

# A pragmatic randomised controlled trial and economic evaluation of family therapy versus treatment as usual for young people seen after second or subsequent episodes of self-harm: the Self-Harm Intervention – Family Therapy (SHIFT) trial

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†In memoriam

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## Scientific summary

### **The Self-Harm Intervention: Family Therapy (SHIFT) trial**

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# Scientific summary

## Background

Self-harm in adolescents is a major public health issue and, globally, suicide is the second most common cause of death in the 10–24 years age group after road traffic accidents. As many as 10% of adolescents self-harm in the community each year, with the most common methods being cutting and overdose. Only one in eight episodes of self-harm leads to a hospital presentation.

The estimates of the risk of 1-year repetition of self-harm vary between 5% and 25% per year. Actual rates may be much higher when repetition that does not come to clinical or medical attention is considered.

There is limited evidence for the effectiveness of clinical interventions for young people who engage in self-harm. Two recent studies have suggested that dialectical behaviour therapy and mentalisation-based treatment may be effective in reducing self-harm. Both had small numbers of participants and shorter follow-up periods than this study and relied on self-report as the primary outcome measure. A systematic review of interventions to reduce self-harm in adolescents calculated pooled risk differences comparing the proportion of young people who self-harmed at least once in the follow-up period of each study versus those who did not self-harm at all. Overall, the proportion of participants who self-harmed was slightly (but statistically significantly) lower in those allocated to treatment interventions. However, the authors acknowledged that the quality of studies examined was poor and that ‘more research and replication of the positive findings by independent groups are urgently required’ (Ougrin D, Tranah T, Stahl D, Moran P, Asarnow JR. Therapeutic interventions for suicide attempts and self-harm in adolescents: systematic review and meta-analysis. *J Am Acad Child Adolesc Psychiatry* 2015;**54**:97–107).

## Methods

### Design

The Self-Harm Intervention: Family Therapy (SHIFT) trial was a pragmatic, Phase III, multicentre, individually randomised controlled trial of family therapy (FT) compared with treatment as usual (TAU) in 832 adolescents aged 11–17 years who had engaged in self-harm on at least two occasions and for whom a recent self-harm episode was a key reason for contact with Child and Adolescent Mental Health Services (CAMHS).

### Objectives

The primary objective assessed the effectiveness of FT compared with TAU as measured by young people’s rates of repetition of self-harm leading to hospital attendance 18 months after randomisation.

The secondary objectives assessed were:

- repetition rates of self-harm leading to hospital attendance 12 months after randomisation
- the cost per self-harm event avoided as a result of FT, measured using a structured, trial-specific health economics questionnaire
- the characteristics of all further episodes of self-harm (both those resulting in hospital attendance and self-report of all episodes)
- changes in a range of measures of participant and family functioning (see *Outcome measures*)
- moderator and mediators influencing benefit from treatment
- therapeutic engagement and adherence.

### Setting and participants

The participants were young people aged 11–17 years who had self-harmed at least twice presenting to CAMHS following an episode of self-harm, recruited from NHS CAMHS across three 'hubs' in England: Greater Manchester, London and Yorkshire. Young people were screened for trial suitability and approached, if eligible, at their first visit to CAMHS following self-harm.

### Interventions

The FT intervention was based on a modified version of the Leeds Family Therapy & Research Centre Systemic Family Therapy Manual. Qualified family therapists were appointed specifically to work on the trial, received standardised training and worked in teams of three or four, providing trial FT as a team for a cluster of CAMHS.

Treatment as usual was the care offered by local CAMHS teams to young people referred following self-harm. It was expected that TAU would be diverse and involve individual and/or family-orientated work, delivered by a range of practitioners with various theoretical orientations.

### Outcome measures

The duration of treatment was designed to be approximately 6 months.

Measures were as follows: Inventory of Callous–Unemotional Traits [(ICU) young person and caregiver self-report at baseline], Family Questionnaire (caregiver self-report at 3 and 6 months), System for Observing Family Therapy Alliances (SOFTA; completed by family therapist and participants at FT session 3) and, at 12 and 18 months, the Suicide Attempt Self-Injury Interview (SASII) with the young person, Children's Depression Rating Scale – Revised (CDRS-R), health economics questionnaire, young person and caregiver self-report for the McMaster Family Assessment Device (FAD), Strengths and Difficulties Questionnaire (SDQ), young person self-report for the Beck Scale for Suicide Ideation (BSS), Hopelessness Scale for Children (young person), Paediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q), EuroQol-5 Dimensions [(EQ-5D) also at 6 months] and caregiver self-report for the General Health Questionnaire, 12 questions (GHQ-12), Health Utilities Index 3 [(HUI-3) also at 6 months] and health economics questionnaire.

## Results

### Characteristics of the sample

A total of 3554 young people were screened within participating CAMHS, of whom the clinician deemed 1603 (45.1%) to be eligible for the trial. The most common reason for a young person to be ineligible was that they had not engaged in self-harm prior to the current CAMHS referral. A total of 993 (61.9%) eligible young people consented to researcher contact, and 832 (83.8%) consented to trial participation and were randomised (51.9% of those eligible): 415 to FT and 417 to TAU.

The mean age at randomisation was 14.3 [standard deviation (SD) 1.38] years in the FT arm and 14.4 (SD 1.35) years in the TAU arm. In both arms there were more females than males: 368 (88.7%) in the FT arm and 369 (88.5%) in the TAU arm. More young people had self-harmed on at least three previous occasions than on two occasions: 369 (88.9%) in the FT arm and 370 (88.7%) the TAU arm. The type of most recent episode was most commonly self-injury, for 297 (71.6%) in the FT arm and 297 (71.2%) in the TAU arm, with self-poisoning attributed to a further 93 (22.4%) and 91 (21.8%), respectively. Those remaining used combined methods. All but two participants were living with their parents/guardians as opposed to in foster care. The majority were in full-time education: 398 (95.9%) in the FT arm and 386 (92.6%) in the TAU arm. Ethnicity was also well balanced between the arms.

Baseline characteristics suggest that participants had experienced significant difficulties and were not dissimilar to UK CAMHS referrals as a whole: 26.2% reported a health or disability problem, 29.3% had been involved with CAMHS in the past, 21.4% reported marked physical abuse and 16.6% reported sexual

abuse. On the total difficulties score of the SDQ, 66.2% of participants scored in the high/very high range, with 69.6% of caregivers reporting scoring participants in this range. On the general functioning subscale of the FAD, 84.7% of participants scored their families as 'unhealthy', with the equivalent figure from caregivers being 75.8%. On the CDRS-R, 65.7% of participants scored themselves as being in the moderate, severely or very severely depressed category. Nearly two-thirds of the participants (63.5%) were referred directly to CAMHS from the community: some had been discharged from hospital without a CAMHS referral and had then been referred via community services; others had never presented to hospital in the first place. The self-harm method used by the young people in the sample was much more slanted towards self-injury than in samples of hospital cases.

### Clinical effectiveness

Primary outcome data were available for 795 out of 832 (95.6%) participants. A total of 221 (26.6%) young people experienced the primary outcome event, that is, a repeat self-harm event leading to hospital attendance within 18 months post randomisation: 118 (28.4%) in the FT arm and 103 (24.7%) in the TAU arm. There was no evidence to suggest a statistically significant difference in self-harm repetition rates between the treatment groups. The hazard ratio for FT compared with TAU was 1.14 [95% confidence interval (CI) 0.87 to 1.49] with a  $p$ -value of 0.3349.

### Cost-effectiveness

Both trial arms showed an increase in the mean EQ-5D over 18 months' follow-up. The largest differences in EQ-5D scores between the two arms were at 6 and 12 months, with the FT group exhibiting higher scores at the 5% significance level than the TAU group, but there were no significant differences in quality of life between the two study arms at 18 months.

