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Effects of a lifestyle intervention on psychosocial well-being of severe mentally ill residential patients: ELIPS, a cluster randomized controlled pragmatic trial

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ABSTRACT

Large studies investigating the psychosocial effects of lifestyle interventions in patients with a severe mental illness (SMI) are scarce, especially in residential patients. This large, randomized controlled, multicentre pragmatic trial assessed the psychosocial effects of a combined diet-and-exercise lifestyle intervention targeting the obesogenic environment of SMI residential patients. Twenty-nine sheltered and clinical care teams were randomized into intervention ($n = 15$) or control ($n = 14$) arm. Team tailored diet-and-exercise lifestyle plans were set up to change the obesogenic environment into a healthier setting, and team members were trained in supporting patients to make healthier choices. The control group received care-as-usual. The Calgary Depression Scale for Schizophrenia (CDSS), Positive and Negative Syndrome Scale (PANSS), Health of the Nation Outcome Scales (HoNOS) and the Manchester Short Assessment of Quality of Life (MANSA) were assessed at baseline and after three and twelve months. Data were available for 384 intervention and 386 control patients (48.6 ± 12.5 years old, 62.7% males, 73.7% psychotic disorder). Linear mixed model analysis showed no psychosocial improvements in the intervention group compared to care-as-usual; the intervention group showed a slightly reduced quality of life (overall) and a small increase in depressive symptoms (clinical care facilities) and psychotic symptoms (sheltered facilities). This may be due to difficulties with implementation, the intervention not being specifically designed for improvements in mental well-being, or the small change approach, which may take longer to reach an effect. Further research might elucidate what type of lifestyle intervention under what circumstances positively affects psychosocial outcomes in this population.

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1. Introduction

Increased awareness of the somatic health of patients with a severe mental illness (SMI) has resulted in a large body of research on lifestyle interventions aiming at weight loss, weight gain prevention or improvements in cardiometabolic health. Lifestyle interventions can improve cardiometabolic risk factors such as waist circumference, triglycerides and fasting glucose in psychotic patients (Bruins et al., 2014). Lifestyle

changes may also affect psychosocial well-being because of the association of lifestyle factors with symptoms of depression and anxiety in the general population (Lang et al., 2015; Penedo and Dahn, 2005; Ross and Hayes, 1988), and with negative and depressive symptoms in schizophrenia (Rosenbaum et al., 2014; Vancampfort et al., 2012).

A number of studies have investigated the effect of lifestyle interventions on psychosocial functioning in SMI patients. For example, programs of physical exercise have shown to reduce psychotic symptoms (Beebe et al., 2005; Rimes et al., 2015; Scheewe et al., 2013), depressive symptoms (Acil et al., 2008; Scheewe et al., 2013), anxiety (Wipfli et al., 2008) and stress (Hoffmann et al., 2005) and improved quality of life was found after a nutritional intervention (Evans et al., 2005) and a psycho-educational weight control program (Mauri et al., 2008). However,

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symptomatic stability or unchanged quality of life were also reported (Ball et al., 2001; Brar et al., 2005; Forsberg et al., 2010; Heggelund et al., 2011; Kwon et al., 2006; Poulin et al., 2007; Wärdig et al., 2016). Drawing firm conclusions about the effect of lifestyle interventions on mental health is complicated due to small sample sizes (Acil et al., 2008; Ball et al., 2001; Beebe et al., 2005; Evans et al., 2004; Forsberg et al., 2010; Heggelund et al., 2011; Kwon et al., 2006; Mauri et al., 2008) or the lack of a control group (Daumit et al., 2011; Hoffmann et al., 2005; Richardson et al., 2005). Moreover, large trials including residential patients are lacking.

Adopting a healthy lifestyle is especially challenging for residential patients, due to the obesogenic environment of residential facilities. An obesogenic environment is characterized by limited opportunities for exercising and easy access to high-calorie food as opposed to healthy alternatives (Swinburn et al., 1999). Small environmental changes have led to weight loss in an uncontrolled inpatient population (Cohn et al., 2010). The Effectiveness of Lifestyle Interventions in PSYchiatry (ELIPS) study was designed to change the obesogenic environment of residential facilities, with the primary aim to improve patients' somatic health (Looijmans et al., 2014). The intervention successfully reduced waist circumference and metabolic syndrome Z-score after three months intervention (Looijmans et al., 2017). The current paper describes the secondary, psychosocial, outcomes of the ELIPS study. We hypothesized that the lifestyle intervention would lead to reduced depressive and psychotic symptoms and improved overall functioning and quality of life.

2. Materials and methods

2.1. Design

The study protocol of this multicentre cluster randomized controlled pragmatic trial was published elsewhere (Looijmans et al., 2014) and will be shortly explained below. The Medical Ethical Committee for Research in Mental Health Care (Metigg) concluded that study protocol and use of anonymized data from Routine Outcome Monitoring (ROM; below) was in accordance with the Declaration of Helsinki and (inter)national regulations, and that the study did not fall under the scope of the Medical Research Involving Human Subjects Act, thereby waiving informed consent. The trial was registered in the Dutch Trial Registry (NTR2720, www.trialregister.nl).

