

SPECIAL ARTICLE

UNITED KINGDOM ALCOHOL TREATMENT TRIAL (UKATT): HYPOTHESES, DESIGN AND METHODS

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Abstract — The United Kingdom Alcohol Treatment Trial (UKATT) is intended to be the largest trial of treatment for alcohol problems ever conducted in the UK. UKATT is a multicentre, randomized, controlled trial with blind assessment, representing a collaboration between psychiatry, clinical psychology, biostatistics, and health economics. This article sets out, in advance of data analysis, the theoretical background of the trial and its hypotheses, design, and methods. A projected total of 720 clients attending specialist services for treatment of alcohol problems will be randomized to Motivational Enhancement Therapy (MET) or to Social Behaviour and Network Therapy (SBNT), a novel treatment developed for the trial with strong support from theory and research. The trial will test two main hypotheses, expressed in null form as: (1) less intensive, motivationally based treatment (MET) is as effective as more intensive, socially based treatment (SBNT); (2) more intensive, socially based treatment (SBNT) is as cost-effective as less intensive, motivationally based treatment (MET). A number of subsidiary hypotheses regarding client–treatment interactions and therapist effects will also be tested. The article describes general features of the trial that investigators considered desirable, namely that it should: (1) be a pragmatic, rather than an explanatory, trial; (2) be an effectiveness trial based on ‘real-world’ conditions of treatment delivery; (3) incorporate high standards of training, supervision and quality control of treatment delivery; (4) pay close attention to treatment process as well as treatment outcome; (5) build economic evaluation into the design at the outset. First results from UKATT are expected in 2002 and the main results in 2003.

INTRODUCTION: ORIGINS AND DEVELOPMENT OF THE TRIAL

In January 1998, the UK Medical Research Council (MRC) funded the United Kingdom Alcohol Treatment Trial (UKATT), a multicentre, randomized controlled trial of treatment for alcohol problems. The impetus for the development of the trial was a meeting convened by the MRC in April 1994 to discuss a range of issues related to research on treatment for alcohol problems. A major conclusion from this meeting was the need for multicentre trials in the UK. Arising from the MRC meeting and following a series of meetings between the investigators during 1994, they were successful in obtaining an MRC Project Grant to study the feasibility of a multicentre clinical trial and to prepare for this trial in various ways. A report on the Feasibility Study together with an application for a Special Project Grant was submitted to the MRC in March 1996. Following a response to referees’ comments and a revision of the application, the trial was funded in January 1998. This revised proposal took account of findings from Project MATCH in the USA, which were beginning to appear at this time. Preparation for the trial commenced in April 1998 and the treatment phase began in January 1999. The trial represents a collaboration between psychiatry, clinical psychology, biostatistics, and health economics. Details of principal investigators (PIs), other research and clinical personnel, and collaborating centres are given in Appendix 1. In addition to their specific roles in UKATT, all PIs have contributed to the background thinking and practical development of the trial, others listed in the Appendix have made significant contributions to it.

THEORETICAL AND RESEARCH BACKGROUND

Need for a multicentre trial of psychosocial treatment

In identifying the key issues the trial should address, UKATT investigators began from evidence that, among general approaches to the treatment of alcohol problems, psychosocial forms of intervention offered the best chances of success (Holder *et al.*, 1991; Finney and Monahan, 1996) and, moreover, could be delivered effectively by the range of professional groups involved in providing such treatment in the UK. Major trials of psychosocial treatment in Britain have been few in number (e.g. Edwards and Guthrie, 1967; Edwards *et al.*, 1977) and the trial by Chick *et al.* (1988) in Edinburgh, in which 152 treatment attenders were randomized to extended or brief treatment, is the largest of these. Although these earlier studies provided valuable findings, trials of this size have insufficient statistical power to detect small to medium size effects in comparisons of one form of treatment with another. When two or more treatment methods conveying basic care and attention are compared, expected effects are moderate at best (Mattick and Jarvis, 1993), but are nevertheless potentially important when widespread application of treatments over a large number of clients is envisaged. Moreover, if treatments differ in costs, the financial implications of even small effect sizes are potentially considerable. The principal reason why many treatment evaluations have small samples and low statistical power is that they are conducted at a single treatment site where, especially after excluding clients who are unsuitable for the trial or unwilling to participate, the collection of a large sample takes an unacceptably long time. The obvious solution to this problem is to conduct multicentre trials in which a suitably large sample can be collected within a reasonable time span.

In addition to this general advantage of multicentre trials, at the time UKATT was being developed, the results of Project MATCH in the USA were beginning to become available.

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Project MATCH studied a large number of individuals in treatment for alcohol problems in order to test hypotheses regarding statistical interactions between individual treatments and client characteristics (i.e. ‘client–treatment matches’). Partly in order to examine some of the implications of MATCH findings for British treatment provision, it was felt that a trial approaching the dimensions of Project MATCH would be timely in the UK. A further advantage of a multicentre trial was that any findings that emerged could be more easily generalized across different geographical sites and client populations, thus enhancing the possible application to practical clinical settings.

Implications of Project MATCH findings for UK treatment provision

Project MATCH, funded in the USA by the National Institute on Alcohol Abuse and Alcoholism, was the largest study of the effectiveness of treatment for alcohol problems ever conducted, involving nine treatment sites and a total of 1726 clients. The project was divided into two parallel, but independent, clinical trials — an out-patient arm and an aftercare arm. The study was specifically designed to assess the benefits of matching clients to three different treatments with respect to a variety of client attributes and, to that end, 16 primary and 11 secondary matching hypotheses were specified (Project MATCH Research Group, 1997*a,b*). Clients within each arm of the study were randomly assigned to three interventions, each defined by a manual and delivered on an individual basis over 12 weeks: Cognitive Behavioural Coping Skills Therapy (CBT), Twelve-Step Facilitation Therapy (TSF), and Motivational Enhancement Therapy (MET). CBT and TSF consisted of 12 therapy sessions, whereas MET consisted of four sessions over 12 weeks.

Results showed that substantial improvements in drinking status took place for all three treatments, but there was little difference in outcome between treatments at either the 1-year (Project MATCH Research Group, 1997*a,b*) or the 3-year (Project MATCH Research Group, 1998*a*) follow-up points. Four potentially useful matching effects were found (Project MATCH Research Group, 1997*a,b*, 1998*a*), but the general hypothesis that careful matching would improve overall outcomes of treatment for alcohol problems was not confirmed.

For the provision of alcohol problems treatment in Britain, we considered the most relevant finding from Project MATCH to be that a less intensive and less costly treatment (MET) did not result in significantly inferior outcomes to two more intensive and expensive treatments (CBT and TSF). This applied to all levels of severity of alcohol problems and to all levels of alcohol dependence among those clients included in the project. Owing to the large number of clients in the two samples and the very high statistical power for detecting main effects, this absence of differential outcome was very unlikely to have been a Type 2 error. Thus, it could be concluded with confidence that, among the normal range of clients attending for specialized treatment in the USA, MET was equal in effectiveness to, and therefore more cost effective than, CBT and TSF. Although Cisler *et al.* (1998) calculated that the cost differentials between the three treatments were less than might be expected from their relative intensities, they nevertheless concluded that MET would be less costly to deliver in non-research settings than TSF or CBT. (It should be noted,

however, that Project MATCH did not conduct a concurrent economic evaluation and that only direct costs were compared by Cisler *et al.*, 1998.)

Whereas TSF is less relevant to formal treatment provision in the UK than in the USA, cognitive-behavioural treatment is widely used in Britain and would be regarded by many treatment providers as the most effective form of psychosocial treatment. Thus, ignoring for the moment any possible differences between the US and British treatment systems that may be relevant to the issue, the *prima facie* deduction is that MET should replace cognitive-behavioural therapy on the grounds of cost-effectiveness. However, before it can be concluded on these grounds that intensive treatment as a whole is cost-ineffective and that all problem drinkers should be offered MET, it is necessary: (1) to conduct a multicentre trial of treatment for alcohol problems in the British treatment system in order to discover whether US findings with respect to MET and more intensive treatment can be replicated; (2) to examine thereby outcomes from any more intensive approach to treatment which both theory and research give grounds for hypothesizing may be more effective than MET; (3) building on matching findings already reported by the US researchers (Project MATCH Research Group, 1997*a,b*; 1998*a*), to enquire what types of client may not benefit from MET and may therefore need a more intensive form of treatment, and what types of client may be especially suited to MET. These considerations provided the main rationale for UKATT.

Social Behaviour and Network Therapy (SBNT)

What, then, was the form of intensive, psychosocial treatment that was best supported by the research literature, that had not been investigated in Project MATCH and that we therefore considered was most likely to yield better overall outcomes than MET? [We have termed this a *Popperian* approach to the issue of intensive vs briefer treatment, since we were concerned to find the best way of *falsifying* the proposition that MET was as effective as, and therefore more cost-effective than, any form of intensive treatment (N. Heather *et al.*, in preparation).] The answer to this question was a treatment modality we have developed for UKATT, SBNT (Copello *et al.*, 2001).

A conclusion from recent reviews of the literature on treatment for alcohol problems (Holder *et al.*, 1991; Thom *et al.*, 1994; Miller *et al.*, 1995; Finney and Monahan, 1996) is that, among relatively intensive treatment modalities, those with the most favourable results tend to contain a strong social or, at least interpersonal, element. For example, in a table summarizing evidence for the effectiveness of specific treatment methods, and based on an analysis of 302 controlled trials of treatment for alcohol problems (the ‘Mesa Grande’, Miller *et al.*, 1998, pp. 206–207), ‘Social Skills Training’, and the ‘Community Reinforcement Approach’ occupy third and fourth places respectively and are exceeded only by evidence in favour of briefer treatment approaches (‘Brief Interventions’ and ‘Motivational Enhancement’). As the table also makes clear, evidence for the two more intensive approaches derives from studies of more severely impaired problem drinkers than that for the briefer treatments. Further support for the crucial contribution of social factors to treatment success comes from evidence that ‘network support for drinking’ has been consistently found to predict poor outcome of treatment

(Havassy *et al.*, 1991; Longabaugh *et al.*, 1993; Beattie and Longabaugh, 1997; Project MATCH Research Group, 1997a). In addition, persuasive arguments based on theory and research have been proposed for the potential contribution of families and friends to the secondary prevention of substance use disorders (Orford, 1994).

In the light of this evidence and the feasibility work carried out by some of the UKATT investigators, SBNT was developed by integrating a number of strategies used previously in other approaches reported in the alcohol treatment literature. These strategies, however, are focused solely on the central aim of helping the client to build 'positive social support for a change in drinking'. Guided by this overall aim and through a collaborative therapeutic relationship, SBNT therapists use a range of cognitive and behavioural strategies to build social networks supportive of change involving the client and other network members (family and friends).

SBNT is carried out over eight sessions combining core and elective topics and lasting 50 min each. Components aimed at developing positive social support for change were drawn from network therapy (Galanter, 1993), behavioural marital therapy (e.g. McCrady *et al.*, 1991), unilateral family therapy (e.g. Thomas and Ager, 1993), social aspects of the community reinforcement approach (e.g. Sisson and Azrin, 1989), relapse prevention (e.g. Chaney *et al.*, 1978) and social skills training (e.g. Oei and Jackson, 1980). However, UKATT is the first occasion on which these various methods and treatment principles have been brought together within a unified social treatment that has theoretical coherence.

Motivational Enhancement Therapy

MET is based on the principles of 'motivational interviewing' (Miller and Rollnick, 1991), but includes feedback to the client of the results of assessments carried out prior to the first session of MET, as used in a form of brief intervention known as the Drinker's Check-up (Miller *et al.*, 1988). Motivational interviewing is an approach to treatment that has become extremely popular in the alcohol problems field over the last decade in many parts of the world, especially Britain. It is the most sought-after form of post-qualification training at a leading centre for training in the addictions (Leeds Addiction Unit, 1999) and is now widely used throughout the country, either as a form of treatment in its own right for clients with relatively less severe problems, or as a component of treatment for those with more severe difficulties. The principles of motivational interviewing are also consistent with recent theoretical formulations of the nature of the addictive process (e.g. Orford, 2000).

The brevity and relatively low cost of MET is also fully in accord with the recent interest in 'brief interventions' in the UK alcohol treatment field. In an influential health care bulletin, Freemantle *et al.*, 1993 concluded that: Evidence from clinical trials suggests that brief interventions (for alcohol problems) are as effective as more expensive specialist treatments'. In a situation of limited resources for healthcare provision and the increasing advocacy of briefer approaches to alcohol problems treatment, many purchasers of alcohol services are seeking to lower the costs of treatment in this service area. While some authors have warned that the available evidence did not justify the application of brief

interventions to those with more severe problems (Chick, 1995; Heather, 1995), the MATCH findings provide strong support for the hypothesis that briefer treatments, at least of the kind represented by MET, can be as effective as more intensive treatments among clients seen by alcohol specialist services.

Owing to the diversity of treatment approaches and practices in the UK, it is not possible to identify a 'routine' treatment with which the effects of an experimental treatment can be compared in a clinical trial. However, UKATT investigators believe that, when the findings of Project MATCH become widely known, this will strengthen an existing tendency towards the commissioning of briefer motivational interventions, a tendency that may be further increased by a more rigorously implemented policy of evidence-based service provision. Thus, in addition to the implication of Project MATCH findings discussed above that MET *should* be the usual treatment for alcohol problems in the UK, we suggest that it is highly likely that it *will* become the usual treatment. For this reason, MET is the appropriate yardstick by which to measure the effects of another treatment, particularly any form of more intensive treatment that was *not* evaluated in Project MATCH. MET can therefore be viewed in the design of UKATT as a usual form of treatment that any other treatment must surpass in effectiveness or cost-effectiveness to be considered for routine application in service provision (cf. Finney, 2000).

The version of MET used in UKATT is a modified form of that used in Project MATCH (Miller *et al.*, 1992), with two changes designed to make MET and its accompanying manual more relevant to the British treatment context and to the requirements of UKATT. First, three sessions are scheduled, rather than four as in the Project MATCH version, because the total treatment time available in the UK trial is less than in the US trial. Thus, the first two sessions of treatment are normally held in weeks 1 and 2, with a follow-up session usually in week 8. Second, to keep MET as distinct as possible from SBNT, a significant other person (SO) is encouraged to attend only the first MET session, rather than two sessions as in the MATCH version. Further, the role of the SO in the UKATT version is confined to providing confirmatory or additional information during the MET session in an attempt to enhance the client's motivation, rather than being enlisted to assist the treatment process outside the session itself, as occurs in SBNT. As in SBNT, all MET sessions in UKATT last 50 min. The aim is to complete both treatments within 8 weeks; in the case of illness or failed appointments, this period may be extended to 12 weeks after entry into the trial, but all treatment must be completed by then.

HYPOTHESES

We express these as null hypotheses for three reasons. First, Project MATCH found that MET was *as effective* as more intensive treatment; our other hypotheses therefore take the null form in the interest of symmetry. Second, null hypotheses enable one to test for departures in either direction by using 'two-sided' tests. Third, Armitage and Berry (1987) advocate two-sided tests, and therefore null hypotheses, unless one can be 'quite certain that departures in one particular direction will always be ascribed to chance, and therefore regarded as

non-significant, however large they are' (p. 98). Thus our main hypotheses are:

(1) Less intensive, motivationally based treatment (MET) is as effective as more intensive, socially based treatment (SBNT).

(2) More intensive, socially based treatment (SBNT) is as cost-effective as less intensive, motivationally based treatment (MET).

The following subsidiary null hypotheses relate to interactions between treatments and clients; if disproved, they would identify prognostic variables that could help the allocation of treatments to clients.

(3) *Clients with weak social networks at initial assessment show the same outcomes from MET as from SBNT.* Project MATCH outcomes in the out-patient arm of the study at 3-year follow-up (Longabaugh *et al.*, 1998) showed that TSF was more effective than MET for clients with networks supportive of drinking and that involvement in Alcoholics Anonymous (AA) was a partial mediator of this matching effect (i.e. those clients with networks supportive of drinking assigned to TSF were more likely to be involved in AA and AA involvement was associated with better 3-year outcomes for these clients). Our third hypothesis seeks to address this MATCH finding but, in line with the development of SBNT, the hypothesis broadens the conception of social support factors that are thought to mediate treatment outcomes and, in particular, any differential outcomes between SBNT and MET. This more general measurement of the strength of social support networks will be taken from the Important People and Activities Inventory (Beattie *et al.*, 1993).

(4) *Clients with low levels of readiness to change drinking behaviour at initial assessment show the same outcomes from SBNT as from MET.* This hypothesis follows from Prochaska and DiClemente's (1992) stages of change model (i.e. clients in Precontemplation or Contemplation stages will benefit more from an intervention, like MET, designed to increase motivation to change, than from an intervention not primarily addressing motivational issues, such as SBNT). In the Project MATCH 1-year follow-up results for the out-patient arm (Project MATCH Research Group, 1997a), it was found that less motivated clients given MET showed a better outcome in terms of number of abstinent days than those given CBT. However, this was not a robust effect over the time elapsing from the end of treatment and was therefore omitted from the list of hypothesized matching effects confirmed by the project. Nevertheless, to investigate this possibility further and because of its theoretical plausibility, hypothesis 4 was included in UKATT.

(5) *There is no interaction between clients' severity of psychiatric morbidity and the relative effectiveness of MET and SBNT.* When the final application for UKATT funding was submitted to the MRC, the only robust matching effect to have emerged from Project MATCH involved level of psychiatric severity (Project MATCH Research Group, 1997a). In the out-patient arm, clients initially low in psychiatric severity showed more abstinent days at 1-year follow-up if they had received TSF than if they had received CBT. Hypothesis 5 was therefore included to see whether any matching effect involving psychiatric morbidity was present in the UKATT data.

(6) *Clients high in anger at initial assessment will show the same outcome from SBNT as from MET.* Since the funding

of UKATT, two other matching effects, in addition to that described under hypothesis 5 above, have been reported by the Project MATCH Research Group (1997b, 1998a). First, in the out-patient arm, clients initially high in anger reported more days of abstinence and fewer drinks per drinking day if they had received MET than if they had received CBT. This effect persisted from the 1-year to the 3-year follow-up point and makes theoretical sense in view of the deliberately non-confrontational nature of MET. Hypothesis 6 was therefore included to see whether the same effect applied to a comparison of MET with SBNT in our data.

(7) *There is no interaction between clients' level of alcohol dependence at initial assessment and the relative effectiveness of MET and SBNT.* The only significant matching effect to emerge in the aftercare arm of the MATCH study was that clients low in alcohol dependence at intake reported more days of abstinence at 1-year follow-up with CBT than with TSF, whereas those high in dependence reported more abstinent days with TSF than with CBT (Project MATCH Research Group, 1997b). Hypothesis 7 was therefore included to see whether any matching effect based on level of dependence was present in the UKATT data.

(8) *Therapists with different characteristics achieve the same outcomes with MET and SBNT.* A further subsidiary null hypothesis was included to investigate the possibility of therapist effects on treatment outcome. The Project MATCH Research Group (1998b) analysed differences in effectiveness between therapists. Most of the variation stemmed from a few therapists whose clients showed poorer outcomes. However, the project selected therapists on the basis of their previous experience in, and enthusiasm for, each of the three treatments. Hence, they could not test whether therapist characteristics were associated with better than average outcomes in one treatment but not in another. In contrast, UKATT allocates therapists at random between treatments. This will enable us to test whether some therapist characteristics lead to better outcomes in one treatment than in the other.

GENERAL FEATURES OF THE UKATT DESIGN

Before describing the design of the trial in any detail, we list some general principles that informed the development of UKATT and determined the kind of trial we wished to carry out.

A pragmatic trial

First and most obviously, we decided to conduct a *pragmatic*, rather than an *explanatory*, trial (Schwartz and Lellouch, 1967). The crucial aspect of this distinction for the present purposes is that explanatory trials are concerned primarily with *understanding*, whereas pragmatic trials are aimed primarily at *decision*. UKATT is not an explanatory trial because treatment intensity (3 vs 8 sessions) and treatment type (motivational vs social) are confounded in the design. If, for example, it transpires that SBNT is more effective than MET, we would not know for sure whether this was because the social approach characterizing SBNT was more effective than the motivational approach of MET, or whether it was because clients given SBNT received more treatment of any kind than those receiving MET. To decide this issue, one would

need to conduct a further study that included a treatment consisting either of eight sessions of MET or three sessions of SBNT. In a pragmatic trial, however, treatments are compared 'under the conditions in which they would be applied in practice' (Schwartz and Lellouch 1967, p. 638) and the findings of the study are intended to be directly applicable to decision making in clinical practice. Furthermore, in the sense that MET is, or will become, the usual form of treatment that any other treatment must improve on to be considered for routine clinical application, MET serves as a control condition to evaluate the effectiveness of SBNT, thus removing the problem of a design confound. Lastly, the inclusion in UKATT of a strong element of economic evaluation further emphasizes the pragmatic nature of the trial.

An effectiveness trial

A related distinction to the above, but with somewhat different implications, is that between *efficacy* and *effectiveness* trials (see, e.g. Flay, 1986; Holder *et al.*, 1999). Efficacy trials are those carried out under optimal conditions with the aim of maximizing internal validity, whereas effectiveness trials are conducted in 'real world' conditions and seek to maximize external validity (i.e. generalizability to practical clinical situations). In these terms, Project MATCH, with its 8 h of pretreatment assessment, five follow-up interviews in the first year after treatment and its use of specially selected and highly trained therapists, was an efficacy trial. It has been claimed that each of the above factors could have blunted potential differences between the treatments studied, with the result that main effects of treatment or client by treatment interactions were made difficult to detect (see Heather, 1999; Orford, 1999). If true, this would render the findings of the trial, so this criticism runs, largely irrelevant to routine clinical practice. So too, the exclusion from the MATCH trial of certain types of client, mainly those who showed dependence on illicit or prescribed drugs, could not name a locator person or were suffering from acute psychosis, reduced the generalizability of the project's findings to real world clinical settings.

Although there are reasons for believing that these criticisms of Project MATCH are misplaced or exaggerated (Heather, 1999), we made an early decision to design a trial with, as far as possible without sacrificing internal validity, high generalizability to the real world of treatment in the UK. Thus, initial assessment is reduced as much as is compatible with the need to collect information on crucial variables; initial assessment is condensed into one 3-h session; and the next occasion on which the client visits the treatment centre is to begin UKATT treatment. Only two follow-up assessments are scheduled during the first year after treatment. Exclusion criteria were limited so as to include as many clients as possible who would normally receive treatment at British specialist centres, again without compromising the viability of the trial. Trial therapists are not employed by UKATT but are selected from treatment staff employed by the treatment services in which the research is taking place. Screening and identification of potential clients for the trial is carried out by clinical staff in conjunction with routine assessment procedures in place in the treatment centres. These aspects of the attempt to increase external validity will be specified in more detail below.

Training, supervision and quality control of treatment delivery

In this aspect of the trial, the UKATT investigators aspired to meet the high standards set by Project MATCH and benefited from the experience of the MATCH investigators (Carroll *et al.*, 1994). Staff are selected for the delivery of a UKATT treatment by the submission of a curriculum vitae and a video-recording of practice demonstrating motivational interviewing skills and the ability to work with two or more clients simultaneously. Evidence of 2 years practice in the addictions field or of substantial experience of working with addiction problems, coupled with demonstrable therapeutic ability, are normally required for therapists to be accepted as trainees. Successful candidates attend a 3-day standardized introduction to the trial and its procedures and training in the treatment type to which they have been randomly assigned. Skills training includes role play and feedback. This intensive introduction takes place at the Trial Training Centre at the Leeds Addiction Unit and is delivered by the principal investigator (PI) responsible for training together with one or more specialists in the treatment being delivered and the supervisor for that treatment. The PI ensures the standardization of training during the three introductory days and the subsequent period of training practice.

Following the 3 days at the Training Centre, trainees are required to complete treatments with at least two clients before being assessed for competence to practise in the trial. These training sessions are video-recorded and a copy sent to the Training Centre where they are supervised by simultaneous viewing of the recording and telephone contact between supervisor and therapist. (Only the therapist is seen on video.) Competence is assessed in line with the procedures for examining skills that are validated for addiction practice modules by the University of Leeds.

On successful acquisition of competence, therapists are able to treat clients randomized to trial treatments. All sessions continue to be video-recorded and copies are sent to the Training Centre. Once competent, therapists have one-third of their sessions supervised in the manner described above in order to prevent drift from the manual protocols for each treatment. The Training Centre supervisors (one for each treatment) are themselves supervised by the PI responsible for training to ensure standardization of the supervision and their own adherence to manual protocols. Both supervisors are practitioner-trainers who are required to practise the treatments they supervise. Supervision of day-to-day problems and adherence to trial procedures outside the delivery of the treatment itself are ensured by the Clinical Manager at each site.

Treatment process

The main focus of UKATT is a comparison of outcomes between two forms of treatment for alcohol problems and possible matching effects, but there is also a commitment to examining treatment process. This is done by both quantitative and qualitative methods. All clients in the trial are given a semi-structured interview lasting approximately 20 min at initial assessment and at both follow-up points. The semi-structured interview has been designed to collect data for qualitative analysis, which it is hoped will illuminate the statistical findings. The initial assessment interview focuses on the client's reasons for seeking treatment and the follow-up interview focuses on perceptions of change during the treatment period.

Interviews are tape recorded, with the client's consent, to permit qualitative analysis.

Independently of the training and supervision process, the delivery of treatment is rated using a manual by a research assistant who is separately supervised. A 10% sample of sessions is assessed for quality of delivery and compliance with treatment protocols as specified in the treatment manuals. These data will also be related to treatment outcome in the analysis.

Economic evaluation

This is an integral component of UKATT. There are few data on the cost-effectiveness of different alcohol treatments and most published studies have used retrospective data or authors' estimates rather than prospective data (Godfrey, 1994). In UKATT, data from clinical sites and clients are being gathered concurrently with all other data. The costs being considered include: the direct costs of the two therapies for each agency; any other services consumed as a direct result of the two UKATT therapies; and costs incurred by clients. Detailed costing of the delivery of UKATT therapies is being undertaken in each clinical centre. The principal individual outcome measure will be changes in drinking. A subsidiary analysis will consider the use of more general health-related quality of life measures to express gains from treatment in terms of net cost/quality adjusted life year. Such calculations allow the results from this evaluation to be put in context of other healthcare procedures. Treatment may also have a number of other consequences that reduce costs to the rest of society. There is considerable research into the potential for treatment to reduce future healthcare costs (Potamianos *et al.*, 1986; Holder, 1987). Crime costs, especially those related to public order, may be reduced after treatment and workplace productivity increased. The UKATT study is attempting to measure individual changes in all these areas after the delivery of UKATT treatments.

The overall purpose of the evaluation is to compare the additional costs and consequences of SBNT compared with MET. All costs and consequences are being considered whoever bears them: publicly funded agencies; individual drinkers and their families; or the rest of society. The social focus of SBNT may have a greater impact on these consequences as well as on individual outcomes. The detailed costing work alongside the potential savings to the public sector will be used to investigate the financial implications of implementing the results of the trial.

DESIGN AND METHODS

Screening

A brief screening of potential candidates for the trial is carried out by clinical staff from among referrals to treatment centres taking part in the trial. The purpose of screening is to eliminate clients who are clearly unsuitable for the trial and to identify those likely to meet exclusion criteria. Screeners are supplied with guidance notes that describe and discuss inclusion and exclusion criteria and they also receive special training in screening requirements from UKATT researchers. In cases where there is doubt as to eligibility, screeners are requested to make a referral to the UKATT research staff.

Trial eligibility interview

The objective of this interview, which is carried out by UKATT research personnel following referral by clinical staff, is to establish eligibility for the trial and willingness to participate, leading to the signing of informed consent and entry to the trial. To make UKATT comparable with Project MATCH and other recent trials in the alcohol field, the formal requirement for inclusion is a diagnosis of alcohol dependence or abuse according to DSM-IV criteria (American Psychiatric Association, 1994). An additional requirement is that alcohol is the client's main problem for which help is sought. It is also necessary that the client has drunk alcohol within the last 3 months. In cases of doubt about inclusion or exclusion criteria, the over-riding principle determining whether a client should be admitted to the trial is whether or not the client would be offered treatment under normal circumstances at the treatment centre in question.

Exclusion criteria

The main principle here is the need to exclude individuals who would be unable to comply with the demands of trial treatments or the research aspects of the trial. However, exclusion criteria were designed to avoid excluding clients who would normally be offered treatment at UK alcohol specialist treatment centres. Exclusion criteria are as follows:

(a) *Age under 16 years.*

(b) *Alcohol not the main problem or client would not normally be offered treatment for an alcohol problem.* Clients showing evidence of dependence on or abuse of other substances are not excluded, provided that alcohol is the chief source of their current difficulties and they would normally have been offered treatment for alcohol problems if the trial had not been in place.

(c) *Stated intention to leave the area or unable to name a trace contact.* Clients are excluded if they state they will be leaving the area before the 1-year follow-up takes place. However, homeless clients are not excluded provided they can give the name of a person or of an organization (trace contact) that can be used to locate them at the time of follow-up.

(d) *Uncontrolled psychotic illness.* Clients with diagnoses of psychotic illness are not excluded provided they are deemed able to comply with and potentially benefit from UKATT treatment.

(e) *Severe cognitive impairment.* Clients are excluded only if they show evidence of cognitive impairment sufficient to prevent them complying with or benefiting from UKATT treatment.

(f) *Illiteracy.* Again, clients are excluded on the ground of illiteracy in English only if it would prevent them from complying, given assistance, with UKATT assessments and relevant parts of the treatment protocol.

(g) *Concurrent treatment for an alcohol problem.* Clients are excluded if they are currently receiving some other form of treatment or counselling directed specifically at an alcohol problem or express the intention of seeking such treatment or counselling during the UKATT treatment period. Thus, current attendance at AA meetings excludes a client.

(h) *Previous participation in UKATT.* Clients who have previously participated in UKATT or who are partners of clients who have participated are excluded.

Basic care package

Since clients entering the trial may have needs that are not catered for in UKATT treatments, there is a requirement for a basic package of care applicable to all clients. This consists of the following elements of care that are made available to any client who needs or requests them before treatment in the trial: alcohol detoxification; treatment of organic pathology; attention to emergency housing needs; and advice on social security and other financial matters in an emergency situation. The provision of basic care is completed *before* the client is randomized to treatment in the trial.

Sample representativeness

To increase the external validity of the trial, characteristics of the final UKATT sample will be compared, using all available data, with those of the total caseloads of each of the treatment sites taking part in the study. This will include counts and descriptions of those not screened for the trial, those screened but not referred to research personnel, those excluded for various reasons and those who decline to take part. In addition, it will be possible to compare the UKATT sample on broad demographic and other variables with limited data from a national census of UK alcohol treatment agencies (Luce *et al.*, 2000).

Randomization

Following assessment of eligibility for the trial, the signing of informed consent and the completion of the pretreatment assessment (see below), clients are randomized between the two treatment groups with stratification for treatment site. To avoid bias, randomization is carried out by telephone or facsimile to the Randomization Service at the Department of Health Sciences and Clinical Evaluation, University of York.

Because SBNT takes about twice as much therapist time as MET, we have set the percentage of trained therapists randomized to SBNT in each site as close to 67% as practical constraints will allow. Because therapists are recruited, randomized, trained and accredited at different times, however, this percentage cannot always be achieved. Our solution is to allocate clients to MET and SBNT in each site with probabilities proportional to the numbers of slots currently available for those treatments in that site (Moser and Kalton, 1971). At worst, this policy would result in unequal randomization between treatments, but the consequent loss of statistical efficiency would be small (Pocock, 1983).

The original design of the trial proposed that clients should be stratified on four other variables in addition to treatment site. However, piloting showed that, with limited numbers of trained UKATT therapists at treatment centres, this stratification would have resulted in slower than desirable recruitment to the trial. These variables will therefore be treated as post-stratification factors in the data analysis — in other words, used retrospectively to check that the allocation of treatments is balanced. This will result in only a small loss of statistical efficiency in the analysis (Moser and Kalton, 1971). The variables are as follows:

Treatment goal. Since a minority of clients attending UK alcohol specialist treatment services are helped to achieve moderate drinking rather than abstinence (Rosenberg *et al.*, 1992), UKATT includes both treatment goals in the design. The decision regarding treatment goal is negotiated with the

client at the screening stage by clinical staff according to the normal practice of the treatment centre. It is possible for the treatment goal to be changed during UKATT treatment if both client and therapist see this as advisable, but this change does not affect the post-stratification. Given sufficient statistical power among those aiming for each of the goals, the hypotheses of the trial can be tested separately among both types of client.

Offer of disulfiram. The alcohol-sensitizing drug disulfiram is often used in the treatment of alcohol problems in Britain, but is usually considered an adjunct to treatment rather than a treatment in its own right (Chick *et al.*, 1992). In UKATT, the role of disulfiram in treatment varies between the treatment centres involved. While allowing the continued use of disulfiram by participating treatment centres, we ensure that this does not produce a confounding factor in the design of the trial by post-stratifying for this variable. Thus, whether or not disulfiram should be *offered* will be decided in negotiation with clients before they are entered in the trial. Since disulfiram is relevant only to clients who are attempting abstinence, this decision will apply only to them.

Offer of acamprosate. This agent is in use in one treatment centre involved in UKATT. It too will be used as a post-stratification variable in the same way as disulfiram.

Prior detoxification. Clients who have recently undergone alcohol detoxification will be admitted to the trial provided detoxification has been completed at the time of screening for UKATT. Detoxification is also included in the UKATT Basic Care Package (see above). Whether or not a decision to detoxify was made prior to entry into UKATT will be a post-stratification variable.

