

shift

Self-harm intervention,
family therapy



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Routine Data – Is it Good Enough for Trials

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Objectives

- **The SHIFT trial**
- **Primary endpoint data collection**
- **The NHS Information Centre**
- **Feasibility and benefits of data collection via the NHS Information Centre**
- **Comparison of results**
- **Conclusions**

The SHIFT trial

‘a pragmatic, randomised, controlled trial, comparing family therapy with treatment as usual for young people seen after second or subsequent episodes of self-harm’

- **Aim to recruit 832 participants from 30 centres (CAMHS) across the England** (Yorkshire, Greater Manchester, London). As of 1st May 2012 recruitment stands at 410 participants.
- **Individually randomised 1:1 between Family Therapy and Treatment As Usual**
- **Evaluating Leeds Family Therapy & Research Centre Systemic Family Therapy Manual (LFTRC Manual)** – development & validation funded by MRC to support trials of FT [*]

* Pote, H., Stratton, P., Cottrell, D., Shapiro, D. & Boston, P. (2003) Systemic family therapy can be manualised: research process and findings. *Journal of Family Therapy*. 25, 236-262.

Primary endpoint data collection

- **Primary outcome: Repetition of self-harm leading to hospital attendance within 18 months of randomisation**
 - Objective rather than subjective
 - Can be obtained from hospital records even if contact has been lost with participants
 - Analysis using time to event methods
- **Requires timely and regular collection of hospital attendance data to inform safety monitoring and the timing of analysis**
- **SHIFT researchers visit hospitals in ‘SHIFT areas’ to manually interrogate local medical records**

Challenges to our collection of primary endpoint data

- **Resource intensive**
- **Episodes may be missed**
- **Differential search processes within hospitals**
- **Lack of linkage within trusts** – Accident & Emergency and Admissions
- **Various obstacles and levels of access to different hospital trusts**
 - 170 hospital NHS trusts in England manage multiple hospitals
 - Approvals obtained from 19/30 trusts identified for SHIFT
 - Data accessed from hospitals with 16 trusts

Routine data - The NHS Information centre

The NHS Information Centre (IC) holds data provided periodically by English Hospitals, their main aim being to provide England-wide statistics to inform frontline decision makers.

HES - Hospital Episode Statistics

- Data submitted by **all** NHS hospital providers in England
- Separate records for every period of care for: **Admitted patients**, Outpatients and experimental data on **Accident and Emergency attendances**

Accessing the data

- Approval for HES extract containing patient identifiable record-level data
 - stringent application procedure
- Provision of our participant linkage data – unique identifiers

Data recently obtained for episodes up to the end of 2011

Feasibility of data collection via the NHS IC

If reliable benefits to the SHIFT trial include:

- Regular, fast England-wide data retrieval
- Avoidance of potentially biased data collection
- Free up researcher resources

A change to the method of primary outcome data collection may be instigated after consideration of:

- % episodes coded appropriately as self-harm episodes
- % required data items retrieved for each episode
- Data quality by Hospital - to ensure recommendations can be made at both study and site level

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Reported hospital episodes

IC data:

- 94% linkage rate
- IC data up to the end of 2011
- 4 missed episodes

Researcher data:

- Unknown linkage rate
- Some 2012 data
- 99 missed episodes

		Researcher			Total
		Episode reported	Episode not reported		
			Hospital searched	Hospital not searched	
IC	Episode reported	97	37	62	196
	Episode not reported	4			4
	Total	101	99		200

*An additional 19 episodes from 2012 have been picked up by the researchers

Self-harm hospital episodes

- **Unable to classify 101 episodes from the IC data > 50%**
 - 16% Admissions data unknown - ICD classifications
 - 73% A&E data unknown - 8 patient group classifications
- **No conflicting episodes**

		Researcher			Total
		SH	Non-SH	Episode not reported	
IC	SH	16	0	19	35
	Non-SH	0	25	35	60
	Unknown type	10	46	45	101
	Episode not reported	1	3		4
	Total	27	74	99	200

Conclusion

Researcher		IC	
Pros	Cons	Pros	Cons
<p>Reliable coding of reason for attendance - SH or not</p>	<p>Individual hospital trust approvals</p> <p>Time consuming</p> <p>Lack of linkage</p> <p>Episodes can be missed</p>	<p>Regular England wide data retrieval</p> <p>Free up researcher resources</p> <p>We can use data to target researcher data collection</p> <p>Avoidance of potentially biased data collection</p>	<p>Lack of required information in the A&E dataset</p> <p>Data cleaning</p> <p>Different data formats</p>

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