**Supported discharge service versus Inpatient care Evaluation (SITE): a randomised controlled trial comparing effectiveness and cost-effectiveness of an intensive community service versus treatment as usual for adolescents with psychiatric emergencies**

Word count 5711, excluding summary and additional materials

Abstract 305

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***Background***

Clinical guidelines recommend intensive community treatment to reduce dependency on adolescent psychiatric inpatient care, but no such provision in the UK has been evaluated in a randomised controlled trial (RCT). We designed a supported discharge service (SDS), an intensive community treatment team, and compared this with treatment as usual (TAU).

***Methods***

106 patients younger than 18 years were admitted for inpatient care and randomised (1:1) to either SDS or TAU. Intention-to-treat primary outcomes were inpatient bed days, Strengths and Difficulties Questionnaire (SDQ) and Children’s Global Assessment Scale (CGAS). Cost-effectiveness was explored using CGAS scores and quality adjusted life years based on the EQ-5D-3L, taking health and social care perspectives.

***Findings***

At six-month follow-up, there was a significant decline in hospital use among patients randomised to SDS in unadjusted analyses (median 34 vs 48 days). The ratio of mean total of inpatient days of TAU to SDS was 1·67 (95% CI: 1·02 to 2·81), t(101)=2·08, p=·04, which decreased to 1·65, (95%CI: 0·99 to 2·77, p=0·057) when adjusted for pre-randomisation differences in hospital use. There were no significant differences in SDQ, CGAS or treatment satisfaction. SDS patients were significantly less likely to report multiple episodes (5 or more) of self-harm (OR=·18, 95%CI: ·05 to ·64) and more likely to reintegrate to community schools (·81 vs ·51, OR=4·14, 95%CI: 1·73 to 9·92). There was no evidence of differential effect in patients with psychosis, severe disability or patients from minority ethnic groups. Cost-effectiveness acceptability curves suggested there was at least a 50% probability of SDS being cost effective.

***Interpretation***

The addition of SDS to TAU improved school reintegration and lowered the risk of multiple self-harm. There was a trend towards reduced bed usage at six-month follow up (47·3 vs 84·3 days). There were no differences in other outcomes.

***Funding***

South London and Maudsley NHS Trust

Protocol registration http://www.isrctn.com/ISRCTN82129964

**Introduction**

Approximately 4,420 adolescents were admitted to specialist child and adolescent mental health units in England and Wales in 2014.[1](#_ENREF_1) This is a two-fold increase in 10 years.[2](#_ENREF_2) The number of children and young people who have presented to Accident and Emergency (A&E) with a psychiatric condition have also more than doubled in recent years (8,358 in 2010/11; 17,278 in 2013/14).[3](#_ENREF_3) Although the proportion of young people being admitted is relatively small, the associated disruption can be severe and prolonged and the accompanying demand on health service resources is very high. The majority of hospitalised young people are likely to have a history of self-harm.[4](#_ENREF_4)

Urgent psychiatric admissions for adolescents can lead to serious distress and it is known that the highest risks of suicide and self-harm are encountered in the period soon after discharge.[5](#_ENREF_5), [6](#_ENREF_6) Despite these concerns, little is known about the optimal models of care for adolescents presenting with urgent psychiatric needs.

Clinical guidelines, such as those of the National Institute for Health and Care Excellence (NICE),[7](#_ENREF_7) recommend Intensive Community Treatment (ICT) for a number of disorders. However, only a small number of RCTs, mainly from the USA, have investigated the effect of ICT for adolescent patients requiring psychiatric hospitalisation.[8](#_ENREF_8) These RCTs reported mixed results in general, showing some impact on hospital use and patient satisfaction. However, research experience in adult ICT studies indicates that the initial positive results may not replicate in further RCTs.[9](#_ENREF_9), [10](#_ENREF_10)

We designed an RCT to assess the benefits of an ICT service (Supported Discharge Service) compared with TAU. Total hospital inpatient bed day use over 6 months, symptoms changes and social functioning were used as the key outcome measures, and cost-effectiveness was explored.

**Methods**

***Study design and patients***

A single-blind, patient-level, parallel-group, randomised controlled study in tertiary inpatient care adolescent psychiatry settings within both rural and urban services of one of the largest Mental Health NHS Trusts in the UK (South London and Maudsley NHS Foundation Trust, SLaM). Patients were all admitted for inpatient treatment from the boroughs of Southwark, Lambeth, Croydon and Lewisham and from Kent. The protocol is available online <http://www.isrctn.com/ISRCTN82129964>).

Inclusion criteria were that the patient was a SLaM patient admitted for inpatient care; aged 12 years 0 months to 17 years 11 months; able and willing to give oral and written informed consent/assent to participate in the study together with a parental consent/assent if applicable. Patients were excluded if, at the first point of assessment by clinicians in the inpatient teams they were judged not to be suffering from a psychiatric illness warranting inpatient care (and therefore ready for immediate discharge), those discharged within 72 hours of being admitted, those admitted from National and Specialist services with assertive outreach capability and those admitted during the times of the SDS teams being at full capacity. Uniquely, we did not exclude patients on the basis of their risk alone.

