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BeZuHG - Being treated at home for mental reconvalescence (Behandelt zu Hause Gesund Werden)

Submission date
06/07/2014

Recruitment status
No longer recruiting

Registration date
11/08/2014

Overall study status
Completed

Last Edited
03/11/2021

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and aim of study
Approximately 48,000 children and adolescents with mental disorders are admitted for in-patient treatment in Germany every year. This can cause a serious amount of stress, fear of stigmatization and there is also a danger of it resulting in social and/or family breakdown. Once the patient has been discharged, the positive effects of their treatment as an in-patient may not be so beneficial in the outside world and the period just after discharge is associated with a higher risk of suicide. At the moment, little is known about how best to treat children and adolescents with mental disorders requiring in-patient admission. In this study, we will test two types (or models) of care for children and adolescents that need to be admitted to hospital as a result of a severe mental illness. The first model (BeZuHG) will involve discharging the patients from hospital earlier than usual, and then treatment with a programme that includes treatment at home, day care, schooling, group therapy and tailored intensive care management for between three to six months. This will be compared to the second model, which involves a regular length in-patient stay and conventional treatment.

Who can participate?
Children and adolescents aged 5 to 18 years who live in families in the study catchment area and who need in-patient care as a result of mental illness.

What does the study involve?
There are three parts to the study.
Part one: Patients are randomly allocated to one of two groups. Group 1 receive usual in-patient care. Group 2 are discharged earlier, are provided with intensive outpatient support and are given treatment via the BeZuHG model.
Part two: 100 patients are randomly allocated to either the study group (BeZuHG) or to treatment as usual (TAU) on the basis of the therapists assessment of diagnosis and need.
Part three: 100 patients are randomly allocated to either BeZuHG or TAU. 50 receive usual in-patient care. The others 50 are not admitted to hospital at all, but instead receive intensive outpatient support and tailored treatment via the BeZuHG model.

What are the possible benefits and risks of participating?
All participants receive a comprehensive psychiatric assessment. Those that then participate in the assessment and follow-up stages of the study may benefit from additional information gained by the administered tools. The anticipated additional risks to subjects participating in the study should be minimal. Filling out the questionnaires or answering questions during the interview may cause psychological stress.

Where is the study run from?
The study is run from the Centre for Psychiatry, Südwürttemberg (Zentrum für Psychiatrie Suedwuerttemberg), Ravensburg, Baden-Wuerttemberg (Germany)

When is the study starting and how long is it expected to run for?
October 2011 to July 2016.

Who is funding the study?
1. The Health Services Research Baden-Württemberg, Junior academy, subdivision University of Ulm, Baden-Württemberg (Versorgungsforschung Baden Wuerttemberg, Nachwuchsakademie) (Germany)
2. The University of Ulm (Germany)
3. ZfP-Suedwuerttemberg (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Versorgungsforschung Baden-Wurttemberg D.3747, ZfP-Suedwuerttemberg Kostenstelle 2562088

Study information

Scientific Title
Effectiveness of home treatment supplemented by clinical elements versus regular in-patient care in children and adolescents with psychiatric disorders

Acronym
BeZuHG

Study objectives
1. Hypothesis for part one (randomized): Early discharge followed by BeZuHG treatment will be as effective as regular psychiatric inpatient treatment in mentally ill children and adolescents requiring inpatient care, inpatient days (thus cost) will be reduced when treated with BeZuHG. Patient statisfaction in both treatment arms will be equal.
2. Hypothesis for part two (non-randomized): BeZuHG is applicable for all mental disorders in children and adolescents, diagnosis and group characteristics won't shift, when therapists indicate which group the patient is allocated to.
3. Hypothesis for part three (randomized): Children and adolescents with mental disorders who present for admission can be allocated to BeZuHG directly without prior admission to inpatient care. Effectiveness and patient satisfaction will remain unchanged.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Ulm, 20/09/2011, ref. 214/11

Study design
Part one and three: randomized controlled trial
Part two: case-series

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental disorders in children and adolescents requiring inpatient care

Interventions
Control: 146 adolescents will receive usual inpatient care
Intervention: 96 patients will be discharged early with intensive community support in combination with clinical elements provided by BeZuHG. 50 patients will receive directly the intensive community support via BeZuHG, without inpatient admission.

