

Supported discharge vs In-patient Treatment Evaluation (SITE)

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| Submission date 16/12/2011 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 31/05/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/08/2017 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

About 2000 adolescents are admitted for in-patient psychiatric care every year. These admissions often lead to serious distress. Suicide is the second leading cause of death in adolescents and the period after discharge from in-patient care is associated with the highest risk of suicide. Little is known about the best way to treat adolescents who need in-patient care. The main aim of this study is to evaluate two models of care for young people aged 12 to 18 requiring hospitalisation as a result of severe mental illness. The first model (treatment as usual) comprises admissions to adolescent units. The second (experimental) model will consist of initial inpatient care followed by early discharge to a newly established Supported Discharge Service, providing a combination of home treatment, day care or intensive case management according to need. For both care models the end point will be a return to routine outpatient care.

Who can participate?

Adolescents from the age of 12 to the age of 18 who are looked after by the South London and Maudsely NHS Foundation Trust and who need in-patient care

What does the study involve?

Participants are randomly allocated to receive either usual in-patient care or to be discharged early with intensive community support provided by the new Supported Discharge Service.

What are the possible benefits and risks of participating?

Participants are given a very comprehensive assessment which may be helpful for adolescents initial psychiatric assessment and treatment. Participants in the assessment and follow-up phases of the study may potentially benefit by having a full research-standard psychiatric evaluation. The anticipated additional risks to subjects as a result of their participation in this study are minimal. The interviews carried out in this study may potentially cause psychological distress in subjects and their parents. Research clinicians, trained and supervised by the psychiatrists or psychologists participating in the study conduct the interviews.

Where is the study run from?

The main centre taking part in this study is South London and Maudsley NHS Foundation Trust. In South London and Maudsley NHS Foundation Trust (SLaM) adolescent inpatient services are

provided by three units: Snowfields Adolescent Unit (SAU), Kent and Medway Adolescent Unit (KAMAU) and the Bethlem Adolescent Unit (BAU). In addition 12 and 13 year old patients may be treated at Acorn Lodge Childrens Unit. When all SLaM adolescent beds are occupied new admissions have to be placed in private adolescent units.

When is the study starting and how long is it expected to run for?
September 2012 to June 2015

Who is funding the study?
The Maudsley Charity and the Guys' and St Thomas' Charity (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01/2012

Study information

Scientific Title
Supported discharge service versus in-patient treatment in adolescents admitted with psychiatric emergencies: a randomised controlled trial

Acronym

SITE

Study objectives

Six months after randomisation, there will have been no difference in the total duration of in-patient psychiatric treatment (occupied bed days) between the young people who undergo usual in-patient treatment and the young people discharged early from an in-patient unit with Supported Discharge Service (SDS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Emergency psychiatry

Interventions

54 adolescents will receive usual in-patient care and 54 will be discharged early with intensive community support provided by the new Supported Discharge Service.

Supported Discharge Service (SDS) is a newly established service aiming to improve patient satisfaction, minimise school disruption, decrease stigma, increase flexibility and reduce overall length of inpatient stay by providing an alternative care pathway for young people who have been admitted for in-patient care. This alternative pathway is provided by a team offering intensive therapeutic support and access to ATIPC strategies, including home treatment, day care and intensive case management.

1. In summary the aim of SDS is:

1.1. To provide an alternative care pathway back to Tier 3 Child and Adolescent Mental Health

Services (CAMHS) for young people who have been admitted for inpatient care

1.2. To enhance therapeutic engagement with young people prior to discharge from in-patient

1.3. To facilitate earlier discharge by helping the young person prepare for discharge and by providing alternatives to inpatient care that are more intensive and supportive than standard Tier 3 care

1.4. To reduce self-harm and suicide during the period of maximum risk - the week following discharge from in-patient care

1.5. To reduce the risk of future readmission by improving overall engagement with CAMHS services

1.6. To reduce the financial costs associated with young people using in-patient services

1.7. To improve patient and carer satisfaction

SDS has good links with borough based Tier 3 CAMHS and other related services providing care for the young people who require a period of inpatient management.

2. Resources

Each SDS team includes one consultant child and adolescent psychiatrist and a range of other professionals.

The nature of the work includes intensive case management, home treatment, day care or any combination of the three according to need. The intensity of work provided is flexible, up to a maximum of 5 weekly contacts. The duration of treatment varies according to individual need, but it is intended that cases are only managed for as long as specialist Tier 4 care is required. Once a case has reached the level where usual Tier 3 can safely be resumed a planned handover to the locality CAMHS service is arranged, using the Care Programme Approach as required.

A comprehensive operational policy covers the following issues:

2.1. Risk assessment process (including management of Serious Untoward Incidents)

2.2. Action following missed appointments/ absence

2.3. Protocol for responding to self-harm events

2.4. Frequency and nature of telephone support

3. Operational plan

The SDS teams operate 9:00 to 17:00 with out-of-hours cover available at the SLAM SDS teams. The teams work closely with in-patient services. SDS teams aim to establish contact with each young person within the first 48 hours after randomisation to SDS care. As soon as the young person's clinical profile is consistent with intensive community treatment the young person and their family is offered supported discharge in consultation with in-patient professionals and SDS staff and the relevant tier 3 service.