Ethical approval was obtained from the NHS National Research Ethics Service (NHS RES London REC 12/LO/0875).

***Randomisation and masking***

Randomisation took place after the initial baseline research assessment and was done via a registered centralised clinical trials unit (King’s College London, UK). Once baseline assessments of eligible patients were completed by the research staff, patient details were sent to the clinical trials unit by the trial administrator. Patients were assigned to either SDS treatment or TAU by use of a computer-generated pseudo-random code with random permuted blocks of varying sizes and was created by the clinical trials unit in accordance with their standard operating procedure and stored on a secure server. Patients were allocated with equal probability (1:1) to each treatment group. Allocation of eligible patients to a treatment group was conveyed to the trial administrator, who relayed this information to the SDS teams and inpatient services. Research associates who completed outcome assessments did not have access to the patient's health service records, and were based at a site away from clinical care. Although patients and treating clinicians were aware of treatment allocation, outcome assessors and data managers were masked to study allocation throughout the 6-month follow-up. All unmasking events were recorded.

***Procedures***

The SDS intervention was delivered by two SDS teams, one based in London and one in a rural area in Kent, called locally Assessment Liaison and Outreach Team (ALOT). Each SDS team included one consultant child and adolescent (CAMHS) psychiatrist, one administrator, 2-4 whole time equivalents of CAMHS practitioners with nursing background and 2-4 whole time equivalents of clinical support workers. The nature of the work included intensive case management, community (including home) treatment, day care in the hospital setting or any combination of the three according to need. The intensity of work provided was flexible, up to a maximum of daily contacts. Staff tasks included assisting young people with creating and carrying out customized care plans, psychiatric care, psychological interventions, school reintegration, optimising physical health care and social support. Further details are available on this website <https://www.national.slam.nhs.uk/services/camhs/supported-discharge-service/>

The duration of treatment varied according to individual need, with the aim of achieving transfer back to usual community mental health service, using the Care Programme Approach [11](#_ENREF_11) as required. The mean duration of SDS care was 116·32 days (SD: 70·09, 95% CI: 90·61 to 142·03, minimum 1, median 107, maximum 274 days). The SDS teams operated 8:00 to 20:00 with out-of-hours 24/7 cover available if required. The following elements of Assertive Community Treatment were used: small caseloads (4-5 families per whole time equivalent), team approach, practising team leader, weekly team meetings and daily informal meeting, continuity of staffing, full responsibility for treatment services, responsibility for hospital discharge planning, no drop-out policy, assertive engagement mechanisms and work with informal support systems. The teams worked closely with in-patient services. Staff from SDS and inpatient services worked across both services to minimize the potential bias associated with staff enthusiasm in new services. SDS teams aimed to establish contact with each young person within the first 72 hours following admission. As soon as the young person’s clinical profile was consistent with intensive community treatment (acceptable risk to self and others) the young person and their family were offered supported discharge in consultation with in-patient professionals and SDS staff and the relevant community services.

TAU was delivered by inpatient services, followed by a return to standard outpatient care (such as Southwark CAMHS described here <https://www.slam.nhs.uk/our-services/service-finder-details?CODE=SU0254>), with or without an interim period of hospital day care. Inpatient and day care were provided according to the model developed by Corrigall and Mitchell,[12](#_ENREF_12) unless all SLaM inpatient beds were full, in which case patients were admitted to private inpatient services. Criteria for inpatient admission included mental illness or suspected mental illness that cannot be safely managed by outpatient services due to risk to self or others. Hospital care was delivered by multi-disciplinary teams, including medical staff, nurses, psychologists, occupational therapists, art psychotherapists, family therapists and social workers. A consultant psychiatrist was leading each service in the TAU arm. Each inpatient service had access to a hospital school. Patients in both the SDS and TAU groups had access to the full range of local NHS support services open to patients in tertiary care.

***Outcomes***

Primary outcome measures were: duration (in days) of the psychiatric in-patient treatment (Occupied Bed Days) in the 6-months period following randomisation, changes in assessment scores of SDQ (Strengths and Difficulties Questionnaire), a broad measure of psychopathology in children and adolescents,[13](#_ENREF_13) and the CGAS (Children’s Global Assessment Scale), a paediatric measure of general functioning.[14](#_ENREF_14) SDQ was added as a primary outcome measure before the study started to ensure that a self-reported measure was used. We collected both self and parent-rated SDQs, however, we only report self-rated SDQs here due to poor completion of parent-rated SDQs (55/106).

Secondary outcomes reported in this paper were changes in self-harm, using the Self-Harm Questionnaire (SHQ),[15](#_ENREF_15) service satisfaction using the Child and Adolescent Service Experience (ChASE), the proportion of the patients who were attending a community school at the point of the 6-month follow-up and the number of days not in education, employment or training over the 6-months. SHQ was added as a secondary outcome before the study started. We used five or more episodes of self-harm, in line with the DSM 5 definition of Non-Suicidal Self Injury, to establish the proportion of young people with multiple self-harm.