Family therapy participants incurred higher costs (mean £1266.23, 95% CI £736.04 to £1796.43) and gained more quality-adjusted life-years (QALYs) (mean 0.034, 95% CI -0.004 to 0.065) than TAU patients, equivalent to an extra 12.4 days of perfect health. The incremental cost-effectiveness ratio (ICER) equalled £36,811.80 per QALY, which is above the recommended threshold range currently specified for National Institute for Health and Care Excellence (NICE) decision-making in England and Wales (£20,000–30,000 per QALY gain). FT was unlikely to be cost-effective in most sensitivity analyses and was dominated by TAU in the complete-case analysis (less effective and more costly).

However, when combining young people's and caregivers' QALY gains, the FT arm incurred higher costs and exhibited better health outcomes than those in the TAU arm, resulting in an ICER of £20,808.21 per QALY gain; this ICER is within the NICE cost-effectiveness range, with a probability of being cost-effective of 41% at £20,000 (and 64% at £30,000) per QALY.

### Secondary clinical outcomes

There were no significant treatment differences in young person questionnaire outcomes on the CDRS-R, PQ-LES-Q, Hopelessness Scale or FAD. However, adolescents treated with FT reported significantly better outcomes on the prosocial scale of the SDQ, with a mean improvement of 0.4 points (95% CI 0.1 to 0.7 points;  $p = 0.0064$ ) at 12 months and of 0.3 points (95% CI 0.0 to 0.7 points;  $p = 0.0337$ ) at 18 months, and on the impact of their problems scale at 12 months (mean improvement of -0.7 points, 95% CI -1.1 to -0.2 points;  $p = 0.0033$ ), but not at 18 months (mean improvement -0.3 points, 95% CI -0.8 to 0.2 points;  $p = 0.2153$ ). There was good evidence of reduced odds of suicide ideation in FT at 12 months, with an odds ratio of 0.64 (95% CI 0.44 to 0.94;  $p = 0.0242$ ), but not at 18 months.

No significant treatment differences were found for the caregiver questionnaire outcomes on the GHQ-12 or Family Questionnaire. However, caregivers reported a range of significantly better outcomes on the SDQ for FT, with the following improvements in scores:

- total difficulties: mean -1.3 points (95% CI -2.4 to -0.2 points;  $p = 0.0260$ ) at 12 months and mean -1.6 points (95% CI -2.9 to -0.4 points;  $p = 0.0131$ ) at 18 months

- emotional problems: mean  $-0.5$  points (95% CI  $-1.0$  to  $-0.1$  points;  $p = 0.0166$ ) at 12 months and mean  $-0.6$  points (95% CI  $-1.1$  to  $-0.1$  points;  $p = 0.0218$ ) at 18 months
- peer problems: mean  $-0.3$  points (95% CI  $-0.7$  to  $-0.0$  points;  $p = 0.0366$ ) at 12 months and mean  $-0.5$  points (95% CI  $-0.9$  to  $-0.1$  points;  $p = 0.0092$ ) at 18 months
- internalising subscale: mean  $-0.9$  points (95% CI  $-1.5$  to  $-0.2$  points;  $p = 0.0111$ ) at 12 months and mean  $-1.1$  points (95% CI  $-1.9$  to  $-0.3$  points;  $p = 0.0074$ ) at 18 months
- at 18 months only, conduct problems: mean  $-0.3$  points (95% CI  $-0.6$  to  $-0.0$  points;  $p = 0.0499$ ) and externalising  $-0.7$  points (95% CI  $-1.3$  to  $-0.0$  points;  $p = 0.0446$ )
- impact subscale: mean  $-0.7$  points (95% CI  $-1.3$  to  $-0.1$  points;  $p = 0.0309$ ) at 12 months only.