Sample size and power analysis

Previous studies (Edwards *et al.*, 1977; Fuller *et al.*, 1994; Project MATCH Research Group, 1997a) suggested that at least 80% of clients can be successfully contacted and interviewed 1 year following entry into a trial. We intend to recruit 240 clients from each of the three UKATT research centres, i.e. 720 in all or 360 per treatment. If 80% of these clients are successfully contacted and interviewed at the major, 1 year follow-up point, this will yield 576 for definitive analysis or 288/treatment. Thus the definitive analysis will have 80% power using a 5% significance level to detect a standardized difference of less than one-quarter (usually regarded as a small effect) between the two treatments under study. Power is likely to be greater than 80% at the 3-month point (minor follow-up) because of the higher proportion of clients it is expected will be followed-up.

As the subsidiary hypotheses 3–7 relate to the prognostic power of modality-specific variables within regression-like relationships, the statistical power of the corresponding tests is difficult to estimate. However, lower bounds for the power of these tests may be estimated by dividing the SNBT and the MET groups into two subgroups at the median of the relevant treatment-specific prognostic variable. As the resulting simplistic tests would each compare an estimated 144 clients below the median and 144 above, each would have 80% power using a 5% significance level to detect a standardized difference of less than one-third (usually regarded as a moderate effect). The real power of the analogous, but more complex, regression tests is almost certain to be greater. However, the power of

the test of hypothesis 8 regarding therapist characteristics will be weaker than for those hypotheses concerned with client characteristics.

Pre-treatment assessment

This is completed directly following the Trial Eligibility Interview and the signing of informed consent, but before randomization. The following measures are included:

Primary outcome measures. (1) Alcohol consumption is derived from an instrument known as Form 90 (Miller, 1996) that permits the calculation of Drinks per Drinking Day and Per cent Days Abstinent, as used in Project MATCH; (2) γ -glutamyl transferase (GGT) which is measured using the Reflotron device (Boehringer Mannheim Diagnostics, 1989); (3) alcohol dependence as measured by the Leeds Dependence Questionnaire (LDQ; Raistrick *et al.*, 1994); (4) an ordinal classification of outcome developed by Heather and Tebbutt (1989), based on changes in alcohol-related problems as measured by the Alcohol Problems Questionnaire (APQ, Drummond, 1990).

Secondary outcome measures. These are concerned with quality of life, economic variables and measures of general health and adjustment: (1) EuroQol EQ-5D (EuroQol Group 1990; Brooks, 1996), a recently validated health status index; (2) SF36 (Garratt *et al.*, 1993), a widely used health status questionnaire; (3) Healthcare Utilization Questionnaire, an instrument developed at the Centre for Health Economics, University of York to record and cost the use made of healthcare and other services by the client during the previous 6 months; (4) General Health Questionnaire (GHQ-28; Goldberg, 1972), a commonly used measure of psychiatric disturbance; (5) Addiction Severity Index (ASI) — Psychiatric Severity composite score (McLelland *et al.*, 1980), a measure of concurrent psychiatric disorder; (6) Family Environment Scale (Moos and Moos, 1986), a measure of current family atmosphere.

In addition to measures of outcome and to sociodemographic and other personal characteristics of clients, data collection covers possible predictors of outcome, including treatment-specific prognostic variables, and information fed back to clients as part of the MET method. (Many of the measures included in assessments serve more than one function in the trial; however, unless otherwise stated, only their principal use is described here.)

Treatment specific prognostic variables. The main instrument used to test hypothesis 3 above is the Important People and Activities Inventory (Beattie *et al.*, 1993), a measure of social functioning that includes information on network support, both generally and specifically in relation to drinking. A subsidiary prognostic variable for SBNT is the Family Environment Scale. The main prognostic variable for hypothesis 4 is taken from the Readiness to Change Questionnaire (Treatment Version) (Heather *et al.*, 1999), an instrument that allocates clients to one of Prochaska and DiClemente's (1992) stages of change. A subsidiary prognostic variable for MET is a score on the Negative Alcohol Expectancies Questionnaire (McMahon and Jones, 1993), a measure of alcohol expectancies that can be predicted to vary as an individual moves through the stages of change. Hypothesis 5 above will be tested by the inclusion of both the GHQ-28 and the Psychiatric Severity composite score of the ASI; the latter will allow us to test Project MATCH findings regarding psychiatric severity. To

examine further the Project MATCH finding about client anger and outcome of MET (our hypothesis 6), we included the State-Trait Anger Expression Scale (Spielberger, 1988). The remaining treatment-specific prognostic variable is the LDQ score for hypothesis 7.

Other predictor variables. Many of the alcohol-specific and other measures included in the pretreatment assessment also serve as potential predictors of outcome of treatment irrespective of treatment modality. However, one measure included specially for this purpose was an adaptation of the Alcohol Abstinence Self-efficacy Scale (DiClemente *et al.*, 1994a) to embrace both abstinence and moderation goals. In the MATCH data (Project MATCH Research Group, 1998a), the strongest predictors of outcome at 3-year follow-up were self-efficacy and readiness to change at initial assessment and our instrumentation allows us to examine both these previous findings.

MET feedback. Another way in which the UKATT version of MET differs from the MATCH version is in the selection of information that is fed back to the client at the first MET session: (a) alcohol consumption (standard units/week, same sex drinking category from census data, % of population drinking above category); (b) level of intoxication [estimated from BAC peaks calculated by Markham *et al.*'s (1993) BACCuS programme] in a typical week and on a heavier drinking day; (c) tolerance level (estimated from BAC peak); (d) problems related to drinking (taken from the total score and eight subscale scores of the APQ); (e) level of alcohol dependence (from the LDQ); (f) results of liver function tests [GGT and alanine transferase (ALT)]. At the first MET session, clients are given a digest of the above information in a Personal Feedback Report and a short document entitled, Understanding Your Personal Feedback Report.

