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Family-Mediated Exercise Intervention (FAME)
Evaluation of a Novel Form of Exercise Delivery After Stroke

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Background and Purpose—Additional exercise therapy has been shown to have a positive impact on function after acute stroke and research is now focusing on methods to increase the amount of therapy that is delivered. This randomized controlled trial examined the impact of additional family-mediated exercise (FAME) therapy on outcome after acute stroke.

Methods—Forty participants with acute stroke were randomly assigned to either a control group who received routine therapy with no formal input from their family members or a FAME group, who received routine therapy and additional lower limb FAME therapy for 8 weeks. The primary outcome measure used was the lower limb section of the Fugl-Meyer Assessment modified by Lindmark. Other measures of impairment, activity, and participation were completed at baseline, postintervention, and at a 3-month follow-up.

Results—Statistically significant differences in favor of the FAME group were noted on all measures of impairment and activity postintervention ($P<0.05$). These improvements persisted at the 3-month follow-up but only walking was statistically significant ($P<0.05$). Participants in the FAME group were also significantly more integrated into their community at follow-up ($P<0.05$). Family members in the FAME group reported a significant decrease in their levels of caregiver strain at the follow-up when compared with those in the control group ($P<0.01$).

Conclusions—This evidence-based FAME intervention can serve to optimize patient recovery and family involvement after acute stroke at the same time as being mindful of available resources. **(*Stroke*. 2011;42:681-686.)**

Key Words: family involvement ■ physiotherapy ■ randomized controlled trial ■ rehabilitation ■ stroke recovery

The most common and widely recognized impairment after stroke is motor impairment and much of the focus of stroke rehabilitation is on the recovery of impaired movements and related functions. In the rehabilitation context, both physiotherapists and occupational therapists have traditionally been the mediators of motor recovery. However, despite advances in clinical and scientific research, it has been suggested that the duration of physiotherapy that is delivered is, at best, "homeopathic."[1] Findings from 2 systematic reviews indicate that additional exercise therapy has a significant impact on functional recovery after stroke[2,3] and research is now focusing on "novel" methods of increasing the duration of exercise therapy that occurs with minimal use of resources. One suggestion has been that "physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy—for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement."[4]

To date, no randomized controlled trial (RCT) has evaluated the delivery of exercises to individuals with stroke by people who are not healthcare workers. However, in a RCT by Lincoln and colleagues,[5] both qualified physiotherapists and physiotherapy assistants delivered 2 different forms of additional exercise therapy to people with acute stroke and no differences were noted between the 2 groups after the 5-week additional intervention. Therefore, the primary aim of this study is to evaluate the impact of family-mediated exercise therapy (FAME) on outcome after stroke.

Methods

Participants

Ethical approval was obtained in 6 acute hospitals and recruitment was conducted between August 2007 and January 2009. Patients were identified from each hospital stroke register. Potential participants were assessed for eligibility at 2 weeks after stroke onset. Eligible participants were those with a confirmed diagnosis of a first unilateral stroke (MRI or CT), no impairment of cognition (≥24 of 30 on the Mini Mental State Examination), ≥18 years of age, participating in a physiotherapy program, and a family member willing to participate in the program. To control for heterogeneity, individuals who scored from 3.2 to 5.2 on the Orpington Prognostic Scale were recruited. This cohort consists of individuals presenting

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with a moderate/severe deficit.[6] Family members were considered eligible if they were willing to participate in the program and were nominated by the person with stroke as the person that he or she would most like to assist him or her in the performance of the exercises. Furthermore, there was a requirement that the family member was medically stable and physically able to assist in the delivery of exercises. Suitability was determined after consultation with the individual, their family, and the physiotherapist in charge of the patient's routine care.

After identification of a suitable individual with stroke and a family member, a face-to-face meeting was arranged with the researcher (R.G.) in which the aims of the project, including the role of each individual, were outlined. Participants were given up to 7 days between receipt of the information brochure and being requested to give written permission as stipulated by the local ethics committees. A second meeting was then arranged in which any further questions were answered and the participants were requested to sign a consent form in the presence of each other. Further details on the methodology for the RCT are described elsewhere.[7] The protocol for the trial is registered with the US National Institutes of Health Clinical Trials registry (NCT 00666744).

Procedures

Group allocation was completed by an independent person using computer-generated random numbers placed in sealed envelopes in advance of the start of the study. Each envelope was opened by this independent person on enrollment of an eligible participant. After allocation was revealed, the appropriate intervention was organized by the researcher.

