

Development of a manual for Extended Brief Intervention for alcohol misuse for adults with mild to moderate intellectual disabilities living in the community; the EBI-LD study manual.

Running title: Alcohol brief intervention for Intellectual Disabilities

Keywords: alcohol extended brief intervention intellectual disabilities

Abstract

Background: Extended brief interventions for alcohol misuse are effective in the general population. The process of manualising the first ever such intervention for people with mild to moderate intellectual disabilities in the UK is the focus of this paper.

Methods: The manual was an adaptation of existing manuals based on Motivational Enhancement and Cognitive Behaviour Therapy and was used in a feasibility randomised controlled trial, the EBI-LD study. The sessions were recorded and scored using an adapted version of the Yale Adherence and Competence Scale (YACS-II). Feedback was provided by therapists. The trial is closed. Registered: isrctn.com; [ISRCTN58783633](https://doi.org/10.1186/17454219/58783633).

Results: The quality of the sessions provided was rated as good. Therapists were able to cover all topics within each session. Main challenges included session duration and homework task completion.

Conclusions: We recommend the duration of the sessions to be extended to 40 minutes to accommodate carers in the session and to enhance their support in homework task completion.

Introduction

Historically intellectual disability (ID) was considered an exclusion criterion for psychotherapy, leaving those affected by such conditions few (if any) options for accessing available psychosocial treatments. There has been of late a growing interest, both within the specialist ID field and at government level, in developing psychological therapies specifically designed for people with intellectual disabilities (ID) and providing them with the same services as for the general population. This premise is enshrined in the Equality Act (2010) but also has been the cornerstone of government policy which strongly advocates the use of universal health services by people with ID (Department of Health, 2001, 2009). Recent studies have shown that people with ID are vulnerable to a number of mental health conditions such as common mental disorders, psychosis, and dementia (Cooper et al., 2007; Lin et al., 2016) as well as substance use disorders (VanDuijvenbode et al., 2015).

People with ID have cognitive deficits that impair their ability to learn new information or generalise new learning. Difficulties include articulating emotional states, limited understanding of abstract concepts, expressive or receptive speech difficulties, delay in processing and retrieving information (Lindsay et al., 1993; 1997; McCabe et al., 2006). Furthermore, a person with ID is likely to have reduced verbal communication skills (Burnip, 2002), and may be more suggestible, tending to change their answers to questions when provided with negative feedback (Everington & Fuller, 1999). People with ID may also try to mask their difficulties in understanding and following verbal communication by drawing on social skills and set phrases that they know are contextually appropriate responses (Hassiotis et al., 2012). In order to compensate for such impairments, existing or newly developed psychosocial therapies require a number of adaptations in the way that they are delivered as well as in content. Central to the adaptations are use of role play and materials in easy read formats, language that is appropriate to the person's understanding; sessions

may need to include breaks and the person may need to be supported by a family or paid carer in order to complete any related homework (Hassiotis et al, 2012; McCabe et al, 2006; NICE PH24;18)..

Cognitive Behaviour Therapy (CBT) with people with mild to moderate intellectual disabilities is the most commonly used psychological treatment and the one widely adapted for this population for common disorders such as depression and anxiety (Hassiotis et al, 2012; Lindsay et al, 1993, 1997; McCabe et al, 2006). More recent work has been carried out on using computers to enable people with ID to engage with CBT interventions (Vereenoghe et al., 2016).

Despite the sparse literature regarding substance misuse in people with ID there is increasing interest in studying such problems because most people with ID now live in the community and are likely to be exposed to substances in their social networks as well as consuming them (Lin et al., 2016; Miller & Whicher, 2010). UK and USA population based studies indicate that the prevalence of substance misuse in people with ID ranges from 0.5% to 2.5% and may be as high as 22.5% for any substance in clinical samples (Copper et al., 2006; Hassiotis et al, 2008; McGillicuddy & Blane, 1999; Pezzoni & Kouimtsidis, 2014; Sturmey et al, 2003). Approximately 5% of youths seen in drug and alcohol services have a degree of ID (Barrett & Paschos, 2006). Alcohol and cannabis are the commonest substances that people with mild to moderate ID use. Those most at risk are young males with mild ID or borderline intellectual functioning (defined as IQ between 1 and 2 standard deviations below the mean) who live independently, in poorer neighborhoods, with minimal support in the community and are less likely to engage in social activities (Barrett & Paschos, 2006; Lin et al, 2016).