All outcome measures were collected six months after the randomisation. Data on Occupied Bed Days were collected using an electronic patient records repository called electronic Patient Journey System (ePJS).

It was not possible to blind the clinical teams delivering the interventions or the patients and their families. Assessors and statisticians remained blind to treatment allocation at all times. There were no unblinding events reported. Researchers remained blinded to the treatment allocation until after the last participant's final 6-month follow-up appointment.

***Economic outcomes***

Two cost-effectiveness analyses were conducted using CGAS scores and quality-adjusted life years (QALYs) based on the EQ-5D-3L.[16](#_ENREF_16) These were assessed at baseline and 6-month follow-up. The perspective of the economic evaluation was the NHS/Personal Social Services perspective preferred by NICE.[17](#_ENREF_17)

Data on resource utilisation were collected using an adapted version of the Child and Adolescent Service Use Schedule (CA-SUS). The CA-SUS was developed in previous research with young people [18-20](#_ENREF_18) and adapted for the purpose of this study. It included all-cause hospital and community-based health and social care services: staffed accommodation (health care and social services based), inpatient stays, outpatient appointments, day patient contacts, accident and emergency contacts, community contacts and mental health related medication. The CA-SUS was administered at 6-month follow-up and covered the period from baseline to 6-month follow-up.

Data on day care contacts with the SDS, which took place in day hospital units, were collected directly from SDS records. Day care appointments were booked by the week and recorded as such regardless of attendance. Bookings were costed in full, irrespective of attendance on the assumption that the place was allocated and could not be allocated to another patient. All other contacts with the SDS were provided on an ad hoc basis and recorded in the CA-SUS, along with all treatment as usual services used by both the SDS and TAU groups.

Total costs were calculated by applying unit costs to individual level resource use data. Nationally applicable unit costs were applied to all services (see Appendix 1 for full details of all unit costs and economic methods). All costs are reported in pounds sterling at 2014-2015 prices. Discounting was not relevant as the follow-up did not exceed 12-months.

***Statistical Analysis***

nQuery Advisor was used to calculate sample size. Results from a Cochrane review [21](#_ENREF_21) show a difference in overall duration of admissions of around 34% in favour of assertive community treatment for seven of the 14 randomised controlled trials that reported this outcome. However, we acknowledged the uncertainty of this finding and allowed for only a 22% reduction in the duration of admissions. To have 80% power in our study for detection of a reduction in mean bed days of 22% (from a mean of 45 days to a mean of 35 days, range 1-90, SD 18·35) with alpha set at 0·05 would require 54 patients in each treatment group (two tailed). Thus, our study’s final sample (n=106) was marginally underpowered.

Data were analysed using STATA 14.0. According to the statistical analyses plan we compared outcomes between groups post-randomisation using an independent student t-test (unadjusted analyses). In a second step we controlled for possible pre-randomisation imbalances by including pre-randomisation outcome as a covariate (adjusted ANCOVA approach). The ratio of the geometric means was used for the hospital use data as the data had to be log-transformed to fulfil assumptions of normality and equal variances. As a sensitivity analysis we also present the adjusted treatment effect of untransformed hospital use data. Cohen’s d (mean difference divided by pooled standard deviation at baseline) is presented as a standardised effect size.

Categorical outcomes were analysed using the same analyses approach using logistic regression where pre-randomisation outcome is adjusted for where it was available. Standard Errors and Confidence Intervals for all parametric analyses were obtained through non-parametric bootstrap methods to account for possible violations of normality assumptions [22](#_ENREF_22) . Multiple self-harm was analysed by comparing proportions of the young people with multiple self-harm using a logistic regression. Occupied inpatient days were analysed as recorded on electronic patient record systems.

While there were no missing data in the main outcome, there was some missingness in the secondary outcome variables. Our complete case analyses may result in biased estimates if missingness is not completely at random. To further evaluate the impact of missing data in the secondary outcome variables, we performed a sensitivity analysis using multiple imputation. Missing data distributions were calculated using demographic and clinical baseline and the follow-up out variables, separately within each treatment arm[23](#_ENREF_23)1). Fifty imputed data sets were created and the datasets were reanalyzed and combined by using Rubin rules as implemented in the ice command, STATA 14[24](#_ENREF_24) . The results are now based on the more realistic assumption of missing at random, that is the results are unbiased if missing is related to some of the other variables in the imputation model

