# **Online supplement**

## **Data supplement DS1**

# Forensic psychiatry in The Netherlands

In The Netherlands out-patient forensic psychiatry operates in parallel to (rather than integrated with) regular mental healthcare.<sup>21</sup> It provides out-patient treatment for people with psychiatric needs who have or are at risk of having contact with the criminal justice system.<sup>22</sup> Formal risk assessment occurs, but infrequently and on an *ad hoc* basis.

#### **Power analysis**

In a pilot study 27% of a sample of forensic psychiatry outpatients (n=83) displayed violent or criminal behaviour during a period of 6 months.<sup>10</sup> A reduction of this percentage to 18%, which corresponds to a statistically small but clinically relevant effect of size 0.20, may be shown with a power of 80% and a two-sided alpha of 0.05 if 340 patients are included in both study groups. In a multilevel study, such as a cluster randomised controlled trial, power will be reduced if the outcome variable shows a non-zero intraclass correlation.<sup>16</sup> For the pilot study this correlation was 0.13 (95% CI 0.00–0.35). Inclusion of a strong covariate in the analyses had a positive effect on power.<sup>23,24</sup> In our pilot study baseline violent or criminal behaviour increased the chance of recidivism 6 months later with an odds ratio of 4.0 (95% CI 0.8–21.6); we therefore chose baseline violent or criminal behaviour as covariate for the present study.

#### Randomisation

All case managers and clients of the participating services were eligible for the study. We first contacted case managers to assess their eligibility for inclusion in the study (box 1 in Fig. DS1). We defined case managers as those with primary responsibility for the care planning of their clients. Case managers who reported during this interview that they were due to leave their post within 6 months, or were without eligible clients, were excluded from the study and thus not randomised (box 2 in Fig. DS1). As part of this initial interview we asked case managers about the client characteristics we needed to evaluate their clients for inclusion in the study. As we expected the intervention to be effective only in longer-lasting treatment relations,<sup>11</sup> we excluded clients with expected discharge within 6 months or with a low frequency of treatment contacts (less than once a month on average). Client participation in a conflicting study was also reason for exclusion (box 3).

After this initial interview with the first author to determine case manager eligibility and characteristics, the second author, masked to the case managers' identities, executed the randomisation procedure (box 4). Case managers were randomised consecutively, in random order, in strata defined by participating service; composition of case-load (predominantly clients with violent *v*. sexual offences); professional background (academic *v*. non-academic) and years of experience in forensic psychiatry (2 or more years *v*. less). Altman's minimisation procedure was used to ensure that the difference in numbers of clients randomised to each study group would not exceed 20.<sup>25</sup> The numbers of case managers with their total number of respective clients who were randomised are shown in boxes 5(a) and 5(b) for the intervention and control groups respectively.

Some case managers (boxes 6(a),(b)) left their post during the study. Preferably, their clients were taken over by a case manager who was randomised to the same study arm as the departing case

manager. For three clients this was not possible, which led to their exclusion from the study. Only after case manager randomisation were case managers asked to enrol their eligible clients formally by providing a baseline assessment of client functioning. For large numbers of clients in both study groups this initial assessment of the client by the case manager did not take place (boxes 7(a),(b)). Therefore we were unable to include these clients in our study. Case managers informed their clients, in word and writing, about various aspects of the study and explained that data would be collected anonymously and by independent researchers, to evaluate the new method of care planning.

Drop-out at both case manager and client level resulted ultimately in 19 case managers contributing a total of 310 clients to the intervention group, by filling out the baseline assessment. Of these clients 133 agreed to participate in an anonymous interview with the research assistant at baseline (box 8(a)). For all 310 clients included in the intervention group, follow-up was completed by case managers. For 97 of the original 133 clients participating in the initial interview a follow-up interview was obtained (box 9(a)). In the control group 20 case managers contributed a total of 322 clients through the completion of a



Table DS1 Participants with an incident report of violent or criminal behaviour obtained by interview for the 6-month periods preceding baseline and follow-up assessments

		Baseline, n (%)			Follow-up, <i>n</i> (%)		
	Whole sample (n = 221)	Intervention group ( <i>n</i> = 133)	Control group (n = 88)	Whole sample (n = 169)	Intervention group (n = 97)	Control group (n = 72)	
Sexual offence Against person aged ≤16 years old Against person aged >16 years old	3 (1.4)	2 (1.5)	1 (1.1)	1 (0.6)	1 (1.0)	0 (0.0)	
or unspecified	1 (0.5)	0 (0.0)	1 (1.1)	1 (0.6)	0 (0.0)	1 (1.4)	
Violence	66 (29.9)	40 (30.1)	26 (29.5)	38 (22.5)	21 (21.6)	17 (23.6)	
Threatening aggression <sup>a</sup>	49 (22.2)	35 (26.3)	14 (15.9)	26 (15.4)	15 (15.5)	11 (15.3)	
Arson	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Stalking	2 (0.9)	1 (0.8)	1 (1.1)	1 (0.6)	0 (0.0)	1 (1.4)	
Property offence	39 (17.6)	23 (17.3)	16 (18.2)	19 (11.2)	10 (10.3)	9 (12.5)	
Substance-related offence <sup>b</sup>	29 (13.1)	17 (12.8)	12 (13.6)	14 (8.3)	6 (6.2)	8 (11.1)	
Any violent or criminal offence <sup>c</sup>	112 (50.7)	69 (51.9)	43 (48.9)	66 (39.1)	39 (40.2)	27 (37.5)	

