

The DEPSY trial – assessing homeopathy for patients suffering from depression in “real world” clinical practice

Viksveen P.¹ and Relton C.¹

1. The University of Sheffield, School of Health and Related Research, Regent Court, 30 Regent Street, Sheffield S1 4DA.
Correspondence: Petter Viksveen, p.viksveen@sheffield.ac.uk

Depression is prevalent in all countries around the world. Although depression is among the most common reasons why patients consult with homeopaths, there is little existing research on this topic. The Depression in South Yorkshire (DEPSY) project comprises a pragmatic randomised controlled trial and a qualitative interview study. The trial will assess the acceptability, effectiveness, cost-effectiveness and safety of treatment by homeopaths for patients suffering from self-reported unipolar depression. The qualitative study will help us understand more about patients' experiences of homeopathic treatment.

Introduction

Depression affects a large proportion of the population and has been ranked by the World Health Organization as one of the world's leading causes of burden of disease¹. Established treatments including the so-called “talking therapies” and antidepressants are of benefit to some patients, but many experience limited or no benefit from these treatments, and antidepressants are also known to cause side-effects. This may in part explain why depression is one of the most common clinical conditions homeopaths are consulted for². In a systematic review published nine years ago³ the authors concluded that, “... *the evidence for the effectiveness of homeopathy in depression is limited due to lack of clinical trials of high quality.*” Since this review, some uncontrolled studies and efficacy trials assessing the benefit of homeopathy in depression have been published. This article briefly discusses the limitations of these studies and the approach taken by the DEPSY project to improve the evidence base.

Uncontrolled studies

Uncontrolled observational studies of treatment by homeopaths most commonly include patients with a wide range of complaints, some of whom suffer from depression. The largest observational study, with a total of 6,544 patients, included 201 diagnosed with depression⁴. Over 70% experienced an overall improvement and more than half felt they were “better” or “much better” after homeopathic treatment. The length of the assessment period for depressed patients was however not specified and the outcome measure has not been validated for this group of patients. The most recently published observational study, reporting on 67 patients diagnosed with depression, used well-established depression outcome measures, including the Hamilton Depression Rating Scale (HDRS)⁵. Results showed

statistically significant improvements for patients at 3, 6, 9 and 12 months ($p=0.001$). Although uncontrolled studies may add valuable information on patients' experiences with treatment, the lack of a control group significantly reduces the possibility to draw any conclusions regarding a cause-and-effect link between patients' experiences and the treatment they have received, as there may be other reasons why patients report improvement.

Efficacy trials (RCTs)

Over the past decade, of three trials which aimed to assess the efficacy of homeopathic medicines in depression^{6,8}, two were unable to recruit sufficient patients to draw any conclusions^{6,7}. Recruitment attrition is a well-known challenge in placebo-controlled double-blinded trials. It may be difficult to recruit patients to a trial when they know that they might receive an inactive placebo pill and not “the real thing”. Such trials may result in resentful demoralization if patients believe they have been allocated to the placebo group⁹, possibly causing patients to drop out of the trial, to comply less well with treatment instructions or to perform less well on outcome measures. The third trial used a placebo-controlled double-dummy method⁸. Homeopathic medicines were found to be non-inferior to an established antidepressant drug (fluoxetine) after 4 and 8 weeks. These results are promising, but do not say anything about any long-term effects of the treatment.

Limitations of efficacy trials

Efficacy trials usually involve narrow inclusion criteria in order to demonstrate the effect of ‘the pill’ compared to the placebo control and ‘the pills’ are often prescribed in a standardised way. Although such trials may answer questions of the efficacy of ‘the pill’, they are unsuited to answer important questions

for clinical decisions in real-world practice¹⁰ and have “*doubtful applicability to most patients, most settings and most clinicians.*” A more recent version of the Consolidated Standards for Reporting Trials (CONSORT)¹¹ recommended authors to provide information to assist readers in determining whether the results are applicable in their own settings.

The DEPSY trial – close to “real world” practice

The Depression in South Yorkshire (DEPSY) trial is the first pragmatic (non-blinded) randomised controlled trial assessing “real world” effectiveness and cost-effectiveness of treatment by homeopaths for patients suffering from self-reported depression. The homeopaths involved are free to practice as they usually do and the inclusion criteria are broad¹², thus the results will be relevant to real world patients, including those with multiple conditions and those using other treatments. To reflect usual homeopathic care, treatment is offered over a 9-month period (with assessments at 6 and 12 months) and duration and frequency of consultations is agreed between homeopaths and patients. Such pragmatic trials are better suited to inform clinical decision-making and to help funders make decisions on reimbursement¹⁰.

Facilitating recruitment and reducing patient drop-out

The DEPSY trial uses the cohort multiple RCT design¹³ i.e. patients with moderate and severe depression are recruited from an already established cohort (<http://www.yorkshirehealthstudy.org/>) including over 22,000 patients in South Yorkshire who have already provided healthcare data and given permission to be contacted again.

Patients in both groups may receive other treatments as usual, with data being collected on all treatments used for statistical and cost-effectiveness analyses. To reduce the burden on patients, we have chosen short questionnaires which they can complete on their own: the depression outcome, the Patient Health Questionnaire (PHQ-9), is used for screening, baseline data collection and assessment of results after 6 (primary outcome) and 12 months (secondary outcome); additional secondary outcome measures include the Generalised Anxiety Disorder (GAD-7) and EuroQol (EQ-5D) which are used to assess cost-effectiveness.

One third of all patients fulfilling the inclusion criteria are randomly selected to be offered treatment by a homeopath, and the remainder serve as a control group. As patients in the control group are unaware of the offer, this avoids ‘resentful demoralisation’.

Learning more from patients

A qualitative semi-structured interview study being carried out as part of the DEPSY project involves a maximum of 30 patients being interviewed 1-2 months and 6 months after their first consultation with a homeopath. Patients are being asked to describe their experiences with the homeopathic consultation and taking the homeopathic medicine, and to







compare this to their experiences with taking antidepressants and having consultations with other practitioners. A mixed methods approach will combine results from the quantitative trial and the qualitative interview study. This study will enable us to learn much about the real world benefits of homeopathy in the treatment of patients suffering from depression.

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