The economic analyses focussed on the probability of one intervention being cost-effective compared to another given the data available, which is the recommended decision-making approach, preferred over traditional reliance on arbitrary decision rules regarding statistical significance.[25](#_ENREF_25) Differences in mean costs and outcomes were analysed using ordinary least squares regressions combined with bootstrapping (repeat re-sampling, 5000 replications, regression models for costs and outcomes based on the same sample) to account for non-normality.[26](#_ENREF_26) The advantage of this approach, as opposed to logarithmic transformation or non-parametric tests, is the ability to make inferences about the mean to determine the total cost for a group of patients.[26](#_ENREF_26) To provide more relevant treatment-effect estimates,[27](#_ENREF_27) regressions to calculate mean differences in costs and outcomes included baseline covariates which could potentially impact costs and outcomes: number of days as an inpatient prior to randomisation, baseline CGAS score, baseline utility, age, gender, ethnicity, social class (based on the main breadwinner of the family) and diagnosis (psychotic versus not psychotic). The primary economic analysis excluded patients with missing cost or outcome data. We tested the effects of missing data in sensitivity analyses (see Appendix 1 for details). Cost-effectiveness was explored using the net benefit approach. QALYs were calculated using the area under the curve approach with linear interpolation between assessments.[28](#_ENREF_28) Uncertainty around the cost and effectiveness estimates was represented by cost-effectiveness acceptability curves.[29](#_ENREF_29) Cost-effectiveness acceptability curves are created from bootstrapped costs and effects to calculate the probability that each treatment is the optimal choice, subject to a range of possible maximum values that a decision-maker might be willing to pay for either an increase in quality-adjusted life years or CGAS scores. These curves incorporate the uncertainty that exists around the estimates of mean costs and effects as a result of sampling variation and uncertainty regarding the maximum cost-effectiveness ratio that a decision-maker would consider acceptable.

***Role of the funding source***

The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. DS and ZA were part funded by the National Institute for Health Research (NIHR) Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King’s College London. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

**Results**

287 patients were referred for inpatient admission during the study recruitment period. 123 patients were eligible for the study. 15 (12%) refused to participate. 108 patients were randomly assigned to a treatment group. 23 patients (21%) were from the Southwark site, 18 (17%) from the Lambeth site, 42 (39%) from the Croydon site, 16 (15%) from the Lewisham site and 9 (8%) from the Kent site. For both SDS and TAU groups, 82 patients (77%) were assessed at 6-months follow-up, although hospital use data were available for 100% of patients (Figure 1).

Two patients, one in each treatment group, were withdrawn from the study. One patient, in the SDS arm, withdrew their consent and another, in the TAU arm, was withdrawn as he had no adequate provision of community clinical care and had to be looked after by the SDS team. The final sample comprised 106 patients.

Descriptive analysis of all outcomes including number of patients with data, mean, SD, median, IQR and range are provided in Appendix 2

***Sociodemographic and clinical characteristics***

Data were available for all 106 patients included in the final sample, 53 in each treatment group. A descriptive comparison did not suggest major differences on any sociodemographic or clinical characteristics (Table 1) between the two groups although there were slightly lower self-rated SDQ scores in the SDS group (mean 16·84, SD 6·99) versus TAU (mean 20·57, SD 6·58).

***Main outcome measures***

*Hospital use*

We had complete data on all patients for this outcome measure. In unadjusted analysis, there was a significant difference in overall hospital use among patients randomised to SDS (median 34 days) versus TAU (median 48). The ratio of the geometric mean total of inpatient hospital days between the TAU treatment group and the SDS treatment group was 1·67 (95% CI: 1·02 to 2·81), t (101) = 2·08, p=·04 as per the primary hypothesis. In the adjusted analysis, the treatment effect was not significant once adjusted for pre-randomisation differences in hospital use, the ratio of mean total of inpatient days of TAU to SDS was decreased to 1.65, (95% CI:0.99 to 2.77, p=0·057). ). An analysis using untransformed hospital use revealed an adjusted treatment effect of -34.1 days (95% C.I. -67.47 to -9.39 days, p=0.01)

*CGAS*

At 6-months follow-up, CGAS data were available for 102 patients in total, 50 in the TAU group (94%) and 52 in the SDS group (98%). The unadjusted analysis revealed a treatment difference of 3·41 CGAS points, (95% CI: -3·26 to 10·09, effect size d= 0·10, p=0.32) which was not statistically significant. In adjusted analyses, mean CGAS scores at 6-month follow-up were 6% lower in the TAU group (59·7, SD 17·8) compared to the SDS group (63·2, SD 16·67). ANCOVA and controlling for baseline CGAS scores revealed a treatment difference of 4·88 CGAS points (95% CI: -1·27 to 11·02, effect size d=0·15, p=0.12) which was not significant.

*SDQ*

At 6-months follow-up, SDQ (self-rated) data were available for 89 patients, 41 in the TAU group (77%) and 48 in the SDS group (91%). The mean SDQ scores at 6-month follow-up were 16·17 (SD=7·3) for the TAU group and mean = 17·64 (SD=7·07) for the SDS group. The unadjusted analysis revealed a treatment difference of 1·48 SDQ points, (95% CI: -1·45 to 4·54, effect size d=0·10, p=0.33) which was not statistically significant. ANCOVA, revealed a treatment difference of –·26, 95% CI: -2·55 to -2·12, effect size d <0·001, p=0.90. There was not enough evidence to suggest a difference in clinical symptoms (SDQ) at 6-month follow-up between the TAU and the SDS treatments, controlling for SDQ scores at pre-randomisation.

