Family mediated exercises for stroke survivors: the FAME trial

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Purpose of talk

- Introduction
- Background literature
- Pilot work
- Randomised controlled trial
- Qualitative element of programme
- Implications for clinical practice
- Future research
- Limitations

Introduction

- Stroke has been shown to be a major cause of death and disability in every society in which it has been studied

- In Ireland, approximately 10,000 people are admitted to hospital each year with a stroke as the primary diagnosis (IHF 2008)

- It is estimated that there are 30,000 people living with residual deficits following stroke (IHF 2008)

Preamble

- Cortical reorganisation post stroke requires a significant level of repetition
- It has been suggested that the 'dose of physiotherapy' delivered post stroke is 'at best, homeopathic'
- Research is now focusing on novel ways to increase the 'dose' of physiotherapy post stroke
- One suggestion has been…

'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.'
(de Weerdt & Feys, 2002)

Aim

- To examine the impact of additional family mediated exercise (FAME) therapy on outcome following acute stroke through the implementation of a randomised controlled trial

- To evaluate the impact of the FAME programme on the person with stroke and their nominated family member using qualitative and quantitative data gathering techniques

Additional exercise therapy

- State of the art
  - Technology mediated therapy
  - Constraint induced movement therapy (CIMT)
  - Massed practise therapy
  - Previous reviews have included control groups that were not having 'routine' exercise therapy

Literature review

- Aim
- Inclusion criteria
- Methodological quality
- Data extraction
- Quantitative analysis

Galvin, R., Murphy, B., Cusack, T., Stokes, E. (2008a). **The impact of increased duration of exercise therapy on functional recovery following stroke - what is the evidence?** *Topics in Stroke Rehabilitation*, 15(4), 365-377.

Main findings

- Meta-analysis
  - no effect of additional exercise therapy on UL function
  - positive impact on walking speed and LL impairment
  - significant impact on function

- Narrative review
  - compliance
  - patient subgroups
  - type of additional exercise therapy
  - number of minutes of additional exercise therapy
  - long term benefits of additional exercise therapy

User surveys

- To investigate the views of potential participants in the FAME programme on the role of family members in physiotherapy and exercise delivery
  - individuals with acute stroke (n=75)
  - family members (n=100)
  - physiotherapists (n=10)

- Mixed methodological approach
  - self-report questionnaires
  - semi-structured interviews
  - focus groups

Individual with stroke

- Self-report questionnaires (n=75)
- 87% (n=65) - FAME was acceptable in hospital and at home as an adjunct to routine PT
- Reasons why FAME was not acceptable
  - It is not the family's role (n=7)
  - The respondent would not feel confident in FAME (n=5)
  - Family would put respondent under too much pressure (n=5)
- Semi-structured interviews (n=10)

Family members

- 91% (n=91) willing to participate in physiotherapy and exercise delivery in hospital and at home
- Commitment to work (n=24) was primary reason that limited participation in PT
  - Overcome by a pre-arranged time of attendance
- Other reasons that limited participation in PT
  - No confidence to deliver exercises (n=20)
  - Unsuitable treatment times (n=13)

Galvin, R., Cusack, T., Stokes, E. (2009a). **To what extent are family members and friends involved in physiotherapy and the delivery of exercises to people with stroke?** *Disability and Rehabilitation*, 31(11), 898-905.

Physiotherapists

- Limited participation - level of interest, availability & motivation of the family members

- Family involvement can impact on recovery in terms of treatment carry-over, assisting the family unit to cope and improving handling skills

- Some negative experiences included:
  - Family over enthusiastic (n=5)
  - Very emotional (n=1) or critical of performance (n=1)

Galvin, R., Cusack, T., Stokes, E. (2009b). **Physiotherapy after stroke in Ireland: a qualitative insight into the patient's and physiotherapist's experience.** *International Journal of Rehabilitation Research*, 32(3), 238-244.

