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Research report

Telephone-administered psychotherapy in combination with antidepressant medication for the acute treatment of major depressive disorder

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ABSTRACT

Background: Telephone-administered psychotherapies (T-P) provided as an adjunct to antidepressant medication may improve response rates in major depressive disorder (MDD). The goal of this study was to compare telephone-administered social rhythm therapy (T-SRT) and telephone-administered intensive clinical management (T-ICM) as adjuncts to antidepressant medication for MDD. A secondary goal was to compare T-P with Treatment as Usual (TAU) as adjunctive treatment to medication for MDD.
Methods: 221 adult out-patients with MDD, currently depressed, were randomly assigned to 8 sessions of weekly T-SRT ($n=110$) or T-ICM ($n=111$), administered as an adjunct to agomelatine. Both psychotherapies were administered entirely by telephone, by trained psychologists who were blind to other aspects of treatment. The 221 patients were *a posteriori* matched with 221 depressed outpatients receiving TAU (controls). The primary outcome measure was the percentage of responders at 8 weeks post-treatment.
Results: No significant differences were found between T-SRT and T-ICM. But T-P was associated with higher response rates (65.4% vs 54.8%, $p=0.02$) and a trend toward higher remission rates (33.2% vs 25.1%; $p=0.06$) compared to TAU.
Limitations: Short term study.
Conclusions: This study is the first assessing the short-term effects of an add-on, brief, telephone-administered psychotherapy in depressed patients treated with antidepressant medication. Eight sessions of weekly telephone-delivered psychotherapy as an adjunct to antidepressant medication resulted in improved response rates relative to medication alone.

1. Introduction

Fewer than half of individuals with major depressive disorder (MDD) respond to acute treatment with antidepressant medication alone. Combined treatment of major depressive episodes (MDEs), with antidepressant medication and adjunctive psychotherapy is more effective than antidepressant medication alone (Oestergaard and Møldrup, 2011; Archer et al., 2012; Cuijpers et al., 2012; Hollinghurst et al., 2014; Oosterbaan et al., 2013; Richards et al., 2013; Spijker et al., 2013). However, 75% of depressed primary care patients report barriers that make it extremely difficult or impossible to attend regular psychotherapy sessions (Mohr et al., 2006, 2010; Dezetter et al., 2015). These barriers to access include time constraints, lack of available and accessible services, transportation problems, and cost (Mohr et al., 2012). Telephone-administered psychotherapies (T-P) can decrease these access barriers. A recent study showed that

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telephone-administered cognitive-behavioral therapy (CBT) for depression is as efficacious as face-to-face CBT (Mohr et al., 2012). Telephone-administered psychotherapies (T-P), a convenient alternative to face-to-face treatment, when administered as an adjunct to antidepressant medication, may improve response rates to acute treatment for MDD. Little is known, however, about outcomes associated with combining these interventions. To the best of our knowledge, there have been no studies investigating T-P as an adjunct to antidepressant medication and comparing different types of T-P as acute treatments for MDE.

Interpersonal and social rhythm therapy (IPSRT) is an empirically supported psychotherapy that combines a focus on interpersonal relationships with behavioral interventions designed to regulate timing of daily routines (Frank, 2005a). IPSRT has demonstrated efficacy an adjunct to pharmacotherapy for the management of mood disorders (Miklowitz, 2008). Treatment with IPSRT is associated with reduced time to recovery from an episode of depression (Miklowitz et al., 2007) and improved psychosocial and occupational functioning (Frank et al., 2008) among patients with type bipolar disorder. IPSRT combines Interpersonal Psychotherapy (IPT) as developed by Weissman et al.(2000) with Social Rhythm Therapy (SRT). The SRT component postulates that disordered circadian biology contributes to the development and maintenance of psychiatric symptoms and that helping patients to develop more regular routines and social patterns will facilitate stabilization of underlying circadian abnormalities, thereby reducing symptoms and improving outcomes. Previous work demonstrates that improved regularity of daily routine mediates improved outcomes in patients treated with IPSRT (Frank et al., 2005b), and SRT has been used as a stand-alone intervention in routine practice setting (Swartz et al., 2011). IPSRT typically lasts from 12 to 26 sessions (Miklowitz et al., 2007; Swartz et al., 2012). To date, no study has evaluated the efficacy of 8-session telephone-administered SRT (T-SRT) for unipolar depression.