*Patient satisfaction*

Patient satisfaction data were available for 81 patients, 36 in the TAU group (68%) and 45 in the SDS group (85%). Mean ChASE scores were similar in both groups; mean = 51·1 (SD 15·54) for the TAU treatment group and mean = 55·4 (SD 14·00) for the SDS treatment group. ANCOVA, revealed a treatment difference of 4·24 points, 95% CI: -2·13 to 10·81, effect size d=0·14, p=0.20, which was not statistically significant.

*Multiple self-harm*

The proportion of patients who reported multiple (5 or more) episodes of self-harm at 6-month follow-up was 16/38 (42%) in the TAU group and 11/45 (24%) in the SDS group. Binomial logistic regression , controlling for baseline scores at pre-randomisation revealed that adolescents randomised to SDS were significantly less likely to report multiple episodes of self-harm, OR = 0·18, 95% CI: ·05 to ·64, p = 0·008. The odds of patients in the SDS group having multiple self-harm episodes was 82% lower than the odds of patients in the TAU group.

*Employment, education and training*

81% of the adolescents of the SDS (43/53) group reintegrated to community schools while 51% (27/53) reintegrated in the TAU group. Binary logistic regression revealed that adolescents randomised to SDS were significantly more likely to attend a community school at 6-months follow-up OR = 4·14, 95% CI: 1·73 to 9·92, p = 0·001. There was a significant difference between the total number of days spent not in employment, education or training favouring the SDS group (SDS Median=49, N=46, TAU Median= 95·5, U= 665·00, N=36, p= 004). There was no evidence of differential effects on any of the above variables in adolescents with psychosis, with low global functioning or adolescents from minority ethnic groups.

Sensitivity analyses

Multiple imputation analyses resulted only in neglectable changes of treatment effects and their inference and did not alter the conclusions.

*Cost-effectiveness*

Full economic data were available for 42 SDS patients (79%) and 36 TAU patients (68%) for the cost-effectiveness analysis based on QALYs, and 37 SDS patients (70%) and 45 TAU patients (85%) for the cost-effectiveness analysis based on CGAS scores. The mean follow-up length was 199 days (31 days SD) in the SDS arm and 231 days (71 days SD) in the TAU arm. All economic costs and outcomes are presented in Table 2. SDS day patient service costs were substantial at around £24,000. Health and social care costs excluding SDS day patient services were significantly lower in the SDS arm by around £29,000 (95% CI -£53,647 to -£4,396, p 0·021). Combining all costs, the SDS group remained cheaper but differences between the groups were no longer significant with an adjusted mean difference of -£3,675 (95% CI -£27,559 to £20,209, p=·77). EQ-5D based QALYs and CGAS scores were similar between the groups at all time points and there were no statistically significant differences between the groups on either outcome at 6-months follow-up. Results based on imputation for missing data were similar with no changes in terms of statistical significance in costs or economic outcomes.

Using complete case data adjusted for covariates, the incremental cost-effectiveness ratio (ICER) based on QALYs was £183,750. As SDS is cheaper and less effective than TAU, the ICER suggests SDS to be cost-effective at a threshold of £20,000/QALY (the interpretation of the ICER for SDS is opposite to that of interventions that are more expensive and more effective than TAU). The cost-effectiveness acceptability curve based on QALYs (Figure 2), which shows the probability that the SDS is cost-effective compared to TAU, suggests that the SDS has around a 60% probability of being cost-effective compared to TAU, at the NICE preferred willingness-to-pay of £20,000 to £30,000 per QALY. The cost-effectiveness acceptability curve based on the CGAS (Figure 3) suggests that SDS has a probability of at least 58% of being cost-effective compared to TAU, irrespective of a willingness-to-pay (jumping up to over a 90% probability at a willingness-to-pay of £5,000). Cost-effectiveness acceptability curves for both QALYs and the CGAS with missing data imputed, suggest that the probability of SDS being cost-effective compared to TAU is 50% or greater, irrespective of willingness to pay (see Appendix 1).

**Discussion**

This represents the first UK randomised controlled trial of an Intensive Community Treatment (Supported Discharge Service, SDS) versus TAU for adolescents with severe psychiatric disorders. In terms of the primary outcomes, there was a significant difference in hospital bed use between SDS and TAU over the 6-month follow up but this was no longer significant after controlling for pre-randomisation differences in hospital use. Advantages in favour of the SDS group for symptoms and functioning were not significantly different at 6-month follow-up. The effect on hospital use and the clinical outcomes are in line with those noted in another RCT undertaken in Germany [30](#_ENREF_30), [31](#_ENREF_31) by a research group independent of the authors of the SDS model.[32](#_ENREF_32)

In terms of secondary outcomes, SDS patients were significantly less likely to report multiple episodes of self-harm, significantly more likely to achieve school re-integration, and spent significantly fewer days out of mainstream school than the control group. There were no significant differences in service satisfaction. In addition, economic analyses suggest that SDS has a probability of being cost-effective compared to TAU of 50% or higher, irrespective of the measure of outcome used (QALYs or CGAS) and irrespective of willingness to pay for outcome improvements.

