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Naturopathic medicine for treating self-reported depression and anxiety: *An observational pilot study of naturalistic practice*

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ABSTRACT

Overview: We conducted the first observational study of a case series of naturopathic consultations of adults who presented with self-reported depression or anxiety.
Aims: To evaluate the efficacy and safety of Australian naturopathy on the outcome of depressed mood and anxiety, assess which interventions are being prescribed, and to explore the patient's experiences of being treated by a naturopath.
Methods: Outcomes from consultations (from one or two follow-up visits over approximately four to six weeks), were assessed via a mixed methods approach. This involved an analysis of quantitative data from DASS-21, POMS-65, and GHQ-28 scales, and qualitative data via subjective feedback of patient's treatment experience from purpose-designed semi-structured questionnaires. Clinician's prescriptions were also categorised and quantified.
Results: Eleven naturopaths provided data for analysis, consisting of 31 consultations from 15 patients. From the eight participants that had follow-up data, across Time from baseline to their final follow-up consultation, a significant reduction occurred for DASS depression, anxiety, and stress; and GHQ somatic symptoms, anxiety/insomnia and social dysfunction. Results were mirrored on the POMS. Nutrient supplementation was prescribed by 67% of practitioners, with 84% prescribing an herbal medicine. Dietary or exercise advice was recommended in 52%, and 32% of consultations, respectively. Meditation/relaxation techniques were taught in 35% of consultations. Sleep hygiene advice was provided in 32% of cases, and counselling was offered 38% of the time.
Summary: Preliminary evidence in this uncontrolled study revealed that naturopathic medicine may be beneficial in improving mood and reducing anxiety. However, insufficient study participation by naturopaths (leading to a small study sample) and the uncontrolled unblinded design, restrict the strength of this conclusion. A future study involving a larger sample, using rigorous methodology is now required to validate this pilot data.

1. Introduction

Naturopathic medicine (naturopathy) is a healing system that adopts a biopsychosocial model to treat people via an individualised person-centred "whole system" approach to address the underlying cause/s of disease [1,2]. This system of medicine also emphasises disease prevention and the enhancement of wellbeing. Naturopathy regards all biological systems as interrelated and fluidic, and views disease causation as being profoundly influenced by a complex of array of internal and external factors. Naturopaths commonly prescribe a range of complementary and alternative medicines (such as herbal medicines and nutritional supplements) and therapies (CAM), in addition to proffering "lifestyle medicine" (e.g. modification of diet, exercise, vices, and relaxation/meditation, work/life balance, sleep hygiene), and in certain jurisdictions minor surgery [2,3]. Some clinicians may also provide counselling, massage, homoeopathy, or acupuncture (depending on training).

While clinical studies using isolated herbal or nutritional supplements are being increasingly conducted, assessment of the actual practice of naturopathy has only been recently explored in a few clinical trials. Studies exploring the naturalistic clinical practice of any system of medicine using randomised controlled trial (RCT) designs is challenging. Many caveats exist when applying a reductive model to determine efficacy of any CAM

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modality [4]. Naturopaths often use individualised prescriptions to treat the individual "whole" person (not just a disease or symptom), and this holistic practice cannot be adequately assessed via RCTs that reduce a complex intervention into single reductive components [5]. Application of "whole systems research", can explore the patient's therapeutic relationship with the practitioner via the use of a qualitative component in studies, and this may clarify patient's perceptions and expectations of the treatment [6].

Mental illnesses, and in particular depression and anxiety, are a major area of treatment for CAM clinicians [7]. Herbal medicine is widely used by individuals for mental health conditions, with US data from the National Comorbidity Survey Replication (2002) [8] finding that adults with mental health issues were significantly more likely to have used herbal medicines than their healthier counterparts. A variety of CAMs are also used prevalently by people with depression or anxiety. US data from a nationally representative sample of 2055 people interviewed during 1997–1998 revealed that 57% of those with anxiety attacks, and 54% of those with severe depression reported using some CAM during the previous 12 months [9]. Twenty percent of the sample with anxiety, and 19% of those with severe depression visited a CAM practitioner for treatment during the year.

As reflected in CAM practice, a variety of eclectic individualised interventions are commonly used in an integrative manner to treat mental health disorders [10]. In treating depression and anxiety, naturopaths view the causation as being complex, with many interrelated influences considered to be involved [11]. The study of integrative healing systems such as naturopathy, may provide advantages in the treatment of non-severe forms of depression and anxiety over conventional pharmaceutical drugs, which may cause side-effects and appear to have at best moderate efficacy in mild-moderate depression [12]. As the causation/s of depression and anxiety can be viewed as multifactorial [13], individualised naturopathic care which treats people with biological, psychosocial, and lifestyle considerations, may provide benefits beyond standard care.

