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Compliance therapy: a randomised controlled trial in schizophrenia

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Abstract

Objective To evaluate the efficacy of "compliance therapy" for improving adherence to prescribed drug treatment among patients with schizophrenia.

Design Randomised controlled trial.

Setting Urban catchment area psychiatric service.

Participants 94 consecutive admissions of patients with schizophrenia, 56 agreed to participate.

Intervention Compliance therapy and non-specific counselling, each consisting of 5 sessions lasting 30-60 minutes.

Main outcome measures Compliance with drug treatment at one year; attitudes to treatment, symptomatology, insight, and quality of life at one year; length of "survival" in the community, bed days, and rehospitalisation rates at two years.

Results Compliance therapy did not confer a major advantage over non-specific therapy in improving compliance at one year (43% (12/28) *v* 54% (15/28), difference - 11% (95% confidence interval -37% to 15%) or in any of the secondary outcome measures—symptomatology, attitudes to treatment, insight, global assessment of functioning, and quality of life.

Conclusion Compliance therapy may not be of benefit to patients with schizophrenia. Attitudes to treatment at baseline predicted adherence one year later and may be a clinically useful tool.

Introduction

People with an illness often have different opinions from their doctor about their treatment. This lack of concordance may lead to adverse health outcomes for people with schizophrenia.¹ Two thirds of people with schizophrenia readmitted to hospital are partially or completely non-adherent with their medication.²⁻⁴ Although few randomised controlled trials of interventions to improve adherence have been published, Kemp and colleagues described encouraging results from a brief and pragmatic intervention based on motivational interviewing.⁵ Patients receiving this "compliance therapy" had better drug compliance, attitudes to treatment, and insight at six months. People allocated to the compliance therapy group also "survived" longer in the community than those allocated to non-specific therapy.⁶

We sought to establish the efficacy of compliance therapy among a consecutive series of patients with schizophrenia.

Participants and methods

Sample

We asked people with psychosis, who had been admitted to St John of God Hospital, Dublin, to participate in the trial. We included those who met the criteria for schizophrenia,⁷ were aged between 18-65 years, had an IQ greater than 80, were fluent English speakers, and had no evidence of organic disturbance.

Assessment instruments

We used a structured clinical interview to assess participants' compliance with drug treatment in the month before their admission.² We rated compliance on a four point scale: 1 for 0%-24% compliance (non-compliant or consistently irregular), 2 for 25%-49% compliance (frequently irregular), 3 for 50%-74% compliance (irregular), and 4 for 75%-100% compliance (regular). Any participant who scored ≤ 3 was classified as having suboptimal compliance.

We assessed participants' subjective response to neuroleptics and attitude toward medication.⁸ We measured symptomatology, insight, overall level of functioning, and quality of life.⁹⁻¹²

Intervention

We randomly allocated consenting patients to compliance therapy or control groups. Compliance therapy is a cognitive behaviour intervention with techniques adapted from motivational interviewing and other cognitive therapies as well as psychoeducation.^{13 14} This intervention comprised five sessions, each lasting 30-60 minutes, and covered a review of the patient's illness history and understanding of illness and his or her ambivalence to treatment, maintenance medication, and stigma.

Control patients received non-specific counselling, which also comprised five sessions each lasting 30-60 minutes. When patients raised matters relating to medication they were asked to discuss them with their treating teams.

Outcome measures

One year after intervention a researcher who was blind to the type of intervention delivered repeated the

assessments of participants' compliance, attitudes to treatment, insight, symptomatology, overall functioning, and quality of life. We also collected data on participants' occupancy of psychiatric hospital beds one and two years after entering the trial.

Sample size

To detect an improvement from 35% compliance at baseline to 75% compliance at completion with 80% power, we required a sample size of 28 in each arm of the study.

Results

Ninety four patients met the criteria for schizophrenia, of whom six were ineligible and 32 declined to enter the trial.

The 56 people who consented to enter the study were randomly allocated equally to the two therapies. Six patients were lost to follow up: two dropped out during therapy (both controls); three (two controls, one compliance therapy) refused follow up, and one (compliance therapy) died in the follow up period.

Baseline compliance could not be measured for the 12 patients who were admitted for their first episode of schizophrenia, five of whom were allocated to compliance therapy and seven to control therapy. Patients randomised to compliance therapy did not differ from control patients in terms of baseline variables (see table).

Outcome measures

Compliance therapy conferred no advantage over non-specific therapy in terms of compliance at one year (12/28 *v* 15/28, odds ratio 0.65 (0.197 to 2.123)) or the secondary outcome measures—symptomatology (mean (SD) symptoms scale 58.2 (17) *v* 52.1 (21), difference 6.1 (−4.7 to 16.9), *P*=0.26), attitudes to treatment (51.3 (8.2) *v* 53.4 (6.2), difference −2.1 (−6.3 to 2.1), *P*=0.32), insight (9.9 (4.1) *v* 10.4 (2.8), difference −0.5 (−2.4 to 1.5), *P*=0.65), level of functioning (52.7 (17.8) *v* 56.9 (25.3), difference −4.2 (−16.8 to 8.4), *P*=0.50), and quality of life (71.8 (21) *v* 75.2 (25), difference −3.4 (−16.6 to 9.9), *P*=0.61).

Patients who received compliance therapy were not significantly different from control patients in terms of occupancy of psychiatric hospital beds at one year follow up (mean (SD) number of bed days 26 (45) *v* 33 (57), difference −7 (−35 to 21), *P*=0.61) and at two years (43(60) *v* 50 (70), difference −7 (−42 to 28), *P*=0.69). Survival in the community, measured by the number of days to first readmission to psychiatric hospital, was not significantly different for the two groups of patients (mean 440 days (95% confidence interval 346 to 534) for compliance therapy *v* 482 days (378 to 586) for control).

