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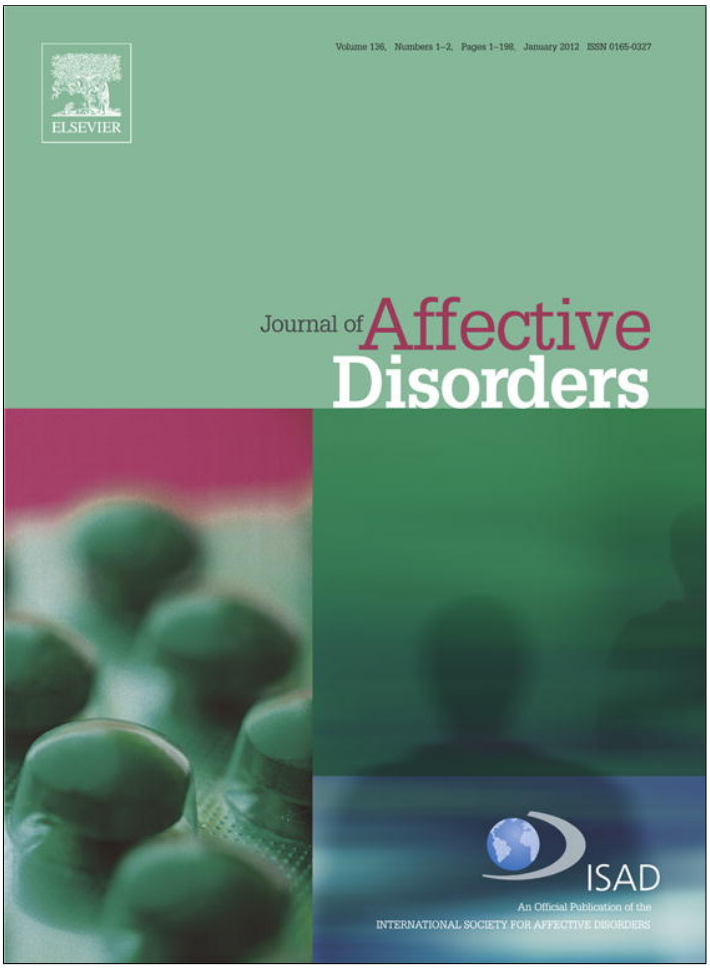

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Journal of Affective Disorders 190 (2016) 6–11

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research report

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

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ARTICLE INFO

Article history:
Received 13 April 2015
Received in revised form
20 July 2015
Accepted 20 July 2015
Available online 8 October 2015

Keywords:
Psychotherapy
Telephone intervention
Adjunctive
Major depressive disorder
Major depressive episode
Antidepressant
Social rhythm therapy
Interpersonal and social rhythm therapy

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.

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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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http://dx.doi.org/10.1016/j.jad.2015.07.052
0165-0327/© 2015 Published by Elsevier B.V.

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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

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signs and symptoms of their disorder and to address issues relevant to medication adherence. SRT uses behavioral strategies to target and modify behaviors that affect regularity of routines, such as going out of bed, having a first contact with another person, start regular daily activity (for example school or work), having dinner, and going to bed. Each session lasts 30–45 min.

ICM is a manual-driven approach to the medical management of MDD that was adapted by E.F. and H.A.S. based on the clinical management strategies (Fawcett et al., 1987) employed in the National Institute of Mental Health Treatment of Depression Collaborative Research (Elkin et al., 1989) and in the earlier study of Maintenance Therapies in Recurrent Depression (Frank et al., 1990). Each session utilizes psychoeducation to help patients become familiar with the signs and symptoms of their disorder and to address issues relevant to medication adherence. The specific elements of ICM include education about MDD, education about the medications used to treat MDD, education about basic sleep hygiene, careful review of symptoms, careful review of adverse effects, medical and behavioral management of adverse effects, and non-specific support. Each session lasts 30–45 min.