BeZuHG is a newly established service for children and adolescents with a psychiatric disorder requiring inpatient admission, which is aiming to improve:
1. Familial and peer-group reintegration
2. Minimize school disruption
3. Decrease stigma
4. Reduce / or avoid overall length of stay by providing an alternative care pathway
BeZuHG is provided by a team of Band 7/8 nurses, a psychologist and a psychiatrist offering

intensive community support as well as access to clinical structures usually unavailable for outpatients.
In summary the aim of BeZuHG is:
1. To facilitate early discharge or even avoid admission at all by offering intensive community support
2. To enhance therapeutic engagement
3. To enable and enhance early reintegration into the familial, social and school environment
4. To reduce the risk of future readmission
5. To reduce financial cost associated with children and adolescents requiring in-patient care due to mental illness
6. To improve patient and carer satisfaction

BeZuHG treatment is individualized according to need (patient and carer). Elements are intensive case management including cooperation with schools and social services, home treatment, day care, hospital schooling, group therapies, psychoeducation, pharmacotherapy. The intensity of treatments provided is flexible, up to a maximum of 3 contacts/week. The duration of treatment varies according to individual need from a few weeks up to 6 months. Once a case has reached a level that allows regular out-patient services a handover to local therapists is arranged.

Treatment model:
The treatment model includes the following elements:
1. Case management: consists of assessment of need, care planning, implementation of the care plan - including crisis prevention plan - and regular review of elements during case-supervision with the psychiatrist/psychologist
2. Home treatment: forms an integral part of BeZuHG treatment. It includes on individual basis: mental state monitoring, administering and supervising medication, monitoring side effects, providing psychoeducation and individual therapy based on the initial formulation. The initial formulation may be adapted along the way where necessary. As it is well recognized that family members play a crucial part in the young people's recovery, BeZuHG engages family members in all aspects of care aiming at improving family skills in handling crises situations, providing psychoeducation, family therapy, advice tailored to the child's/adolescents problems, aiming at improving the family climate.
3. Clinical elements: On an individual basis the young person still has access to in-patient treatment elements such as hospital schooling, social skills training, diagnoses related group therapies, day care status, music therapy, occupational therapy and hippo therapy.
4. Wider Systems: Social networks such as schools, court and social services are involved where necessary. The interventions target at reintegrating the child/youth in his natural surroundings, developing a functional support network and improving the young people´s school performance.
BeZuHG treatment is delivered in any variety of settings that include the young persons natural environment (e.g. home, school, community)

Control:
Controls will be treated in the well established regular intensive in-patient care treatment program with access to resources and supervision of the hospital setting. 24h/7d a week services are available. Treatment standard is standardized and adapted regularly. Usual length of stay is on average 43.3 (children)/39.4 (adolescents) days.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
Generally there are 3 timepoints for both primary and secondary outcomes at which data is collected:
T1 - within 14 days after inclusion into the study
T2 - after completion of treatment (control group: discharge from inpatient stay, intervention group: completion of BeZuHG treatment)
T3 - 6 month follow up

1. Duration of psychiatric inpatient stay during treatment and a 6 month follow-up period (i.e. T2 and T3)
2. CGAS (Childrens global assessment Scale) This is a paediatric measure of general functioning (T1, T2 and T3)

Key secondary outcome(s))
1. SDQ (strengths and difficulties questionnaire, childrens and parents version) This is a broad measure of psychopathology in children and adolescents (T1, T2 and T3)
2. HoNOSCA (Health of the Nation Outcome Scales for Children and Adolescents). It is a clinician rated tool, that assesses symptom severity and function across a range of psychosocial domains (T1, T2 and T3)
3. ZUF 8 (Fragebogen zur Patientenzufriedenheit - Questionnaire for service satisfaction) (T2 and T3)
4. Qualitative semi-structured interview regarding patient satisfaction (T3)
5. Cost: Information on the use of inpatient hospital services, community services, out-patient services, social services, school support will be collected over the study period (T2 and T3)
6. Clinical diagnosis: K-SADS-PL (schedule for affective disorders and Schizophrenia for school-age children, Present and Lifetime Version) (T1)
7. Columbia Impairment Scale (T1, T2 and T3)

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Part one and two: Hospital inpatient stay for more than 72 hours

All parts:
1. Age: Between 5 and 18 years
2. Psychiatric diagnosis (DSM IV/ICD10)
3. Child/adolescent lives in a family setting
4. Youth and family live within the catchment area in a reasonable distance (max 1 hour travel) to allow home treatment on a regular basis
5. IQ> 70

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
18 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Youth lives in a youth welfare setting
2. Absence of consent of parents or child/youth
3. Limited language skills in families whose first language is not German

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
Child and Adolescent Psychiatry ZfP-Suedwuerttemberg
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88212

Sponsor information

Organisation
University of Ulm

ROR
https://ror.org/032000t02

Organisation
ZfP-Suedwuerttemberg

Funder(s)

Funder type
Other

Funder Name
Health Services Research Baden-Württemberg, Junior academy, subdivision University of Ulm, Baden-Württemberg [Versorgungsforschung Baden Wuerttemberg, Nachwuchsakademie, University of Ulm] (Germany)

Funder Name
Zfp-Südwürttemberg (Germany)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No
Results article	4 year outcomes	03/09/2021	03/11/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes