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# Effectively Working on Rehabilitation Goals: 24-Month Outcome of a Randomized Controlled Trial of the Boston Psychiatric Rehabilitation Approach

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**Objective:** To investigate the effect of the Boston Psychiatric Rehabilitation (PR) Approach on attainment of personal rehabilitation goals, social functioning, empowerment, needs for care, and quality of life in people with severe mental illness (SMI) in the Netherlands.

**Method:** A 24-month, multicentre, randomized controlled trial was used to compare the results of PR to care as usual (CAU). Patients with SMI were randomly assigned by a central randomization centre to PR ( $n = 80$ ) or CAU ( $n = 76$ ). The primary outcome of goal attainment was assessed by independent raters blind to treatment allocation. Measures for secondary outcomes were change in work situation and independent living, the Personal Empowerment Scale, the Camberwell Assessment of Needs, and the World Health Organization Quality of Life assessment. Effects were tested at 12 and 24 months. Data were analyzed according to intention to treat. Covariates were psychiatric centre, psychopathology, number of care contacts, and educational level of the professionals involved.

**Results:** The rate of goal attainment was substantially higher in PR at 24 months (adjusted risk difference: 21%, 95% CI 4% to 38%; number needed to treat [NNT] = 5). The approach was also more effective in the area of societal participation (PR: 21% adjusted increase, CAU: 0% adjusted increase; NNT = 5) but not in the other secondary outcome measures.

**Conclusions:** The results suggest that PR is effective in supporting patients with SMI to reach self-formulated rehabilitation goals and in enhancing societal participation, although no effects were found on the measures of functioning, need for care, and quality of life.

Clinical Trial Registration Number: ISRCTN73683215

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### Clinical Implications

- Implementation of PR with adequate fidelity is possible in different care settings.
- PR is a useful tool for exploring and realizing patients' personal rehabilitation goals.
- PR can contribute to patients' participation in work and daily activities.

### Limitations

- A subjective assessment—goal attainment—was used as the primary measure of realizing personal goals.
- Patients could not be blinded after randomization, and an expectancy effect cannot be ruled out.
- A significant number of participants were already living independently, and this may have introduced a ceiling effect for the changes in living situation, social functioning, and quality of life scores.

**Key Words:** *psychiatric rehabilitation, vocational rehabilitation, societal participation, goal attainment, severe mental illness*

In the past decades, systematic PR approaches have been developed that consider the needs or characteristics of people with SMI.<sup>1-5</sup> For many of these patients, their needs for care concern the areas of living independently, having social contacts and work, or having meaningful activities in the community.<sup>6,7</sup> RCTs in this area point to the effectiveness of integrating social skills training and cognitive-behavioural therapy in improving daily functioning<sup>8,9</sup> and the effectiveness of forms of vocational rehabilitation in obtaining employment.<sup>10-13</sup>

The PR approach, developed by Anthony et al,<sup>14,15</sup> Rogers et al,<sup>16</sup> Anthony et al,<sup>17</sup> and Farkas,<sup>18</sup> remains relatively underresearched, yet is widely used in parts of the United States and in European countries, such as the Netherlands and the Scandinavian countries. The approach uses a methodology that helps patients to explore, choose, and realize their rehabilitation goals in the areas of working, learning, social contacts, and living environment. It was developed for different professionals: MHC nurses, social workers, psychologists, and vocational workers, in both in- and outpatient settings. Some small-scale RCTs do exist. Shern et al<sup>19</sup> reported that homeless psychiatric patients receiving PR improved on unmet needs, housing status, quality of life, and psychological health. Gigantesco et al<sup>20</sup> observed an improvement in social functioning in patients engaged in a rehabilitation program inspired by PR, compared with the control subjects. However, in an RCT on vocational rehabilitation reported by Rogers et al,<sup>21</sup> PR and control groups displayed similar improvement in work participation. Given that PR is widely used while there is limited evidence to support its effectiveness, a multisite RCT was carried out in Dutch MHC, studying its effect as a general methodology for patients with a wish for positive change in the areas targeted by rehabilitation. The study examined whether PR was successful in its mission: to help patients attain their personal rehabilitation goals and to improve functioning in an environment of choice with the least amount of professional help.<sup>17</sup> The primary outcome—success in rehabilitation—was defined as reaching a personal rehabilitation goal in one of the rehabilitation areas. There were 4 secondary outcomes:

1. improvement in social functioning, independent living and societal participation in volunteer and paid work, and schooling
2. improvement of quality of life
3. empowerment defined as freedom of choice in common life domains
4. independence of professional help measured as a decrease in (unmet) needs for care

## Methods

The study was conducted at units in 4 MHC regions, serving 900 patients with SMI, in the Netherlands, operationalized as a severe psychiatric diagnosis, during 2 years' treatment and enduring psychiatric disabilities.<sup>22</sup> Recruitment was conducted between June 2005 and June 2006, and, to advance generalization to regular care,<sup>23</sup> targeted a heterogeneous group of in- and outpatients. Patients were randomly assigned to PR or CAU. Outcomes were measured at baseline, and after 12 and 24 months.

