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THE SYSTEMATIC ACTIVATION METHOD
A NURSING INTERVENTION STUDY FOR PATIENTS WITH
LATE LIFE DEPRESSION

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VRJIE UNIVERSITEIT

THE SYSTEMATIC ACTIVATION METHOD
A NURSING INTERVENTION STUDY FOR PATIENTS WITH
LATE LIFE DEPRESSION

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus prof.dr. V. Subramaniam,
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ten overstaan van de promotiecommissie
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door

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geboren te Apeldoorn

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Dit proefschrift is opgedragen aan

J.E. (Sjors) Clignet
(1932 - 2011)

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1

General introduction

Introduction

This thesis concerns the implementation and testing of a Behavioral Activation (BA) intervention in inpatients with a Late Life Depression (LLD). The primary aim of this thesis is the development and testing of easy manageable version of BA (i.e. the Systematic Activation Method) for inpatients with LLD when implemented by mental health nurses in routine daily care.

LLD is a heterogeneous disorder, which seriously impairs daily living (Lepine & Briley, 2011; Beekman, Penninx, Deeg et al. 2002). Patients who suffer from LLD are often trapped in a circle of anhedonia, inactivity, and beliefs that they are unable to change their situation. As a result, they tend to withdraw themselves from social activities and social participation. This phenomenon is described as the circle of depression (Lewinsohn, Hobermann, Teri & Hautzinger, 1985).

To break through this depression circle, treatment of LDD requires a multidisciplinary approach in which activation is a major focus. This is especially relevant for mental health nursing practice given their close contact with these patients during everyday care and treatment (Kok, 2008, Harvath & McKenzie, 2005). However, activation is a true challenge in patients with LLD. Given the nature of the depressive disorder, patients tend to reject participation in activation programs.

When I worked as a nurse, and later as a clinical nurse specialist in an inpatient setting for mental health care in old age psychiatry, LDD was the most frequent diagnosis. I personally experienced that it took a lot of effort to successfully activate these patients. The following case from my practice was an exception, which triggered my interest in the topic of activation of patient with LLD:

At the ward, one of the “house rules” was that every evening all patients were supposed to be present at “coffee-time” in the conversation room. However, the reality was that only a few patients attended to this evening event. Most of the patients stayed in their room despite all the efforts of the nursing staff to involve them in social activities. The patients considered themselves as too depressed to participate. However, the Sunday evening was a notable exception: nearly all patients were present at coffee-time to watch a Dutch dating show on television called “Boer zoekt vrouw” [Farmer wants a Wife]. The patients visibly enjoyed the television program with no evident signs of depression. There were vivid discussions about the love affairs of the farmers. When the program had ended, a few of the patients stayed in the conversation room, but most of them went to bed and followed their “normal” routine.

It was striking that the patients seemed to “forget” the misery of their depression during this television program. This anecdote showed the positive impact of a pleasant day-to-day activity on their mood and behavior. And this was my motivation to study activation as a purposefully and systematic intervention in the treatment of LLD as described in this thesis.

Late life depression

The prevalence of a major depressive disorder (MDD) in late-life (LLD) varies between 1-5% (Beekman, Copeland & Prince 1999; Blazer, 2003; Seitz, Purandare & Conn, 2010; Fiske, Wetherell & Gatz, 2009). However, there is no consensus on the question when “late life” begins. In some studies, ‘late life’ is considered as older than 55 years (Licht-Strunk, Van Marwijk, Hoekstra et al. 2009, Houtjes, van Meijel, Deeg & Beekman, 2010), but other studies regard 60 years as the cut-off point for “late life” (Frazer, Christensen & Griffiths, 2005).

The two core symptoms of MDD as defined in the DSM-V (American Psychiatric Association, 2013) are: (1) a depressed mood and (2) a loss of interest or pleasure in (nearly) all life activities. In MDD at least, these two symptoms need to be present, for at least two weeks most of the day, in combination with at least five other symptoms as described in box 1. These symptoms should cause clinically significant impairments in daily functioning. This general definition is not age-related but scientific literature suggests that the elderly population shows a different symptom profile compared to their younger counterparts. In LLD, other symptoms are reported more frequently by the elderly. These are, somatic symptoms (a lack of appetite, decreased energy, pain; Frazer et al. 2005), cognitive impairments and behavioral inhibitions (Alexopoulos & Kelly, 2009).

At least five of the symptoms listed below are present in MDD, in which a depressed mood (1) and diminished interest or pleasure in all or most activities (2) are present most of the day during a period of (minimal) two weeks.

1. Depressed mood most of the day.
2. Diminished interest or pleasure in all or most activities.
3. Significant unintentional weight loss or gain.
4. Insomnia or sleeping too much.
5. Agitation or psychomotor retardation noticed by others.
6. Fatigue or loss of energy.
7. Feelings of worthlessness or excessive guilt.
8. Diminished ability to think or concentrate, or indecisiveness.
9. Recurrent thoughts of death

Box. 1: Diagnostic Criteria of a Major Depressive disorder according to the DSM-V (American Psychiatric Association, 2013)

Nursing care in inpatients with late life depression.

Although there is a large body of knowledge on biological and psychological treatments in LLD (Allen & Ebmeier, 2013; Blazer, 2003; Cuijpers, Karyotaki, Pot, Park & Reijnders III, 2014), nursing research in LLD is scarce (Kok, 2008). The “elderly addendum” of the Dutch multidisciplinary guideline for depression (Kok, 2008) describes nineteen activities that could be carried out by nurses to support patients with LLD. These activities can be divided in 1) “crisis related activities” such as suicide prevention, 2) “disorder related activities” such as activation, 3) “comfort related activities” such as providing emotional support, 4) “activities related to personal functioning” such as helping with household activities and 5) “activities related to social functioning” such as supporting informal care providers. The guideline describes these activities as “stand alone” activities, but it is evident that in clinical practice nurses will execute these activities in combination, (in the best conditions) tailored to the individual needs of a patient. However, their effectiveness is unclear due to lack of research.

Most publications in this field can be considered as level IV evidence (e.g. Kurlowicz, 1997), in which the opinions of authorities or consensus panels provide the directives for clinical practice (Melnick & Fineout-Overholt, 2005). More recently, there is growing evidence on activation as a nursing intervention in LDD in patients with dementia (Verkaik, Francke, van Meijel et al. 2011) and residential care homes (Dozeman, van Schaik, van Marwijk et al., 2011; Meeks, Looney, Van Haitsma & Teri 2008). These studies are based on the integrative behavioral model of depression (Lewinsohn et al. 1985). The model aims to break through the depression circle by increasing the number of positive reinforcers such as pleasant activities.

The intervention that is central in the present thesis is also based on this integrative behavioral model of depression. We called it the Systematic Activation Method (SAM). We made our SAM-intervention suitable for implementation by mental health nurses in routine inpatient psychiatric care for the elderly.

Behavioral Activation and Depression.

The Systematic Activation Method (SAM) is based on the theoretical assumptions of Behavioral Activation (BA). BA¹ was developed by the American psychologist Pete Lewinsohn (1974) in the early seventies of the last century. It formed the bases for several intervention strategies, including the “Coping with Depression” course (CWD), which is an effective treatment in depression (Cuijpers, Muñoz, Clark & Lewinsohn, 2009).

¹ Behavioral Activation also refers to Activity Scheduling. In research, these terms are used interchangeably but refer to the same underlying principles. For reasons of clarity we use the term Behavioral Activation.

In the late seventies BA was incorporated in the “Cognitive Behavioral Therapy” (CBT), developed by Beck and colleagues (Beck, Rush, Shaw & Emery, 1979).

The underlying theoretical framework is called the integrative theory of depression (Lewinsohn et al., 1985) and is summarized in figure 1. The main assumption is that stressful events (A in the scheme) can lead to major disturbances in the normal life pattern of a person, which can induce a negative response (B in the scheme). As a result, the negative response leads to a reduced rate of positive reinforcement or an elevated rate of aversive experiences (C in the scheme). This will lead to negative expectations, self-criticism and decreased self-image (D in the scheme) and, as a result, to an increase of depressive symptoms (E in the scheme). These are in turn responsible for a decrease in functioning at behavioral, cognitive and emotional level (F in the scheme), which leads to increasing disturbances in the normal life pattern. The susceptibility of a person to get stuck in this negative circle depends on individual predisposing vulnerabilities (G in the scheme). The aim of BA is to break through this negative circle by increasing the number of positive reinforcers (C in the scheme).

BA is based on three assumptions (Lewinshon & Graf, 1973; Lewinshon & Amerson, 1978):

1. In depressive patients, there is a low rate of response-contingent positive reinforcers.
2. A low rate of response-contingent positive reinforcers is predictive for extinction. This means that a decrease in activity level can lead to further decrease of activity levels and, as a result, an increase of depressive symptoms.
3. The total amount of response-contingent positive reinforcers depends on three factors:
 - a. The personal interest of a person, which makes him or her prone for positive reinforcers.
 - b. The degree of access to (potential) positive reinforcers.
 - c. The possibilities of a person to engage in (potential) positive reinforcers (e.g. required skills, financial possibilities)

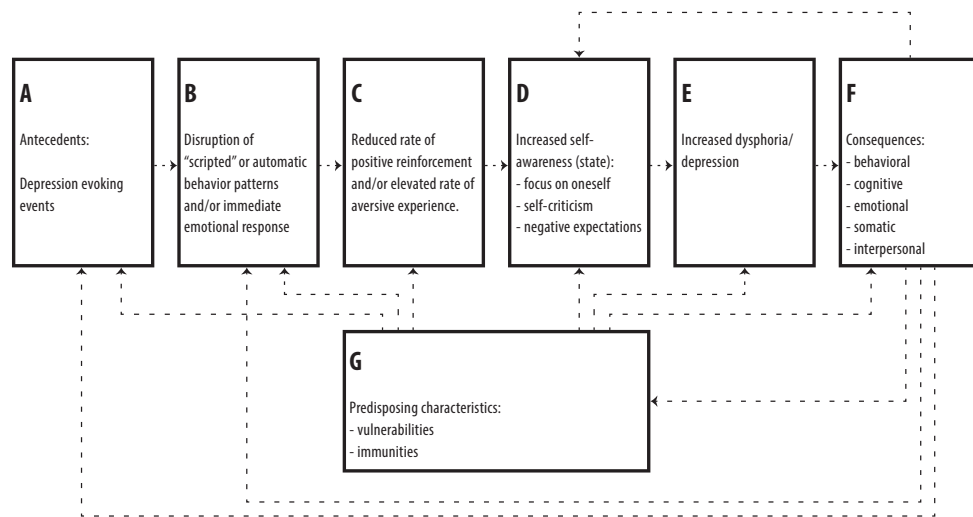


Figure 1. Integrative Theory of Depression (Lewinsohn et al., 1985).

As noted earlier, BA was integrated in the cognitive behavioral therapy, developed by Beck and colleagues (Beck et al. 1979). However, BA as a stand-alone therapy regained interest in the late nineties of the last century. A dismantling study by Jacobson and colleagues (Jacobson, Dobson, Truax, et al. 1996), in which the behavioral components and cognitive components of CBT were tested independently on their effectiveness, showed that BA was as effective as CBT. This was a striking finding, since BA was considered an easy manageable therapy, which required less intensive training and education compared to CBT. The findings of this study induced a rapid increase of studies on BA (e.g. Hopko, Lejuez, Lepage, Hopko & McNeil 2003; Dimidjian, Dobson, Kohlenberg, et al. 2006; Folke, Hursti, Tungström et al., 2014; Ekers, Webster, Van Straten et al. 2014; Ekers, Richards, McMillan, Bland, Gilbody, 2011; Richards, Ekers, McMillan, et al., 2016). These studies showed unambiguously that BA is an effective therapy in the treatment of depression and is less costly compared to e.g. CBT. In LLD, a review of Polenick & Flora (2013) suggests that BA is an effective treatment across a wide spectrum of settings, but the research findings are inconclusive.

The Systematic Activation Method

The Systematic Activation Method (SAM) is a brief behavioral intervention in book format with duration of seven weeks. The format of the SAM is based on the Coping With Depression course (CWD) (Voordouw, Kramer & Cuijpers, 2002; Persons, Davidson & Tompkins, 2001). Just as in CWD, our intervention contains information, homework assignments and the use of mood diary for monitoring purposes. The SAM consists of six consecutive steps to be carried out by the individual patient and is solely focused on the increase of positive activities (see box 2). The nurses support the patient in carrying out the SAM. They received a brief training of 2 x 4 hours and supervision meetings once every two weeks. The execution of the SAM is described in more detail in chapter three.

The stepwise approach of the Systematic Activation Method.

| Step | Theme | Activities | Time |
|------|---|--|-----------|
| 1 | Monitoring mood through a diary. | - Education on LLD - Practice how to keep up a mood diary. | 1 week. |
| 2 | Execution of positive activities. | - Education on executing positive activities. - Selecting and executing positive activities from the activity scheme. | 1 week. |
| 3 | Developing a positive activity plan. | - Education on developing a positive activity plan. - Developing and executing a positive activity plan | 2 weeks. |
| 4 | Using resources. | - Education on how to use the help of others. - Developing and executing a "resource plan". | 1 week. |
| 5 | Setting up an "Activity Experiment (AE)". | - Education on setting up an AE. - Selecting an activity for the AE. - Planning and execution of the AE. | 1 week. |
| 6 | Evaluation and relapse prevention | - Education about risk factors. - Systematic evaluation of the patients' strengths and pitfalls. | 1 session |

Box 2. The outline of the Systematic Activation Method

Aims and outline of this thesis.

It is well acknowledged that mental health nurses play a crucial role in activating inpatients with LLD. It is also acknowledged that activating patients, who have lost interest in nearly all activities, is challenging. Moreover, due to a lack of research, mental health nurses have to rely on opinion-based knowledge by experts, as well as on their own experiences in activating inpatients with LLD. Because mental health nurses are challenged on a daily basis in the activation of these patients, there is a need for a solid, theory-based intervention, which is tested on its effects in routine nursing practice.

This study will add scientific knowledge about the effects of activation in patients with LLD. It also studies the factors that affect the implementation of this intervention in routine practice. The intervention we developed enables mental health nurses to contribute to the treatment of inpatients with LLD by the deliberate and purposeful use of activation. This thesis has three major aims. The first aim is to test the clinical effects of the Systematic Activation Method (SAM) in inpatients with LLD when implemented in nursing practice. The second aim is to explore possible barriers and facilitating factors, which affect the actual implementation of the SAM in nursing practice in an inpatient health care facility. The third aim of this thesis is to obtain a better understanding of unmet needs, provided care and satisfaction with care in patients with LLD. For this purpose we used the data of a previous study carried out by Houtjes et al. (2010).

In **chapter two** – as an introductory chapter - a meta-analysis of psychological interventions in inpatients is described. In this study, the effects of twelve randomized trials of psychological treatments concerning CBT, BA, Interpersonal Psycho-Therapy, family therapy, couple therapy, and social skills therapy are investigated.

In **chapter three**, a case report describes the content and the process of implementation of the Systematic Activation Method (SAM) by a mental health nurse to a 77-year-old patient (Susan). This chapter contains a thorough description of the stepwise approach of the SAM. Each of the themes of the SAM is described in detail, including a preliminary description of the barriers and facilitators when using the SAM as a treatment model in mental health nursing.

Chapter four describes the RCT research protocol, which was developed to test the effects of the SAM. This protocol describes a multicenter clustered randomized controlled trial according to the CONSORT criteria (Rennie, 2001).

In **Chapter five** the results from the RCT are presented. The study was performed in ten old age psychiatric wards in nine mental health institutions. The main outcome was the level of depression. Furthermore, anxiety and mastery were measured as secondary outcome measures.

In **Chapter six** the results of an evaluation study on implementation factors are presented. In this study a qualitative approach was used to study implementation factors on the level of nurses, patients and context of care delivery. The design was based on the COREQ criteria (Tong, Sainsbury & Craig, 2007).

Chapter seven describes a study on unmet needs, care provision and satisfaction with care in a sample of 99 outpatients. The aim of this study was to gain insight in the care patients with LLD receive for their unmet needs, as well as their satisfaction with the care they received. Also the association was studied between satisfaction with care and level of depression. The general discussion will be presented in **Chapter eight**, where main findings of this study are summarized and discussed.

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2

Psychological treatment of depression in inpatients: A systematic review and meta-analysis.

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Introduction

It is well-established that psychological interventions are effective in the treatment of depressive disorders in adults (Churchill, Hunot, Corney, Knapp, McGuire, Tylee et al., 2001; Cuijpers, van Straten, Warmerdam, & Smits, 2008), although the effects may have been overestimated because of publication bias (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010) and because of the relatively low methodological quality of many studies in this area (Cuijpers, van Straten, Bohlmeijer, Hollon, & Andersson, 2010). Most research on psychological interventions for depression have been conducted in outpatients with mild to moderate depressive disorders (Churchill et al., 2001; Cuijpers et al., 2008), often recruited via advertisement or in the general public. Psychological treatments have been found to be less effective in outpatients with chronic depression (Cuijpers, van Straten, Schuurmans, van Oppen, Hollon, & Andersson, 2010), and possibly severe depression (Elkin, Shea, Watkins, Imber, Sotsky, Collins et al., 1989), although evidence is not conclusive (Driessen, Cuijpers, Hollon, & Dekker, 2010).

Apart from these studies in depressed outpatients, several studies have examined the effects of psychological treatments in depressed inpatients in the past decades. The number of studies in this area, however, is not as large as the number of studies examining psychological treatments for depressed outpatients, presumably because most patients are treated in outpatient settings. Inpatient treatment remains an important treatment option for patients with more severe and chronic depression, who cannot safely stay in their own environment (Wolpert, 2001).

Inpatients belong to the most severe and disabled patient populations. Many of these patients suffer from severe and chronic forms of depression, and better treatment options may improve their recovery and reduce the suffering from themselves as well as their relatives. It is important, therefore, to examine the possibilities of psychological treatments to contribute to the reduction of the suffering of depressed inpatients.

Although some studies found positive effects of psychological treatment for depressed inpatients (De Jong, Treiber, & Henrick, 1986; Hopko, Lejuez, Lepage, Hopko, & McNeil, 2003; Lemmens, Eisler, Buysse, Heene, & Demyttenaere, 2009), several other studies did not find significant effects (Barker, Scott, & Eccleston, 1987; Bowers, 1990; De Jong-Meyer, & Hautzinger, 1996; Miller, Norman, & Keitner, 1989). Meta-analysis can be used to integrate the results of these studies to get a better estimate of the overall effect size. Because no meta-analysis has attempted to integrate the results of the studies examining the effects of psychological treatments of depressed inpatients until now, this study is aimed at presenting the results of

Key words

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|------------------|-------------------------|
| major depression | psychological treatment |
| dysthymia | psychotherapy |
| inpatients | meta-analysis |

Abstract

Research on psychological treatment of depression in inpatients is not conclusive, with some studies finding clear positive effects and other studies finding no significant benefit compared to usual care or structured pharmacotherapy. The results of a meta-analysis investigating how effective psychological treatment is for depressed inpatients are presented. A systematic search in bibliographical databases resulted in 14 studies with a total of 570 respondents. This set of studies had sufficient statistical power to detect small effect sizes. Psychological treatments had a small ($g=0.29$), but statistically significant additional effect on depression compared to usual care and structured pharmacological treatments only. This corresponded with a numbers-needed-to-be-treated of 6.17. Heterogeneity was zero in most analyses, and not significant in all analyses. There was no indication for significant publication bias. Effects were not associated with characteristics of the population, the interventions and the design of the studies. Although the number of studies was small, and the quality of many studies was not optimal, it seems safe to conclude that psychological treatments have a small but robust effect on depression in depressed inpatients. More high-quality research is needed to verify these results.

such a meta-analysis. Our hypothesis for this study was that psychological treatments would result in better outcomes compared to the care usually given to depressed patients in inpatient settings.

Methods

Identification and selection of studies

A database of 1,120 papers on the psychological treatment of depression was used. This database has been described in detail elsewhere (Cuijpers, van Straten, Warmerdam, & Andersson, 2008) and has been used in a series of 25 earlier published meta-analyses (www.evidencebasedpsychotherapies.org). The database is continuously updated and was developed through a comprehensive literature search (from 1966 to January 2010) in which 10,346 abstracts in Pubmed (1,831 abstracts), PsycInfo (2,943), Embase (3,087) and the Cochrane Central Register of Controlled Trials (2,485) were examined. These abstracts were identified by combining terms indicative of psychological treatment and depression (both MeSH-terms and text words). For this database, the primary studies from 42 meta-analyses of psychological treatment for depression were also checked to secure that no published studies had been missed (www.evidencebasedpsychotherapies.org). For the current study, the full texts of these 1,120 papers were examined. The reference lists of earlier reviews of psychotherapies for chronic depression and dysthymia were also examined (Stuart, Wright, Thase, & Beck, 1997; Cole, Elie, McCusker, Bellavance, & Mansour, 2000; Huber, 2005), as well as the references of the included primary studies.

We included (a) randomized trials (b) in which the effects of a psychological treatment (c) was compared to the effects of a control group (d) in adults who were hospitalized in a psychiatric setting during the treatment and (e) who had a depressive disorder (established with a diagnostic interview) as the primary presenting problem. Only studies were included in which structured and standardized psychotherapies referring to a protocol or clearly defined method were used, which were clearly different from the standard care. Studies in patients with comorbid substance use disorders and depression in substance use disorders units were excluded (Bowman, Ward, Bowman, & Scogin, 1996; Daughters, Braun, Sargeant, Reynolds, Hopko, Blanco, & Lejuez, 2009), because depression was not the primary disorder in these patients, and the treatment units differed too much from other psychiatric inpatient settings.

Quality assessment

The validity of included studies was assessed with four criteria of the 'Risk of bias' assessment tool, developed by the Cochrane Collaboration (Higgins, & Green, 2008). This tool assesses possible sources of bias in randomized trials, including the adequate generation of allocation sequence; the concealment of allocation to conditions; the prevention of knowledge of the allocated intervention; and dealing with incomplete outcome data. The two other criteria of the 'Risk of bias' assessment tool were not used in this study. One is aimed at selective outcome reporting (which is only possible in the tool if the study protocol is available, or other very clear indications of reporting only a selection of outcomes; none of studies reported publication of a study protocol), the other criterion is a rest category of possible problems that could put the study at a high risk of bias (but we did not find any indication for this).

Meta-analyses

For each comparison between a psychological treatment and a control group (or another active treatment), the effect size indicating the difference between the two groups at post-test was calculated (Cohen's *d* or standardized mean difference). Effect sizes were calculated by subtracting (at post-test) the average score of the psychological treatment group from the average score of the comparison group, and dividing the result by the pooled standard deviations of the two groups. Effect sizes of 0.8 can be assumed to be large, while effect sizes of 0.5 are moderate, and effect sizes of 0.2 are small (Cohen, 2008). Because several studies had small sample sizes we corrected the effect size for small sample bias according to the procedures suggested by Hedges and Olkin (1985).

In the calculations of effect sizes, we only used those instruments that explicitly measured symptoms of depression, such as the Beck Depression Inventory (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960). If more than one depression measure was used, the mean of the effect sizes was calculated, so that each study only provided one effect size. If means and standard deviations were not reported, we used the procedures of the Comprehensive Meta-Analysis software (see below) to calculate the effect size using dichotomous outcomes. If insufficient data were reported to calculate an effect size, the study was excluded (which was the case in one study, which reported no data or tests for the four conditions to which the subjects were randomized; Waring, Chamberlaine, McCrank, Stalker, Carver, & Fry, 1988).

To calculate pooled mean effect sizes, we used the computer program Comprehensive Meta-Analysis (version 2.2.021). As we expected considerable heterogeneity among the studies, we decided to calculate mean effect sizes using a random effects model.

In the random effects model it is assumed that the included studies are drawn from 'populations' of studies that differ from each other systematically (heterogeneity). In this model, the effect sizes resulting from included studies not only differ because of the random error within studies (as in the fixed effects model), but also because of true variation in effect size from one study to the next.

The standardized mean difference is not easy to interpret from a clinical point of view. Therefore, we transformed the standardized mean differences into the numbers-needed-to-be-treated (NNT), using the formulae provided by Kraemer and Kupfer (2006). The NNT indicates the number of patients that have to be treated in order to generate an additional positive outcome in one of them (Smit, Ederveen, Cuijpers, Deeg, & Beekman, 2006).

As a test of homogeneity of effect sizes, we calculated the I^2 -statistic which is an indicator of heterogeneity in percentages. A value of 0% indicates no observed heterogeneity, and larger values show increasing heterogeneity, with 25% as low, 50% as moderate, and 75% as high heterogeneity (Higgins, Thompson, Deeks, & Altman, 2003). We also calculated the Q-statistic, but only report whether this was significant or not.

Subgroup analyses were conducted according to the mixed effect model. In this model, studies within subgroups are pooled with the random effects model, while tests for significant differences between subgroups are conducted with the fixed effects model. For continuous variables, we used meta-regression analyses to test whether there was a significant relationship between the continuous variable and the effect size, as indicated with a Z-value and an associated p-value.

Publication bias was tested by inspecting the funnel plot on primary outcome measures, and by Duval and Tweedie's trim and fill procedure (Duval, & Tweedie, 2000) which yields an estimate of the effect size after the publication bias has been taken into account (as implemented in Comprehensive Meta-analysis, version 2.2.021).

Power calculation

Because we expected a limited number of studies, we conducted a power calculation to examine how many studies should be included in order to have sufficient statistical power to identify relevant effects. We conducted a power calculation according to the procedures described by Borenstein and colleagues (2009). We aimed at a sufficient number of studies to be able to identify a small effect size of 0.3. These calculations indicated that we would need to include at least 20 studies with a mean sample size of 30 (15 participants per condition), to be able to detect an effect size

of $d=0.3$ (conservatively assuming a medium level of between-study variance, τ^2 , a statistical power of 0.80, and a significance level, alpha, of 0.05). Alternatively, we would need 15 studies with 40 participants each to detect an effect size of $d=0.30$, or 14 studies with 50 participants.

Results

Selection and inclusion of studies

In Figure 1, a flowchart describing the inclusion of studies is presented. A total of 10,346 abstracts were examined, of 1,122 the full texts were retrieved, of which 879 were excluded. A total of 263 trials were identified and included in our database (www.evidencebasedpsychotherapies.org). Fourteen trials were aimed at inpatients, met our inclusion criteria and were included in the current meta-analysis.

Characteristics of included studies

The twelve studies included a total of 570 respondents (308 in the psychotherapy conditions and 262 in the control conditions). Selected characteristics of the studies are presented in Table 1.

Two studies were aimed at patients with chronic depressive disorder, lasting for at least two years. One was specifically aimed at older adults. In nine studies one treatment was compared with a control group, while in the remaining three studies two treatments were compared with one control group. This resulted in 15 comparisons between a psychological treatment and a control group. In seven comparisons cognitive behavior therapy (CBT) was examined, behavioral activation therapy in two, and the remaining six comparisons examined other therapies (family therapy, interpersonal psychotherapy, problem-solving therapy, social skills training and a mix of different approaches).

Table 1. Selected characteristics of psychological treatment of depression in inpatient

| Definition of depression | Excluded comorbidity | Conditions | N | Psychotherapy | Format | Nsess | Control interventions | Concurrent pharmacotherapy | Follow up | Instruments | Country |
|--------------------------|--|---|----------------|---|--------|----------|---|---|------------|--------------------|---------|
| Barker, 1987 | Chronic MDD (> 2 years) (RDC) AND treatment refractory | 1. CBT 2. Control | 10 10 | Cognitive behavior therapy | I | 15 | No description reported | 6 weeks phenelzine, L-tryptophan + lithium; followed by another combination | Post-test | HAMD | UK |
| Bowers, 1990 | MDD (DSM-III) | 1. CBT 2. Relaxation 3. Control | 10 10 10 | CBT according to Beck et al., 1979 | I | 12 | Usual attention from treatment team, including activity therapy, occupational therapy, recreational therapy | Nortriptyline | Dis-charge | HAMD; BDI | US |
| Bowers, 1993 | MDD (DSM-III-R) + HRSD ≥ 15 + BDI ≥ 15 | 1. CBT 2. unguided CBT 3. Control | 8 6 8 | CBT according to Beck et al., 1979 | I | 8 | Participation in the activities of the ward, including milieu therapy, occupational therapy, vocational rehabilitation. | Pharmacotherapy according to the choice of the treating physician | Post-test | HAMD; BDI | US |
| Brand, 1992 | Geriatric patients with MDD (RDC) | 1. BAT 2. Control | 27 26 | Behavioral activation therapy | G | 8 | Standard hospital programs, including adjunctive therapies (e.g., art, music), regular sessions with treatment team members | Not further specified | Post-test | HAMD; BDI | US |
| De Jong, 1986 | Chronic MDD + dysthymia (DSM-III) + BDI > 20 | 1. BAT+SST+CT 2. CBT 3. Nonspecific control | 10 10 10 | 1. Behavioral activation therapy + social skills training + cognitive restructuring 2. Cognitive restructuring | C | 33 47 | Occupational / recreational therapy, relaxation training, exercise, team members | No pharmacotherapy during therapy in all three conditions | 6 months | HAMD, BDI, D-scale | GER |
| De Jong-Meyer, 1996 | Endogenous depression (ICD-9) + MDD (DSM-III-R) | 1. CBT 2. Control | 36 44 | CBT according to Beck et al., 1979 | I | 24 | General supportive therapy | Amitriptyline | 12 months | HAMD; BDI | GER |
| Hautzinger, 1996 | MDD or dysthymia (DSM-III-R) + neurotic depr (ICD-9) + HAMD/BDI ≥ 20 | 1. CBT 2. Control | 20 22 | Cognitive behavior therapy according to Beck et al., 1979 | I | 24 | General supportive therapy | Amitriptyline | 12 months | HAMD; BDI | GER |

Table 1. Continued

| | | | | | | | | | | | |
|---------------|---|---|----------------|---|----|----------|--|--|-----------------|-------------|-----|
| Hopko, 2003 | MDD | 1. BAT 2. Control | 10 15 | Behavioral activation therapy | I | 6 | Token economy system; no further description provided | SSRIs or TCAs (not further specified) | Post-test | BDI | US |
| Lemmens, 2009 | MDD (DSM-IV) | 1. Single family therapy 2. Multi family therapy 3. Control | 25 35 23 | Systemic couple therapy for depression; multi-family group therapy (conceptually identical) | FG | 7 | Non-verbal therapies; cognitive behavioral approaches; systemic therapy; activation, | Not further specified | 12 months | BDI | BEL |
| Miller, 1989 | MDD (DIS) + BDI > 17 + M-HRSD > 17 | 1. CBT 2. SST 3. Control | 15 14 17 | CBT according to Beck et al., 1979; Social skills training (Bellack et al., 1981) | I | 10 12 | daily meetings with nursing staff, occupational therapy, social work evaluation of the family (no psychotherapy) | semi-structured medication protocol | 6 and 12 months | M-HAMD, BDI | US |
| Nickel, 2004 | Depression / adjustment disorder (SCID) | 1. Couple therapy 2. Control | 15 16 | Couple therapy | I | 6 | Standard psychotherapy, including group Gestalt therapy, breathing therapy, and exercise | Only 3 of 31 had used pharmaco-therapy in past 2 years (not further specified) | Post-test | BDI | GER |
| Schramm, 2007 | MDD (SCID) + HAMD > 16 | 1. IPT 2. Control | 63 61 | Interpersonal psychotherapy | C | 11 | Clinical management (psychoeducation and supportive therapy); no further description | Standardized pharmacotherapy (sertraline as first line treatment) | 12 months | HAMD; BDI | GER |

Abbreviations: BAT: Behavioral activation therapy; BDI: Beck Depression Inventory; BEL: Belgium; C: combination of individual and group; CAU: care-as-usual; CCBT: Computerized cognitive behavior therapy; Comb: combined individual/group; CT: cognitive restructuring; DIS: Diagnostic Interview Schedule; D-scale: Depression scale; FG: combined family and group format; G: group; GER: Germany; Grp: group; HAMD: Hamilton Depression Rating Scale; Ind: individual; I: individual; IPT: Interpersonal psychotherapy; MDD: major depressive disorder; M-HAMD, Modified HAMD; Pharm: pharmacotherapy; RDC: Research Diagnostic Criteria; SCL-90-D: Symptom Checklist – 90 – depression scale; SST: Social skills training; UK: United Kingdom; US: United States

In eight therapies an individual treatment format was used, one used a group format, and the remaining six used another format (family therapy or combined format). The number of sessions ranged from six to 47 (six studies had six to nine sessions, 5 had 10 to 15 sessions, and 4 more than 15 sessions). In two studies the majority of participants did not receive pharmacotherapy in any condition (0% in De Jong et al., 1986; 9.7% in Nickel et al., 2004), while in the other studies all participants received pharmacotherapy (in one study one of the patients did not receive pharmacotherapy; Lemmens et al., 2009). The HRSD was used in 9 of the 14 studies, the BDI was used in 10 studies. Only one study used another instrument to assess depression (De Jong and colleagues used the D-scale, as well as the HRSD and the BDI; von Zerssen, 1976). Five studies were conducted in the United States, five in Germany, and two in other European countries (the United Kingdom and Belgium). Nine studies were written in English, three in German.

Quality of included studies

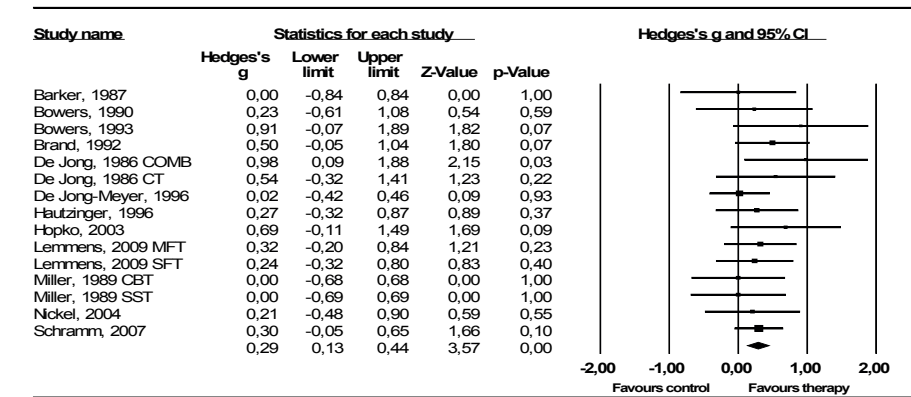
The quality of the studies was not optimal. Seven of the 12 studies gave insufficient information whether the allocation sequence was generated adequately. Nine studies gave insufficient information about whether the allocation was adequately concealed. We assessed whether incomplete outcome data were adequately addressed, by conducting intention-to-treat analyses with all randomized subjects being included in the analyses. This was the case in 5 of the 12 studies. In 6 studies knowledge of the allocated interventions was adequately prevented by blinding of the assessors, while in three studies only self-report measures were used. Three studies met all four quality criteria (Lemmens et al., 2009; Nickel et al., 2004; Schramm et al., 2008).

Effects of psychological treatments for inpatients

The overall mean effect size indicating the difference between psychological treatments and control groups was $g=0.29$ (95% CI: 0.13~0.44; $p<0.001$), which corresponds with a NNT of 6.17. Heterogeneity was zero and not significant. These results are summarized in Table 2, and in Figure 2.

A post-hoc power calculation showed that our set of studies had sufficient statistical power to detect a significant effect size of $g=0.27$. This was based on the mean number of participants in the studies (which was 48), and the finding that the between-study variance (τ^2) was zero, which results in higher statistical power to detect significant effect sizes.

Figure 2. Standardized effect sizes of psychological treatments for depressed inpatients at post-test: Hedges' g



In this meta-analysis we included three studies in which two psychological treatments were compared with the same control group. This means that multiple comparisons from these three studies were included in the same analysis. These multiple comparisons, however, are not independent of each other, which may have resulted in an artificial reduction of heterogeneity and may have affected the pooled effect size. We examined the possible effects of this by conducting an analysis in which we included only one effect size per study. First, we included only the comparison with the largest effect size from the studies with multiple comparisons. Then we conducted another analysis in which we included only the smallest effect size. As can be seen from Table 2, the resulting effect sizes were almost the same as in the overall analyses. Heterogeneity did not increase, and remained zero in these analyses.

We also calculated the effect sizes based on the BDI (while excluding the effect sizes based on other measurement instruments), and found comparable results ($g=0.24$; 95% CI: 0.08~0.40; $I^2=0$; NNT=7.46). The effect size based on the HRSD was also comparable with the overall effect size ($g=0.33$; 95% CI: 0.14~0.52; 5.43), and although there was some heterogeneity ($I^2=4.81\%$), this was very small and not significant.

Neither the funnel plot nor Duval and Tweedie's trim and fill procedure pointed at a significant publication bias. The effect size indicating the difference between the treatment and control condition was remained exactly the same after adjustment for publication bias (number of trimmed studies: 0).

At 12 months follow-up, the difference between the experimental conditions were reported by five studies (six comparisons). The overall effect size was $g=0.32$ (95% CI: -0.01~0.66) with a trend ($p=0.057$) indicating that the psychotherapy conditions may be more effective than the control conditions. Heterogeneity was moderate to high ($I^2=57.28$) and significant ($p<0.05$). These results have to be considered with caution, because these were naturalistic follow-ups in which it was not clear which treatments patients received during the follow-up periods.

Subgroup and meta-regression analyses

We examined possible moderators of outcome in a series of subgroup analyses (Table 2). As can be seen, we found no indication for a significant difference between different types of psychological treatments (CBT, behavioural activation therapy; other therapies), between different treatment formats (individual; group; mixed or other); region (USA; Europe); between studies with 6 to 9 sessions, and those with 10 to 15 sessions, and 16 or more sessions; between studies in which patients received pharmacotherapy and those in which (the majority of) patients did not receive pharmacotherapy; and between high-quality and other studies (met all four quality criteria; other).

We also conducted a series of meta-regression analyses, in which we examined the association between the effect size on the one hand, and on the other hand the number of sessions, the mean age of respondents, and the percentage of women. None of these three analyses was significant.

Sensitivity analyses

Because there were several important differences between studies, we conducted a series of sensitivity analyses. In these analyses we selected the subgroup of studies examining cognitive behavioral therapies and examined the overall effect size, and the effect size based on the HRSD and the BDI. We also examined in this subset of studies whether the multiple comparisons from one and the same studies affected the overall outcome. We conducted the same analyses for the subset of studies in which the interventions had 6 to 15 sessions (studies with more sessions were removed), as well as for the subset of studies in which all participants received pharmacotherapy (the two studies in which patients received no pharmacotherapy were removed). The results of these analyses are presented in Table 2. As can be seen, the results of these analyses resulted in comparable analyses as the main analyses, and we found no indication that these subsets of studies were associated with differences in effect size, or higher levels of heterogeneity.

Table 2. Meta-analyses of studies examining the effects of psychological treatments for depressed inpatients: Hedges' g

| Study | | N_{comp} | g | 95% CI | Z | I^2 ^{a)} | p ^{b)} | NNT |
|---|-------------------|------------|------|------------|---------|---------------------|-------------------|------|
| All studies | | 15 | 0.29 | 0.13~0.44 | 3.57*** | 0 | | 6.17 |
| One effect per study (highest) ^{d)} | | 12 | 0.30 | 0.13~0.47 | 3.41** | 0 | | 5.95 |
| One effect per study (lowest) ^{d)} | | 12 | 0.27 | 0.10~0.45 | 3.12** | 0 | | 6.58 |
| Only HRSD | | 11 | 0.33 | 0.14~0.52 | 3.39** | 4.81 | | 5.43 |
| Only BDI | | 14 | 0.24 | 0.08~0.40 | 2.91** | 0 | | 7.46 |
| Subgroup analyses | | | | | | | | |
| Psychotherapy | CBT | 7 | 0.19 | -0.07~0.44 | 1.43 | 0 | 0.367 | 9.43 |
| | BA | 2 | 0.56 | 0.11~1.00 | 2.44* | 0 | | 3.25 |
| | Other | 6 | 0.30 | 0.07~0.52 | 2.61** | 0 | | 5.95 |
| Format | Individual | 8 | 0.24 | -0.02~0.50 | 1.82 | 0 | 0.691 | 7.46 |
| | Mixed/group/other | 7 | 0.31 | 0.11~0.51 | 3.10** | 0 | | 5.75 |
| Number of sessions | 6 to 9 | 6 | 0.41 | 0.15~0.67 | 3.09** | 0 | 0.472 | 4.39 |
| | 10 to 15 | 5 | 0.18 | -0.08~0.44 | 1.37 | 0 | | 9.80 |
| | 16 or more | 4 | 0.32 | -0.06~0.69 | 1.64 | 26.42 | | 5.56 |
| Pharmacotherapy | Yes | 12 | 0.26 | 0.09~0.42 | 3.02** | 0 | 0.314 | 6.85 |
| | No | 3 | 0.51 | 0.05~0.97 | 2.16* | 0 | | 3.55 |
| Region | USA | 6 | 0.35 | 0.05~0.64 | 2.32* | 0 | 0.633 | 5.10 |
| | EU | 9 | 0.26 | 0.08~0.45 | 2.76 | 0 | | 6.85 |
| Quality of study | High | 4 | 0.28 | 0.04~0.52 | 2.27* | 0 | 0.96 | 6.41 |
| | Other | 11 | 0.29 | 0.08~0.49 | 2.76** | 0 | | 6.17 |
| Sensitivity analyses | | | | | | | | |
| Only cognitive-behavioral therapies | | | | | | | | |
| All studies | | 9 | 0.28 | 0.06~0.50 | 2.45* | 0 | | 6.41 |
| One effect per study (highest) ^{d)} | | 8 | 0.26 | 0.03~0.49 | 2.21* | 0 | | 6.85 |
| One effect per study (lowest) ^{d)} | | 8 | 0.31 | 0.08~0.54 | 2.59* | 0 | | 5.75 |
| Only HRSD | | 9 | 0.35 | 0.10~0.60 | 2.75** | 15.50 | | 5.10 |
| Only BDI | | 9 | 0.26 | 0.04~0.49 | 2.34* | 0 | | 6.85 |
| Studies with more than 15 sessions removed | | | | | | | | |
| All studies | | 11 | 0.29 | 0.11~0.48 | 3.15** | 0 | | 6.17 |
| One effect per study (highest) ^{d)} | | 9 | 0.32 | 0.12~0.53 | 3.17** | 0 | | 5.56 |
| One effect per study (lowest) ^{d)} | | 9 | 0.31 | 0.11~0.52 | 3.04** | 0 | | 5.75 |
| Only HRSD | | 7 | 0.37 | 0.14~0.59 | 3.18** | 0 | | 4.85 |
| Only BDI | | 10 | 0.24 | 0.06~0.43 | 2.55* | 0 | | 7.46 |

Table 2. Continued

| No pharmacotherapy studies removed | | | | | | |
|---|----|------|-----------|---------|------|------|
| All studies | 12 | 0.26 | 0.09~0.42 | 3.02 ** | 0 | 6.85 |
| One effect per study (highest) ^d | 10 | 0.28 | 0.10~0.46 | 3.00 ** | 0 | 6.41 |
| One effect per study (lowest) ^d | 10 | 0.27 | 0.09~0.45 | 2.88 ** | 0 | 6.58 |
| Only HRSD | 9 | 0.28 | 0.09~0.48 | 2.84 ** | 3.37 | 6.41 |
| Only BDI | 11 | 0.22 | 0.05~0.39 | 2.53 * | 0 | 8.06 |

o: $p < 0.10$; *: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$.

^a) The Q statistic was significant in none of the analyses.

^b) This p-value indicates whether the effect sizes between subgroups differ significantly from each other.

^c) In these analyses only one comparison from each study was used.

Discussion

We found clear indications that psychological treatments of depression have a small, but significant effect on depressed inpatients compared to care-as-usual or structured pharmacotherapies. The number of patients that have to be treated in order to generate one additional positive outcome compared to usual care is 6.17. This outcome was quite robust, and in almost all analyses heterogeneity was zero and not significant. We also did not find indications that the effects were related to characteristics of the patients, the interventions, or general characteristics of the studies.

Effects we found for psychological treatments for inpatients were relatively small, compared to those found in outpatients (Churchill et al., 2001; Cuijpers et al., 2008). That should not come as a surprise. In most included studies patients received many different kinds of therapy, including pharmacotherapy, occupational therapies, and unstructured support from nurses and other staff members. From this perspective, it would be better to compare the effects of psychological treatments in inpatient settings to the additional effects of psychotherapy to pharmacotherapy. In these studies, the effect sizes for psychological treatments are also relatively small (Cuijpers, van Straten, Warmerdam, & Andersson, 2009; Cuijpers, Dekker, Hollon, & Andersson, 2009), and comparable with the outcomes we found in inpatients. This suggests, that psychological treatments have small but robust effects on depression in inpatients as well as in outpatients, when these are added to other treatments.

Another possible reason for the relatively small effect may be comorbidity as hospitalization often relates to more severe symptoms and comorbidity. Comorbid disorders, such as personality disorders and anxiety, are known to be present in many cases of severe depression, and they may very well influence the outcome. Future studies on inpatients with depression should preferably report comorbidity rates better, including the role of medication and cognitive functioning which might affect outcome of psychological treatments. It may also be that outpatient studies to a greater extent include first-episode cases of depression, whereas patients who are hospitalized are more likely to have had repeated episodes. Indeed, the natural course of depression is likely to have an influence on the likelihood of recovery (Paykel, 2008), and as we know that psychological treatments are less likely to benefit more severe and chronic cases (Cuijpers et al., 2010) smaller effects are likely to be found in hospitalized patients.

Although this study has shown that psychological treatments for depressed inpatients have a positive effect, it is not clear whether this effect is relevant from a clinical or economical point of view. On the one hand it could be said that a numbers-needed-to-treat of six is a considerable contribution to relieving the burden of disease in these patients. On the other hand it could be argued that treating six patients of which only will benefit sufficiently from the therapy does not justify such an intervention. This is even more complicated by the fact that the outcomes at the longer term are not known.

The positive effects found in this study should be an encouragement to conduct more research. High-quality studies with sufficient statistical power should focus on the longer-term effects of these treatments, and should not only focus on the clinical outcomes but also on economical cost-benefit analyses. An important question is why the psychological treatments examined in these studies have an additional effect to the therapies that are part of the usual care of most settings. Perhaps this can lead to a better understanding of what works in these therapies, and how brief interventions with larger effect sizes can be developed.

This study has several limitations. First, the number of included studies was relatively small, although we had sufficient statistical power to detect small overall effect sizes. However, the number of studies was not sufficient to examine moderators of outcome in subgroup-analyses, because each subgroup contained only a limited number of studies. On the other hand, the statistical heterogeneity was zero in virtually all analyses, suggesting that the results are quite robust in different settings and populations. Second, there were several differences between the studies we examined, including differences between the settings, the treatments, the patients,

the in- and exclusion criteria, and the control groups. We found few indications, however, that the results of the studies differed between these groups of studies. A third important limitation was that the quality of many included studies was not optimal and research in psychotherapy for depressed outpatients has shown that the effect sizes are strongly related to the quality of the studies (Cuijpers et al., 2010). On the other hand, in the current study we found no evidence that the high-quality studies had significantly lower effect sizes than other studies.

Despite these limitations it seems safe to conclude that psychological treatments have a small but robust effect on depression in depressed inpatients. Offering these interventions to all depressed inpatients will result in a positive outcome in one of every six patients, compared to the usual care. Considering the huge disease burden of depression and the suffering of individual patients and their families, these positive results should be reason enough to examine these therapies better in high-quality studies and perhaps in the longer term to disseminate such treatments in routine care.

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3

The Systematic Activation Method (SAM) in Depressed Elderly: A Case Report.

Clignet, F., van Meijel B., van Straten A., Lampe, I., & Cuijpers, P. (2012). The systematic activation method (SAM) in depressed elderly: A case report. *Perspectives in Psychiatric Care*, 48. – with small adjustments-

Introduction

One of the major consequences of a major depressive disorder (MDD) is a decrease in activity level, because of a diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (American Psychiatric Association, 2000). When patients with MDD are admitted to a clinical ward, (re)activation is an important intervention carried out by nurses (Kurlowicz, 1997; Kurlowicz & Harvath, 2008). In (re)activation, nursing care is focused on encouraging patients to engage in everyday activities, social activities, and leisure activities. Although most nursing guidelines prescribe (re)activation as a nursing intervention, little is known about the procedures and effects of this intervention. Nurses tend to rely on self-reports by the patients (Parrish, Peden, & Staten, 2008) or are guided by their intuition (Hassall & Gill, 2008). Especially for depressed elderly, it is difficult for them to engage in activities because of reduced physical capabilities and a decrease in social contacts. It is therefore vital to focus on an increase in activity level within the possibilities of the depressed elderly.

We developed (re)activation as a brief systematic course for depressed elderly, which we called the Systematic Activation Method (SAM; Clignet, van Meijel, van Straten, Lampe, & Cuijpers, 2008). The SAM is based on Behavior Activation (BA), a behavioral treatment for depression, which is also often referred to as behavioral activation treatment. Recent studies show that BA is an effective treatment for depressed patients (Cuijpers, van Straten, & Warmerdam, 2007; Dimidjian et al., 2006; Hopko, Lejuez, Lepage, Hopko, & McNeil, 2003). BA is an accessible intervention, is easy to understand, and focuses explicitly on an important consequence of MDD.

This case report describes the implementation of the SAM by the first author (FC) to Susan, a 77-year-old woman suffering from MDD. Susan was admitted to an inpatient healthcare facility for elderly with psychiatric disorders. Although her depressive symptoms decreased, she still felt no pleasure in life. She was afraid to go home for the weekends because of her feelings of loneliness and grief. She was indicated for the SAM because of her inability to engage in pleasant activities because of her depression. The purpose of this case report is to illustrate the use of the SAM as a nursing intervention in depressed elderly inpatients.

Abstract

Purpose: The study aims to describe the implementation of Behavioral Activation (BA) as a nursing intervention in an inpatient population of older adults with a major depressive disorder.

Design/methods: In a single case report, the implementation of the intervention was described.

Findings: This case report shows that BA, when adapted into a brief and prescriptive course, can be beneficial for depressed elderly in an inpatient care setting.

Practice implications: Although previous research shows promising results, there is a need for additional research on the effectiveness of the intervention when BA is executed by nurses.

The Systematic Activation Method as a Nursing Intervention

BA was developed in the early 1970s by Peter M. Lewinsohn (a psychologist) and his colleagues (Lewinsohn, Biglan, & Zeiss, 1976), as a treatment modality in depressed patients. A key assumption of BA is that a decrease in positive reinforcers can be responsible for an increase in depressive symptoms (Lewinsohn & Libet, 1972). The initial BA protocol was focused on increasing pleasant activities in combination with relaxation, social skills training, and cognitive restructuring. In the late 1970s, Beck and colleagues (Beck, Rush, Shaw, & Emery, 1979) incorporated BA into cognitive behavioral therapy (CBT). In CBT, the focus of treatment is to explore and modify the automatic thoughts and their underlying assumptions that are responsible for depressive behavior. BA, within CBT, is used as a modifier for dysfunctional automatic thoughts. A study by Jacobson et al. (1996), in which the behavioral components and the cognitive components of CBT were divided, showed that BA was as effective as CBT. These findings focused renewed attention on BA as a stand-alone treatment with promising results (e.g., Dimidjian et al., 2006; Hopko et al., 2003). In a recent meta-analysis by Cuijpers et al. (2007), the effectiveness of BA was estimated from 16 studies. In these studies, BA was compared with CBT, supportive therapy, and waiting list conditions. The overall effect of BA was 0.87, indicating a strong effect. BA is considered an effective and easy-to understand intervention for depressed patients. Hopko et al. (2003) conducted an experimental pilot study with 25 depressed inpatients. In this study, BA was compared with supportive group therapy. The results show an effect size of 0.73 in favor of BA, indicating a large effect. To our knowledge this is the only BA study with an inpatient elderly population.

We developed the SAM as a nursing intervention for depressed elderly (Clignet et al., 2008), based on Lewinsohn's model (Lewinsohn et al., 1976). The most important principle is that the SAM focuses on those activities that serve as positive reinforcers from the patient's perspective. This means that the patient's (positive) reaction to that specific activity is leading, and not the activity itself.

Analogue to the "Coping with Depression Course" (Cuijpers, 2000), we developed the SAM as a highly structured and prescriptive intervention. The "Coping with Depression Course" contains several elements of BA. We added the following items to complete the SAM: "Ask for help from others" and "Setting up an Activity Experiment."

The SAM was developed as a brief individual course of 7 weeks and consists of six sequential steps. These steps are (a) monitoring of mood, (b) executing pleasant activities from an existing pleasant activity list, (c) designing and executing a personal pleasant activity plan, (d) the use of external resources, (e) setting up an Activity Experiment (AE),

and (f) consolidation. The stepwise approach avoids the patients feeling overwhelmed by the need to engage in activities. Such feelings can be responsible for avoidant behavior. A key component of the course is the monitoring of mood. Throughout the course, the patients are asked to score their moods every day. The higher the score, the better a patient feels. The scores vary between 0 and 10 in which 0 represents "worst mood ever" and 10 represents "best mood ever." When patients score their moods while performing positive activities, they become aware of the relationship between executing positive activities on the one hand, and their moods on the other hand. At the beginning of the course, all patients receive a course book, which contains a brief explanation of the treatment rationale and a description of each step. The course book serves as a guideline for the weekly sessions and helps the patients to monitor their own progress.

For registered nurses, a treatment manual has been developed that contains a theoretical background of the SAM, together with guidelines on how the SAM should be executed and how motivational strategies can be applied (Clignet et al., 2008). A brief training program (two 4-h sessions) is available for these nurses. Although all components of BA are present, the SAM differs on some points from existing protocols. All of the adjustments are aimed at increasing the accessibility of BA for the elderly population. The most striking differences are:

1. Goal setting: In the current BA protocols, treatment goals between patient and therapist are developed at the beginning of therapy. In the SAM, the treatment goals of each individual session are presented in the course book. This is helpful for the patient for it is difficult for depressed elderly to describe feasible overall goals for the complete treatment program.
2. Therapist: The current BA protocols are mainly executed by psychologists. The SAM is developed as a treatment program for registered nurses in order to increase the accessibility for depressed elderly.
3. Use of activity logs: In current BA protocols, patients describe all their activities per hour. During the execution of SAM, patients describe their activities three times a day (morning, afternoon, and evening). Furthermore, in the SAM, only the "mood scores" are used in logs, without the mastery scores, as used in current BA protocols. These simplifications are necessary to avoid overwhelming patients by the use of logs.
4. Duration of the treatment program and intensity: The duration of the current BA protocols varies between 8 and 15 weeks, with an intensity of one session per week. The SAM is a brief course of 7 weeks, with an intensity of at least one session per week with the possibility to increase the intensity of personal contact, depending on the needs of the patient.

Based on our clinical experiences, it is difficult for depressed elderly to stay engaged in a treatment program over a long period of time, especially when active involvement from the patient is required. Therefore, it is necessary to develop the SAM as briefly as possible with all of the key components of BA being present. In a period of 7 weeks, both of these aspects are taken into account. Furthermore, the aspect of cost effectiveness was taken into consideration when developing the intervention.

Criteria for Using the SAM

We developed the SAM as a nursing intervention that can be added to the usual treatment. It is recommended that the SAM be used with some reluctance in combination with other psychological therapies, so as to prevent excessive patient overload.

The SAM was developed for depressed patients with mild to severe depressive symptoms (score greater than 20 on the Montgomery Åsberg Depression Rating Scale ([MADRS], Montgomery & Åsberg, 1979). Furthermore, the SAM is not suitable for patients with severe cognitive impairments (score less than 23 on the Minimal Mental State Examination ([MMSE], Folstein, Folstein, & McHugh, 1975). The SAM can be executed in both inpatient and outpatient care facilities.

Patients may be referred to the SAM when there is a lack of pleasant activities in their lives, and when additional motivational interventions are required for the patient to become engaged in these activities.

Case Report: Susan

Susan is a 77-year-old woman with recurrent MDD according to the Diagnostic and Statistical Manual of Mental Disorders (fourth edition, text revised) criteria (APA, 2000). She scored 30 on the MADRS score (Montgomery & Åsberg, 1979), indicating MDD, and 30 on the MMSE (Folstein et al., 1975), indicating no cognitive problems. In 1987 and 1995, she had depressive episodes; in 2006, she was admitted to a clinical ward because of a depressive episode. During her depressive episodes, Susan suffers from uncontrollable hand movements (comparable with epileptic seizures). There are no neurological abnormalities. In 2007, her husband died, which led to strong feelings of grief. In 2008, she underwent hip surgery and she got depressed. Although she was treated with antidepressant medication, her depressive symptoms worsened, so clinical admission was necessary. She felt as if she did not have enough time to grieve about the loss of her husband because of her hip surgery.

Susan lives alone and has a housekeeper who helps her clean the house once a week. She has three children who are concerned about their mother but who are also vulnerable to stress, so their practical and emotional support to their mother is limited. Susan is an active member of the Young Women's Christian Association (YWCA), from which she has many friends. Although her social network is broad, it is difficult for her to ask for help because she is convinced that the only reason others help her is that they feel sorry for her.

After admission, Susan adjusted quickly to the regime of the ward. The support from the staff and the distraction of the therapy program worked well for her. Because she was sensitive to many antidepressant medications, the possibilities of treatment with medication were limited. During the first weeks after her admission, Susan attended both grief counseling and CBT sessions. Although her depressive symptoms decreased, she still felt no pleasure in life. She was afraid to go home for the weekends because of her feelings of loneliness and grief. She was indicated for the SAM because of her inability to engage in pleasant activities because of her depression. Nursing care focused on increasing her activity level during the weekends. Together with the nurse, Susan would schedule her activities for the next weekend, which were evaluated every Monday. Susan carried out only a few of the scheduled activities and tended to postpone all social activities, like going to church on Sunday or visiting relatives and friends.

She argued that she would undertake these activities when she felt better. Susan tended to avoid going home on weekends.

Treatment With the SAM

Three days before the first appointment, Susan received the course book. The course book contains an overview of the treatment rationale, an introduction to the SAM, and a description of each session. Except for the first session, all sessions have about the same structure. Each session starts with an evaluation of the homework, followed by an introduction on the objectives of the session, and the central theme. Next, attention is focused on the activities to be executed in the following week (see Table 3). A session ends with a brief evaluation of the session and making appointments for the next week.

First Session

In the first session, mutual expectations were discussed between Susan and the nurse. The nurse explained that the effectiveness of the SAM depends on active involvement by the patient. An active involvement not only includes engaging in activities but also

active monitoring of the state of mood and activity level by using the course book. The treatment rationale was also explained, emphasizing the here-and-now focus of the SAM and success rather than failure. Susan had already read the first chapter of the course book and could identify with the principle that a lack of pleasant activities can contribute to a decrease in mood. After the general introduction, the next step was to monitor her mood. Susan had been asked to score her mood at three different times on the previous day (morning, afternoon, and evening) and to describe her activities at these times. This exercise was a prelude to her homework. At the end of the first session, Susan was asked to monitor her mood during the following week, using a scheme that was provided in the course book.

Second Session

At the beginning of the second session, the homework was discussed. Susan had monitored her mood after lunch, after dinner, and every evening before she went to bed. This took about 10–15 min of her time each day. A clear pattern emerged from her mood scores. In the morning hours, her mood score was very low but improved as the day progressed. Generally, she felt more energetic in the afternoon and evening. There was a slight increase in her mood score when her son visited her and when she went for a stroll with a friend. When these scores were discussed, she argued that she did not feel 100% yet but she certainly enjoyed these events and activities.

