Methodological Challenges of Multiple-Component Intervention: Lessons Learned from a Randomized Controlled Trial of Functional Recovery After Hip Fracture

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Abstract We conducted a randomized controlled trial to assess the efficacy and safety of a multiple-component intervention designed to improve functional recovery after hip fracture. One hundred seventy-six patients who underwent surgery for a primary unilateral hip fracture were assigned randomly to receive usual care (control arm, $n=86$) or a brief motivational videotape, supportive peer counseling, and high-intensity muscle-strength training (intervention arm, $n=90$). Between-group differences on the *physical functioning*, *role-physical*, and *social functioning* domains of the SF-36 were assessed postoperatively at 6 months. At the end of the trial, 32

intervention and 27 control patients (34%) completed the 6-month outcome assessment. Although patient compliance with all three components of the intervention was uneven, over 90% of intervention patients were exposed to the motivational videotape. Intervention patients experienced a significant ($P=0.03$) improvement in the *role-physical* domain (mean change, -11 ± 33) compared to control patients (mean change, -37 ± 41). Change in *general health* ($P=0.2$) and *mental health* ($P=0.1$) domain scores was also directionally consistent with the study hypothesis. Although our findings are consistent with previous reports of compre-

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hensive rehabilitation efforts for hip fracture patients, the trial was undermined by high attrition and the possibility of self-selection bias at 6-month follow-up. We discuss the methodological challenges and lessons learned in conducting a randomized controlled trial that sought to implement and assess the impact of a complex intervention in a population that proved difficult to follow up once they had returned to the community.

Key words functional recovery · hip fracture · methodology · psychosocial intervention · randomized controlled trial · rehabilitation

Introduction

Poor functional outcomes after hip fracture can occur despite successful surgical repair and rehabilitation. Prospective studies have suggested that there may be several potentially modifiable risk factors that predict poor functional recovery after hip fracture. These include low muscle strength [1], fear of falling, and lack of confidence [2], low self-efficacy [3], and infrequent contact with one's social network [4]. We conducted a randomized controlled trial to assess the efficacy and safety of a multiple-component intervention designed to improve functional outcomes after hip fracture by addressing these risk factors *in combination*. However, we encountered several serious methodological challenges that undermined the trial. In addition to presenting our results, we discuss the challenges and lessons learned in conducting a randomized controlled trial that sought to assess the impact of a complex intervention in hip fracture patients.

Materials and methods

Patient population

Patients for this study were recruited over a multiple-year period from the combined fracture service at the New York Presbyterian Hospital—Weill Cornell Medical Center and the Hospital for Special Surgery in Manhattan, and at the New York Hospital Queens, a regional network affiliate. The study was approved by the institutional review boards at all three participating hospitals.

Potentially eligible patients were identified by a member of the study research team in consultation with the participating orthopedic surgeons at the time of the patient's admission to the hospital. Patients eligible for the study included men and women age 65 years and older who had sustained a primary unilateral fracture of the hip and underwent successful surgical repair. There were six exclusion criteria: (1) patients who were unable to give informed consent, and those unable to give coherent responses to the Folstein Mini-Mental State Exam [5], (2) patients whose underlying hip fracture was pathologic (i.e., secondary to malignancy), (3) non-English speaking patients, (4) patients for whom exercise was contraindicated (e.g., patients with critical aortic stenosis, unstable angina,

end-stage cardiomyopathy) or whose primary physician believed that exercise was contraindicated, (5) patients who did not have access to a telephone or could not be reached by telephone, and (6) patients who intended to relocate upon discharge or did not live in the New York tristate area.

