions addressing ADL and IADLs were recoded into a binary score of 1 (any difficulty) versus 0 (no difficulty) and then summed to create a total score (range, 0–12).[36] Lower scores for both s-mRS and ADL/IADL indicate better function. Other secondary outcomes include unplanned hospital readmissions, stroke/transient ischemic attack recurrence, and home time. Stroke/transient ischemic attack recurrence was determined from the final discharge diagnoses of any unplanned readmission. 90-day home time was calculated by subtracting the number of days spent in a medical or nursing facility since returning home.

Sample Size and Statistical Analysis

Details of sample size calculations are reported in the Data Supplement and elsewhere.[20] The target number of subjects included in the statistical analysis was 214; in anticipation of attrition, the target number of patients randomized was increased to 252. Furthermore, to account for the exclusion of patients whose rehabilitation stays extended beyond 4 weeks (which occurred before randomization), the target number of enrolled patients was increased to 320.

Descriptive statistics (frequencies, means) were generated for all randomized patients.

The primary outcomes of PROMIS-10 (GPH and GMH subscales) and PAM were analyzed as linear (continuous) variables using Proc Mixed (SAS V9.4, Cary, NC). Seven-day and 90-day outcomes were analyzed as correlated continuous responses within patient. The statistical model for the mean response comprised of an intercept, 2 indicators for group-2 and group-3 (group-1 as referent), 1 indicator for time 90-day (7-day as referent), and 2 group-by-time interactions. Hence the model for the mean response is:

$$\beta_0 + \beta_1(\text{group-2}) + \beta_2(\text{group-3}) + \beta_3(90\,\text{days}) + \beta_4(\text{group-2} \times 90\,\text{days}) + \beta_5(\text{group-3} \times 90\,\text{days})$$

The change from 7-day to 90-day in mean response in group-1 is β_3; the corresponding change in group-2 is $\beta_3+\beta_4$. Hence, the group-by-time interaction coefficient β_4 is the comparison of group-2 to group-1; β_5 is the analogous comparison of group-3 to group-1. The combined 2-degree freedom test of the group-by-time interactions (ie, $\beta_4=\beta_5=0$) identifies whether the mean change over time differed between treatment groups. From here on out, we refer to this interaction as a difference-in-differences (D-in-D) analysis or result.[38] This modeling approach has the advantage of increasing the number of observations used in the intention-to-treat available case analysis because subjects with data from only one time point can be included. Pairwise contrasts (with 95% CIs) were generated to compare treatment groups with each other.

We conducted a limited number of hypothesis-generating interaction tests with age, stroke severity, discharge destination, and consented caregiver. In sensitivity analyses, we examined the impact of missing data (see Data Supplement for description of methods). We also analyzed individual PROMIS-10 items separately, as suggested by previous authors.[31,32] Secondary outcomes of Patient Health Questionnaire-9, Neuro-QOL

anxiety, s-mRS, and ADLs/IADLs were also analyzed using the linear D-in-D model; 90-day readmission and stroke/transient ischemic attack recurrence were analyzed using logistic regression. Ninety-day home time was analyzed using a 90-day inflated negative binomial model. Analyses were conducted by Drs Reeves and Nasiri; Dr Reeves had full access to the data and is responsible for the integrity of the analyses.

RESULTS

The MISTT study screened 1793 subjects to reach its enrollment target of 320 patients with stroke (Figure 2). Fifty-six patients (17%) consented via proxy. Fifty-five (17%) consented patients were dropped before randomization, largely due to rehabilitation stays >4 weeks (n=36; Figure 2), thus 265 patients were randomized. The mean age was 66 years, 49% were female, 21% nonwhite, 86% had ischemic stroke (Table 1). Forty-four percent were discharged directly home, whereas 47% and 9% were discharged to acute or subacute rehabilitation, respectively. The average time from hospital admission to returning home was 14 days. Sixty-four percent (n=169) of patients also had a caregiver enroll in the study.

