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Drop the drop-out! Use instruments! The Effect of the Use of Instruments in Outpatient Substance Abuse Treatment to Enhance Treatment Compliance!

Submission date
25/08/2009

Recruitment status
No longer recruiting

Registration date
11/09/2009

Overall study status
Completed

Last Edited
05/10/2011

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Veerle Raes

Contact details
De Sleutel
Department of Research and Quality Assurance
Jozef Guislainstraat 43a
Gent
Belgium
B-9000
veerle.raes@fracarita.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multicentre randomised controlled trial on the effectiveness of using instruments in outpatient individual substance abuse treatment to enhance treatment compliance

Study objectives
The main focus of this study is to prove evidence in favour of the use of instruments by clinical workers as an integrated part of a treatment plan, in order to enhance the number of individual sessions - i.e. treatment adherence/retention/compliance - in outpatient substance abuse treatment centres.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethics Board for the Mental Health Sector of the n.p.o. Provincialat of the Brothers of Charity, Bierbeek, approved on the 13th November 2006 (ref: OG054-2006-19)

Study design
Multicentre randomised controlled trial (Zelens design)

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
Substance abuse

Interventions
The treatment consists of individual counselling sessions, starting from the information from the EuropASI-interview. In the experimental group, the treatment plan includes five standardised sessions or session parts:
1. Explaining to the patient about the specific interventions to expect, in order to get informed consent

2. Introduction of the Readiness for Change Questionnaire with completion by the patient
3. Giving feedback on RCQ, using the stages of change motivation circle and associated work-sheets
4. The PREDI-interview
5. Giving feedback on PREDI, using a standardised form, representing the focused area(s) for further actions and a time schedule

The first session should take place the first or second time at the latest that the patient presents him/herself to start individual counselling sessions, after randomisation and completion of the full intake procedure. The second session should take place within the same session or the next session at the latest. The third session should follow the next session after the RCQ has been completed. The fourth session could take place in one or two of the following three sessions. The fifth session should take place as soon as possible after the PREDI has been taken off. Then, session 2 and 3 should be repeated consecutively, each time after 4 to 5 weeks. Later PREDI feedback could be given, using graphical representation of evolution in patients' ratings on problems/resources and/or change-wish by focused area(s).

The control group was exposed to treatment as usual, which means that no instruments were used in further individual sessions.

A total of 12 months is needed: the individual counselling sessions for treatment as usual (control group) as well as for the treatment using instruments (experimental group) will take about 6 months and the post-treatment satisfaction measurement will take another 6 months (first sending of questionnaire 3 months after the end of treatment; second sending of questionnaire another 3 months later).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Drop-out rate, decided to at the latest six months after the last individual counselling session of a participant. If a participant did not attend sessions anymore since, it is evaluated as a drop-out.
2. Number of individual counselling sessions, each time the participant is attending an individual counselling session, the date is entered in the data management system. After the participants have left the individual counselling session program or episode, the total number of individual counselling sessions he/she attended can be counted.

Data-entry on frequency, type and intensity of sessions, start and end date of each type of treatment program or episode, as well as the way of leaving the program, into the VPN-based data management system of the De Sleutel network, is part of the normal procedure in the participating outpatient centres and occurs continuously. All this information can be retrieved continuously by the researcher from the system. Definite measurement only can occur six months after the participants last individual counselling session, when the clinicians evaluate the way of leaving.

Secondary outcome measures

1. Time in program, this is the number of days between the date of the first individual counselling session and the date of the last individual counselling session attended by the participant, within the same treatment program or episode
2. Way of leaving treatment, decided to at the latest six months after the last individual counselling session of a participant. If a participant did not attend sessions anymore since, it is evaluated as a drop-out.
3. Patient satisfaction with treatment, it is foreseen to let all participants complete the Mental Health Thermometer (MHT) at the end of the individual counselling session program, in case the participant is compliant until that time. Participants that left the program previously are sent the Mental Health Thermometer (MHT) by post-mail about three months after leaving.

Data-entry on frequency, type and intensity of sessions, start and end date of each type of treatment program or episode, as well as the way of leaving the program, into the VPN-based data management system of the De Sleutel network, is part of the normal procedure in the participating outpatient centres and occurs continuously. All this information can be retrieved continuously by the researcher from the system. Definite measurement only can occur six months after the participants last individual counselling session, when the clinicians evaluate the way of leaving.

Overall study start date
15/03/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
All patients that presented for help at one of the five outpatient treatment centres of the De Sleutel - network, that completed the full intake-procedure - consisting of at least three sessions which are: a social/medical check-up, the EuropASI-interview and a feedback session on EuropASI with treatment advice - and that are referred to individual counselling sessions at the same outpatient treatment centre, where they presented.

Other criteria:
1. Aged greater than or equal to 18 years, either sex
2. Informed consent
3. Well enough understanding of the Dutch language
4. No psychiatric comorbidity
5. Effective start of the individual counselling sessions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
At least 200

Key exclusion criteria
Patients referred to another type of treatment than individual counselling sessions (example: medical treatment, substitution therapy, group sessions, daily activation program, etc.)

Date of first enrolment
15/03/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Belgium

Study participating centre
De Sleutel
Gent
Belgium
B-9000

Sponsor information

Organisation
Ghent University (Belgium)

Sponsor details
Department of Family Medicine and Primary Health Care
University Hospital - 1K3
De Pintelaan 185
Gent
Belgium
B-9000
+32 (0)9 332 35 42
jan.demaeseneer@UGent.be

Sponsor type
University/education

Website

http://www.primarycare.ugent.be

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Charity

Funder Name
De Sleutel, n.p.o. Provincialat of the Brothers of Charity (Belgium)

Funder Name
Ghent University (Belgium) - Department of Family Medicine and Primary Health Care

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	25/05/2011		Yes	No