The feasibility and efficacy of intensive home treatment (IHT)

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27418

Bron
NTR

Verkorte titel
IHT-trial

Aandoening

Acute psychiatric crisis for which clinical crisis care is indicated.

Ondersteuning

Primaire sponsor: Arkin Mental Health Care
Overige ondersteuning: Stichting tot Steun VCVGZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of admission days.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-11-2016
Aantal proefpersonen:	230
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46022
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A