The effectiveness of Activity Scheduling as a nursing intervention in inpatient depressed elderly; an intervention study

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Main objective: to get insight in the effectivity of the SAM on depressive symptoms, quality of life, activity level, mastery and costs compared to treatment as usual in clinical admitted depressive elderly.Sedundary objective: to get an insight in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON35499

Source
ToetsingOnline

Brief title
Effectiveness of an nursing intervention in depressed elderly

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Altrecht;instelling voor ggz en VU afdeling Klinische Psychologie. Er wordt nog gezocht naar aanvullende financiering.

Intervention

Keyword: activity scheduling, depressive disorder, nursing

Outcome measures

Primary outcome

depressive symptoms (geriatric depression schale [GDS] and Montgommery Asberg

Depression rating Scale [MADRS]),

Quality of life, (MOS 36 items Short Forms Health Survey [SF-36]),

Mastery (Pearlin Mastery Scale),

Costs (Trimbos/iMTA questionnaire for costs associated with Psychiatric Illness

[Tic-P]),

Activty level.

Secondary outcome

Factors of implementation

Study description

Background summary

About 2% of the Dutch elderly population suffers from a major depressive disorder (MDD). A MDD has serious consequences for daily living (e.g. withdrawal from social activities and neglecting ones self-care). These consequences can lead to admission to a clinical ward. Activity Scheduling is a useful treatment modality. It is a brief behavioural treatment for a depressive disorder. Research has shown that Activity Scheduling is an effective treatment with an overall effect size of .87. We developed Activity Scheduling is an intervention which can be executed by mental health nurses. The intervention is a short course in which the patients learn the influence of pleasant activities on their mood. It is called the Systematic Activation Method (SAM). The nurses will be trained to guide the participants throughout the course. Although activity scheduling is a promising intervention there is a little known about the effects of activity scheduling executed by nurses.

Study objective

Main objective: to get insight in the effectivity of the SAM on depressive symptoms, quality of life, activity level, mastery and costs compared to treatment as usual in clinical admitted depressive elderly.
Sedundary objective: to get an insight in the factors which influence the implementation of the SAM

Study design

Study design: This study will be performed as a multicentre randomized clinical trial. Five mental health institutions will be selected. On each of these institutions 2 units will be selected for inclusion (elderly, the wards are treatment units, nursing staff > 3FTE). The units will be matched for concurrent treatments (Cognitive Behavioral therapy), and the matched units will be randomized to an experimental and a control unit. Patients will be randomized at unit level. With an estimated effect size of .7, *=.5, *=.8, estimated dropout =25% and 25% extra inclusion due to randomisation at unit level there will be 102 included in the study (51 per condition).
After a short training, Activity Scheduling will be executed by mental health nurses on the experimental unit as an additive treatment to treatment as usual (TAU). On the control unit TAU is provided. Effects will be measured at the T0= baseline, T1= 10 weeks after T0 and T1= 3 months after T1.

Intervention

The SAM is a short course of 7 weeks which will be followed by the patients. the course contain the following steps: reflection on mood fluctuations, execute pleasant activities randomly, to develop and execute a pleasant activity schedule and the use of resources. the nurses wille be trained to guide the patients throughout the course.

Study burden and risks

Extend of burden: a 7 weeks course and 5 -10min of homework every day.
Risks: none

Contacts

Public
Vrije Universiteit

van der Boechorststraat 1
1081 BT Amsterdam

NL
Scientific
Vrije Universiteit

van der Boechorststraat 1
1081 BT Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 60 y and older,
- depressive disorder DSM-IV-tr: codes 296.2x, 296.3x. Diagnose determined with MINI (M.I.N.I interational neuropsychiatric interview, van Vliet et al.2000)
- abbility to read and write in Dutch,
- approval by means of the informed consent procedure

Exclusion criteria

- cognitive problems (score <24 on the Minimal Mental State Examination [MMSE])
- obssesive compulsive disorder, determined with MINI (M.I.N.I international neuropsychiatric interview van Vliet et al. 2000)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL26878.029.09