Caregivers in the FT arm also reported significantly better outcomes on the roles subscale of the FAD at 12 months, with a mean improvement of  $-0.1$  points (95% CI  $-0.2$  to  $-0.0$  points;  $p = 0.0020$ ), but not at 18 months.

The numbers of participants with other 'administrative' outcomes, such as referrals to other services, including to inpatient units, and safety outcomes, including re-referrals to CAMHS, accident and emergency (A&E) attendances and hospital admissions for any reason, were similar in both treatment arms.

### Moderator analyses

Significant interactions with treatment, indicating moderation, were detected for the unemotional subscale on the young person-reported ICU ( $p = 0.0104$ ) and for the affective involvement subscale on the caregiver-reported FAD, for both the score ( $p = 0.0338$ ) and the categorisation of healthy versus unhealthy families ( $p = 0.0444$ ).

Young people in the FT arm whose scores on the unemotional subscale suggested that they had difficulty talking about their feelings at baseline had higher risk of self-harm than those in the TAU arm, while those in the FT arm whose scores indicated that they found talking about their feelings to be easier had a lower risk of self-harm than those in the TAU arm.

Among young people whose caregivers reported higher affective involvement scores (the degree to which family members are involved and interested in one another) on the FAD, risk of self-harm was higher in the FT arm than in the TAU arm, while among those with lower affective involvement scores risk of self-harm was lower in the FT arm than in the TAU arm.

## Conclusions

This study did not demonstrate that SHIFT manualised FT following repeated self-harm reduced subsequent hospital attendances for self-harm when compared with TAU.

The high proportion of young people whose index episode of self-harm involved self-injury and who were referred into CAMHS through the community rather than recruited directly following admission to hospital means that the sample is representative of self-harm referrals to CAMHS. However, the findings may not be generalisable to the smaller subset of adolescents who present to hospital following a first episode of self-harm.

There was some evidence to support the effectiveness of FT over TAU in reducing self-harm when caregivers reported poor family functioning, particularly in relation to talking about feelings, or young people reported ease in discussing emotions. Conversely, when the young people themselves reported difficulty in expressing emotion, or families reported healthy functioning on the affective involvement scale, FT was not as effective as TAU.

Although there was no evidence of cost-effectiveness of FT in the base-case analysis and most sensitivity analyses focused on health benefits to young people, there is a suggestion that FT may be cost-effective if health benefits to the caregiver are additionally taken into account.

There was clear evidence that FT had a statistically significant, positive impact on young people's prosocial behaviour at 12 and 18 months and on suicidal ideation at 12 but not 18 months and on caregivers' views on young people's total difficulties and emotional and peer problems at 12 and 18 months and conduct problems at 18 months.

### **Recommendations for future research**

There remains a need for research exploring effective interventions to reduce self-harm. Self-harm is likely to be the final common pathway for a wide range of interpersonal and mental health predicaments. Future research needs to evaluate interventions targeted at the characteristics of specific subgroups who self-harm. Obvious candidate groups arising from this research would be families who self-report poorer family functioning and young people who are more unemotional.

Further research into the characteristics of these two groups is also indicated. What is the exact nature of the family dysfunction that some groups report and how might psychological interventions be targeted at this group? Are unemotional traits shared by other family members and is it possible that these two findings are aspects of the same underlying issue?

The accumulation of health benefits for the young person and the carer requires further exploration as to how health economic benefits might be aggregated for family members.

Studies with longer follow-ups are needed to explore any longer-term impact of interventions. The National Institute for Health Research Health Technology Assessment programme has already provided funding to allow follow-up of the SHIFT participants for a further 18 months, looking at the primary outcome only.

The significant differences observed in self-reported episodes of self-harm and episodes requiring hospital attendance and the very different patterns of self-harm recorded suggest that further work is needed to clarify the most appropriate outcome measures in self-harm research and how these might best be measured.

### **Trial registration**

This trial is registered as ISRCTN59793150.

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