After completion of this homework evaluation, Susan chose some day-to-day activities that were perceived as pleasant from the “List of Pleasant Activities,” which consists of 49 daily activities, varying from social activities like “meeting friends” or “having a lively conversation,” to more personal activities like “listening to music” or “taking a bath.” The list is useful as a guideline, with the possibility of adding one’s own personal pleasant activities to the list. The purpose of this step is twofold. First, it shows that everyday activities can be pleasurable. Second, by planning these pleasant activities, a patient is able to regain his/her sense of mastery. At first, Susan selected almost all of the activities from the list. She argued that, when she does not feel depressed, most of the activities from the list are pleasant for her. The nurse explained that it would be better to confine oneself to no more than 10–15 activities that are easy to execute and probably pleasant. If she fails to execute all activities, or some activities are not as pleasant as expected, the likelihood is that she will feel disappointed. This can lead to an increase of depressed feelings. After selecting 15 pleasant activities, she filled in these activities in a scheme in the course book. Her homework was to execute these activities randomly throughout the following week. At the end of each day, Susan had to mark the activities she had performed and score her mood. At the end of the week, the scheme provided a clear overview of the influence of pleasant activities on her mood (see Table 1).

Table 1. Scheme of random activities (session 2)

| Activity | Mo | Tue | Wed | Thu | Fr | Sat | Sun |
|---|----|-----|-----|-----|-----|-----|-----|
| Take a bath | X | | | X | | X | |
| Go for a stroll | X | X | X | X | X | X | X |
| Call my daughter | | | | X | | X | |
| Listen to music | | X | | X | X | | |
| Reading | X | X | | | | X | |
| Have a conversation with a close friend | | X | | X | | | |
| Smile at a person | X | X | | | | | |
| Sleep well at night | | | | | | X | X |
| Feel the presence of God | | | | | X | | X |
| Wear clean clothes | X | | X | | | X | |
| Have a nice meal | X | X | | X | | | |
| Other | | | | | | | |
| Mood Score | 7 | 7 | 5.5 | 7.5 | 6.5 | 7 | 6 |

Third Session

The third session started again with a review of her homework. It was noticeable that she had executed some activities more than once and that she had added some other activities to the list. For example, she enjoyed taking a stroll (alone or with a friend/relative), so she undertook this activity nearly every day. She also added “reading” to her list of activities because she was better able to concentrate on reading than before. It was striking that she scored lower when she had a difficult task to execute, for example, a meeting with her psychiatrist about her vulnerability to a recurrent depressive disorder. Susan explained that such events occupied her entirely so that she was not able to perform any pleasant activities. The nurse pointed out that in these situations, it is very important to distract oneself after a difficult event in order to avoid dwelling on negative thoughts. This was visible on her mood score in which the score was 1 point below her average score.

After the homework had been discussed, the next step was to develop a structured plan for pleasant activities. Such a plan has two functions. First, it reminds Susan to engage in pleasant activities every day, as depressed patients have a tendency to focus excessively on their burden and therefore avoid engaging in pleasant activities. Second, it helps patients to restore their sense of mastery, by assisting them in actively influencing their mood. Great attention was paid to a balanced weekly plan and graded task assignment.

During this session, it became clear that it was difficult for Susan to plan for more than 3 days at a time. The nurse suggested that she confine herself to a 3-day plan. At first, Susan was reluctant to fill in the schedule because of her assumption that the schedule was binding. For example, she was afraid that she was obliged to go to church when it was scheduled into the plan. She argued that she could not yet judge if she was emotionally ready for church attendance. The nurse explained that she had a tendency to make her activity level dependent on her mood. This is one of the well-known pitfalls of patients with MDD. An activity plan helps patients to avoid this pitfall. The nurse suggested replacing the church visit with a more feasible alternative in order to increase her feelings of success. It would be possible to add a church visit to her plan at a later date. Her initial pleasant activity plan consisted of a daily stroll, a visit from a friend, and a visit to the YWCA.

Fourth Session

During the fourth session, Susan continued with her pleasant activity plan. Meanwhile, she was transferred to the ambulatory care facility. This had no effect on the execution of the SAM despite the fact that the intensity of face-to-face contact was lower in the ambulatory care facility. Her mood pattern was similar to the previous sessions: When she was engaged in a pleasant activity, her scores were about 0.5 point above her average daily score. There was one exception: When her son visited her unexpectedly, her mood scored 1.0 point above average. Susan explained that this day started as an ordinary day and her mood was below average because she felt lonely. Her son's visit came as a pleasant surprise and his visit reduced her feelings of loneliness. When the nurse asked how she evaluated this situation, she admitted that she was fortunate that her son came. The nurse explained to Susan that a pleasant activity plan would prevent an improvement in her mood from depending merely on fortunate circumstances. Planning pleasant activities could help her to gain mood control and could make her less dependent on external (fortunate) circumstances. In cooperation with the nurse, she filled in her activity plan. First, she started to schedule her weekly appointments with the ambulatory care facility. Second, she filled in recurrent pleasant activities like "taking a stroll" and "going to the YWCA". Third, she planned some new activities like visiting friends. A complete weekly schedule is shown in Table 2.

Table 2: A weekly schedule. The grey areas are recurrent activities.

| Name: Susan _____ | | Week no: _____ | | | | | |
|-------------------|--|--|----------------------------------|---|--|----------------------------------|----------------------------------|
| Day/ Period | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
| Morning | | | YWCA meeting | Ambulatory care facility | Going to the fair | | Church |
| Afternoon | Supermarket | | Supermarket | | -Call Mrs. X to go to the church together. | -Taking a stroll -Supermarket | -Drinking coffee with a friend. |
| Evening | -Taking a stroll -Taking a bath -Watch TV/ reading or writing letters | -Taking a stroll -Watch TV/ reading or writing letters | -Having dinner with some friends | -Taking a stroll -Taking a bath -Call my daughter | -Taking a stroll | -Taking a bath | -Taking a stroll -Call my son |
| Score | 6.5 | 7 | 7.5 | 7 | 7.5 | 5.5 | 7 |

Fifth Session

The fifth session started with an evaluation on the execution of the weekly plan. Susan had undertaken most of the pleasant activities and enjoyed them.

The central theme in the fifth session was to ask for help from others. Susan argued, like many depressed patients, that others helped her because they pitied her and that she was a burden to others. Together with the nurse, Susan explored the help she had already received since her discharge from the ward and how she had experienced this help. She found that she had already had more help than she actually realized. She was surprised that she was more accepting of help than she imagined. This was an eye opener to her.

After that, Susan defined what kind of help she needed in using her pleasant activity plan. She decided to ask to visit the market as planned on Friday. Normally she liked to go to the market (alone or with a friend) but now she felt uncertain in public places because she feared that other people would notice that she was depressed, although she knew rationally that this was not true. These thoughts make it difficult to ask for help. On the one hand, she realized that a friend could help her to get over this threshold, but on the other hand, she was convinced that she ought to be able to go

to the market alone. Susan explored how she could be helped with this point. For example, she could ask someone to accompany her. She could ask a friend from the YWCA to join her, or she could call her daughter the evening before her intention to visit the market. Susan was determined to go to the market so she decided to use both possibilities. If she failed to invite a friend, she could call her daughter. Susan filled in the "resource scheme" from the course book. The scheme consists of four rows containing the items (a) Who can help me?, (b) Which activity?, (c) How can he/she help me?, and (d) How can I reach that person? The purpose of this scheme is twofold. First, it helps her to ask for help in particular situations only. Second, it encourages her to use these resources.

Sixth Session

During the evaluation of her homework, Susan reported that she had not been able to invite a friend to the market because the friend she had in mind was occupied during the YWCA meeting. She admitted that she was actually relieved that she could not ask this friend because of her idea of being a burden to others. Instead, she called her daughter although she had the same feelings of being a burden. Her daughter suggested that they go together as she had planned to visit anyway. When the nurse asked how Susan reviewed her homework, she told her that she was relieved she went to the market, according to her plan. After the evaluation of her homework, the central theme of this session, namely the execution of an "Activity Experiment," (AE) was discussed. An AE is executed when an activity is perceived as being difficult to perform. There are various reasons for this perceived difficulty: for example, "no belief that it will work," "no belief that I am able to perform this activity," "being afraid that I will not succeed," etc. In an AE, a patient executes one difficult activity once and experiences what happens. The central motto is "I'm not feeling great, but I'll try it anyway." In the case of Susan, she chose a dinner date to which she had been invited. She was afraid that a lot of attention would be paid to her recent life events (her psychiatric treatment, becoming a widow), which could lead to feelings of sadness at home afterwards. Susan said that she was not ready for an emotionally charged conversation with her friends, although these friends knew about her problems. Together with the nurse, she explored the possibilities and pitfalls. The first thought that came into her mind was to postpone the dinner date. The nurse said that this could be a good solution if Susan was not ready yet. But the nurse also suggested focusing on other possibilities besides this one. To postpone activities that are difficult can also be one of the pitfalls in depressive patients. Other possibilities mentioned by Susan were going to the dinner and starting conversations herself on more neutral or positive topics like plans for the holidays. Furthermore, she mentioned that she could ask her hosts to avoid dwelling on her life events and explain to them why

this was important for her. The nurse asked her what she would do if she felt sad afterwards nevertheless. Susan suggested that she would distract herself by reading a book or watching television. After she explored these possibilities in more detail, she chose the most suitable solution and wrote it in the "AE form" that is provided in the course book. On this occasion, Susan chose to accept the invitation and to start a conversation herself on more neutral subjects. When the conversation became too emotionally charged, she would ask her hosts to change the subject.

Furthermore, she planned to read a chapter of a book if she felt sad afterwards.

Seventh Session

The seventh and final meeting started, as usual, with the homework evaluation. Attention was paid to two aspects.

First, the execution of the pleasant activity plan was discussed. Second, the AE was discussed. Although Susan had not engaged in all of the described activities, she was generally satisfied with her activity level. She enjoyed the YWCA meetings and her visits to the church were no longer problematic for her. Her only concern was Saturday. On Saturday she had no particular pleasant activities except taking a stroll. Most of her friends were occupied and she did not want to bother her son or daughters every Saturday when she felt lonely. Her evaluation concerning the AE was positive. She enjoyed her dinner date. The conversations were pleasant and she brought up some of the conversation topics, according to her plan. Her recent life events were briefly discussed but this did not affect her in a negative way. When she came home, she felt lonely. She described her homecoming as coming into a dark, lifeless house after a pleasant evening. Although Susan had planned to read a chapter of her book, she related that she was not able to read because she felt tired.

The central theme of the last session is the use of (parts of) this course in the future. Susan looked back on the course together with the nurse to explore these possibilities. Although the course could not take away her feelings of loneliness, she had experienced it as a valuable tool to gain control over her activity level and make it less dependent on her mood. The most striking session was the second session where she selected everyday activities that were potentially pleasant. She was surprised that she had forgotten how everyday activities like taking a bath or going out for a stroll could be pleasant. She also learned that undertaking pleasant activities has a positive influence on her mood. She admitted that she selected an activity (a dinner date) for the AE that was not too difficult for her. Although her concerns about the attention to her recent life events were genuine, she was able to cope with this burden. Susan argued that

there were no activities that were extremely difficult. More importantly, starting “new” activities in general was difficult because of her diminished self-esteem. This course helped her to engage in (pleasant) activities even when it was difficult.

A summary of the sessions is presented in Table 3.

Follow up

A follow-up meeting was planned 6 weeks after the last session, at which Susan’s progress was evaluated. She reported that she felt depressed again. At first, her depressive feelings decreased after finishing the course and when performing the pleasant activities by herself. She enjoyed the activities she performed although she still had difficulties starting them. A few weeks after the last session, she got sick twice (colds). As a consequence, the depressive feelings increased as well as her feelings of grief. During this period, her activity level declined. She said that she felt too sick to engage in pleasant activities. For example, she skipped the YWCA meetings. Susan related that it was difficult for her to execute pleasant activities again, even when she felt physically better. In order to restore her activity level, she used a contact from her resource scheme (see fifth session) to assist her in going to a YWCA meeting again. Although she still felt depressed at times, she followed most of the pleasant activities from her activity plan, which she enjoyed performing. The expectation is that her depressive feelings will decrease when the pleasant activities are better integrated in her daily life.

Discussion

The purpose of this case report was to illustrate the systematic and goal-directed use of activity scheduling in inpatient nursing practice.

Advantages of the SAM

As shown, the SAM provided a number of advantages in the treatment of a depressed patient. The SAM intervenes directly in one of the major symptoms of depressive disorder (i.e., loss of interest and pleasure). It is an intervention that is easy for patients to understand, and it shows quick results on mood and activity level. These results are important in guiding and encouraging the patient. Furthermore, its protocolled nature makes it possible to continue the SAM when patients are transferred from a clinical facility to an outpatient care facility.

By using activation as a goal-directed intervention, there is a sufficient balance between “forced activities” and “no activities.” If patients are forced to engage in activities, they are often resistant or avoidant. If there is no activation, depressed patients tend to decline into more and more inactivity. By using the SAM, the patients are encouraged to increase their activities gradually and at their own pace. If it is too difficult to perform an activity, the patient is encouraged to execute a more feasible activity. Furthermore, the SAM enables the patient to monitor his/her mood more adequately and to relate mood state at some point to his/her activity level.

Considerations When Implementing the SAM

Although the SAM provides a number of advantages, there are several considerations regarding the implementation. One concern is that execution of the SAM requires some cognitive skills and, therefore, is not suitable for all depressed patients. We expect that patients with serious cognitive problems will not be able to fully profit from the SAM in its current form. For this group of patients, the intensity of supervision should be increased. Also, for patients with bipolar disorder (depressive episode), some restrictions apply because of their vulnerability to sudden changes in mood.

Furthermore the effect of the SAM depends on the personal efforts of the patient. In order to motivate patients to perform their homework, specific therapeutic techniques are necessary because of the avoidant tendencies of depressed patients.

When patients are admitted to a clinical ward, the possibilities for engaging in pleasant activities are limited. This implies that, when a patient is treated with the SAM, the conditions required to engage in individual pleasant activities should be provided.

Limitations of the Case Report

Although this case report shows the usefulness of the SAM as a nursing intervention, there are some limitations. The case of Susan shows how the SAM is executed in a patient who was recovering from a depressive episode. It is important to notice that we used a motivated patient to describe the execution of the SAM properly. In order to execute the SAM as effectively as possible, it is necessary to adjust it to the personal state of the patient with regard to their possibilities.

Implications for Nursing Practice

By using the SAM, behavioral therapy is added as a treatment modality into the nursing domain. Together, with other treatments like Problem Solving Therapy (Haverkamp, Areán, Hegel, & Unützer, 2004), CBT, or Interpersonal Therapy (Parrish et al., 2008), mental health nurses can use psychological techniques in their own

practices. The SAM, as a nursing intervention, contains four major elements: (a) it is theory based; (b) it is a structured intervention; (c) it is from a patient perspective; and (d) it describes the patient/therapist relationship.

Although the SAM is heralded as an easy intervention, guiding the patients in executing the SAM (as with any other behavioral treatment) requires specialized skills in behavioral therapy. Depressed elderly tend to be resistant or avoidant in engaging in activities. Nurses who are experienced with depressed elderly are generally prepared to use these techniques. In order to use the SAM adequately, a training program for registered nurses has been developed in which these skills are educated.

Although the SAM is a promising intervention, there is a need for further research. Until now, BA has been tested only as a psychological intervention executed by psychologists. It is unknown if the results of previous research are transferable to nursing practice because of the differences in the professional perspectives and competencies between psychologists and nurses. As pointed out by Parrish et al. (2008), nurses generally use a holistic approach in their treatment of depressed patients, whereas previous research is mainly focused on a reduction of depressive symptoms. Nursing outcome is not only measured by the decrease in depressive symptoms but also by quality of life, level of mastery, and activation level in depressed patients. Therefore, we are currently preparing a randomized clinical trial in which the effects of the SAM will be tested on depressive symptoms, quality of life, mastery, and activity level.

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4

The Systematic Activation Method as a nursing intervention in depressed elderly: a protocol for a multi – center cluster randomized trial.

Clignet, F., van Meijel, B., van Straten, A., & Cuijpers, P. (2011). The systematic activation method as a nursing intervention in depressed elderly: A protocol for a multi-center cluster randomized trial. *BMC Psychiatry*, 12, 144. – with small adjustments-

Abstract

Background

Depression in later life is a common mental disorder with a prevalence rate of between 3% and 35% for minor depression and approximately 2% for Major Depressive Disorder (MDD). The most common treatment modalities for MDD are antidepressant medication and psychological interventions. Recently, Behavioral Activation (BA) has gained renewed attention as an effective treatment modality in MDD. Although BA is considered an easy accessible intervention for both patients and health care workers (such as nurses), there is no research on the effectiveness of the intervention in inpatient depressed elderly.

The aim of study, described in the present proposal, is to examine the effects of BA when executed by nurses in an inpatient population of elderly persons with MDD.

Methods/Design

The study is designed as a multi-center cluster randomized controlled trial. BA, described as The Systematic Activation Method (SAM) will be compared with Treatment as Usual (TAU). We aim to include ten mental health care units in the Netherlands that will each participate as a control unit or an experimental unit. The patients will meet the following criteria: (1) a primary diagnosis of Major Depressive Disorder (MDD) according to the DSM-IV criteria; (2) 60 years or older; (3) able to read and write in Dutch; (4) have consented to participate via the informed consent procedure. Based on an effect size $d=0.7$, we intend to include 51 participants per condition ($n=102$). The SAM will be implemented within the experimental units as an adjunctive therapy to Treatment As Usual (TAU). All patients will be assessed at baseline, after eight weeks, and after six months. The primary outcome will be the level of depression measured by means of the Beck Depression Inventory (Dutch version). Other assessments will be activity level, mastery, costs, anxiety and quality of life.

Discussion

To our knowledge this is the first study to test the effect of Behavioral Activation as a nursing intervention in an inpatient elderly population. The medical research ethics committee for health-care settings in the Netherlands has approved this research (NL26878.029.09) and is listed in the Dutch Trial Register (NTR No.1809).

Introduction

Depression in later life is a common mental disorder. Prevalence rates for depressive symptoms range for minor depression approximately 10% (Beekman, Copeland & Prince, 1999), and for Major Depressive Disorder (MDD) 2% (Beekman, Deeg, van Tilburg et al. 1995). The prognosis of MDD in later life is poor: in three quarters of cases, the disorder becomes chronic (Beekman, Smit, Schoevers, 2002). MDD has serious consequences for everyday life (e.g. withdrawal from social activities, neglect of one's self-care), with a risk of increased health care consumption (Bijl & Ravelli, 1998; van het Land & Fotiadis, 2008). MDD has one of the largest disease burdens, comparable with other chronic diseases such as diabetes or COPD. About one third of patients with MDD will be referred to a mental health care facility (ambulatory or residential) (van het Land & Fotiadis, 2008). The elderly are particularly at risk of developing persistent MDD because of their vulnerability to physical illnesses, which may contribute to the onset and persistence of MDD (Alexopoulos, 2005).

The most common treatment modalities for MDD are antidepressant medication and psychological interventions (or a combination thereof) (NICE Clinical Guidelines, No. 90, 2010). Antidepressants seem to be efficacious in treating late-life depression, although the treatment outcomes may be less positive for the subpopulation of older elderly (Tedeschini, Levkovitz, Iovieno et al. 2010). There are several psychotherapeutic options in depression treatment. Among adults in general, these different options are comparable in their effectiveness (Cuijpers, van Straten, Warmerdam & Smits (2008). Recently, Behavioral Activation (BA) has gained renewed attention as an effective treatment modality in MDD. In BA, patients learn techniques to monitor their mood and daily activities and to gain insights into the connection between the two. The patients then learn how to develop a plan that increases the number of pleasant activities and positive interactions with their environment. A meta-analysis has demonstrated large effect sizes for BA interventions ($d=0.89$) when compared to a waiting list condition (Cuijpers, van Straten & Warmerdam 2007). Furthermore, direct comparisons between Cognitive Therapy (CT) and BA have demonstrated that the effectiveness of the two interventions is comparable (Dimidjian, Dobson, Kohlenberg et al., 2006; Jacobson, Dobson, Truax et al. 1996). Since BA seems to be more accessible for many patients than CT, BA might be a preferred treatment option. Another meta-analysis shows that, in general, psychotherapy seems to be as effective for older individuals as for younger adults (Cuijpers et al. 2008). However, this meta-analysis did not include studies focusing on severely depressed or hospitalized patients. In general, psychological treatments have been found to be less effective in outpatients with chronic depression (Cuijpers, van Straten, Schuurmans et al. 2010) and possibly severe depression (Elkin, Shea, Watkins et al., 1989) although the evidence is not conclusive (Driessen, Cuijpers, Hollon & Dekker, 2010).

Inpatient treatment remains an important treatment option for patients who cannot safely stay in their own environment (Wolpert, 2001). Many of these patients suffer from severe and chronic forms of depression, and effective treatment options are needed to improve their recovery and reduce their suffering. The number of studies on psychological treatment for inpatients is limited. Recently, we summarized those studies in a meta-analysis and demonstrated small but robust effects (Cuijpers, Clignet, van Meijel, et al., 2011) However, there was a considerable variation in treatment setting, content of treatment, number of sessions, and inclusion and exclusion criteria applied. Furthermore, the quality of most of the studies was not optimal.

To our knowledge, there is only one study in which BA is tested in an inpatient population (Hopko, Lejuez, Lepage et al., 2003) In this study, a total of 25 inpatient depressed adults were allocated either to BA (N=10) or to Supportive Psychotherapy (SP) (N=15). Despite the small sample, the study demonstrated the effectiveness of BA, with an effect size of 0.73. It is noteworthy that in this study, BA was executed by clinicians who had Master's degrees, although BA is supposed to be an intervention, which requires no complex skills.

The aim of study described in the present proposal is to examine the effects of BA when executed by nurses (RNs) in an inpatient population of elderly people with MDD. In this study, BA takes the form of a brief behavioral course of treatment lasting seven weeks, known as the Systematic Activation Method (SAM).

Methods/Design

Study design

The study is designed as a multi-center cluster randomized controlled trial with the participation of ten mental health-care facilities in the Netherlands according to the CONSORT statement (Rennie, 2001). The Systematic Activation Method (SAM) will be compared with Treatment As Usual (TAU) for inpatient depressed elderly.

The study has been approved by the medical research ethics committee for health-care settings in the Netherlands (No. NL26878.029.09) and is listed in the Dutch Trial Register (NTR No. 1809).

The units and randomization

The study will include ten mental health care units, which will be randomized to the experimental (SAM) or control (TAU) conditions. The following inclusion criteria will be used to select the units: (1) the units must specialize in the treatment of

elderly patients with psychiatric disorders; (2) there must be at least three registered nurses (RNs) available who are able and willing to execute the intervention. Units that specialize in a specific disorder or treatment method (e.g. Electro Convulsion Therapy) will be excluded from the study.

Within each mental health institute, the aim is to find two units, which are comparable. Matching of units is based on two criteria which will be applied in the following order: (1) level of restraint – both units should either be open or closed; (2) the presence of other treatments containing elements of the SAM, i.e. occupational therapy (because it focuses on activation), psychological treatment (because it focuses on influencing cognition).

For matching purposes, staff members at the participating units will be asked to fill in a self-developed evaluation form providing information on the specific features of the unit. This form includes a number of general questions concerning characteristics of the patient group, followed by more specific questions about the treatment program and level of restraint.

After matching the units into pairs, one unit will be allocated to the experimental condition and the other to the control condition. Allocation will be performed by an independent researcher (AvS) who will not maintain contact with the participating units. A random allocation generator will be used.

Inclusion and exclusion criteria

The following patient inclusion criteria will be applied: (1) a primary diagnosis of Major Depressive Disorder (MDD) according to the criteria of the Diagnostic and Statistic Manual of Mental Disorders fourth edition text revisions (DSM-IV-tr, American Psychiatric Association 2000). Patients with multiple diagnoses (e.g. comorbid personality disorder) are eligible as long as the primary diagnosis is MDD; (2) 60 years or older; (3) able to read and write in Dutch; (4) the patient must have consented to participation via the informed consent procedure.

Patients with severe cognitive problems (see below) will be excluded from this study because the intervention requires cognitive skills such as planning and evaluating activities and the structured monitoring of mood state.

Recruitment of the study sample

The participating units will keep a list of all newly admitted patients and their primary diagnosis. All patients older than 60 with a primary diagnosis of MDD will be approached by a staff member and informed about the study. Once verbal consent is

obtained and there are no cognitive problems according to the Minimal Mental State Examination (MMSE score ≥ 23) (Folstein, Folstein & McHugh, 1975) the patients will be approached by one of the researchers. Confirmation of the psychiatric diagnosis will be executed by means of a diagnostic interview using the MINI Plus, a standardized instrument to assess psychiatric disorders according to the DSM-IV criteria (Van Vliet, Leroy & Van Megen, 2002). Patients who satisfy the inclusion criteria will then be included in the study. Due to the nature of the intervention, it will not be possible to perform the study as either a single-blind or double-blind trial.

Intervention

We developed the Systematic Activation Method (SAM) as a brief behavioral nursing intervention, which focuses on increasing a positive mood change by increasing the number of positive activities. The SAM is based on Behavioral Activation (BA), developed by Lewinsohn and colleagues (Lewinsohn, Antonuccio, Steinmetz Breckenbridge, & Teri, 1984; Lewinsohn, 1974; Lewinsohn, Biglan & Zeis, 1976; Lewinsohn, & Graf, 1973; Lewinsohn, & Cuijpers, 1996; MacPhillamy & Lewinsohn, 1974) and Hopko et al. (2003). The underlying assumption is that positive reinforcement of a low response rate acts as an eliciting stimulus for depressive behaviors and serves as a sufficient explanation for inactivity in a depressed individual (MacPhillamy & Lewinsohn, 1974). The SAM is presented as a brief seven-week course. In order to make the SAM accessible for the elderly inpatient population, we have made some adjustments to the existing BA protocols. First, the goals of each session are described in the course book. This differs from the existing protocols, in which the first session is used for mutual goal setting. It is difficult to describe the overall goals of treatment for inpatient elderly with MDD; that is why the goals have been described at the beginning of each session. Second, the course is presented as a nursing intervention instead of a psychological intervention in order to increase its accessibility. Third, we simplified the activity logs to avoid overloading the patients. Fourth, the duration of the intervention has been shortened to seven weeks, in contrast to the existing treatment protocols, which last between eight and 15 weeks.

The SAM consists of six sequential steps: 1) monitoring the patient's mood; 2) having the patient execute pleasant activities, randomly selected from an existing list of 49 activities (Lewinsohn, & Graf, 1973); 3) having the patient develop a positive activity plan; 4) having the patient explore how to use external resources; 5) setting up an activity experiment; 6) evaluation and consolidation. There is a one-week time interval for each step except the third step (developing a positive activity plan), for which two one-week intervals are required. If necessary, the time interval between the sessions can be reduced or extend. Each session is highly structured and starts

with a review of the patient's homework. After that, the nurse and patient discuss the central theme of the session and the patient is given his or her homework assignments for the coming week. The SAM is described in more detail elsewhere (Clignet, Van Meijel, Van Straten, Lampe & Cuijpers, 2012).

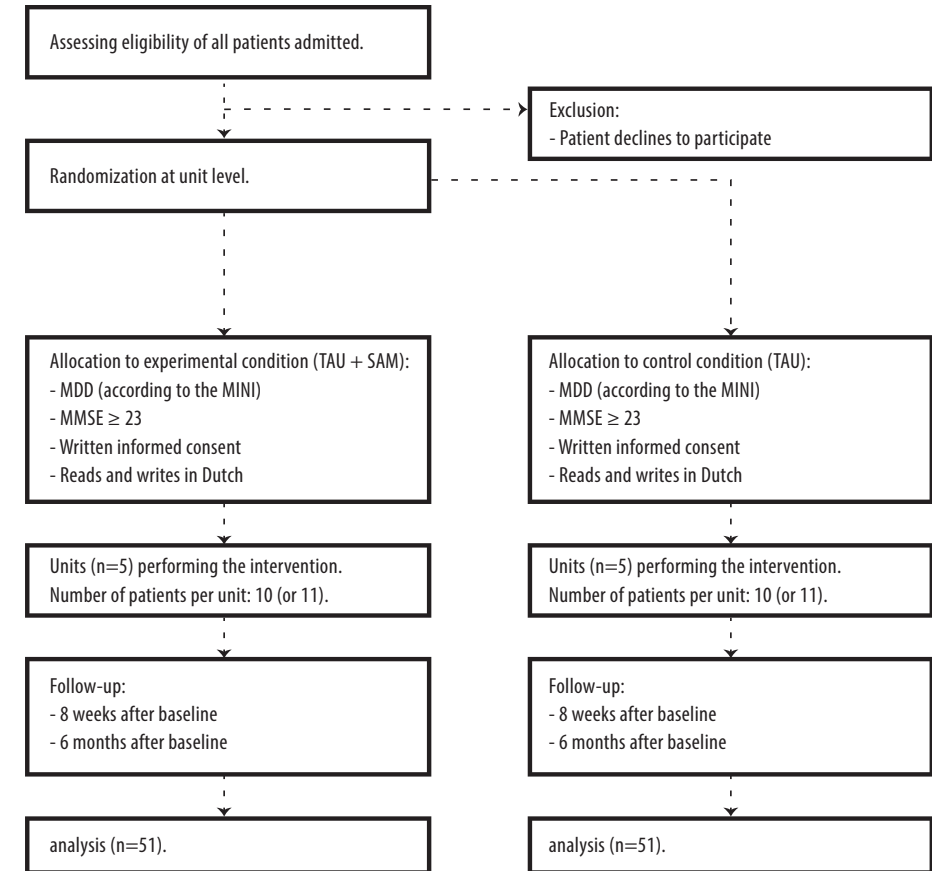


Figure 1: Flowchart

The SAM requires the patient's active involvement. This is often difficult due to the nature of MDD. The nurses participating in this study will therefore be given a brief training course of two four-hour sessions on guiding patients in executing the SAM. Training consists of two components. First, the nurses will be taught the structure and process of the SAM. Second, they will be trained in using motivational techniques. Many patients with MDD have difficulty engaging in structured activities, this being one of the essential components of the SAM. The use of motivational techniques is therefore vital for the effective execution of the SAM.