The goal of this study was to compare telephone-administered social rhythm therapy (T-SRT) and telephone-administered intensive clinical management (T-ICM) as adjuncts to antidepressant medication for MDD. A secondary goal was to compare T-P with Treatment as Usual (TAU) as adjunctive treatment to medication for MDD. We hypothesized that assignment to T-SRT would result in greater symptom reduction than assignment to a control telephone-administered non-specific psychotherapy (T-ICM) when administered as adjuncts to antidepressant medication for the treatment of acute MDE. Secondarily, we hypothesized that telephone-administered psychotherapy (T-SRT or T-ICM) would yield greater symptom reductions than treatment as usual (TAU) when administered as an adjunct to antidepressant medication.

2. Methods

2.1. Design

The current trial was embedded within a larger 8-week prospective multicentre study of 721 patients with MDD treated with agomelatine (Corruble et al., 2014). A randomized controlled ancillary study was performed to compare Social Rhythm Therapy administered by telephone (T-SRT) ($n=110$) or Intensive Clinical Management administered by telephone (T-ICM) ($n=111$). The randomization sequence was generated by simple randomization. No blocking or stratification was employed. Once a patient consented to participation, the study investigator phoned the study coordinator who was responsible for the randomization, obtained the participant's psychotherapy assignment, and informed the participant. The investigator remained blind to the psychotherapy assignment until the end of the study. Patients were assessed at the beginning of treatment (W0), and 2 weeks (W2) and 8 weeks (W8) later.

To compare telephone-administered psychotherapy (either T-SRT or T-ICM) with treatment as usual (TAU), a case-control study was performed, in which 221 subjects from the larger trial were a posteriori matched for age, gender, number of previous MDE and initial severity of depressive symptoms as measured by the Quick Inventory of Depressive Symptoms-Clinician Version (QIDS-C) (Rush et al., 2003) with the 221 patients from the ancillary randomized controlled study.

2.2. Patients

Participants were outpatients meeting Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for Major Depressive Disorder, currently depressed, as assessed by the Mini International Neuropsychiatric Interview (MINI) (Lecrubier et al., 1997), and for whom initiation of a antidepressant medication was indicated. The current MDE had to be of moderate to severe intensity, as evidenced by a Clinical Global Impression (CGI) (Guy, 1976) severity score of 4 or more (at least 'moderately ill') and a Quick-Inventory for Depressive Symptomatology, Clinician Rating (QIDS-C) score ≥ 16 at inclusion. In addition, patients were required to be >18 years old, speak fluent French, possess a social security number, and give written informed consent. The study was registered by the French National Agency for Medicines and Health Products Safety (ANSM) and the Commission Nationale de l'Informatique et des Libertes (CNIL) and was approved by the Ethics Committee of Paris-Boulogne, France. Confidentiality and anonymity were maintained.

Exclusion criteria were DSM-IV diagnoses of schizophrenia or any psychotic disorder, bipolar disorder, dysthymia, and current substance abuse or dependence. Also excluded were those currently receiving mood stabilizers, engaging in shift work, currently pregnant or breast feeding, and those with somatic conditions or biological abnormalities precluding treatment with agomelatine or better explaining depressive symptoms. Psychotherapies of psychoanalytic or cognitive behavioral or systemic types, comprising at least one session per week, also constituted exclusion criteria.

All patients received open-label treatment with agomelatine (25–50 mg/d), an antidepressant that stimulates MT_1/MT_2 receptors with simultaneous blockade of $5HT_{2C}$ receptors. The synergistic action of these receptors (de Bodinat et al., 2010) leads to antidepressant efficacy in trials of agomelatine versus placebo and comparators (Taylor et al., 2014) and phase shifting properties, inducing a phase advance of sleep, body temperature decline and melatonin onset in human studies (Kasper et al., 2010).

2.3. Treatments

The T-P group was randomly assigned to either T-SRT or T-ICM.

T-SRT is an 8-session intervention based on IPSRT (Frank, 2005a) and manualized by study authors (E.F., H.A.S.). SRT is the social rhythm component of IPSRT. It is based on the social zeitgeber hypothesis (Ehlers et al., 1988) of unipolar depression. Briefly, this hypothesis argues that episodes of depression occur in individuals who are biologically vulnerable to mood episodes in the context of disruptions in social cues that entrain underlying biologic rhythms. The hypothesis further argues that regularity of social routines has a protective effect in mood disorders. Indeed, multiple studies demonstrate disruptions in circadian biology with attendant disturbances in sleep, wake, and arousal cycles in patients with mood disorders. SRT helps patients regulate their social rhythms (daily routines) and levels of daily activity/stimulation in order to achieve regularity of underlying biologic rhythms. It also utilizes psychoeducation to help patients become familiar with the