Manual for Compliance Therapy in Alcohol Pharmacotherapy

NDARC Technical Report No.157

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MANUAL FOR COMPLIANCE THERAPY IN ALCOHOL PHARMACOTHERAPY

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NDARC Technical Report No.157

ISBN 1 877027 44 8
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INTRODUCTION

This manual describes an approach to improve patient compliance with prescribed pharmacotherapy for alcohol dependence. The first half of the manual describes the findings of previous studies of pharmacotherapies for alcohol and the extent of the compliance issue. The second part of the manual provides practical guidelines for compliance therapy. Illustrative case examples are given in the description of the therapy. The third part of the manual contains information sheets and worksheets for the client. This manual was developed as part of a clinical trial of naltrexone and acamprosate. Both the subjects and clinicians will be blind to the medication prescribed; therefore, the manual is written to apply to medication for alcohol dependence generally.

Our Experience

The effective application of compliance therapy, as with any psychological intervention, assumes that the clinician observe the general principles of clinical practice, including;

- respect for clients,
- flexibility, and
- a client-centred approach.

These are fundamental components of psychological interventions that are integral to client engagement and retention in treatment. This manual is a tool that aided us in the consistent delivery of this new psychological intervention, compliance therapy.

Our experience of developing and implementing compliance therapy for alcohol pharmacotherapies has been most interesting and challenging. We have used the manual with over 40 clients to date. Our greatest challenge was to balance our adherence to the structure of compliance therapy while allowing sufficient time for clients to "ventilate" the multitude of crises that beset them.

We believe that clients need to be "heard" to engage in treatment. We were therefore challenged to integrate our active stance towards compliance with pharmacotherapy with a recognition of the clients' own reservations about "taking drugs". Ultimately, we learned that taking a more neutral stance with respect to the prescribed pharmacotherapy reduced clients' resistance. This manual helped us achieve this more neutral stance.

The motivational techniques of frequently reiterating the clients' own concerns and reasons for seeking treatment were of utmost importance in increasing their commitment to change. We also learned that attitudes towards, and beliefs about, pharmacotherapy needed to be addressed as early as possible in treatment to dispel unrealistic expectations and disappointment.

We hope that you find this manual helpful.

ACKNOWLEDGEMENTS

Professor Kevin Gournay, Institute of Psychiatry in London generously spoke to Maree Teesson of compliance therapy and its applications during a visit in 1996. Professor Anthony David kindly provided copies of the manual for compliance therapy in psychotic patients and helpful advice along the way. Their input enabled this research. Professor Wayne Hall supported the research and made the link between RPA (Haber) and the National Drug and Alcohol Research Centre (Teesson). Maree Teesson and Claudia Sannibale took the project from idea to practice and developed this manual. Funding from Sydney University and the research skills of Sophie Reid, Michyo Matsuda and Heather Proudfoot provided the ability to research compliance therapy.

This manual draws from the following references:

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PART ONE: BACKGROUND

Pharmacotherapy of Alcohol Dependence

Alcohol dependence is one of the most prevalent and costly mental disorders in the general population (Hall, Teesson, Lynskey, & Degenhardt, 1999, Teesson, Hall, Lynskey, & Degenhardt, 2000). In the past 12 months, 6.5% of Australians 18 years and over had an alcohol use disorder. This increases to 1 in 10 for males aged between 18 and 35 years.

Recently, with improved understanding of brain neurobiology new pharmacological treatments have been developed. These have been used mainly in the area of relapse prevention. Two new pharmacotherapies, acamprosate and naltrexone have been shown to improve relapse rates in people with alcohol dependence in randomised controlled trials (Volpicelli et al., 1997; Whitworth et al., 1996).

Naltrexone is a long acting (up to 72 hours depending on dose) opioid antagonist. Naltrexone blocks both the analgesic and euphoric effects of opioids and can be administered orally, making it a potentially useful maintenance drug. Studies have produced evidence that naltrexone can reduce drinking in persons with alcohol dependence and may be particularly effective in preventing full-blown relapses in persons who have had a "slip" after achieving abstinence (Volpicelli et al., 1997). This is significant in treatment because approximately 50% of people who are alcohol dependent relapse within 3 months of treatment.

Acamprosate (calcium bis-acetyl homotaurine) is a synthetic GABA analogue. Its mechanism of action is not clear but appears to involve either stimulation of inhibitory GABA transmission and/or inhibition of excitatory amino acid neurotransmitters, particularly glutamate. Acamprosate inhibits alcohol consumption in experimental animals in a dose dependent manner (Le Magnen, Tran, Durlach, & Martin, 1987). Acamprosate is safe in the usual doses given clinically and does not cause dependence. Diarrhoea may be dose limiting, but is uncommon when less than 2 g/day are given.

Most studies of acamprosate showed benefits from treatment, but there remain doubts regarding the appropriate candidates for treatment and suitable adjunctive measures. A number of randomised controlled clinical trials in alcohol dependent people have shown beneficial effects of treatment (Moncrieff & Drummond, 1997). Meta-analysis of 11 European trials (n=3338) has shown that acamprosate was significantly superior to placebo (Sass, Pergeiter, & Lehert, 1995). The rates of patient attendance (50% acamprosate group vs 40% placebo) and abstinence (67% vs 54%), and the duration of drink-free periods were all improved. Poldrugo (1997) has confirmed these findings. However like earlier studies, this study had high exclusion and dropout rates (73.3% and 49.1% respectively). Pelc et al (1997) compared two doses of acamprosate (1998mg/day and 1332mg/day) and found a trend towards a better outcome for the higher dose. Besson et al (1998) followed patients for one year of treatment and a further one year follow-up and allowed concomitant voluntary usage of disulfiram. The duration of abstinence was increased in the group taking both drugs and no adverse drug interactions were reported.

The findings from a recent review of pharmacotherapy for alcohol dependence are summarised below (AHCPR, 1999):

Naltrexone

- Trials of naltrexone in the treatment of alcoholism are recent and of generally good quality.
- There is good evidence that naltrexone reduces relapse and number of drinking days in alcohol-dependent subjects.
- There is some evidence that naltrexone reduces craving and enhances abstinence in alcohol-dependent subjects.
- There is good evidence that naltrexone has a favorable harms profile.

Acamprosate

- Trials of acamprosate in alcohol dependence are large but limited to European populations.
- There is good evidence that acamprosate enhances abstinence and reduces drinking days in alcohol-dependent subjects.
- There is minimal evidence on the effects of acamprosate on craving or rates of severe relapse in alcohol-dependent subjects.
- There is good evidence that acamprosate is reasonably well tolerated and without serious harms.

Compliance

One important limitation to any pharmacological treatment is patient compliance. Many of the programs using pharmacotherapies report substantial drop-out rates and poor compliance with treatment. One study reported that less than 10% of patients who began naltrexone treatment for opiate dependence were still taking the medication after 2 months (Greenstein, 1981). The robust treatment effect size for naltrexone relative to placebo has been shown for compliant subjects only. The issue of patient acceptance has added urgency with the release of the drug in Australia during 1999. Much of the research to date has occurred in the U.S.A., where the poor availability of access to treatment arguably could make patients more compliant. It may be that patients in countries where more treatment options are available will find naltrexone's antagonist properties unattractive.

The potential of pharmacotherapies in the treatment of alcohol dependence relies on the compliance of the individual. The results from international studies would indicate that treatment compliance is of serious concern.

Previous studies attempting to improve compliance with pharmacotherapy

Although treatment compliance is recognised as a major problem with alcohol pharmacotherapy, no research has been reported to specifically redress this issue. However some related research suggests possible new approaches. Haynes et al (1996) in a review of the literature on compliance with interventions concluded that multiple interventions to improve compliance are more likely to be effective than a single intervention. Approaches may include reminder letters and phone calls (Lash, 1999). Use of medication timers has also been associated with increased compliance in HIV therapy (Samet et al, 1992).

A new brief behavioural intervention termed 'compliance therapy' has recently been shown to increase compliance with antipsychotic medications (Kemp et al., 1996). Based on motivational interviewing, 'compliance therapy' was compared with a non-specific counselling (control) condition in a randomised controlled trial. Both groups showed a substantial improvement in symptoms following treatment. However, those patients receiving the compliance therapy showed significantly greater compliance than the control group. Mean difference in compliance between the two groups was 1.6 (based on a 7-point compliance scale) which is equivalent to a 23% improvement due to the compliance therapy. This improvement was sustained over the 6 month follow-up. As well individuals receiving compliance therapy had significantly better insight into their psychotic disorder and were more likely to have improved in global social functioning at 6 months follow-up (odds ratio 8, CI 1.5-42.6).

Preliminary results with alcohol pharmacotherapy

The success of compliance therapy with antipsychotic medications led to the development of this manual, a pilot study of compliance therapy with alcohol pharmacotherapies and a randomised controlled trial.

An open label pilot study of compliance therapy with acamprosate was commenced at Royal Prince Alfred Hospital in July 2000. Twenty subjects were recruited to the pilot. Compliance therapy with alcohol pharmacotherapy was delivered according to this manual. At three months the number of drinking days per month fell from 25 to 14 ($p=0.08$), the number of standard drinks consumed per drinking day fell from 20 to 10 ($p=0.03$) and the GT levels at baseline and 3 months were 167 and 23 respectively (NS).

A randomised controlled trial of compliance therapy with acamprosate was then undertaken (Reid, Teesson, Sannibale, Matsuda, Haber, in preparation). Subjects were recruited through local general practitioners, advertisements in newspapers, health centres and self referred. Subjects were excluded if they had a dependency on a drug other than alcohol (excluding tobacco), an unstable psychiatric disorder, pregnant or serious liver disease. The treatment program was four months and all patients were prescribed acamprosate (Campral: ii tds 333mg tablets).

Subjects were randomly allocated to usual medical care (6 medical appointments at 1,2,4,8 &16 weeks) or usual medical care plus compliance therapy (6 sessions weekly-fortnightly). The mean age of subjects in both groups was 44 years, just over half were male, and just over half were employed. At 16 weeks, the compliance therapy group had taken acamprosate for 60 days compared to 32 days for the usual medical care group, although this was not significantly different. There was also a trend for an increased length of time to relapse for the compliance therapy group (113 days compliance therapy and 23 days usual medical care)

PART TWO: COMPLIANCE THERAPY

Introduction

Compliance therapy is based on motivational interviewing and cognitive approaches to medication compliance. The principles and techniques of compliance therapy are outlined in this section.

Motivational interviewing is a cognitive behavioural technique developed in the addictions field to help people work through ambivalence about behaviour change (Miller & Rollnick, 1991). The intervention is based on the assumption that most patients do not consult services in a state of readiness to change their patterns of behaviour. Therefore straight advice-giving is of limited value because the clinicians' arguments for change are met by resistance from the patient. In contrast, motivational interviewing aims to help patients articulate for themselves the reasons for concern and the arguments for change. Information-giving is still central but is a patient-centred activity which maximises freedom of choice for the individual. The technique aims to help people change their behaviour while avoiding the confrontation and stalemate of many conventional clinician-patient interactions.

Note: It may be useful to read Miller & Rollnick's book and view the video tapes on motivational interviewing developed by Dr Amanda Baker. This would especially be the case if you are unfamiliar with the technique of motivational interviewing. The tapes are available for purchase through: Training, Health & Educational Media, Pty. Ltd., PO Box 2131, Bendigo Mail Centre, VIV 3554; or email: themedia@hitech.net.au.

The following modifications were made to the traditional motivational interviewing method to adapt it to the improvement of patient compliance with medication:

- A more active therapeutic stance with less reliance on self-generation of material in view of the focussed nature of the intervention. In traditional motivational interviewing the arguments for change are left to the individual. While this is ideal, the focussed nature of the intervention warrants a more active therapeutic stance.
- A flexible approach to session length with more frequent short sessions.
- Increased educational component including information about symptoms, medication uses and side effects
- Paced intervention with a defined hierarchy of goals:
    1. willing to discuss problem and treatment
    2. accept alcohol problems in self
    3. accept the need for medication/treatment
    4. accept need to continue treatment (where appropriate) even when not drinking.

The Key Principles of Compliance therapy

A key principle is recognising that readiness to change is on a continuum and confrontation and argument are to be avoided. The therapist proceeds with what the individual presents, asking open-ended questions. The key components of compliance therapy follow closely those from motivational interviewing and are outlined below:

Ambivalence

Ambivalence should not be taken as a sign of unwillingness to change behaviour. Ambivalence may reflect the conflict an individual feels between wanting to continue to take medication or stop. The aim of compliance therapy is to move this ambivalence to action.

Empathic listening

In compliance therapy a non-judgmental attitude should be used with the individual. The individual's comments are reflected back, slightly modified or reframed but always with an attitude of acceptance. Empathic listening does not imply agreement.

Self-motivational statements

Eliciting self-motivational statements from the individual is one of the aims of compliance therapy. Appropriate self-motivational statements include statements which indicate a willingness to accept pharmacological treatment, an acknowledgment that alcohol or drugs are causing problems and a desire to maintain compliance with medication. Positive statements regarding self-efficacy – the individual's ability to make the treatment work – can be coupled with the notion that medication enhances this ability.

Counselling skills

Counselling skills are central to successful compliance therapy. In particular they include the use of open-ended questions, reflective listening, affirmations and summarising.

Resistance

Resistance is observable behaviour or statements that occur during a treatment session. Behaviours such as arguing, interrupting, denying and ignoring indicate resistance from the individual. Resistance behaviours are often responses to the style of an interaction. Ensuring that you avoid evoking or strengthening resistance to change in the individual is central to compliance therapy. The basis of compliance therapy as based on motivational interviewing is "rolling with resistance" - using non-confrontational methods such as empathic listening to deal with resistance. It is how you respond to resistance that makes the difference, and that distinguishes compliance therapy based on motivational interviewing from other approaches (Miller & Rollnick, 1991).

Below are some strategies for handling resistance:

The individual through the course of treatment may say

"I hate taking the medication and I don't want to "

Three ways of responding are outlined below:

<u>Simple Reflection</u>
Responding to resistance with non-resistance for example:

"You can't see any reason for taking the medication?"

<u>Amplified Reflection</u>
Responding to resistance with an amplified or exaggerated statement to elicit the other

side of the individual's ambivalence.

"In fact it might be hard for you to change your mind and continue taking the medication."

Double sided reflection
Respond by acknowledging what the individual has said and also add the other side of the individual's ambivalence.

"You hate taking the medication yet you acknowledge that sometimes you have trouble with not drinking and the medication helps."

Summary

Key principles of Compliance Therapy

- Emphasis on personal choice and responsibility
- Non-judgemental approach
- Focus on eliciting the patient's concerns
- Express empathy
- Support self-efficacy

Key Techniques

- Reflective listening
- Regular summarising
- Inductive questioning
- Explore ambivalence
- Develop discrepancy between present behaviour and broader goals

Avoid

- Lecturing or preaching
- Turning session into a debate
- Asking a series of questions (instead use selective reflection)

Method of Compliance Therapy

The implementation of compliance therapy techniques varies with the treatment needs of the individual and the goal stage as outlined above. The therapy is divided into 3 phases:

1. eliciting beliefs about problem and treatment;
2. exploring ambivalence towards treatment; and finally
3. highlighting the need for treatment maintenance – addressing overconfidence.

However, moving through these areas depends on the individual's progress on the hierarchy of goals (see hierarchy of goals).

Phase One: Eliciting beliefs about problem and treatment: Sessions 1-2

Review of history

The first session is crucial for rapport and sets the tone and the expectations for counselling. The therapist should reiterate:

- The purpose of these counselling sessions and the role of the counsellor *(eg "to assist*

clients to complete their treatment program and attain their drinking goals", "to discuss any concerns they may have about their treatment and medication." If clients have other pressing concerns unrelated to their drinking for which they would like assistance an appointment can be arranged with a counsellor.)

- The approximate number of sessions their length and interval.
- Check if there is anything the client would like to clarify before commencing the session.

Initially individuals are asked to review their alcohol use histories. A good way to begin this process is by reviewing the assessment results (eg dependence scale scores, depression & anxiety etc) and checking the client's understanding and thoughts about these results. The first two sessions are about clarifying the individual's conceptualisation of the problem, or if they acknowledge any problem. Such reflective listening can help to establish rapport. If the individual acknowledges a problem or concern with alcohol use then common explanations offered by the individual may range from lack of self control, attribution of actions to others or genetics.

Examples from individuals: *"Why I have a problem with alcohol…"*

"It's the way I respond to problems "

" *I don't know*"

"Drinking helps me forget"

Reviewing the individual's alcohol use history in detail is useful to remind them about less good aspects of drinking. Even if the individual digresses with personal history details, concerned attention will strengthen rapport, and may also provide clues to underlying dysfunctional cognitions (eg "*I have to be the best*").

Linking treatment completion with effecting change

The person's treatment history may reveal what has facilitated or hindered changes in drinking behaviour in the past. For example, dropping out of treatment may have been associated with an early relapse. If so, assuming the integrity and evidence-base of previous treatment, the relationship between treatment cessation and relapse should be highlighted to encourage retention in treatment and adherence to the treatment regimen.

Formulating Model of Beliefs about problems and treatment

Individuals who deny any problems with alcohol

Individuals may deny the existence of any problem and be hostile to such a suggestion. It is important to recognise that denial of problems is a common response to any problem – not just to problems with alcohol use . This denial is not challenged. However, the individual may be then asked why others think there may be a problem (eg why your spouse asked you to come for treatment). Similarly, with individuals who acknowledge a problem but minimise the significance, a gentle inquiry is made into the social consequences or lifestyle disruption that may have been occurring. It is important to do this in a non-threatening and non-confrontational manner, expressing interest and

concern. Denial of problems is an important factor in poor compliance.

Responding to past treatment failures

Past treatment failures may be associated with hopelessness and loss of self-efficacy. The circumstances leading to past relapses should be explored and any patterns should inform the current treatment process and plan. The client should be encouraged to take an active role in treatment and to assist with feedback on what is useful and what is not.

At the end of this phase there should be a formulation of the individual's stance regarding the problem and treatment. For example,

Jeff is a 26-year-old male, who presented for treatment because he had been missing work due to hangovers from his alcohol use. He is married with two children. His wife encouraged him to seek help about his drinking. Jeff had begun drinking at the age of 15 years and started regular consumption at 18 years. By the time he was 20 years old, he was drinking four to six schooners of beer regularly through the week and on Friday and Saturday nights. In the last year he had begun binge drinking, drinking up to 15 or more schooners. He was also drinking on the next day in order to recover. His recent alcohol use was two schooners of beer before work, four schooners at lunch and another five schooners of beer after work. A recent medical examination revealed that while Jeff's liver was not enlarged, there were elevated levels of a number of liver enzymes. Jeff has tried treatment before and failed on three occasions. He believes that the drinking is of concern now that it is affecting his work; previously he believed that it was more a problem for his wife. He is concerned that the treatment will fail again and is unclear whether medication can help him.

Phase One Summary

- Review individual's current health status
- Link medication/treatment completion with effective change ~~cessation and relapse~~
- Formulate model of individual's view of the problem and treatment

Phase Two: Explore ambivalence towards treatment: Sessions 3-4

Predicting common beliefs about treatment

Four basic sources of reluctance to take medication must be considered: unwanted effects of medication; denial of difficulties with alcohol use; misconceptions about treatment; and difficulties associated with remembering to take medication and consequences of forgetting. Certain attitudes can be anticipated from the initial phase and further explored. The therapist openly predicts certain common misgivings:

i) misconceptions – effectiveness and side effects of medication
ii) stigma - identify as an 'alcoholic', with no self control ("no willpower")
iii) common tendency to stop medication when one feels well or to "test" oneself

with a drink to “see what will happen”

iv) belief that if they miss taking the medication, they have failed and will relapse

The therapist prompts the patient to comment on these commonly held reservations. The opportunity for clarification and correcting misconceptions regularly presents itself at this point.

The following strategy is a good first step in exploring beliefs:

1. Exploring good and bad aspects of treatment

The individual is encouraged to examine the good and bad things about taking medication. The sheet in Appendix A may be helpful in summarising. Always record the answers in the individuals own words.

Good things: Build rapport by beginning the session by asking:

"*What are some of the good things about taking medication?*

Acknowledge and summarise all the good things about taking medication.

More negative things: Identify "more negative" aspects of taking medication by asking

"What are some of the more negative aspects of taking medication?"

Prompt for specific reasons why the individual believes these things to be negative.

Acknowledge and summarise all the negative things about taking medication.

Exploring concerns: You should not assume that a "more negative thing" is a concern for the individual. Prompt for the level of concern about these, for example:
“How do you feel about that?"

"Is that a problem for you?"

It is only the areas of concern about the negative aspects of medication which are likely to motivate an individual to change.

Summarising: Summarise the information elicited above in the individual’s own words. Do not simply list all the "more negative things", rather summarise those that are of concern. The aim is to assist the individual in feeling that the good things outweigh the concerns.
Eg. *"So on the one hand, you've noticed some nausea, which you don't like, but then, the medication has certainly helped you not to drink"*

2. Focussing on the effects of the medication

The therapist can feed back the symptoms reported by the individual as being target problems for treatment. For example, one of the reported effects of the medication is to reduce the craving for alcohol. The effectiveness of medication in stopping relapse for alcohol dependence can be emphasised. Some clients may report a lack of discernible effects from medication (ie neither positive nor negative). This may be explained in terms

of an absence of psychotropic or mood altering effects of the medication (particularly campral) a feature that is unrelated to its effectiveness in reducing the likelihood of relapse. Many individuals will want information on how the medications work, and the complexity of the information offered will depend on the individual.

The person who remains adamant that they are not dependent on alcohol can still enter dialogue at this point. For example, individuals who believe they can stop drinking whenever they like may concede that the medication may help them to do this.

Indirect medication benefits

Identifying indirect medication benefits can increase personal relevance. This may be achieved by exploring life satisfaction through discussion of role difficulties, responsibilities, and/or losses associated with alcohol use.

Life Satisfaction: This strategy should only be used with individuals who are concerned about their alcohol use.

Looking forward: ~~A~~sk:

"How would you like things to be different in the future?"

The aim is to elicit expressions of concern about alcohol or drug use and how remaining on treatment may reduce the chances of these events occurring.

Summarise: Summarise future aspirations in relation to the present and emphasise the role of treatment in achieving these goals.

Developing discrepancy for individuals ambivalent about complying with treatment.

The therapist aims to build up a degree of cognitive dissonance, ie that poor compliance with treatment is actually disadvantageous to the individual in view of his/her life situation, needs and goals. For example:

Therapist: *So, from your point of view you feel you can stop drinking whenever you like and you don't need treatment.*
Individual: *Well, I'm going to take the medication for a week but I'll probably stop then.*
Therapist: *You are agreeable to try the medication?*
Individual: *My work said that I had to try. And my wife says that it is not true that I can stop when I want to. It is to keep them happy.*
Therapist: *Your ability to stop yourself – to use self-control - is very important to you. But what about the less pleasant aspects of continuing to drink, the work problems, the hangovers.*
Individual: *Yes, they are a problem.*
Therapist: *And have they gotten better since you started the treatment?*
Individual*: Yes, I've stopped drinking, the boss is happy, the wife is happy and I haven't had those problems.*
Therapist: *You said you'd probably stop the medication after a week. Is this because you feel the effects you get from drinking are worth the problems it caused at work and at home?*
Individual: I don't know. I'd rather not have those problems.

Therapist: *You would prefer not to have those problems again, still you reckon you will stop the medication. You are prepared to take that risk?*

Phase Two Summary

- predict common beliefs
- guide consideration of benefits and highlight indirect benefits

Phase Three: Highlighting the need for treatment maintenance – addressing overconfidence: Sessions 5-6

Normalising Strategies

A learning model of alcohol dependence is used to explain the way in which patterns of thought can lead to excessive drinking and the importance of replacing these behaviours with more health coping mechanisms.

The aim here is to counter the stigma associated with alcohol dependence and seeking treatment. The prevalence of alcohol problems is pointed out. Examples are given of famous people who have had problems with alcohol. The aim is to reduce feelings of hopelessness.

Acknowledging the tendency to stop treatment when one feels well
Some people after being abstinent for a short time may feel overconfident and stop treatment. The therapist should draw examples from the client's own previous attempts at abstinence and returning to drinking prematurely with negative effects (outline these from *Review of history*). Other examples from personal experience can be given of individuals who felt like they no longer had a problem with alcohol, stopped treatment and medication too soon and began drinking again with unwanted consequences for their work and family.

Providing Information

Education is a crucial aspect of treatment. In particular, individuals will vary in the extent of their knowledge about the medication they are taking and their treatment. This is despite the information sheets which have been handed to the individual at the start of treatment. Some individuals will hold realistic ideas and information about the medication and others will hold unrealistic ideas. Importantly, some knowledge will not be accurate. For example, some individuals may believe that the medication *will stop all pleasurable sensations.* It is important that individuals are given accurate information about their problems. Education provides a knowledge base that gives the individual greater control over the management of their medication compliance. Greater control in turn is likely to lead to reduced feelings of helplessness.

Goal of Education

The main goal of education is to facilitate understanding about the medication and its effects, as it relates to each individual. In particular, the following information will be important:

1. Medication is effective.
2. The goal of treatment is to get well and stay well
3. Potential side effects of medication and their recognition

It may also be useful to provide information on the following issues:

1. The prognosis of the alcohol dependence following treatment
2. Recognising and acting upon early warning signs

The following are some points that could be made here if appropriate.

- Taking medication for a minimum 6 months after withdrawal will significantly improve the client's chances of remaining well.
- Some clients resume some alcohol use. This may re-instate urges and cravings and result in relapse within a short time.
- Early signs of reinstated dependence (including drinking more or for longer than intended, reducing activities and neglecting role or responsibilities in order to drink, trying but being unable to control drinking, etc)
- If this occurs, clients should return for one or two sessions of treatment (relapse prevention) at their local Alcohol and Other Drug treatment service.

During this phase individuals should be encouraged to ask questions and to become actively involved in the management of their alcohol problem and medication adherence. The aim in doing this is to encourage them to learn control over their problem more effectively thus reducing disruption and suffering to themselves and their families.

Guidelines for conducting education sessions

Adequate preparation for education sessions is very important and the handouts in Appendix B & C may be useful. The education process can be thought of as being a two-way interaction. Not only does the individual receive information, but the individual is also educating the clinician about their unique experiences. In many cases individuals will have developed their own beliefs about medication. It is important to assess existing beliefs before trying to teach a contradictory explanation. Much of this will have been achieved in the first two sessions.

Aids to compliance

The compliance package contains the brief intervention described above and assertive reminders for appointments. The final session should encompass reinforcement of the use of the following aids to compliance:

- *Assertive reminders* which will consist of mailed reminder cards twice for missed appointments.
- *The Webster system,* where each dose is separately packaged with dosage times marked, will be used to dispense trial medications.
- *Monitoring card,* a wallet sized card provided to each individual.

The Medication Tips sheet should be reviewed at this stage. An important technique is chaining - that is linking the taking of the medication with other routine activities such as teeth brushing, meals. Encourage the individual to nominate a time and place that the medication will be taken and write this on the Medication Tips sheet. Give a copy of the annotated Medication Tip sheet to the individual.

Phase Three Summary

- Use normalising strategies
- Encourage self-efficacy
- Predict consequences of not taking medication
- Emphasise value of staying well to achieve goals
- Explain other aids to help compliance

Case Example

Jeff is a 26 year old male, who presented for treatment because he had been missing work due to hang-overs from his alcohol use. He is married with two children. His wife encouraged him to seek help about his drinking. Jeff had begun drinking at the age of 15 years and started regular consumption at 18 years. By the time he was 20 years old, he was drinking four to six schooners of beer regularly through the week and on Friday and Saturday nights. In the last year he had begun binge drinking, drinking up to 15 or more schooners. He was also drinking on the next day in order to recover. His recent alcohol use was two schooners of beer before work, four schooners at lunch and another five schooners of beer after work. A recent medical examination revealed that while Jeff's liver was not enlarged, there were elevated levels of a number of liver enzymes. Jeff met DSM-IV criteria for alcohol dependence.

Session One and Two: Jeff had tried treatment before and failed on three occasions. On each occasion he underwent detoxification and follow-up counselling, although he attended only one or two sessions of follow-up. He felt angry that he had tried three times and failed and blamed the treatment staff. He believes that the drinking is of concern now that it is affecting his work; previously he believed that it was more a problem for his wife. He was concerned that the treatment will fail again and was unclear whether medication could help him. He was invited to consider how stopping the treatment may be linked to relapse.

Session Three and Four: Jeff admitted that he was worried that he would have to stay on the medication for the rest of his life and that he would become addicted to the medication. The medication effects were then described to Jeff and the non-addictive nature highlighted. Jeff was still of the strong belief he could do it himself and didn't need the medication. The notion of the medication assisting Jeff in his endeavours was emphasised, assisting him to resist the urge to drink.

Session Five and Six: Jeff's strongly held feeling that he could manage to stop drinking without the medication was explored. Jeff had failed to fill his second script and this was cause for concern. The interaction below followed:
Therapist: *How are you going Jeff ?*
Jeff: *Well, I feel a lot better since I have stopped drinking. My wife has stopped being annoyed with me and I am coping much better at work.*
Therapist: *That's great, I noticed that you haven't collected your next prescription. Are you having a problem with the medication?*
Jeff: *No, I was just thinking that I don't need it any more. I mean, I feel great, I don't want to drink, why should I take the medication?*
Therapist: *Well, it might be that the medication is helping you, and if you stop you might have more cravings?*
Jeff: *It really doesn't seem to do much. I couldn't tell if I was getting anything from it - I just thought, why bother?*
Therapist: *Yes, that makes sense. But if you aren't having any side effects, why not take it for the recommended length of time - it certainly isn't hurting and it might help.*
Jeff: *I suppose, I guess I didn't want to be dependent on anything and I thought I could do it myself. I guess I should finish the medication.*

Therapist: *Well, if you are not having any side effects and you are doing so well. It's you who has the motivation to stay sober, it's not the medication that is doing that but I think the medication can offer some insurance, and prevent any slips from becoming serious.*
Jeff: *I guess so. I just keep forgetting to take them.*
Therapist: *Well, a lot of people have problems with that - let me go over some suggestions to help you.*
(This is an opportunity to review the compliance aides.)

Stigma-related concerns for Jeff were then addressed - how he felt about being labelled as someone who couldn't drink.

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APPENDICES

Appendix A: Pros and cons of taking medication

Good things about taking medication	More negative things about taking medication

Appendix B: Information on frequently asked questions about Naltrexone

1. Does naltrexone really work?
In research evaluating the effects of naltrexone for alcohol dependence, people with alcohol dependence who received naltrexone were twice as successful in remaining abstinent and in avoiding relapse as those who received placebo-an inactive pill.

2. How does naltrexone help me stop drinking?

Naltrexone blocks the effects of drugs known as opiods. It competes with these drugs for opioid receptors in the brain. While the precise mechanism of action for the naltrexone's effect in alcohol treatment is unknown, there are three kinds of effects. First, the medication can reduce craving, which is the urge or desire to drink. Second, the medication helps patients remain abstinent. Third, the medication may interfere with the tendency to want to drink more if a recovering patient has a drink.

3. If I drink, will naltrexone make me sober if I take it?
No, the medication will not stop you being drunk if you drink. It does not reduce the effects of alcohol that impair coordination and judgement.

4. How long does naltrexone take to work?
The medications effects on blocking opiate receptors will occur shortly after you have taken the first dose. The effects of medication in helping patients remain abstinent and avoid relapse to alcohol use also occur early after first use.

5. Are there some people who should not take naltrexone?
Medication for alcohol dependence should not be used with pregnant women, individuals with severe liver or kidney damage or with patients who cannot achieve abstinence for at least 5 days prior to initiating medications.

6. Is naltrexone addictive?
No, the medication is not addictive.

7. Will naltrexone effect my ability to feel pleasure?
While it does seem to reduce alcohol craving, it does not interfere with the experience of other types of pleasure such as sexual pleasure.

8. What does it feel like on naltrexone?
Patients usually report that they are largely unaware of being on medications. The medication usually has no psychological effects and patients don't feel either "high" or "down"

9. What are the side effects of naltrexone?
In the large research studies of naltrexone side effects occurred in less than 1 in 10 people. The side effects that occurred were nausea, headache, dizziness, fatigue, insomnia, anxiety, and sleepiness. These side effects were usually mild and of short duration. In treating alcohol abuse nausea has been severe enough to discontinue the medication in less than 10% of the patients starting it. For most other patients side effects are mild or of brief duration.

One serious possibility is that medication can have toxic effects on the liver. Blood tests of liver function are performed prior to the onset of treatment and periodically during treatment to determine whether naltrexone should be started and whether it should be discontinued if the relatively rare side effect of liver toxicity is taking place.

10. Can I take other medications with naltrexone?
The naltrexone you are taking for your alcohol dependence is likely to have little impact on other medications patients commonly use such as antibiotics, non-opioid analgesics (e.g., aspirin, acetaminophen, ibuprofen), and allergy medications. You should inform your physician of whatever medication you are currently taking so that possible interactions can be evaluated.

The major active effect of the medication for alcohol dependence is on opioid drugs. This class of drug is used to treat pain. The medication may therefore block the effect of any painkillers. Tell your physician if you are taking painkillers and they can prescribe non-narcotic pain reliever which can be used effectively while you are on the medication for alcohol dependence.

11. Will I get sick if I drink while on naltrexone?

No. The medication may reduce the feeling of intoxication and the desire to drink more, but it will not cause a severe physical response to drinking.

Some answers adapted from the pamphlet Guidelines for the Use of Naltrexone in the Treatment of Alcoholism by Bruce J. Rounsaville, M.D., Stephanie O'Malley, Ph.D., and Patrick O'Connor, M.D.

The APT Foundation, 904 Howard Avenue, New Haven, CT 06519.

Appendix C: Information on frequently asked questions about Acamprosate

The concept of dependence
When an individual consumes alcohol steadily over a long period, physiological processes gradually change so that the body can still function more or less normally despite the effects of alcohol. Subsequently, the body can only function properly when the alcohol is present. When alcohol is not present, the symptoms of withdrawal become evident. The symptoms of withdrawal can be present for several months even when completely abstinent.

Effect of alcohol and acamprosate (Campral ®) on the brain
Short-term exposure to alcohol increases the actions of GABA on the GABA receptors and decreases those of excitatory amino acids such as glutamate on NMDA receptors. The result is that the electrical impulses triggered in the neurones are reduced, and activity in the brain and the nerves is depressed. With long term exposure, the body adapts by decreasing the activity of the GABA-ergic system and increasing the activity of the glutamate system.

When alcohol intake ceases, the depressant effect disappears, however, the neurones remain hyperexcitable. It takes many months for the brain to readapt and during this time alcohol withdrawal symptoms are experienced. Campral acts to restore the GABA-ergic and glutamate neurone activity to "normal" levels.

Acamprosate does not act like disulfram (antabuse), it does not block the rewarding effects of alcohol (like naltrexone), it is not a substitute for alcohol (like a tranquilliser or methadone in the case of heroin dependence), nor does it alter the effects of alcohol.

Physical symptoms: Acamprosate can protect against the CNS effects induced by alcohol withdrawal, such as shaking, cerebellar tremors, nervous twitches, and convulsions. Acamprosate has no effects on the cardiovascular, haemodynamic, respiratory, gastrointestinal or renal systems.

Absorption: After a single dose the maximum concentration is reached in 5 hours. At recommended dose (two 333mg tabs three times per day) steady state (or blood concentration levels) is reached at the end of 7 days. After this is achieved, the half life of Campral is 20.8 hours. Acamprosate is mainly eliminated unchanged in the urine, it is not metabolised.

FAQs

1. **When should I start taking Campral?** It's recommended that patients should stop drinking for between 2-7 days before commencing treatment.

2. **How long do the tablets take to work?** Steady blood concentrations are reached after 7 days.

3. **What are the side effects?** Diarrhoea is the most common, followed by nausea, stomach pains, and an allergic skin reaction. Most side effects remit after a few weeks of treatment.

4. **What will I feel taking these tablets?** Unless you experience any of the side effects, you may not notice anything. Campral will not make you feel “high” or sedated.

5. **Will I have any cravings while taking Campral?** Yes, Campral is not a magic tablet. It will help take the edge off the cravings and support your hard work in achieving abstinence.

6. **What happens if I drink whilst taking Campral?** Nothing. Campral does not alter the effects of alcohol. It is important to keep taking Campral even on days when you have had a drink. As Campral is quickly eliminated by the body, all doses (two tablets three times a day) need to be taken to maintain optimal blood concentration levels.

7. **Is Campral addictive?** You can stop taking Campral at any time without feeling symptoms of withdrawal from Campral. It is not habit forming.

8. **What if I miss a dose?** If you miss a dose, do not take extra tablets to make up for it. Take the next dose at the usual time.

9. **Do I have to take Campral with food?** It is best to take Campral with food, as this can help any stomach upset that you might experience.

10. **Can I take other medications if needed?** There are no known interactions with other medications. If necessary, Campral can be used with antidepressants, tranquillisers or disulfram. Taking Campral will not interfere with medication taken for long term illness such as diabetes, high blood pressure or peptic ulcers.

11. **Do I have to take Campral for the rest of my life?** No, the standard course of treatment is 6 months.

This information has been adapted from the Campral Product Monograph and the Campral Product Information forms, produced by Alphapharm, Pty Ltd.

Appendix D: Medication Tips

It is important to take your medication as prescribed. Here are some hints to help you do this:

Take your medication at the same time each day. Make it part of your routine. If you are going to be taking it in the morning and you eat breakfast or have coffee then put the medication on your kitchen table or with your breakfast cereal and take them with your breakfast. Or if you prefer take them when you brush your teeth and keep them in the bathroom with your toothbrush. You may prefer to take them before you go to bed in the evening, so put them next to your bed. The main thing is to associate taking the medication with something that you do every day.

If you feel comfortable with it, ask someone to remind you to take the medication.

Put a note on the fridge or anywhere else to help you remember. Move the not around so that it doesn't fade into the background.

Remember to set the alarm on your watch to remind you.

If you feel like missing the medication talk to someone (preferably your counsellor) about it first.

RECORD

Standard drinks

1 can of beer = 1.5
1 stubby of beer = 1.5
1 middy of beer = 1
1 schooner of beer = 1.5
1 glass of wine = 1
1 bottle of wine = 7
1 nip of spirits = 1

Mood

1 = excellent
2 = good
3 = moderate
4 = poor

Craving: Give a number between 1 and 10 of the worst craving in the day

1 = no craving……. 10 = unbearable craving

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