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Clinical decision making and outcome in the routine care of people with severe mental illness across Europe (CEDAR)

Short title: Clinical decision making in mental health care

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Abstract

Aims. There is a lack of knowledge on clinical decision making and its relation to outcome in the routine treatment of people with severe mental illness. This study examined preferred and experienced clinical decision making from the perspectives of patients and staff, and how these affect treatment outcome.

Methods. CEDAR (ISRCTN75841675) is a naturalistic prospective observational study with bimonthly assessments during a 12-month observation period. 588 adults with severe mental illness were consecutively recruited from caseloads of community mental health services at the six study sites (Germany, UK, Italy, Hungary, Denmark, and Switzerland). Clinical decision making was measured using two instruments (Clinical Decision Making Style Scale, CDMS; Clinical Decision Making Involvement and Satisfaction Scale, CDIS) from patient and staff perspectives. Outcomes assessed were unmet needs (Camberwell Assessment of Need Short Appraisal Schedule, CANSAS). Mixed-effects multinomial regression was used to examine differences in involvement in and satisfaction with actual decision making. The effect of clinical decision making on outcome was examined using hierarchical linear modelling controlling for covariates.

Results. Shared decision making was preferred by patients ($\chi^2=135.08$; $p<0.001$) and staff ($\chi^2=368.17$; $p<0.001$). Decision making style of staff significantly affected unmet needs over time, with unmet needs decreasing more in patients whose clinicians preferred active to passive (-0.406 unmet needs per two months, $p=0.007$) or shared (-0.303 unmet needs per two months, $p=0.015$) decision making.

Conclusions. A shift from shared to active involvement of patients is indicated, including the development and rigorous test of targeted interventions.

Introduction

The implementation of effective interventions hinges upon clinical decisions made between patients and mental health professionals. Clinical decision-making in persistent conditions differs from well-defined acute care situations many ways. Clinical decision-making in the treatment of severe mental illness (SMI) is characterized by a focus on long-term disease management and patients being highly knowledgeable about their illness. A high number of decisions have to be made frequently, often together with more than one service provider and/or informal carer (Watt, 2000). Defining features of decision making include context (direct and indirect background variables such as information and preferences), the actual process of decision making and its evaluation, and outcome (Entwistle & Watt, 2006; Puschner et al., 2010; Wills & Holmes-Rovner, 2006).

Three general types of decision making have been proposed to characterise the degree of patient involvement in decision making: passive or paternalistic (decision is made by the staff, patient consents), shared (information is shared and decision jointly made), and active or informed (staff informs, patient decides) (Charles et al., 1997; Coulter, 2003). Over the past 20 years, shared decision making has been advocated as a pillar of patient-centred care with the potential to improve patient-orientation and quality of health care (Del Piccolo & Goss, 2012; *The Lancet*, 2011). Although it has been shown that people with mental illness want to be informed about and have a say in their care (Hamann et al., 2005; Hill & Laugharne, 2006), practitioners have largely failed to adopt principles of shared decision making including adequate patient information in their daily routine (Goss et al., 2008; Karnieli-Miller & Eisikovits, 2009; las Cuevas et al., 2012; Légaré et al., 2010; Storm & Edwards, 2013). Furthermore, the evidence base for the impact of shared decision making on patient health status is limited and results are inconclusive (Joosten et al., 2008), especially in mental health care (Duncan et al., 2010). Longitudinal studies are necessary to provide relevant empirical data about these important clinical issues (Hölzel et al., 2013).

In summary, there is a lack of knowledge on clinical decision making and its relation to outcome in the routine treatment of people with severe mental illness. Specifically, the process of decision-making in real-time encounters, including satisfaction with decisions made has been under-researched (Karnieli-Miller & Eisikovits, 2009; Kon, 2010). This paper addresses these knowledge gaps by examining the following research questions:

- (a) Which clinical decision making style is preferred by patients and staff?
- (b) What are the levels of involvement and satisfaction with clinical decisions from patient and staff perspectives, and how do these change over time?
- (c) How are these aspects of clinical decision making related to outcome?