So far, five other trials have investigated the use of intensive community care versus inpatient treatment in children and adolescents with severe psychiatric disorders.[8](#_ENREF_8) Using intensive community services was associated with clinical improvements similar to inpatient care in most studies. Where differences in clinical outcomes existed, they tended to favour intensive community treatment.

The unique contribution of the authors of the SDS model and their collaborators in Germany lies in the first ever independent assessment of an intensive community treatment model (SDS) across two different mental health systems. In addition, unlike previous studies, the SDS model of intensive community care was tested in pragmatic mental health care settings.

The use of intensive case management, day care in the hospital setting and community (including home) treatment with small caseloads may account for the significant effects of SDS. Studies of ICT in adults have found that initial positive results do not appear to be sustained as the model is implemented more widely. We have maximised the generalizability of the findings by establishing real-world SDS teams, by maximising work crossover between the inpatient and the SDS staff members and by having very broad inclusion criteria. An important finding of the SITE is the significant reduction in the proportion of the young people who repeatedly self-harmed in the SDS group versus TAU. Given that self-harm is the strongest predictor of death by suicide in children and adolescents this result does not correlate with the reported increase in suicidality in adults who receive intensive community care in naturalistic studies

The strengths of the SITE, in addition to being a randomised controlled trial, include good follow-up participation rates, and the inclusion of school re-integration as an outcome measure. The SDS model has now been shown effective in the largest number of adolescent patients (n=206) of any intensive community care model, across two different countries. This study provides much-needed empirical evidence of the effectiveness of an ICT model of care by showing that SDS may lead to a reduction in hospital use and can improve school re-integration and reduce self-harm. These findings are important in view of research findings that young people hospitalised for severe psychiatric disorders are more likely to have persistent mental health disorders in adulthood, completed suicide and all-cause mortality.

No routinely available data exist to show whether the care pathways investigated in this RCT are similar to other sites in the UK. However, at some sites, adolescents with psychiatric emergencies might not always receive care in adolescent psychiatric units or have access to intensive community mental health teams. We recorded no adverse events attributable to SDS or TAU, although adverse events were reported in patients. Our RCT had broad inclusion criteria and few exclusion criteria, to reflect how services operate in usual NHS care.

Limitations of this study include a significant heterogeneity in the quality of the inpatient care received by the adolescents in the TAU arm. It ranged from multi-award winning NHS inpatient services in the largest provider of mental health services in the UK to private providers. However, we regard this limitation as being beneficial for increasing the generalisability of our findings. We will analyze the data on private inpatient services and on reasons for admissions in further publications. A reported difference at baseline between groups for SDQ scores is likely to be a chance finding. It indicated a greater severity of psychopathology in the SDS arm and, if anything, has led to under-estimation of the SDS effects.

Our study might have been underpowered to detect statistical improvement in inpatient bed usage, symptoms, patient satisfaction and function at 6-month follow-up. Patient satisfaction outcome is surprising, given previous research in this field and given the results of the qualitative study from this RCT.[33](#_ENREF_33) Some patients were more severely ill and had been ill for longer than we had expected, thus requiring longer durations of SDS treatment and a graduated transfer to aftercare with clear recommendations for ongoing care that extended after the 6-month primary outcome endpoint. We lost some patients during follow-up in this study, but this loss of follow up was lower than in many other service evaluations.[34](#_ENREF_34) Another important limitation of our study was that full masking proved impossible to achieve and that no detailed procedure of enquiring about unblinding events was in place. However, interview and self-report measures of outcome showed a similar pattern of results.

There were also some limitations in the economic evaluations. Firstly, length of follow-up was variable due to the difficult nature of engagement with this population (some patients could not be followed up on the 6-month follow-up date, and the follow-up time ranged from 4-11 months). There were longer follow-up times in the in the TAU group which could mean that any difference in costs could be due to the fact that the supported discharge service group had a shorter follow-up period. Secondly, the economic evaluation was reliant on self-reported resource use data which is subject to recall bias. However, this approach was necessary due to the fact that even within health and social care resource use, all data is not available from one source and would require data from multiple sources. Further, there is evidence that self-reported resource use is reliable even in populations who have cognitive deficits [35](#_ENREF_35), [36](#_ENREF_36) and there is no reason to believe that any biases related to data collection would be imbalanced between the two trial arms. Thirdly, the willingness to pay for a point improvement on the CGAS is unknown, and unlikely to be as high as £50,000. However, the probability of SDS being cost-effective compared to TAU was greater than 50% irrespective of willingness to pay. Finally, the economic results were sensitive to adjustment for baseline covariates and imputation and thus, given this and the small sample size, caution must be taken in the interpretation of these results.

It would be important to demonstrate cost effectiveness as well as effectiveness of SDS beyond a six-month follow-up. More studies are required in order to be able to generalise around the use of SDS in other similar well-resourced service systems in high-income countries.