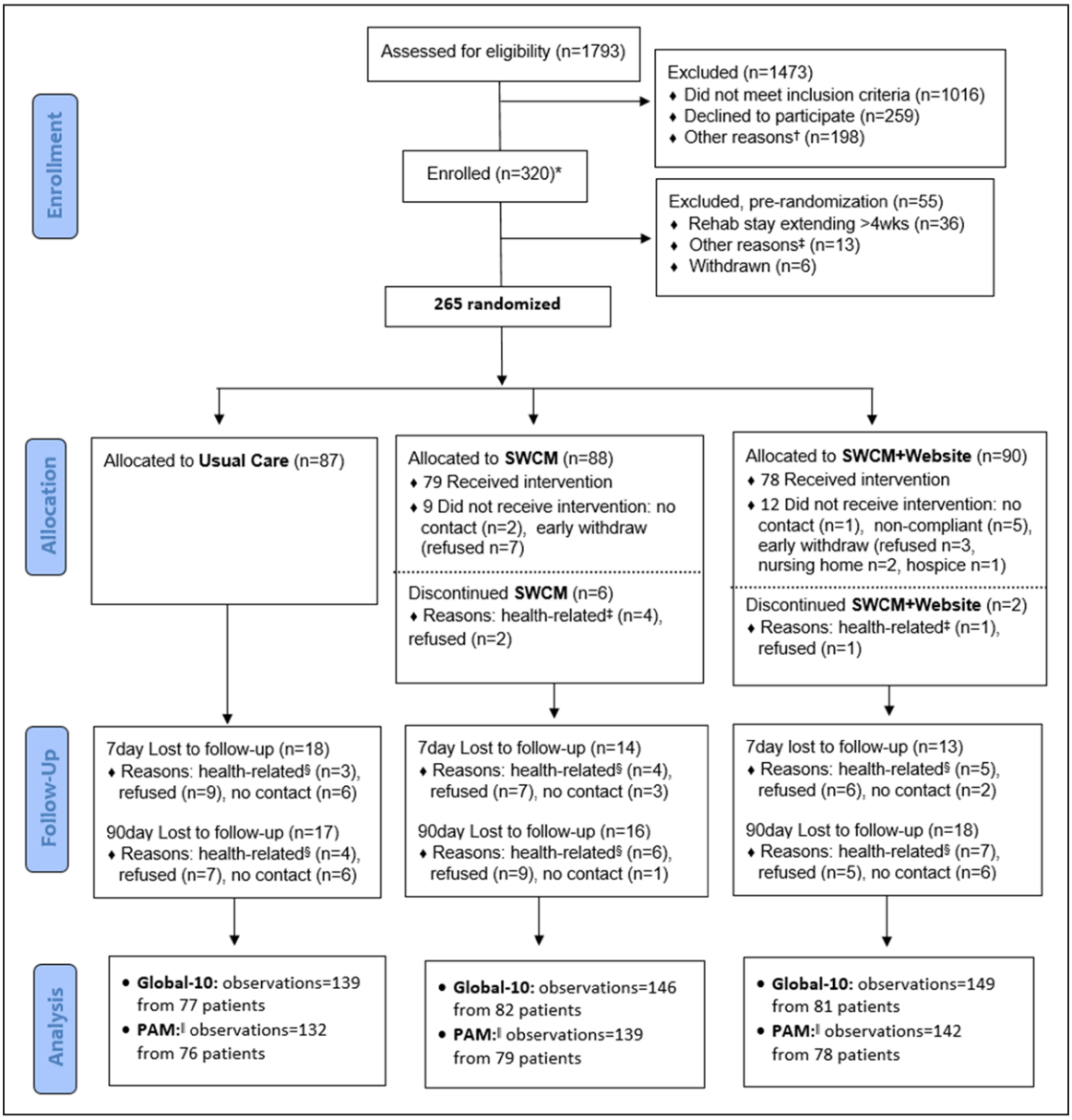

Figure 2. Patient participation CONSORT flow diagram.
Group-1, usual care; group-2, social worker–led case management (SWCM); and group-3, SWCM plus access to the MISTT (Michigan Stroke Transitions Trial) website (SWCM+MISTT Website). *Of 320 enrolled patients, 56 were enrolled via proxy. †Includes eligible patients that either did not make a timely decision (n=115) or were not approached about study participation (n=83). ‡Includes health-related reasons (ie, deceased, admission to hospice, nursing home, or long-term care facility; n=7) and miscellaneous reasons (n=6). §Includes deceased, hospice care, readmitted, and unable to participate due to poor health. IAvailable data differs from Patient-Reported Outcomes Measurement Information System Global 10 because Patient Activation Measure (PAM) questions were not included in abbreviated or proxy versions of the interview.[21]

