The feasibility and efficacy of intensive home treatment (IHT)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27418

Source
NTR

Brief title
IHT-trial

Health condition

Acute psychiatric crisis for which clinical crisis care is indicated.

Sponsors and support

Primary sponsor: Arkin Mental Health Care
Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Outcome measures

Primary outcome

The number of admission days.

Secondary outcome

- Safety of the patient and his/her direct social environment

- Mental well-being

- General functioning

- Quality of life

Study description

Background summary

Rationale: The availability of intensive home treatment (IHT) is hypothesized to reduce the need for hospitalisation of patients in a psychiatric crisis situation. This is done without jeopardising the quality and clinical outcome of treatment by organising and managing IHT care in the home situation of patients. IHT care is delivered by professionals in co-operation with family, friends and informal care network of the patient during the first weeks following a psychiatric crisis. A psychiatric crisis is a situation in which there is an urgent need for professional intervention arising at least in part from mental health problems (Johnson et al., 2011). A psychiatric intervention at this stage will often be in the form of hospitalization. The duration of hospitalization needed is dependent on the duration of the acute crisis, but also on the outpatient intervention opportunities following hospitalization.

Objective: To test the (cost-) effectiveness, safety and feasibility of 6 week IHT compared to care-as-usual (CAU) for patients in or immediately following a psychiatric crisis.

Study design: We will perform a 2-centre, 2-arm Zelen double consent randomised controlled trial. In this trial we aim to include 230 patients. Assessments take place at baseline, 6-10, 26, and 52 weeks after baseline. Participants will be recruited from the crisis departments of 2 mental health treatment centres based in Amsterdam, the Netherlands.

Study population: Patients experiencing an acute psychiatric crisis for whom a psychiatric admission is indicated by a psychiatrist.

Interventions: IHT is a treatment modality that addresses some of the imperfections of inpatient care by providing intensive care in the patients' home setting, thus maximising the utilization of the patient's social system in providing crisis care and support and limiting the duration of hospitalisation following psychiatric crisis. It also allows for a more gradual

transition between in-patient care and low intensity out-patient/out-reaching care. IHT starts immediately after reference by a specialised health care professional. Care as Usual (CAU) commonly starts with inpatient care. During hospitalisation, mental health workers in the psychiatric hospital will stabilize and treat the patient and prepare his/her return to the home situation, in collaboration with outpatient mental health workers (excluding the IHT team). The outpatient care in the CAU condition is much less intensive than IHT.

Main study parameters/endpoints: Primary outcome measure is the number of admission days. Secondary outcomes include safety of the patient and his/her direct social environment, mental well-being, general functioning, and quality of life. In addition to reporting clinical outcomes and hospitalisation duration, an economic evaluation alongside the RCT is planned.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The literature does not indicate there is an elevated risk on adverse events in IHT in comparison to CAU (Murphy et al., 2012; Hubbeling & Bertram, 2012). According to Murphy et al. (2015) IHT improved the mental state of service users more than standard care, it was more acceptable and satisfactory to service users, their families and caregivers, placed less burden on families and carers, and it reduced the stigmatization of hospitalisation.

Study objective

As our primary outcome, we expect a 33% reduction in hospitalisation days at 52 weeks post-treatment allocation in IHT.

Study design

Patient:

Baseline = T0

Post-treatment 6-10 weeks after baseline = T1

26 weeks follow-up = T2

52 weeks follow-up = T3 (primary endpoint)

Family/informal caregivers:

Baseline = T0

Post-treatment 6-10 weeks after baseline = T1

26 weeks follow-up = T2

Healthcare professionals:

Baseline = T0

Post-treatment 6-10 weeks after patient signed informed consent = T1

Intervention

Intervention: Intensive home treatment is a treatment modality that addresses some of the imperfections of inpatient crisis care by providing intensive care in the patients' home setting, thus maximising the utilization of the patient's social system in providing crisis care and support and limiting the duration of hospitalisation following psychiatric crisis. It also allows for a more gradual transition between in-patient care and low intensity out-patient/out-reaching care. IHT starts immediately after reference by a specialised health care professional.

Control (Care As Usual): CAU commonly starts with inpatient care. During hospitalisation, mental health workers in the psychiatric hospital will stabilize and treat the patient and prepare his/her return to the home situation, in collaboration with outpatient mental health workers (excluding the IHT team). The outpatient care in the CAU condition is much less intensive then IHT.

Contacts

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Eligibility criteria

Inclusion criteria

- Admission to a clinical crisis care department is indicated (or compulsory).

- There is at least one axis I or II disorder diagnosed in the patient.

- The patient is a resident of Amsterdam area, the Netherlands.

- Age ≥ 18 and < 65 years.

- Written informed consent has been provided by the patient.

Exclusion criteria

- Patient is homeless.

- Primary diagnosis of the patient is substance use disorder for which referral to a specialized unity for detoxification is indicated.

- Patient is currently receiving (F)ACT care.

- Patient has had previous IHT treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2016
Enrollment:	230
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46022
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6020
NTR-old	NTR6151
CCMO	NL55432.029.16
OMON	NL-OMON46022

Study results

Summary results
N/A