Both members of the control group and the experimental FAME group received "routine" physiotherapy for the duration of the 8-week trial. All "routine" therapy was delivered by physiotherapy staff who were not linked to the project. Participants attended "routine" therapy as inpatients in the acute hospital or inpatients in a rehabilitation unit. A "rehabilitation unit" is a unit where patients who are not longer in the acute phase of their admission are located and where the focus is on multidisciplinary rehabilitation. This may be a unit within an acute hospital or linked to the hospital but geographically elsewhere. Individuals who were discharged home from these units before the end of the trial received "routine" therapy as outpatients in that particular unit. The duration of "routine" therapy received by participants in each group was not recorded.

In addition, participants in the experimental group received individualized FAME programs that were conducted for 35 minutes daily at the bedside with the assistance of their nominated family member. This may have been delivered in the hospital or the home setting, depending on the location of the individual. Each program comprised training the family member with the skills necessary to carry out the additional exercises. In instances in which the nominated family member was unable to complete the exercises, a second family member attended the FAME session that particular week. The treatment protocol for each patient was individual with the exception of the time component. Treatment goals were set weekly after feedback from the treating physiotherapist, the individual with stroke, and their family member. Exercises were designed according to the participants' ability and were progressed accordingly. The emphasis of the program was on achieving stability and improving gait velocity and lower limb strength based on patterns derived from findings reported in a systematic review of 151 intervention studies on stroke rehabilitation.[8] Compliance with therapy time was documented through the use of an exercise diary, in which the number of exercises completed and time taken to complete the exercises were recorded daily.

Outcome Measures

The primary outcome measure used was the lower limb (LL) section of the Fugl-Meyer Assessment (FMA) modified by Lindmark.[9] The modified LL-FMA is a measure of LL impairment and consists of 12 items that assess the individual's ability to perform selective active movements in supine, sitting, and supported standing. A score of 0 indicates that the person is unable to perform the movement and a score of 3 indicates that the person can perform the movement normally. The original FMA scores item performance on a 3-point scale, whereas the modified FMA scores each item on a 4-point scale. Gladstone and colleagues[10] suggest that expanding the grading system of the original scale contributes to the ability of the scale to detect change. The modified FMA is used in the clinical and research setting and its psychometric properties have been previously established.[9,11] A series of secondary outcome measures were also used including the Motor Assessment Scale,[12] the Berg Balance Scale,[13] the 6-Minute Walk Test,[14] and the 100-point original Barthel Index.[15] These outcomes were administered at baseline, postintervention, and at a 3-month follow-up. The Reintegration to Normal Living Index[16] and the Nottingham Extended Activities of Daily Living Index[17] were used to record participants' level of participation and were administered postintervention and at follow-up. Furthermore, caregiver strain was measured using the Caregiver Strain Index[18] at these 2 time points. All measurements were completed by a physiotherapist (E.O.G.) who was not involved in the individuals' care and who was unaware of group allocation. All assessments were completed using a standardized assessment kit.

Statistical Analysis

The study sample size calculations were based on the modified LL-FMA. Based on a 2-independent-group comparison, a minimum of 36 participants was required to detect an increase of 8 points on the LL-FMA at a 2-sided significance level of 5% and a power of 80%. Therefore, a sample size of 40 participants was recruited to the FAME RCT to allow for attrition.

Differences in baseline values between the groups and differences in the change in scores between the groups from baseline to postintervention and from postintervention to follow-up were tested with the χ^2 test, the Mann Whitney U test and independent t tests. Each hypothesis was tested with a 2-tailed analysis and 0.05 as the level of significance. Analyses were by intention to treat and a last measurement carried forward method was used to account for attrition.

Results

Forty (6.4%) of a total of 622 individuals were eligible for inclusion in the study (Figure). The distribution of group allocation did not differ among the study sites ($P=0.96$) and the baseline study characteristics and outcome measures were similar in both groups (Table 1). There was a difference in the mean age of the 2 groups; however, this difference did not reach statistical significance.

Control Group

One participant withdrew before the postintervention assessment (medically unwell). The mean duration of stay in the acute hospital setting in the remaining 19 participants was 40.1 day with a SD of 15 days (range, 23 to 83 days). Six participants were discharged home before the postintervention assessment. Thirteen participants were discharged to a "rehabilitation unit". The mean length of stay in the "rehabilitation unit" for these participants was 52.3 days with a SD of 40 days (range, 21 to 164 days). All individuals received "routine" physiotherapy in these settings. Two further participants, who completed the postintervention assessment, died before the follow-up assessment (second stroke).