Study participants were treated by teams consisting of a psychiatrist and a psychologist. Medication visits were administered in-person while psychotherapy visits were delivered by telephone. Subjects' treatment teams remained the same throughout the protocol. Thirty to forty minute sessions of T-P (T-SRT or T-ICM) were delivered once a week by a trained psychologist, entirely over the telephone. All psychologists received an initial two-day training in T-SRT and T-ICM and completed at least 3T-SRT and T-ICM training cases under the supervision of investigators (E.F., H.A.S. and T.B.). Once trained, all therapists participated in ongoing group supervision on a monthly basis throughout the course of the study. All psychologists provided both T-SRT and T-ICM to eliminate therapist effects. Specific rules to ensure privacy and safety were discussed in the first session, such as being in a private place during telephone calls and not engaging in therapy while driving (Mohr et al., 2012). Protocols were in place to ensure safety, which could include calling local emergency personnel to conduct a health and safety check in the event of severe suicidality. All sessions were audiorecorded. To prevent confounding through differences in the management of nonadherent patients across treatment arms, the therapist protocol included specific instructions for handling missed sessions and cancellations. If patients missed a session, they received three telephone calls from their therapist, after which, if still nonresponsive, the patients were determined to have discontinued treatment. Participants did not pay for treatment.

The treatment as usual (TAU) group received face-to-face treatment with a psychiatrist and antidepressant medication agomelatine, but no T-P and no other formal face-to-face psychotherapy.

3. Outcome assessment

3.1. Depression

The primary outcome is the percentage of responders on the QIDS-C after 8 weeks of treatment. The 16-item QIDS-C (Rush et al., 2003) was used to assess depression severity. Responders were defined by a decrease in the QIDS-C score of at least 50% from baseline to follow-up. Remitters were defined by a QIDS-C score of 5 or less at follow-up. The 16-item Quick Inventory for Depressive Symptomatology-Self Rated (QIDS-SR) (Rush et al., 2003) was used as a self-report measure of depressive symptoms. The Clinical Global Impression, Severity of Illness subscale (CGI-S) (Guy, 1976) was used as a global assessment of the severity of illness. The QIDS-C and QIDS-SR were rated at W0, W2, and W8, the CGI-S at W0 and W8. All psychiatrists were trained to rate QIDS-C and CGI-S during a half-day training session. Psychiatrists were blind to psychosocial treatment assignment.

3.2. Social rhythms

The secondary outcome is the Social Rhythm Metrics (SRM) (Monk et al., 1990, 1991). This 5-item questionnaire was used to assess the regularity of social circadian rhythms. Participants recorded the time at which five activities (getting out of bed, having first contact with another person, beginning work or activities, having dinner, going to bed) occurred each day. Data from a given week are scored as a unit, yielding an overall score between 0 and 7. Higher scores indicate more regular rhythms. Participants were asked to complete the SRM throughout the day for 7 consecutive days before each study visit (W0, W2, and W8).

3.3. Statistical analysis

Univariate descriptive statistics were based on percentages for qualitative variables and means (standard deviation [sd]) for quantitative variables. Variables were examined for normality of distribution before using parametric statistics. A graphical representation was used to assess the normality of distribution of social rhythms at W0 and W8 visits. Q–Q (quantile) plots showed that the dependent variables each approximated a normal distribution.

Logistic regressions were performed to compare the percentages of responders and remitters in the T-SRT and T-ICM groups and in the T-P and TAU groups. Change in depression and social rhythm scores over time were evaluated using analyses of variance for repeated measures. Differences between treatment groups in depression and social rhythm scores over time were evaluated by examining time × treatment interactions of analyses of variance for repeated measures. All tests were two-tailed. Statistical significance was set at an alpha level of 0.05.

4. Results

4.1. Study population

From the initial sample of 721 individuals (Corruble et al., 2014), 442 patients were analyzed, of whom 110 were treated with T-SRT, 111 were treated with T-ICM and 221 matched patients who received TAU.