Study procedures

Baseline assessment All eligible patients were approached in the hospital on the fourth or fifth postsurgical day, during which time written informed consent was obtained at the bedside. Patients who consented to participate in the study then completed baseline assessments. These assessments included historical and demographic data; physical examination, laboratory and radiological data; Tinetti falls-related self-efficacy scale [6]; Center for Epidemiologic Studies-Depression (CES-D) scale [7]; Holmes and Rahe Social Readjustment Rating Scale [8], a measure of stress-related life events; Mattis Dementia Rating Scale [9], a measure of cognitive function; a physical therapy functional milestones assessment developed at the Hospital for Special Surgery; and the Medical Outcomes Study SF-36 Health Survey questionnaire [10], a multipurpose measure of health status that is constructed of 36 items, eight scales, and two summary measures that provide a valid and reliable measure of functional health and well-being, as well as a psychometrically based assessment of physical and mental health. The items that comprise the eight domains of the standard (4 weeks) recall version of the SF-36 are scored from 0 (poorest health) to 100 (best health).

Randomization process Randomization schedules were developed from tables of random numbers and were balanced at intervals, with the exact balancing interval blinded to all study investigators except the study statistician. After completion of baseline assessments, patients were then randomized to one of two study arms.

Usual care control arm Patients randomized to the control arm received the usual postoperative care and rehabilitation services available to all patients seen on the fracture service at the participating hospitals. Usual care comprised weight bearing on the leg of the fracture hip and routine range-of-motion and low-intensity strengthening exercises. In order to equalize for attention, patients in the usual care control arm also received supportive telephone contact after discharge from the hospital that was almost identical to that of patients in the intervention arm.

Intervention arm In addition to the usual care all study patients received, patients randomized to the intervention arm received an intervention program comprising three major components: (1) a novel, in-hospital, postoperative motivational patient videotape, entitled *Getting Up Again, Getting Better*, and a corresponding patient information

booklet designed to address falls-prevention self-efficacy, both of which were shown and given to the patient prior to hospital discharge; (2) an in-hospital supportive visit by a recovered hip fracture patient of similar age who had received brief training in peer counseling and whose visit was intended to model successful recovery and provide social support; and (3) a hospital-based, 8-week out-patient program of physical therapy consisting of tailored exercises and progressive muscle-strength training [11, 12].

Follow-up After discharge from hospital, all patients received weekly socially supportive telephone calls until they were seen by their surgeon for their first postoperative follow-up visit (usually at about 4–5 weeks after surgery). Patients in the intervention arm were cleared at this time to participate in the strength-training component and scheduled for a standardized physical therapy evaluation consisting of range of motion, flexibility, strength (including one-repetition maximum of hip flexors and knee extensors), and observational gait analysis. Based on the results of this evaluation, an individualized exercise program was prescribed to address the impairments and functional limitations of each patient. Patients were then scheduled for their supervised exercise program as outpatients.

Patients were supposed to receive physical therapy and the tailored supervised exercise program for 8 weeks. This program consisted of individualized balance retraining, gait, and exercise, which was based on the results of the patient's physical therapy evaluation. Strength training was performed using free weights. The level of resistance was set at 60% of the one-repetition maximum for the hip flexors and knee extensors, and was progressively increased accordingly. For the one-repetition maximum, the patient was seated in a standard chair with free weights (cuff weights) attached proximal to the ankle and asked to fully flex the hip or to fully extend the knee. The amount of weight was adjusted so that the patient could complete the task for only a single repetition. Weight (to the nearest 1 kg) was recorded for each leg for each muscle group. In addition to performing isolated muscle strengthening of the quadriceps, hamstrings, hip flexors, and extensors, patients were placed on a Kinetron in both the seated and standing position, and a stationary bicycle with varied resistance.

All patients were followed for 6 months. Follow-up consisted of periodic telephone calls by a research assistant during which time patients were asked to complete the SF-36 outcome measure at 3- and 6-month intervals. At 6 months, patients were asked to revisit the hospital in person for a final follow-up assessment and exit interview. At least three attempts were made by the research assistant to schedule patients for their 6-month follow-up assessments.

Outcome assessment The SF-36 was administered to assess functional status as the study's primary outcome at 6-month follow-up. Six months has been shown to be the point at which most of the recovery from hip fracture has

taken place [13]. The *physical functioning*, *role-physical*, and *social functioning* scales from the SF-36 were used to assess functional status because we considered these domains to be the most appropriate and maximally responsive to the patient-specific outcome of interest in functional recovery after hip fracture. In addition, data were collected on the *bodily health*, *general health*, *vitality*, *role-emotional*, and *mental health* domains of the SF-36.

Sample size calculation and statistical analyses

To calculate a sample size, we estimated the postoperative within-patient changes using data from a prospective study of patients undergoing coronary artery bypass surgery and patients undergoing elective total hip arthroplasty. A 5-point change in score on any one of the three SF-36 scales was considered clinically significant. With an assumed difference of 10 points between groups and an alpha of .0167, we estimated that 90 patients per group would give us power of .81. All data were analyzed using PC-SAS (version 7) and SPSS (version 9). We analyzed the data for main effects between groups, efficacy, and safety. To compensate for the multiple outcomes without increasing the Type I error at 81% power, the alpha level for testing the significance of the principal outcome was set at $P=0.0167$ (Bonferroni correction of $0.05 \div 3$).

Results

Figure 1 shows that 1,102 potentially eligible patients were screened, 628 of whom were excluded due to failure to meet study inclusion criteria. We were unable to obtain informed consent from 91 patients and 207 refused to participate in the study. Informed consent was obtained from 176 eligible patients (mean age 79 years) who completed the baseline assessment and were randomized to the control ($n=86$) or intervention ($n=90$) arm. Fifty-nine (34%) patients (27 control and 32 intervention) completed both baseline and full 6-month assessments. Of those patients who died (three control and five intervention), none of the deaths were related to participation in the study.

Baseline patient characteristics

Table 1 shows the sociodemographic characteristics of the study sample at baseline. Of the 59 patients who participated in the study and completed the full 6-month outcome assessment, the mean age was 77 ± 8 years (control, 77 ± 8 ; intervention, 78 ± 7). Although more women participated in the study than men, assignment of women and men within intervention and control arms was balanced. There were no significant differences in assignment on marital status ($P=0.07$), religious affiliation ($P=0.2$), education ($P=0.10$), or employment status ($P=0.8$).

Because of the high attrition and possibility of selection bias, we compared those patients who completed the study and those who did not on demographic characteristics and SF-36 recall scores at baseline. Those patients who

Fig. 1. Flow of patients through the trial, including patients screened, enrolled, and followed to 6 months

completed assessments at 6 months were younger ($P=0.03$) and better educated ($P=0.004$) at baseline than those who did not complete the study. There were no significant differences between completers and noncompleters on

gender ($P=0.2$), race ($P=0.4$), marital status ($P=0.2$), religious affiliation ($P=0.3$), employment status ($P=0.5$), or income ($P=0.9$). Table 2 shows that patients who completed the study consistently scored better (n.s.) on

Table 1 Sociodemographic characteristics of the study sample at baseline ($n=59$)

Characteristic	Control ($n=27$)	Intervention ($n=32$)	<i>P</i>
Age (mean, all patients, 77 ± 8)	77 ± 8	78 ± 7	0.9
Gender			0.8
Men	6	8	
Women	21	24	
Marital status			0.07
Married	6	13	
Separated or divorced	0	4	
Widowed	11	8	
Single	10	6	
Religion			0.2
Catholic	11	9	
Jewish	8	11	
Protestant	3	9	
None	4	1	
Other	0	2	
Education			0.10
Some high school	2	1	
High school graduate	10	6	
Some college	4	4	
College graduate	4	1	
Professional or graduate school	7	18	
Employment			0.8
Employed full-time	2	1	
Employed part-time	4	6	
Retired	18	24	
Not employed and seeking work	3	1	

Data shown in the table are the baseline values for the 59 patients who provided useable responses on the outcome assessments at the 6-month follow-up. There was one missing value for marital status, one for religion, and two for education. Sociodemographic characteristics did not differ between the groups at 6 months.

their prefracture SF-36 recall scores than those who did not complete the study.

Compliance with the intervention

All intervention patients were exposed to at least one of the three intervention components (i.e., videotape + strength

training + peer counseling), with 10 receiving all three components and 15 receiving two of the three components. Ninety percent of intervention patients viewed the videotape and received a copy of the patient information booklet during their hospitalization. Patients randomized to the intervention could have received up to a maximum of 16 postdischarge muscle-strength training sessions. The average number of sessions per patient was 10 and the average number of sessions for intervention patients who did participate in the strength training ($n=24$) was 13 ± 3 . However, of the 32 intervention patients, 17 received no strength training; four of these 17 patients lived in a nursing home at the time of their fall and were unable to attend the outpatient strength training program, and the remainder refused the strength training program. The period of time during which all strength-training sessions were completed by patients was wide, ranging from 8 weeks to 3 months. Thirty of the 32 intervention patients were visited by a peer counselor and received supportive telephone calls.

Outcomes

We used analysis of covariance to examine the group differences at 6 months. Table 3 shows the SF-36 scores for prefracture functional status (as recalled by the patient at baseline assessment) and postfracture functional status at the 6-month follow-up, as well as the change score between recall and 6 months, for both intervention and control patients. Using the recall score as the covariate and the 6-month score as the dependent value, patients randomly assigned to the intervention had a significant ($P=0.03$) positive change in the *role-physical* scale (mean score, -11 ± 33) as compared to those in the control arm (mean score, -37 ± 41). A straight two-group comparison of the between-group differences at 6 months outcome assessment also yielded a significant difference for *role-physical*, control 37 ± 41 and intervention 12 ± 33 , $P=0.01$, indicating that the 6-month score was closer to the recall value as a result of being exposed to the intervention. No

Table 2 Comparison of SF-36 health survey (standard 4-week recall) scores for prefracture functional status as recalled by patients at baseline assessment for those who completed 6-month assessment and those who did not ($n=176$)

SF-36 Domain	Completed 6-Month Assessment ($n=59$)			Did Not Complete 6-Month Assessment ($n=117$)			<i>P</i>
	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD	
Primary outcome domains							
Physical functioning	58	57	35	114	54	31	0.6
Role-physical	58	81	35	114	68	43	0.4
Social functioning	58	87	24	112	83	23	0.3
Other domains							
Bodily pain	58	85	22	113	81	24	0.4
General health	58	74	24	112	70	20	0.2
Vitality	58	63	23	113	58	24	0.2
Role-emotional	58	94	20	113	87	31	0.08
Mental health	58	79	19	113	75	20	0.2

The data shown are baseline data for 27 control and 32 intervention patients who completed the 6-month assessment and for 59 control and 58 intervention patients who did not. The higher the mean score, the better the score is. Data for one patient in the intervention arm are missing.

Table 3 SF-36 health survey (standard 4-week recall) scores for prefracture functional status as recalled by patients at baseline assessment and postfracture functional status at 6-month follow-up, and change in score (6 months recall), for both study groups ($n=58$)

SF-36 domain	Control (<i>n</i> =27)						Intervention (<i>n</i> =31)						Assignment <i>P</i> for Group
	Prefracture Recall		Postfracture 6 Months		Change		Prefracture Recall		Postfracture 6 Months		Change		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Primary outcome domains													
Physical functioning	54	38	45	29	−8	36	59	33	50	25	−9	30	0.7
Role-physical	87	29	50	42	−37	41	75	38	65	37	−11	33	0.03
Social functioning	88	21	77	34	−12	30	85	26	70	29	−16	38	0.4
<i>Other Domains</i>													
Bodily pain	83	24	71	26	−12	29	86	21	71	23	−16	28	0.8
General health	74	26	68	25	−6	15	75	23	74	22	−1	14	0.2
Vitality	64	26	60	23	−4	26	62	20	59	15	−4	21	0.2
Role-emotional	93	23	80	35	−12	30	95	17	78	34	−17	38	0.7
Mental health	80	20	72	23	−8	23	78	18	79	12	0	17	0.1

A negative mean score means that patients did not achieve their recall functional status by 6 months. Change scores may not be exact due to rounding errors. Data for one patient in the intervention arm are missing.

significant postintervention differences were observed in the change on the *physical functioning* ($P=0.7$) and *social functioning* ($P=0.4$) scales. Although there was no significant between-group difference in change scores for any of the five other SF-36 scales, the change was directionally consistent with our hypothesized intervention effect for *general health* ($P=0.2$) and *mental health* ($P=0.1$).

