Development of instruments for the monitoring of Patient progress in the mental health care and the direct feedback to social worker and/or client.

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Further development and validation of two tools to measure patient progress in the psychiatric health care; the behavioral health status (BHS) questionnaire and the Heart Rate Variability (HRV) measures.

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON32006

Source
ToetsingOnline

Brief title
Monitoring instruments in Patient Progress in mental health care

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
psychiatric complaints

Research involving
Human

Sponsors and support

Primary sponsor: Louis Bolk Instituut

Source(s) of monetary or material Support: Nutsohra

Intervention

Keyword: effect evaluation, Heart Rate Variability, monitoring

Outcome measures

Primary outcome

An, to the Dutch situation, adapted BHS questionnaire, with data on its repeatability, internal consistency for the specific domains and responsiveness to the HRV measurement, resulting in a set of reliable tools to monitor patient progress.

Secondary outcome

not applicable

Study description

Background summary

Within the psychiatric health care treatment of patients can be very specific for the individual client. To measure effectiveness of treatment, specific measurement tools are needed. The Behavioral Health Status (BHS) questionnaire and the Heart Rate Variability (HRV) measurements might be good monitoringsystems to evaluate patients progress. Before these methods can be used, the validity of the methods need to be assessed.

Study objective

Further development and validation of two tools to measure patient progress in the psychiatric health care; the behavioral health status (BHS) questionnaire and the Heart Rate Variability (HRV) measures.

Study design

Clients starting outpatient treatment because of psychiatric complaints will be asked to participate. At three times (start of the treatment, after 3 and 6 months) measurements will be performed. Next to the new methods BHS and HRV

measurement, a set of validated questionnaires will be filled in. Repeatability, internal consistency for the specific domains of the questionnaire and responsiveness of the HRV will be tested.

Study burden and risks

No risks of any kind is expected from this study. This study does not influence the treatment the participants will receive, and no risks are to be expected from filling out questionnaires and participating in a non-invasive HRV measurement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Presence of psychiatric complaints
Start of policlinical treatment in a mental health care unit
Motivated to start a treatment

Exclusion criteria

Not capable of speaking/reading the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	130
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL22746.097.08