## Participants

The research was approved by a national medical ethics board for MHC and by the standing review boards of the 4 MHC centres. During recruitment, 423 patients were informed by their MHC professionals and invited to participate. After patients filled out a form to show interest in the project, they were contacted by a local research coordinator, who checked the following inclusion criteria: desire for a positive change in one of the rehabilitation areas and willingness to participate in a rehabilitation process. Motivation was not assessed. Patients were only excluded if they had contact with a rehabilitation worker in the last 3 months. Among the 305 patients who showed an interest in the project, 156 (51%) could be included; 137 did not meet the criteria, mainly because they did not want to participate in research or accept extra professional help; and 12 were excluded for other reasons, such as moving to another region (Figure 1). All eligible patients gave their written informed consent. The characteristics of the patients are reported in Table 1.

## Randomization

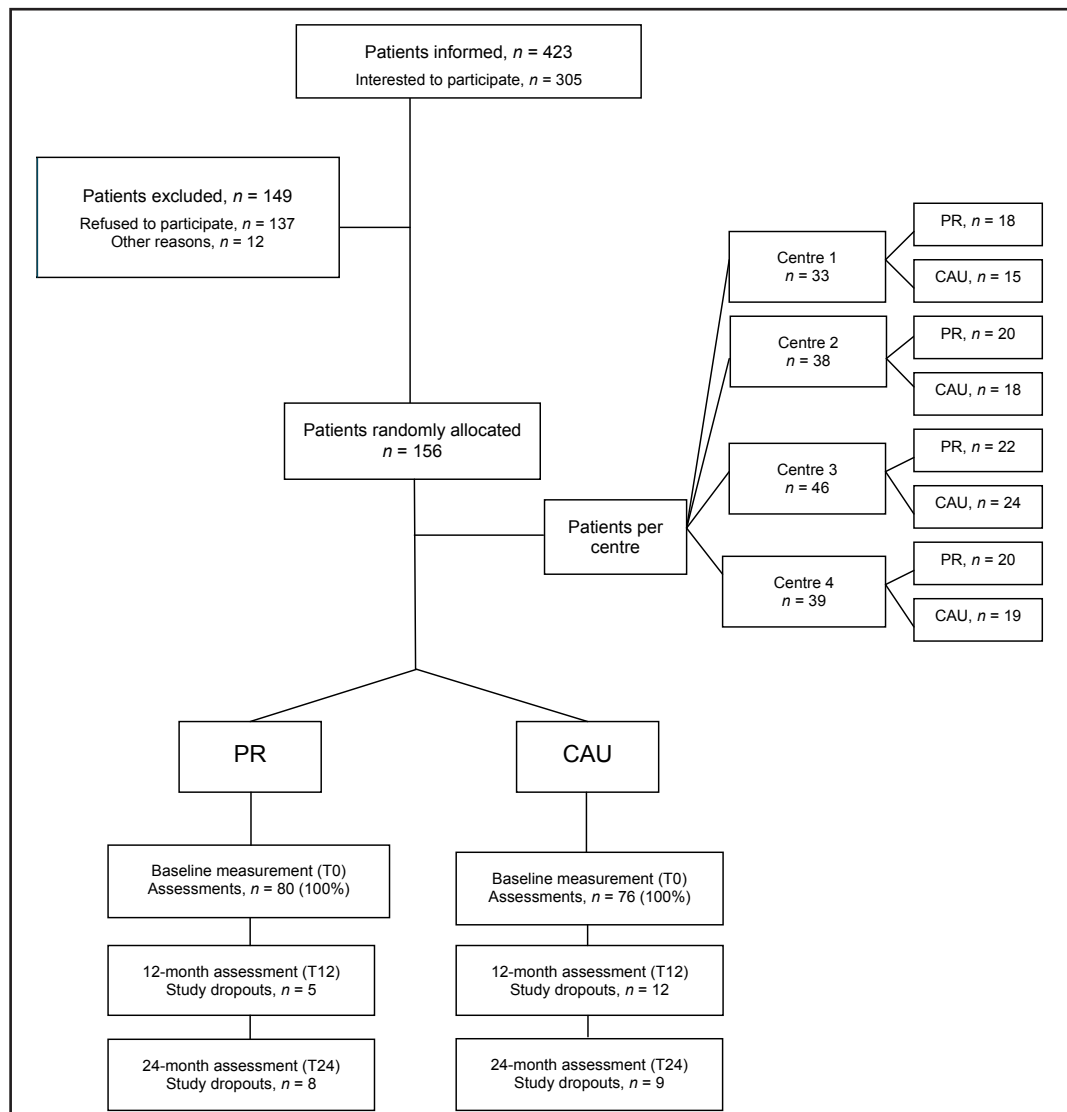
Randomization was done by a university randomization centre that employed a stratified block randomization.<sup>24</sup> Stratification factors were centre and setting (outpatient, inpatient and [or] sheltered living). Immediately after the first interview, 80 patients were assigned to PR and 76 to CAU. To prevent contamination of conditions and results, patients were recruited from units where no PR was offered.