**Contributors**

All authors wrote the manuscript. DO was the chief investigator, DO and RC obtained funding, designed the study, and interpreted the data. TZ designed the study, supervised and delivered treatment, and interpreted the data. MS, VS designed the study, delivered treatment, and interpreted the data. DH supervised data collection, analysed and interpreted the data. PR designed the study and analysed and interpreted the data. JP was the trial manager, supervised the research assessments, and analysed the data. DS and ZA designed the study, analysed and interpreted the data. SB, MH and BN designed and conducted all economic analyses as well as writing the economic sections of the paper. KM analysed and interpreted the data. JI and MC designed the study and supervised data collection ET designed the study and interpreted the data.

**Declaration of interests**

DO, RC, TZ, MS, VS, JI, MC,DH and KM work for South London and Maudsley NHS Foundation Trust. Other authors declare no competing interests.

**Acknowledgments**

The authors would like to thank Jo Fletcher, Dr Bruce Clark and Professor Emily Simonoff for helping to obtain research funding and facilitating the creation and running of the SDS teams. We would like to thank all the research assistants and MSc students who contributed to the study.

**Research in context**

**Evidence before the study**

Intensive community services may provide an alternative to inpatient care but there is little systematic evidence of their efficacy. We undertook a systematic review of randomised controlled trials (RCTs) reporting efficacy of intensive community services versus inpatient care in youth. Method: Data sources were identified by searching Medline, PsychINFO and EMBASE databases from the first available article to of the 31st of December 2014 using a combination of search terms denoting different settings of care, such as “Early Intervention” and “Crisis Care” and common psychiatric diagnostic categories.. RCTs published in English language comparing intensive community services versus inpatient care in children and adolescents (through age 18) were included. Six unique RCTs including 569 youth were identified. The RCTs examined the efficacy of specialist outpatient treatment, multisystemic therapy, day patient treatment, intensive home treatment and supported discharge services versus inpatient care. Using intensive community services was associated with clinical improvements similar to inpatient care in most studies. Where differences in clinical outcomes existed, they tended to favour intensive community treatment. Using intensive community services was associated with shorter hospitalizations, lower costs and greater patient satisfaction. There were no independent replications of the results. Few studies investigated the use of intensive community treatment as an alternative to inpatient care in children and adolescents with severe risk. Intensive community services appear to be a viable alternative to TAU. Independent replication of results achieved by specific intensive community treatment models is a research priority.

**Added value of this study**

Our study was the first UK multicentre, outpatient RCT in adolescent patients with psychiatric emergencies, comparing an intensive community treatment model with usual care. We demonstrated improved school reintegration with SDS and no differences in any of the clinical outcomes or patient satisfaction by 6-months' follow-up compared with usual care. There was a trend for reduced hospital bed day use. The proportion of the patients who had multiple self-harm was lower with SDS.

**Implications of all the available evidence**

Overall, in adolescent patients with severe psychiatric disorders requiring hospital treatment, SDS involving intensive community treatment shows some evidence of clinical effectiveness compared with usual care after 6-months although most outcomes do not differ between the groups. SDS should be cautiously considered for implementation by other treatment centres.

**Contributions**

All authors wrote the manuscript. DO was the chief investigator, DO and RC obtained funding, designed the study, and interpreted the data. TZ designed the study, supervised and delivered treatment, and interpreted the data. MS, VS designed the study, delivered treatment, and interpreted the data. DH supervised data collection, analysed and interpreted the data. PR designed the study and analysed and interpreted the data. JP was the trial manager, supervised the research assessments, and analysed the data. DS and ZA designed the study, analysed and interpreted the data. SB, MH and BN designed and conducted all economic analyses and wrote the economic sections of the paper. KM analysed and interpreted the data. JI and MC designed the study and supervised data collection. ET designed the study and interpreted the data.

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**Table 1: Description and comparison of demographic and clinical characteristics of Treatment As Usual (TAU) and Supported Discharge Service (SDS) groups**

|  |  |  |
| --- | --- | --- |
|  | **TAU**  Mean (SD)  N=53 | **SDS**  Mean (SD)  N=53 |
| **Age(years)** | 16·34 (1·70) | 16·23 (1·54) |
| **CGAS** | 46·79 (11·32) | 44·62 (8·42) |
| **SDQ** | 16·84 (7·00) | 20·57 (6·58) |
|  | **TAU**  n/N (%) | **SDS**  n/N (%) |
| **Gender**  Male  Female | 20/53 (37·7)  33/53 (62·3) | 17/53 (32·1)  36/53 (67·9) |
| **Ethnicity**  White British  Other | 24/53 (45·3)  29/53 (54·7) | 28/53 (52·8)  25/53 (47·2) |
| **Social Class**  Highly paid professionals  Low paid professionals  Skilled non-manual workers  Skilled manual workers  Non-skilled workers  Unemployed, students  **Psychosis**  **Multiple self-harm (5 or more times)** | 1/53 (1·9)  8/53 (15·1)  9/53 (17)  10/53 (18·9)  9/53 (17)  16/53 (30·2)  16/53 (30·2)  22/49 (44·9) | 6/53 (11·3)  7/53 (13·2)  8/53 (15·1)  11/53 (20·8)  5/53 (9·4)  16/53 (30·2)  15/53 (31·0)  32/52 (61·5) |