a. Includes threatening verbal and non-verbal aggression

 b. Includes sale or production of illegal substances and driving while under the influence of a substance. Does not include use or misuse of illegal substances.
c. Numbers do not add up owing to fitting multiple categories and multiple incidents during observation periods. Low numbers prevented testing for differences on individual types of incident

Table DS2     Intervention effect on reported violent or criminal incidents								
	Case-file reports (	(n = 632)	Interview reports ( $n = 169$ )					
	OR (95% CI)	Р	OR (95% CI)	Р				
Incidents at baseline (yes)	2.14 (1.32–3.47)	< 0.01	9.24 (4.71–19.39)	< 0.01				
Duration of follow-up	0.98 (0.94–1.02)	0.35	0.97 (0.91–1.03)	0.29				
Intervention	1.46 (0.89–2.44)	0.15	1.17 (0.56–2.42)	0.67				

baseline assessment; 88 of these clients consented to participate in the baseline interview (box 8(b)). Case managers provided followup information for all 322 clients included in the control group. For 72 of the initial 88 clients agreeing to the interviews a follow-up interview did take place (box 8(b)).

# **Rating of historical risk factors**

In accordance with the START manual,<sup>26</sup> case managers rated the stable, historical risk factors of their clients (such as early maladjustment, history of violence, and prior supervision failure) at baseline, using the Historical, Clinical, Risk Management - 20 (HCR-20).14 These historical factors are meant to serve as background information for the interpretation of the variable, dynamic, factors scored on the START. To maintain comparability between the intervention and control groups, case managers in both groups rated their clients' historical risk factors at baseline.

# **Violence screen**

An extended version of the MacArthur Violence Screens was used, which also includes theft, robbery, vandalism, threatening behaviour, arson, burglary, handling of stolen goods, carrying an illegal weapon, animal cruelty, selling drugs, stalking, sex with a minor, fraud and driving while under the influence of alcohol or drugs.15

#### Differences between included and excluded clients

There were some minor, clinically irrelevant differences between included and excluded clients. On average the latter had been in care for 23.7 months (s.d. = 19.8) and had been eligible for inclusion for a similar period to those included: mean 4.3 months (s.d. = 4.7) v. 4.1 months (s.d. = 5.7); P = 0.68. They were younger than the clients who did participate (mean 37.1 years (s.d. = 11.1)

v. 39.6 years (s.d. = 11.9); P < 0.01), but did not differ on gender. Furthermore, these clients were more likely to have started treatment voluntarily (62.3% v. 54.9%, P = 0.04), to have a history of violent offences (69.9% v. 53.9%, P<0.01) and to have been diagnosed with attention-deficit and disruptive behaviour disorders (15.9% v. 10.8%, P = 0.03). They were less likely to have been diagnosed with paraphilia (7.7% v. 20.1%, P<0.01), a psychotic disorder (3.7% v. 6.9%, P=0.04), mood disorder (12.9% v. 18.9%, P = 0.02) or to have a personality disorder (58.9% v. 67.3%, P = 0.01).

# **Model fidelity**

Model fidelity was assessed by observing interventions of seven individual case managers and rating them on a specifically designed checklist of the trained elements of the intervention protocol (details available from the author). Discussion of vulnerabilities identified by the client was conducted according to protocol on 85% of the elements concerned, strengths identified by the client on 71%, vulnerabilities according to the case manager on 62% and protective factors on 67%.<sup>18</sup>

#### **Client-reported incidents**

For both study groups combined a significant reduction from baseline (21.5%) to follow-up (15.3%) was found in the proportion of clients with an incident reported by the case manager in the client's case file (reduction 6.2%, 95% CI 2.3-10.1, n = 632; McNemar's  $\chi^2$  (1) = 8.75, P < 0.01). This effect was also found when analysing data from the client interviews, where 52.1% reported an incident at baseline and 40.8% at follow-up (reduction 11.3%, 95% CI 3.7–18.9, n = 169; McNemar's  $\chi^2$ (1) = 7.20, P < 0.01); see Table DS2. Results for client interviewbased analyses were: 'as treated', OR = 1.21, 95% CI 0.56-2.62, *P* = 0.62; and 'as planned', OR = 1.27, 95% CI 0.48–3.39, *P* = 0.63.

## **Additional references**

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