

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

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<b>Registration date</b> 11/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/10/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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**

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**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?
<a href="#">Results article</a>	results	25/05/2011		Yes	No