Methods

“Clinical Decision Making and Outcome in Routine Care for People with Severe Mental Illness” (CEDAR) is a naturalistic prospective longitudinal observational study with bimonthly assessments during a 12-month observation period (T0-T6). The study has been registered (ISRCTN75841675) and is reported in line with the STROBE statement (Elm et al., 2007). The six study sites reflect the diversity across Europe in the organisation of mental health services.

Ulm, Germany (coordinating centre): The Department is responsible for the provision of mental health care in a large catchment area in rural Bavaria (population 671,000). Multidisciplinary teams (psychiatrists, psychologists, social workers, nurses, occupational therapists) offer the full range of pharmacological and psychosocial interventions in inpatient, outpatient and day care clinics. The Department collaborates closely with office-based psychiatrists and psychotherapists in the area. London, UK: The site comprised three specialist community teams: early psychosis, assertive outreach and Rehabilitation & Recovery. All teams are multidisciplinary (n=10-15), comprising clinical psychology, nursing, occupational therapy, psychiatry and social work professionals, as well as support

workers and administrative staff. These teams provide a service across the London Borough of Croydon (population 330,000) as part of a range of services for adults aged 18 to 65, including three community mental health teams, home treatment team, community forensic team, and in-patient beds. Naples, Italy: The Department includes inpatient and outpatient units and one day hospital. The outpatient units include specialist clinical teams for the management and treatment of psychotic disorders, mood disorders, eating disorders, obsessive-compulsive disorders. Specialist teams for early detection and management of psychoses and for cognitive and psychosocial rehabilitation are available. Debrecen, Hungary: The Department provides in- and outpatient mental health care for the city of Debrecen (population 200,000). The team is completed by an occupational therapist and a social worker professional who keeps contact with the regional rehabilitation institutions and mental homes. Aalborg, Denmark: The Psychiatry Region North includes various treatment centres, including inpatient treatment, outpatient teams and early psychosis teams. The collaborating centres in the CEDAR study were organised within Universities of Aarhus, Aalborg, Copenhagen, and Southern Denmark. Others were provincial hospitals with associations to Aarhus University. Furthermore, CEDAR collaborated with office-based psychiatrist. Zurich, Switzerland: The Department takes responsibility for a defined catchment area in Zurich City of about 390,000 inhabitants. It comprises 488 beds and additionally offers specialized care in a crisis centre and centre for psychiatric rehabilitation.

Participants

The study was approved by the ethical review boards at each study site. Participants were recruited from caseloads of outpatient/community mental health services. Inclusion criteria were: adult age (18-60 years) at intake, mental disorder of any kind as main diagnosis established by case notes or staff communication using SCID criteria (First et al., 1997); presence of severe mental illness (Threshold Assessment Grid ≥ 5 points (Slade et al., 2003)

and illness duration ≥ 2 years); expected contact with mental health services (excluding inpatient services) during the time of study participation; sufficient command of the host country's language; and capability of giving informed consent. Exclusion criteria were: main diagnosis of mental retardation, dementia, substance use or organic brain disorder; cognitive impairment severe enough to make it impossible to give meaningful information on study instruments; and treatment by forensic mental health services. A paired member of staff was identified by the service user. Data were collected via questionnaires (filled in by the patient and their key worker) or via interviews conducted by the *CEDAR* study workers every two months for one year. Data entry modes were via computer or paper-pencil forms. Figure 1 shows the flow of participants through the phases of the study. Between November 2009 and December 2010, 708 patients were screened for inclusion of which 588 were included after having given written informed consent.

insert Figure 1 about here

Measures

The *Clinical Decision Making Style Scale* (CDMS; Puschner et al., 2013) measured preferences for decision making at baseline. Parallel patient (CDMS-P) and staff (CDMS-S) versions both have 20 items rated on a five-point Likert scale in three sections: (A) 6 items referring to general preferences regarding patient autonomy in decisions; (B) 9 items referring to decision making preferences in three scenarios; and (C) 5 items referring to desire for information. CDMS sub-scales are Participation in Decision Making (PD) which consists of the mean of items in sections A and B (with a higher score indicating a higher desire by the service user to be an active participant in decision making), and Information (IN) consisting of the mean of items in sections C (ranging 0-4, 0 with a higher score indicating a higher desire by the service user to be provided with information). Categorical sum scores were

formulated on the basis of utility where an emphasis was placed on separating categories according to clinical meaningfulness. Categories for the PD sub-scale were “passive” (<1.5), “shared” (1.5-2.5) and “active” (>2.5), and for the IN sub-scale were “low” (<2.0), “moderate” (2.0-3.0), and “high” (>3.0).

