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A trial comparing the effectiveness of Assertive Community Treatment enhanced with evidence based interventions with standard Assertive Community Treatment

Submission date
03/03/2013

Recruitment status
No longer recruiting

Registration date
15/03/2013

Overall study status
Completed

Last Edited
10/07/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
For the severely mentally ill, Assertive Community Treatment (ACT), an intensive approach to mental health care delivery, has been shown to be better than other types of care delivery in keeping in contact with the patients, who are often very reluctant to have care, and are difficult to engage. In previous trials, other outcomes also appeared to improve. However, more recent trials including one carried out by our group, did not show important positive changes to number of inpatient days, symptoms, or social functioning. Therefore, we think that the treatment content of standard ACT is not enough to accomplish more important improvements. We thought that carrying out evidence based interventions, such as psycho-education, family interventions, cognitive behavioural therapy, and individual placement and support, in addition to standard ACT, and carried out by dedicated therapists from outside the ACT team might improve how well ACT works in reducing admission days and improving social functioning and symptom severity. The objectives of the study were to see how well it works.

Who can participate?
Severely mentally ill patients who were going to receive care by one of the two new ACT teams working in the same catchment area in the city of Leeuwarden, were selected by their Health of the Nations Outcomes Scale (HoNOS) scores. The scores had to be at least 14 to be included in the study: if this was the case they were scored again, and if the score was still at least 14, the patients were randomly allocated to one of the two ACT teams.

What does the study involve?
One of the teams was randomly selected to have their patients receive the evidence-based interventions from external dedicated therapists. Patients in that team were screened for eligibility and asked to participate in each one of the four mentioned interventions. If they were willing to participate, the intervention was carried out, as long as the patient agreed or until the goals were accomplished. This procedure gave us information on the feasibility of these interventions in a difficult to engage group of patients. The given treatment thus depends on

the willingness of the patient and having the opportunity to engage in the offered treatments. We then compared the effects of the enhanced ACT with standard ACT to see whether the interventions had any effect on the number of inpatient days or functional and symptomatic outcomes.

What are the possible benefits and risks of participating?
The delivered therapies might have improved functioning, severity of symptoms, and most importantly the ability to stay out of the psychiatric hospital. There were no known risks.

Where is the study run from?
The study was conducted with the two ACT teams of Friesland Mental Health Services in Leeuwarden (Netherlands).

When is the study starting and how long is it expected to run for?
The study started in 2008, and patients were recruited between July 2008 and July 2009; the final assessments were completed in 2011 and data collection was completed by July 2012.

Who is funding the study?
Netherlands Organisation for Health Research and Development (ZonMw) and Friesland Mental Health Services (Netherlands).

Who is the main contact?
Dr S. Sytema, Senior Researcher at University Medical Center Groningen
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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

60-60110-98-162

Study information

Scientific Title
The effectiveness of Assertive Community Treatment (ACT) enhanced with evidence based interventions vs. standard ACT: an open randomized controlled trial

Acronym
ACT+

Study objectives
Enhanced ACT, including evidence based interventions carried out by non-team professionals, will be superior to standard ACT in terms of reducing admission days (primary outcome), and improving social functioning and symptomatic outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of the University Medical Center Groningen did not judge the trial to need ethical approval (patients were treated conforming to usual care standards and evidence based practice, in both the experimental and control conditions, and data were gathered by routine outcome monitoring. The randomization to one of two study arms did not influence regular care.

Study design
Open randomized 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Severely mentally ill patients with multiple diagnoses: schizophrenia, other non-affective psychoses, affective psychoses, other persistent and severe mental illness, often with comorbid substance abuse, always having led to functional deficits

Interventions
The experimental arm was assertive community treatment with additional evidence based interventions (psycho-education, family interventions, cognitive behavioral therapy and individual placement and support carried out by non-team members). These interventions were proposed to the eligible patients and carried out conforming to the guidelines as long as the patients would be willing to participate or until the goals were accomplished. Patients who did not participate would not drop out of the study (intention to treat).

The control arm was Assertive Community Treatment according to the standards (DACTS fidelity scale) without evidence based interventions carried out by non-team therapists. The mean (sd) number of sessions in successful interventions were: 24.3 (14.0) in family interventions, 4.5 (2.4) in psycho-education, 7.0 (4.2) in individual placement and support and 8.3 (1.5) in cognitive behavioral therapy. The feasibility of the interventions was one of the results of this study and will be described in a paper.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Admission days

Secondary outcome measures
1. Symptom severity, measured by the Positive and Negative Syndrome Scale (PANSS) and the Montgomery Asberg Depression Rating Scale (MADRS)
2. Social functioning (Social Functioning Assessment Scale [SOFAS])
3. Needs for care (Camberwell Assessment of Needs Short Assessment Scale [CANSAS])
4. Quality of life (Manchester Short Assessment Scale [MANSA]); the PANSS, MADRS and SOFAS were rated by routIne outcome monitoring nurses during the interview sessions, the CANSAS and MANSA were self-rated by the participants. There were two assessments, the first one closely after inclusion in the trial and the second one two years later.

Overall study start date
01/07/2008

Completion date
01/07/2012

Eligibility

Key inclusion criteria
1. Adult (male and female) severely mentally ill patients living in the city of Leeuwarden, the Netherlands
2. With an indication for ACT
3. Repeated Health of the Nation Outcome Score (HoNOS) total score of at least 14 before inclusion

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Age less than18 years

Date of first enrolment
01/07/2008

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Sixmastraat 2
Leeuwarden
Netherlands
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Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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Sponsor type
Research organisation

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http://zonmw.nl

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https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) ref: 60-60110-98-162

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/05/2014	Yes	No