A variety of approaches have been tried for the treatment of alcohol disorders in people with mild to moderate ID, such as education about the risks associated with substance misuse, motivational interviewing, behavioural modification, adaptation of materials by AA or similar organisations with interventions mostly delivered in group settings (Christian & Poling, 1997; Degenhardt, 2000; Didden et al., 2009; Forbat, 1999; Lindsay et al., 1991; McCusker et al., 1993; McGillicuddy & Blane, 1999; McMurrin & Lismore, 1993; ; Mendel & Hipkins, 2002). As a whole, these studies suggest that the capacity of people with ID to learn new information is enhanced by providing additional cues and using techniques such as modelling, videotaped vignettes and role-playing. Often, sessions are augmented with coping skills lessons and assertiveness training (McCusker et al., 1993; McGillicuddy & Blane, 1999). Two studies merit further attention as they test similar interventions for a similar population. One is a study of three sessions of group motivational interviewing delivered over a two week period conducted with seven offenders with learning disabilities in a medium secure unit (Mendel & Hipkins, 2002). The authors found that the participants showed increased determination to reduce drinking at the end of the treatment. The second study (McCusker et al., 1993), is a 10 week evaluation of assertiveness training and modelling compared to waiting list to educate about substance misuse and to help the participants (N=84 randomised to treatment and waiting list controls) to respond appropriately when offered substances in their social network. The authors found that knowledge of the risks associated with use of illicit substances increased at the end of the intervention and this was maintained at six months follow up. The methodological limitations of the studies include the uncontrolled design and possibility of type 2 error in the former study, and insufficient methodological details in the latter to allow appraisal of the findings, as well as the inclusion of several substances which may have compromised the specificity of the intervention.

The National Institute for Health and Clinical Excellence (NICE, 2010) recommends a variety of brief interventions for the treatment of hazardous and harmful drinking. For hazardous

drinkers (excessive drinking above recommended levels without associated harm experienced yet), NICE recommends brief advice (1 session of 10 minutes) to be delivered by a health professional within non-specialist healthcare settings. For harmful drinkers (excessive drinking above recommended levels with associated harm experienced) extended brief interventions (EBI) are recommended, consisting of 3-5 individual sessions, based on motivational interviewing/enhancement techniques, delivered by alcohol specialists within specialist services. The aim is either to reduce alcohol intake to within recommended limits or to consider abstinence, and to reduce associated risk taking behaviour. The duration of EBI sessions varies from 20 to 30 minutes and follow-up is offered.

In this paper we report the adaptation of an EBI manual to treat hazardous and harmful use of alcohol in adults with mild to moderate ID living in the community as part of a funded feasibility study (Kouimtsidis et al, 2015), which is the first phase of a potential full RCT. EBI represents the most intensive of the treatment options recommended for these groups of alcohol users. It is though a relatively low intensity intervention and can be delivered by trained professionals in the public and voluntary sector.

Method

Study design

The adaptation of the study manual was the first stage of a two stage feasibility study (Kouimtsidis et al, 2015). The manual would underpin the intervention provided in a single blind parallel two arm Randomised Control Trial (RCT) of the clinical and cost-effectiveness of EBI in reducing hazardous and harmful drinking in adults with mild to moderate ID living in the community. Participant and family/paid carer assessments were conducted at baseline, at two and three months post randomisation. Participants were recruited from three areas in England covering urban and semi-rural and inner London sites. Participants were (i) adults with mild to moderate ID aged 18 years and over; (ii) referred by professionals as having alcohol problems; (iii) scoring ≥ 8 on the Alcohol Use Disorder Identification Test (AUDIT)

and with a cumulative score ≤ 9 in response to questions 4, 5 and 6 of the AUDIT, which specifically assess alcohol dependence (Babor et al, 2001); and iv) having an IQ <70 as assessed by the Wechsler Abbreviated Scale for Intelligence (WASI), unless a previous assessment was available.