Table 1. Characteristics of Randomized Patients by Treatment Group

Variable	Total n (%)	Group-1 (UC), n (%)	Group-2 (SWCM), n (%)	Group-3 (SWCM+MISTT Website), n (%)
Total	265	87 (33%)	88 (33%)	90 (34%)
Age, y, mean (SD)	66.2 (13.2)	65.2 (13.9)	67.5 (13.0)	66.1 (12.7)
Female	131 (49%)	42 (48%)	48 (55%)	41 (46%)
Race				
White	209 (79%)	66 (76%)	68 (77%)	75 (83%)
Nonwhite	56 (21%)	21 (24%)	20 (23%)	15 (17%)
6-item cognitive screen score (SIS-6), mean SD*	5.4 (1.0)	5.5 (0.9)	5.2 (1.3)	5.5 (0.7)
Proxy consent	33 (13%)	8 (9%)	13 (15%)	12 (13%)
Stroke type				
Ischemic	228 (86%)	74 (85%)	74 (84%)	80 (89%)
Hemorrhagic	37 (14%)	13 (15%)	14 (16%)	10 (11%)
Stroke severity†				
Mild	190 (72%)	66 (76%)	60 (68%)	64 (71%)
Moderate	56 (21%)	12 (14%)	21 (24%)	23 (26%)
Severe	19 (7%)	9 (10%)	7 (8%)	3 (3%)
NIHSS at admission, mean (SD)	4.9 (5.2)	5.5 (5.2)	4.4 (4.2)	4.9 (4.9)
Hospital length-of-stay, d, mean (SD)	5.1 (4.2)	5.5 (4.4)	5.1 (4.0)	4.7 (4.3)
Discharge mRS				
Score ≤2	178 (67%)	62 (72%)	62 (71%)	54 (60%)
Score ≥3	87 (33%)	25 (29%)	26 (30%)	36 (40%)
Hospital discharge				
Home	117 (44%)	49 (56%)	32 (36%)	36 (40%)
Acute rehabilitation	124 (47%)	29 (33%)	47 (53%)	48 (53%)
Subacute rehabilitation	24 (9%)	9 (10%)	9 (10%)	6 (7%)
Time admit-discharge home, d, mean (SD)	13.6 (10.9)	12.4 (11.7)	13.8 (9.7)	14.5 (11.2)
Past medical history/comorbidities				
Stroke	41 (16%)	12 (14%)	18 (21%)	11 (12%)
Transient ischemic attack	21 (8%)	4 (5%)	6 (7%)	11 (12%)
Myocardial infarction	24 (9%)	6 (7%)	7 (8%)	11 (12%)
Coronary arterial disease	58 (22%)	17 (20%)	16 (18%)	25 (28%)
Atrial fibrillation	37 (14%)	12 (14%)	17 (19%)	8 (9%)
Diabetes mellitus	97 (37%)	31 (36%)	33 (38%)	33 (37%)
Hypertension	205 (77%)	60 (69%)	67 (76%)	78 (87%)
Hyperlipidemia	130 (49%)	46 (53%)	41 (47%)	43 (48%)
Caregiver Information				
Caregiver consented	169 (64%)	58 (67%)	57 (65%)	54 (60%)
Caregiver lives with patient	128 (76%)	44 (76%)	45 (79%)	39 (72%)
Caregiver relationship				
Spouse	102 (60%)	33 (57%)	33 (58%)	36 (67%)
Other	67 (40%)	25 (43%)	24 (42%)	18 (33%)

Group-1, UC; group-2, SWCM; and group-3, SWCM plus access to the MISTT website (SWCM+MISTT Website). GCS indicates Glasgow Coma Scale; MISTT, Michigan Stroke Transitions Trial; NIHSS, National Institutes of Health Stroke Scale; SWCM, social worker–led case management; and UC, usual care.

