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

David J Cottrell,1* Alex Wright-Hughes,2 Michelle Collinson,2 Paula Boston,1 Ivan Eisler,3 Sarah Fortune,1 Elizabeth H Graham,2 Jonathan Green,4 Allan O House,1 Michael Kerfoot,4† David W Owens,1 Eirini-Christina Saloniki,1 Mima Simic,5 Sandy Tubeuf1 and Amanda J Farrin2

1Leeds Institute of Health Sciences, University of Leeds, Leeds, UK
2Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK
3Institute of Psychiatry, Psychology & Neuroscience, King’s College London, London, UK
4Division of Neuroscience and Experimental Psychology, University of Manchester, Manchester, UK
5South London and Maudsley NHS Foundation Trust, London, UK

*Corresponding author d.j.cottrell@leeds.ac.uk
†In memoriam

Declared competing interests of authors: Amanda J Farrin is a member of the Health Technology Assessment (HTA) Clinical Evaluation and Trials Board and the HTA Commissioning Strategy Group. Allan O House is a member of the HTA Efficient Study Designs Board. Sarah Fortune worked as a Consultant Clinical Psychologist in the NHS prior to this project. Sandy Tubeuf is a member of the National Institute for Health Research Programme Grants for Applied Research Committee.

Published March 2018
DOI: 10.3310/hta22120
Scientific summary

The Self-Harm Intervention: Family Therapy (SHIFT) trial
Health Technology Assessment 2018; Vol. 22: No. 12
DOI: 10.3310/hta22120

NIHR Journals Library www.journalslibrary.nihr.ac.uk
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

© Queen’s Printer and Controller of HMSO 2018. This work was produced by Cottrell et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.
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.

**Funding**

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.
Criteria for inclusion in the Health Technology Assessment journal

Reports are published in Health Technology Assessment (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/141/03. The contractual start date was in November 2015. The draft report began editorial review in June 2016 and was accepted for publication in January 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen’s Printer and Controller of HMSO 2018. This work was produced by Cottrell et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).
Health Technology Assessment Editor-in-Chief

Professor Hywel Williams  Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May  Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson  Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

Dr Catriona McDaid  Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie  Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross  Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood  Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact:  journals.library@nihr.ac.uk