2.2. Study population

Out of eighteen sheltered and 11 long-term clinical care teams of two psychiatric institutions (Lentis and GGZ Friesland) in the Netherlands, clusters were made for teams that were comparable in terms of institution, location (rural or city), living situation (sheltered or clinical), and caseload (ranging from 20 to 65). Within each cluster, teams were randomly assigned to the lifestyle intervention or the treatment as usual control group, by a computerized random number generator by a non-participating research nurse. Recruitment was from September 2010 till December 2011. Patients taking part in the annual ROM

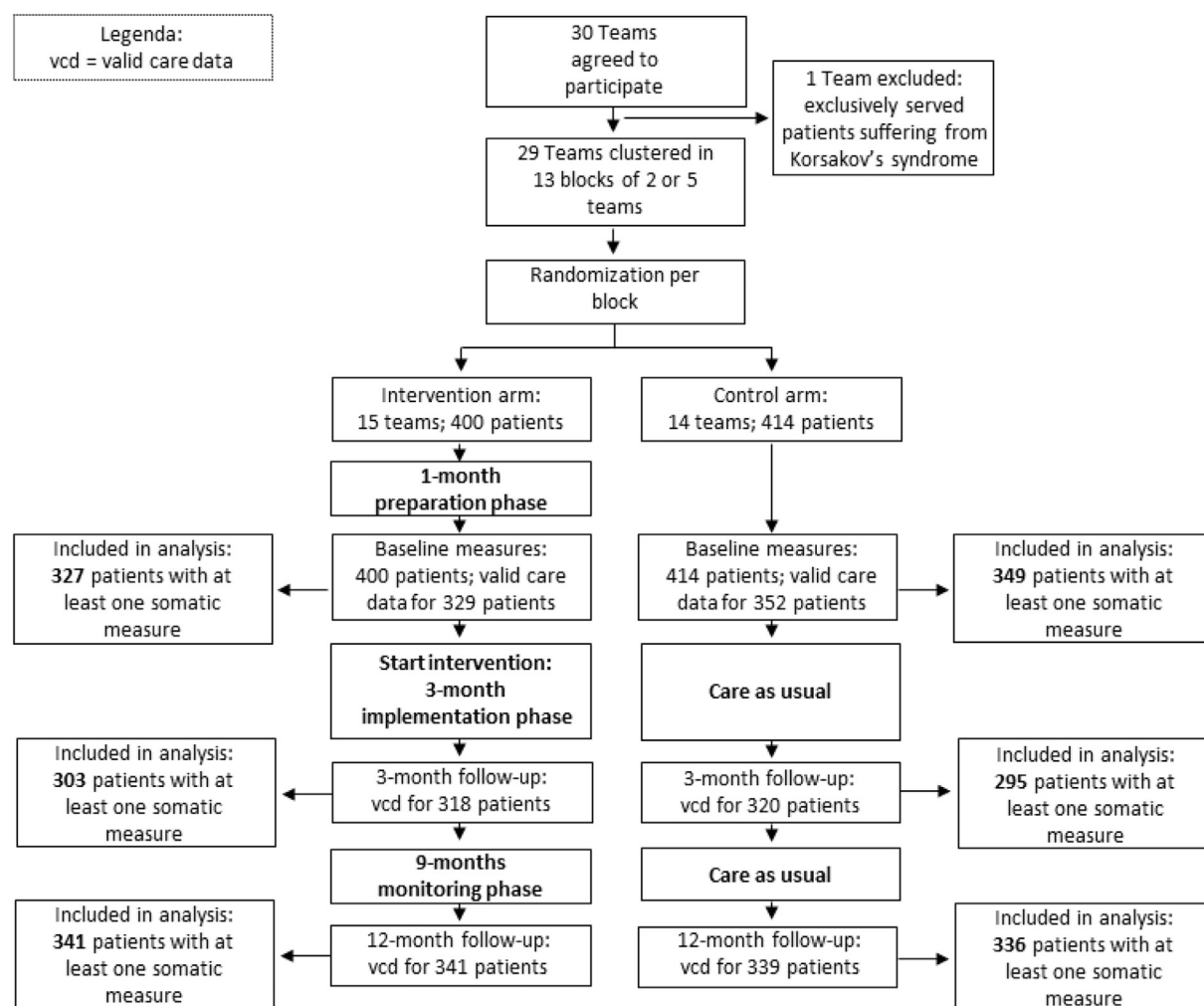


Fig. 1. Flowchart of patients in the ELIPS trial. A total of 770 patients have at least one psychosocial measure at baseline or 12-months follow-up and were included in the analysis (not retraceable in flow).

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