The *Clinical Decision Making Involvement and Satisfaction Scale* (CDIS; Slade et al., 2014) measured involvement and satisfaction with a specific decision at all time points. In order to have a common unit of analysis, patient and staff rated the decision identified by the patient as being the most important made at the latest treatment session. The scale has parallel patient (CDIS-P) and staff versions (CDIS-S). Each of the 6 items of the Satisfaction sub-scale is rated on a five-point Likert scale from “strongly disagree” (1) to “strongly agree” (5), yielding a total score of the mean of all items, ranging from 1 (low satisfaction) to 5 (high satisfaction). Clinical utility categories for the Satisfaction sub-scale were “low” (<3.0), “moderate” (3.0-4.0), and “high” (>4.0). The Involvement sub-scale comprises one item about level of involvement experienced, which uses five categories which were collapsed into 3 (“active”, “shared”, and “passive” involvement). The CDMS and CDIS in all five study languages can be downloaded at www.cedar-net.eu/instruments.

Needs were assessed at all time points by the patient-rated version of the *Camberwell Assessment of Need Short Appraisal Schedule* (CANSAS-P; Trauer et al., 2008) which measures the presence of a met or unmet need in 22 domains, yielding a total score indicating number of unmet needs ranging from 0 (low) to 22. Further measures included the *Global Assessment of Functioning Scale* (GAF; Jones et al., 1995) which is a staff-rated one-item global measure of symptomatology and social functioning, ranging from 1 (worst) to 100, and the *Client Sociodemographic and Service Receipt Inventory* (CSSRI-EU; Chisholm et al., 2000) which is a standardized method for collating information on socio-economic status and service use. Participants were assessed by trained researchers not involved in the care process.

Sample size

Sample size calculation for the analyses of the primary outcome (effect of decision making on unmet needs over one year) via hierarchical linear modelling taking into account the centre-effect yielded a needed sample size of $N = 561$ (94 per centre). See study protocol for details (Puschner et al., 2010).

Statistical analysis

Chi-square tests were used to compare proportions of the four nominal CDMS subscales. Baseline differences and change over time of the nominal CDIS subscales were examined by four mixed-effects multinomial regression models with time as fixed effect (Hedeker, 2003). Based on concepts of causality (Bollen, 1989) and modelling change (Singer & Willett, 2003), it was specifically tested for the one-year observation period whether time-invariant (CDMS at baseline and covariates) and time-varying (CDIS at T0-T5) predictors affected subsequent unmet needs two months thereafter (T1-T6). This was done using of hierarchical linear modelling (Raudenbush & Bryk, 2002) with the time variable months (0, 2, 4, 6, 8, 10, 12). Fixed effects were time, clinical decision making variables, and covariates to control for confounding (study centre, patient age, duration of illness, and diagnosis). Clustering of data (patients nested in key workers) was taken into account by specifying participants and staff as random effects.

Double-sided critical levels for significance tests were used. Prorating was used to deal with missing items in the computation of subscales for each participant, so long as there were fewer than 20% missing items for that participant, or else the scale was set to missing. Scales with specific instructions were exempted from this rule (as in the case of the CANSAS). Otherwise, there was no imputation of missing values. EpiData and SPSS versions 19-21 were used for data acquisition and checking, SuperMix 1 for the mixed-effects multinomial regression models, and S-PLUS (version 6.2) for the hierarchical linear models.