FAME Group

Two participants withdrew before the postintervention assessment (1 second stroke, 1 myocardial infarction). The mean length of stay in the acute hospital for the remaining 18 participants was 35.7 days with a SD of 10.5 days (range, 23

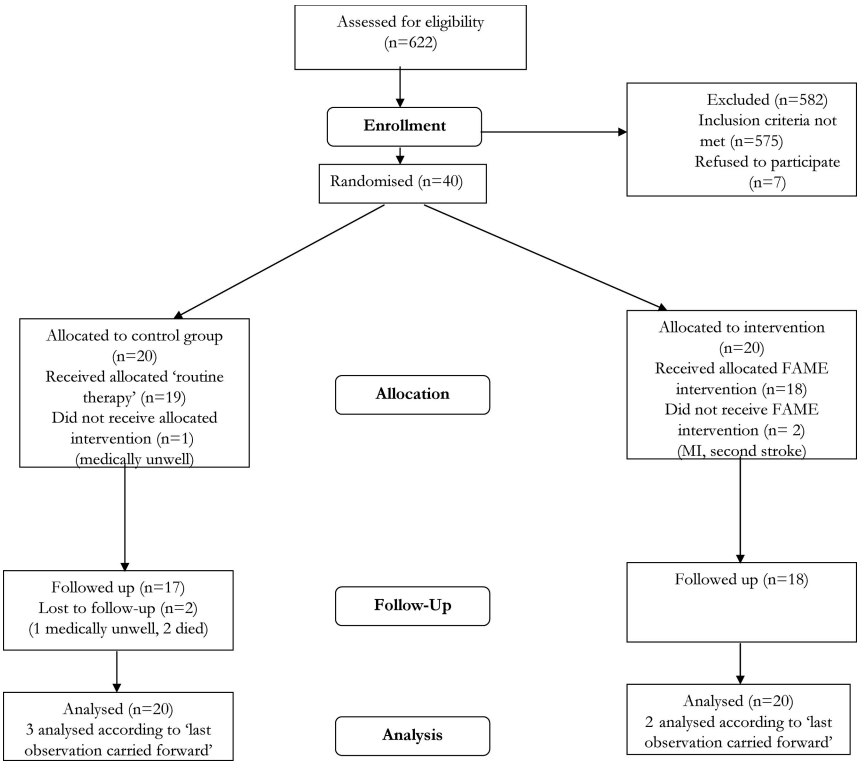

Figure. FAME trial profile.

to 61 days). During this time, participants received "routine" physiotherapy for the duration of their hospital stay, similar to the control group. Eleven participants were discharged home before the postintervention assessment. Seven participants were discharged to a "rehabilitation unit". The mean length of stay in the "rehabilitation unit" for these participants was 40.3 days with a SD of 9.6 days (range, 28 to 52 days).

There was a significant difference between the overall amount of additional exercise therapy planned and the amount of additional therapy actually completed by participants in the FAME group ($P=0.046$). A mean of 227 minutes (SD, 34 minutes) of additional therapy was actually delivered each week, whereas 245 minutes of additional exercise therapy was planned for each participant. A post hoc analysis, excluding 2 participants who did not complete at least 1200 minutes of additional therapy, demonstrated no significant difference between the overall amount of therapy planned and the amount actually delivered.

Table 1. Baseline Characteristics of Patients

Baseline Variables	Control Group (n=20)	FAME Group (n=20)
Age*	69.95 years (11.69)	63.15 years (13.3)
Male/female	7/13	13/7
Left/right side stroke	14/6	9/11
Cerebral infarction	18	16
Cerebral haemorrhage	2	4
OPS score* (3.2–5.2)	3.8 (0.8)	4.1 (0.7)
Time from stroke onset to start of intervention,* days	19.7 (3)	18.9 (2.9)
LL-FMA* (0–36 points)	25.7 (11.9)	21.1 (11.3)
MAS* (0–48 points)	29.7 (12.9)	24.3 (11.1)
BBS* (0–56 points)	26.8 (18.1)	22.3 (17.6)
SMWT,* meters	118.4 (119.6)	67.7 (81.2)
BI* (0–100 points)	65.5 (27.9)	56.3 (27)

*Mean and SD.

OPS indicates Orpington Prognostic Scale; MAS, Motor Assessment Scale; BBS, Berg Balance Scale; BI, Barthel Index.

