Acceptance, Attrition, and Outcome in an Outpatient Treatment Programme for Alcoholics

A Comparison Between a Randomized and a Non-Randomized Process-Outcome Study

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Summary. Acceptance, attrition and outcome of the same outpatient treatment programme for alcoholics was studied first in a non-randomized and later in a randomized study. There was a lower (15%) rate of acceptance and a higher (19%) rate of attrition in the randomized study. Among treatment completers drinking outcome during the third year after commencement of treatment did not differ between the non-randomized and the randomized study. It is concluded that the characteristics of subjects accepting a randomly assigned study should always be clearly presented. The absence of a patient-therapist matching in a randomized design could negatively effect attrition and probably also acceptance of treatment, while it seems to be less influential on outcome in those completing therapy.

Key words: Alcoholism treatment – Attrition – Outcome – Randomization – Treatment acceptance

Introduction

Randomization is a key concept of controlled outcome studies. The randomized controlled trial is considered the best method to determine acceptance of new drugs and treatment techniques for clinical use. The random assignment in itself, however, may influence the treatment process and possibly also the outcome. Research on the effect of the randomization procedure is difficult, although necessary in order to evaluate the influence of the experimental design on outcome, and thus the generalizability of the results. Commenting on the results of studies of alcohol treatment and of psychotherapy in general, several authorities have stressed that randomization mainly has been used in non-clinical settings and is rarely used in clinical treatment programmes (Institute of Medicine 1990; Parloff, 1982; Garfield, 1990). Further, many subjects who seek treatment do not understand the process of random assignment (Appelbaum et al. 1983) with consequences for attrition and treatment.

This study presents a comparison of acceptance, attrition and outcome of the same outpatient treatment programme for alcoholics in 2 types of studies. Initially the programme, in the following presentation referred to as "psychiatric treatment", was evaluated in a non-randomized process-outcome study (study 1) and later in a randomly assigned study (study 2).

Subjects and Methods

Sample

Both study 1 and study 2 were carried out at the Department of Psychiatry at the University Hospital of Lund, where the outpatient alcoholism treatment programme is an integral part of the services. The patients were referred either by themselves, from the acute services, the general outpatient clinic or from any of the acute wards. Subjects were referred to these programmes in 1981–1983 and in 1983–1985, respectively.

The patients took part in an initial information session about the treatment options. At a second session, about 1 week later, he/she decided whether or not to join the programme. The patient had be sober at both sessions and an outpatient at the second session. There were no other exclusion criteria. The clinical director of the programme was the same psychiatrist in both studies (M. B.).

All patients who wanted information about the treatment programme were included in the studies. Patients were also informed about other treatment options available in the area.

Study 1. In the non-randomized process-outcome study the patients were informed about the 2-year outpatient treatment programme by their future therapists. The programme has been described in detail elsewhere (Öjehagen and Berglund, 1986). The patient was informed about the treatment programme, and he/she also had the possibility to discuss his/her problems with the therapist.

The treatment length was 2 years. The number of sessions was not planned in advance. Accepters of the programme (n = 58) were more often socially stable compared with rejecters (n = 24), i.e. more often married/cohabiting, while they did not differ concerning age, employment status or previous treatment for alcoholism, severity of alcoholism or personality disturbance. (Öjehagen and Berglund, 1986).

Study 2. In the randomized study the patients were informed about the programme by the clinical director (M.B.). The patients were randomly assigned to psychiatric treatment (as in study 1), or multimodal behavioral therapy (Nathan 1979), and to 1 or 2 years duration in each programme with 30 treatment sessions in all alternatives (Öjehagen et al., 1991, 1992). In order to evaluate the importance of treatment length, both programmes were given during 1 and 2 years. In both programmes written contracts were used with defined goals and methods. The information sessions included a standardized description of the two treatment programmes. As in study 1, the patient's own responsibility for the process of change was stressed. At a second session the patient decided whether or not to accept the programmes as well as the research design. At a third session the patient met an independent researcher, who performed different tests. Thereafter, the randomization concerning type of therapy and treatment length took place; 36 patients were assigned to psychiatric treatment, and 36 patients to multimodal behavioral therapy. Finally, at the fourth session the patient met

Both accepters and rejecters in study 2 had similar social characteristics, and they were socially stable as were the accepters in study 1 (Öjehagen et al., 1991).

Outcome Assessment

Study 1. A follow-up interview was made by an independent researcher 2 years after termination of the 2-year treatment programme (Öjehagen et al., 1988). In this study, drinking outcome only during the third year after start of treatment will be reported. The drinking outcome could be categorized for all 50 patients who completed therapy, including 4 patients who died during the 2 year follow-up period (Öjehagen et al., 1988).

Study 2. An independent researcher made outcome assessments after 3, 6, 12, 24 and 36 months. Drinking outcome was categorized for 43 of 47 treatment completers, 22 of 24 patients in psychiatric treatment and 21 of 23 patients in multimodal behavioral therapy (Öjehagen et al., 1991).

The corroboration of the drinking pattern was satisfactory and similar in both studies using key informants, liver function tests and record data, which have been reported previously (Öjehagen et al., 1988, 1991).

"Abuse day" was defined as a day with a consumption of more than four drinks (one drink = 3.8 cl of 40% liqour) during continuous drinking or more than six drinks at occasional drinking (more than 2 days) (Sobell and Sobell, 1978). A favourable drinking outcome during the third year was defined according to a previous unrelated study, i.e. when there were no more than 14 abuse days in 12 months (Nordström and Berglund, 1987).