Process measures

Apart from the semi-structured interview, the treatment process is addressed by the Working Alliance Inventory (Horvath and Greenberg, 1989). This is completed by both client and therapist at the end of the first therapy session and after the last session. We also give the Process of Change Questionnaire as used in Project MATCH (DiClemente *et al.*, 1994b). Since MATCH data showed that the major part of change in drinking behaviour occurred soon after the inception of treatment (DiClemente, 1998), this is completed by the client following the second treatment session and after the last session of either SBNT or MET. Lastly, at the end of every treatment session, clients and therapists are requested to fill in a short form asking about their feelings in relation to the session just completed. Therapists complete a short summary form at the end of treatment.

Three-month follow-up

Clients are followed up 3 months from entry to the trial and asked to take part in a personal interview. For those who have completed the scheduled treatment programme, this serves as a post-treatment assessment. However, an attempt is also made to follow-up those who have dropped out of treatment to obtain an interim assessment of outcome. Instrumentation at the 3 month follow-up includes most of the measures taken at pretreatment assessment. Owing to resource limitations, it is not possible to carry out this follow-up blind to allocated treatment.

One-year follow-up

Clients are followed-up and interviewed 1 year from trial entry to yield data for the main outcome analysis. This follow-up is carried out by research personnel blind to treatment group allocation and at the outset of the interview the client is asked not to reveal anything which might indicate what type of treatment they have received. Measures are again similar to those of the pretreatment assessment, including the use of the Reflotron for liver function tests.

Therapists

Trial therapists are recruited from among local staff at each of the treatment centres taking part in UKATT. They have a professional qualification in nursing, social work, occupational therapy, counselling, psychiatry or addiction studies counselling. When applications to become UKATT therapists have been accepted, they are randomized to one of the two treatments. (We also offer to provide training in the alternative treatment after the trial has been completed.) All training is centralized at the Training Department of the Leeds Addiction Unit, as outlined above. Criteria for clinical training accredited by the University of Leeds and the Leeds College of Health for Diploma Level Addiction Studies modules have been adapted for the assessment of training in the study treatments.

To test hypothesis 8 above, all trainees are given the NEO Five-Factor Inventory (Costa and McCrae, 1992) at the start of therapist training. Combined with socio-demographic data and information on previous experience as therapists, personality variables will enable us to look for interactions between therapist characteristics and outcome of treatment in general and outcome for each type of treatment. Therapist characteristics will also include therapist style (i.e. the extent of empathic or confrontational elements — Miller *et al.*, 1993), as rated from sessional video-tapes.

Statistical analysis

This will follow three basic principles. First, since this is a pragmatic trial, analysis will be by 'intention to treat'. Data from all clients will be analysed within the group to which they were allocated at random, whether they received the corresponding therapy in full, in part or not at all. To exclude clients who did not receive their allocated therapy is typical of explanatory trials concerned with understanding to the exclusion of practical decision making (Schwartz and Lellouch, 1967).

Second, analysis will focus on changes in outcome measures between the pretreatment assessment and follow-up after 3 and 12 months. Because this approach uses each client as his or her own control, it has the potential to enhance the power of the trial (Armitage and Berry, 1987).

Third, we will check for imbalances between treatment groups at the pretreatment assessment. When there is evidence of imbalance, we will use analysis of covariance to adjust changes in outcome accordingly. Where the outcomes are more or less normally distributed, this analysis will take the form of linear regression; where outcomes are ordinal or binary, it will take the form of logistic regression (Armitage and Berry, 1987).

Drinking outcome will be analysed both as continuous variables measuring consumption and as ordinal variables focusing on changes in alcohol-related problems (Heather and Tebbutt, 1989). Patients who are not successfully followed-up

will be regarded as treatment failures wherever there is some corroboration. Changes in outcome will be analysed both at 3 months (to assess the short-term effect of therapy) and at 12 months (to assess the medium-term effect — the main outcome of this trial).

Subsidiary hypotheses 3–7 (see above) will be tested by examining interactions between client characteristics and treatment type in their effects on treatment outcome. Where possible, these interactions will be tested by analysis of covariance (linear or logistic as appropriate), rather than by splitting predictive variables at their median (statistically weaker). Subsidiary hypothesis 8 will be tested by examining interactions between therapist characteristics and treatment type in their effects on treatment outcome, in the same manner as for interactions between client characteristics and treatment type. Because UKATT will have far fewer therapists than clients, however, the power of tests for therapist \times treatment interactions will be weaker than the corresponding tests for client characteristics. Thus, the more important benefit from randomizing therapists is likely to be avoiding bias in testing main hypotheses.

Trial schedule

Recruitment to the trial will be completed by mid-2001 and follow-up by mid-2002. A sample description and 3-month follow-up results will be submitted for publication in 2002. The main results from the 1-year follow-up will be submitted for publication in 2003.

This is the largest trial of treatment for alcohol problems ever conducted in the UK and has been designed to be of direct relevance to clinical practice. We hope that the results will contribute to the quality of treatment service provision in Britain.

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APPENDIX 1: UKATT RESEARCH TEAM AND COLLABORATING CENTRES

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UKATT research centres

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Cardiff Addiction Research Unit, Centre for Applied Public Health Medicine, University of Wales College of Medicine
Leeds Addiction Unit, Leeds Community Mental Health NHS Trust
Centre for Alcohol and Drug Studies, Newcastle City Health NHS Trust and University of Northumbria at Newcastle
Centre for Health Economics, University of York
Department of Health Sciences and Clinical Evaluation, University of York

Treatment sites

Cardiff Community Addiction Unit
Cardiff Community Alcohol Team
VADT Alcohol and Drug Team, Barry
Community Drug and Alcohol Team, Mid-Glamorgan
Leeds Addiction Unit
North Birmingham Community Alcohol Team
Community Alcohol Team Addiction Services, Wolverhampton

EDITOR'S NOTE

This article was not peer-reviewed for obvious reasons, but received full editorial attention.