## Sample Size

The power analysis was based on earlier findings<sup>25,26</sup> that 40% of the patients reach their rehabilitation goals with PR after 12 to 18 months, while practice-based findings estimate the proportion of success for CAU at less than 15%. A minimum of 45 patients in each group completing the

## Abbreviations

BPRS	Brief Psychiatric Rating Scale
CAU	care as usual
GAF	Global Assessment of Functioning
MHC	mental health care
NNT	number needed to treat
PR	psychiatric rehabilitation
RCT	randomized controlled trial
SMI	severe mental illness
WHOQOL-BREF	World Health Organization Quality of Life—abbreviated version

**Figure 1** Consort diagram

study was needed for a power of 80% ( $P < 0.05$ , 2-sided). Assuming an attrition rate of 20% to 40%, 80 patients in each condition were required. Based on earlier research with a comparable patient group, 80 was also the number of patients sufficient to detect differences in changes in quality of life (using the WHOQOL-BREF).<sup>27</sup>

### Intervention

The intervention was PR by trained professionals (social workers or MHC nurses, or vocational therapists). The approach has 3 clearly described phases<sup>17</sup>: setting a goal, that is, helping patients gain insight into their goals in the rehabilitation areas of work or study, social contacts and living environment, and into the skills and resources needed to attain these goals; planning, that is, describing necessary interventions (skill training, support) to achieve these goals, and; carrying out these interventions. All PR workers had completed training addressing these phases and practical experience with PR under the supervision of the Dutch PR Foundation.

Certified, experienced MHC professionals offered usual care. Like the workers in PR, they were given the instruction to support patients in clarifying and realizing their rehabilitation goals but now based on generic models of MHC nursing care, social work, and vocational rehabilitation. No other effort was made to standardize CAU. In both conditions, patients were offered individual sessions at least once every 3 weeks, with no preset maximum. In the PR condition, 39 professional caregivers were involved in the PR condition and 53 in CAU. Monthly supervision by trained supervisors was available for all professionals, based on either PR or generic MHC methodology. The mean number of years of work experience was 15 (SD 7.9) for the PR professionals and 14 (SD 8.9) for professionals in the control condition. The PR professionals had a higher educational level (81% specialized and [or] university training) than the professionals in the control condition (54% specialized and [or] university;  $\chi^2 = 13.34$ ;  $df = 1$ ;  $P < 0.05$ ), which was controlled for in our statistical analyses. How professionals were working on rehabilitation

goals with patients was monitored in both conditions by local research coordinators and monthly written reports. To assess fidelity, all 39 PR professionals were interviewed using the PR fidelity questionnaire<sup>28</sup> developed by the Dutch PR foundation in collaboration with Boston University. In interviews with the PR workers about 1 randomly chosen patient, 5 PR experts graded the degree to which the PR technique was used<sup>9</sup> during the rehabilitation process. Scores ranged from 0 to 30 (insufficient application), 30 to 40 (fair), and 40 to 50 (good). This questionnaire could not be used for the CAU workers because the protocol and terminology used was unfamiliar to them.

### **Outcome Measures**

Patient interviews (duration 75 minutes) were administered by trained interviewers at baseline, and at 12- and 24-month follow-up. Rehabilitation workers, MHC workers in the CAU condition, and psychiatrists filled in questionnaires. At baseline, patients and professionals were blind to treatment allocation; they could not be blinded thereafter. The interviewers remained blind to treatment allocation. Asked about this, the interviewers stated that for 80% of patients they could not guess to which kind of help they were assigned.

