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An observational, “real life” trial of the introduction of assertive community treatment in a geographically defined area using clinical rather than service use outcome criteria

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Abstract *Introduction* Assertive outreach methods of service delivery hold promise, but have been evaluated mostly in the context of short-lived experiments of limited sustainability and a focus on service use outcomes. The aim of the current investigation was to conduct an observational, “real life”, pre-post comparison of the introduction of assertive outreach in a geographically defined area using clinical rather than service use outcome criteria. *Method* Assertive outreach was implemented in 2002 in a catchment area of 250,000, where cumulative routine outcome measure-

ments had been in place since 1998. Clinical outcome, defined as making a transition to meeting the recently introduced remission criterion, was compared for two non-overlapping cohorts of patients treated in the period 1998–2001 and in the period 2002–2005. *Results* The proportion of patients that made the transition to remission increased from 19% in the period before the introduction of assertive outreach, to 31% in the period after (OR = 2.21, 95% CI 1.03–4.78). *Conclusion* Assertive outreach in real life routine clinical practice brings about detectable changes in clinical outcome. ACT may bring improvement to the lives of patients living in countries characterised by fragmented and hospital-based mental health services.

Key words ACT – remission – SMI – schizophrenia – outcome – services

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Introduction

Reviews of assertive outreach methods of service delivery such as assertive community treatment (ACT) have found that more patients remain in care and that hospital admission rates and duration of hospitalisation are reduced [1–3]. The recent Dutch schizophrenia guideline recommends ACT as the primary method of service delivery for patients with severe mental illness [4]. Key features mediating the effectiveness of ACT may be smaller caseloads (between 15 and 20 patients per case manager), a high percentage of contacts at home, responsibility for both health and social care, multidisciplinary teams and a psychiatrist integrated in the team [5–7]. There remains some debate, however, about the effectiveness of ACT. Comparative analyses of ACT have shown that reduction in admission rate and duration of hospitalisation are not as strong in the UK and in Western Europe as in the original U.S. studies [5, 7–

10]. Rather than differences in ACT “fidelity”, the US–UK divergence may be explained by differences in the standard care received by the control group, which in the U.S. may be associated with longer admissions, whereas in Western-Europe the treatment programme was more based on social psychiatric paradigms [11].

There are other reasons for caution in the interpretation of RCTs on assertive outreach. For example, a systematic review of all the RCTs of home treatment services showed a remarkable lack of sustainability of the experimental treatments, as 44% of the ACT experimental treatments were untimely ended [12].

In addition, those experimental services that were still active by the end of the study had lost a major proportion of their key components that distinguishes assertive outreach as a unique programme. Thus, RCTs are different from broad implementation of ACT in mainstream mental health practice, where sustainability of ACT, once implemented, does not depend on temporary financial sources associated with RCTs. In an experimental trial, subjects receive more attention and innovative services receive strong backing in a context of strong leadership, giving rise to the so-called Hawthorne effect [12, 13]. In addition, the interventions are tested in relatively short periods of time, whereas in reality these interventions are part of long-term treatment plans. Therefore, in addition to short-lived RCTs, data are also needed from longer term studies reflecting routine clinical practice, including all patients with severe mental illness in a regional catchment area, measuring clinically meaningful outcomes.

The focus on improvement of service outcomes, such as reduction of admission rates and duration of hospitalisation [1, 3, 5, 7–9] is subject to geographical variation and has limited clinical validity [14, 15]. Recently, symptomatic remission criteria for schizophrenia have been formulated [16]. It has been shown that the definition of symptomatic remission is clinically meaningful, appears achievable for a significant proportion of patients in routine clinical practice and is applicable across the course of illness [17]. In addition, change over time in symptomatic remission criteria was associated with substantial changes in unmet needs, GAF-scores, satisfaction with services and, to a lesser extent, quality of life [18]. Therefore, in evaluating ACT, remission may be useful as a benchmark for its effectiveness as a method of service delivery in a defined catchment area.

“Function-ACT” (F-ACT) is a Dutch variation of ACT, allowing for a mix of patients with intensive and less intensive treatment needs within the same team. In F-ACT the good aspects of general case management that are used in psychiatric rehabilitation are combined with ACT. During the better periods patients remain in the team and individual case managers continue care based on rehabilitation principles and ACT is reactivated when care needs to be intensified. Therefore, continuity of care is ensured

[19, 20]. Case-loads consequently are around 20–30 patients per case manager.

The aim of the present study was to conduct a “real life”, observational trial comparing a F-ACT service with standard care using the remission criteria in a geographically defined area. In 2002, assertive outreach in the form of F-ACT was initiated in the mental health region of Maastricht, The Netherlands (a catchment area of 250,000 people). It was hypothesised that the proportion of subjects reaching symptomatic remission would increase following the introduction of assertive outreach in the region.

Method

■ The cumulative needs for care register

Data were obtained from the local Cumulative Needs for Care Register (CNCR), a cumulative data set of psychopathology, well being and functioning of patients diagnosed with severe mental illness both inside and outside the hospital, living in a sub-region of South Limburg with a population of 650,000 [18, 21]. The CNCR is in operation since 1998, and represents an initiative of the mental health service providers, the province and local consumers to assess the match between patients’ need for care and the level and outcome of service provision. All patients with a severe mental illness registered according to the DSM-IV classification system [22] are included in the CNCR, and mental health professionals (nurses, social workers, psychiatrists, psychologists) are trained to administer CNCR forms providing clinical case information for individual feedback as well as cumulative data for the CNCR. CNCR forms include various validated clinical instruments: the Camberwell Assessment of Need (CAN) [23, 24], the Brief Psychiatric Rating Scale (BPRS) [25, 26], the Global Assessment of Functioning Scale, split in its Psychopathology (GAF-p, sample range 1–95) and Impairment (GAF-i, sample range 1–95) components [22], a single item on Satisfaction with services (Satisfaction), and several brief dimensions of quality of life. CAN, BPRS and GAF are scored by clinicians; while satisfaction and quality of life are scored by the patient on 7-point Likert scales [21, 27]. Evaluation of changes in treatment delivery in the catchment area is possible as outcome data are cumulatively and routinely assessed every year and with every major change in treatment or setting (e.g. hospitalisation, start of a new psychiatric treatment, and discharge). In keeping with current legal requirements, patients are informed that anonymised routine clinical data are used for the purpose of regional and scientific analysis, and given the choice to “opt out”, in which (very rare) case data are not used.

■ Function-ACT teams

In 2002, the care providers in the Maastricht area initiated an assertive outreach method of service delivery. Fragmented services (community mental health centre, daycentre, a hospital ward for acute admissions, sheltered housing and rehabilitation for patients with psychotic disorders) were pooled and reshuffled to form three identical, multidisciplinary teams with direct access to their own in-patient facilities. Patients were eligible for F-ACT when they were diagnosed with Severe Mental Illness. Thus, predominantly patients diagnosed with psychotic disorders were included as well as some other patients (non-psychotic disorders) when the referring professional expected beneficial effects. In F-ACT the team decides whenever more intensive treatment like ACT or hospital admission is needed. The guidelines for allocating to ACT are defined by current indications for mainstream ACT [3, 10].

Table 1 Descriptives of the study sample

	Mean	SD	Range	# Subjects
Duration of care (in years)	16.1	11.2	1–48	128
Days between interviews	372.3	255.0	1–1247	154
Age at baseline (in years)	38.6	11.7	19–65	154
Number of CNCR assessments	4	1.5	2–9	154

■ Outcome definition

Remission status was based on schizophrenia symptomatic remission criteria defined by the international remission working group, using items of the BPRS [16, 17]. Patients met the remission criteria if they scored 3 or less on all the following items: paranoid delusions, grandiosity, unusual thoughts, hallucinations, incoherent thinking, flat affect and mannerism [16, 17]. The duration criterion of six months was not used in the present analyses. However, the outcome of the severity criterion was considered to represent a clinically relevant outcome in daily life practice in patients with severe mental illness and previous work using CNCR data had shown good validity of the severity criterion in terms of needs, functioning and patient subjective outcomes [18].