Women comprised 70.1% of the final sample, and the average age was 46.8 years (SD = 11.1). 59.2% of the participants were married, 17.9% were divorced, and 22.9% were single or had another marital status. Educational level was as follows: less than high school: 41.3%; high school: 30%; more than high school: 28.7%. 73.8% of patients were currently employed/homemakers/students; 16.7% were not employed, and 9.5% were retired. The mean (SD) number of previous MDEs was 1.9 (3.2). The mean lifetime duration of MDD, excluding the present episode, was 9.9 years (SD = 10.4).

4.2. Comparison of T-SRT and T-ICM

Improvement of depressive symptomatology was observed with the QIDS-C, QIDS-SR and CGI-S both in the T-SRT group and in the T-ICM group (Table 1). Improvement of social rhythm regularity was also observed in the T-SRT group and in the T-ICM group (Table 1). Both groups experienced significant declines in symptoms over time for QIDS-C ($P < 0.0001$), QIDS-SR ($P < 0.0001$)

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Table 1
Means and standard deviations over 8 weeks of depression severity and social rhythm regularity for T-SRT and T-ICM.

	T-SRT						T-ICM					
	Week 0		Week 2		Week 8		Week 0		Week 2		Week 8	
	Mean	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*
QIDS-C	19.8	2.39	13.6	4.86	9.5	5.4	19.4	2.46	12.4	4.54	8.4	5.2
QIDS-SR	17.93	4.67	12.76	5.30	9.72	5.91	16.31	4.93	11.04	4.99	9.29	6.10
CGI-S	4.87	0.51	–	–	3.62	1.42	4.93	0.55	–	–	3.84	1.33
SRM	4.15	1.2	4.47	1.38	5.02	1.1	4.50	1.29	4.71	1.32	4.98	1.35

T-SRT: Telephone-administered social rhythm therapy.
T-ICM: Telephone-administered intensive clinical management.
QIDS-C: Quick Inventory for Depressive Symptomatology-Clinician.
QIDS-SR: Quick Inventory for Depressive Symptomatology-Self-rated.
CGI-S: Clinical Global Impression-Severity.
SRM: Social Rhythm Metrics.

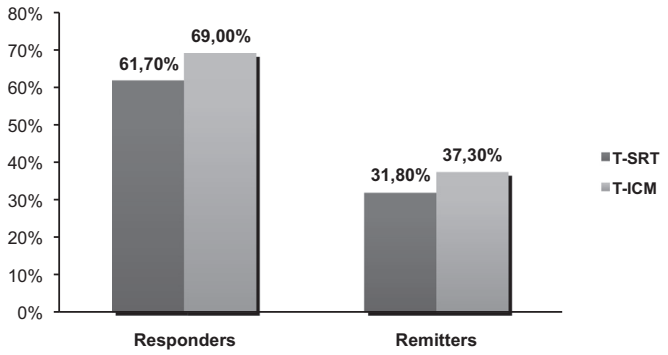

Fig. 1. Percentages of responders and remitters with T-SRT and T-ICM. T-SRT: Telephone-administered social rhythm therapy T-ICM: Telephone-administered intensive clinical management.

and CGI-S ($P<0.0001$) and improvement in social rhythm regularity over time based on their SRM scores ($P<0.0001$). There were no significant "time × treatment" interactions. Percent of participants responding and remitting at W8 did not differ significantly between those who received T-SRT versus T-ICM (Fig. 1) (61.7% vs 69% and 31.8% vs 37.3% respectively).

4.3. Comparison of telephone-administered psychotherapy and treatment as usual

The T-P group experienced significant declines in symptoms over time as measured with QIDS-C ($P<0.0001$), QIDS-SR ($P<0.0001$) and CGI-S ($P<0.0001$) and improvement in social rhythm regularity over time ($P<0.0001$) (Table 2). The TAU group experienced declines in symptoms over time as measured with QIDS-C ($P<0.0001$), QIDS-SR ($P<0.0001$) and CGI-S ($P<0.0001$) and improvement in social rhythm regularity over time ($P<0.0001$) (Table 2).