Results

Sample

Table 1 gives an overview of sample characteristics. GAF score indicates serious symptomatology and social disability, indicating that the TAG threshold had successfully resulted in a sample of participants who can be characterised as having severe mental illness. The “other” category for professions included nurses, district nurses, support time and recovery workers, and psychiatric trainees.

insert Table 1 about here

Preferred and experienced clinical decision making

Differences in proportions were significant for all four CDMS subscales. Both patients and staff indicated “shared” as their preferred style of participation in decision making, with staff showing a stronger preference than patients. Desire for information was predominantly high in patient report, and mostly moderate in the view of staff (**Table 2**).

insert Table 2 about here

For the CDIS it was found that at baseline involvement in the last decision made was predominantly rated as “shared” by both patients and staff (see intercepts in upper part of Table 3 and starting levels in Figure 2). Furthermore, patient ratings of “shared” involvement significantly increased over time, accompanied by a decrease in rating of “active” and “passive”. A similar trend of involvement ratings was found for staff (see month 2 – month 12 in upper part of Table 3).

insert Table 3 and Figure 2 about here

Furthermore, the majority of the patients rated high the satisfaction with the way the last decision was made, a considerable proportion were moderately satisfied, and hardly any indicated low satisfaction. In comparison, staff satisfaction ratings were mostly moderate, closely followed by high, and hardly ever low (see intercepts in lower part of Table 3 and starting levels in Figure 3). With only minimal changes, satisfaction ratings by both patients and staff were rather stable over time (Table 3).

insert Figure 3 about here

Clinical decision making and outcome

As shown above in Table 2, there was a decrease in number of unmet needs over time. An unconditional hierarchical linear model showed that at baseline, starting level (intercept) was 3.30 unmet needs which significantly declined over time by -0.16 points per two months (slope; $t = -9.06$; $p < .001$; 3,640 observations of 586 participants). To control for effects of study drop-out, this analysis was repeated for participants for whom number of unmet needs were available at all seven measurement points ($N = 378$), resulting in a similar pattern with intercept = 3.05 unmet needs and slope = -0.18 ($t = -9.41$; $p < .001$; 2,646 observations).

As shown Table 4, a conditional hierarchical linear model yielded that slope constant was no longer significant in the model indicating that the included predictors substantially contributed to explaining variance of the rate of change of unmet needs (Singer & Willett, 2003). Slope was affected by CDMS-S Participation, indicating that reduction of unmet needs over time was significantly higher in patients whose key workers rated their decision making style as active at T0 (vs. passive). No effects were found for the other variables in the model.

When recoding the reference category to shared, the effect of CDMS-S participation on slope remained (active: $\beta = -0.303$, $t = -2.417$, $p = 0.015$).

###insert Table 4 about here ###

Discussion

This observational study on clinical decision making in routine care for people with severe mental illness analyzed the relationships of decision making style and both the involvement and satisfaction with decision making with patient outcome, from both the patient and staff perspective. The study design was longitudinal with seven assessment points.

In line with previous evidence (Hamann et al., 2005; Hill & Laugharne, 2006), people with severe mental illness and their key workers predominantly stated a preference for a shared (rather than passive or active) decision making style. Both patients and staff indicated that involvement in decision making during their last treatment session was mainly shared. This trend increased over time, with about 10% more patients and key workers indicating that decision making one year later was shared. Furthermore, satisfaction with the decision made at the last treatment session was mostly high in patients and moderate in staff and hardly changed over time. This finding corresponds with high and rather stable patient satisfaction ratings on various aspects of mental health service provision (Ruggeri et al., 2006).

Patient-rated unmet needs significantly decreased over time, even when restricting the analysis to participants who had completed all seven measurement points, indicating that the decrease in unmet needs is not due to selective attrition. A comprehensive hierarchical linear model controlling for confounding effects showed that a staff-rated active decision making style was causally related to a significant reduction in patient-rated unmet needs. After one year, reduction of unmet needs in patients whose clinicians indicated a preference for an active decision making style was 2.44 (0.406×6 , cf. Table 4) compared to passive, and 1.81

compared to shared (cf. above). This effect is also meaningful because of the evidence of a fundamental relationship of unmet needs with important outcome and process variables such as quality of life (Slade et al., 2005) and the therapeutic alliance (Junghan et al., 2007).