During the study, the participating nurses will receive training on the job, with the researcher visiting the units for in biweekly supervision meetings. In addition, the researcher will maintain telephone and e-mail contact. During the supervision meetings, the nurses will be invited to reflect on their experiences during execution of the SAM intervention and – in the event of problematic implementation – adjustments and alternative strategies can be discussed. The biweekly meetings will therefore be used to establish treatment integrity, along with a random audit of the course books and a written evaluation by the patients in order to register the received components of the SAM intervention.

The participating patients will receive the SAM as an individual adjunctive therapy combined with their existing primary treatment.

Control group.

The control group will receive Treatment As Usual (TAU). The most common treatment for patients with MDD is a combination of medication, occupational therapy and a form of psychological treatment such as Cognitive Behavioral Therapy (CBT) or Problem Solving Treatment (PST). Nursing care focuses on assisting patients in their self-care activities, and encouraging them to participate in the unit's daily activity program. Nurses also discuss the patient's overall progress on a regular basis (weekly or biweekly). TAU is recorded at unit level. Before participating in the study, the units describe their treatment program for MDD using a structured form developed by the authors. This form is based on the NICE standard for MDD (NICE, 2009) and the Dutch guideline for MDD (Centraal Beleidsorgaan voor intercollegiale toetsing, 2005).

Assessment

All patients will be assessed at baseline, after eight weeks, and after six months. Each assessment will involve patients filling in a questionnaire. At baseline, we will collect demographic data (gender, social status, education, and ethnicity) and some information about the disease history (former episodes of MDD, frequency and

nature of former treatments [outpatient treatments and/or clinical admittance], and psychiatric co-morbidity).

Primary outcome

Our primary outcome is the level of depression. This is measured by means of the Beck Depression Inventory, second edition (BDI-II-NL) (Beck, Steer & Brown, 1996; van der Does, 2002). The BDI-II is a self-report scale, which contains 21 items clustered in four response categories. The BDI-II is divided into two components, an affective component (e.g. mood) and a physical component (e.g. loss of appetite). The cut off scores are: 0 – 13 for minimal depression, 14 – 19 for mild depression, 20 – 28 for moderate depression, and 29 – 63 for severe depression. The Dutch version of the BDI-II has a high internal consistency (Chronbach's $\alpha \geq 0.90$) and a strong correlation with other depression instruments (Evers, van Vliet-Mulder & Groot, 2005).

Secondary outcome

Secondary outcomes are: level of activity, anxiety, mastery, quality of life, costs and health care use.

An Activity Log (AL) will be used to measure the level of activity. This is a form in which the patient fills in his or her activities over the past week. The AL contains a week schedule which is divided into morning, afternoon and evening activities. The patients will be asked to fill in the activities they have executed during the past week at baseline and after six months. The number of activities and the type of activity will be used to calculate the activity level of each patient.

The seven anxiety items of the HADS (Hospital Anxiety Depression Scale) (Zigmond & Snaith, 1983) will be used to measure anxiety. A four-point Likert scale is used to score the items (0 – 3) and the total score therefore ranges from 0 (no anxiety) to 21 (very anxious). The cut-off score is ≥ 8 , as an indication for an Anxiety Disorder.

Mastery will be measured by means of the Pearlin Mastery Scale (Pearlin & Schooler, 1978). This is a five-item self-report scale measuring internal locus of control. The items are presented as statements to be scored on a five-point Likert scale. The scores on the Pearlin Mastery Scale range from 5 (minimum level of mastery) to 25 (maximum level of mastery).

Quality of life will be measured by means of the SF 36 (MOS Short Forms Health Survey) (Ware, Snow, Kosinski, Gandek, 1993). The scale contains 36 questions divided into eight subscales with three underlying dimensions: (1) Functional Status: physical

functioning (10 questions), social functioning (2 questions), role functioning – physical problems (4 questions), role functioning – emotional problems (3 questions); (2) Welfare: mental health (5 questions), vitality (4 questions), pain (2 questions); (3) Evaluation of health care: general health perception (5 questions), change in health care (1 question). The response options vary from dichotomous to a six-point Likert scale. The SF-36 was translated into Dutch by Van der Zee & Sanderman (1993).

Costs will be measured by means of the TiC-P (Trimbos/iMTA questionnaire for costs associated with Psychiatric Illness) (Hakkaart-van Roijen, van Straten, Donker & Tiemens, 2002).

This questionnaire consists of two parts: direct costs of care consumption and indirect costs of care consumption. The TiC-P is a broad questionnaire, which can be adjusted to the relevant population.

This study will make use of the categories ‘care consumption’, ‘informal care consumption’, and ‘use of medication’. All items have dichotomous ‘yes/no’ response options. The questionnaire will be completed by the patient as a self-report instrument. Table 1 provides an overview of the instruments.

| Instrument | Time Inclusion | T0 | T1 = 8 weeks after T0 | T2 = 6 months after T0 |
|--------------------------------|----------------|----|-----------------------|------------------------|
| Cognition: MMSE | X | | | |
| Diagnosis: MINI | X | | | |
| Baseline | | X | | |
| Depression: BDI-II-NL | | X | X | X |
| Mastery: Pearlin Mastery Scale | | X | X | X |
| Anxiety: HADS-A | | X | X | X |
| Quality of life: SF-36 | | X | X | X |
| Health care costs: TiC-P | | X | | X |
| Activity Log | | X | | X |

Statistical analyses

The primary outcome is level of depression as measured with the BDI-II-NL (van der Does, 2002). This outcome will be used to test the effect of the SAM as a nursing intervention in inpatient depressed elderly compared with TAU. The SAM is considered effective if there is a significant decrease in the level of depression in the treatment group compared to the control group. To test the effects of the SAM intervention, a linear mixed model will be used. In order to investigate differences in demographic

and clinical variables, t-tests and Chi-square tests will be executed in which the baseline characteristics are used as covariates. Furthermore effect sizes will be calculated by subtracting the mean within difference from the two groups and by dividing them by the pooled standard deviation. Effect sizes of 0.00–0.32 can be considered as small, 0.33–0.55 as medium, and >0.56 as large (Lipsey, 1990; Lipsey Wilson, 1993). Data will be analyzed according to the ‘intention-to-treat’ principle as well as the ‘completers only’ principle. In order to correct for missing values, Last Observation Carried Forward and Multiple Imputation will be used as a sensitivity analysis.

Secondary outcome variables are quality of life (SF-36), costs (TiC-P), level of mastery (Pearlin Mastery Scale) and activities (Activity Log).

Anxiety is considered a co-variable because of its close association with MDD.

Sample size

Effect sizes (d) will be used to calculate the sample size. A meta-analysis by Cuijpers et al. (2007) found an overall effect size of d=0.87 in favor of Behavioral Activation (BA) compared to a waiting list condition. A study in an inpatient population found an effect size of d=0.73 in favor of BA compared to supportive therapy (Hopko et al. 2003).

Our study will be performed in an inpatient elderly population with severe MDD. Because of the large effect sizes in previous studies, an effect size of d=0.7 is expected. With $\alpha=0.05$ and a power (1- β) of 0.8, 34 patients are needed per condition. In other studies (Persons, Burns, & Perlof, 1988; Cuijpers et al. 2007), the dropout rate shows a large variability (2% – 50%). For this study, we assume an average dropout rate of 25%. Another rule of the thumb is to increase the study population by 25% when patients are randomized at ward level. That means that 51 patients are required for each condition. In total, 102 patients will be included in this study. The sample size will be calculated using the G*power 3.0 software program (Faul, Erdfelder, Lang, Buchner, 2007).

Discussion

This study will test Behavioral Activation (BA) as a nursing intervention in an inpatient elderly population. The study is innovative in two respects. First, in previous studies psychologists with Master’s degrees carried out this intervention (Cuijpers et al., 2007; Dimidjan et al., 2006; Hopko et al., 2003). In our study, BA has been adapted to make it a nursing intervention – the SAM – to be carried out by registered nurses (Clignet et al., 2012). This makes BA more accessible for a larger group of patients.

Second, to our knowledge, most of the research on BA has mainly been conducted in outpatient adult populations. Only one other study (Hopko et al. 2003) was executed in an inpatient adult population (N=25) and, as far as we are aware, there are no studies in elderly inpatient populations. Studies in the elderly population are relatively scarce and have focused on outpatients (Thompson & Gallagher, 1984; Thompson, Gallagher & Breckenridge, 1987) or depression in combination with dementia (Teri, Logsdon, Uomoto & McCurry, 1997; Verkaik, Francke, van Meijel et al. 2010). To our knowledge, this is the first BA effect study in an elderly inpatient population worldwide.

In addition to the innovative nature of this study, there are some difficulties concerning the study design. First, the study is vulnerable to selection bias. The SAM will be implemented in five mental health care units, and decisions regarding patient inclusion will depend partially on the anticipated efforts of the staff nurses. In order to minimize selection bias, the researcher will make an initial selection of eligible patients. Despite this, however, selection bias cannot be ruled out entirely, because it is ultimately the nurse who must motivate the patient to participate in the study, and this is expected to depend on the nurses' belief that the SAM will be helpful for the patient. This may lead to selection bias in the experimental group, while the selection of patients in the control group will probably be free of bias. We will correct for any differences between the two groups.

This study will furthermore be vulnerable to information bias because a blind trial at intervention level is not possible. In order to avoid information bias, only self-report scales will be used in this study.

Finally, the standardized execution of the intervention is a point of concern. The SAM will be implemented at five units for elderly persons with psychiatric disorders. Although the SAM is presented as a highly prescriptive intervention, we expect that – due to differences in patient characteristics – individual variations in the execution of the SAM may occur that will be difficult for the researchers to control. Coaching meetings will be organized to promote treatment integrity.

Ethical considerations

In the experimental condition, the SAM will be implemented as an adjunctive treatment modality. This means that patients with MDD will have an opportunity to benefit from the SAM while receiving treatment as usual. Although the study is intended for a broad category of patients, some patients will be excluded from the study, even though the nurses believe they could benefit from the SAM or parts thereof. These patients will also have an opportunity to engage in the SAM, but they will not be included in the study.

The SAM will be implemented in the control group units after all the patients have been included.

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5

The effectiveness of Behavioral Activation in hospitalized depressed elderly: A Pragmatic Clustered Randomized Clinical Trial.

- submitted -

Key words

Behavioral Activation, Inpatient
Depression Nursing
Elderly

Abstract

Background: Psychological treatments for elderly inpatients with MDD are beneficial but scarcely offered. Behavioral Activation (BA) provided by nurses, might be a useful solution. In the present study, we examined the effectiveness of a BA program, which we called the “Systematic Activation Method (SAM)”.

Design: A pragmatic multicenter cluster-randomized clinical trial. Ten hospital units were randomized to either experimental units where the SAM was provided (n=5), or to control units where the patients received care as usual (n=5). Outcome variables were depression, anxiety and mastery, which were measured at baseline (T0), post-intervention (T1=eight weeks after T0) and follow-up (T2 = six months after T0).

Results: 55 patients were included in the study (n=30 experimental, n=25 control). The results showed that (1) depressive symptoms decreased significantly during the intervention period for both the intervention and control patients; (2) there were moderate post-intervention effects of SAM in the reduction of depressive symptoms (g=0.35), level of anxiety (g=0.18) and level of mastery (g=0.31), but these effects were not statistically significant; and (3) at follow-up the drop-out rates of the intervention group were high (response 37%) and thus follow-up results are tentative.

Conclusion: BA might have a small to moderate effects on depression, anxiety and mastery for inpatient elderly with MDD, but the results are inconclusive because of a lack of statistical power.

This trial is listed in the Dutch Trial Register as NTR 1809 and approved by the medical research ethics committee for health care settings in the Netherlands (NL26878.029.09).

Introduction

A Major Depressive Disorder (MDD) is a prevalent condition, which affects about one in six persons in their life-time (Volkert Schulz, Härter, Włodarczyk, & Andreas, 2013). Point prevalence estimates for affective disorders among the elderly (55 years and older) vary enormously but seems to be about 10% for minor depression and 2% for MDD (Beekman, Copeland & Prince, 1999). The prognosis for MDD among the elderly is generally poor: more than 40% has an unfavorable but fluctuating course and in about a third of the cases there is a severe and chronic course (Beekman et al. 2002). Some of those chronic and severe cases need hospitalization.

There are several effective psychological treatments available for MDD, which also seem to be effective among the elderly (Polenick & Flora, 2013; Cuijpers, Karyotaki, Pot, Park & Reijnders III, 2014). However, these studies have generally been conducted in outpatients and there is some discussion about their effectiveness for the most severe and disabled populations (Brand & Clingempeel, 1992, Snarski et al. 2011). A meta-analysis on the effects of psychological treatments for hospitalized depressed patients showed a small (hedges $g = 0.29$) but statistically significant effect compared to usual care including pharmacological treatment. There were no statistically significant differences in effects between the different types of treatments although the treatments based on Behavioral Activation (BA) showed a non-significantly higher effect size (hedges $g=0.56$) than CBT ($g = 0.19$) and other therapies (such as, interpersonal therapy, problem solving treatment $g=0.30$ (Cuijpers, Clignet, van Meijel, van Straten, Li & Andersson, 2011).

Even though psychological treatments seem to be moderately effective they are not commonly offered to inpatients, and psychotherapists in inpatient settings are scarce. The most common treatments in routine inpatient care are medication, occupational therapy, and psychosocial support delivered by nurses (National Institute for Health and Clinical Excellence (NICE), 2009; Kok, 2008). An effective and probably viable option in inpatient care might be to use psychiatric nurses to deliver protocolled evidence-based psychological treatments. Behavioral Activation (BA) seems to be the best candidate because of its effectiveness and because the treatment is relatively easy to carry out. A recent study demonstrated that BA yields the same effect as Cognitive Behavioral therapy (Dimidjian et al. 2006), while BA can be delivered by less highly trained staff (Richards et al, 2016).

BA aims to make patients aware of the association between mood and the number of pleasant activities. The first step is to monitor mood and positive activities. The patient will become aware that his mood is slightly better after having been engaged in pleasant activities. The next step is to increase those positive activities. This in turn will lead to a

further improvement in mood. In BA, the therapist serves as a coach to re-engage patients with pleasant activities while monitoring mood and thus creating positive reinforcements (Lewinsohn & Cuijpers, 1996).

In the present study, we investigated the effectiveness of BA delivered by nursing staff in inpatient elderly with MDD.

Methods

Design

A pragmatic multicenter cluster-randomized clinical trial was conducted between May 2009 and April 2011 according to the CONSORT criteria (Rennie, 2001). Hospital units were randomized to either experimental units where patients received SAM as an adjunctive intervention (next to care-as-usual), or control units where the patients only received care-as-usual. This trial is registered in the Dutch Trial Register as NTR 1809. The study protocol is described in detail by Clignet, Van Meijel, Van Straten and Cuijpers (2012a). The study was approved by the Medical Ethics Committee of the VU Medical Center.

Psychiatric hospitals

The study was conducted in ten inpatient mental health units in six psychiatric hospitals in the Netherlands. These units provide treatment for elderly (≥ 60 years) patients with different types of mental disorders, with the exception of dementia. Two units were restricted (meaning that patients could only leave the building after permission of the staff) and eight were open (meaning that patients could leave if they want).

Initially, we approached 14 mental health units for participation. Two units declined and two were excluded because they could not deliver sufficient staff to carry out the interventions due to reorganizations. The remaining 10 units were matched in five pairs of two comparable units. Matching was based on level of restraint (open or closed units), and an estimation of the average time spent on occupational therapy and other therapeutic activities. The matched units were randomized by an independent researcher with a random allocation generator. After inclusion of a unit the independent researcher revealed the condition to the principal investigator. This means that the randomization allocation was blinded.

In- and exclusion criteria

All patients admitted to one of the ten included units could potentially participate. They had to suffer from a Major Depressive Disorder (MDD) according to the Diagnostic and Statistical Manual for Mental Disorders fourth edition (DSM-IV; American Psychiatric Association, 2000). This had to be the primary diagnosis or the secondary one next to an anxiety disorder. The principal researcher (FC), using the MINI International Neuropsychiatric Interview (Van Vliet, Leroy & Van Megen, (2000), ascertained the diagnosis. Other inclusion criteria were: a) age 60 years or older; b) able to read and write in Dutch; c) giving written informed consent. The only exclusion criterion was: cognitive impairments. This was measured with the Minimal Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975). Patients with a MMSE score of 23 or lower were excluded.

Recruitment procedure

The main research nurse (FC) weekly visited every participating unit to check for newly admitted patients with MDD as a primary or secondary diagnosis. Those who were eligible were then informed about the study by nurses working on the unit. They handed out the information brochure, the informed consent form and the baseline questionnaire. Those patients who were willing to participate were then contacted for a telephone interview with the main research nurse. During this interview, the study was further explained, if necessary, and the MINI and the MMSE were administered. The signed informed consent forms and baseline questionnaires were gathered during the next site visit.

The Intervention

We called our BA intervention, specifically for this older inpatient groups and adapted for use by mental health nurses in their daily practice, the Systematic Activation Method (SAM). The SAM aims to reduce depressive symptoms by increasing positive activities. It is a highly structured seven-week course: week 1- monitoring mood on a 10-point scale (0 = I feel very bad to 10 = I feel very good) three times a day (morning, afternoon, evening) for a week; week 2- increasing the number of pleasant activities. To stimulate their memory about pleasant activities we used the "pleasant activity list" (Lewinsohn PM and Amenson 1978; MacPhillamy DJ, Lewinsohn, 1982), which contains 49 activities. The patient is asked to engage in some pleasant activities for one week and simultaneously monitor his or her mood 3 times a day; week 3 and 4- the patient is asked to engage more structurally in positive activities by planning his or her positive activities in advance; week 5- the patient explores how to use external resources (friends or relatives) to support them during the execution of the positive activity plan; week 6- the patient sets up an Activity Experiment in which the patient

engages in a positive activity, which he or she believes is very difficult to execute. The aim of an Activity Experiment is to challenge the patient's negative assumptions that he or she will be unable to perform the activity because it is too difficult; week 7- the patient learns how to use the SAM in relapse prevention by discussing his or her strengths and the possible pitfalls

These steps are described in a course book, which every patient receives at the start. It contains all the necessary schemas and diaries. Coaching took place individually by registered nurses from the participating unit. On average, the nurse met with the patient once a week to discuss the progress. The aim of the coaching was to further explain the homework (if needed) and to stimulate patients to engage in the therapy. On average, the coaching took about 45 minutes per week per patient.

Prior to the implementation of the SAM in the units, the nurses were trained by a registered nurse with additional education at master level. The training consisted of two four-hour sessions in which attention was paid to the theoretical underpinning of the intervention program, the use of motivational techniques and the way the SAM was executed. In order to maximize treatment integrity, biweekly supervision meetings at the unit were organized, and additional consultation was provided via telephone or e-mail. We measured adherence to the intervention by asking patients to fill out how many lessons and homework assignments they had performed. The intervention is described in more detail by Clignet, Van Meijel, Van Straten, Lampe & Cuijpers. (2012).

Care-as-usual

All participants (experimental and control) received Care-as-Usual (CAU). CAU in inpatients usually consists of occupational therapy, medication, and other therapeutic activities. We monitored the use of psychiatric medication for each patient. The other therapeutic activities were not measured at patient level but the average number of hours for a typical week per unit was assessed. We assessed the following components of the typical week program: total number of hours occupational therapy was provided (including activities such as hobby training, art classes etc.), total number of hours possible other forms of psychotherapy were provided (group or individual), and the average time of individual contacts with a psychiatrist and with a nurse.

Data collection and measurements

All data were collected through self-report paper and pencil questionnaires. We measured: at baseline (T0), eight weeks later (post intervention=T1), and six months later (follow-up=T2). At baseline, we registered socio-demographic characteristics

(age, gender, nationality, marital status, educational level), information about former episodes of MDD, previous treatment for mental health problems, co-morbid physical or psychiatric diseases, cognitive status and current medication use. At each assessment we measured depressive symptoms (primary outcome), and symptoms of anxiety and level of mastery (secondary outcomes). Depressive symptoms were measured by the Dutch version of the Beck Depression Inventory, second edition (BDI-II-N; Beck & Steer & Brown, 1996; Van der Does, 2002) that contains 21 items. All items are rated on a four-point Likert scale (0= no problems to 3= severe problems). The total score ranges from 0 (no depression) to 63 (severe depression). Anxiety was measured because of its high comorbidity with depression (Hirschfeld, 2001). It was measured by the Anxiety subscale of the Hospital Anxiety Depression Scale (HADS-A) (Zigmond & Snaith, 1983). This subscale includes 7 items, which are rated on a four-point Likert scale (0= no problems to 3= severe problems). The total score ranges from 0 (no anxiety symptoms) to 21 (severe anxiety symptoms). Increasing mastery is one of the main working mechanisms of SAM. The level of mastery was assessed with the five-item Pearlin Mastery Scale (Pearly & Schooner, 1978). The items are rated on a five-point Likert scale (1= no control to 5= maximum control). The total score ranges from 5 (low mastery) to 25 (high mastery).

Statistical analyses

To test if randomization had been successful we examined the differences between the intervention and control group at baseline. We used independent t – tests for continuous data and chi-square tests for categorical data.

To answer the primary research question (whether the SAM is considered an effective adjunctive intervention compared to care-as-usual) we used two statistical procedures. First we used multilevel linear models. These models take account the hierarchical structure of the data (unit and patient level) and calculate the changes in the dependent variables over time. The model included a between-factor (group: experimental vs. control) and a within-factor (time: T0, T1, and T2). We examined for each of the dependent variables (BDI, HADS-A, PMS) a group main effect, a time main effect, and a group*time interaction effect. A first order autoregressive level-one error structure was used in the final model, as it was the only structure that showed convergence.

Secondly, we calculated the size of the effects with Hedges' *g* (and their 95% confidence intervals). We used intention-to-treat analyses and imputed missing data. First, we imputed the missing values on item level by using a corrected item mean. This means that the item score is estimated based on the overall mean performance of the person on the questionnaire as well as the mean performance on the items

across persons (Kadengye, Ceulemans & Van den Noortgate, 2012; Van Ginkel & van Ark, 2005). Second, we imputed total scores for patients who did not fill out the questionnaire at all. We used the multiple imputation procedure (using Fully Conditional Specification) as provided in the SPSS software package and described by Van Buuren (2007). We created twenty datasets and Hedges'g was calculated on pooled means and standard deviations of these datasets.

Hedges' g is calculated by subtracting the mean between group scores and by dividing them by the pooled standard deviation, adjusted for small sample bias. Effect sizes of 0.00–0.32 can be considered as small, 0.33–0.55 as medium, and >0.56 as large (Lipsey, 1990; Lipsey & Wilson, 1993).

For the calculation of Hedges' g we used an effect size calculator (derived from <http://www.cem.org/effect-size-calculator>, 03-17-2015). All other analyses were performed in SPSS 20.

Results

Participants' flow

A total of 704 patients were admitted to the participating units during the inclusion period (May 2009-April 2011) and 294 of them were potentially eligible for inclusion because they were admitted with a MDD as a primary or secondary diagnosis. Of this group, 23 patients were excluded because they were too severely cognitively impaired or did not meet criteria for depression during our MINI interview. Another 152 patients declined participation, 45 were discharged before inclusion could take place, and 19 were not included for other reasons (e.g. admittance to a general hospital for surgery). Thus, a total of 55 participants were included in the study: 30 were allocated to an intervention unit and 25 to a control unit (see flowchart, Figure 1).

Of the 55 patients, 10 (18%) patients dropped out at T1 (n=3 control group, n=7 experimental group). At T2 a further 12 patients dropped out (all experimental group). The total drop-out at T2 was 22 (40%). The baseline characteristics of the patients who dropped out at T2 did not differ significantly from the patients who completed the entire study. The reasons for dropout are described in fig. 1.

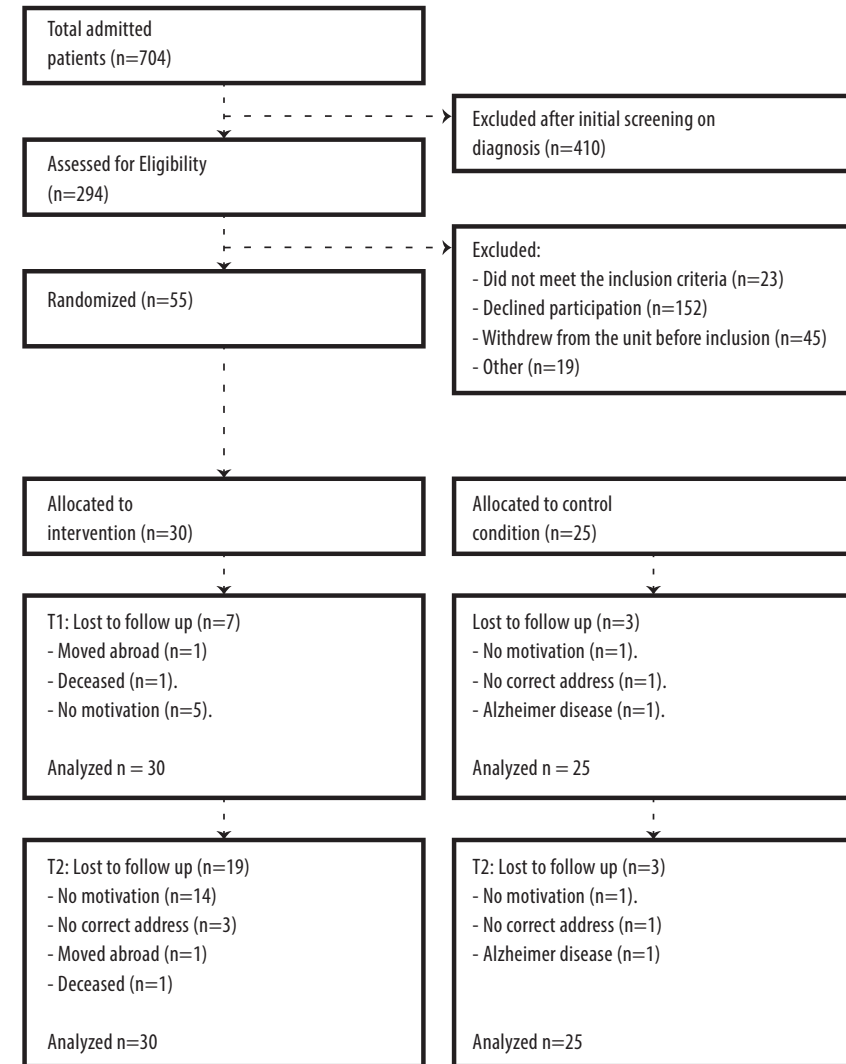


Figure 1: flowchart of the patients

Description of the sample

The baseline characteristics of the 55 participants are summarized in table 1. The average age was 73 years (SD \pm 7.78) and most of the participants were female (n=34, 61.8%). Furthermore, about half of the participants were living alone (n=29, 52.7%), most were of Dutch origin (n=51, 92.6%), about half had 10 years or less of formal education (n=26, 52%) and about a third (36%) had four or more co-morbid physical diseases. Almost all participants (n=44, 80%) had a history of depression and almost 30% had been hospitalized three times or more in the past. The mean depression score (BDI) was 26.29 (SD \pm 9.53) and the mean anxiety score (HADS) was 10.98 (SD \pm 3.77). The mean Mastery score was 11.37 (SD \pm 3.88). There were no statistically significant differences at baseline between the people in the intervention and control group.

Table 1: Differences in baseline characteristics between the intervention and control group.

| Characteristic | Total | Intervention (n=30) | Control (n=25) | P value |
|--|----------------|---------------------|------------------|-------------------|
| Age, mean \pm SD | 73 \pm 7.78 | 73,4 \pm 7.6 | 72,5 \pm 8.2 | 0.68 ^a |
| Female n (%) | 34 (61.8) | 18 (60.0) | 16 (64.0) | 0.76 ^b |
| Living alone n (%) | 29 (52.7) | 16 (52.2) | 13 (53.3) | 0.92 ^b |
| Education \leq 10 years n (%) | 29 (52) | 18 (60) | 11 (44) | 0.24 ^b |
| Non Dutch origin n (%) | 4 (7.4) | 2 (6,7) | 2 (8) | 0.85 ^b |
| \geq 4 somatic diseases n (%) | 20 (36.4) | 13 (43) | 7 (28) | 0.24 ^b |
| History of depression n (%) | 44 (80) | 25 (89.3) | 19 (76) | 0.20 ^b |
| \geq 3 previous psychiatric admissions n (%) | 16 (29.1) | 8 (28,6) | 8 (32) | 0.79 ^b |
| Depression score (BDI) mean \pm SD | 26.3 \pm 9.5 | 28.2 \pm 9.8 | 24.30 \pm 8.9 | 0.14 ^a |
| Anxiety score (HADS) mean \pm SD | 11.0 \pm 3.8 | 11.7 \pm 3.3 | 10.1 \pm 4.1 | 0.12 ^a |
| Pearlin Mastery Scale, mean \pm SD | 11.4 \pm 3.9 | 10.9 \pm 3.4 | 11.9 \pm 4.4 | 0.26 ^a |
| Cognitive functioning (MMSE), mean \pm SD | 27,9 \pm 2.1 | 27,62 \pm 2.07 | 28,22 \pm 2.09 | 0.31 ^a |

a= T-test, b= Chi square test

Care as Usual

The average length of clinical admission in both groups was approximately 100 days (experimental group 95 days; SD=58), control group 104 days (SD=73; p = 0.65). Eight weeks after baseline, at T1, about half of the patients were still hospitalized (57% control group; 48% experimental group), about a quarter were discharged but still receiving outpatient care (33% control group; 22% experimental group) while the remaining patients were discharged without any further care (5% control group & 30% experimental group).