We also conducted an analysis to assess the impact of the small sample size (32 intervention and 27 controls) at 6 months on the power of the trial with alpha set at 0.0167. For the *physical functioning* scale ($SD\pm 30$, difference of 1, which is too small to be clinically meaningful), power was 0.02; *role-physical* scale ($SD\pm 36$, difference of 26), power was 0.82; and *social functioning* ($SD\pm 30$, difference of 5), power was 0.05.

Discussion

Previous studies [14–16] have shown that an accelerated program of postoperative hip fracture rehabilitation can lead to cost-effective reductions in length of hospital stay with a modest short-term improvement in physical independence after discharge. Progressive resistance training has been shown to be safe and effective in increasing strength and functional performance and reducing disability [17, 18]. Moreover, timing and intensity of physical therapy, and whether other aspects of therapy are optimized, may be important in the recovery of function after hip fracture [19].

The known decline in functioning despite successful surgical repair of hip fractures led us to develop a multiple-component intervention that was designed to address in combination three potentially modifiable risk factors for poor functional recovery: motivation and self-efficacy, social isolation, and muscle strength. Our initial intervention plan called for in-hospital motivational patient education (including a motivational videotape and accom-

panying patient information booklet), a supportive visit by a former hip fracture patient whose presence was intended to model successful recovery, and outpatient high-intensity muscle-strength training. However, the lack of patient compliance with all three of the intervention components, together with the low rate of postintervention assessment of patients for the main trial outcomes, was problematic.

Our intervention attempted to combine components to enhance motivation, confidence, and falls-related self-efficacy, as well as muscle strength in the lower extremities. It produced a modest comparative improvement in the *role-physical* domain score of the SF-36, which means that patients exposed to the intervention reported having fewer role limitations due to physical health and were thus better able to fulfill their work and other activities than those in the control arm. Because exposure to the motivational videotape, which was designed specifically to address confidence and self-efficacy related to preventing future falls, was the common intervention component for more than 90% of patients, it is plausible that the effect we did observe on this one measure of functional recovery may have been a result of addressing these key psychosocial factors. However, the fact that patients were able to take advantage of a “menu” of intervention activities, including limited social support, may also have been important in achieving this outcome.

Methodological challenges

We encountered several methodological challenges that undermined the trial and deserve comment. First, 6-month attrition, largely due to refusals to complete the entire outcome assessment protocol between 5 and 7 months, was high in both the control and intervention arms of the study and was the most serious problem. Despite multiple attempts, many patients refused the 6-month outcome assessment because of practical difficulties associated with returning to the hospital, the timing of assessments, and the

number of previous assessments. For example, failure to return to the hospital may have been due to the fact that many elderly patients who have undergone surgery of the lower extremities may be dependent on others for transportation, and, without the assistance of a companion or an adult child, transportation may be difficult to arrange. In addition, many patients were simply unavailable for the physical assessment because they had temporarily relocated out-of-state for extended vacations or visits with family. Had we the available resources to undertake patient assessments in the community or in the home, rather than in the hospital, as a British study [20] of elderly hip fracture patients at 1 year after fracture has demonstrated is feasible, or even by telephone, we might have obtained higher completion rates. However, compliance in studies of this type is still usually better in the United Kingdom than in the United States.

Second, patients enrolled in the intervention arm of the study often deviated from the planned intervention protocol, with only 10 patients receiving all three components of the intervention. Although patients randomized to the intervention could have received up to a maximum of 16 postdischarge strength training sessions, not all patients completed the maximum number of sessions. Nor did all patients in the intervention receive a socially supportive visit; those who did not typically refused the visit because they reported being overwhelmed while in the hospital. The difficulty we encountered in arranging for such visits eventually resulted in our subsequently withdrawing this intervention component toward the end of the trial. However, although the strength-training component of the intervention was not uniformly completed as planned, patients were universally exposed to the motivational videotape and accompanying patient education booklet. Had compliance with all three components of the intervention protocol been achieved, it is possible that greater differences in functional outcome—perhaps in all three of the relevant SF-36 domains—might have been observed. Given the unanticipated divergence from the study protocol that we experienced, the results presented here may be indicative of what might be realistically expected if aggressive strength training were to be adopted in community hospital settings.

