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Research report

Manualised Individual Cognitive Behavioural Therapy for mood disorders in people with mild to moderate intellectual disability: A feasibility randomised controlled trial

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ABSTRACT

Background: Evaluation of complex interventions, including standardisation of the intervention, types of outcomes selected and measures of change, is a fairly novel concept in the field of intellectual disabilities. Our aim was to explore these issues in a feasibility study of Manualised Individual Cognitive Behaviour Treatment (M-iCBT) compared to the treatment as usual alone (TAU).

Methods: Service users with mild to moderate intellectual disability experiencing a mood disorder or symptoms of depression and/or anxiety (mini PAS-ADD total score >10 or 7 respectively) were randomly assigned to either.

Results: In total, 32 participants were randomly assigned to 16 sessions of M-iCBT ($n=16$) in addition to TAU or TAU alone ($n=16$). We explored recruitment and accrual rates, willingness to participate, acceptability of the intervention and suitability of assessment tools. Mean change (95% CI) in the Beck Depression Inventory-Youth (BDI-Y) score from baseline to the 16 week endpoint (primary variable) was 0.10 (95% CI: −8.56, 8.76) and in the Beck Anxiety Inventory-Youth (BAI-Y) 2.42 (95% CI: −5.27, 10.12) in favour of TAU. However, there was a clear trend in favour of CBT in depressed participants with or without anxiety.

Limitations: The intervention targeted both depression and anxiety following a transdiagnostic model. This may have impacted the anticipated size of change in the primary outcome. The precise impact of cognitive limitations on ability to use therapy effectively is not fully understood.

Conclusions: This study demonstrates that it is feasible to carry out a pragmatic randomised controlled trial of M-iCBT for people with mild to moderate intellectual disability. However, uncertainties about its clinical and cost effectiveness can only be fully answered by further examination of its superiority against other treatments.

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1. Introduction

Epidemiological studies show that people with intellectual disability share at least similar risk to others of developing common mental disorders (Cooray and Bakala, 2005; Cooper et al., 2007), with depression and anxiety being diagnosed most often (Azam et al., 2009). Two British birth cohort studies reported a four- to six-fold increase in mood disorders in people with mild intellectual disability compared to the typical population (Richards et al., 2001; Collishaw et al., 2004), which appear to run a chronic course (Hall et al., 2005).

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Cognitive Behaviour Therapy (CBT) is an effective treatment for depression and anxiety (Driessen and Hollon, 2010; Otte, 2011), but its application in adults with mild to moderate intellectual disability may be hampered by the pre-existing cognitive limitations that present as lack of ability to differentiate between thoughts, feelings and behaviour. However, recent studies showed that people with mild intellectual disability are able to link situations to emotions (Dagnan et al., 2000), identify emotions correctly (Joyce et al., 2006) and have the capacity to differentiate between thoughts, feelings and behaviour (Sams et al., 2006). Training in skills such as cognitive mediation before starting a course of CBT (Haddock and Jones, 2006) has been postulated to be useful in enhancing the impact of the therapy. Several authors have suggested that use of role play and visual aids, thought-feeling diaries, and identification of automatic negative thoughts may facilitate understanding and processing of relevant information during therapy sessions (Brown and Marshall, 2006; Haddock and Jones, 2006; Jahoda et al., 2009). Psycho-education is thought to be an essential component of treatment but engagement in treatment and generalisation of knowledge outside the sessions can be a barrier to the efficacy of the treatment (Willner and Tomlinson, 2007). Individual or group CBT has been used in clinical settings to treat a variety of mental disorders in people with intellectual disability e.g. anger (Taylor et al., 2005; Willner et al., 2011), psychosis (Kirkland, 2005), obsessive-compulsive disorder (Willner and Goody, 2006), and mood disorders (McCabe et al., 2006; McGillivray et al., 2008). These case reports or case series point toward sustained improvements (Lindsay, 1999; Willner et al., 2002).