Randomised controlled trial

- Rationale
- Study design
- Sample size
- Ethical approval
- Recruitment

Galvin, R., Cusack, T., Stokes, E. (2008a). **A randomised controlled trial evaluating family mediated exercise (FAME) therapy following stroke.** *BioMed Central Neurology* [online]. Available at: ‹URL: http://www.biomedcentral.com/1471-2377/8/22›, 8(22).

Methodology

- Inclusion criteria
  - Assessment at 2 weeks following stroke onset
  - Formal diagnosis of first unilateral stroke
  - Orpington Prognostic Score 3.2 - 5.2
  - Participation in physiotherapy programme
  - No receptive/expressive dysphasia
  - Nominated family member willing to give informed consent

- Group allocation
  - Independent person
  - Group A - 'routine therapy'
  - Group B - 'routine therapy' + additional 'FAME therapy'

Intervention

- Duration - 8 weeks

- Content of additional programme
  - 35 minutes of additional exercise therapy assisted/supervised by nominated family member
  - Individual and specific to each participants needs
  - Progression as appropriate
  - Emphasis on LL exercises (Van Peppen et al 2004)
  - Completion of daily 'exercise log/diary'

- Re-evaluation and progression every week

Assessment

- Completed by a blinded outcome assessor
- Baseline (T1), post-intervention (T2), three month follow-up (T3)
- Outcomes at the level of impairment, activity and participation
  - LL section of the modified Fugl-Meyer Assessment (LL-LMA)
  - Berg Balance Scale (BBS)
  - Motor Assessment Scale (MAS)
  - Six Minute Walk Test (SMWT)
  - Barthel Index (BI)
  - Nottingham Extended Activities of Daily Living (N-EADL)
  - Re-integration to Normal Living Index (RNLI)
- Nominated 'family member/friend'
  - Caregiver Strain Index (CSI)

Statistical analysis

- Differences in baseline values between groups
  - Normality of data distribution – graphical, K-S test
  - X^2 test (corrected) – side of paresis, gender distribution
  - Independent t-tests – age, SMWT
  - Mann Whitney test – OPS, LL-LMA, MAS, BBS, BI
- Change in scores from T1 to T2 and T2 to T3
- Two tailed analysis and 0.05 as level of significance
- Intention to treat and 'last observation carried forward'
- Graphical representation of data using boxplots

Results

- Screening
  - 622 people with stroke
  - 40 eligible for participation in the study
- Exclusion
  - Discharged home (21.5%), discharged from PT (13.4%)
  - Other reasons – cognitive impairment, dysphasia, previous CVA, medically unstable, OPS>5.2
  - Family member unwilling to participate (1.2%, n=7)
- No significant difference in baseline scores on any independent variables or outcome measures

Demographic details

VARIABLES	CONTROL	FAME
n	20	20
Mean age (SD)	69.9 (11.9) years	63.15 (13.3) years
Gender	Male = 7 Female = 13	Male = 13 Female = 7
Type of stroke	Haemorrhagic = 2 Ischaemic = 18	Haemorrhagic = 4 Ischaemic = 16
Side of Paresis	Left = 6 Right = 14	Left = 11 Right = 9
OPS score (SD)	3.8 (0.8)	4.1 (0.7)

Results

- **Control group**
  - n=19
  - 6 discharged home, 13 discharged to rehabilitation unit

- **FAME group**
  - n=18
  - 1818 minutes of additional exercise therapy actually completed (mean 227 minutes per week v planned 245 minutes)
  - significant difference in planned versus actual therapy (p=0.04)
  - 11 discharged home, 7 discharged to a rehabilitation unit

Post-intervention…

- There was a statistically significant difference in the change in scores from T1 and T2 in favour of the FAME group on the LL-LMA, MAS, BBS, SMWT and the BI
- There was no significant difference between the groups in the N-EADL and RNLI scores documented at T2
- There was no significant difference in the levels of carer strain reported by the family members in both groups at T2