At the postintervention assessment, there was a significant difference in the change in scores on all outcome measures of impairment and function from baseline between the 2 groups in favor of the FAME group (Table 2). A general linear model (analysis of covariance) was constructed for each outcome to determine if the change in scores was influenced by variables including group allocation, age, and Orpington Prognostic Scale score. Only group allocation had a significant effect on the change in scores in all measures of impairment and activity at this time point ($P<0.05$). There was no significant differences between the groups in Reintegration to Normal Living Index scores ($P=0.96$) or Nottingham Extended Activities of Daily Living Index scores ($P=0.45$) postintervention.

At the follow-up assessment, there was a statistically significant difference in the change in scores from postintervention on the 6-Minute Walk Test, Reintegration to Normal Living Index, and the Nottingham Extended Activities of Daily Living Index in favor of the FAME group ($P<0.05$). There was no significant difference between the groups in the change in scores from postintervention to follow-up on the LL-FMA, Motor Assessment Scale, Berg Balance Scale, and Barthel Index (Table 3).

At follow-up, family members in the FAME group reported a significant decrease in their levels of caregiver strain from postintervention when compared with family members in the control group ($P<0.00$).

Table 2. Outcomes Postintervention and Change in Scores From Baseline to Postintervention

	Control Group (n=20)		FAME Group (n=20)		
Outcome Measure	Mean Score Postintervention	Mean Change From Baseline	Mean Score Postintervention	Mean Change From Baseline	P*
LL-FMA	27.5 (10.3)	1.75 (6.3)	30.6 (5.5)	9.5 (9.9)	0.01
MAS	34.5 (11.6)	4.75 (6.2)	36.1 (10.2)	11.9 (7.8)	0.00
BBS	35.8 (17.2)	9 (9)	45.1 (14.9)	22.8 (18.1)	0.02
SMWT, meters	165.6 (146.1)	47.2 (50.6)	231.8 (131.3)	164.1 (128.7)	0.00
BI	81.8 (18.7)	16.3 (14.2)	88.5 (15.6)	32.3 (24)	0.04

Mean (SD).
*Difference in change in scores in favor of the FAME group.
MAS indicates Motor Assessment Scale; BBS, Berg Balance Scale; BI, Barthel Index.

Discussion

In this small but homogenous group of individuals with acute stroke, additional family-mediated therapy significantly improved active range of movement of the LL. Family members in the FAME group also reported a significant decrease in levels of caregiver burden when compared with family members in the control group. Although the minimal clinically important difference on the modified LL-FMA is not established, a 20% improvement in motor scores in the intervention group over the control group has been previously considered as clinically important.[19] In this RCT, the mean modified LL-FMA scores in both groups at baseline ranged from 21.1 to 25.7 points. Hence, a 30% difference in change in scores between the groups from baseline to postintervention represents a clinically meaningful difference in level of impairment of the groups. Significant differences were also observed in balance, walking ability, and activities of daily living. These differences in efficacy were most evident postintervention. This finding is in keeping with previous studies in which a significant improvement was noted in participants after an additional focused exercise therapy program that was delivered by healthcare workers.[20,21] However, this was the first RCT that examined the involvement of family members in structured, quantifiable exercise delivery. This family-mediated additional exercise program is accompanied by more confidence and experience on the part of the individual with stroke and a reduced caregiver burden.

From the postintervention assessment to the 3-month follow-up, the differences in recovery patterns were smaller, similar to the findings of previous studies of this nature.[20] The 6-Minute Walk Test was the only measure of activity that improved significantly more in the FAME group than the control group. This finding could be due to a number of reasons. First, given the continuous nature of the measure, the possibility of a ceiling effect was negated. Second, the exercises were task-oriented, functional exercises aimed at improving LL impairment, balance, and mobility. The initial significant improvement in impairments, as noted by the LL-FMA, may have led to a later improvement in a functional activity such as walking. Other authors have postulated that the lack of significant findings at follow-up assessments may be in part due to the later ongoing recovery in the control group; in essence, the control group eventually "catch up" with the intervention group in the performance of activities.[20] However, this is not evident in this study because both groups were comparable in their rate of recovery on the primary outcome measure. The lack of significant changes in both groups from postintervention to follow-up suggests that the

Table 3. Outcomes at Follow-Up and Change in Scores From Postintervention to Follow-Up (3 Months)