Evidence for the effectiveness of either individual or group CBT in people with mild intellectual disability and mental disorders is weak as previous research does not include standardisation of the treatment provided, e.g. by using a manualised approach (Prout and Nowak-Drabik, 2003) or a controlled design. A study of adapted group CBT aiming to improve socialisation and change negative cognitions reported the use of randomised allocation but it does not contain further information on aspects such as type of randomisation, blinding and masking (McCabe et al., 2006).

In addition, previous work has not included an economic perspective in the context of cost-effectiveness analysis. Psychological therapies, such as CBT, have attracted policy support since evidence from research and practice in a wide range of mental disorders suggests they are effective in reducing care costs through improving outcomes and preventing or delaying the need for ongoing health and social care support (Layard et al., 2007; Knapp et al., 2011). Nevertheless, the cost-effectiveness of any type of psychological therapy in people with (mild to moderate) intellectual disability and mood disorders has not been explored.

In order to address the gaps in evidence based practice, we designed and carried out a feasibility study of a standardised intervention, Manualised Individual Cognitive Behaviour Therapy (M-iCBT), for adults with mild to moderate intellectual disability and common mood disorders. Our primary aim was to investigate the acceptability of the trial to clinicians and service users and to examine potential effect size of the primary outcome that could be used to power a large scale trial. A secondary aim was to investigate costs associated with M-iCBT to inform the categories of cost data to be collected during a full evaluation with a larger sample.

2. Methods

2.1. Study population

Male and female service users aged 18 years or over with mild to moderate intellectual disability as determined by the participating community intellectual disability services were recruited. The level of intellectual disability is commonly assessed following initial referral in order to establish suitability for receipt of services. Psychologists rate each person as 1 (mild; need for supportive environment and/or encouragement to be independent rather than active assistance), 2 (moderate; need for assistance with activities of daily living and extensive support with activities), or 3 (severe; significant limitations in communication and need for support at all times). Cases from psychiatry psychology and nursing caseloads, identified as having depression, anxiety or mixed affective states based on clinical or ICD-10 diagnosis (World Health Organization, 1992) were referred to the study. All participants were registered with general practitioners and lived independently or with intermittent support. Exclusion criteria were severe intellectual disability, co-morbid conditions such as substance misuse, autism and currently in receipt of regular psychological treatment, e.g. weekly counselling sessions or CBT provided in service. The two services are situated within inner London.

2.2. Screening process

Eligible service users provided written informed consent prior to being screened using the Mini Psychiatric Assessment Schedule for Adults with Developmental Disability (Mini PAS-ADD; Moss and Brennan, 2002). Those with scores of 10 or above (range 11–32) for depression and 7 or above (range 7–18) for anxiety were randomised into the study following baseline assessments.

Each participant was also administered the British Picture Vocabulary Scale-third edition (BPVS-S3). It provides norm referenced scores and does not require reading or writing. The scores allowed us to estimate the participants' language development and approximate mental age, which mapped onto the main outcome measure age profiles.

For the participants randomised into the intervention group only, the therapists administered the Test for Reception of Grammar (TROG-2; Bishop, 2003) which is designed to assess the understanding of grammatical structures in English and commonly used by Speech and Language Therapists with adults with intellectual disability. This assessment informed how the therapist modified the language used in the session, the choice of homework materials from the manual and the design of behavioural experiments to test core beliefs in order to aid adaptive functioning (Dagnan, 2008). The TROG has been used in therapeutic settings previously (Abbeduto et al., 2004; Joyce et al., 2006). For the purpose of the study, the therapists received guidance in its administration by the Speech and Language Therapy co-applicant who was available to provide further support if required throughout. Expressive language was not formally tested but the therapists formed opinions of the person's verbal ability during conversations in the initial sessions.

2.3. Study design

2.3.1. Ethics

The feasibility study of a complex intervention (M-iCBT) was conducted from April 2010 to September 2011 at two community based intellectual disability services in inner London. It was approved by the Joint UCL/UCLH Committees on the Ethics of Human Research Committee Alpha (protocol reference 08/H0715/07). Service users eligible to take part met with the research assistant who assessed their capacity to consent and obtained written consent prior to baseline assessments being carried out. The participant information sheet included a section on the process of randomisation. All participants had adequate verbal skills to engage in therapy and to be interviewed about their views.

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