There were no significant differences between the two groups in the percentage of patients using anti-depressant medication (SSRI's: control group=50% & experimental group=47,4%, SNRI's; control group=0% & experimental group=5.3%, TCA's; control group=45% & experimental group=36.8%) or benzodiazepines (control group=65% & experimental group= 68.4%) at post intervention (T1). The use of antipsychotics however, differed significantly: 45% of patients in the control group used antipsychotics compared to 15.8% in the experimental group at post intervention (T1; p=0.05).

There were no significant differences between the two groups in in the amount of time spent in a typical week on occupational therapy (control group= 9 hs p/w \pm SD 4.7 & experimental group= 15 hrs p/w \pm SD 6.2), psycho-therapy group (control group= 2 hrs p/w \pm SD 1.2 & experimental group= 2 hrs p/w \pm SD 1.6), psychotherapy individual (control group= 1hrs p/w \pm SD 1.3 & experimental group= 1 hrs p/w \pm SD 2.3), weekly contact with a psychiatrist (control group= 30 minutes p/w \pm SD 15 & experimental group= 17 minutes p/w \pm SD 12.6) and weekly contact with a nurse (control group= 56 minutes p/w \pm SD 7.5 & experimental group= 69 minutes p/w \pm SD 61.5).

Treatment adherence and evaluation

Of the 30 patients randomized to the intervention 17 (57%) returned the evaluation form about the intervention. On average the SAM was executed for a period of five weeks with an average of four meetings with a nurse. About a quarter of the patients (24%) participated in the SAM for three weeks or less, almost half of the patients (47%) participated for four or five weeks, while the remaining patients (29%) participated for six weeks or more. With respect to the number of meetings, 29.4% of the participants had 0-2 two meetings, 29.4% had four or five meetings and 17% had six meetings. One patient had ten meetings.

Post intervention effects

At post-test there were no significant differences in mean scores between the experimental and control group on depression, anxiety or mastery (Table 2). The post-test between-group effect sizes were (very) small. We also calculated between group effect sizes for the change scores (T0-T1). The experimental group improved more ($g=0.35$ 95% CI= -0.19 – 0.88) on depression than the control group. The same was true for anxiety ($g=0.18$ (95% CI= -0.35 – 0.72) and mastery ($g=0.31$; 95% CI= -0.24 – 0.84). However, as can be seen from the 95% confidence intervals, none of the effect sizes were statistically significant.

Table 2: Mean (pooled-means) scores on primary and secondary outcomes and the between group effect sizes (Hedges g) and their 95% confidence interval.

| Instrument/ time | | Experimental group (n=30) mean ± SD | Control group (n=25) mean ± SD | Hedges' g | 95% Confidence interval for effect size | | P value |
|------------------|-------|---|--------------------------------------|-----------|---|-------|---------|
| | | | | | lower | upper | |
| BDI | T0 | 28.20 (9.84) | 24.29 (8.78) | | | | |
| | T1 | 18.85 (17.64) | 19.80 (13.67) | 0.06 | -0.59 | 0.47 | 0.82 |
| | T2 | 21.99 (5.48) | 18.45 (11.93) | -0.39 | -0.92 | 0.15 | 0.45 |
| | T0-T1 | 9.35 (15.77) | 4.20 (13.49) | 0.35 | -0.19 | 0.88 | 0.18 |
| | T1-T2 | 2.84(16.22) | -1.21 (9.01) | -0.45 | -0.83 | 0.24 | 0.30 |
| HADS-A | T0 | 11.7 (3.34) | 10.12 (4.13) | | | | |
| | T1 | 9.21 (6.32) | 8.62 (5.88) | 0.09 | -0.44 | 0.63 | 0.71 |
| | T2 | 10 (11.56) | 9.75 (5.23) | -0.03 | -0.50 | 0.56 | 0.92 |
| | T0-T1 | -2.49 (5.77) | -1.50 (4.66) | 0.18 | -0.35 | 0.72 | 0.68 |
| | T1-T2 | -0.86 (10.37) | -1.03 (3.53) | 0.02 | -0.51 | 0.55 | 0.94 |
| PMS | T0 | 10.86 (3.17) | 11.69 (4.57) | | | | |
| | T1 | 13.87 (6.68) | 12.57 (5.52) | 0.21 | -0.32 | 0.74 | 0.41 |
| | T2 | 11.47 (12.18) | 14.07 (8.74) | -0.24 | -0.77 | 0.29 | 0.40 |
| | T0-T1 | 2.95 (7.55) | 0.56 (8.10) | 0.31 | -0.23 | 0.84 | 0.26 |
| | T1-T2 | -2.57 (8.73) | 1.43 (5.91) | -0.52 | -1.06 | 0.02 | 0.13 |

The linear mixed model showed that both groups improved significantly between baseline and post-test on depression (BDI; $F(1, 131)=10.89$, $p=0.01$), anxiety (HADS; $F(1, 128)=5.49$, $p=0.02$) and mastery (PMS; $F(1, 85)= 9.74$, $p=0.02$; Table 3). The model also showed that there were no significant differences in improvement between the

experimental and control group. This was true for depression (BDI; $F(1, 131)= 1.141$ $p=0.29$), anxiety (HADS; $F(1, 128)= 0.890$ $p=0.35$) as well as for mastery (PMS; $F(1, 85)=1.03$ $p=0.31$).

Effects at follow-up

Six months after baseline there were no statistically significant differences in depression, anxiety or mastery scores between the experimental and control group. The scores for depression and mastery were worse in the intervention group than in the control group. The corresponding between group post-test effect sizes were $g=0.39$ (95% CI= -0.15 – 0.92, $p= 0.18$) and $g=0.24$ (95% CI=-0.77 – 0.29, $p=0.40$). For anxiety, the effect size was close to zero ($g=-0.03$, 95% CI= -0.50 – 0.52, $p=0.92$). Again, we also compared change scores (between post-test and follow-up) thus taking into account any post-test differences. The effect sizes for depression and anxiety remained almost the same. The effect size for mastery increased ($g= 0.52$, 95% CI= -1.06 – 0.02, $P=0.13$) in favor of the control group. The results were not statistically significant.

The linear mixed model showed that there were no statistically significant improvements between post-test (8 weeks after baseline) and follow-up (6 months after baseline). The depression, anxiety and mastery scores remained unchanged. In addition, the linear mixed model showed that there were no significant differences in improvement (or deterioration) between the experiment and control group between T1 (8 weeks) and T2 (6 months). Again, this was true for depression (BDI; $F(1; 130)=0.04$ $p=0.95$), anxiety (HADS-A; $F(1;125)=1.09$ $p=0.30$) and mastery (PMS; $F(1;84)=0.12$ $p=0.73$).

Table 3: Linear Mixed Models.

| | Group differences | | | T0 vs T1 | | | T1 vs T2 | | | Group*T0 vs T1 | | | Group*T1 vs T2 | | |
|------|-------------------|------|------------|----------|------|--------------|----------|------|------------|----------------|------|------------|----------------|------|------------|
| | b | bSE | 95% CI | b | bSE | 95% CI | b | bSE | 95% CI | b | bSE | 95% CI | b | bSE | 95% CI |
| BDI | -1.29 | 2.13 | -5.51-2.93 | 5.96 | 1.96 | 2.08-9.84* | 2.24 | 1.96 | -2.66-7.14 | -2.91 | 2.73 | -8.31-2.48 | -0.20 | 3.11 | -6.35-5.96 |
| HADS | -0.36 | 0.85 | -2.03-1.32 | 1.78 | 0.75 | 0.28-3.28* | 1.00 | 0.95 | -0.88-2.88 | -1.02 | 1.08 | -3.17-1.12 | -0.713 | 1.23 | -3.15-1.73 |
| PMS | -0.41 | 1.11 | -2.64-1.83 | -1.68 | 0.60 | -2.860-0.49* | -0.41 | 0.74 | -1.89-1.07 | 0.82 | 0.81 | -0.79-2.43 | -0.33 | 0.93 | -2.18-1.53 |

All outcomes marked with $*=p<0,05$. Other outcomes are not significant.

Discussion

In this study on inpatient elderly patients with a depression we examined the effects of Behavioral Activation (BA), which was offered by nurses in routine care in comparison to care as usual. The results showed that (1) depressive symptoms decreased significantly during the intervention period for both the intervention and control patients; (2) there were moderate post-intervention effects of SAM in the reduction of depressive symptoms ($g=0.35$), level of anxiety ($g=0.18$) and level of mastery ($g=0.31$), but these effects were not statistically significant; and (3) at follow-up CAU non-significantly outperformed SAM. However, since the drop-out rates of the intervention group were high (response 37%) these results are tentative.

One of the main reasons for the non-significant post-test results may be the lack of statistical power. Power was calculated, based on previous research (Hopko, Lejuez, Lepage, Hopko & McNeil, 2003; Cuijpers et al. 2007), with an estimated effect size of $d=0.7$ ($\alpha= 0.05$, power $1-\beta= 0.8$). We aimed to include 102 participants (Clignet et al. 2012a) but only managed to include 55. This low number of patients, together with the lower than expected effect size, means that our study was underpowered to demonstrate the effects with statistical significance. Post hoc power analysis, showed that we should have included 260 participants in order to have been able to demonstrate the effect size of $g=0.35$ for depression with significance (Faul, Erdfelder, Lang & Buchner, 2007).

The low inclusion rate was mainly due to the higher than expected rate of patients declining to participate in the trial. More than 50% of the eligible patients declined mostly because they were not motivated enough. This lack of motivation is due to the nature of MDD itself, but it is also possible that the nurses in the units lacked adequate skills to motivate patients or lacked motivation themselves. Our study was based on the assumption that BA is a treatment modality, which is easy to carry out, and is therefore also suitable for patients with more severe depressive disorders (Dimidjan et al. 2006; Cuijpers et al. 2007). Unfortunately, this did not seem to be true. It must be stressed though that compared to other studies with similar populations (Snarsky et al. 2011; Cuijpers et al. 2014; Brand & Clingempeel, 1992; Hopko et al. 2003) this study can still be considered as large.

Previously, high effect sizes were found for BA in outpatient settings Cuijpers et al. 2007) as well as in inpatient settings (Hopko et al. 2003). There are two reasons, which could explain the low to moderate effect sizes we found. Firstly, because treatment integrity was lower than expected. Therefore it is likely that the contrast between the control and intervention condition was too small to show a larger effect. The low

treatment integrity was partly caused by a lack of motivation but also by patients being discharged before having been able to finish the intervention. Low treatment integrity was also found in other studies as an important factor for non-significant results (Dozeman et al. 2011; Snarski et al. 2011). For example, in the study of Dozeman et al. (2011) only 21% of the patients completed BA.

Secondly, both groups received considerable care already (occupational therapy etc), which might explain why patients in the control group also recovered significantly. This means that there might have been little room for additional effects of the SAM. Moreover, patients in the control group received significantly more anti-psychotic medication. This is an indication of possible differences in treatment regimes between the experimental or control groups as antipsychotic cotreatment is superior to mono treatment with antidepressants in the acute treatment of psychotic depression (Farahani A & Correll, 2012). We must stress though that the change score effect size of depression ($g=0.35$) is comparable to the one found in the meta-analysis of psychological interventions for inpatients in our meta-analysis (Cuijpers et al. 2011), except that the effect size we found in this study was not significant.

There were no significant long-term effects (after the intervention until 3 months later) although it seems worrying that the care-as-usual group performed (non statistically significant) better than the patients in the intervention group. This might mean that the SAM is actually harmful in the long term, however this seems unlikely. First, it must be stressed that the response rate for the intervention group was very low. Therefore, the results are no more than an indication. Second, we think that the results might also be explained by differences between the groups. Most notably, 95% of the control group received some type of care after discharge compared to 70% for the experimental patients. There are no clear indications, which could explain these differences in aftercare. It is most likely that the level of ambulatory care differs per region and the control groups are situated in regions in which the ambulatory care is provided to more patients after discharge.

Strengths and limitations

Our study has the following strengths. First, it can be considered a large study within the field of elderly inpatients. As far as we are aware studies on psychological therapies for inpatients only included up to 53 patients (Brand & Clingempeel, 1992). Second, this is one of few studies on Behavioral Activation (BA) in this elderly population. And third, BA has been adapted so that nurses are able to execute the intervention. There are also a number of limitations that should be mentioned. Some limitations can be attributed to randomization at unit level. Firstly, this means that

there might have been differences between the care-as-usual of the experimental and control units. We stratified randomization on “usual therapy program” but we cannot rule out that there were still differences. Secondly, there might have been differences in the patient groups. Although the baseline characteristics were not significantly different, there might have been differences in characteristics we did not measure. Furthermore, it was not possible to perform a subgroup analysis because of the relatively small sample size. This means that we were not able to calculate for which patients SAM was most effective.

Conclusion

Our results show that BA in this study (i.e. the SAM) seems to have small to moderate effects in addition to care as usual in inpatients with MDD. However, these results were not statistically significant. This might be due to the small sample size but also to other design factors (such as unit level randomization) or implementation factors (such as non-adherence to intervention). Therefore, we feel that BA should not be disregarded yet. We think that additional research is necessary. First, the moderate effects we found for the reduction of depressive symptoms and increased mastery at post-intervention are indicators that patients could benefit from SAM, certainly when the differences in patient characteristics and the low treatment integrity are taken into account. Second, in future research, it is important to focus more intensively on the nurses’ motivational skills in order to increase the uptake of BA and to ensure treatment integrity. However, this can only be done when adequate organizational conditions have been created e.g. when nurses are given enough time to carry out SAM in addition to all their other demanding tasks.

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A Qualitative Evaluation of an Inpatient Nursing Intervention for Depressed Elderly: The Systematic Activation Method.

Clignet, F., van Meijel, B., van Straten, A. and Cuijpers, P. (2016). A Qualitative Evaluation of an Inpatient Nursing Intervention for Depressed Elderly: The Systematic Activation Method. *Perspectives in Psychiatric Care*, sept. 14, 1-9, doi:10.1111/ppc.12177

Introduction

The prevalence of late life depression (LLD) varies from 0.9% to 9.4% in private households and from 14% to 42% in institutional settings (Djernes, 2006). LLD is the third leading contributor to the global burden of disease (World Health Organization, 2008). Persons with LLD are particularly vulnerable to deterioration in quality of life (Doraiswamy, Khan, Donahue, & Richard, 2002). The most common treatment for patients with LLD is a combination of medication and psychological interventions, provided in outpatient or inpatient treatment settings (National Institute for Health and Clinical Excellence [NICE], 2009). A recent meta-analysis of psychotherapy in depressed inpatients indicates that psychological treatments have a small but significant effect on depression (Cuijpers et al., 2011). Although the results are promising, the actual implementation of these treatments is complex because— within the Dutch healthcare system, but probably in other countries— psychotherapists are not usually available to systematically treat all patients. An alternative solution could be the implementation of psychological interventions by nurses. The overall assumption in implementation research is that when an intervention can be executed relatively easily, chances are higher that it will actually be used in routine practice (Francke, Smit, De Veer, & Cristiaen, 2008). Research shows that behavioral activation (BA) is a highly effective treatment modality in major depressive disorder (MDD; Cuijpers, Van Straten, & Warmerdam, 2007). It is relatively easy to execute and is useful for mental health nurses, as activation is an important focus in nursing care for patients with MDD. Therefore, we developed BA as a brief structured course to make it suitable for inpatient nursing care for patients with LLD. The primary focus of the treatment is on activating the patient, and it is therefore called the Systematic Activation Method (SAM).

The SAM focuses on increasing positive reinforcement (e.g., pleasant activities), with the ultimate aim of achieving an improvement in the patient's mood (Clignet, van Meijel, van Straten, Lampe, & Cuijpers, 2011). In previous research, most of the barriers to implementing evidence-based interventions were ascribed to three factors. First, there are factors related to the healthcare workers (e.g., nurses), such as a negative attitude toward the intervention, resistance to scientific research, and lack of knowledge and awareness of available evidence (Fisher, 2014; Forsner et al., 2010; Francke et al., 2008). Second, patient characteristics influence the implementation of evidence-based guidelines, such as lack of knowledge, skills, or motivation (Francke et al., 2008). And finally, contextual aspects play a role, such as lack of time, insufficient support from management, and lack of autonomy in decision-making among nurses (Fisher, 2014; Francke et al., 2008; Forsner, Hansson, Brommels, Åberg Wistedt, & Forsell, 2010; Wensing et al., 2014). Although scientific knowledge concerning

Abstract

PURPOSE: This article describes the evaluation of the implementation of a nursing intervention, that is, the Systematic Activation Method (SAM), among inpatients with late life depression (LLD).

METHODS: A qualitative study in four clinical units for old age psychiatry.

RESULTS: We identified facilitators and barriers relating to patient and nurse characteristics, as well as to contextual factors, from the perspective of mental health nurses. The nature of the LLD and the quality of the therapeutic relationship were major aspects that affected the implementation of the SAM.

PRACTICE IMPLICATIONS: Given the complexity of the implementation process, careful supervision and monitoring, with the active participation of management and the multidisciplinary team, are necessary.

the implementation of evidence-based interventions (including psychological interventions) in nursing practice is growing, implementation studies in the field of old age psychiatry are scarce (Ekers et al., 2014; Cuijpers et al., 2011). It is thus unclear which implementation factors are most relevant to this specific population. Our assumption is that the nature of LDD and age-related factors require specific attention in the implementation of psychosocial interventions. Therefore, the aim of this study is to explore the nurses' perceptions of the barriers and facilitators in the implementation of an intervention (SAM) in mental health nursing care. Barriers and facilitators are described on the level of nursing staff and patients, and in the context of care provision.

Methods

Design

We conducted a qualitative study, using a questionnaire and qualitative group interviews with the nurses who participated in the experimental condition of a cluster randomized controlled trial (RCT) on the effectiveness of the SAM intervention (Clignet, van Meijel, van Straten, & Cuijpers, 2012). The RCT was carried out in 10 units for elderly psychiatry in seven psychiatric hospitals throughout the Netherlands. Five units were randomized to the control condition (care-as-usual), the other five to the experimental condition in which the SAM intervention was implemented. The study was performed in accordance with the consolidated criteria for reporting qualitative research (COREQ) criteria (Tong, Sainsbury, & Craig, 2007).

Settings

All participating units were specialized in the care and treatment of elderly patients (≥ 60 years) with severe psychiatric disorders. The SAM intervention was added to the usual treatment programs, which consisted of psychological treatments and occupational therapy, in combination with medication. Four experimental units participated in the present implementation study. The fifth experimental unit declined to participate, due to a reorganization that was taking place. Three participating units were open units; the fourth was a closed unit. The size of the units varied between 12 and 24 beds.

Participants

Inclusion criteria for the participants were (a) being a member of the nursing staff (registered nurses or healthcare workers such as social workers), (b) at least 1 year's employment at the participating unit, (c) active involvement in the implementation of the SAM, and (d) being employed for at least 24 hr/week, to ensure continuity of

participation. The participants were informed orally and in writing about the study. All participants gave written informed consent. For the allocation of patients to the nurses, no formal procedures were applied. In most cases, the primary nurse carried out the intervention. Per unit, three to six nursing staff members were trained to carry out the SAM, depending on the size of the unit.

Implementation of the Systematic Activation Method (SAM).

We developed the SAM as a structured 7-week module based on the "Coping with Depression" course (Cuijpers, 2000). The aim of the intervention is to increase patients' awareness of the positive influence of pleasant activities on their mood. The course consists of six consecutive themes. These are summarized in Table 1. The patient receives a course book outlining the rationale of the intervention, practical instructions for its execution, and the schedules to fill in the homework assignments. The patient records his or her mood on a daily basis and has weekly meetings with a nurse to discuss mood, the progression of the execution of the intervention, and possible problems. A nurse coaches the patients individually once a week. These coaching sessions last about 45–60 min per session. The execution of the SAM is described in more detail elsewhere (Clignet et al., 2012). The SAM was implemented using the following strategies:

- Before actual implementation, the intervention was introduced to the nurses from the experimental units in information meetings.
- These meetings were followed by a brief training program, which consisted of two 4-hr sessions. The principal investigator (FC) conducted the training. The first meeting consisted of an introduction to motivational techniques. During the second meeting, the nurses were instructed how to execute the SAM in combination with the motivational techniques. All nurses who participated received a SAM manual.
- During the actual execution of the SAM intervention, FC visited the units once every 2 weeks to monitor the progress of implementation and discuss the barriers to successfully implementing the SAM on the ward. Furthermore, the nurses could contact FC by e-mail or telephone if difficulties arose.

Table 1: An overview of the Systematic activation Method (SAM)

| Theme | Activities | Interval |
|--|--|----------------------------|
| Theme 1: Monitoring the mood. | Introduction to the treatment rationale, Exercise on monitoring the patient's mood | One session in one week. |
| Theme 2: Selecting positive activities. | Selecting 5 – 15 activities from an existing list with potential pleasant daily activities. Executing these activities in the following week. | One session in one week. |
| Theme 3: Plan your mood in advance. | Developing and executing a pleasant activity plan. | Two sessions in two weeks. |
| Theme 4: Who is helping me? | Defining who are able to help the patient stay engaged in activities. | One session in one week. |
| Theme 5: The Activity Experiment. | Defining an activity, which is difficult to carry out. Develop a plan and execute this activity. | One session in one week. |
| Theme 6: Evaluation. | Evaluation of the intervention. Defining the possibilities and pitfalls. | One session in one week. |

Data Collection

Data were collected at unit level. To obtain broad and in-depth insight into the factors that affected the implementation of the SAM, we used a stepwise approach. First, a short questionnaire was sent to all the participating nurses. The questions are displayed in Table 2. The results from these questionnaires were used for the group interviews. To maximize participation, the interviews took place at the participating units. The second author, who has extensive experience in qualitative research methods, moderated the interviews. The first author, being the principal investigator, was also present during the interviews, making notes and monitoring the interview protocol, which was developed for this study. Each interview started with a general introduction, followed by exploring the process of implementation, with particular emphasis on barriers and facilitators on the level of the patient, the nurses, and the organization. Four interviews were held (one per unit). The interviews were conducted in groups. All interviews were audiotaped and transcribed verbatim. The data were gathered between March 2012 and June 2012. The duration of the interviews varied between 46 and 68 min. In addition to these interviews, we determined the actual implementation status on each ward. Therefore, we used a patient evaluation form, on which the patients who received the SAM intervention reported the extent to which they had carried out the SAM with support from their nurse. The 10-item questionnaire consisted of two questions regarding the number of meetings and the duration of these SAM meetings; six questions in which the patients evaluated the different steps of the intervention; and two questions in which the patients evaluated the extent to which the SAM contributed to their recovery.

Table 2: The participant evaluation form.

| Evaluation form SAM participants |
|---|
| In general, what are your experiences in working with the SAM? Answer: |
| How did you experience the training beforehand, and the support during the execution of the SAM? Answer: |
| How was the collaboration with the patients during the implementation of the SAM? Answer: |
| Which organizational factors affected the implementation? Answer: |
| What would you change in the implementation of the SAM if you were in charge? Answer: |

Patient characteristics concerned age, sex, days of admission, former episodes of depression, level of depression, and cognitive functioning. Level of depression was measured using the Dutch version of the Beck Depression Inventory (BDI; Van der Does, 2002). This is a 21-item self-report scale. Each item can be scored from 0 to 3. The cutoff scores are 0–13 (minimal depression), 14–19 (mild depression), 20–28 (moderate depression), and 29–63 (severe depression).

Level of cognitive functioning was measured using the Minimal Mental State Examination (MMSE; Zigmond & Snaith, 1983). The MMSE comprises 11 questions regarding memory, language, and attention. The maximum score is 30, and a cutoff score of <24 is regarded as an indicator for cognitive problems.

Data Analysis

For the analysis of the data, thematic content analysis was applied (Elo & Kyngäs, 2008), making use of the MAXQDA-11 software for qualitative text analysis. The primary researcher (FC) conducted initial data analysis. First, all interview texts were read several times, and relevant passages were coded provisionally. Based on these provisional code words, a preliminary code tree was constructed in the MAXQDA-11 database and organized according to the previously mentioned levels of analysis, that is nurse-, patient-, and context-related factors. Next, the interview texts were imported in MAXQDA-11 and relevant text fragments from the interviews were coded. During the coding process, new code words were constructed and existing code words were renamed or relocated, based on new insights obtained during the process of analysis. These codes were analyzed by two researchers (FC and BvM) independently, and differences in coding were discussed. After coding the interviews,

all text fragments belonging to one code word were discussed and reanalyzed by the two researchers. The factors that contributed to or hampered the implementation of the SAM were extracted under the nurse-, patient-, and contextual categories.

Results

Participants' Characteristics

The questionnaire that was distributed prior to the interviews was returned by eight of the 12 nurses. All 12 nurses participated in the interviews. Per unit three nursing staff members participated. The characteristics of the participants are summarized in Table 3.

Table 3: Characteristics of the participants

| | | |
|---|---------------------------|-------------|
| Gender (n) | Female | 9 |
| | Male | 3 |
| Level of education (n) | Registered Nurse | 6 |
| | Bachelor | 4 |
| | Social worker | 1 |
| | Clinical Nurse Specialist | 1 |
| Professional experience (years + range) | | 16.8 (2-40) |
| Working on the ward (years + range) | | 8.25 (2-26) |

Table 4: patient characteristics

| Patient Characteristics | | n=26 |
|--------------------------------------|--------|------------|
| Age (years ± sd) | | 73.7 (7.5) |
| Gender (%) | Female | 57.7 |
| | Male | 42.3 |
| BDI score (± sd) | | 30.2 (10) |
| MMSE (± sd) | | 27 (2) |
| Admission days (± sd) | | 47 (22) |
| More than one depressive episode (%) | | 85 |

Implementation of the SAM

The characteristics of the patients, with whom the intervention was implemented, are summarized in Table 4. Of these patients, five dropped out early owing to lack of motivation (19%). From the remaining 21 patients, we received 15 evaluation forms (71%). They participated in the SAM for 5.5 weeks on average (range 3–12 weeks) and averaged four meetings with their nurse (range 0–10 meetings). There was one patient who had zero meetings. She reported that she executed the SAM independently.

Factors Related to the Nursing Staff

Attitude Toward the Intervention.

At the outset, most participants believed the SAM to be a useful intervention, which appeared easy to carry out. They had confidence in their ability to do so effectively. The participants understood the treatment rationale. They were already using activation in their daily routine, but not in a systematic manner as prescribed by the SAM. The structured and systematic approach was considered to be the most innovative aspect of the SAM intervention as exemplified in the following discussion between two participants:

- R1: *“With the SAM, I am more aware of what I am doing. Normally I act routinely.”*
 R2: *“I agree with R1: The SAM is more of a guideline to me, it is well structured. When I think about it, we were already activating the patients but not as consistently as we did with the SAM. We already discussed with the patients what they would like to do in the future. Now it is clearly written down in black and white.”*

Some participants, however, were less optimistic about the SAM. They doubted if the intervention would be beneficial to their patients.

Intervention Fidelity.

Most of the participants made substantial efforts to execute the intervention as thoroughly as possible and felt helped by the structured procedure, as this quotation illustrates:

“This man was intellectually disabled and very depressed, very negative, so he really wanted nothing anymore. I tried to use the method together with him. However this stagnated at some point. If I think back, I guided him for a long period of time, while I would have stopped much earlier without a structured intervention, especially with this man.”

During the actual implementation, the participants found that the intervention was not as easy to carry out as expected in most of the patients, which jeopardized intervention fidelity in a number of cases. The efforts to persuade the patients to engage in positive activities did not always lead to the expected results as this quotation illustrates:

"It took a lot of energy. I don't mind if it costs me energy but eh.... I had to put considerable investment into it ...and the effect was low".

It was important that the efforts showed some results, such as satisfactory completion of the homework assignments or the patients' awareness that positive activities would lead to improved mood. In particular, the latter aspect also increased mutual motivation to persevere with the SAM. One participant stated:

"It is important that they (the patients) have a positive experience as a result of the execution of the intervention as soon as possible. It doesn't matter how small it is, as long as it something we can use together (nurse and patient), as an extra motivation to continue the SAM intervention".

This citation underpins the importance of mutually experienced effects as a motivator. Furthermore, despite the coherent nature of the SAM, in some cases the execution of only a small number of its components was achieved when execution of the complete intervention protocol was not attainable. The following discussion between two nurses illustrates how the SAM was adapted to individual patients:

R1: *"Well, I used only parts of the SAM. I left out some of the themes because these were too complicated for the patient, although I think these parts could be useful for this patient".*

R2: *"Yes, you can use the SAM intervention as a whole, but for some patients it is better to use it [the SAM] in a more flexible way and improvise".*

Knowledge and Skills

Nearly all the participants completed the training program prior to the implementation. Only one participant missed one of the two training sessions. The training was regarded as useful and the content easy to understand. According to most participants, the use of motivational techniques was already part of their basic skill set. Some participants, however, reported that additional training was advisable because of the specific skills required to carry out the motivational techniques in patients with LLD. In the actual implementation, the participants relied more on

their implicit knowledge, which is a blend of experience and intuition. The following quotation is a representative example of how the participants rely on their (implicit) clinical judgment:

"It goes without saying, I just sense it, if someone [a patient] doesn't want to get out of bed. You become more forceful in a natural way, instead of using motivational interventions, it is a specific feeling".

The Therapeutic Relationship

The participants regarded a poor therapeutic relationship as the main barrier to successful implementation of the SAM intervention. Therefore, they made considerable effort to establish a good relationship with the patients, in which "trust" is a keyword. The participants endeavored to gain the patient's trust by empathizing with the patient's suffering. But at the same time, the SAM required active participation by the patients themselves. The discrepancy between the two interests often led to increased stress on the therapeutic relationship. Most participants believed that it was necessary to adopt a more forceful attitude with the patients. Only then could they break the vicious circle of depression, in which a lack of activities leads to an increased level of depressive symptoms, which, in turn, leads to more inactivity. Therefore, the activating aspects of the SAM were used, even when the patient was reluctant to cooperate. This regularly led to one-way communication in the relationship between patient and nurse. The consequence of this was that the nurse adopted a commanding and steering role and the patient a passive and resistant one. This inequality in the relationship became highly visible during the execution of the SAM and reinforced the participants' skepticism toward the intervention, hampering further implementation.