The percentage of W8 responders was significantly higher among patients who received T-P compared to those who received TAU (figure 1) (65.4% vs 54.8%; χ^2 (1df)=4.93 P=0.02). The percentage of W8 remitters was also somewhat higher, but only at a trend level, among those who received T-P, as compared to those who received TAU (Fig. 1) (33.2% vs 25.1%; χ^2 (1df)=3.24; P=0.06) (Fig. 2).

No significant differences were shown in social rhythm regularity between patients who received T-P and those who received TAU (Table 2).

5. Discussion

In this randomized controlled study, no difference was shown between T-SRT and T-ICM as an adjunct to the antidepressant medication agomelatine, in terms of impact on depressive symptoms and social rhythms. However, patients who received telephone-administered psychotherapy, either T-SRT or T-ICM, in addition to agomelatine had higher response rates after 8 weeks of treatment than matched patients who received agomelatine alone. This result is in line with those of several studies (Zobel et al., 2011;, Hollon et al., 2014) and reviews (Oestergaard and Møldrup, 2011; Cuijpers et al., 2012) showing improved depression outcomes by enhancing antidepressant therapy with non-pharmacological interventions. Our results go beyond these published

Table 2
Means and standard deviations over 8 weeks of depression severity and social rhythm regularity for telephone-administered psychotherapy and Treatment as usual.

	TAU						T-P					
	Week 0		Week 2		Week 8		Week 0		Week 2		Week 8	
	Mean	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*	*Mean*	*sd*
QIDS-C	19.3	2.17	13.1	5.15	9.7	5.53	19.6	2.43	20.0	4.73	8.9	5.34
QIDS-SR	18.04	4.12	12.78	5.82	10.03	6.22	17.16	4.85	11.99	5.22	9.50	5.99
CGI-S	4.90	0.53	–	–	3.73	1.37	4.99	0.6	–	–	3.48	1.31
SRM	4.46	1.4	4.65	1.34	5.0	1.27	4.32	1.25	4.59	1.36	5.0	1.23

T-P: Telephone-administered psychotherapy (T-SRT or T-ICM).
TAU: Treatment as usual.
QIDS-C: Quick Inventory for Depressive Symptomatology-Clinician.
QIDS-SR: Quick Inventory for Depressive Symptomatology-Self-rated.
CGI-S: Clinical Global Impression-Severity.
SRM: Social Rhythm Metrics.

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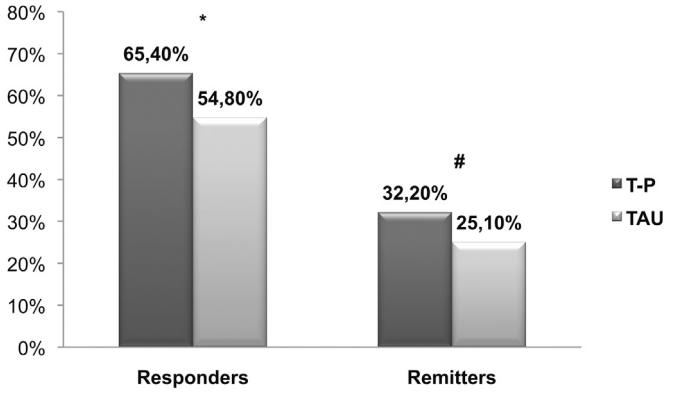

Fig. 2. Percentages of responders and remitters with T-P and TAU. T-P: Telephone-administered psychotherapy (T-SRT or T-ICM) TAU: Treatment as usual $^{*}P < 0.05$ and $\#P = 0.06$.

studies because they show improvement in outcomes with brief telephone-administered psychotherapies. Prior trials of telephone psychotherapy have been longer in duration (Mohr et al., 2012); in this study, benefit was seen with even 8 sessions. Although brief psychotherapeutic interventions have shown efficacy in face-to-face trials (Barkham et al., 1996; Swartz et al., 2014), this is the first study to show benefit of a brief telephone intervention for depression administered in conjunction with pharmacotherapy. Telephone-administered psychotherapies – in contrast to in-person interventions – decrease access barriers and make psychotherapies more accessible for patients.