CGAS=Clinical Global Assessment Scale, SDQ=Strengths and Difficulties Questionnaire (self-reported)

Social class classification was done on the basis of the main breadwinner of the family

**Table 2: Costs at 6 months (2014/5 prices) and economic outcomes at baseline and 6 months**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **SDS** | | **TAU** | |  |  |  |  |  |  | |
| **Cost component** | **Valid n** | **Mean £ (SD)** | **Valid n** | **Mean £ (SD)** | **Unadjusted mean**  **difference** | **95% C.I.** | **p-value** | **Adjusted mean**  **difference$** | **95% C.I.** | **p-value** | |
| SDS day patient services | 53 | 24,150 (20,102) | 53 | 0 (0) | 24,150 | 18,819 to 29,481 | <0.001 | 24,052 | 18,411 to 29,693 | <0·001 | |
| Other health & social care costs | 45 | 37,601 (38,870) | 37 | 64,767 (65,122) | -27,166 | -50,905 to -3,427 | 0.026 | -29,022 | -53,647 to -4,396 | 0·023 | |
| Total costs – complete case | 45 | 63,621 (39,604) | 37 | 64,767 (65,122) | -1,146 | -24,949 to 22,657 | 0.93 | -3,675 | -28,487 to 21,138 | 0·773 | |
| Total costs – imputed missing data | 53 | 64,355 (36,692) | 53 | 63,463 (55,254) | -892 | -16,926 to 18,710 | 0.92 | -612 | -16,775 to 15,551 | 0·940 | |
| **Cost component** | **Valid n** | **Mean (SD)** | **Valid n** | **Mean (SD)** | **Unadjusted mean**  **difference** | **95% C.I.** | **p-value** | **Adjusted mean**  **difference$** | **95% C.I.** | **p-value** |
| **Baseline** |  |  |  |  |  |  |  |  |  |  |
| EQ-5D utility | 51 | 0·52 (0·32) | 50 | 0·61 (0·39) | -0·09 | -0·23 to 0·05 | 0·21 | -0·05 | -0·18 to 0·07 | 0·39 |
| CGAS | 53 | 44·62 (8·42) | 53 | 46·79 (11·32) | -2·17 | -5·92 to 1·58 | 0·25 | -0·70 | -4·20 to 2·81 | 0·70 |
| **6 months** |  |  |  |  |  |  |  |  |  |  |
| EQ-5D utility | 44 | 0·62 (0·31) | 38 | 0·73 (0·28) | -0·11 | -0·23 to 0·02 | 0·09 | -0·06 | -0·20 to 0·09 | 0·44 |
| EQ-5D based QALYs | 42 | 0·30 (0·14) | 36 | 0·34 (0·15) | -0·04 | -0·11 to 0·02 | 0·21 | -0·02 | -0·05 to 0·02 | 0·39 |
| CGAS | 52 | 63·15 (16·66) | 50 | 59·74 (17·84) | 3·41 | -3·39 to 10·22 | 0·32 | 3·71 | -2·74 to 10·15 | 0·27 |
| Imputed QALYs | 53 | 0·30 (0·13) | 53 | 0·35 (0·15) | -0·05 | -0·10 to 0·00 | 0·057 | -0·02 | -0·04 to 0·01 | 0·17 |
| Imputed CGAS | 53 | 63·28 (16·28) | 53 | 59·85 (17·36) | 3.43 | -2·99 to 9·85 | 0·29 | 4·48 | -1·54 to 10·49 | 0·14 |

$ Adjusted for covariates: baseline CGAS, baseline EQ-5D based utility, inpatient days prior to randomisation, gender, age, ethnicity, diagnosis and social class.

Higher EQ-5D based utility and CGAS scores indicate better outcomes.

**Figure 1 Patients’ flow**

287 patients were referred for inpatient admission during the study recruitment period

123 patients eligible for study

52 admitted when SDS teams were full

37 admitted two times; four admitted three times

41 discharged before a contact could be made

26 admitted from National and Specialist teams with outreach capacity

15 declined participation:

9 declined SDS input

4 gave no reason

2 intended to disengage from all services

108 randomly assigned to a treatment group

2 patients excluded:

1 withdrew consent

1 no adequate provision of clinical care

106 total patients

53 SDS

53 TAU

82 assessed at 6-month follow up

TAU=treatment as usual, SDS=supported discharge service.

**Figure 2: Cost effectiveness acceptability curve from a health and social care perspective for Supported Discharge Service versus treatment as usual at 6-months based on Quality Adjusted Life Years (based on adjusted analyses)**

**Figure 3: Cost effectiveness acceptability curve from a health and social care perspective for Supported Discharge Service versus treatment as usual at 6-months based on the Clinical Global Assessment Scale (based on adjusted analyses)**