*SIS-6=6 item cognitive screen tool available for n=254.

†Stroke severity was categorized as mild (NIHSS, 1–5 or GCS, 13–15), moderate (NIHSS, 6–13 or GCS, 5–12), and severe (NIHSS, 14–42 or GCS, 3–4).

Primary Outcomes

Data on the PROMIS Global-10 measure were available for 220 (83%) patients at 7 days and 214 (81%) at 90 days; 240 patients (91%) provided 434 observations for the intention-to-treat available case analysis (Figure 2). Loss-to-follow-up was evenly distributed across groups (Figure 2). For PROMIS GPH, a statistically significant increase in least-square mean *T* scores over time was observed in the SWCM+MISTT Website group (+3.66; *P*<0.001; Table 2). Changes over time in GPH *T* scores were minimal for UC and were marginally significant in the SWCM group (+1.26; *P*=0.07). The overall test of significance in the D-in-D model was statistically significant for GPH (group×time interaction *P*=0.003; Table 2). The mean change in *T* scores for the SWCM+MISTT Website group was significantly greater when compared with the SWCM (D-in-D, +2.4, *P*=0.016), or UC (D-in-D, +3.4, *P*<0.001) groups. No statistically significant results were observed for the GMH subscale (group×time interaction *P*=0.56; Table 2).

For PAM, a statistically significant increase in least-square mean scores was observed over time in the SWCM+MISTT Website group (+5.90, *P*=0.002; Table 2). Changes over time in PAM scores were small and not statistically significant in both UC and SWCM groups. The D-in-D analysis for PAM was statistically significant (group×time interaction *P*=0.042); the mean change in PAM scores for SWCM+MISTT Website was significantly higher than that in SWCM (D-in-D, +6.7, *P*=0.016) and marginally significantly higher than UC (D-in-D, +5.0, *P*=0.07).

Secondary Outcomes

Within each treatment group, there were minimal changes over time in Patient Health Questionnaire-9 or Neuro-QOL anxiety, and the D-in-D tests for interaction were not significant (*P*=0.97 and *P*=0.49, respectively; Table 3). However, changes were observed in both s-mRS and ADL/IADL combined scores. For s-mRS, statistically significant decreases were observed over time in both the UC and SWCM+MISTT Website groups (*P*=0.01 and *P*<0.001, respectively; Table 3). The D-in-D analysis for s-mRS was statistically significant (group×time interaction *P*=0.036); patients in the SWCM+MISTT Website group had a half unit decline in s-mRS compared with the SWCM group (D-in-D, −0.48, *P*=0.01). Similar changes were seen for the combined ADL/IADL scores; the SWCM+MISTT Website group had significantly lower scores compared with the SWCM group (D-in-D, −1.41, *P*=0.007; Table 3).