Depression and anxiety are prevalent disorders, which are personally and socioeconomically destructive [14], and as discussed above, a significant percentage of sufferers seek CAM healthcare to treat these conditions [15,16]. However, to date no evidence exists exploring the prescriptive practices in this specific area, and the potential efficacy of naturopathic medicine in treating depression or anxiety (which often occur comorbidly) [17]. Due to this, research is vital to fill this gap in the field for the potential benefit of the profession and for sufferers of mental illness. The *Naturopathic Medicine for Improving Mood and Reducing Anxiety Study* was created to address this [18]. The primary aims of the observational pilot study were to evaluate the efficacy and safety of Australian naturopathy on the outcome of depressed mood and anxiety, assess which interventions are being prescribed, and to explore the patient's experiences of being treated by a naturopath.

2. Methods

2.1. Design and assessments

The study was a naturalistic observational exploration of naturopathic consultations for the primary complaint of depression or anxiety, conducted over one to three consultations occurring over a four to six week period. Patient inclusion criteria consisted of any adults (aged 18–70) presenting with either self-reported depressed mood or/and anxiety (ongoing for more than two weeks) as their primary complaint and reason for treatment (although they could have other comorbid health issues). Due to the naturalistic observational design, the only exclusion criterion was that participants must have had competent English skills to be able to understand and fill out the assessment forms. Data collection occurred during week 0 (first visit baseline) and at two subsequent follow-up consultations, as following the naturalistic naturopath/patient treatment process. Treatment effects were assessed on the Depression Anxiety Stress Scale (DASS) [19] [primary outcome] consisting of depression, anxiety, and stress subscales; the Profile of Mood States (POMS-65) [20], consisting of tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia, confusion-bewilderment and vigour-activity subscales, in addition to a total mood disturbance score (obtained by adding the five factors and subtracting the vigour-activity); and the General Health Questionnaire (GHQ-28)[21] consisting of a somatic, anxiety/insomnia, social dysfunction, depression symptom subscales. While these scales are not commonly used by naturopaths, they are validated assessment tools used in psychiatry research to quantify treatment effects on mood, anxiety, and general health.

Participant experiences and side-effects were explored via a semi-structured qualitative assessment form which asked participants to write about their perceived benefits or negative experiences, or unusual effects from naturopathic treatment (qualitative forms were filled out at follow-up consultations). Naturopaths also filled out a purpose-designed form to chart their prescription, with tick-boxes listing common naturopathic treatments under the headings: General Interventions (e.g. dietary advice), Supplements (e.g. Omega-3), and Herbal Medicines (e.g. St John's wort). Treatment by naturopathic clinicians was not influenced by participation in the study, i.e. each naturopath practiced and prescribed as they would normally. Participants paid for their consultations and supplements as per a standard consultation (thereby not biasing the results due to potential confounding of financial inducement). Compliance, withdrawal, and dosage data were not sought, due to the need to keep the time requirements of study involvement limited.

2.2. Procedure

The two main aspects of participation in the study involved:

1) Patients filling out demographics, mood and anxiety, and qualitative assessment forms.
2) Naturopaths filling out a purpose-designed form detailing their prescription.

Interested naturopaths were recruited from private practice and training colleges (3rd or 4th year students under supervision) via email and print advertising, and were shown the study process via a webinar (video instruction provided via a web link). They were provided an information sheet and consent form stating they wished to participate in the study and that they will ask patients with mood or anxiety symptoms (as their principle complaint) to participate in the study to record their experiences. Clinicians did not perform any formal diagnoses of psychiatric disorders (e.g. via DSM). In the first session, consenting patients filled out a basic demographics form (de-identified), and completed the DASS-21, POMS-65, and GHQ-28. After the naturopathic prescription was decided, the naturopath filled out the prescription form documenting the interventions used. During subsequent follow-up sessions (occurring usually after one to three weeks), the consultation followed normal procedure as per the clinician's treatment protocol. Patients continued to fill out at the end of the sessions the DASS-21, POMS-65, and GHQ-28, in addition to the qualitative form. Clinicians were asked to ensure that the patients could fill the forms out in private, and have them placed in an envelope to be self-sealed (to encourage an honest disclosure of their experiences).