### **Primary Outcome**

At baseline, patients were interviewed about what rehabilitation goals they wanted to reach. Goals were categorized:

1. vocational or educational goals (societal participation)
2. goals related to social contacts
3. goals related to the living situation (for example, “wants to move out of parents’ house into an apartment by himself”)

After 4 sessions, patients and therapists agreed as to which of the stated goals they wanted to work on. Workers were encouraged to ensure that this rehabilitation goal was the patient’s own choice and not a goal tailored to the expectations of the professional. The written rehabilitation plan, with the goal selected by patients, was used in the interview after 12 and 24 months. The interviewers, who remained blind to treatment allocation, quoted the selected goal and asked the patients to respond to a prestructured item, with the options “goal (largely) attained” or “not attained or attained to a degree.” Probing questions were added to help patients decide on goal attainment, asking them, for example, to describe actions undertaken and results. The interviewer also recorded the information given on changes in living, working or educational situation, and social contacts. At 12 months, 17 patients (PR: 5 [6%]; CAU 12 [16%]) were not available for the interview. For 16 of these 17, goal attainment was assessed indirectly by 4 researchers blinded for the condition based on available data (such as treatment case notes and information from MHC professionals). For one patient, no information was available and the primary outcome was conservatively set

to negative. At 24 months, 34 patients (PR: 13 [16%]; CAU: 21 [28%]) were not available for the interview and none of them had been followed for sufficient time during the second year to allow indirect assessment of the outcome.

### **Secondary Outcomes**

Social functioning was measured using the 79-item self-report Social Functioning Scale.<sup>29</sup> One of the 7 Social Functioning subscales, Employment, could not be included because items were not applicable to pensioners; at follow-up, 9% of all participants were in receipt of old-age pensions.

Information about the living and working situation was collected from patients. Independent living was defined as: owning or renting one’s own accommodation, alone or with others (yes or no). Societal Participation was operationalized as the presence of meaningful occupation, defined as: paid work, regular volunteer work, vocational training or academic study, or full-time care of a family.

Unmet needs for care, rated according to the patient’s view, were assessed with the 22-item Camberwell Assessment of Need Short Appraisal Schedule.<sup>30,31</sup> Quality of life was assessed with the 26-item self-report WHOQOL-BREF.<sup>32</sup> The 10 items of the Personal Empowerment Scale<sup>33</sup> indexing control in life domains were selected to measure patients’ freedom of choice.

Data on possible confounders included psychiatric history and service use. The patient’s psychiatrist administered the 24-item BPRS—Extended version<sup>34,35</sup> and provided information on diagnosis (the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition), psychiatric history, and GAF—symptoms and disabilities.<sup>36</sup> The rehabilitation workers provided information on service use with the Client Socio-demographic and Service Receipt Inventory—European version.<sup>37</sup> These data were collected to compare the 2 conditions. As the study primarily focused on the effectiveness of PR on attaining personal goals, an economic analysis of differences in costs was not a part of the design.

Finally, data were collected on the professional caregivers (educational level, work experience, and rehabilitation attitude measured with the 26-item PR Beliefs, Goals and Practices scale<sup>38</sup>) and the rehabilitation process (number of contacts and the 36-item Working Alliance Inventory; worker’s perspective<sup>39</sup>).

### **Analysis Strategy**

Data were analyzed according to intention to treat. Analyses were conducted using Stata, release 10.1<sup>40</sup>; *P* levels are 2-sided. The primary outcome was assessed at 24 months. Effects were expressed as risk differences (for example, if 50% improved in PR and 20% in CAU, the effect size is 50% minus 20% equals 30%), from which the NNT was derived. Risk differences and NNTs were calculated unadjusted and adjusted for centre, psychopathology, and number of contacts and educational level of professional