Table 2. Primary Continuous Outcomes: Changes in LSM and D-in-D Analyses

	LSM [95% CI]			Pairwise Difference [95% CI], *P* Value		
	UC	SWCM	SWCM+MISTT Website	SWCM vs UC	SWCM+MISTT Website vs UC	SWCM+MISTT Website vs SWCM
PROMIS-10 global physical health (n=434 observations)				D-in-D analysis; test of group×time interaction: *P*=0.003		
7-day (n=220)*	42.8 [41.4 to 44.14]	41.9 [40.6 to 43.3]	40.7 [39.4 to 42.0]			
90-day (n=214)	43.1 [41.7 to 44.5]	43.2 [41.8 to 44.6]	44.4 [43.0 to 45.8]			
Change [95% CI]; *P* value	+0.29 [−1.12 to 1.71]; 0.68	+1.26 [−0.12 to 2.65]; 0.07	+3.66 [2.30 to 5.02]; <0.001	+0.97 [−1.01, to 2.95]; 0.34	+3.37 [1.41 to 5.33]; <0.001	+2.40 [0.46 to 4.34]; 0.016
PROMIS-10 global mental health (n=434 observations)				D-in-D analysis; test of group×time interaction: *P*=0.56		
7-day (n=220)	46.0 [44.0 to 47.9]	45.2 [43.4 to 47.1]	45.8 [44.0 to 47.7]			
90-day (n=214)	47.1 [45.2 to 49.1]	45.4 [43.4 to 47.3]	47.3 [45.4 to 49.2]			
Change [95% CI]; *P* value	+1.19 [−0.67 to 3.05]; 0.21	+0.12 [−1.70 to 1.95]; 0.90	+1.45 [−0.34 to 3.23]; 0.11	−1.06 [−3.67 to 1.55]; 0.42	+0.26 [−2.33 to 2.84]; 0.84	+1.32 [−1.24 to 3.88]; 0.31
PAM (n=413 observations)†				D-in-D analysis; test of group×time interaction: *P*=0.042		
7-day (n=210)	65.7 [61.9 to 69.6]	61.4 [57.6 to 65.1]	63.60 [59.9 to 67.3]			
90-day (n=203)	66.6 [62.5 to 70.7]	60.6 [56.6 to 64.6]	69.50 [65.5 to 73.5]			
Change [95% CI]; *P* value	+0.87 [−3.10 to 4.85]; 0.67	−0.78 [−4.64 to 3.08]; 0.69	+5.90 [2.12 to 9.68]; 0.002	−1.65 [−7.20 to 3.90]; 0.56	5.02 [−0.47 to 10.52]; 0.07	6.67 [1.26 to 12.08]; 0.016

Group-1, UC; group-2, SWCM; and group-3, SWCM plus access to the MISTT website (SWCM+MISTT Website). D-in-D indicates difference-in-differences; LSM, least-square means; MISTT, Michigan Stroke Transitions Trial; PAM, Patient Activation Measure; PROMIS, Patient-Reported Outcomes Measurement Information System; SWCM, social worker–led case management; and UC, usual care.

*No. of patients.

†Available data differs from PROMIS Global 10 (n=434 observations) because PAM and secondary outcomes were not included in the abbreviated or proxy versions of the interview.[21]

Table 3. Secondary Continuous Outcomes: Changes in LSM and D-in-D Analyses

	LSM [95% CI]			Pairwise Difference [95% CI]; *P* Value		
	UC	SWCM	SWCM+MISTT Website	SWCM vs UC	SWCM+MISTT Website vs UC	SWCM+MISTT Website vs SWCM
PHQ-9 (depression; n=378 observations)*				D-in-D analysis; test of group×time interaction: *P*=0.97		
7-day (n=193)	6.0 [4.7 to 7.3]	5.8 [4.6 to 7.1]	6.2 [4.9 to 7.4]			
90-day (n=185)	5.5 [4.1 to 6.9]	5.1 [3.8 to 6.4]	5.6 [4.3 to 6.9]			
Change [95% CI]; *P* value	−0.53 [−1.86 to 0.80]; 0.43	−0.74 [−2.00 to 0.51]; 0.25	−0.56 [−1.82 to 0.70]; 0.38	−0.21 [−2.05 to 1.62]; 0.82	−0.03 [−1.86 to 1.81]; 0.98	+0.19 [−1.59 to 1.97]; 0.84
Neuro-QOL anxiety (n=351 observations)*				D-in-D analysis; test of group×time interaction: *P*=0.49		
7-day (n=180)	50.6 [48.3 to 52.8]	48.3 [46.1 to 50.4]	49.8 [47.7 to 51.9]			
90-day (n=171)	50.4 [48.0 to 52.8]	47.8 [45.5 to 50.1]	47.8 [45.5 to 50.1]			
Change [95% CI]; *P* value	−0.15 [−2.55 to 2.25]; 0.90	−0.44 [−2.73 to 1.84]; 0.70	−2.01 [−4.32 to 0.30]; 0.09	−0.29 [−3.60 to 3.02]; 0.86	−1.86 [−5.19 to 1.47]; 0.27	−1.57 [−4.82 to 1.68]; 0.34
s-mRS (n=431 total observations)*				D-in-D analysis; test of group×time interaction: *P*=0.036		
7-day (n=217)	1.94 [1.65 to 2.23]	1.91 [1.62 to 2.19]	2.21 [1.94 to 2.49]			
90-day (n=214)	1.56 [1.27 to 1.86]	1.71 [1.43 to 2.00]	1.54 [1.25 to 1.82]			
Change [95% CI]; *P* value	−0.37 [−0.64 to −0.10]; 0.01	−0.19 [−0.45, 0.07]; 0.15	−0.68 [−0.93 to −0.42]; <0.001	+0.18 [−0.20 to 0.55]; 0.35	−0.31 [−0.68 to 0.07]; 0.11	−0.48 [−0.85 to −0.12]; 0.01
ADL/IADL combined score (n=380 total observations)*				D-in-D analysis; test of group×time interaction: *P*=0.025		
7-day (n=195)	4.81 [3.95 to 5.68]	4.50 [3.66 to 5.33]	5.23 [4.41 to 6.06]			
90-day (n=185)	3.89 [3.02 to 4.76]	4.11 [3.27, 4.95]	3.44 [2.60 to 4.28]			
Change [95% CI]; *P* value	−0.93 [−1.69 to −0.16]; 0.02	−0.39 [−1.11, 0.34]; 0.29	−1.80 [−2.52 to −1.07]; ≤0.0001	+0.54 [−0.51 to 1.59]; 0.31	−0.87 [−1.92 to 0.18]; 0.10	−1.41 [−2.43 to −0.39]; 0.007