	Control Group (n=20)		FAME Group (n=20)		
Outcome Measure	Mean Score at Follow-Up	Mean Change From Postintervention	Mean Score at Follow-Up	Mean Change From Postintervention	P
LL-FMA	28.8 (10.4)	1.3 (5.2)	32.2 (5.4)	1.6 (2.4)	0.12
MAS	35.2 (10.8)	0.7 (2.6)	37.9 (9.7)	1.8 (3.8)	0.59
BBS	37.6 (16.2)	1.8 (8.5)	46 (14.2)	0.9 (2.5)	0.7
SMWT, meters*	162.1 (143.4)	−3.5 (32.7)	271.6 (154.5)	39.8 (55.4)	0.01
BI	83.3 (19)	1.5 (11.6)	92.3 (13.8)	3.8 (8.3)	0.36
N-EADL*	32 (20.7)	3.6 (7.8)	41.5 (15.5)	7.6 (8.3)	0.02
RNLI*	32.9 (7.1)	0.4 (2.9)	37.4 (5.6)	4.7 (4.3)	0.00
CSI*	3.2 (2.7)	−0.2 (1.1)	2.6 (1.3)	−1.3 (1)	0.00

Mean (SD). *P* value difference in change in scores favor of FAME group.
*$P<0.05$ for difference in change in scores between groups.
MAS indicates Motor Assessment Scale; BBS, Berg Balance Scale; BI, Barthel Index; N-EADL, Nottingham Extended Activities of Daily Living Index; RNLI, Reintegration to Normal Living Index; CSI, Caregiver Strain Index.

optimal time for recovery is in the early stages after stroke, particularly in the first 3 months. These findings support the early initiation of intensive stroke rehabilitation as an important feature of specialized stroke care.[20]

The additional family-mediated intervention improved reintegration to community living after discharge from the hospital and the performance of extended activities of daily living. Many people with stroke experience a low level of satisfaction with community reintegration after hospital discharge.[21] As many as 39% to 65% of community-dwelling people with stroke report limitations in daily activities and restrictions in reintegration into community activities.[22] Several studies have examined the effect of stroke-related factors, for example, physical impairments and mental status, on satisfaction with community reintegration and a link between physical function and satisfaction with reintegration has been reported.[23] The significant improvement in mobility in the FAME group over the control group at follow-up may have contributed to their increased integration to the community because many of the topics explored in the 2 measures examine the extent to which people can perform mobility-related tasks in their home environment and community.

Family members in the FAME group also reported significantly reduced levels of caregiver strain at follow-up when compared with their counterparts in the control group. Kalra and colleagues[24] suggest that the use of a structured program of activities under professional supervision during inpatient rehabilitation may serve to empower consenting informal caregivers in their future role by teaching them appropriate skills. Mant et al[25] also reported that additional family support after stroke significantly increased social activities and improved quality of life for caregivers.

Compliance with the additional program was very good and participants completed the additional exercises at least 6 days per week. Poor compliance has been reported as an issue by other authors who have delivered additional exercise interventions to people with stroke.[5] Compliance was optimized through the use of a daily exercise diary, weekly follow-up meetings with the research therapist, and the involvement of the family from the outset. Blennerhassett and Dite[26] suggest that individuals with stroke are more likely to practice motor activities when they are supervised. Furthermore, the additional exercise therapy was delivered primarily in the evening time between 6 and 8 PM outside of routine physiotherapy hours. This prearranged time of exercise delivery allowed the individual with stroke to participate in his or her routine rehabilitation program during the day and also allowed the nominated family member to continue with their daily working schedule.

An important limitation of this study is its multicenter nature, lending to the possibility that participants may not have received comparable amounts of "routine" therapy in each center. However, a number of different acute clinical sites were chosen to improve recruitment. In addition, although the duration of each session was the same for all participants, the content of each exercise program varied according the individual, making the content difficult to quantify. Nevertheless, all exercises delivered were evidence-based regardless of the specific neurological treatment approach. Finally, the RCT is also open to systematic bias in which contamination of the therapists that provided the "routine" therapy to individuals in the control group and FAME group may have occurred. Blinding the therapists that delivered the "routine" therapy for the duration of the FAME trial was not possible in this study.

Conclusions

This RCT demonstrates that additional family-mediated exercise therapy has a significant impact on recovery after acute stroke. The FAME study responds to the clear need for the provision of an evidence-based intervention that can be delivered in the hospital or the community setting and that is acceptable to people with stroke and their family members. In the current healthcare climate, it is imperative that healthcare professionals identify interventions such as FAME that can serve to optimize recovery and family involvement after stroke at the same time as being mindful of available resources.

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Disclosures

None.

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