**Table 1 Patient characteristics at baseline**

Variable	PR <i>n</i> = 80		CAU <i>n</i> = 80	
	<i>n</i>	%	<i>n</i>	%
Women	46	57.5	34	44.7
Age, years				
≤20	2	2.5	2	2.6
21 to 30	19	23.8	12	15.8
31 to 40	17	21.3	25	32.9
41 to 50	23	28.8	17	22.4
51 to 60	13	16.3	13	17.1
≥61	6	7.5	7	9.2
Housing situation				
Living independently	43	53.8	43	56.6
Psychiatric hospital	22	27.5	16	21.1
Sheltered living	15	18.8	15	19.7
Other	0	0	2	3.9
Paid work	7	8.7	5	6.6
Primary clinical diagnosis				
Schizophrenia or schizoaffective disorder	36	45.0	32	42.1
Bipolar disorder	4	5.0	8	10.5
Depressive or anxiety disorder	13	16.3	9	11.8
Personality	16	20.0	12	15.8
Addiction	2	3.8	2	2.6
Cognitive disorder	2	3.8	5	6.6
Other	6	7.5	5	6.6
Medication: antipsychotics				
FGA	14	17.5	15	19.7
SGA	26	32.5	19	25.0
FGA and SGA	2	2.5	1	1.3
Not born with Dutch nationality	10	12.5	8	10.5
		Mean (SD)		Mean (SD)
Years since first contact MHC		12.8 (8.4)		11.3 (8.6)
GAF symptoms		58.6 (11.3)		60.3 (13.6)
GAF disabilities		51.3 (15.2)		51.1 (13.5)
BPRS		46.5 (12.2)		46.3 (12.7)
Days admitted to hospital in the 3 months before inclusion		15.6 (32.4)		21.2 (36.7)

caregiver (basic nursing training, compared with specialized or university training) in regression models. No adjustment was made for individual MHC workers given that most workers coached 1 or 2 patients. Outcomes at 12 months were analyzed in the same way to gain insight into differences between short- and long-term effects. A sensitivity analysis was undertaken, excluding patients who, at 12 or at 24 months, had not been available for interviews and for whom the outcome had been rated indirectly, as described, to assess whether the results would be sustained. Adjustment for symptomatology and number of contacts was carried

out because care intensity and psychotic symptoms can influence rehabilitation outcome.<sup>41,42</sup> Educational level of professionals was controlled for because of the previously mentioned higher level of education in PR professionals.

Secondary outcomes were continuous variables indexing social functioning (excluding work-related activities), care needs, quality of life and freedom of choice in life domains or binary variables indexing societal participation, and independent living. Means and proportions of these variables at baseline and 12 and 24 months were modelled using both multilevel linear (for continuous variables)

**Table 2 Cumulative goal attainment rate at 12 and 24 months**

Time, months, and treatment	Goal not obtained		Goal obtained		RD goal obtained, %	95% CI	NNT	ARD <sup>a</sup> , %	95% CI	ANNT
	<i>n</i>	%	<i>n</i>	%						
12										
PR	55	68.7	25	31.3	15.5	1.2 to 27.2	8	16.4	1.9 to 30.8	7
CAU	64	84.2	12	15.8						
24										
PR	41	51.9	38	48.1	16.5	1.3 to 31.7	7	20.7	3.8 to 37.6	5
CAU	52	68.4	24	31.6						

<sup>a</sup>Adjusted for centre, psychopathology (GAF-S), number of contacts, and educational level of professional caregiver.  
ANNT = adjusted NNT; ARD = adjusted risk difference; RD = risk difference

**Table 3 Secondary outcome analysis continuous<sup>a</sup>**

Treatment, time	Quality of life <sup>b</sup>				CAN unmet needs <sup>c</sup>			
	Mean (SD)	<i>n</i>	Effect time	95% CI	Mean (SD)	<i>n</i>	Effect time	95% CI
CAU								
Baseline	82.6 (13.9)	73			4.6 (3.2)	76		
12 months	86.8 (15.4)	58	4.2	1.0 to 7.5	2.5 (2.9)	64	-2.1	-2.8 to -1.4
24 months	88.3 (12.7)	47	4.3	0.8 to 7.9	2.9 (2.8)	54	-1.8	-2.5 to -1.0
PR								
Baseline	81.7 (13.2)	68			4.7 (2.7)	80	109.0 (8.8)	
12 months	88.0 (16.3)	71	4.5	1.3 to 7.6	2.9 (3.2)	74	-1.7	-2.4 to -1.0
24 months	89.7 (16.9)	59	6.2	2.8 to 9.5	2.4 (2.8)	66	-2.2	-2.9 to -1.5
Group × Time	$\chi^2$	<i>df</i>	<i>P</i>		$\chi^2$	<i>df</i>	<i>P</i>	
12 months <sup>f</sup>	0.01	1	0.92		0.7	1	0.40	
24 months	0.54	1	0.46		0.7	1	0.39	
Treatment, time	Social functioning <sup>d</sup>				Empowerment <sup>e</sup>			
	Mean (SD)	<i>n</i>	Effect time	95% CI	Mean (SD)	<i>n</i>	Effect time	95% CI
CAU								
Baseline	108.2 (9.3)	76			30.5 (5.5)	76		
12 months	109.5 (11.1)	64	1.5	-0.6 to 3.7	31.4 (4.8)	62	0.7	-0.6 to 2.0
24 months	108.6 (13.0)	55	1.1	-0.8 to 3.2	31.5 (4.5)	53	0.8	-0.6 to 2.2
PR								
Baseline	109.0 (8.8)	80			30.9 (5.5)	80		
12 months	110.1 (10.2)	74	1.2	-0.8 to 3.2	31.6 (5.7)	74	0.9	-0.3 to 2.1
24 months	110.2 (11.3)	67	1.1	-1.0 to 3.1	32.5 (5.0)	65	1.8	0.5 to 3.0
Group × Time	$\chi^2$	<i>df</i>	<i>P</i>		$\chi^2$	<i>df</i>	<i>P</i>	
12 months <sup>f</sup>	0.05	1	0.82		0.05	1	0.83	
24 months	0.00	1	0.99		0.90	1	0.34	