■ Risk set

The risks set for analysis consisted of measurements when patients were “at risk” for remission, i.e. not in remission at that moment and, therefore, at risk for transition to remission at the next follow-up measurement. The CNCR data set contains observations of patients with either one or more assessments over time between 1998 and 2005. Within this data set, the risk set for analysis consisted of patients who (i) had at least two assessments and (ii) were “at risk” for remission at least once. Thus, only patients diagnosed with schizophrenia or related psychotic disorder were included.

■ Psychiatric Case Register

CNCR data were merged with data from the local Psychiatric Case Register (PCR) [28, 29]. The PCR monitors mental health care provided by all regional mental health facilities to all patients, since 1983. For each patient, the number of days of admission, number of outpatient contacts and number of days in day care are cumulatively registered. CNCR and PCR data were anonymously matched using a case identification code with an encryption algorithm and the date of the CNCM interview. Using this information, the exact number of inpatient days and outpatient contacts between two assessments was added to the data set, in order to evaluate the service outcome of F-ACT.

■ Analysis: pre-post comparison before and after introduction of assertive outreach

In order to assess the impact of assertive outreach, remission rates were compared for two non-overlapping cohorts each followed for a maximum of 4 years: (i) individuals in the pre-assertive outreach risk set using CNCR follow-up assessments of individuals over the period 1998–2001 and (ii) similarly the post-assertive outreach risk set using CNCR follow-up assessments over the period 2002–2005. The cohorts were non-overlapping because assessments after the start of assertive outreach of patients that had their first assessment before this introduction were excluded to prevent contamination.

The STATA [30] command `xtrans` was used to assess changes in the “at risk” for remission group to develop remission between the subsequent CNCR assessments in the two cohorts. In order to evaluate these unadjusted results, multilevel logistic regression analyses, yielding odds ratios, was performed. Odds ratio effect sizes were also transformed into risk difference effect sizes using the Stata `MF` procedure for ease of interpretation. Given the sensitivity of pre-post comparisons to confounding, results were conservatively adjusted for remission status at the first entry in the CNCR, age (in years), gender, and duration of illness (in years).

Additionally, the association between remission and inpatient days and outpatient contacts was analysed using multilevel regression analysis. Because these outcome variables were skewed they were transformed using the natural logarithm (\ln).

Results

A total of 154 subjects, diagnosed with a clinical diagnosis of non-affective psychotic disorder (DSM 295, 297 and 298), were included in the risk set. The mean time between two assessments was 372 days (Table 1).

The two cohorts pertaining to the pre- ($n = 116$) and post-assertive outreach period ($n = 38$) had similar clinical characteristics (Table 2). The percentage of subjects that reached remission in the pre-

Table 2 Demographic and diagnostic characteristics by time (pre- and post-F-ACT)

	Pre-assertive outreach ($n = 116$)			Post-assertive outreach ($n = 38$)		
	Mean	Sd	Min–max	Mean	Sd	Min–max
Age at baseline	39.1	10.8	19–62	36.9	13.8	20–65
Duration of illness (in years)	16.6	11.0	1–48	12.6	11.4	1–41
N inpatient days ^a	122	220.5 ^b	0–990	64	84.1 ^b	0–266
N outpatient contacts ^a	9.6	18.0 ^b	0–96	1.2	3.6 ^b	0–9
	Number	%		Number	%	
Sex male	75	65		28	74	
Incident cases	4	3.7		1	4.0	
Number of patients in hospital $n = 108^a$	68	67.3		5	100	

