

# Effectiveness of Cognitive Remediation Training (CRT) and vocational rehabilitation (IPS), in persons with early psychosis.

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The present study focusses especially on the value of cognitive skill training within a program of work integration by means of IPS. Research shows that these interventions indeed lead to enhanced cognitive skills (Wykes et al. 2011). According to...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44176

### Source

ToetsingOnline

### Brief title

Effectiveness of CRT and IPS in Early Psychosis

### Condition

- Psychiatric disorders NEC

### Synonym

early psychosis, first psychotic episode

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Trimbos-instituut

**Source(s) of monetary or material Support:** Ministerie van Sociale zaken en werkgelegenheid

## Intervention

**Keyword:** Cognitive Remediation Training (CRT), combined effectiveness, early psychosis, Individual Placement and Support (IPS)

## Outcome measures

### Primary outcome

The primary goals of this research is to investigate the effects of an cognitive remediation therapy (Circuits), combined with Individual Placement and Support (IPS) on participation in regular employment or education in people with early psychosis. In addition, the effects of the combined training are evaluated specifically looking at work functioning and the effects on memory, attention and executive functioning.

As primary outcome measure for participation, \*the number of hours worked in regular jobs or education\*, was used.

### Secondary outcome

As secondary outcome measures different participation questionnaires were taken and also some cognitive tests.

- Social Participation questionnaire
- Number of days to regular job or education
- Amount of salary earned in regular work
- Amount of absence in regular work or education program
- Work situation: type of job, satisfaction with work, discomfort experienced because of psychological symptoms

- Hindering factors by searching and maintaining a regular job/education
- Implications of the job experienced by the patient
- BACS cognitive battery (Brief Assessment of Cognition in Schizophrenia)
- Memory
- Attention
- Executive function
- Trailmaking test
- Executive functioning
- CFQ questionnaire (Cognitive Failure Questionnaire)
- Subjective cognitive functioning
- Psymate (computerized experience sampling)
- Mood
- Activities
- NEL questionnaire (Nederlandse Empowerment Lijst)
- Empowerment
- ISMI questionnaire (Internalized Stigma of Mental Illness)
- Self-stigma
- SES questionnaire (Rosenberg Self-Esteem Scale)
- Self-Esteem
- PANSS questionnaire (Positive And Negative Symptom Scale)
- Positive and Negative symptoms of psychosis

## Study description

## Background summary

When a person experiences a period of psychosis, a condition is meant in which someone lost the connection with everyday reality. A psychosis is a disturbance of the activity of certain brain areas. As a result, people experience different phenomena such as: delusions, hallucinations, disturbances in reasoning and thought and strange or disordered behaviour. The term, \*early psychosis\* refers to the first couple of years (usually three) after the start of the first psychosis.

A recent international meta-analysis of Van Os (2009) shows that approximately 8% of the adult general population has had previous psychotic experiences and that 4% reported psychotic symptoms with suffering and need for help. Another meta-analysis of McGrath (2004), studying the incidence of psychotic disorders, computed a median of 15 new cases of psychosis per 100.000 people each year. In the north of the Netherlands a incidence of 11 new cases per 100.000 (age 15-44) was found in the 80s (Giel, 1980). And recently another study in the north of Holland reported 22 new cases per 100.00 (Boonstra, 2008). In the Hague the incidence of non-affective psychosis was 35 per 100.00 (Veling, 2006). Approximately 3000 young adults experience their first psychosis each year in the Netherlands (Handboek Vroege Psychose, 2013).

Usually a psychosis arises in adolescence or early adulthood (McGorry, 2011). This period is crucial for the development of identity, independency, entering into relationships and correct decision making in education and work. The psychosis tends to disrupt the natural course of development of these important processes, thus damaging the personal and social development of these young people. This damage is not always repairable. The longer the psychosis remains and the longer the development stays disrupted, the more social relationships are lost and the more difficult it is to get started again. But there are more reasons that emphasize the need for quick and intensive treatment.

There are indications that recovery after a period of psychosis, in particular in the short term, is harder after a longer period between onset and treatment (Marshall, 2005). The duration of untreated psychosis is related to a smaller chance of full recovery, slower recovery of social and community functioning and a higher risk of relapse. In addition, quick recognition and treatment are associated with full recovery and better progress.

Research shows that young people with psychotic experiences have a lower quality of life experience than their healthy peers. This effect remains visible on different areas of life such as, work, education, living, social contacts and leisure time (Trimbos, 2012; van Wel & van Weethel, 2012; Lester et al. 2012). Early guidance in education and work in combination with supporting and strengthening the occupational competence seem important opportunities for improvement, according to the literature.

Also within the subject of employment and previous education, youngsters experiencing early psychosis seem to fall short (Hendriksen et al. 2013). Finding a job or resuming education or professional training seems to be a difficult task in which support is needed. Individual Placement and Support (IPS) is an evidence based method that is developed to support and assist in the (future) wishes with respect to work and education among people with early psychosis. The effectiveness of IPS on employment has been acknowledged in many trials (Crowther et al. 2001; van Busschbach et al. 2011; Knapp et al. 2013). Especially in people with early psychosis beneficial results were found (Drake et al. 2013; Dudley et al. 2013).