<sup>a</sup> Adjusted for centre, psychopathology (GAF-S), number of contacts, and educational level of professional caregiver

<sup>b</sup> Based on the mean raw data score of the WHOQOL (following directions of van de Willege et al<sup>27</sup>); possible scores range from 26 through 130; higher scores indicate improvement

<sup>c</sup> Possible scores on the subscale Unmet Needs for care of the Camberwell Assessment of Need Short Appraisal Schedule range from 0 to 22, with higher scores indicating more unmet care needs

<sup>d</sup> Based on Social Functioning Scale scores (excluded the subscale work); possible ranges from 55 = most impaired to 135 = minimally or not impaired

<sup>e</sup> Based on the subscale Control over Common Life Domains of the Personal Empowerment Scale, with possible scores ranging from 10 to 50 with higher scores indicating increasing control

<sup>f</sup> Expressed as adjusted risk difference

Table 4 Secondary outcome analysis binary variables <sup>a</sup>							
Treatment, time	Living independently <sup>b</sup>				Effect time, %	95%CI	NNT
	No		Yes				
	<i>n</i>	%	<i>n</i>	%			
CAU							
Baseline	33	43.4	43	56.6			
12 months	24	37.5	40	62.5	6.6	-0.1 to 14.0	16
24 months	25	45.5	30	54.5	2.3	-5.7 to 10.3	44
PR							
Baseline	37	46.3	43	53.7			
12 months	32	42.7	43	57.3	3.9	-3.0 to 10.9	26
24 months	27	40.3	40	59.7	4.6	-2.8 to 11.9	22
Group × Time	$\chi^2$	<i>df</i>	<i>P</i>				
12 months <sup>d</sup>	0.3	1	0.60				
24 months	0.2	1	0.68				
Treatment, time	Societal participation <sup>c</sup>				Effect time, %	95%CI	NNT
	No		Yes				
	<i>n</i>	%	<i>n</i>	%			
CAU							
Baseline	44	63.8	25	36.2			
12 months	37	63.7	21	36.2	-2.4	-14.3 to 9.5	42
24 months	29	59.2	20	40.1	-0.1	-13.7 to 11.7	1000
PR							
Baseline	55	72.4	21	27.6			
12 months	42	60.9	27	39.1	12.0	1.0 to 22.9	9
24 months	31	5.0	31	50.0	21.4	9.8 to 33.0	5
Group × Time	$\chi^2$	<i>df</i>	<i>P</i>				
12 months <sup>d</sup>	3.1	1	0.08				
24 months	6.5	1	0.01				

<sup>a</sup> Adjusted for centre, psychopathology (GAF-S), number of contacts, and educational level of professional caregiver.

<sup>b</sup> Defined as owning or renting one's own accommodation, alone or with members of the household, compared with living in hospital or residential care

<sup>c</sup> Defined as presence of paid work, regular volunteer work, vocational training or academic study, and full-time housewife caring for a family; this excluded patients aged 62 years or older, or 65 years or older, who were entitled to an old-age pension

<sup>d</sup> Expressed as adjusted risk difference

and logistic (for binary variables) regression analyses in which each person (level 2 in the multilevel regression model) contributed 3 observations (level 1 in the multilevel regression model), adjusting for centre, psychopathology, number of contacts, and educational level of the professional. Treatment effects were quantified using the Time (baseline, 12 months, and 24 months) × Group (PR, CAU) interaction, assessing whether change in a particular outcome differed significantly between the 2 groups over time. These effects were calculated by linear combination of the appropriate terms in the model containing the Time × Group interaction term (Stata's *lincom* procedure).