Factors Related to the Patient

Severity of the depressive disorder

When depressed patients are admitted to a psychiatric inpatient care unit, they usually exhibit extremely passive and dependent behavior. All participants agreed that implementation of the SAM was not possible right after admission. Treatment was limited to medication and following the daily routine at the unit. The following quotation is a representative example:

"The patients who are admitted, especially nowadays, are not able to remain at home anymore, despite all the ambulatory care. The patients are too depressed and not even capable of rating their mood, they have no energy at all".

According to the nurses, the cognitive impairments, as a consequence of LLD, such as temporary memory loss and diminished concentration, made it difficult for some of the patients to engage in the active execution of the SAM. These patients experienced the SAM as an obstacle, and it confronted them with their inabilities. Most patients were more accepting regarding active participation in the SAM after the most severe depressive symptoms receded. The participants found that a reduction of depressive symptoms increased the patients' hope and belief in their recovery, as this quotation illustrates:

"She [a patient] was motivated. She got through the most serious episode of her depression and was motivated to do everything that would help her. First, she was very depressed but at a certain point she realized that she actually could recover from her depression and from that point on her mood improved".

Personal Characteristics

Apart from the depressive symptoms, some patients' characteristics turned out to be obstacles to the implementation of the SAM. The participants noticed that some exhibited dependent behavior, which they attributed to low self-esteem. For these patients, the amount of reading material and exercises seemed overwhelming, and they had no confidence that they would be able to complete them. This increased these patients' reluctance to engage in the SAM.

Age-related factors hampered the implementation of the SAM in two ways. First, the patients tend to use their age a priori as an excuse not to cooperate actively in the intervention. This quotation typifies the participants' powerlessness when age is used as an excuse:

"Yes, there were people who said 'I'm 80 now, must I still do a course? I'm not going back into the classroom', things like that".

A traditional view of the treatment of depression hampered the implementation of the SAM, as this discussion between two nurses shows:

- R1: *"Well I wonder because they [the patients] are generally, in my experience, more passive and dependent on the doctor "who knows it all."*
R3: *"The doctor is placed on a pedestal".*

Second, some participants deliberately took the patient's age into account when implementing the SAM. They reported that they felt compassionate and tended to be less strict with older patients. For example, they did not ask them to complete their homework assignments. Moreover, some participants felt encumbered in implementing the SAM in elderly patients due to the age differences, as this quotation illustrates:

"Sometimes I felt uncomfortable as a younger person, about guiding a patient who is the same age as my grandfather through a course [the SAM]".

Factors Related to the Context

The context in which the SAM was implemented was described as highly dynamic. The 24/7 admission function of the units made it difficult for the participants to implement the SAM on a regular basis because of the high turnover of patients and the unpredictable nature of the disorders in some of their patients. Furthermore, the irregular shifts often led to lack of continuity. To optimize continuity, the SAM was transferred to colleagues when necessary as this quotation illustrates:

"For many of my shifts, the patient was at home for the weekend or followed his rehabilitation program and it was difficult to find time, literally, so I worked together with P [name of colleague]".

Finally, execution of the SAM turned out to be a complex and time-consuming activity, which resulted in an additional workload. Although the nursing staff members were loyal to each other, they sometimes felt awkward about leaving their colleague with the other patients in the unit while executing the SAM, as this quotation shows:

"Sometimes I felt that I had to be accountable to the other team members—that I had to explain what I was doing".

The above citation also indicates the importance of a positive attitude within the nursing team regarding the extra time necessary to implement the SAM within existing routines. In three units, the participants indicated that it was easy for them to discuss issues regarding the implementation throughout their shifts and at the changeovers. In one unit, however, it was difficult for the nurses to discuss their implementation issues because these nurses worked alone. The participants addressed nearly all the problems, such as lack of time or problematic patient characteristics and tended to discuss and solve these problems and issues within their own team. Less attention was paid to their problems in the therapeutic relationship. This became evident in

the involvement of the principal investigator. Although the participants considered the regular supervisory visits by the principal investigator as useful, they rarely used these visits to discuss complex cases.

Multidisciplinary collaboration in the implementation of the SAM depended to a large extent on the efforts of the unit managers. In two units, the managers facilitated multidisciplinary collaboration by integrating the SAM in the existing multidisciplinary meetings such as morning reports and treatment plan meetings. Participants reported that multidisciplinary involvement was helpful when patients were extremely difficult to motivate and where there were concerns about the fruits of their efforts. The nurses characterized the role of the multidisciplinary team members as advisory. When managers did not facilitate multidisciplinary involvement, the nurses sometimes experienced frustration due to the fact that it was unclear to them how to discuss these complex cases in the multidisciplinary team. The following quotation illustrates this frustrating process:

“Yes, maybe I should discuss it with B [name of the manager] but I don’t know if it is my job to discuss this. At a certain point, when it didn’t work out with a patient, I discussed it with the members of the treatment team and they were cooperative, but after a week it wasn’t an issue anymore, as if it had disappeared into thin air”.

Discussion

To our knowledge, this is the first study in which the implementation process of a research-based intervention in old age mental health nursing is described. The results of the interviews show that there are several factors, which contributed to a successful implementation of the SAM in daily practice. Contributing factors are (a) a positive attitude among the nurses, (b) adaptation of the intervention to the specific circumstances of the patient and his/her context, (c) a supportive nursing team, (d) integration of the SAM in the multidisciplinary treatment plans, and (e) active involvement of the unit manager in the integration of the SAM in the multidisciplinary treatment. On the other hand, there are several factors, which hampered the implementation of the SAM. These factors are (a) the complexity of the intervention, (b) lack of time, (c) the severity of the MDD, and (d) patient-related factors such as dependent behavior, cognitive impairments, and patients’ beliefs. Although these factors were also found in other studies (Francke et al., 2008; Wensing et al., 2014), our research shows that the patient-related factors in particular were challenging for the implementation of the SAM in mental health nursing. Owing to

the specific nature of the psychiatric disorder, that is, LLD, patients’ motivation to engage in activities was already low beforehand, leading to reluctance to participate. A study comparable to ours is the Behavioral Activities Intervention (BE-ACTIV) study of Meeks, Looney, Van Haitsma, and Teri (2008), in patients with LLD in nursing homes. In this study, a mental health practitioner implemented the treatment program (BE-ACTIV) in close cooperation with nursing staff members. This study shows, in line with our findings, that adapting the execution of the intervention to the specific patient characteristics and contextual situation improves the chances of successful implementation. Furthermore, the Meeks study showed that a positive attitude among the staff members, as well as the support of and cooperation with other team members contributed positively to the implementation process. Similar results were found in our study. A lack of time among the nurses and patient’s refusal were factors that negatively affected the implementation in the Meeks study that are in line with our results. Although the studies show similarities, it is noteworthy to mention that the settings differ, as does the severity of LLD in the participating patients. This might explain why patient characteristics and severity of depression affected the implementation negatively in our study, but not in the study of Meeks et al. (2008).

To stimulate the patient to engage in the activation method, the nurses placed considerable emphasis on establishing a therapeutic relationship, which they considered to be a pivotal element in the activating treatment of the patients (or, as the nurses stated, a major barrier when the relationship was poor). This is also discussed extensively in other studies. A study by McCabe and Priebe (2004) shows that the therapeutic relationship is a reliable predictor of patient outcomes. Cahill, Paley, and Hardy (2013) recommend that nurses keep a focus on the therapeutic relationship, as their study shows that patients regarded the therapeutic relationship as the most helpful regardless of the type of therapy (i.e., psychodynamic interpersonal therapy vs. cognitive behavioral therapy).

During the actual implementation of the SAM, the nurses noticed that the intervention method was more complex than they had assumed in advance, this despite the fact that the nurses had considerable experience with the patient group. It took a lot of time and effort to implement the intervention within the daily routine of the unit, which sometimes led to frustration. Only a few nurses acknowledged beforehand the difficulties in carrying out the SAM, particularly with respect to motivating the patients with severe depression. This is in line with the findings from the study of Paley Shapiro, Myers, Patrick, and Reid (2003), where the nurses were surprised and frustrated with respect to their experience that what seemed simple during the training period proved to be complex in actual clinical practice. Puentes (2003) argues

that a clear understanding of the psychotherapeutic approach and the skill level of the practitioner will enhance the treatment outcomes. Although most nurses in this study considered their motivational skills to be sufficient, the complexity of carrying out motivational techniques to patients with LLD became highly visible. In keeping with Puentes' arguments, more emphasis on motivational techniques in the training as well as the supervision meetings might have led to a more effective implementation of the SAM. Although all patients gave informed consent to participate in the intervention program, it is possible that some were unaware of the effort required, leading to demotivation, which hampered (or delayed) further implementation. According to the participating professionals in the present interview study, the SAM was not suitable for all patients. Maybe, in line with Puentes, more attention should be paid to assessing the patients for their motivation and necessary skills to effectively participate in the intervention program, with the likelihood of better treatment outcomes.

In most of the cases, the SAM was adjusted to the individual preferences and skills of the professionals, the preferences of the individual patients, and contextual circumstances. Initially, the SAM was presented as a highly prescriptive intervention, but during the implementation process the nurses used it in a more flexible way. This means that the nurses only used the elements that were regarded as useful. This probably explains the variation in the dosage of the intervention the patients received. In these adjustments, the nurses relied on their professional knowledge, experience, and intuition. However, in many cases it remained unclear what the underlying motives were for the adjustments they made. Their tailored methods sometime contradicted the structured and systematic approach of the SAM, which was meant to guide clinical decision-making in a clear and transparent manner (see also MacNeela, Scott, Treacy, & Hyde, 2010).

In conclusion, of the wide range of factors that affect the implementation of innovative therapies, certain factors impact every setting or patient group to a greater or lesser extent. Our study shows that the therapeutic relationship is the cornerstone of nursing care and therefore should be the starting point in the implementation of new therapies, such as the SAM, in inpatients with LLD.

Limitations of the Study

This study has a number of limitations. First, although all the healthcare professionals we interviewed were part of the nursing team, there were differences in level of education, which could have influenced the implementation process in separate cases. We have tried to minimize the influence of these differences by developing

the SAM as a highly prescriptive intervention, suitable for registered nurses at bachelor level or higher, but also for other team members. They all underwent the same standardized training program. Furthermore, one of the inclusion criteria was working experience of at least 1 year with the target group, to ensure sufficient experience and skills in all the participating professionals.

A second limitation is that the results are based on a relatively small sample of 12 participants, and therefore transference of the results to all mental health nurses requires caution. As this is an explorative study, further research is highly recommended in this patient group to strengthen the knowledge base concerning the implementation of complex nursing interventions in mental health care.

Implications for Nursing Practice

This study has highlighted the complexity of the implementation process of research-based interventions, such as the SAM, requiring integration of scientific evidence, professional expertise, and patients' experiences and preferences. Careful supervision and monitoring of these implementation processes is necessary, as is the active participation of management and the multidisciplinary team (see also Puentes, 2003). A thorough analysis must be made both before and during the process of implementation of (possible) barriers and facilitators for successful implementation on the level of content and complexity of the intervention, the patient group, the nurses, the nurse-patient interaction, and organizational factors. Targeted influencing of these barriers and facilitators may contribute to more efficient and effective implementation of the intervention.

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7

Unmet care needs and care provision and patient satisfaction in patients with a late life depression: a cross-sectional study.

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Key words

depression
unmet needs

satisfaction
late life

Abstract

Background: Research has shown that some 30% of total care needs in people with late-life depression (LLD) are unmet. It is not known to what extent patients actually don't receive any care for these needs or consider the care to be insufficient. Furthermore, it is unknown to what extent this is related to overall satisfaction with care.

Aim: The aim of this study is to obtain insight into the care provided in relation to the reported unmet care needs and satisfaction with the total care provided is examined.

Method: A cross-sectional study of 99 people with LLD in an ambulatory setting. Care needs were measured with the Camberwell Assessment of Needs for the Elderly (CANE), and depression severity was measured with the Montgomery- Åsberg Depression Rating Scale (MADRS).

Results: In 67% of patients, at least one unmet need was ascertained. In most cases (80%) care was actually provided for those needs by professionals and/or informal caregivers. Patients were satisfied with the care delivered for 81% of the reported care needs. Satisfaction was lowest for social care needs (67%). For six specific care needs it was demonstrated that dissatisfied patients were significantly more depressed than satisfied patients.

Conclusion: Even though patients might receive care for certain needs, this does not mean that their needs are met. A substantial proportion of patients with LDD feel that they need additional help for unmet needs.

Introduction.

The prevalence of severe depression in later life is estimated at 1% to 5%, while some 15% of older adults experience less severe, but clinically significant depressive symptoms (Fiske, Wetherell & Gatz, 2009). Late-life depression (LLD) has major consequences for daily functioning and quality of life of the older person (Beekman, Penninx, Deeg et al., 2002, Doraiswamy, Khan, Donahue & Richard, 2002). The prognosis for LLD is poor when it is not or inadequately treated (Licht-Strunk, van Marwijk, Hoekstra et al., 2009; Licht-Strunk, Beekman, de Haan, van Marwijk, 2009).

The diagnosis and treatment of depression in older adults have been set out in various guidelines (National Institute of Clinical Excellence (NICE), 2009; Spijker et al., 2013; Kok, 2008). In these guidelines, the emphasis is mainly on psychological and pharmacological treatment. The guidelines contain limited attention for the care needs that accompany the depressive disorder, such as social problems, or difficulties with self-care. However, it is important to give due consideration to these, because such problems may have a negative influence on the course of the depression and the quality of life (Slade, Leese, Ruggeri et al., 2004). Moreover, it has been shown that unmet care needs can have a detrimental effect on treatment motivation (Stobbe, Wiersma, Kok et al., 2015).

Within the context of our research, a care need may be defined as: *"A physical, psychological, social or environment-related demand for help, care or a service, with the goal of solving or reducing a problem that is experienced or expressed by an older person in relation to an underlying psychiatric condition."* (Houtjes, 2015). A distinction can be made between met and unmet care needs (Hancock, Woods, Challis & Orrell, 2008). A care need is met when a person receives adequate help, or found an otherwise suitable solution for a problem. A care need is unmet when a problem exists for which no adequate solution has been found (Houtjes, van Meijel, Deeg & Beekman, 2010).

In recent decades, there has been increased research on care needs for various psychiatric disorders, including depression, schizophrenia, bipolar disorder and dementia (Houtjes et al., 2010; Passos, Sequeira & Fernandes, 2012; Cummings & McClure, 2008; Dautzeberg, Lans, Meesters et al., 2016; Meesters, Comijs, Dröes et al., 2013; Futuran & Draper, 2012). Regarding LLD, it has been shown that nearly 30% of reported care needs remain unmet (Houtjes et al., 2010). Particularly in the areas of psychological distress, daytime activities and intimate relationships, many unmet care needs are reported. It has been empirically demonstrated, that there is a significant positive relationship between the number of care needs and the severity of the depression (Houtjes et al., 2010), and that the presence of a depression is a

significant predictor of an increase in both met and unmet care needs (Cummings & McClure, 2008). Moreover, depressed patients evaluate a care need as unmet significantly more often than their professional caregivers (Houtjes, Van Meijel, Deeg & Beekman, 2012). This discrepancy may be explained by the possibility that the professional caregiver does not recognise the care need, or that there is a difference in interpretation as to whether a care need actually exists or not. Depression is known to have a negative influence on cognitive functioning. Cognitive functioning in the areas of attention, memory, executive and psychomotor functions are impaired, as is information processing. This means that depressed patients are more likely than others to view events in their lives more negatively (Gonda et al., 2015; Lam, Kennedy, McIntyre & Khullar, 2014). This may result in a distorted picture of the actual care that depressed patients receive for their reported unmet needs, as well as the perceived outcomes. At the same time, explicitly taking account of the patient's perceptions of the care provided might constitute an important means to improve the quality of care (Barg et al., 2010). At the same time, perceived quality of life strongly determines the patient's perception of the quality of care and the patient's satisfaction with the care provided (Al-Abri & Al-Balushi, 2014).

Despite the increasing focus on care needs in psychiatric disorders, including those of patients with LLD, little is known about the actual care provided for the reported unmet care needs. This is remarkable, as insight into this area is important for systematic attention to these unmet care needs and the need to tailor the care accordingly (Cummings & McClure, 2008; Houtjes et al., 2010). Moreover, we know little about the extent of satisfaction among depressed elderly about the care provided or whether there is an association between satisfaction with provided care and severity of the depression.

In this study, we provide answers for the following research questions: (1) what care do patients with late-life depression receive for their experienced unmet care needs? (2) Are patients with late-life depression satisfied with the formal and informal care that they receive for their care needs? (3) Is there a relation between level of satisfaction with the care provided and severity of the depression?

Method

Design

This cross-sectional research was conducted within the context of a larger cross-sectional study on care needs among older outpatients with a depressive disorder (Houtjes et al., 2010, 2012). The study was carried out according to the STROBE-

guidelines on the reporting of observational studies (von Elm, Altman, Egger, Pocock, Gøtzsche & Vandenbroucke, 2007). The study was reviewed by the medical-ethics committee of the University of Utrecht, and by the local review boards of the participating institutions.

Setting and procedure

The patients were recruited from ambulatory care units for Geriatric Psychiatry in six psychiatric care organisations in the centre and east of the Netherlands. Inclusion criteria for the patients were: a) aged over 55 years, b) a minimum of six months in ambulatory care; c) a primary diagnosis of depressive disorder, according to the Diagnostic and Statistical Manual of Mental Disorders (Diagnostic and Statistical Manual for psychiatric disorders fourth revised edition, American Psychiatric Association, 2000), as ascertained by a primary treating clinician (psychiatrist or clinical psychologist) at the start of treatment, and d) signed informed consent.

Clinicians from the participating organisations requested the consent of those patients who met the inclusion criteria to be approached by researchers with a view to participating in the study. After consent was given, these patients were telephoned by one of the researchers, who provided them with information about the study. Patients who verbally agreed to participate then forwarded the informed consent, and an appointment was made for an interview at their home address. The interviews were conducted by skilled research nurses with experience in geriatric psychiatry, who had been trained in the application of the measuring instruments used. The entire interview took some 30 minutes.

Instruments

Two instruments were used for the data collection: The Camberwell Assessment of Needs for the Elderly (CANE) and the Montgomery - Åsberg Depression Rating Scale (MADRS).

The purpose of the CANE is to provide a detailed assessment of the care needs of older people and their satisfaction with the care provided, focussing on 24 aspects of functioning (Droës, van Hout & van der Ploeg, 2004; Reynolds Woods, Hoe et al., 2000; Hancock et al., 2008). For each of the 24 items, it is first ascertained whether an individual has a problem in the relevant aspect of functioning. If this is so, then it is established that a care need exists. In the case of an existing care need, the question is asked whether the person is receiving care for this specific need. A distinction is made between informal care (partner, family, friends) and formal care (professionals). Then the patient is asked whether he/she is satisfied with the care provided for that

care need and whether it is adequate. If the patient finds the care adequate, then his/her care need is considered to be met. Conversely, if no care is offered, or if the care is experienced as inadequate, the care need is considered to be unmet. The results for care received for unmet needs are clustered on the basis of the following categories: environmental, physical, psychological and social care needs (Field & Orrell, 2004; Houtjes et al., 2010). The CANE has a good reliability and validity (Reynolds et al., 2000). The Dutch version has been subjected to psychometric testing, which has shown acceptable construct validity, criteria validity and test - retest reliability (van de Roest, Meiland, van Hout, Jonker & Droës, 2008).

The MADRS scale was used in this study to establish the severity of the depression (Hartong & Goedkoop, 1985). It consists of 10 items: mood, inner tension, sleeping pattern, appetite, concentration, sluggishness, absence of feelings, pessimism and suicidal ideation. Each item is scored on a scale of 0 to 6, with the total score ranging from 0 to 60. The following cut-off scores were used to rate the severity of the depression: 0-10 no depression, 11-20 mild depression, 21-30 moderate depression, 31-60 severe depression. The psychometric properties of the MADRS have been rated as good (Iannuzzo, Jaeger, Kafantaris, Sublette, 2006; Hartong & Goedkoop, 1985).

We also registered the following demographic data: gender, age, geographical living environment (rural, urban), education level (low/intermediate/high), and civil status.

Data analyses

To answer the first research question on care received for unmet care needs, we used descriptive statistics. The following categories were used: 1) no care offered, 2) only formal care, 3) only informal care, and 4) both formal and informal care are offered.

Descriptive statistics were likewise used to answer the second research question about the degree of satisfaction with the care provided. The results are presented in a table, showing the percentages at both item and category level. The satisfaction scores are shown for both met and unmet care needs.

We used the Mann-Whitney *U* test to measure whether there were significant differences in the depression score between the satisfied and dissatisfied patients. The level of satisfaction for each item was used as group variable (satisfied/ dissatisfied) and the MADRS-score as test variable. If a score was $p \leq .05$, it was considered to be significant. All statistical analyses were conducted with SPSS 23.

Results

Demographic data

Of the total group of patients ($n=99$), 66% were female. The average age was 72.7 years ($sd= 7.7$). Slightly more than half of all patients were living alone (52.5%), and had a low level of education (56.6%). The majority lived in an urban environment (62.7%). A large majority (84%) had an informal carer. The average MADRS-score of the patients was 19.46 (range= 0-43; $sd= 10.64$). This means that, on average, the severity of depression was mild to moderate. Over half (58.2%) of the patients had been admitted to inpatient care at least once in the past for psychiatric problems. Table 1 contains an overview of patient characteristics.

Table 1: Patient characteristics

| Demographic characteristics | | |
|-----------------------------|----------------------|---------------|
| Total Sample | | N=99 |
| Gender | Male | 33,3% |
| | Female | 66,7% |
| Age | Mean (SD) | 72.2 (7.7) |
| | Mean age Male (SD) | 71.2 (8.2) |
| | Mean age Female (SD) | 73.4 (7.4) |
| Geographical environment | Rural | 37.3% |
| | Urban | 62.7% |
| Level of education | Low | 56.6% |
| | Medium | 26.2% |
| | High | 17.2% |
| Marital Status | Married | 47.5% |
| | Single | 14.1% |
| | Widow | 38.4 |
| MADRS score | Mean (SD) | 19.46 (10.64) |
| | Mean Male (SD) | 18.34 (10.86) |
| | Mean Female (SD) | 20.02 (10.58) |

Care received for unmet needs

Altogether, the 99 patients reported 232 unmet needs. The average number of unmet needs per person is 2.3 (sd 6.7; range 0-12). Two thirds (67%) of all patients reported one or more unmet need. No care was provided for 49 (21%) of the 232 reported unmet needs. Formal care was provided for 45 unmet needs (19.4%); informal care for 44 unmet needs (18.9%); and both formal and informal care for the remaining 94 unmet needs (40.5%).

Most of the care was provided for the unmet “psychological care needs”. Four of the 71 patients with unmet needs did not receive any care in this domain, while 67 received formal care (n=16; 22.5%), informal care (n=10; 14.1%) or a combination of both (n=41; 57.7%). Furthermore, on the items “memory”, “behaviour”, “deliberate self-harm” and “psychotic symptoms” formal and/or informal care was provided on all reported unmet needs.

The least amount of care was provided with respect to “environmental care needs”: 26 patients out of the 39 expressed unmet needs (67.7%) even though some form of care was given. Within this category care is offered more commonly by informal caregivers, i.e. for 41% (n=16) of the unmet care needs versus 15.4% (n=6) by formal caregivers. At item level, 50% of the patients received no care on their reported unmet care needs on the items “food (n=5)” and “financial benefits” (n=3).

A total of 44 unmet needs were reported within the category “physical health”. In 22,7% of the reported unmet needs, no care was provided (n=10).

A total of 78 unmet needs were reported for the category “social needs”. In 22 of those cases (28,2%) care was provided. The least amount of care was offered for the item “information”, i.e. for 6 of the 11 (55%) reported unmet needs. Table 2 contains an overview of the care provided for unmet care needs.

Table 2: overview of the care provided for unmet care needs.

| Item on the CANE | Unmet Needs | | | Unmet needs and received no care | | Unmet needs with only formal care | | Unmet needs with only informal care | | Unmet needs with both both types of care | |
|----------------------------------|-------------|----|------|----------------------------------|------|-----------------------------------|------|-------------------------------------|------|--|--|
| | N | n | % | N | % | n | % | n | % | | |
| Environmental needs (total) | 39 | 13 | 33.3 | 6 | 15.4 | 16 | 41 | 4 | 10.3 | | |
| Accommodation | 7 | 0 | | 2 | | 4 | | 1 | | | |
| Household skills | 5 | 2 | | 0 | | 3 | | 0 | | | |
| Food | 10 | 5 | | 2 | | 3 | | 0 | | | |
| Money/ budgeting | 3 | 0 | | 0 | | 2 | | 1 | | | |
| Financial benefits | 6 | 3 | | 0 | | 2 | | 1 | | | |
| Caring for someone else | 8 | 3 | | 2 | | 1 | | 1 | | | |
| Physical needs (total) | 44 | 10 | 22.7 | 10 | 22.7 | 6 | 13.6 | 18 | 40.9 | | |
| Physical health | 9 | 1 | | 1 | | 1 | | 6 | | | |
| Medication | 4 | 1 | | 1 | | 1 | | 1 | | | |
| Eyesight/ hearing/ communication | 16 | 5 | | 3 | | 2 | | 6 | | | |
| Mobility/ falls | 9 | 2 | | 2 | | 1 | | 4 | | | |
| Self-care | 4 | 1 | | 2 | | 1 | | 0 | | | |
| Continence | 2 | 0 | | 1 | | 0 | | 1 | | | |
| Psychological needs (total) | 71 | 4 | 5.6 | 16 | 22.5 | 10 | 14.1 | 41 | 57.7 | | |
| Psychological distress | 31 | 1 | | 8 | | 2 | | 20 | | | |
| Memory | 13 | 0 | | 3 | | 6 | | 4 | | | |
| Disruptive behavior | 7 | 0 | | 1 | | 1 | | 5 | | | |
| Alcohol | 5 | 2 | | 1 | | 1 | | 1 | | | |
| Deliberate self – harm | 3 | 0 | | 0 | | 0 | | 3 | | | |
| Inadvertent self – harm | 5 | 1 | | 2 | | 0 | | 2 | | | |
| Psychotic symptoms | 7 | 0 | | 1 | | 0 | | 6 | | | |
| Social needs (total) | 78 | 22 | 28.2 | 13 | 16.7 | 12 | 15.4 | 31 | 39.7 | | |
| Company | 15 | 1 | | 3 | | 1 | | 10 | | | |
| Intimate relationships | 24 | 7 | | 4 | | 4 | | 9 | | | |
| Daytime activities | 27 | 7 | | 2 | | 6 | | 12 | | | |
| Information | 11 | 6 | | 4 | | 1 | | 0 | | | |
| Abuse/ neglect | 1 | 1 | | 0 | | 0 | | 0 | | | |

Degree of satisfaction with the amount of care

The patients reported their level of satisfaction about the care provided in relation to 876 met and unmet needs (table 3). The patients were satisfied with the care they received for 718 out of the 876 needs (82%). The highest level of satisfaction was expressed for help with environmental and physical needs (both 88%). Satisfaction concerning psychological needs also scored almost 82%. The patients were the least satisfied with the care offered for their social needs (67.3%). This low score is chiefly attributable to the relatively high level of dissatisfaction with the care for daytime activities (39%) and loneliness/intimate relationships (36%).

Relation between degree of satisfaction and severity of depression

For 18 of the CANE items no statistically significant differences were found in depression scores among the patients who were satisfied (S) compared to those who were dissatisfied (Ds) about the care provided. However, for 6 items significant differences were found. These are the items "household skills" (S(Mdn=21) vs Ds (Mdn=27), $U= 92.5$, $p=0.04$), "financial benefits" (S(Mdn=19) vs Ds(Mdn=38.5), $U= 8$, $p=0.02$), "memory" (S(Mdn=20.5) vs Ds(Mdn=29), $U= 54.5$, $p=0.02$), "disruptive behaviour" (S(Mdn=22) vs Ds(Mdn=36), $U= 11.00$, $p=0.05$), "alcohol" (S(Mdn=11) vs Ds(=36), $U= 4.00$, $p=0.004$) and "daytime activities" (S(Mdn=18) vs Ds (Mdn=27), $U= 234.50$, $p=0.00$). For these items, the dissatisfied patients are significantly more depressed than those who are satisfied with the care provided. These items are spread across all 4 categories of care needs. Table 3 contains an overview of the results.