Third, surgeons participating in the study could not be effectively blinded. At least two control patients are known to have received more intensive physical therapy, i.e., muscle-strength training, than they would have otherwise. We believe that once the surgeons sensed that patients receiving intensive physical therapy were responding well, the surgeons were likely to have encouraged their patients to get more physical therapy, thus further diluting the impact of the intervention.

Fourth, although attrition in our study was high, it is not uncommon for trials of recovery after hip fracture to report significant attrition due to refusal, withdrawal, and dropout, or large amounts of missing data. Penrod et al. [19] reported missing outcome data on a large number of patients at 6 months, which limited the analysis of the relationship between early and later physical therapy and

mobility at 2 and 6 months after hip fracture. Moreover, incomplete or inconsistent compliance with multiple intervention components is also a common problem in trials. For example, there was considerable variation in the proportion of patients receiving various components of a multicomponent intervention in a study [18] that was designed to improve functional recovery after hip fracture. Thus, high refusal and high dropout rates can be expected when enrolling patients in complex or lengthy trials. Elderly patients and those who have returned to the community after resolution of an acute health problem such as hip fracture may be especially difficult to follow once they have resumed their normal lives.

Lessons learned

The increasingly complex nature of clinical intervention research, the patient populations that randomized controlled trials seek to enroll, and the outcome and other assessment measures on which the investigator seeks to collect data during and at the end of a trial in order to observe the hypothesized relationship can pose a daunting host of methodological challenges. In fact, it is unlikely that even the best planned trials go precisely as they were intended. It is when unexpected challenges arise in trials and cannot be easily overcome that the question under study may go unanswered at the conclusion of the trial. Moreover, in the context of orthopedic and musculoskeletal research, new efforts to reduce pain or improve functioning often require testing intervention approaches that combine medical or surgical treatment in combination with psychosocial and other intervention components. Such multiple-component intervention has been viewed as increasingly necessary to address the multiple determinants of self-management in chronic disease as well as in the restoration of functional independence after acute or traumatic injury. But, as our experience demonstrates, such interventions can be complex, costly, and difficult to implement.

What then can be learned from this trial? First, implementing multiple-component interventions among elderly hip fracture patients whose physical conditioning has been compromised can be problematic. Complex interventions that require elderly patients to return to the hospital setting may be inconvenient, and may create burdens that reduce the patient's compliance with post-discharge exercise programs and follow-up assessments. Efforts to engage the patient's own family, caregivers, and social support network to assist patients in complying with postfracture rehabilitation programs may help to reduce noncompliance and facilitate follow-up. In addition, rather than expecting patients to participate in all of the possible components of a comprehensive program, a menu approach to participation that encourages patient preferences may be more appropriate.

Second, although maximizing the recovery of lower-extremity strength in elderly hip fracture patients may be a necessary factor in helping them to achieve return to independent living, requiring participation in aggressive physical therapy on a regular outpatient basis may not

always be feasible. As such, home-based delivery of such aggressive strength training, in addition to reinforcement of psychosocial components, may be a more practical means by which to approach elderly hip fracture patients who return to the community.

Third, clinical studies that seek to increase the response rate of outcome assessment at follow-up should budget sufficient resources to support data collection over the long term. This should include adequate resources for arranging follow-up assessments around existing physician visits, reimbursing patient transportation costs, and scheduling home visits with patients whose mobility may still be limited.

In conclusion, despite demonstrating a statistically significant reduction in role limitations due to physical health, our trial was undermined by several methodological difficulties. Although the findings of this trial can be viewed as encouraging and consistent with several recent reports of more comprehensive rehabilitation efforts for hip fracture patients, the results have to be considered equivocal because of the high attrition and the possibility of self-selection bias at follow-up. Such results are likely to be expected in community settings where multiple-component intervention is implemented in rehabilitation after hip fracture.

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