Predictors of compliance at one year

A logistic regression model (for the 44 patients with complete baseline data) identified baseline compliance, baseline attitudes to treatment, female sex, and carer involvement as predictors of compliance at one year follow up (see bmj.com). Undergoing compliance therapy was not a predictor of compliance at one year.

Baseline sociodemographic and clinical characteristics of patients with schizophrenia who received compliance therapy or non-specific counselling. Values are numbers of patients unless stated otherwise

Baseline measures	Compliance therapy (n=28)	Non-specific counselling (n=28)
Mean (SD) age (years)	32 (9)	32 (9)
Men	19	22
Mean (SD) No of years of illness	6 (7)	4 (5)
Mean (SD) No of bed days in psychiatric hospital in previous 2 years	77 (64)	83 (52)
First episode of schizophrenia	5	7
Detained under Mental Treatment Act	4	5
Mean (SD) national adult reading test (NART) score	111 (7)	114 (6)
Mean (SD) neuroleptic dose (chlorpromazine equivalents)	835 (507)	883 (715)
Carers involved	11	11
Domestic situation:		
Living alone	2	3
Living with family or friends	22	22
In residential services	4	2
Homeless	0	1
Marital situation:		
Single	26	25
Married or cohabiting	2	3
Substance misuse:		
None	15	14
Alcohol only	4	5
Multiple substances	8	7
Education:		
No state exams (education to 12-14 years old)	6	6
State exams (education to 15-18 years)	15	13
Third level education	7	9
Clinical measures:		
Full compliance at baseline*	8/23 (35%)	4/21 (19%)
Mean (SD) symptoms score (PANSS)	71 (22)	66 (17)
Mean (SD) functioning score (GAF)	36 (14)	31 (12)
Mean (SD) attitude to treatment (DAI)	50 (8)	50 (7)
Mean (SD) insight score (SAI)	9 (4)	9 (4)
Mean (SD) quality of life score	67 (22)	66 (22)

*Excluding patients for whom this was their first episode of schizophrenia. PANSS=positive and negative symptoms scale, GAF=global assessment of functioning, DAI=drug attitude inventory, SAI=schedule for assessment of insight.

Discussion

In this study, compliance therapy for patients with schizophrenia conferred no advantages over non-specific therapy in terms of patients' adherence to treatment, attitudes to medication, insight, symptomatology, global social functioning, quality of life, or time to readmission to a psychiatric hospital. We were therefore unable to replicate the findings of the previous trial of compliance therapy.^{5,6}

There were, however, important methodological differences between our study and that of Kemp et al, which may help to explain the different findings.^{5,6} In our study, evaluators at baseline and one year were blind to the intervention offered to the patients. Furthermore, unlike Kemp et al, we focused exclusively on people with schizophrenia. Kemp et al, while reporting an overall positive finding, suggest that those with schizophrenia had a less favourable outcome "in terms of social functioning, symptom level, insight and treatment attitudes."⁶ Our findings indicate that people with schizophrenia may not benefit from compliance therapy.

Limitations of study

The patients in our study were not representative of the entire spectrum of people with schizophrenia because

What is already known on this topic

Non-concordance with drug treatment is a major reason for relapse in schizophrenia

Substantial advantages have been attributed to compliance therapy on measures of patients' insight, attitudes to treatment, compliance with treatment, social functioning, and survival in the community before readmission to hospital

What this study adds

This randomised controlled trial of compliance therapy for schizophrenia failed to replicate the previous findings and found no advantage over non-specific therapy in terms of patients' adherence

Attitudes to medication and carer involvement were useful predictors of compliance a year later

they were consecutively admitted patients from a geographically defined area. In this group, we found a non-compliance rate of 72%, which is similar to that previously found in this area and markedly more than that of a typical outpatient group.¹⁵

Like Kemp et al, we relied on the reports of patients and their relatives and healthcare professionals for our measure of compliance. This is not ideal but we have no reason to believe that using a self report method led to a systematic bias.

Furthermore, because our sample size was modest we cannot exclude the possibility that compliance therapy had the desired effect. Although we had limited power to detect subtle changes in second line outcome measures, it was sufficient to confirm previously identified predictors of adherence.

Predicting compliance with drug treatment

This study also prospectively confirmed that measuring a patient's attitudes to drug treatment with a self report instrument predicts adherence one year later. Given the serious personal, familial, and societal consequences of non-compliance, self report instruments have a potential role in clinical practice. However, our findings suggest that, although non-

compliance may be increasingly identifiable and predictable, it remains difficult to solve.

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A memorable patient

The importance of being understood

I have not yet graduated from medical university, and my experience with patients is therefore quite limited. However, I am sure that I will never forget a patient whom I met in my fourth year of study. During our clinical years at the university, we students assist in ward rounds every day and get involved with patient care. Each of us is responsible for a patient and must report on the daily course of his or her disease.

It was early morning on a winter day during one of my internal medicine ward rounds. It was still dark outside, and the patients were just waking up and getting ready for a new day. My patient was an old lady from the countryside—her simple rural background meant she was none too familiar with modern medicine. That morning, I saw that she had a running nose, so I asked her innocently, "Oh, dear, have you caught a cold?" She

looked suspiciously at me, so I thought that she had not understood my question. "I can see you have a running nose," I said, trying to explain myself.

"Oh, no, miss," she replied, "It is because of these new medicines I have just put into my nose, they melt very easily."

Those "new medicines" were indometacin suppositories that my patient had been given for renal colic. I suppose that neither I nor the staff (the doctor who prescribed the drugs and the nurses) paid enough attention to explaining how to use suppositories. I still wonder why she did not swallow them. By their shape, she must have assumed that they were to be fitted into her nostrils.

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