Group-1, UC; group-2, SWCM; and group-3, SWCM plus access to the MISTT website (SWCM+MISTT Website). ADL indicates Activities of Daily Living; D-in-D, difference-in-differences; IADL, Instrumental Activities of Daily Living; LSM, least-square means; MISTT, Michigan Stroke Transitions Trial; PHQ-9, Patient Health Questionnaire-9; QOL, quality-of-life; s-mRS, Simplified Modified Rankin Score; SWCM, social worker–led case management; and UC, usual care.

*Number of available observations differ between outcomes due to missing data.

Hospital readmission occurred in 55 (20.8%) of the 265 subjects, but rates did not differ between treatment groups (*P*=0.85; Table 4). Recurrent stroke/transient ischemic attack occurred in 24 patients (9.1%), but rates were similar across groups (*P*=0.20). Relatively, few patients (25%) spent any time away from home during the 90-day period; the distribution of home time was not statistically different between groups (*P*=0.77;Table 4).

Intervention Participation

Of 88 group-2 patients randomized to SWCM, 9 (10%) did not receive the intervention (Figure 2). Of 90 patients randomized to the SWCM+MISTT Website group, 12 (13%) did not receive both interventions as intended (Figure 2). Across both group-2 and group-3, there were 160 subjects who started SWCM. The mean number of unmet needs per case was 4.6 (range, 2–9); stroke knowledge, stroke education, financial needs, and pre-existing health problems were the most common. Overall, the mean duration of case management was 63 days (range, 8–98) with an average of 25 interactions per case (range, 4–101). Case management services were stopped early (ie, before 52 days) in 8 cases (5%; reasons included death/hospice [n=3], refused [n=3], illness [n=1], no further needs [n=1]), and were extended (ie, beyond 68 days) because of ongoing needs in 28 cases (18%).

Among the 90 group-3 subjects randomized to SWCM+MISTT website, 10 (11%) declined training in the use of the website, 55 (61%) received training but never accessed the website, and 25 (28%) accessed the website on their own. These 25 subjects accessed the website an average of 3.3 days (range 2–9), with an average of 25 (range, 5–79) total page views.