## Results

Randomization was successful as indicated by absence of significant differences between groups at baseline for patient characteristics and (drug) treatment (Table 1). The

GAF and BPRS scores presented indicate moderate to marked illness severity,<sup>43</sup> with most participants having spent more than 10 years in MHC.

### *Intervention; Working on Patients' Goals*

A total of 66 patients (43%) focused on a vocational or educational goal, 30 on social contacts (19%), 43 on goals related to the living situation (27%), and 17 (11%) on combinations. Personal rehabilitation depended on the patient's personal wishes for change in a particular area. Thus the goals formulated varied from wanting outdoor activities to having a paid job; from better housekeeping to living independently. In 85% of the PR group and 84% of the CAU group, patients and workers agreed to work on a goal area that was mentioned in the first interview.

In both conditions, patients were offered individual sessions to work on their goals at least once every 3 weeks. The



time invested in working on patients' goals did not differ significantly between conditions. The total mean number of rehabilitation worker contacts was 15 (SD 15.2) for PR and 17 (SD 17.1) for CAU. The mean duration of the rehabilitation trajectory was 12 months in both conditions (SD 7.6). In the experimental condition, 86% of the PR professionals received a score of "fair" or "good" on the PR fidelity scale. As mentioned, CAU was not standardized (that is, did not use one specific methodology).

PR and CAU showed equal success in establishing a working alliance after 4 sessions (Working Alliance Inventory mean 3.9 [SD 0.4] in both conditions). No differences were found in the pattern of care use. The overall mean number of hospital inpatient days was 62.0 (SD 124.3) in the first year and 42.0 (SD 108.0) in the second year (including the patients permanently admitted to hospital). The overall mean number of outpatient and daycare attendances was 2.4 (SD 6.4) per month at T1 and 3.2 (SD 7.4) at T2. Lastly, there were no differences between conditions in the medication regime regarding using first- and (or) second-generation antipsychotics.

### Primary Outcomes

Data for the main outcome were available for all 156 patients for at least 1 time point. The goal attainment as rated by patients themselves, was higher in PR at 24 months (adjusted risk difference: 21%; 95% CI 4% to 38%; NNT = 5; Table 2). Inspection of the areas of goal attainment revealed that PR was numerically more successful in goal attainment in the areas of societal participation (PR 19 of 34 patients successful with work or educational goals: 56%; CAU 9 of 32 patients: 28%) and social contacts (PR 9 of 18 patients: 50%; CAU 3 of 12 patients: 25%), but not in the area of the living situation (PR 8 of 21 patients 38%; CAU 11 of 22 patients: 50%). Comparable positive effects for the rate of goal attainment with PR were found at 12 months (risk difference: 16%; 95% CI 2% to 31%; NNT = 7). The positive results were sustained in sensitivity analysis when we exclude the 17 patients at 12 months and the 34 patients at 24 months for whom the outcome was missing or assessed indirectly: adjusted risk difference at 12 months: 14%, 95% CI 2% to 30%; NNT = 8; adjusted risk difference at 24 months: 18%, 95% CI 2% to 34%; NNT = 6.

### Secondary Outcomes

Quality of life increased over time to an equal degree in both groups. The same applies to reduction of the number of unmet needs for care (Table 3). Social functioning (excluding work) and independent living did not change over time, regardless of the group (Tables 3 and 4). The degree to which patients experienced freedom of choice in common life domains did not increase significantly more for subjects in PR than in CAU (Table 3).

Changes in societal participation differed between PR and CAU: the proportion of patients who were engaged in vocational activities as defined in societal participation

increased from 36% at baseline to 40% at 24 months in the control group, much smaller than the increase from 28% to 50% in the PR group (Group  $\times$  Time interaction:  $\chi^2 = 6.5$ ,  $df = 1$ ,  $P = 0.01$ ; Table 4).

## Discussion

Our study has attempted to increase the evidence base for PR. The trial was randomized, sufficiently powered, focused on the entire area of rehabilitation goals, carried out with trained personnel and an active control condition, and able to measure conservatively over an extended period of time. The research was carried out in real-life practice with a heterogeneous group of patients to advance generalization.

PR had a significant impact on the primary outcome of goal attainment defined by patients themselves, and more specifically, on the areas of societal participation and social contacts. Therefore, the study suggests effectiveness of PR in its main mission of helping patients adhere to their personal rehabilitation goals in these areas.