Results…

OUTCOME MEASURE	CONTROL		FAME		p value
	Mean change in score (T1 to T2)	SD	Mean change in score (T1 to T2)	SD	
LL-LMA	1.75 points	6.28	9.5 points	9.9	**0.01**
MAS	4.75 points	6.2	11.9 points	7.8	**0.00**
BBS	9 points	9	22.8 points	18.1	**0.02**
SMWT	47.2 metres	50.6	164.1 metres	128.7	**0.00**
BI	16.3 points	14.2	32.3 points	24	**0.04**

Three month follow-up

- Significant difference in change in scores from T2 to T3 in favour of the FAME group on the SMWT, N-EADL and RNLI

- There was no significant difference between the groups in the change in scores between T2 and T3 on the following outcome measures: LL-LMA, MAS, BBS and BI

- The decrease in levels of carer strain from T2 to T3 was significantly greater in family members in the FAME group when compared to the control group ($p<0.00$)

Results…

OUTCOME MEASURE	CONTROL		FAME		p value
	Mean change in score (T2 to T3)	SD	Mean change in score (T2 to T3)	SD	
LL-LMA	1.3 points	5.2	1.6 points	2.4	0.12
MAS	0.7 points	2.6	1.8 points	3.8	0.59
BBS	1.8 points	8.5	0.9 points	2.5	0.7
SMWT	-3.5 metres	32.7	39.8 metres	55.4	0.01
BI	1.5 points	11.6	3.8 points	8.3	0.36
N-EADL	3.6 points	7.8	7.6 points	8.3	0.02
RNLI	0.4 points	2.9	4.7 points	4.3	0.00
CSI	-0.2 points	1.1	-1.3 points	1	0.00

Qualitative results

- Semi-structured interview with individual with stroke (n=15) and their family member (n=15) following the additional FAME intervention
- Aim - to explore the impact of the programme on their daily lives
- Completed by a person unknown to the individual
- Content and analysis based upon the principals of phenomenology

Individual with stroke

- Identified several benefits to themselves, both physically and psychologically, as a result of their participation

'My confidence grew all the time, every time I made progress, my confidence improved' (TCD 03)

'The exercise diary also helped... it made you do it.' (TCD 03)

'It gave me a structure where I would have done my physio...and that would've been it really, whereas I had this exercise programme, it was structured, it was well thought out and it was, you know, it motivated me again at 6 o' clock in the evening - I had something else to do.' (TCD 10)

'The fact that I had XX (wife) pushing me as well with the exercises and making sure I did them, that was very important' (TCD 11)

Family member

- Identified benefits to the person with stroke in terms of an improvement in physical impairments, mobility, balance and confidence
- Participation in the FAME programme was not reported to be a source of additional pressure

'I think it gave me a sense that I could do something, because, you know one of the worst things for me, was the feeling of helplessness, that I couldn't, I couldn't change this, I couldn't actually do much about it, and at least it gave me something positive that I could do when I was visiting... it did give me a sense that at least I could contribute something towards recovery, emm rather than just sitting and encouraging him, you know...' (TCD FM 09)

Implications for clinical practice

- Kernel of programme - family involvement
- Inclusion criteria - may not need to be as stringent in clinical practice
- Importance of early intervention
- 'Out of hours' physiotherapy
- Qualitative aspect of assessment

Future research

- RCTs
  - Other subgroups
  - Different time points post stroke
  - Community roll out
- Economic impact
- Mixed methodologies
- Long term impact

Limitations

- Multi-centre study
- Routine physiotherapy
- Therapist motivation
- Satisfaction with programme – patient/physiotherapist encounter
- Individual nature of the exercise programme

Conclusion

- Significant improvement in levels of impairment and activity following an 8 week programme of additional FAME therapy
- Improvement maintained at the 3 month follow-up
- People in the FAME group were significantly more integrated into their community at the 3 month follow-up
- Both people with stroke and their family members identified several benefits to themselves and each other as a result of their participation
- FAME study responds to a need for the provision of an evidence based intervention that can be delivered in the hospital and the community setting

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