Participant characteristics

Thirty individuals were equally randomised to the intervention or control arm. Thirteen individuals received the intervention (one was excluded and one declined to participate following randomisation). The mean age of those randomised to the intervention was 45 years (SD = 8.6), 10 (66.6%) were male, 12 (80%) were white, 10 (66.6%) were living alone and 9 (60%) had a mild ID. The results of the study are presented elsewhere (Kouimtsidis et al, 2017).

Manual development

The adapted treatment manual was based on existing manuals of EBI for harmful drinking in the general population (see below). The manual was divided into three parts: part I provided an introduction to alcohol use disorders, brief interventions for these, interventions in people with ID, principles in communication with people with ID, and the role of carers in therapy; part II included the treatment protocol and session content, and part III consisted of appendices with all therapy aids. The first five sessions were 30 minutes long and were offered weekly. The final session (session 6) was a follow-up (booster) session, it was 1 hour long and was offered at week 8. The first session aimed to build a therapeutic relationship. Sessions 2 and 3 aimed to enhance motivation and were adapted from the Motivational Enhancement Therapy (MET) published in the UKATT MET Manual (UKATT research team, 2011). Sessions 4 and 5 aimed to develop new skills and were adapted from the UKCBTMM manual (Kouimtsidis et al, 2007). Finally, session 6 was a consolidation session, in which changes in drinking and lifestyle that had been achieved were reviewed.

MET is based on the transtheoretical model of behaviour change or Stages of Change model (Prochaska, DiClemente & Norcross, 1992). The model proposes that the process of recovery from an addictive behaviour involves transition through stages: (i) pre-contemplation in which no change drinking is contemplated; (ii) contemplation in which change is contemplated for the near future; (iii) preparation, in which plans are made on how to change behaviour in a definite way; (iv) action stage in which the plans are put into action and change takes place; and (v) maintenance in which a new pattern of behaviour emerges, is established and maintained. CBT is used to identify high risk situations for drinking, explore ways to avoid them, develop strategies to cope with them, and finally, implement appropriate lifestyle changes to support a healthier lifestyle of either controlled drinking or total abstinence. Specific modifications that the research team considered necessary in order to account for the cognitive deficits and communication needs of adults with ID included practical aspects such as increasing the number of sessions to five; the duration of each session to 30 minutes, adding a one hour long booster session, and developing easy read materials to be used during and in between sessions.

Format and themes of the sessions

The first five weekly sessions were divided into three parts of 10 minutes each. The first part is an introduction to each session, discussing the theme of the session, and reviewing the completion of assignments allocated in the previous session. The last part provides a link with the next session and the assignments to be agreed for the following week. The specific themes of each session are as follows: building therapeutic rapport, introducing the intervention, the role of the carer, and discussing the relevant treatment practicalities (session 1); exploration of the participant's current lifestyle and personalised advice about his/her drinking patterns (session 2); enhancing motivation, increasing the participant's willingness to change and negotiating treatment goals (session 3). In session 2, the therapist

can use additional motivational strategies to overcome resistance such as simple reflection or reflection with amplification or double-sided reflections, as well as shifting the focus of discussion and rolling with resistance rather than confrontation with the client. During session 3, several motivational strategies are used, such as exploring discrepancy between intentions and drinking behaviour; exploring and resolving any ambivalence about drinking; “eliciting change” talk; providing information and advice about drinking; discussing options for treatment aims and promoting freedom of choice.

In session 4, the therapist defines and identifies the participant’s hierarchy of high risk situations where drinking may be likely; reviews past and current coping strategies; anticipates future high risk situations; identifies potential unpredictable events and develops a personal generic coping plan with the participant. In session 5, the therapist re-assesses current lifestyle and promotes potential positive changes that will support an alcohol-free lifestyle or healthier options. The booster session (session 6) aims to consolidate the participant’s motivation to change their drinking patterns, review successful changes and promote further changes consistent with the goal of therapy.

Special role of family or paid carer

The important role of family and of the social environment in the treatment of alcohol disorders has been well recognised (NICE PH24;18). The advantages as well as challenges of involving family or paid carers in the treatment of people with ID has been discussed in the literature (Willner, 2006). As far as alcohol treatment for people with ID specifically is concerned, family or paid carers may support the person with ID to move successfully through the programme, by encouraging practice in between sessions and providing feedback that can help the person to commit to change their behaviour. The inclusion of a support person in sessions -with the expressed approval of the participant with ID- can, however, be challenging although it has been employed successfully in a previous study (Hassiotis et al., 2012). It is important to regulate the involvement of the carer to ensure that

the participant does not become dependent on or rely too heavily on the carer during the course of treatment. Confidentiality issues need to be addressed before treatment begins. For the reasons outlined above, special attention was paid to the role of family members or paid carers and their involvement during the course of the treatment. Specific instructions for the therapist of how to involve the carer in the session, how to promote their special role and examples of how to handle and resolve some common challenges associated with carer involvement (such as the risk of negative comments, judgements and over critical attitude or reluctance to change their own drinking behaviour) were added in the manual for each session and in the therapeutic programme as a whole as a separate chapter in Part I. In order to help carers understand their role as well as that of the purpose of the treatment, the researchers developed a leaflet for carers. Participation of the carer was decided upon at the beginning of each session. The majority of carers (7) were either paid or family members (4) and 2 were health professionals. The majority of carers were invited to attend part of the session. Two 2 family members have attended the whole duration of the first few sessions. Carers feedback is presented elsewhere (Kouimtsidis et al, 2017).

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Manual evaluation-Treatment fidelity

- A self-rated checklist assessing the therapist's own reflection of treatment delivery was scored after every session and used during supervision.
- Therapy sessions were audio recorded. Recorded sessions were rated by CK using a modified version of the Yale Adherence and Competence Scale (YACS II) (Nuro et al., 2005). This is a widely used tool that assesses both the frequency/intensity (quantity), and how well techniques of MET and CBT are used (quality), with a score from 1-7, with 4 considered as acceptable (quantity=somewhat; quality=adequate) (Nuro et al., 2005).
- Sessions 3 and 4 were piloted with two adults with ID and past alcohol use disorders in order to test acceptability of themes and techniques used, the clarity of the language and

the homework tasks and materials. The sessions were audio recorded and assessed by CK and KS, both experienced in developing, implementing and evaluating therapy interventions in the field of ID (KS) and in addiction psychiatry (CK). Feedback was given to the therapist and the recordings (with the permission of clients) were used in the training of the other three therapists, recruited subsequently. The four sessions were also scored using the YACS II in order to assess inter-rater reliability of the modified version used in the study, as well as a way for the two potential raters having mutual supervision, comparing the scoring of the two rates (CK and KS). The analysis was based on n=2 participants, measured repeatedly over sessions. The dataset contains 34 dimensions that have been assessed by CK and KS. For those measures, we have computed Cohen's Kappa coefficient (Cohen, 1960). The resulting statistics suggests that there is no evidence of substantial negative values. However, only for a few of the items do the point estimates exceed 0.7, which is usually considered as a threshold for "high reliability", indicating that while aligned, the assessments are not exactly the same. There was a consistency of the vicinity of rating, with ratings in the same direction. To that effect and given the small number of sessions requiring scoring, it was decided that scoring by two raters was not necessary

Therapist training

Four therapists were trained and provided the intervention across the study sites. They were psychology graduates employed as assistant psychologists or equivalent, working in ID services in the NHS. They were offered one day training on motivational interviewing and the use of the manual and were supervised by CK. During the training, each session was discussed in detail, and role play of how to use motivational interviewing and CBT techniques was used. Therapists were advised that whilst they should make an effort to adhere to the recommended session duration, their ultimate aim should be to deliver all the components of the session. Following this, therapists received weekly supervision by CK while seeing their first study participant. Subsequently, feedback on sessions recorded and scored was provided within a week from submission and full supervision was provided at

least once a month. A self-check list for each session was completed by the therapists and used as the basis for supervision. The audio material from the recorded and scored sessions was also used to inform supervision.

Results

Therapist feedback

One therapist provided therapy for all participants recruited from two of the three recruiting sites (in total 7 participants). The other three therapists were recruited and trained in sequence and delivered therapy to 6 participants (3, 2 and 1 respectively). Overall the 13 participants attended a median of five sessions (range 2-6). Nine participants attended all six sessions, one attended five, one three sessions, and two attended only two sessions.

All therapists reported that the manual was helpful to their work and easy to use. Therapist confidence improved over time as reported in supervision and was shown in the self-rated checklists.

Therapists were able to cover all topics within each session as shown by the completed checklists following each session. The first therapist (7 participants) reported for session three “often needed more time to cover all the material whereas session six did not require the full hour”. This was not reported by the rest of therapists. However, all therapists found that most of the five weekly sessions were difficult to be kept to 30 minutes, with the average duration of sessions recorded being 40 minutes (therapist1: 32; therapist 2: 46; therapist 3: 49; therapist 4: 27). Extension of the duration of the session was mostly necessary when the carer was involved during the whole duration of the session.

Therapists reported challenges with arranging attendance to the sessions, in particular the initiation of treatment. In between sessions practice (mostly drinking diaries), also proved challenging for some participants. Support provided by carers was paramount in identifying the most suitable environment for the session to take place, starting on time, securing

enough time for the session to be completed, as well as provision of support for homework completion. Drinking diaries were developed for each day having a different colour for each day. Each day was divided in three parts defined by the three meals of the day (breakfast, lunch, dinner) in an attempt to promote healthy lifestyle. During the last part of each session extensive demonstration and advice of how to use the diaries was given.

Fidelity to the manual

Forty-three out of 68 delivered sessions were audio recorded and 32 (47%) sessions were scored by CK using the YACS II in order to assess fidelity of treatment delivery to the manual. The sessions scored were selected across all sessions recorded, from 9 participants (4 participants declined to be audio recorded), from three participating therapists (none of the 2 sessions of the last therapist were included, as only one was partially recorded). The median score for sessions for frequency/intensity (quantity) of techniques used was above the acceptable score of 4 (in 29 out of 32 sessions). The median score for how well (quality) techniques were implemented for all sessions was above 4 for the majority of sessions (30/32), see Table 1. As session 1 aimed to build therapeutic relationship, it was challenging to evaluate it using the YACS- II. Regarding the techniques used and assessed by the YACS II, "role playing" was used only during 5/32 therapy sessions with a median quality score of 4.

Table 1

Discussion

As people with ID live in the community, they are subject to peer pressure and are vulnerable to alcohol promotion strategies such as low price for alcoholic beverages similarly to the rest of the population. Therefore, alcohol misuse needs to be recognised early and people at risk should receive advice and early support in order to modify their drinking and reduce the risk of physical, psychological or social harms. Furthermore, during the screening

for this study we found that a small number of the potentially eligible participants were not only misusing alcohol but were alcohol dependent (to that effect excluded for the current study). However, none of them had received treatment tailored to their needs by either specialist substance misuse services, or specialist ID services. Ensuring that health and social care professionals including third sector and community support workers have the necessary materials to help those who might develop an alcohol disorder is essential for secondary prevention.