The RCT was set up conservatively, given that the professional in the CAU condition also received explicit instructions in the context of a trial to work on the patient's rehabilitation goals. Finally, the outcome was assessed from the patient's point of view by independent interviewers blind to treatment allocation, reducing the possibility of reporting bias. However, as patients could not be blinded after randomization, an expectancy effect cannot be ruled out.

Nevertheless, the claim of PR as an effective way to help people improve their functioning and satisfaction with life could not be supported. Compared with the control group, PR did not have an extra effect on needs for care, social functioning (excluding work-related activities), or subjective quality of life. As for the specific rehabilitation domains among the secondary outcomes, PR did not produce changes in the area of living independently, but did prove to be more successful in societal participation.

The outcome on societal participation is more positive than the findings by Rogers et al,<sup>21</sup> where the control and experimental groups did not differ on any aspect, including societal participation. However, the lack of effect on the other secondary outcomes contrasts with earlier findings that reported changes in the areas of housing and quality of life,<sup>19</sup> and improvement in general functioning.<sup>20</sup> A possible explanation is that these studies focused on groups with more severe problems, such as homelessness, whereas in the current study goals were directed at more subtle changes, which may have led to a ceiling effect. It is also possible that for these more subtle changes, goal attainment constitutes a more sensitive outcome than generic measures assessing functioning or quality of life,<sup>44,45</sup> measuring, for instance, subtle improvements in residential conditions other than independent living. A limitation of our study is that these results on subjective goal attainment may be considered less substantial. However, we found a significant

impact on societal participation, implying that progress in personal goal attainment has concrete results in the living situation. However, apart from this, our study provides evidence for a limited effectiveness of PR, with no insight in how subjective goal attainment adds quality to the life of patients. In addition, no benefits from a societal perspective were found other than the personal experience of patients that it is possible to attain your own goals and to have some part in the design of your own life.

## Conclusion

The findings support a contribution of PR toward subjective goal attainment defined by patients in work and (or) study and social contacts and in enhancing objective societal participation, although no effects were found on measures of functioning and quality of life. Based on our findings, we suggest that future research should compare PR to other rehabilitation approaches and elucidate specific elements contributing to change in outcomes.

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## Résumé : Travailler efficacement aux objectifs de la réhabilitation : résultat à 24 mois d'un essai randomisé contrôlé de l'approche de réhabilitation psychiatrique de Boston

**Objectif :** Rechercher l'effet de l'approche de réhabilitation psychiatrique (RP) de Boston sur l'atteinte des objectifs personnels de réhabilitation, le fonctionnement social, l'habilitation, les besoins de soins, et la qualité de vie chez des personnes souffrant de maladie mentale grave (MMG) aux Pays-Bas.

**Méthode :** Un essai randomisé contrôlé multicentrique de 24 mois a été conduit pour comparer les résultats de la RP avec les soins habituels (SH). Les patients souffrant de MMG ont été affectés au hasard par un service de randomisation central à la RP (n = 80) ou aux SH (n = 76). Le résultat principal, l'atteinte des objectifs, était évalué par des juges indépendants à l'insu de l'affectation aux traitements. Les mesures des résultats secondaires étaient les changements de situation relative au travail et de vie autonome, l'échelle de reprise de pouvoir personnelle, l'évaluation des besoins de Camberwell, et l'évaluation de la qualité de vie de l'Organisation mondiale de la santé. Les effets ont été testés à 12 et à 24 mois. Les données ont été analysées en conformité avec l'intention de traitement. Les covariables étaient le centre psychiatrique, la psychopathologie, le nombre de contacts avec les soins, et le niveau d'instruction des professionnels concernés.

**Résultats :** Le taux d'atteinte des objectifs était substantiellement plus élevé dans la RP à 24 mois (différence de risque corrigée : 21 %; IC à 95 % 4 % à 38 %; nombre nécessaire pour traiter : [NNT] = 5). L'approche était également plus efficace dans le domaine de la participation sociétale (RP : 21 % d'augmentation corrigée, SH : 0 % d'augmentation corrigée; NNT = 5) mais pas dans les mesures des autres résultats secondaires.

**Conclusions :** Les résultats suggèrent que la RP est efficace pour aider les patients souffrant de MMG à atteindre des objectifs de réhabilitation auto-formulés et à accroître la participation sociétale, bien qu'aucun effet n'ait été observé sur les mesures du fonctionnement, des besoins de soins, et de la qualité de vie.

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