Per-Protocol, Interactions, and Sensitivity Analyses

Regardless of the specific definition of noncompliance utilized, the per-protocol results were similar to the

Table 4. Secondary Outcomes of 90-Day Hospital Readmission, Stroke/TIA Recurrence, and Home Time: Logistic Regression and Negative Binomial Regression Model Results

Logistic Regression Models			
Outcome / Group	**n (%)**	**Odds Ratio [95% CI]**	**Odds Ratio [95% CI]**
90-day hospital readmissions (n=265)		Type 3 χ^2 global test: *P*=0.85	
UC	17 (20%)	1.0	…
SWCM	20 (23%)	1.21 [0.59–2.51]	1.0
SWCM+MISTT Website	18 (20%)	1.03 [0.49–2.16]	0.85 [0.42–1.74]
Stroke/TIA Recurrence (n=265)		Type 3 χ^2 global test: *P*=0.20	
UC	7 (8%)	1.0	…
SWCM	5 (6%)	0.69 [0.21–2.26]	1.0
SWCM+MISTT Website	12 (13%)	1.76 [0.66–4.70]	2.55 [0.86–7.58]

Negative Binomial Regression Model					
Outcome / group	**n (%) <90 d**	**Mean, d (SD)**	**Median, d (IQR)**	**IRR* [95% CI]; *P* value**	**IRR* [95% CI]; *P* value**
90-day home time (n=265)				Type 3 χ^2 global test: *P*=0.77	
UC	21 (24%)	87.7 (8.1)	90 (90–90)	1.0	…
SWCM	22 (25%)	87.8 (5.2)	90 (89–90)	1.06 [0.45–2.48]; 0.90	1.0
SWCM+MISTT Website	24 (27%)	87.1 (8.9)	90 (89–90)	0.80 [0.34–1.84]; 0.59	0.75 [0.33–1.78]; 0.50

Group-1, UC; group-2, SWCM; and group-3, SWCM plus access to the MISTT website (SWCM+MISTT Website). IQR indicates interquartile range; IRR, incident rate ratio; MISTT, Michigan Stroke Transitions Trial; SWCM, social worker–led case management; TIA, transient ischemic attack; and UC, usual care.

*IRR (incident rate ratios) <1.0 indicate fewer days at home compared with the referent group; estimates >1.0 indicate more days away at home compared with referent group.

intention-to-treat analysis (Table I in the Data Supplement). Statistically significant treatment×subgroup interactions were observed only for discharge destination (ie, home, acute rehabilitation, subacute rehabilitation) and the PAM outcome (Table II in the Data Supplement). There were no significant intervention effects in the patients discharged directly home, but UC was particularly unfavorable to patients who first spent time in a rehabilitation setting (Table III in the Data Supplement). Accounting for missing data had a minimal impact on the PROMIS Global-10 outcomes; however, the overall D-in-D results for PAM became marginally significant (*P*=0.08; Tables IV and V in the Data Supplement).

Item-specific analyses of PROMIS Global-10 raw scores were concordant with the subscale results (Table VI in the Data Supplement); 2 of the GPH items (Global03 [physical health], Global08 [fatigue]) both showed differences that were similar to the overall GPH subscale. None of the individual GMH items showed significant changes.

DISCUSSION

MISTT tested 2 complementary interventions designed to improve QOL and increase activation in patients who return home after stroke. The case management program identified and addressed unmet needs using a patient-centered service plan. The SWs coordinated medical and social services, identified and referred community resources, provided education, support, and problem-solving. The MISTT website was designed to complement the case management program by providing information on stroke prevention, recovery, and community-based resources with the goal of increasing patient activation, engagement, and self-management.[39] Patients randomized to the combination of the SWCM program plus the MISTT website (group-3) had an increase in PROMIS GPH and PAM compared with both the SWCM program alone (group-2) or UC (group-1). Validation work on PROMIS Global-10 in patients with stroke is in its early stages,[31,32] and information on minimally important differences to aid clinical interpretation is limited.[40] From a clinical perspective, the size of the group-3 differences in GPH likely represent modest increases (equivalent to effect sizes of 0.25–0.33). The increase in PAM observed in group-3 exceed the commonly used minimally important differences benchmark of 5 points.[41] The clinical importance of the changes observed for GPH and PAM is bolstered by the changes observed in both s-mRS and ADL/IADL, which indicate that group-3 patients also reported improved function.

Despite the encouraging results seen in the SWCM+MISTT Website group, there remains uncertainty regarding the exact mechanisms behind them because utilization of the MISTT website was quite limited; only 25% of group-3 subjects used the site on their own. Although the treatment effects observed in this trial are somewhat paradoxical, counterintuitive findings related to QOL are common and can sometimes be

explained by the phenomena of response shift,[42] which results in changes in the meaning of a QOL measure as experienced and reported by patients. Our results may, in part, be a reflection of such mechanisms.