^aNot all patients in the CNCR could be linked to PCR data and therefore the number of patients is lower in these rows of the table (pre $n = 108$, post $n = 6$)

^bStandard deviation “between” in the multilevel data

Table 3 Association between period (pre-post assertive outreach) and remission

Remission	OR	95%CI	<i>p</i>	Risk difference	95% CI	<i>p</i>
Post-assertive outreach (<i>n</i> = 154)	2.21	1.03–4.78	0.043	0.15	–0.01–0.30	0.062
Adjusted ^a Post-assertive outreach (<i>n</i> = 128)	1.77	0.64–4.88	0.27	0.10	–0.10–0.30	0.31

^aadjusted for: age at previous assessment, sex, time spent in hospital, time receiving care, remission at baseline

assertive outreach period was 19%. The number of subjects that reached remission after the start of assertive outreach was 31%, yielding a Number Needed to Treat (NNT) of 8. Multilevel regression analyses showed that the probability of remission was higher in the post-assertive outreach era (OR = 2.21, 95% CI: 1.03–4.78; Table 3). The odds ratio expressed as additive effect size yielded a risk difference of 15% increase in remission after the introduction of assertive outreach. After adjustment for confounders, the association between assertive outreach and remission was only slightly decreased although statistically inconclusive (OR = 1.86) (Table 3).

There were no differences in number of inpatient days or outpatient contacts before and after the introduction of F-ACT, in the subgroup of patients that could be matched with the PCR, but numbers in the post F-ACT group were small (see Table 2). In addition, patients that were in remission had more outpatient contacts (5 contacts more, *p* = 0.04, 160 observations in 114 patients), but data did not show an association between remission and inpatient contacts.

Discussion

Results suggested that the introduction of assertive outreach in the region may have had a positive effect on the proportion of patients with higher scores on the BPRS in terms of reaching symptomatic remission criteria. The strength of the association decreased en was no longer significant after conservative correction for confounding. The present analysis was a pre-post comparison based on the intention-to-treat principle; not all patients in the region received F-ACT in the post-F-ACT era. A proportion of the subjects with a diagnosis of psychotic disorder received long-term treatment within sheltered homes, chronic wards or by the community mental health team that is no part of F-ACT. These departments all participate in the CNCR. Therefore, effects of assertive outreach might have even been stronger.

The introduction of assertive outreach doubled the likelihood of reaching symptomatic remission criteria. The effect size was only slightly reduced after conservative adjustment for confounding, indicating that the results are not reducible to confounding alone. The risk set was small and there were missing values for confounders, so that adjusted results consequently were statistically imprecise because of lack of power. The findings nevertheless indicate that introduction of

F-ACT in a routine clinical setting results in measurable improvements in clinical and service use outcomes, as the results pertained to all patients in the catchment area rather than a clean subsample. These results are relevant, because apart from the UK and Denmark, F-ACT as a form of service delivery has not been implemented in any significant measure in any of the European countries, where fragmented and hospital-based services remain the norm [31].

In addition, because data were matched with service use (PCR) data, the validity of the remission criteria could be checked. Patients in remission had more outpatient contacts. Probably, these are maintenance contacts, while patients not in remission were in need of more intensive types of care. The analyses did not show evidence for an association between remission and decrease in inpatient days, but this can be the result of a loss of power when matching the data with the PCR-data.

The sustainability problems in RCT studies (see introduction) may arguably also play a role in the region of the present research. To date, no change in resources allocated to F-ACT in the region were introduced. Indeed, the promising results of the present study will continue to encourage policymakers to continue F-ACT, without amendment of key components. F-ACT services in the region are subject to a national evaluation of ACT fidelity. Although not formally analysed, initial results suggest satisfactory fidelity for the region.

Methodological issues

The present analysis can be considered as an exploratory, hypothesis-generating study and findings need to be replicated in future work. First the present analyses were intention-to-treat. In future CNCR-analyses it will be possible to identify patients that actually received assertive outreach, which allows for a more accurate comparison but falls short of the goal of improving levels of care for the region as a whole. The intention-to-treat analysis results in an underestimation of the effect of F-ACT and therefore the results are conservative.

