



Review

Factors affecting recruitment into depression trials: Systematic review, meta-synthesis and conceptual framework



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ABSTRACT

Background: Depression is common and clinical trials are crucial for evaluating treatments. Difficulties in recruiting participants into depression trials are well-documented, yet no study has examined the factors affecting recruitment. This review aims to identify the factors affecting recruitment into depression trials and to develop a conceptual framework through systematic assessment of published qualitative research. **Methods:** Systematic review and meta-synthesis of published qualitative studies. Meta-synthesis involves a synthesis of themes across a number of qualitative studies to produce findings that are “greater than the sum of the parts”. ASSIA, CINAHL, Embase, Medline and PsychInfo were searched up to April 2013. Reference lists of included studies, key publications and relevant reviews were also searched. Quality appraisal adopted the “prompts for appraising qualitative research”.

Results: 7977 citations were identified, and 15 studies were included. Findings indicate that the decision to enter a depression trial is made by patients and gatekeepers based on the patient’s health state at the time of being approached to participate; on their attitude towards the research and trial interventions; and on the extent to which patients become engaged with the trial. Our conceptual framework highlights that the decision to participate by both the patient and the gatekeeper involves a judgement between risk and reward.

Limitations: Only English language publications were included in this review.

Conclusions: Findings from this review have implications for the design of interventions to improve recruitment into depression trials. Such interventions may aim to diminish the perceived risks and increase the perceived rewards of participation.

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1. Introduction

Depression is a major health problem and is predicted to become the single leading cause of disease burden worldwide by 2030 (World Health Organization, 2004; World Health Organization, 2013). A significant number of patients do not fully recover despite treatment (National Collaborating Centre for Mental Health, 2009; Torpey and Klein, 2008; Hardeveld et al., 2010). Thus there remains a significant need to develop effective interventions for managing depression.

Whilst clinical trials are the most scientifically rigorous way of comparing alternative treatments, delivery of such trials is limited in a large part by poor recruitment and retention of research participants (Tenhaven et al., 2003; Sacks et al., 1982; Barton, 2000). Difficulties with recruiting participants into clinical trials are very common: 45% of publicly funded trials require an extension and 80% of industry trials do not meet enrolment deadlines (Sully et al., 2013; Centerwatch, 2009). To our knowledge there have been no studies establishing the scale of recruitment problems specifically for depression trials, so the exact magnitude of difficulties in this area is unknown. However, there is a general consensus that depression trials experience particular challenges with recruitment, and many fail to recruit their proposed sample of participants to target, or indeed fail altogether (Hunt et al., 2001; Fairhurst and Dowrick, 1996; Woodford et al., 2011; Rendell and Licht, 2007; Hetherington et al., 2004; Garnham et al., 2011; Ruddell et al., 2007; Stek et al., 2007; Katz et al., 2005; Minas et al., 2005; Haberfellner, 2000; Yastrubetskaya et al., 1997). Other consequences of poor recruitment include increased costs and effort, reduction in statistical power, and delays in the generation of evidence and the subsequent adoption of effective interventions (Halpern et al., 2002; Patel et al., 2003; Drüeke et al., 2003).

Historically, recruiting into trials has commonly been considered an “art” rather than a “science”, whereby the recruitment experience has been thought to be unique to each trial and each recruiter (Bonvicini, 1998; Baquet et al., 2008; Timmerman, 1996). The importance of recruitment and retention to research, clinical practice and policy received relatively little attention (Froelicher and Lorig, 2002). Whilst a large number of individual interventions to address recruitment difficulties have been reported in the literature, very few of these interventions have robust evidence of effectiveness, leading to the conclusion that “recruiting for science has not been underpinned by a science of recruitment” (Bower et al., 2009, p. 393). All systematic reviews undertaken on the topic have called for an urgent need for systematically evaluated recruitment interventions, particularly those that are tested in real-world trials (Foy et al., 2003; Watson and Torgerson, 2006; Woodall et al., 2010; Prescott et al., 1999; Campbell et al., 2007; McDonald et al., 2006; Fletcher et al., 2012; Uybico et al., 2007; Caldwell et al., 2010; Johnson et al., 2011; Rendell et al., 2007; Treweek et al., 2013). Furthermore, recruitment is now highlighted as

the methodological research priority for clinical trials units in the United Kingdom (Smith et al., 2014).

The MRC Complex Interventions Framework can be adopted to develop and evaluate recruitment interventions using a multi-phased approach (Craig et al., 2008; Tramm et al., 2013). Within the Framework, evidence synthesis and qualitative research are important methodologies in intervention development (Peters, 2010). Here, we use qualitative meta-synthesis to identify and synthesise the evidence base on factors affecting recruitment into depression trials, to assist in the development of interventions aimed at improving recruitment into depression trials.

Systematic reviews provide the most reliable research findings by applying explicit methods that minimise bias (Higgins and Green, 2011; Antman et al., 1992; Oxman and Guyatt, 1993). Systematic reviews of qualitative research aim to apply similar methodology to the exploration of subjective experiences about meanings, processes or interventions (Pettigrew and Roberts, 2006). There have been numerous systematic reviews investigating various aspects of recruitment into clinical trials, and recently two of these reviews have adopted the meta-synthesis approach to investigate reasons for participating in trials in general; and willingness of patients of Chinese heritage to participate in trials (McCann et al., 2013; Limkakeng et al., 2013). However few have focused on mental health, and of those, the first reviewed barriers to participation in mental health research, focusing on gender, ethnicity and age (Woodall et al., 2010); the second reported on the inclusion of Latinos with obsessive compulsive disorder in clinical trials (Wetterneck et al., 2012); and the third examined barriers to recruiting ethnic minorities to mental health research (Brown et al., 2014). None of these mental health reviews adopted a meta-synthesis approach, nor focused on the specific factors affecting the recruitment of participants into depression trials.

Our aims in undertaking this review were firstly to systematically identify relevant qualitative studies describing factors affecting recruitment of participants into depression trials; and secondly to perform a meta-synthesis to identify common themes that describe factors affecting recruitment into depression trials, to develop a conceptual framework of factors influencing the decision to participate in depression trials.

2. Method

The method we employed was meta-synthesis (Stern and Harris, 1985). Much as meta-analyses for quantitative studies focus on combining results from different studies with the aim of identifying patterns among study results, meta-synthesis attempts to integrate results from a number of different but inter-related qualitative studies to generate new insights. The process involves both induction and interpretation. However, whilst meta-analysis typically aggregates data

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