Our finding of no difference between T-SRT and T-ICM may be explained by the fact that all participants received agomelatine, an antidepressant with resynchronizing properties (Corruble et al., 2014). T-SRT's specific impact on social rhythms may have been over-shadowed by overlapping rhythm-altering effects of agomelatine. This is supported by the finding that all three groups (T-SRT, T-ICM, and TAU) showed time-dependent improvement on SRM scores suggesting that agomelatine may have created a "ceiling effect" on this measure. Absence of a difference between T-SRT and T-ICM might also be explained by the efficacy of T-ICM. Indeed, there are only a few studies assessing the effectiveness of Intensive Clinical Management (ICM) on adult patients with MDD. Although the publications in this area are sparse, they suggest that ICM and its principal dimension of psychoeducation, are effective in improving the clinical course, treatment adherence, and psychosocial functioning of depressed patients (review in Donker et al., 2009; Tursi et al., 2013). Our results also suggest a specific antidepressant effect of T-P in line with previous findings demonstrating that telephone interventions may be as effective as face-to-face psychotherapy (Mohr et al., 2012).

This study has several limitations. First, the comparison of telephone-administered psychotherapy as an adjunct to antidepressant drug with antidepressant drug alone was not a randomized trial but a case-control study. This raises the possibility that unmeasured factors explain differences between groups. Assessments were conducted by psychiatrists who were involved in patients' care. Although they were blinded to therapy condition, they were members of the treatment team, which may have contributed to biased assessment. Therapists administered both psychotherapies in order to control for therapist effects, but this methodologic decision also increased the risk of cross-contamination of treatments. Finally, an eight-week trial is relatively short for a psychotherapy intervention, raising the possibility that the impact of these psychosocial interventions would be more likely to be detected if the time frame of the trial were extended.

To conclude, 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.

Both T-SRT and T-ICM, when administered with medication, resulted in reductions in depression scores and an increased likelihood of remitting compared to matched subjects receiving antidepressant medication alone. No differences were detected between T-SRT and T-ICM, when administered with the antidepressant agomelatine. Thus, the results of this study support the usefulness of weekly telephone-administered psychotherapy, either T-SRT or T-ICM, as an adjunct to antidepressant medication as compared to antidepressant medication alone, in the acute phase treatment of patients with MDD. Telephone-delivered adjunctive psychotherapy, either T-SRT or T-ICM, should be considered as an adjunct to antidepressant medication in the acute phase of depression treatment.

Declaration of interest statement

This study was supported by a research grant from Servier. Servier had no involvement in the design, organization, analysis, or preparation for publication of the study.

Emmanuelle Corruble has received consulting fees from AstraZeneca, Bristol Myers Squibb, Eisai, Lundbeck, Otsuka, Sanofi, Servier, in the last 3 years.

Holly A. Swartz has received royalties from UpToDate in the last 3 years.

Thierry Bottai has no conflict of interest.

Philippe Courtet has received consulting fees and honoraria from AstraZeneca, Bristol Myers-Squibb, Lundbeck, Sanofi, Servier, Pierre Fabre, Pfizer in the last 3 years.

Frank Bayle has received consulting fees and honoraria from Janssen-Cilag, Eutherapie, Lundbeck, Phi laboratories in the last 3 years.

Pierre-Michel Llorca has received consulting fees and honoraria from AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Servier, Lundbeck and Sanofi in the last 3 years.

Guillaume Vaiva has received consulting fees and honoraria from AstraZeneca, Bristol Myers-Squibb, Janssen, Lundbeck, Servier in the last 3 years.

Ellen Frank has received consulting fees and honoraria from Servier, a consulting fee from Vanda Pharmaceuticals, honoraria from Lundbeck and royalties from Guilford Press and American Psychological Association Press in the last 3 years.

Philip Gorwood has received consulting fees and honoraria from AstraZeneca, Bristol Myers-Squibb, Lundbeck, Sanofi, and Servier in the last 3 years.

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