The manual reported in this paper, brings the principles of a widely used public health intervention for alcohol misuse to people with ID. The manual was tested in a feasibility RCT, hence there is no definitive evidence yet that the intervention itself is effective or cost effective. The feasibility study showed though that the intervention as described in the manual can be delivered to community based populations by suitably qualified professionals with minimal training and support, and thus could be incorporated into routine NHS care or non-statutory services. The manual, as a stand-alone product, is a practical resource that can be useful for NHS practitioners and third sector workers in delivering treatment for alcohol misuse to people with ID or those with cognitive and social communication impairments resulting from other disorders.

A report by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (Bellg et al., 2004) recommended five broad areas in which fidelity could be enhanced during clinical trials: study design, training of treatment providers, delivery of treatment, receipt of treatment, and enactment of treatment skills. Specific suggestions to avoid threats to fidelity included the following: development of a treatment manual that includes information about treatment dose (length and number of contacts) and specific content of each contact; standardisation of therapist training; monitoring the intervention with fidelity checklists; and inclusion of strategies to measure the recipient's comprehension and enactment of the intervention principles addressed. Hence the development of a treatment manual is the first step in ensuring fidelity.

In the EBI-LD study we followed Bellg et al.'s (2004) suggestions. We have used a standardised tool to assess fidelity scored by one rater, given that the pilot assessments done by two raters although aligned, they were not exactly the same. We paid particular attention to the fidelity of the sessions provided in line with the manual, with a priority on covering all topics and aspects in each session, and less emphasis on the duration of the session. We encouraged therapists to extend the duration of the sessions if required in order to cover all relevant topics, rather than diverting from the manual. Certain sessions were more challenging to be delivered within the allocated time, particularly session 3. In between the sessions practice, in the form of homework was challenging for some participants. This might be due to the frequency of drinking of the people participating in this study, which was less than daily for the majority of them. This raises the question of how essential completion of daily drinking diaries for this population might be. Nevertheless support and encouragement by both therapist (with in-session practice) and carer were considered essential, supporting the importance of involving carers in therapy (NICE, 2010). Adjustment of the session duration was required to enable the involvement of the carer in the session (Hassiotis et al., 2012). Therefore, a duration of 40 minutes would be recommended in clinical practice to enable therapists to provide all aspects of the intervention. Despite the fact that drinking diaries are considered an essential part of CBT interventions in alcohol use disorders, in particular in the effort to regaining control over drinking as well as monitoring treatment compliance and progress (Kouimtsidis et al., 2007), if this manual were to be rolled out, drinking diaries should not have such an essential role and should be replaced by a simpler way of monitoring of and reflecting on drinking events during the previous week.

A key focus in this feasibility study was on how to ensure treatment fidelity. Given the small sample size of the feasibility study, no special measures were taken to train raters of the YACS II, nor for the reduction of rater drift (Mulsant et al., 2002). This is a limitation of the study. Nevertheless, the YACS II proved a useful tool for the evaluation of session content,

with the exception of session 1. It showed that therapists found certain aspects challenging, e.g., role playing. This is in contrast with previous work (McCusker et al.,1993), which indicated that role playing was one of the successful strategies for behavioural change. This could be attributed to the fact that the manual did not emphasise the importance of role play and it was not highlighted in the training as a core CBT technique - this is a limitation which should be addressed in future research and also in the use of the manual in clinical practice. Other techniques or interventions such as identification of high risk situations, past or future, were difficult to incorporate in the early sessions, as the focus of those sessions was mostly on motivational enhancement. Motivational techniques proved relevant across all sessions. A session specific, rather than intervention specific adaptation of the YACS II is recommended for use in future trials. Accordingly, motivational interviewing items from the YACS II should be used to rate the first three sessions, and CBT items for sessions 4 and 5. The combined (motivational interviewing and CBT items) tool, used in this study, could also be used for the booster session.

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