Over the observation time, unmet needs decreased, and patient and staff ratings of experienced shared involvement in decisions increased, even though CEDAR neither delivered an intervention nor encouraged a specific decision making approach. The finding of decreased unmet needs might indicate the general effectiveness of specialist community treatment over one year. However, this result is inconsistent with other research showing relative stability in unmet needs in people with severe mental illness over time at both four-year (Lasalvia et al., 2007) and ten-year follow-up (Arvidsson, 2008). Furthermore, changes in experienced involvement may be due to social desirability bias, although it is unclear why such bias should increase over time. It is also possible that the increase over time was solely due to study participation, perhaps associated with increased self-monitoring or an assumption – even though not held by the study team – that a move towards shared decision making was optimal. Nonetheless, it cannot be ruled out that the participation in the study might have been an important stimulus toward shared involvement, at least for staff. Moreover, clinical decision making might differ in subgroups (e.g. by diagnosis, study site, or staff profession). Further analysis of the CEDAR data will examine these important issues.

Limitations

Strengths of the study include a large sample size of people with severe mental illness from six European countries, and that assessment of clinical decision making incorporated both patient and staff perspectives. While adjusted for a number of variables, analyses could still be affected by confounders not controlled for, e.g. change of service provider of dissatisfied patients. It should also be noted that the instruments used to assess decision making did not measure actual behaviour, but preferences and subjective experiences with decision making.

Furthermore, outcomes were patient-reported, so results might differ if staff- or observer-rated outcomes were used, as patient-rated scores might have been affected by study participation. Finally, even though overall dropout rates were low, the sample size varied in the different analyses of this paper, with missing values increasing with complexity.

Conclusions and outlook

This study provides much needed evidence to improve decision making by professionals, and at the same time provides tools (CDMS and CDIS measures) for assessing vital aspects of clinical decision making (Légaré et al., 2010). For the first time, a staff-based causal influence of clinical decision making on outcome could be demonstrated, with two additional patient needs being met over one year being a substantial improvement. This means that decision making style of staff is a prime candidate for the development of targeted interventions building upon shared decision making approaches (Torrey & Drake, 2010). If proven effective in future rigorous trials, this would pave the ground for a shift from shared to active involvement of patients including changes to professional socialization through training in principles of active decision making.

CEDAR study group

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Conflict of Interest

None.

Ethical standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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Table 1. Characteristics of patients (n=588) and staff (n=213)

Patients	
Study centre: Ulm, <i>n (%)</i>	112 (19.05)
London, <i>n (%)</i>	85 (14.46)
Naples, <i>n (%)</i>	101 (17.18)
Debrecen, <i>n (%)</i>	97 (16.49)
Aalborg, <i>n (%)</i>	98 (16.67)
Zurich, <i>n (%)</i>	95 (16.16)
Gender; female, <i>n (%)</i>	307 (52.21)
Age; years, <i>Mean (SD)</i>	41.69 (10.74)
Married; <i>n (%)</i>	149 (25.38)
Ethnic group; Caucasian; <i>n (%)</i>	552 (94.04)
Years in school; <i>Mean (SD)</i>	10.43 (1.88)
Living alone; <i>n (%)</i>	231 (39.55)
Paid or self employed; <i>n (%)</i>	110 (18.74)
Receiving state benefits; <i>n (%)</i>	425 (72.40)
Illness duration; years, <i>Mean (SD)</i>	12.51 (9.27)
Diagnosis: Psychotic disorder, <i>n (%)</i>	269 (45.75)
Mood disorder, <i>n (%)</i>	200 (34.01)
Other, <i>n (%)</i>	119 (20.24)
TAG; <i>Mean (SD)</i>	7.54 (2.24)
GAF; <i>Mean (SD)</i>	49.03 (10.96)
Staff	
Study centre: Ulm, <i>n (%)</i>	48 (22.54)
London, <i>n (%)</i>	38 (17.84)
Naples, <i>n (%)</i>	17 (7.98)
Debrecen, <i>n (%)</i>	8 (3.79)
Aalborg, <i>n (%)</i>	59 (27.69)
Zurich, <i>n (%)</i>	43 (20.19)
Gender; female, <i>n (%)</i>	128 (61.84)
Age; years, <i>Mean (SD)</i>	46.03 (10.47)
Profession: Psychiatrist, <i>n (%)</i>	75 (36.41)
Psychologist, <i>n (%)</i>	19 (9.22)
Social Worker, <i>n (%)</i>	11 (5.34)
Other, <i>n (%)</i>	101 (49.03)
Working in outpatient mental health services; years, <i>Mean (SD)</i>	9.41 (8.44)
Working in mental health services; years, <i>Mean (SD)</i>	14.99 (9.66)
Number of patients in study; <i>Mean (SD)</i>	2.76 (4.46)

Missing values patients: N=1 (married, ethnic group, work, benefits), N=4 (living), N = 11 (school), N=29 (GAF). Missing values staff: N = 6 (gender), N=7 (profession), N = 54 (working outpatient), N = 41 (working mental health).