Second, it would be interesting to compare remission outcomes in ACT-areas and standard-care areas. This was not possible in the present study because the CNCR was only recently introduced in two adjacent areas where F-ACT is not implemented yet and, therefore, not enough data were available for this comparison.

Third, the results of the pre-post F-ACT comparison did not reach statistical significance most likely because of lack of power of the study. The number of patients further decreased when including confounders, because age of onset was missing for 26 patients.

The strength of the present pre-post comparison was the use of two non-overlapping cohorts (1998–2001 vs. 2002–2005). The first cohort included all patients in the region before the introduction of F-ACT, whereas the second cohort was composed of patients in this same region after F-ACT was implemented. Data obtained after 2002 of patients who had their first CNCR assessment before 2002 were excluded from the analyses, in order to avoid selection bias (patients with long treatment histories are treated during the pre- and the post F-ACT phase, which would have led to a double count).

Furthermore, in order to guarantee test-retest reliability, mental health professionals are trained on a regular basis and protocols require supervision of new mental health professionals when assessing the CNCR forms. This resulted in satisfactory test-retest reliability (unpublished results).

■ Limitations

The present study had several limitations. First, recently, the CNCR data registration has been expanded to all SMI diagnostic categories, rather than psychotic disorders. However, all patients that fulfilled the remission criteria at the previous assessment were excluded (not “at risk” for remission) and, therefore, all included patients suffered from psychotic psychopathology at one of the assessments. Furthermore, diagnosis was adjusted for in the analyses.

Second, some transitions to non-remission may be missing from the data, because some patients are assessed only once a year. However, when a patient deteriorates this often leads to a change in treatment or setting, and then a new assessment is indicated according to the CNCR-protocol. In addition, we do not expect differences in proportion of missing transitions to non-remission before and after the introduction of F-ACT and, therefore, it is highly unlikely that this would have biased our results.

Furthermore, because the present analysis is a pre-post comparison, we have excluded from the post assertive outreach-group the patients that had been in care before the introduction of assertive outreach. This was done to create two comparable groups and prevent bias by time in the database. This procedure may have resulted in a higher proportion of incident cases in the post-assertive outreach group. However, results showed that the proportion of incident cases was very low in both groups (Table 2).

The international working group also defined symptomatic remission as being present for at least 6

months. However, the interval between assessments differs and is not 6 months in the majority of the cases. In addition, remission status of a patient cannot be classified between two measurements, making the full remission definition extremely difficult to apply in routine databases such as the present. In order to extend our results closer to the complete set of remission criteria a sensitivity analysis was performed. For this analysis, a patient was defined as being in remission only when he or she met remission criteria at two consecutive measurements or when there was no successive measurement. Although the time interval between the two measurements has not been 6 months and patients may not have been in remission between the two assessments, this analysis comes closer to the more conservative definition of remission. This sensitivity analysis showed even stronger results (OR = 2.85, 95% CI: 1.28–6.34, $n = 162$, $p = 0.010$; adjusted OR = 2.10, 95% CI: 0.71–6.23, $p = 0.18$, $n = 136$). Therefore, we may conclude that reported effects also apply when a more conservative definition of remission is applied.

The assessments were done by clinicians involved in the treatment, including F-ACT clinicians. Because assessments were not blinded, assessments may have been biased when clinicians enthusiastic by the new way of working interpret patients’ improvements too positively. On the other hand, routine assessments are part of everyday work in all settings and were in place years before the introduction of F-ACT. Hence, clinicians, social workers and nurses do not consider the assessments as evidence of the short-term effectiveness of their working method anymore. In daily practice, the feedback data serves as a life-chart for patients with severe mental illness, offering possibilities for better understanding the needs and predictive factors of course in the longer term.

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