People experiencing early psychosis often feel hindered by decreased concentration and less ability to organize their daily life independently. Practical tasks such as planning and organising take more effort, time and energy. Young patients report to attach great importance to training in this area (Hendriksen et al. 2013). According to recent findings, cognitive skill training needs to include learning- and problem solving strategies for the training to have an effect on daily life (Wykes & Spaulding, 2011).

## **Study objective**

The present study focusses especially on the value of cognitive skill training within a program of work integration by means of IPS. Research shows that these interventions indeed lead to enhanced cognitive skills (Wykes et al. 2011). According to recent findings, cognitive skill training needs to include learning- and problem solving strategies for the training to have an effect on daily life (Wykes & Spaulding, 2011). In the multidisciplinary guideline for schizophrenia the practical value of cognitive remediation therapy as \*stand alone\* intervention is doubted. There is a risk that the learned skills do not generalize to daily life. But there is hope for the inclusion of CRT in a labor reintegration program. If well supported, the enhanced cognitive skills such as, planning, organising, memory and social cognition can be directly put to use (McGurk et al. 2007). This way, people are more equipped to sustain their work or education.

The primary goal of this study is to investigate the effects of a cognitive remediation training (Circuits), offered in combination with Individual Placement and Support, on participation in regular employment or education in people suffering from early psychosis. Secondly, we look at the effects of the combination of CRT and IPS, on functioning in regular employment and we investigate the effects on memory, attention and executive functioning.

## **Study design**

A Randomised controlled trial with two arms is performed, in which the program Circuits, as CRT, combined with IPS, is compared to IPS in combination with a

placebo intervention. The placebo intervention consists out of computer activities that have no known effects on cognitive abilities. The participants are divided at random in one of the two conditions by an independent statistician. The participants are, however, assigned by their own locations. The IPS trainer and CRT trainer are two different persons. Therefore, the effect remains pure. A baseline measurement is done at T0 and three times after, at 6 months and 18 months follow up. Independent research assistants collect patient information blindly. According to the power analysis, 200 participants are needed, 100 participants in each condition, to achieve the needed effect size.

## **Intervention**

This intervention consists out of a combination of IPS and Circuits (CRT). CIRCuITS (Computerised Interactive Remediation of Cognition-Training for Schizophrenia) is a computer program for cognitive remediation developed by Wykes and this research Team (Institute of of Psychiatry, Kings College, London). The program consists out of different exercises to train cognitive skills such as, memory, attention, cognitive flexibility and metacognitive skills. The exercises vary in the degree of abstraction. Tasks can be adjusted automatically to the abilities of the participants and also it is possible to compose an individual program. A usual program consists out of 40 sessions of 15-60 minutes, at least three times a week with additional homework. The original program is written in English and for this research especially, it was translated in Dutch.

IPS supports patients with severe psychotic disorders in getting and keeping paid work. The method originates in America, where it was developed in \*90 by Becker and Drake (1993). In comparison with the usual employment integration, IPS distinguishes itself by directly searching for paid jobs instead of starting with training first. And also IPS-workers are integrated within the mental health care team. The wish of the client to find work is considered a main point and is directive for the employment counselling. The placebo intervention consists out of a selection of different computer games of which no effect on cognitive functioning is to be expected. The frequency and duration of the therapist guidance is equal to the experimental condition. The therapist offers weakly 60 to 90 minutes of guidance, distributed over two sessions.

## **Study burden and risks**

This intervention does not focus on the treatment of complaints. The exercises in the intervention are focused on the possible increase of cognitive abilities and supporting and finding a paid job or education. The taken measures don't have any risks. Also we don't expect the intervention to have any negative outcomes or risks. The participants invest 3 times 1,5 \* 2 hours of their time

doing measurements. After which they participate in the intervention for 15 following weeks.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

Inclusion criteria:

- Age > 18 years
- Have had their first psychosis in the past 5 years and are currently under care of an early psychosis team or (F)ACT Team (Flexible-Assertive Community Treatment).
- All identified subtypes of psychosis are included except psychosis by acquired (and detectable) brain injury and psychosis after substance use
- Interest for guidance in finding or keeping a regular job or education
- Interest in improving cognitive skills and interest in following a cognitive training program

- Demonstrable cognitive deficits at baseline
- Willingness to informed consent.

## Exclusion criteria

Exclusion criteria:

- Psychosis by acquired brain injury
- Psychosis after substance use
- Inadequate knowledge of the Dutch language (estimation made by team members and baseline measurement)
- Intellectual disability (IQ < 70)
- Patients that already participate in other studies that cannot be combined with the present study
- Unwillingness to informed consent

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2014
Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO



Date:	12-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27685  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL50176.029.14
OMON	NL-OMON27685