Table 2: Preferred clinical decision making style (participation and information) at baseline, and unmet needs over time

			N	Difference
CDMS-P Participation	passive, <i>n</i> (%)	175 (29.9)	586	$\chi^2 = 135.08$; $p < 0.001$
	shared, <i>n</i> (%)	319 (54.4)		
	active, <i>n</i> (%)	92 (15.7)		
CDMS-P Information	low, <i>n</i> (%)	21 (3.6)	587	$\chi^2 = 292.02$; $p < 0.001$
	moderate, <i>n</i> (%)	207 (35.3)		
	high, <i>n</i> (%)	359 (61.2)		
CDMS-S Participation	passive, <i>n</i> (%)	124 (22.0)	563	$\chi^2 = 368.17$; $p < 0.001$
	shared, <i>n</i> (%)	397 (70.5)		
	active, <i>n</i> (%)	42 (7.5)		
CDMS-S Information	low, <i>n</i> (%)	45 (7.9)	570	$\chi^2 = 205.80$; $p < 0.001$
	moderate, <i>n</i> (%)	324 (56.8)		
	high, <i>n</i> (%)	201 (35.3)		
CANSAS-P unmet needs	baseline, <i>Mean</i> (<i>SD</i>)	3.45 (3.09)	574	
	month 2, <i>Mean</i> (<i>SD</i>)	3.15 (2.99)	526	
	month 4, <i>Mean</i> (<i>SD</i>)	2.81 (2.86)	514	
	month 6, <i>Mean</i> (<i>SD</i>)	2.43 (2.67)	501	
	month 8, <i>Mean</i> (<i>SD</i>)	2.33 (2.81)	510	
	month 10, <i>Mean</i> (<i>SD</i>)	2.41 (2.76)	497	
	month 12, <i>Mean</i> (<i>SD</i>)	2.66 (2.82)	518	

CDMS = Clinical Decision Making Style Scale; CANSAS = Camberwell Assessment of Need Short Appraisal Schedule.

Table 3. Experienced clinical decision making (involvement and satisfaction) over time