4. Treatment model

Case management and home treatment

Case management follows these four steps: assessment of need, care planning, implementation of the care plan and regular review within the framework of care programme approach (CPA). Home treatment forms an integral part of this approach including mental state monitoring, administering medication, side effects monitoring, providing psychoeducation and delivering a range of evidence-based individualised psychological therapies, based on the initial formulation. Case management also includes individualised interventions aimed at improving young people's access to education, housing, social care and leisure. Optimal crisis resolution and crisis prevention forms an important part of the SDS treatment model.

5. Enhanced day care

SDS therapists contribute to the establishment and running of the expanded day care provision. They facilitate skills training groups aimed at developing young peoples emotional regulation capacity, mindfulness, interpersonal skills, social skills, facilitate behavioural activation and cognitive restructuring. Young people have access to a range of other treatments available including art psychotherapy, music therapy, occupational therapy as well as education provided by the hospital school.

6. Family involvement

It is well recognised that family members play a crucial part in young peoples recovery. SDS engages family members in all aspects of care. When indicated by the case formulation, pragmatic family therapy is undertaken. SDS interventions aim to improve caregivers parenting practice, improve family emotional climate and provide psychoeducation and advice tailored to the individual young persons needs. Each treatment plan is designed in collaboration with the young person and their family members.

7. Wider systems

SDS targets wider systems in young peoples lives to promote recovery. The interventions specifically target those factors in each young persons social network that are contributing to their difficulties. SDS aims to optimise the peer network, improve young peoples school or vocational performance, engage young people with positive recreational activities and develop a functional support network on the basis of the family members, peers, members of the community and the professionals young people interact with.

SDS treatment is delivered in a variety of settings that include the young peoples natural environment (e.g., home, school, community).

Control: In-patient care

The operational model, resources and treatment models of all four units are similar and have been described elsewhere (Corrigall & Mitchell, 2002). Same staff members will have an opportunity to work across the in-patient and the SDS teams and will have access to the same academic programme and psychotherapy supervision resources.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Current primary outcome measures as of January 2013 (updated 16/08/2017):

1. Duration (in days) of the psychiatric in-patient treatment (Occupied Bed Days) in the 6 month period following randomisation
2. The CGAS (Childrens Global Assessment Scale). This is a paediatric measure of general functioning (Shaffer, Gould, Brasic, et al, 1983)
3. The SDQ (Strengths and difficulties questionnaire, childrens and parents versions). This is a broad measure of psychopathology in children and adolescents (Goodman, 1999)

Previous primary outcome measures:

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Secondary outcome measures

Current secondary outcome measures as of January 2013 (updated 16/08/2017):

1. Self Harm Questionnaire
2. The CGI-I (Clinical Global Impression, Improvement). This is a brief clinician rated scale assessing clinical improvement. This scale has now been validated for a range of conditions in both psychotherapy and pharmacotherapy trials (Haro, Kamath, Ochoa, et al, 2003; Huber, Lambert, Naber, et al, 2008; Perez, Barrachina, Soler, et al, 2007; Zaider, Heimberg, Fresco, et al, 2003)
3. Service satisfaction survey
4. Proportion of the young people who disengage from treatment
5. The HoNOSCA (Health of the Nation Outcome Scales for Children and Adolescents) is a clinician rated tool that assesses symptom severity and function across a range of psychosocial domains (Gowers, Harrington, Whitton, et al, 1999)
6. Qualitative experience of the young people studied using Phenomenological Interpretative Analysis (Smith, 1996; Smith & Osborn, 2003)
7. Cost: in order to estimate the overall cost of each intervention, information on the use of all hospital and community services will be collected prospectively for each patient over the study period. A number of sources will be used including the electronic Patient Journey System, family interview at 6 months follow up and local authority social services departments records.
8. Clinical diagnosis: K-SADS-PL (Schedule for Affective Disorders and Schizophrenia for School-Age Children--Present and Lifetime Version)
9. Number of days attending education employment or training
10. Columbia Impairment Scale (Bird et al 1993)

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Overall study start date

01/09/2012

Completion date

01/06/2015

Eligibility

Key inclusion criteria

1. Young people aged 12-18
2. Patients of South London and Maudsley NHS Foundation Trust
3. Admitted for in-patient care

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

108

Key exclusion criteria

1. Emergency admissions who at the first point of assessment by clinicians in the inpatient teams are judged not to be suffering from a psychiatric illness warranting inpatient care (and therefore ready for immediate discharge)
2. Those discharged within 72 hours of admission
3. Young people admitted from Tier 4 National and Specialist services

Date of first enrolment

01/01/2014

Date of final enrolment

01/06/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Maudsley Hospital
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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Sponsor type

University/education

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ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

South London and Maudsley NHS Foundation Trust

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

A publication of the main results will be submitted by October 2018.

Intention to publish date

17/10/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Dennis Ougrin (dennis.ougrin@kcl.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/07/2017 | | Yes | No |