Table 3: satisfaction with received care and differences with MADRS score.

| Item on the CANE | Satisfied with provided care | | Not satisfied with provided care | | Difference MADRS scores and satisfied/not satisfied | | |
|------------------------------------|------------------------------|----|----------------------------------|----|---|---------------------------|---------------|
| | n | n | % | n | % | Difference re "satisfied" | P* (2-tailed) |
| Environmental needs | | | 88 | | 12 | | |
| Accommodation | 24 | 21 | 87.5 | 3 | 12.5 | 7.14** | 0.15 |
| Household skills | 58 | 51 | 87.9 | 7 | 12.1 | 9.04 | 0.04 |
| Food | 36 | 29 | 80.6 | 7 | 19.4 | 7.42 | 0.11 |
| Money/ budgeting | 34 | 34 | 100 | 0 | 0 | - | - |
| Financial benefits | 22 | 18 | 81.8 | 4 | 18.2 | 17.22 | 0.02 |
| Caring for someone else | 17 | 15 | 88.2 | 2 | 11.8 | 0.70 | 0.94 |
| Physical needs | | | 88 | | 12 | | |
| Physical health | 68 | 64 | 94.1 | 4 | 5.9 | 3.52 | 0.54 |
| Medication | 43 | 38 | 88.4 | 5 | 11.6 | 6.64 | 0.09 |
| Eyesight/ hearing/ communication | 54 | 42 | 77.8 | 12 | 22.2 | 6.38 | 0.052 |
| Mobility/ falls | 45 | 40 | 88.9 | 5 | 11.1 | 4.08 | 0.44 |
| Self-care | 20 | 17 | 85 | 3 | 15 | 14.77 | 0.06 |
| Continence | 22 | 21 | 95.5 | 1 | 4.5 | -1.48 | 0.75 |
| Psychological needs | | | 81.7 | | 18.3 | | |
| Psychological distress | 77 | 63 | 81.6 | 14 | 18.2 | 4.52 | 0.14 |
| Memory | 45 | 38 | 84.4 | 7 | 15.6 | 10.93 | 0.01 |
| Behavior | 20 | 16 | 80 | 4 | 20 | 13.38 | 0.05 |
| Alcohol | 11 | 6 | 54.5 | 5 | 45.5 | 18.17 | 0.04 |
| Deliberate self – harm | 34 | 30 | 88.2 | 4 | 11.8 | 4.65 | 0.47 |
| Inadvertent self – harm | 17 | 13 | 76.5 | 4 | 23.5 | 5.56 | 0.34 |
| Psychotic symptoms | 30 | 26 | 86.7 | 4 | 13.3 | 12.60 | 0.06 |
| Social needs | | | 67.3 | | 32.7 | | |
| Company | 32 | 25 | 75 | 8 | 25 | 4.63 | 0.34 |
| Intimate relationships /loneliness | 44 | 28 | 63.6 | 16 | 36.4 | 4.50 | 0.14 |
| Daytime activities | 64 | 39 | 60.9 | 25 | 39.1 | 9.27 | 0.00 |
| Information | 48 | 36 | 75 | 12 | 25 | -0.50 | 0.84 |
| Abuse/ neglect | 11 | 9 | 81.2 | 2 | 18.8 | 2.83 | 0.81 |

*Calculated with a Mann-Witney U test.

**a positive score means that patients who are not satisfied have a higher score on the MADRS.

Discussion

This study aims to answer three research questions: 1) What care was provided to patients who reported unmet care needs; 2) Were the patients satisfied with the care provided; and 3) Is there a significant relation between level of satisfaction and severity of the depression?

Our study has shown that 67% of patients in the study reported one or more unmet care needs. Care was provided for nearly 80% of these unmet needs: formal care, informal care or a combination of both. For the remaining 20% the patients received no help. With regard to satisfaction with the care provided, patients indicate that they are satisfied with the care provided for 82% of their care needs. Patients were least satisfied (67%) with care offered for social care needs. For six items (of the 24) we saw significant differences in depression scores between the satisfied patients and the dissatisfied patients. These items are "household skills", "financial benefits", "memory", "behaviour", "alcohol" and "daytime activities". For these items, the dissatisfied patients had significantly higher depression scores compared to the satisfied group.

Our research findings showed that care was provided for the vast majority of reported unmet care needs. It seems most care needs were indeed identified and addressed by professional and/or informal carers. However, at the time of the study these care needs were considered unmet by the patients. An explanation could be that the patients were still in the process of receiving treatment, and finding a solution to the care need indicated takes time. It can therefore be expected that as the treatment progresses or is completed, the unmet care needs will be met. A second possible explanation may be found in the negative / pessimistic perceptions of the patient: depressed patients have the tendency to focus disproportionately on negative details, and pay less attention to positive aspects (Lam et al. 2014; Gonda et al. 2014). Accordingly, improvements in meeting care needs may not be recognised as such by the patients, and the needs continue to be seen as 'unmet'. It is also known that depressed patients tend to rate their depression as more severe, compared to their carers (Papageorgiou et al., 2015). This may also give rise to discrepancies in ascertaining care needs, with the carer rating the need for help lower than the patient. Moreover, depression is in itself a risk factor for evading care, due to lack of confidence in the solutions offered by professionals and informal carers and/or a sense of being considered troublesome (Cummings & McClure 2008; Martinio et al. 2011; Walters, Iliffe & Orrell M 2001). We support the recommendation of Hancock et al. (2003) that in the treatment and care for this target group, considerable weight should be given to the patient's perspective, in order to gain a sound understanding of the problems experienced, the care needs, the care provided, and satisfaction with care. This would expose any discrepancies in

experience and evaluation between patients, professionals and informal carers, and allow these to be adequately addressed. The implication is that caregivers should more readily question whether the care provided sufficiently matches the care needs as experienced by the patient. Sometimes, the solution can be to step up the care when the patient finds it inadequate. As an alternative, or in addition, the topics for discussion could include the thinking and experience of patients regarding their life situation and how they perceive their illness symptoms and care requirements.

Furthermore, the findings highlight the important role of informal caregivers in providing care. The informal caregiver is an important partner in the treatment and care for patients with late-life depression. These conclusions concur with those of Lin & Wu (2011), which assert that a large share of the care for patients with late-life depression is provided by informal caregivers. However, the risk is that these (older) caregivers become overburdened. It is therefore important that professional caregivers also pay attention to the care burden and capacity of the informal caregivers, particularly if the treatment is of long duration (Lin & Wu, 2011; Ho, Chan, Woo & Sham, 2009; Zegwaard, Aartsen, Grypdonck & Cuijpers, 2015).

The results of our study furthermore show that most patients are satisfied with the care they receive. We note the low satisfaction score for social care needs, particularly in the areas of "intimate relationships" and "daytime activities". Apparently, the patients have a major need for meaningful daily occupation, which would also provide opportunities for friendships and intimacy. The care needs expressed in this area are in line with the conclusion of Dautzenberg et al. (2015) that care for this target group should not only be limited to the psychological sphere, but that also account should be taken of social care needs within the services provided. This is all the more true, as it is known that both social and causal factors can exert a significant influence on the course of a depression (Areán & Reynolds III, 2005).

On a number of points, satisfaction with the provided care is related to the severity of the depression. In the case of six care items, dissatisfied patients are significantly more depressed than satisfied patients. Five of these items ("memory", "behaviour", "alcohol", "daytime activities" and "household skills") are related to a greater or lesser extent to the depressive disorder. The above-cited negative perceptions that belong to depression may play a role here in determining the patient's evaluation of the care provided. It may be expected that the dissatisfied patients will become more satisfied according as the depression diminishes (Hamaker, Nesselrode & Molenaar, 2007). An additional explanation could be that these patients were too severely depressed to be appropriately helped by ambulatory care, and the care provided was therefore

inadequate for the needs related to these items. The sixth item for which a relation was found between satisfaction with care and the severity of depression concerned “financial benefits”. As such, this variable is not directly related to the severity of the depression. The question whether someone is eligible for financial benefits depends on various kinds of legislation and regulations. However, it is known that older people with limited financial resources are known to incur a greater risk of depression (Fiske et al., 2009). It may therefore be assumed that when a patient’s financial situation improves (through adequate care provision), the severity of the depression lessens.

Strengths and limitations

This study has the following strengths. Firstly, in this study we have explored the care that patients with LLD received on their unmet care needs, as well as the care they received and their satisfaction with the care. To our knowledge, this study is the first to establish which formal and informal care is actually provided for reported unmet care needs in patients with LLD. Secondly, patients were included at various stages of their treatment course. Consequently, there is a wide range of depressive symptoms (MADRS-scores between 0-43), which enabled us to measure the extent to which satisfaction with the care received was correlated with depressive symptoms. Some patients were already in symptomatic remission, but were nonetheless still receiving care, on account of the existence of care needs in various areas.

Besides these strengths, the study has a number of limitations. Firstly, there are some care items, as measured with the CANE, for which few care needs are reported (≤ 5). Consequently, for these aspects it is not possible to make a reliable distinction between met and unmet care needs (e.g., the item “alcohol”). A further limitation concerns the generalizability of the results. The research was conducted in the Netherlands where access to psychiatric care services is generally good. The findings cannot be automatically generalised to other countries with different health care systems.

Conclusion

We may conclude that a large percentage of patients (67%) have unmet care needs, but that in the vast majority of these cases (80%), care is in fact provided. Satisfaction with the care given is predominantly high. For six of the items on the CANE scale, the level of satisfaction is significantly correlated to the severity of the depressive symptoms. Importantly, the role of informal carers is at least as large as that of formal caregivers. This means that professional caregivers need to be conscious of maximising effective support of these informal carers, while at the same time realising that the possibility of (older) informal carers becoming overburdened deserves attention. Our study makes it clear that not only a systematic assessment

of care needs is important (see Houtjes et al., 2010), but that a systematic analysis is also required of the extent to which the care given constitutes an adequate response to these needs, and whether the care meets with the satisfaction of the patient. The CANE scale is an excellent instrument for identifying any deficiencies or bottlenecks in the care provided.

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8

General Discussion

One of the main topics of this thesis is the evaluation of Behavioral Activation (BA), which we renamed the Systematic Activation Method (SAM), for inpatients with late life depression (LLD). The content and the effects of the intervention are presented, its effects and the factors influencing implementation in routine practice by mental health nurses are studied. By means of this study, we have added to the scientific knowledge about the implementation and effectiveness of the SAM in an inpatient population of patients with LLD and contributed to the further development of the body of knowledge of mental health nursing.

Two main aims were formulated for this thesis. These are:

1. To test the effectiveness of the SAM, an intervention for inpatients with LLD offered by nurses;
2. To explore facilitating factors and barriers which affect the implementation of the SAM in nursing practice in inpatient mental health care facilities.

In this chapter, the findings of this thesis are briefly summarized, followed by a discussion of a number of key issues around this topic, including the characteristics of the target group, the development and execution of the intervention, the challenges for mental health nurses to carry out the SAM, and the specific context of old age inpatient psychiatry, where the SAM was implemented. Furthermore, the strengths and limitations of this thesis, the clinical implications and recommendations for further research are discussed.

Summary of the main findings

In preparation for the main study we carried out a meta-analysis into the effectiveness of psychological interventions in depressive clinical inpatients. The results of this meta-analysis—described in **Chapter two**—show that psychological interventions have a small but robust effect on symptoms of depression compared to usual care in inpatient populations (Hedges' $g = 0.29$). Two of the twelve studies specifically examined BA and those two studies showed a relatively large effect, i.e. $g=0.56$. The literature suggests that BA can be delivered by nurses. This is shown in the case report in **Chapter three** which describes how BA was delivered by nurses to an elderly patient with severe depression. **Chapter four** presents the design of the randomized controlled trial (RCT) into the effectiveness of the SAM. The results of this RCT are described in **Chapter five**. The results show that the effectiveness of BA (as translated to the SAM) compared to usual care for LLD, is only very limited. This limited effect may be attributable to the limited power of the study as the sample size was relatively small. However, there were also problems with the implementation

of the intervention. The barriers and facilitating factors for implementation of the SAM are further examined in **Chapter six**. Finally, **Chapter seven** describes a cross-sectional study into the care needs of ambulant elderly with depression, the degree to which these care needs are met, and the level of satisfaction of patients with the care offered.

Patients

The chapters in this thesis describe three different groups of patients. The meta-analysis in **Chapter two** focuses on an adult inpatient population. This meta-analysis contains only one study which focuses on elderly patients (Brand & Clingemeel, 1992). However, other recent reviews (Cuijpers, Karyotaki, Pot, Park & Reynolds III, 2014; Polenick & Flora; 2013) confirm that psychological interventions, including BA, are also effective in the elderly. Though, in these later reviews of the elderly, the number of studies of inpatients is under-represented.

The patients that were included in our RCT were characterized by a chronic disease profile (multiple depressive episodes, multiple admissions). It was difficult to motivate them to participate in the SAM intervention. There are two possible underlying reasons for this. Firstly, it can be assumed that due to the increasingly ambulant character of the Dutch mental health services, only those patients with the most severe and complex depression are still clinically admitted (Bijenhof, Folkertsma, Kommer, Slobbe & Polder, 2012). In the event of a severe depression, it is difficult, often both literally and figuratively, to activate the patient. Presumably, this also applies to active participation in the SAM. Secondly, clinical observations of our population suggests that comorbid personality characteristics had a negative influence on carrying out the SAM. Although we did not systematically measure these factors in this study, the nurses in **Chapter six** reported low self-esteem, extreme passivity and dependent behavior of the study population. These factors have been described in the literature to have a negative influence on depression (Kim, Kim, Cho, Kwon et al. 2016; Koorevaar et al. 2013; Wiersma et al. 2011). Personality characteristics can predispose to maintaining depression (Lewinsohn, Hoberman, Teri & Hautzinger, 1986). We observed that intensive support by the nurses was necessary for patients to take part in positive activities. In addition, patients were shown to have the tendency to give up quickly.

The sample described in **Chapter seven** comprises a population of ambulant patients with a depressive disorder. The depression scores varied widely: from depression in remission to severe depression. This study illustrates that many unmet care needs exist in almost all life domains. This is in line with previous studies into the impact

of depression on functioning in daily life (Lepine & Briley, 2011; Beekman, Penninx, Deeg et al. 2002). In the context of this thesis, it is striking that most unmet care needs relate to performing “daily activities”. The level of dissatisfaction with the provided care with respect to this item is higher in people with severe depression than in people with milder depressive symptoms. This implies that patients with severe LLD require more help in the domain of daily activities. It is possible that the SAM may be effective as an additional intervention here. However, it could also be the case that the unmet care needs on the “daily activities” item may be due to unmet care needs in other domains such as physical health or living conditions, and not necessarily be a symptom of the depression itself. In implementing SAM, it is important to take into account the complete range of unmet care needs which could restrict carrying out positive activities.

It may be concluded that elderly patients with depression in specialized mental health care often have a chronic disease profile with a long history of treatment and unmet care needs in almost all life domains, but in social care needs in particular. It would appear that in these patients a poor level of activity and low motivation is not always attributable to a depressive disorder, but may also be partially due to comorbid personality characteristics or unmet care needs in other domains. Therefore, in order to utilize SAM effectively, it is important to systematically establish those care needs and comorbid personality characteristics of the patient that may be restricting the delivery of the SAM.

Intervention: development, implementation and effect

Development of the SAM

The SAM, is based on an existing method of treatment—Behavioral Activation (BA)—which we modified for nursing care. We chose BA because it has a number of important strengths, i.e., a) it has been proven effective in both younger and older ambulant depressive patients, b) it has a solid theoretical base, c) it has a protocol, and d) extensive training is not necessary in order to be able to implement it. The SAM is based on the “Coping with depression course” (Voordouw, Kramer & Cuijpers, P., Muñoz, R.F., Clarck, G.N & Lewinsohn, 2009), since this is a well structured intervention which is simple to execute. The SAM comprises seven weekly meetings at which both the nurse and the patient know clearly what the goal of the session is, and how to work towards it. The structured approach of the SAM is intended to contrast with the individual and intuitive approach which characterizes current mental health nursing. The aim of the patients’ course book is to place the responsibility of progress as much

as possible with the patients themselves. In addition, the structure of SAM means that a patient can continue the intervention even in case he or she is discharged. This is illustrated by the patient in our case report in **Chapter three**. In the current format, the SAM appears to be equally applicable in an ambulant setting to those patients with care needs in the domain of daily activities, as described in **Chapter seven**.

If we compare SAM with the BA formats which were used in the two BA studies included in the meta-analysis (**Chapter two**; de Jong, Treiber & Henrich, 1986; Hopko, Lejeuz, Lepage, Hopko & Mc Neal, 2003), then we see that there are similarities (e.g. the gradual expansion of positive activities, and the monitoring of these by means of a mood diary) as well as some differences. Firstly, in the studies included in the meta-analysis BA was carried out by psychologists (Treiber et al., 1986), or other care providers with a Master’s degree (Hopko et al. 2003) while our BA is aimed to be delivered by nurses. Secondly, in the studies in the meta-analysis, BA is applied more intensively (3 or 4 sessions per week) than in our study (one session per week). Possibly, the SAM could have had more effect if it were to be more intensively delivered.

Implementation of the SAM during the RCT

The implementation of the SAM during the RCT was challenging, as the patients were difficult to motivate to take an active part in the SAM. In addition, some patients were opposed to the course book as they found it overwhelming. This implies that using the SAM, as an intervention in a clinical population of the elderly, may possibly be more complex than originally thought. Possibly, it burdens patients with too many demands and they might not be able to take on the responsibility. It turned out that delivering the SAM demands a lot of time and effort, both from the nurse and the patient. These findings correspond with those of other studies (Francke, Smit, de Veer & Mistaen, 2008; Paley Myers, Patrick & Reid, 2003; Folke, Kanter & Eksillius, 2016). The rule of thumb is: “The more complex the intervention, the more difficult the implementation” (Franke et al. 2008). As implementation of the SAM required more time and effort than originally expected, the intervention was more difficult to fit into the daily rhythm of the unit. This was probably one of the main reasons for the incomplete implementation of the SAM during the study.

Effects

The results in **Chapter five** show that the SAM had small to moderate post-intervention effects on anxiety, depression and mastery. However, these effects were not statistically significant so therefore we were not able to convincingly demonstrate the effectiveness of SAM in the RCT. There are two potential causes of this lack of effect: too small a sample size and too little contrast between the SAM

and the control condition; the latter resulting from the incomplete implementation of the SAM in practice. The same phenomenon can be observed in other studies on the elderly with depression (Dozeman et al., 2011; Snarski et al., 2011). In these other studies, non-significant findings are also partially attributed to an incomplete implementation of the intervention. This implies that in future studies into the effectiveness of psychological interventions in patients with LLD, more emphasis should be placed on the implementation of the intervention during the study. As we have described above, the results of the BA studies in **Chapter two** are difficult to compare with the RCT carried out for this thesis. A more recent study from Ekers and colleagues (Ekers, Richards, McMillan, Bland & Gilbody, 2011) shows that BA can be effectively implemented in depressive patients by nurses. In this study, BA is presented as a structured 12-week intervention during which patients are taught to avoid depressive behavior and to develop alternative behavior by carrying out positive activities. The nurses received a five-day training and demonstrated a large effect (ES 1.15) in favor of BA compared to a waiting-list condition. An important difference between our study and the one of Ekers is the patient group. In Ekers' study, the patients were younger and recruited from primary care. We suspect that this group does not have the same chronic profile as our population. In the second place, we suspect that the contrast between the experimental and the control condition is greater than in our study. In Ekers' study, the control patients were on a waiting list, while the patients in our control group were hospitalized and already being treated for their disorder. This may potentially explain the differences in the effects between our RCT and Ekers' study.

It can be concluded that the effectiveness of the SAM could not be demonstrated due to the limited sample size in combination with incomplete implementation. This implementation problem may also be referred to as a type III error or, in other words, "the implementation error" (see Schwartz & Carpenter, 1999). The null hypothesis is accepted (there is no difference between the groups), but this cannot be solely attributed to the ineffectiveness of the intervention as such, but rather to the fact that it was incompletely implemented.

Nurses

While designing the SAM, we attempted to make it compatible with the competences as formulated in the professional profile which was developed by the Dutch association of psychiatric nurses (*Nederlandse Vereniging van Psychiatrisch Verpleegkundigen* [NVPV], 2004). In this profile, the purposive and systematic delivery of care is regarded as a core competence of nursing practice. However, the results in **Chapter six** show that nurses

did not fully succeed in delivering the SAM in a systematic manner. Instead, the nurses adapted the SAM to the specific (and often limited) abilities of the patients meaning that ultimately only some parts of the SAM were carried out. This means that there was a lot of variation in the way SAM was delivered and, in many cases, delivery was suboptimal. This might have limited the effects. In addition, the nurses placed a lot of emphasis on the relationship with the patient, i.e. acknowledging the suffering and by extension the feelings of helplessness experienced by the patient. Implementing the SAM puts pressure on the relationship with the patients, as the SAM requires an active involvement of the patient and this contradicts with the acknowledging the patients' suffering. As shown by the evaluation study, the nurses often found it difficult to burden the patients even more by carrying out this activating intervention. These findings are in accordance with other studies (McNeela, Scott, Treacy & Hyde 2009; Forsner, Hansson, Brommels, Åberg Wisted & Forsell, 2010; Bauer, 2002), and imply that complying with protocolled interventions has still not found any common ground. It is important that, during training the nurses become fully aware of the possible benefits of activation as a systematic and purposeful intervention. It is important that they realize that it is necessary to stimulate the patient in order to break the spiral of inactivity and depression. This means that nurses must not only strive for good contact with the patient, but also to deliver structured interventions (such as activating interventions) in order to reduce the patients' symptoms. The aims associated with the various themes of the SAM could be helpful with this.

A possible second explanation for the incomplete implementation of the SAM is the nature of the work of the nurses. Many of the contacts between patients and nurses take place in an informal and unstructured way in the daily rhythm of the unit. Nurses are required to be continually flexible and to deal with all the routine duties and activities within the unit. These findings are in concordance with the study of McNeela et al. (2009) which shows that the clinical decision-making process of mental health nurses is not only based on a judicious decision-making process in the context of structured working, but that action is often required on acute situations. It is possible that some nurses gave less priority to the execution of the SAM because they were too focused on their daily routines. As a result this may have limited the commitment to the SAM (Paley, Myers, Patrick & Reid, 2004; Forsner et al. 2010; Alanen, Välimäki & Kaila for the ECCE Study Group, 2008). The study of Paley et al. (2004) shows that when a new model is introduced, that initially nurses need time to get used to the new specifications and techniques. This leads to feelings of unfamiliarity for nurses within their routine daily routine. We also saw this with the implementation of SAM. Due to the low inclusion rate of patients, the nurses were not able to deliver (and practice) the SAM frequently. This meant that the feeling of unfamiliarity did not disappear. More opportunities to practice on the units, and direct coaching from an expert, might have increased commitment to the intervention.

If we compare the results of this thesis with current developments in nursing in general, and in mental health nursing in particular, we see (large) differences between what is expected of nurses and what is actually achieved in practice. The Dutch Association of Mental Health and Addiction Care (GGZ Nederland, 2012) places even more emphasis on a goal-oriented and systematic approach than the professional profile of the NVPV (2004). In addition, more emphasis is paid to task shifting in mental health nursing, an example of which is nurses delivering psychological interventions (e.g. Ekers et al. 2011). We feel that in the Netherlands, the concept of nurses delivering psychological interventions is still very much in its infancy. Our study appears to be ahead of current advances in relation to the professional development of mental health nurses.

In order to work in a focused and systematic manner, a change in the mindset of mental health nurses is necessary, as working with guidelines and intervention protocols (i.e. interventions such as SAM) requires enormous adjustments when compared with the traditional way of working, where personal clinical experience are the most important (Forsner et al. 2010).

Furthermore, the current skill levels of nurses do not appear to be sufficiently compatible with the skills required to deliver SAM effectively. Most nurses felt that the motivational techniques that were covered in the short training sessions were already known to them. However, the actual delivery of these techniques to the group of patients in our study proved to be much more complex than they originally thought. This leads us to question the extent to which the nurses had actually mastered the motivational techniques in practice. They might have overestimated their own competencies which leads to a decreased interest in additional training motivational techniques.

We did not measure the differences in the execution of the SAM between registered nurses and Bachelor's degree nurses. However, looking at the professional profiles it seems that the Bachelor's degree nurses, in particular, should be able to deliver the intervention effectively to patients with LLD. After all, the delivery of SAM requires the application of advanced clinical reasoning in a complex patient population. This requires the creative and flexible application of motivational techniques, intensive support and psychoeducation and these are the skills that are compatible with graduate competencies (Dutch Association of Mental Health and Addiction Care, 2012; Haspeslagh, Eeckloo & Delesie, 2012).

In conclusion, it can be stated that in this study the SAM was suboptimal implemented by the nurses because, to some degree, they continued working in an unstructured way in which they emphasized a good relationship with the patient. This led to the SAM being delivered according to personal preference and insight and being adapted to local circumstances and opportunities. This variation in delivery might have limited its intended effectiveness. The delivery problems might be partially explained by the limited opportunities for nurses to implement the SAM, as well as by the limited level of skills in methodological working and in executing motivational techniques to patients with LLD.

Context

The barriers and facilitating factors for implementation of the SAM are also identified in other studies on the implementation of (nursing) guidelines in various settings, i.e., care homes (Meeks, Looney, Van Haitsma & Teri 2008), general hospitals (McCaughan, Thomson, Cullem, Sheldon & Thomson, 2002), general healthcare centers (Alanen et al. 2008) and psychiatric hospitals (Forsner et al. 2010). Certain factors such as "lack of time" and "lack of support from the management" are also seen in these studies which shows that they are not specifically linked to the clinical setting in which our RCT took place.

The suboptimal implementation of the SAM might also be explained by two factors that are related to the context of the clinical setting (i.e. the psychiatric hospitals). These are *nursing teamwork* and *multidisciplinary teamwork*. In an inpatient healthcare setting, nurses are largely dependent on each other and this reinforces the importance of nursing teamwork. Multidisciplinary teamwork is a core aspect of the treatment of inpatients. The nurses from the four participating units reported that they considered support from other members of the team to be an important facilitating factor (**Chapter six**). However, not all the nurses felt that this support had been optimal. Some nurses felt uncomfortable about freeing up time for the patients to work with SAM as it left their colleagues with the regular work to do. In addition, a number of nurses were skeptical about the how SAM would work in a clinical population in advance. This constrained peer consensus about the importance of carrying out SAM. A study by Ploeg, Davies, Edwards, Gifford & Miller (2007) shows, that a common objective to improve patient care is a pre-condition for obtaining cooperation in the implementation of guidelines. We presume that the initial belief that SAM was an effective intervention began to diminish when no convincing results emerged. This, in turn, led to decreased commitment to the intervention, causing a further decline in both implementation and results. Belief in the intervention seems

to be an important condition for a common objective, especially if it differs within the individual team members. This implies that the focus should be explicitly on developing and retaining a common objective among the members of the nursing teams. Management has an important part to play in this by creating those conditions necessary to consolidate consensus (Forsner et al. 2010).

The interviews in which nurses also revealed that multidisciplinary teamwork facilitate the delivery of the intervention. However, the role of the multidisciplinary team in the RCT was limited. The multidisciplinary team, in which different types of professionals are represented, was mainly used by the nurses to discuss difficult and complex cases. It was striking that e.g. occupational therapists were not asked to collaborate in supporting the patients in the undertaking of positive activities. This suggests that the SAM was not a fully integrated part of the existing methods of treatment. This may be due to our implementation strategy during the RCT. We implemented the SAM as a traditional one-on-one psychotherapeutic model and not as a multidisciplinary intervention. We did not stress possible collaborations between nurses and other disciplines. In addition, it is possible that the nurses' perception of their role was unclear. The SAM requires the nurses to have a role as therapist in the treatment of patients with LLD, while traditionally nurses have a more supportive role throughout the entire treatment process (McNeela et al. 2009; NVPV, 2004). This traditional perception of a support-oriented role is also reflected in other studies. A recent case report from Folke et al. (2016), in which BA was implemented in a clinical setting, shows the role of the nurse to be mainly supportive of the actual therapy. This implies that a clear shift in role patterns from a more supporting professional to a role as a more directive therapist is necessary if nurses are going to deliver psychological interventions such as the SAM on clinical units.

In conclusion, it can be stated that the implementation of new nursing interventions such as the SAM on clinical units can be facilitated by support from other team members and by having a common objective. In respect of multidisciplinary teamwork, not only the nurses but also other members of the multidisciplinary team should be aware of the change of the role of the nurse to include the implementation of psychological interventions such as the SAM.

Implications for practice

In this thesis, we have not been able to convincingly demonstrate the effectiveness of the SAM. However, we think that it could be worthwhile to implement the SAM into routine practice as long as the recommendations in this thesis are taken

into consideration. The potential of the intervention has been demonstrated in earlier research e.g. by Ekers and colleagues (2011). We think that it needs further development with more emphasis on effective implementation. We recommend to introduce the intervention first on a small scale, and study the effects in daily practice. This will provide more insight into the conditions that are necessary for effective implementation. We think that there are good opportunities to deliver SAM effectively as long as it is properly implemented. This thesis has given us preliminary insight into those factors that play a role in the implementation of the SAM in practice and that lead to focused recommendations with respect to the target group, the intervention itself, the professional competences of the nurses and the context of the implementation. Further research is desirable in order to introduce more effective implementation pathways, with the expectation that the effectiveness of the SAM intervention will then also be demonstrated.

Patient group

In order to be able to offer the SAM intervention effectively, it is important that we know the severity of the depression, but also the personality characteristics and the unmet care needs of the patients. Instruments such as the Camberwell Assessment of Needs in the Elderly (CANE); Droës, van Hout & van der Ploeg, 2004) can be useful to measure those care needs. Additionally, hetero-anamnestic assessment is necessary in order to evaluate the extent to which passive behavior and a lack of self-esteem can be attributed to depression, or to personality characteristics. That would facilitate knowing where the emphasis should be placed in activating patients.

The SAM

As the SAM is a complex intervention, further training is necessary for nurses who wish to deliver this intervention. The short period of training that we provided for the RCT proved unsatisfactory. A more extensive training program is necessary in which the main focus should be on the use of motivational techniques in this target group. The work of Miller and Rolnick (2013) is a suitable source of information, but it is particularly important to translate this information into specific skills that can be effectively delivered by nurses. Attention should also be paid to the consequences of delivering a structured activating intervention for the relationship with the patient, and on effective ways for nurses in coping with this. In order to bring this about, it is necessary that nurses are given ample opportunity to rehearse these skills in practice and to reflect on the process at supervised meetings embedded in the training program (Paley et al., 2004).