Parameter	CDIS-P Involvement ^a				CDIS-S Involvement ^b				CDIS-P Involvement ^a				CDIS-S Involvement ^b			
	shared vs. passive		active vs. passive		shared vs. passive		active vs. passive		shared vs. passive		active vs. passive		shared vs. passive		active vs. passive	
	Est.	S.E.	z	p	Est.	S.E.	z	p	Est.	S.E.	z	p	Est.	S.E.	z	p
Intercept	1.15	0.18	6.49	<.001	0.32	0.20	1.62	0.106	0.79	0.17	4.53	<.001	-1.03	0.28	-3.75	<.001
month 2	0.47	0.23	2.08	0.038	0.72	0.25	2.92	0.004	0.31	0.22	1.41	0.159	0.59	0.28	2.06	0.039
month 4	0.50	0.23	2.15	0.031	0.37	0.26	1.44	0.150	0.48	0.24	2.05	0.040	0.80	0.30	2.67	0.008
month 6	0.62	0.24	2.63	0.009	0.41	0.27	1.56	0.120	0.62	0.24	2.58	0.010	0.71	0.31	2.31	0.021
month 8	0.67	0.24	2.83	0.005	0.35	0.27	1.29	0.196	0.78	0.24	3.26	0.001	0.03	0.33	0.08	0.934
month 10	0.78	0.24	3.20	0.001	0.30	0.28	1.06	0.289	0.39	0.26	1.49	0.137	0.07	0.34	0.20	0.845
month 12	1.13	0.24	4.74	<.001	0.70	0.27	2.59	0.010	0.75	0.24	3.12	0.002	0.21	0.31	0.67	0.505
Parameter	CDIS-P Satisfaction ^c				CDIS-S Satisfaction ^d				CDIS-P Satisfaction ^c				CDIS-S Satisfaction ^d			
	moderate vs. low		high vs. low		moderate vs. low		high vs. low		moderate vs. low		high vs. low		moderate vs. low		high vs. low	
	Est.	S.E.	z	p	Est.	S.E.	z	p	Est.	S.E.	z	p	Est.	S.E.	z	p
Intercept	2.73	0.35	7.90	<.001	3.05	0.35	8.72	<.001	3.29	0.41	8.09	<.001	3.13	0.41	7.56	<.001
month 2	1.12	0.40	2.77	0.006	0.58	0.41	1.40	0.162	0.03	0.39	0.08	0.939	-0.54	0.40	-1.35	0.178
month 4	0.16	0.35	0.47	0.640	-0.33	0.36	-0.93	0.353	-0.25	0.39	-0.63	0.528	-0.93	0.41	-2.29	0.022
month 6	0.80	0.40	2.00	0.046	0.45	0.41	1.10	0.272	-0.03	0.41	-0.08	0.936	-0.52	0.42	-1.23	0.219
month 8	0.40	0.38	1.06	0.290	0.19	0.38	0.48	0.629	0.52	0.49	1.06	0.291	0.39	0.50	0.79	0.431
month 10	0.14	0.37	0.37	0.709	0.18	0.37	0.47	0.637	0.73	0.60	1.23	0.219	0.84	0.60	1.40	0.163
month 12	0.88	0.40	2.22	0.026	0.63	0.41	1.56	0.119	0.85	0.51	1.66	0.096	0.51	0.52	0.97	0.330

CDIS-P/S = Clinical Decision Involvement and Satisfaction Scale Patient or Staff version; Est. = Estimate; S.E. = standard error; ^a2,444 observations of 651 patients; AIC = 4456.06; ^b2,223 observations for 621 patients; AIC = 3800.63; ^c2,447 observations of 650 patients; AIC = 3,947.11; ^d2,227 observations for 621 patients; AIC = 3375.79.

Table 4. *Effect of clinical decision making on unmet needs*

		β	S.E.	CI 95% lower	CI 95% upper	t	p
Slope constant		-0.290	0.329	-0.935	0.355	-0.88	0.377
CDMS-P	shared	-0.049	0.067	-0.180	0.082	-0.74	0.461
Participation	active	-0.128	0.111	-0.346	0.089	-1.16	0.248
CDMS-P	moderate	0.080	0.151	-0.216	0.376	0.53	0.596
Information	high	0.109	0.149	-0.183	0.401	0.74	0.462
CDIS-P	shared	0.032	0.090	-0.145	0.210	0.36	0.720
Involvement	active	0.005	0.103	-0.198	0.207	0.05	0.964
CDIS-P	moderate	0.000	0.155	-0.305	0.305	0.00	1.000
Satisfaction	high	-0.026	0.156	-0.331	0.280	-0.16	0.870
CDMS-S	shared	-0.100	0.088	-0.272	0.072	-1.14	0.253
Participation	active	-0.406	0.149	-0.698	-0.114	-2.73	0.007
CDMS-S	moderate	0.170	0.128	-0.082	0.421	1.32	0.186
Information	high	0.175	0.132	-0.084	0.434	1.33	0.184
CDIS-S	shared	0.058	0.083	-0.106	0.222	0.69	0.488
Involvement	active	-0.023	0.112	-0.242	0.196	-0.20	0.838
CDIS-S	moderate	0.069	0.181	-0.285	0.424	0.38	0.702
Satisfaction	high	0.068	0.182	-0.290	0.425	0.37	0.711