Statistics

Differences between proportions were tested with the chi square test (Siegel, 1956) and differences between means with the Student's t test.

Results

Acceptance, treatment completion and outcome are present in Fig.1. The results of the multimodal behavior therapy have been included as a reference group.

The number of treatment accepters was lower in study 2 than in study 1, 56% (72/129) versus 71% (58/82) (P < 0.05).

Eighty-six percent (50/58) of the patients in study 1 completed the programme in comparison with 67% (24/

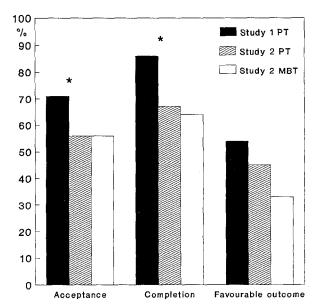


Fig. 1. Comparison of treatment acceptance, completion and favourable outcome during the third year in psychiatric treatment (PT) between a non-randomized study, study 1, and a randomized study, study 2 (also including multimodal behavioral therapy, MBT). *P < 0.05, comparison between PT results in study 1 versus study 2

36) in psychiatric treatment in study 2 (P < 0.05). In study 2, 75% (9/12) of patients with 1 year of treatment, and 63% (15/24) of those with 2 years of treatment completed the programme (n.s.). Background data and initial characteristics did not differ between treatment completers and the others.

In study 1, all 8 patients who did not complete therapy were still alive and living in the area at the end of therapy. In study 2, 3 patients deceased (2 of them committed suicide), and 2 among the 12 patients who left therapy prematurely moved to another area.

Outcome. In study 1, 54% (27/50) of treatment completers had a favourable drinking outcome during the third year compared with 45% (10/22) in psychiatric treatment in study 2. Drinking outcome in 1 and 2 year alternatives of treatment was 38% (3/8) and 50% (7/14) respectively. Favourable drinking outcome among treatment completers in multimodal behavioral therapy was 33% (7/21) (Öjehagen et al., 1992).

Only one of the therapists participated in both studies. The attrition rate of her patients was 6% (2/34) in study 1, and 33% (7/21) in study 2 (P < 0.05), and 47% (15/32) and 50% (6/12, 2 patients were not followed-up) of her treatment completers respectively had a favorable outcome.

The number of treatment sessions did not differ between the two treatment settings, 21, SD 8 in study 1, and 23, SD 8 in study 2.

Discussion

This study appear to us to be unique in presenting a comparison between a non-randomized process-outcome

study, and a randomized study of the same treatment programme in a clincial setting concerning acceptance, attrition and outcome.

The possibility of identifying effects of randomization in this study is confounded by several factors. In clinical settings, many factors can not be controlled for, and there might be differences in the patient populations from which samples for the two studies were drawn. The sample applying for treatment in the second study were socially stable, and thus similar to accepters in the first study. More suitable patients were probably referred to the programme in study 2 when in became better known. The differences in acceptance rate probably would have been greater if socially unstable alcoholics had also been referred to the second study.

The different treatment durations in study 2 could be an influential factor on outcome. Perhaps the positive outcome rate during the third year would have been higher if all subjects had received 2 years of treatment. If so, our conclusion of no outcome differences between the studies probably would have been more explicit. Further, study 1 and study 2 differed in the number of treatment sessions required (unplanned versus 30 sessions), and in outcome assessment (1 versus 5 follow-up interviews in study 2).

A comparison between psychiatric treatment and multimodal behavioral therapy in study 2 is presented in detail in another paper (Öjehagen et al., 1992).

Our first finding was that the treatment programme was less often accepted in the randomized study. In conclusion, the research design has an influence on acceptance. The alcoholics had to accept the randomization procedure, i.e. accepting both 1 and 2 years of treatment, and both psychiatric treatment and multimodal behavioral therapy. In addition, they had to take part in a comprehensive research protocol administered by an indepedent researcher before treatment, as well as after 3, 6, 12, 24 and 36 months.

Our second finding was that the attrition rate was higher in the randomized study. In psychotherapy, the importance of patient-therapist matching is well recognized (Luborsky and Auerbach, 1985). In study 2, the patients did not meet their future therapist until after the randomization procedure, while, in study 1, the treatment programme was introduced by the future therapist. The acceptance of the programme in study 1 probably also included the therapist.

Our third finding was that the rate of favourable drinking outcome in psychiatric treatment completers did not differ significantly between the initial and the randomized study. Thus, the randomization procedure seems not to have negatively effected the outcome in patients remaining in treatment.

It could be argued that the conditions for the randomized and the non-randomized studies were too dissimilar to permit anything but a descriptive comparison. Still, the topic is of great importance and more sophisticated designs are very difficult to implement in clinical studies.

We therefore regard it important to publish the data in order to make it possible for future researchers to confirm/or not to confirm our results. Without such confirmation our results are not very conclusive.

In summary, there was a higher rejection of treatment as well as attrition from the programme in the randomized study in comparison with the non-randomized process-outcome study. These findings have implications for the generalizability of the findings. The characteristics of patients accepting a randomly assigned treatment should always be clearly presented. The absence of patient-therapist matching could negatively effect attrition and probably also acceptance, while it seems to be less influential on outcome in those completing therapy.

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