Comparisons between our study and prior work involving patients with stroke is complicated by the fact that our results are relevant to several distinct but interrelated areas, including case management, self-management, stroke education, and care transitions, each of which involve an array of different mechanisms, intervention targets, and outcomes. Prior reviews of transitional care studies targeting patients with stroke,[8] and of trials testing educational or support strategies provided to patients with stroke,[18,43] have found limited effects of any given strategy, methodological limitations, and poor generalizability. A 2016 Cochrane review of stroke self-management[44] identified 14 randomized trials that tested the efficacy of self-management programs (versus UC or an education-only control group) on QOL, self-efficacy, activity, and participation levels in stroke survivors. A meta-analysis, conducted on data from only 6 studies, found modest evidence of improvement in QOL and self-efficacy but no significant effect on physical functioning.

Increases in patient activation (as reflected by PAM) are thought to occur through mechanisms that involve tailored education, skill building, and support.[45] The increase in PAM scores observed in group-3, therefore, likely reflect the combined effects of SWCM with access to online information to increase stroke knowledge, skills, and support. Other studies have utilized websites to provide stroke education similar to that used in MISTT, but there has been relatively little published on their uptake and effectiveness.[46,47] A Cochrane review of trials testing various information provision strategies in patients with stroke did not include studies that relied on website-based approaches.[18]

Finally, direct comparison between our results and prior social work based transition trials is complicated by variation in their scope, size, and target populations, as well as their emphasis on reducing hospital readmissions.[12–14]

Tackling the problem of poor stroke transitions is a complex undertaking; on a patient-level, there are a myriad of individual differences in clinical severity, pre-stroke function, needs, resources, support, self-efficacy, and engagement. On a systems level, stroke transitions are complicated by the fragmented involvement of multiple providers, settings, and community-service organizations who often have limited communication with each other. Unfortunately, many of the challenges stroke survivors face are difficult to anticipate and do not emerge until after they return home. Assessment of these challenges and needs are complex and often falls outside the scope of traditional medical- and rehabilitation-focused follow-up appointments.[48] These observations suggested to us that an SWCM approach which, by including a biopsychosocial assessment to identify patient needs and goals, should provide meaningful benefit. The fact that the SWCM intervention on its own (group-2) failed to induce positive changes in any outcomes was surprising, particularly for the GMH outcome that we hypothesized would be responsive to the SWCM activities that target psychosocial issues.

The MISTT trial has several strengths. It is one of the few trials designed to test the efficacy of a social work based intervention and to use PROMIS-based measures.[28] It also took a pragmatic approach and included community-based hospitals to increase its generalizability. MISTT also has limitations. Although it was intended that the phone interviewers would be blinded to group assignment, this proved impractical because patients often reported (without prompting) their experience with the social work interventions. However, the primary outcomes were based on validated multi-item instruments with standardized response options that did not require interviewer interpretation or observation, which likely reduced the potential for measurement bias. The 3-arm design of MISTT precluded us from quantifying any potential interaction effects between the SWCM and MISTT website interventions. Finally, although we tracked discharge practices at each hospital to ensure there were no major changes during the trial, we did not measure specific transition-related services that each participant received. Thus, we are unable to assess and compare the continuity of services provided to the UC and intervention groups.

In summary, the combination of SWCM plus access to a curated online stroke information resource produced greater gains in patient-reported physical health and activation compared with case management or UC alone. Our results highlight future research priorities including identifying clinical subpopulations at risk of poor transitions, and understanding the barriers and facilitators of using online resource during the transitional care period. Additional work is also needed to identify outcomes, derived from a combination of patient-reported, clinical, and administrative-data sources, that are appropriately sensitive and responsive to transitional care interventions.[49] Finally, incorporating current national-level reimbursement,[50] and care model strategies[15] into future research will be critical to the implementation and sustainability of future stroke transitional care programs.

ARTICLE INFORMATION

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Disclosures

None.

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