We also recommend some changes in the intervention itself. We propose that the SAM be supplemented by an introductory section consisting of psychoeducation and obtaining a history of (pleasant) activities in the past. This methodology is consistent with guidelines on depression in dementia (Verkaik et al. 2011). It has been shown prior that providing psychoeducation can effectively reduce depressive symptoms (Donker, Griffiths, Cuijpers & Christensen, 2009). An activity history can help to create realistic expectations in relation to the possibilities for, and wishes of, a patient in carrying out activities. Help and support from significant others such as family members, neighbors, partners etc. can also be included in this. In addition, we recommend that SAM should be delivered more intensively by spreading the number of meetings over two or three short meetings each week, as in the protocols of Hopko et al. (2003) and Treiber et al. (1986).

The professional development of the nurse

In order to implement research-based interventions in practice, current working practices must be altered to include a clear differentiation in the roles of the nurses. Additionally, the responsibilities of nurses in their role as autonomous professionals must be clearly emphasized. This will not be achieved in the short-term. Based on the latest nursing proficiency profiles for mental health nurses, we are optimistic about the future. In these profiles emphasize a more differentiated role for nurses with varying levels of training, and working towards the optimal development and utilization of professional competences within these levels (V&VN 2012). We also think that a number of modifications to current nursing practice are necessary to stimulate changes on the work floor. These are:

1. Differentiation of function based on the complexity of care. Taking the complexity of care in the populations studied into account, we recommend that the SAM be implemented from a Bachelor's degree nurses, and that the supportive tasks be primarily done by registered nurses (e.g. helping patients to fill out the mood diary) (Haspelslagh et al. 2012).
2. Setting up a compulsory quality register for nurses in which continuing professional education a requirement. According to current Dutch regulations (www.bigregister.nl/herregistratie/-criteria-per-beroep/verpleegkundige), nurses can re-register on the grounds of work experience and are not required to follow any extra education. The quality register should require continuing professional education and a minimum of intervision hours, whereby these requirements would be centrally regulated.
3. The deployment of clinical nurse specialists. In addition to their role as therapists, clinical nurse specialists have also developed competencies in the areas of innovation as well as in coaching nurses. Furthermore, they fulfill an important bridge between science and practice, which makes them particularly suitable for the role of "local opinion leader" (Verkaik et al., 2011; V&VN, 2012a).

The context

Routine care innovations require that the managers of the clinical units play a central role. They have the important task of stimulating the professional development of the nursing team and to create the right conditions for this. An important aspect of this is that a learning environment should be established. This is characterized by a culture that supports professional learning and in which training sessions and (inter-) supervision are integrated into nursing practice (Houghton, 2015). Furthermore, management must provide the nurses with sufficient time for their change in professional roles from supportive to therapeutic.

Methodological considerations

This thesis contributes to the existing body of knowledge about effectiveness of BA and provides insight into the knowledge about barriers and facilitators for implementation of the SAM in clinical patients with LLD. Fifty-five patients were included in the RCT. In the setting of a clinical population of elderly psychiatric patients, this can be regarded as a relatively large study. However, during the study it became apparent that the inclusion of patients was not going to reach the number that had been estimated in the power analysis that preceded the study. This may partially explain the lack of significant differences between the experimental and the control group. **Chapter seven** further elaborates on the severity of the problems of patients with LLD from the perspective of their care needs. The CANE proved to be a helpful instrument in documenting both fulfilled and unmet care needs in relation to the help that was actually offered from professional and informal care providers. It also showed the extent patient's were satisfied with this care.

In addition, it should be pointed out that the implementation study was carried out in the context of an RCT. This might not give a complete and accurate overview of facilitating factors and barriers for implementation since the RCT added further demands e.g. with respect to the inclusion procedure, and the contribution to data collection.

Another limitation is that the results of our RCT, in which nurses delivered the intervention, are difficult to compare with the results of the meta-analysis in **Chapter two**, in which psychologists carried out the treatments. In the RCT we did not only measure the effect of BA but also the effect of implementation by nurses for whom the delivering of psychological therapy was a reasonably new activity.

In the sample that we used in the evaluation study in **Chapter six**, we interviewed twelve nurses some time after the study had been completed which may possibly have introduced recall bias, as they could not remember all the details, or their interpretation of these details may have changed over the passage of time. In addition, we only interviewed those nurses who at that time were prepared and available to take part in the interview. This means that we are not certain we have been able to correctly document the perspectives of all the nurses. It is likely that it was, in fact, only the most motivated nurses who took part.

In conclusion, in this thesis we used different patient populations. The meta-analysis in **Chapter two** mainly focused on adult outpatient populations, the RCT in **Chapter five** and the evaluation study in **Chapter six** represent a clinical population, and the population in **Chapter seven** comprises ambulant patients. This means that the results of the various sub studies are difficult to compare with one another.

Considerations for further research

As has already been stated, it is desirable to first implement the SAM on a small scale in order to obtain a better picture of the conditions in which it can be effectively implemented within nursing care. This implementation could be based on the results of this thesis. The SAM could be implemented into routine practice on some units by means of a targeted strategy. Ideally, a new effectiveness study should take place, with enough statistical power, after successful implementation. The SAM would be available as part of the multidisciplinary treatment program and would be delivered by trained and experienced nurses.

In this thesis, we did not examine the influence of specific patient characteristics and care needs that might influence the adaptation of the SAM. However, we did examine the unmet care needs of patients with LLD in an outpatient setting (**Chapter seven**), but these cannot be automatically compared to those of patients in a clinical setting. A study into the unmet care needs in a clinical setting may contribute to wider knowledge of clinical populations and result in the better estimation of what is expected of the nurses in the delivery of interventions such as SAM.

Finally, a study into the comorbid personality characteristics of clinical patient populations with LLD is necessary. The SAM is based on the integrative theory of depression (Lewinsohn et al. 1985) in which it is proposed that the circle of depression is broken by increasing the number of positive reinforcers. A study into comorbid personality characteristics may increase knowledge into the predisposing factors that maintain the circle of depression. This might be used to create more personalized interventions to activate patients.

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Summary / samenvatting

The Systematic Activation Method: a Nursing Intervention Study for Patients with Late Life Depression.

Summary

The prevalence of severe later life depression (LLD) varies between 1-5%. Depression has a huge impact on the daily functioning of people. Those people affected by depression often feel trapped in a circle of severe somberness, anhedonia, inactivity and loss of faith in their ability to change anything about the situation. In order to break out of this circle, a multidisciplinary approach is necessary in which "activation" is an important focus of treatment. Due to their direct and intensive contact with the patient, nurses can play an important part in this process. However, research into the effectiveness of nursing care for patients with depression in later life is very limited. Most publications in the field of nursing care are regarded as being Class IV evidence, which means that "evidence" is based on the opinions of the authorities in the areas concerned (in our case, mental health nursing). This doctoral thesis aims to contribute to the body of scientific knowledge in the field of mental health nursing. It concerns the development and testing of the Systematic Activation Method (SAM) used as a nursing intervention in patients with severe late life depression.

Chapter 1 is the general introduction to the thesis. It includes a description of the integrated depression theory of Lewinsohn, Hoberman, Tery & Hautzinger (1985) on which the SAM is based. One of the main propositions of this theory is that a certain event can lead to a depression which is followed by a drop in the number of positive reinforcers. This limitation in the number of positive reinforcers can maintain or even worsen depression. This theory forms the basis of a form of therapy that is known as Behavioral Activation (BA). Studies have demonstrated that behavioral activation is effective in patients with severe depression. The SAM was developed as an accessible form of behavioral activation that can potentially be applied in the daily practice of nurses. **Chapter 1** gives an overview of the structure and content of the SAM.

It closes with a description of the three main aims of this thesis: 1) the testing of the effects of the Systematic Activation Method as a nursing intervention in patients with severe late life depression, who have been admitted to hospital, 2) research into the factors that influence the implementation of the SAM in practice, and 3) obtaining more understanding of the unfulfilled care needs and satisfaction of care in patients with late life depression.

By way of an introduction to the main study **Chapter 2** of this thesis describes a meta-analysis of psychological treatments in depressive adults who have been admitted to hospital. A total of twelve studies were included in this meta-analysis. The results show a significant overall effect size of Hedges' $g=0.29$ (95% CI: 0.13 – 0.44; $p<0.001$) in favor of psychological therapies (cognitive behavioral therapy (CBT), behavioral activation (BA) and other therapy forms) on comparison with a control condition. The sub-group analyses show that cognitive behavioral therapy, BA and the other forms of therapy are all effective. Additional subgroup analyses demonstrate striking differences in effect sizes, whereby the effect of BA (Hedges' $g=0.56$) is larger than the effect of CBT (Hedges' $g=0.19$) and also of the other forms of therapy (Hedges' $g=0.30$). The conclusion is that psychological interventions have a small but robust effect on depression in a clinical population. It should be pointed out that the patient populations in the individual studies mainly comprised adult patient populations, a limited number of whom were elderly, which means that the results cannot be automatically generalized to patients with a LLD.

Chapter 3 goes on to describe a case report of the implementation of SAM in daily practice. The SAM was designed to be a prescriptive and systematic intervention to last for seven weeks during which time, six themes would be covered. The SAM is based on a previously-developed "Coping with depression course", which is also based on the principles of BA, but has been adapted to become an intervention that can be delivered by nurses in clinical practice. In this case report, the situation of a patient called Susan shows that the SAM is focused on an important symptom of late life depression, i.e., a lack of interest in almost all activities and the inactivity that results from this. This case report shows that the intervention is easy to understand and that it can be effectively delivered in nursing practice. The keeping of a Mood Diary offers the possibility of giving the patient insight into the positive effects that activity has on the mood.

Chapters 4 and **5** describe the study into the effectiveness of the SAM, tested in a pragmatic multicenter randomized trial (RCT). In the research protocol (**Chapter 4**), we postulated a group size of 102 patients in total, equally distributed over the experimental group and the control group. Outcome variables were depression (BDI), anxiety (HADS-A), mastery (PMS), quality of life (SF-36), costs (TiC-P), and the level of activation (measured by means of an inventory list which was part of the SAM). Measurements were taken at three time points, i.e., baseline (T0), post-intervention (T2 = 2 months after T0), and a follow-up measurement (T2 = 6 months after T0).

In **Chapter 5** the results of the RCT are described and discussed. During the study it proved that the number of assessment instruments discouraged people from taking part in the study. On the basis of this interim finding, after approximately six months of inclusion it was decided to stop administering the SF-36 and the TIC-P.

We carried out the study on ten units (five experimental and five control units). Ultimately, 55 patients were included (n=30 experimental group and n=25 control group). The results demonstrate that on comparison with the baseline measurements, the patients significantly improved on the BDI, HADS-A and PMS on T1. This was true for both groups. The differences between the experimental group and control group were not significant. The differences on T2 were not significant between the groups in relation to T1. We found an average effect size in the drop in BDI scores on T1 in favor of the experimental group over the control group (Hedges' $g=0.35$), but this was not significant.

In conclusion it can be stated that the SAM does not have a significant additional effect on the improvement of a depressive disorder when compared with usual care.

Chapter 6 describes the results of a qualitative evaluation of the implementation of the SAM by nurses who participated in the RCT in the experimental group. We interviewed the nurses in groups per setting. A total of twelve nurses, divided into four groups, took part in these interviews. Using semi-structured interviews, barriers and facilitators of the SAM were studied. These were analyzed on the level of the nurses, the patients and the context of treatment. The following facilitating factors emerged: the nurses' positive attitude towards SAM, the opportunities to adapt SAM to the specific circumstances of patients and their environment, team support for the implementation of the intervention, the degree of integration of SAM into multidisciplinary treatment, and the active involvement of the unit manager. Important barriers were: the complexity of the intervention, lack of time, severity of depression and other patient-related characteristics (such as strongly dependent behavior). The delivery of the SAM proved to be more complicated than initially expected. It was concluded that intensive training and supervision was necessary during the implementation and delivery of the SAM.

Chapter 7 describes a cross-sectional study in 99 ambulant elderly patients with severe depression, the aim of which was to gain insight into the provided care relating to reported unmet care needs. The level of satisfaction concerning the provision of care in this group of patients was also examined. We used the Camberwell Assessment of Needs of the Elderly (CANE) for these purposes. It emerged from this study that

two-thirds of patients had one or more unmet care needs. Care was provided for 80% of these unmet care needs. Generally, there was a high level of satisfaction with the available care, with the exception of social care needs. Further, on six items we found a significant association between satisfaction with the care offered and the severity of the depression. These are the items 'household skills', 'financial benefits', 'memory', 'behavior', 'alcohol' and 'daytime activities'. Dissatisfied patients had significantly higher depression scores than satisfied patients ($p<0.05$). The conclusion is that regular monitoring of care needs is vitally important, and the level of satisfaction in relation to the available care must be identified. All this is aimed at providing qualitatively high-grade care to the target group that is consistent with their individual care needs and preferences.

In **Chapter 8** the results of the aforementioned studies are discussed further. The meta-analysis shows that psychological treatment methods, implemented mainly in adults in a clinical setting, have a small but robust effect in relation to a control condition. However, this effect could not be demonstrated in the delivery of the SAM to the elderly in a clinical setting. Two main explanations are purported for this, i.e., too small a sample and incomplete implementation. The study into care needs presented in this doctoral thesis shows that the patients with a chronic disease profile had unmet care needs in almost all life domains. Their level of dissatisfaction with care needs in the social domain, in particular, was high. The intensive support in relation to activating activities, as incorporated into the SAM, may potentially contribute positively towards fulfilling these social care needs. The SAM was developed to be an accessible intervention for both patients and nurses, however, in many cases motivating patients to participate proved to be a complicating factor. In addition, the studies show that nurses adhered closely to a traditional manner of unstructured working and had difficulty in implementing the SAM fully. Despite the fact that the effect of the SAM could not be adequately shown, we are of the opinion that the SAM can be effective as long as it is properly implemented. Investment in training and supervision in order to further develop nursing competencies (including the domain of motivating strategies), is expected to contribute to better implementation and, in this way, to increase the effectiveness of the intervention. In respect of the clinical setting, the results show that only limited use was made of multidisciplinary cooperation. Future research will show if the complete implementation of SAM is more effective than usual care. Facilitating and restricting factors should be translated into an effective implementation strategy, with a particular focus on adequate training and supervision and on the optimal embedding of the SAM into the multidisciplinary treatment program.

The Systematic Activation Method: a Nursing Intervention study for patients with Late Life Depression.

Samenvatting

De prevalentie van een ernstige depressie op latere leeftijd varieert tussen de 1 en 5%. De depressie heeft een grote impact op het dagelijks functioneren van mensen. De mensen die door een depressie worden getroffen voelen zich vaak gevangen in een cirkel van ernstige somberheid en anhedonie, inactiviteit en het gebrek aan vertrouwen om nog iets aan de eigen situatie te veranderen. Om deze cirkel te doorbreken is een multidisciplinaire aanpak nodig waarin “activeren” een belangrijke focus is van de behandeling. Verpleegkundigen kunnen hieraan een belangrijke bijdrage leveren gezien hun directe en intensieve contact met de patiënt. Onderzoek naar de effectiviteit van de verpleegkundige zorgverlening bij patiënten met een depressie op latere leeftijd is echter zeer beperkt. De meeste publicaties binnen het vakgebied van de verpleegkunde worden beoordeeld als klasse IV bewijs, wat betekent dat het “bewijs” bestaat uit de opinies van autoriteiten in het betreffende vakgebied (in ons geval de ggz-verpleegkunde). Dit proefschrift gaat over het ontwikkelen en testen van de Systematische ActiveringsMethode (SAM) als verpleegkundige interventie bij patiënten met een ernstige depressie op late leeftijd.

Hoofdstuk één beschrijft de algemene inleiding van de proefschrift. Er wordt een beschrijving gegeven van de integratieve depressietheorie van Lewinsohn, Hoberman, Tery & Hautzinger (1985) waarop de SAM gebaseerd is. Een belangrijk uitgangspunt van deze theorie is dat een bepaalde gebeurtenis kan leiden tot een depressie met als gevolg een daling van het aantal positieve bekrachtigers. Deze beperking in het aantal positieve bekrachtigers kunnen een depressie in stand houden of verergeren. Deze theorie vormt de basis van een therapievorm die gedragsactivatie wordt genoemd. Onderzoek heeft laten zien dat gedragsactivatie effectief is bij patiënten met een ernstige depressie. De SAM is ontwikkeld als een toegankelijke vorm van gedragsactivatie die mogelijk effectief kan worden toegepast binnen de alledaagse praktijk van verpleegkundigen. Dit hoofdstuk biedt een overzicht van de opbouw en inhoud van de SAM.

Besloten wordt met een beschrijving van de drie hoofddoelstellingen van dit proefschrift: 1) het testen van de effecten van de Systematische ActiveringsMethode als verpleegkundige interventie bij patiënten met een ernstige depressie op latere leeftijd die klinisch zijn opgenomen, 2) onderzoek naar de factoren die invloed

hebben op de implementatie van de SAM in de praktijk, en 3) het verkrijgen van een beter begrip van de onvervulde zorgbehoeften en tevredenheid van zorg bij patiënten met een depressie op latere leeftijd.

Hoofdstuk twee van dit proefschrift beschrijft – mede ter inleiding op de hoofdstudie - een meta-analyse naar psychologische behandelingen bij depressieve volwassen patiënten die klinisch zijn opgenomen. Er worden 12 studies geïnccludeerd in deze meta-analyse. De resultaten laten een significante overall effectgrootte zien van $\text{hedges}'g = 0,29$ (95% CI: 0.13 – 0.44; $p < 0.001$) ten gunste van psychologische therapieën (cognitieve gedragstherapie (CGT), behavioral activation (BA) en overige vormen) in vergelijking met een controleconditie. Uit de subgroep analyses blijkt dat zowel cognitieve gedragstherapie, BA als de overige therapievormen effectief zijn. Subgroep analyses laten verder zien dat er opvallende verschillen zijn in effectgroottes, waarbij het effect van BA (Hedges' $g = 0,56$) groter is dan het effect van CGT (Hedges' $g = 0,19$) en de overige therapievormen (Hedges' $g = 0,30$). De conclusie is dat psychologische interventies een klein maar robuust effect hebben op een depressie bij een klinische populatie. Opgemerkt dient te worden dat de patiëntenpopulaties in de afzonderlijke studies voornamelijk bestaan uit volwassen patiënten, en slechts beperkt uit ouderen, waardoor de resultaten niet zonder meer te generaliseren zijn naar de ouderenpopulatie met een ernstige depressie.

Hoofdstuk drie beschrijft vervolgens aan de hand van een case report de implementatie van de Systematische ActiveringsMethode (SAM) in de dagelijkse praktijk. De SAM is opgezet als een prescriptieve en systematische interventie, met een duur van 7 weken waarin 6 thema's worden behandeld. De SAM is gebaseerd op de eerder ontwikkelde cursus 'Omgaan met depressie', die eveneens uitgaat van de principes van behavioral activation (BA), maar is vervolgens aangepast als een interventie die goed toepasbaar is voor verpleegkundigen in de klinische praktijk, waarbij de focus ligt op het activeren. De situatie van patiënte Susan in dit case report laat zien dat de SAM zich richt op een belangrijk symptoom van depressie op late leeftijd, te weten gebrek aan interesse in bijna alle activiteiten en de hieruit voortkomende inactiviteit. Het case report laat zien dat de interventie eenvoudig te begrijpen is en effectief binnen de verpleegkundige praktijk kan worden uitgevoerd. Het biedt via het bijhouden van een stemmingsdagboek goede mogelijkheden om de positieve effecten van activiteiten op de stemming inzichtelijk te maken.

De **hoofdstukken vier en vijf** beschrijven het onderzoek naar de effectiviteit van de SAM, getest in een pragmatische multicenter gerandomiseerde trial (RCT). In het onderzoeksprotocol (hoofdstuk 4) gingen we uit van een groepsgrootte

van 102 patiënten in totaal, gelijk verdeeld over de experimentele groep en de controlegroep. Uitkomstvariabelen waren depressie (BDI), angst (HADS-A), mastery (PMS), kwaliteit van leven (SF-36), kosten (TiC-P), en het activiteitsniveau (gemeten via de inventarisatielijst die onderdeel uitmaakt van de SAM). Er werd gemeten op drie tijdstippen, te weten op baseline (T0), post-intervention (T1 = 2 maanden na T0), en in een vervolgmeting (T2 = 6 maanden na T0).

In hoofdstuk 5 worden dan de resultaten van de RCT beschreven. Tijdens de studie bleek dat door de hoeveelheid meetinstrumenten patiënten ontmoedigd werden voor deelname aan de studie. Op basis van deze tussentijdse bevinding is na ongeveer een half jaar besloten om de SF-36 en de TiC-P niet verder af te nemen.

We hebben de studie uitgevoerd op 10 afdelingen (5 experimentele en 5 controleafdelingen). Er zijn uiteindelijk 55 patiënten geïnccludeerd (n=30 experimentele groep en n=25 controlegroep). De resultaten laten zien dat de patiënten significant verbeterden op de BDI, HADS-A en PMS op T1 ten opzichte van de baselinemeting. Dit gold voor beide groepen. De verschillen tussen de experimentele groep en controlegroep waren niet significant. De verschillen op T2 waren zowel binnen als tussen de beide groepen niet significant ten opzichte van T1. We vonden een gemiddelde effectgrootte in de daling van de BDI scores op T1 in het voordeel van de experimentele groep ten opzichte van de controlegroep (hedges'g=0,35) maar deze was niet significant.

Concluderend kan gesteld worden dat de SAM geen additioneel effect lijkt te hebben op het verbeteren van een depressieve stoornis ten opzicht van de gebruikelijke zorgverlening.

Hoofdstuk zes beschrijft vervolgens de resultaten van een kwalitatieve evaluatie naar de implementatie van de SAM door de verpleegkundigen die deelgenomen hebben aan de RCT in de experimentele groep. We hebben de verpleegkundigen in groepen per setting geïnterviewd. In totaal hebben 12 verpleegkundigen aan deze interviews deelgenomen, verdeeld over 4 groepen. Met behulp van semigestructureerde interviews zijn de bevorderende en belemmerende factoren van de implementatie van de SAM bestudeerd. Deze zijn uitgewerkt naar het niveau van de verpleegkundigen, de patiënten en de context van hulpverlening. Als bevorderende factoren kwamen naar voren: een positieve houding van de verpleegkundigen ten aanzien van de SAM, de mogelijkheden om de SAM te kunnen aanpassen aan de specifieke omstandigheden van de patiënt en de diens omgeving, ondersteuning vanuit het team bij de uitvoering van de interventie, de

mate van integratie van de SAM in de multidisciplinaire behandeling en actieve betrokkenheid van de unitmanager. Belemmerende factoren waren: complexiteit van de interventie, gebrek aan tijd, ernst van de depressie van de patiënt, en andere patiënt-gerelateerde kenmerken (zoals sterk afhankelijk gedrag). De toepassing van de SAM bleek gecompliceerder dan aanvankelijk verwacht. Geconcludeerd werd dat supervisie noodzakelijk is gedurende de implementatie en toepassing van de SAM.

Hoofdstuk zeven beschrijft een cross-sectionele studie bij 99 ambulante oudere patiënten met een ernstige depressie met als doel om inzicht te krijgen in de geboden zorg bij gerapporteerde onvervulde zorgbehoeften. Tevens werd gekeken naar de mate van tevredenheid over de zorgverlening bij deze groep patiënten. Hiervoor hebben we gebruik gemaakt van de Camberwell Assessment of Needs of the Elderly (CANE). Uit dit onderzoek komt naar voren dat bij tweederde van de patiënten sprake is van één of meer onvervulde zorgbehoeften. Bij 80% van deze onvervulde zorgbehoeften wordt wel zorg geboden. De tevredenheid over de geboden zorg is overwegend groot, met uitzondering van de sociale zorgbehoeften. Verder vonden we op zes items een significante associatie tussen tevredenheid en de ernst van de depressie. Dit zijn de items 'household skills', 'financial benefits', 'memory', 'behavior', 'alcohol' en 'daytime activities'. Ontevreden patiënten lieten een significant hogere depressiescore zien dan de tevreden patiënten ($p < 0.05$). De conclusie is dat regelmatige monitoring van zorgbehoeften van wezenlijk belang is, waarbij ook de tevredenheid van de patiënt ten aanzien van de geboden zorg vastgesteld dient te worden. Dit alles met het oog op het bieden van kwalitatief hoogwaardige zorg aan de doelgroep die aansluit bij hun individuele zorgbehoeften en voorkeuren.

In **hoofdstuk acht** worden de resultaten van de voorgaande studies nader bediscussieerd. Uit de meta-analyse komt naar voren dat psychologische behandelmethodes, uitgevoerd bij voornamelijk volwassenen in klinische settings, een klein maar robuust effect hebben ten opzichte van een controleconditie. Dit effect kon echter niet worden aangetoond bij toepassing van de SAM binnen een klinische setting voor ouderen. Er zijn twee belangrijke verklaringen voor te geven, te weten de kleine steekproef en onvolledige implementatie. De studie in dit proefschrift naar zorgbehoeften laat zien dat de patiënten een chronisch ziekteprofiel hadden met onvervulde zorgbehoeften op vrijwel alle levensgebieden. Met name ten aanzien van de zorgbehoeften op sociaal gebied was de ontevredenheid hoog. De intensieve begeleiding ten aanzien van activerende activiteiten, zoals opgenomen in de SAM, zou mogelijk een positieve bijdrage kunnen leveren aan de vervulling van deze sociale zorgbehoeften. De SAM is als een toegankelijke interventie voor patiënten en verpleegkundigen ontwikkeld, maar het motiveren van de patiënten

tot deelname bleek in veel gevallen een complicerende factor is. Daarnaast lieten de studies zien dat verpleegkundigen sterk vasthielden aan een traditionele manier van (ongestructureerd) werken en veel moeite hadden om de SAM volledig te implementeren. Ondanks dat het effect van de SAM onvoldoende kon worden aangetoond denken we wel dat de SAM effectief kan zijn bij patiënten mits deze goed wordt uitgevoerd. Daarnaast is er in toenemende behoefte aan eenvoudige, toegankelijke en goedkope interventies zoals de SAM. Tevens zal het investeren in scholing en supervisie om de competenties van verpleegkundigen – onder meer op het gebied van motiverende strategieën - verder te ontwikkelen zal naar verwachting bijdragen aan een betere implementatie en daarmee aan een grotere effectiviteit van de interventie. Ten aanzien van de klinische setting laten de resultaten zien dat er beperkt gebruik is gemaakt van de multidisciplinaire samenwerking. Toekomstig onderzoek moet uitwijzen of de SAM, bij een volledige implementatie, effectiever is dan de gebruikelijke zorg. Hiervoor is het nodig om de patiënten kenmerken goed in kaart te brengen en om aanwezige bevorderende en belemmerende factoren te vertalen in een effectieve implementatiestrategie, met bijzondere aandacht voor adequate scholing en supervisie en optimale inbedding van de SAM in het multidisciplinaire behandelaanbod.



Dankwoord / over de auteur

Dankwoord

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2 Move Your Ass

instellingen wil ik bedanken. Zij hebben de Systematische Activiteiten Methode moeten uitvoeren bij een uiterst complexe doelgroep.

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Maar de “eternal friends” die mij 10 jaar lang begeleid hebben bij mijn onderzoek zijn toch mijn “hardloopschoenen” en “my four string passive 1983 Fender jazz bass”..... because Rock and Roll will never die (N. Young).

Over de auteur.

Frans Clignet is geboren op 10 december 1964. Hij heeft de MAVO gedaan en daarna de MTS (electrotechniek) maar heeft deze opleiding niet afgerond. Na zijn militaire dienstdienst is Frans in 1987 begonnen met de inservice – opleiding voor B-verpleegkunde aan de Sint Josephstichting in Apeldoorn (thans GGNet). Nadat hij zijn diploma had behaald is hij gaan werken in de ouderenpsychiatrie van deze instelling. Hij is in 1991 gestart met de opleiding tot “middenkaderfunctionaris” aan de Hogeschool Nijmegen (thans de HAN). Intussen was Frans van functie gewisseld van verpleegkundige naar waarnemend groepscoördinator. Begin 1998 heeft Frans de overstap gemaakt naar sociotherapeut op een groepstherapeutische gemeenschap voor mensen met een borderline persoonlijkheidsstoornis. In september van dat jaar is Frans begonnen aan de studie Verplegingswetenschap aan Universiteit van Maastricht maar heeft, in het kader van het zogenaamde MUG³ verband, de studie aan de Universiteit Utrecht gevolgd bij prof.dr. M. Grypdonck. De titel van zijn afstudeerscriptie is: “Het bieden van dagstructuur; een dilemma tussen doen en laten.” In juni 2000 is Frans begonnen bij Altrecht als 1^e verpleegkundige en onderzoeker op een gespecialiseerde afdeling voor oudere patiënten met depressieve stoornis. In maart 2008 is Frans gestart met zijn promotieonderzoek. Daarnaast is hij in september 2008 gestart met de tweejarige opleiding Master of Advanced Nursing Practice aan de Hogeschool Utrecht. Momenteel werkt Frans nog steeds bij Altrecht, als regiebehandelaar van een groep oudere patiënten met een ernstige psychiatrische aandoening (EPA patiënten). Daarnaast werkt hij een avond per week als praktijkondersteuner GGZ bij een huisartsenpraktijk.

Frans is getrouwd met Sonja en zij hebben 3 kinderen; Marith (24), Joost (21) en Silke (17). In zijn vrije tijd doet Frans aan lange afstand hardlopen (trailrunning) en is een gepassioneerd bassist.

³ MUG verband is samenwerkingsverband tussen de universiteiten van Maastricht, Utrecht en Groningen. Dit samenwerkingsverband is inmiddels opgeheven.

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Geaccepteerd voor publicatie

Clignet, F., van Meijel, B., van Straten, A., & Cuijpers, P. Unmet care needs and care provision and patient satisfaction in patients with a late life depression: a cross-sectional study. In *Aging & Mental health*.

Ingediend:

Clignet, F., van Meijel, B., van Straten, A., & Cuijpers, P. The effectiveness of Behavioral Activation in hospitalized depressed elderly: A Pragmatic Clustered Randomized Clinical Trial.