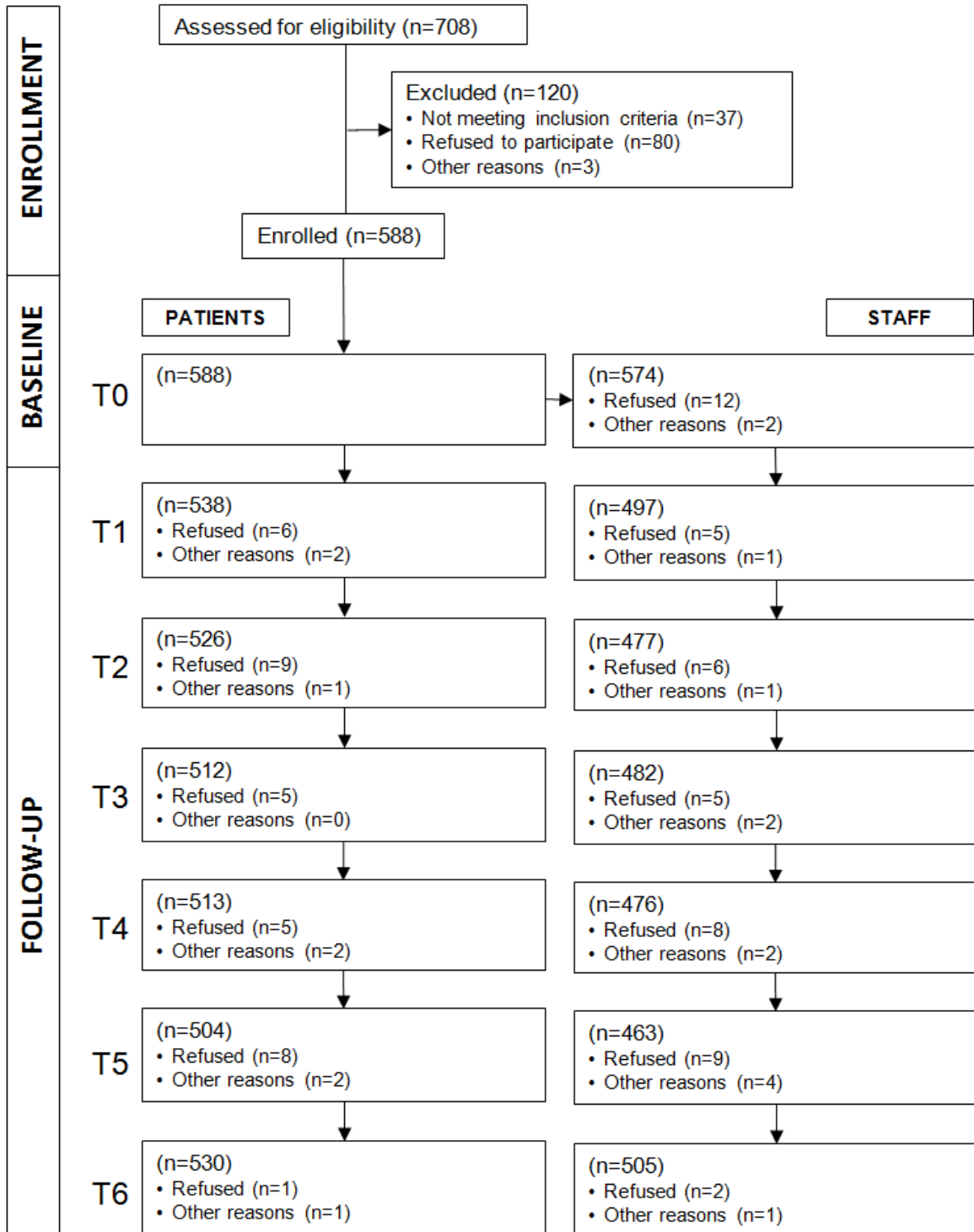
β = effect estimate; S.E. = standard error; CI = confidence interval; 1,726 observations of 499 patients within 189 key workers. Akaike Information Criterion (AIC) = 7668.6. CDMS-P/S = Clinical Decision Making Style Scale Patient or Staff version; CDIS-P/S = Clinical Decision Involvement and Satisfaction Scale Patient or Staff version. Reference categories: “passive” for CDMS-P/S Participation and CDIS-P/S Involvement; “low” for CDMS-P/S Information and CDIS-P/S Satisfaction. Results of control variables in the model not reported.

Figure legends

Figure 1. Study participant flow.

Figure 2. CDIS Involvement over time from patient and staff perspectives.

Figure 3. CDIS Satisfaction over time from patient and staff perspectives.



Numbers given for staff indicate observations per patient, not number of staff.

