Are depression trials generalizable to clinical practice? Something clinicians always wanted to know about RCTs, but were afraid to ask.....

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Chapter 5

Sociodemographic features of participants in randomized controlled trials for major depression: Generalizability and individualization

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ABSTRACT

Rationale, Aims and Objectives: It is important for clinicians to know to what extent the results of randomized controlled trials (RCTs) are generalizable to their psychiatric practice, since RCTs are considered to be the most reliable source of evidence for treatment guideline development. Furthermore, it is important to know whether results from individual randomized controlled trials (RCTs) can be directly compared to each other. Sociodemographic and socioeconomic (SES) features influence treatment outcome in major depressive disorder (MDD). Differences in (reporting of) SES features of participants in RCTs will hamper comparison and jeopardize the external validity (generalizability) of their results. We explored the reporting of SES features in RCTs for depression.

Methods: We selected 45 antidepressant efficacy trials (AETs) and 19 psychotherapy efficacy trials (PETs). We listed the reported sociodemographic and -economic features.

Results: Reporting on SES features was very diverse and often limited. Especially important SES features like educational level, socioeconomic status and income were reported insufficiently. The mean age of RCT participants in MDD trials was 41 years. Participants are predominantly female (62%) and white (89%). Of the participants 61% were employed and 45% of the participants were married/cohabitating.

Conclusions: Standardisation of reporting on sociodemographic and socioeconomic status is needed to adequately judge the generalizability of RCTs to daily practice and to facilitate comparisons within the body of RCTs.

INTRODUCTION

Major depression is one of the most common psychiatric disorders, affecting about 121 million people worldwide [1]. Improvement of the quality of depression treatment would be beneficial to many people [2-4]. During the past decades, the selection of treatment for patients suffering from depression has shifted from an approach based on clinical expertise towards evidence based medicine. This has resulted in guidelines based on results from randomized controlled trials (RCTs) of antidepressants and/or psychotherapy [5,6]. There are long standing concerns regarding the generalizability of the results from the strictly controlled RCTs to the treatment of patients in "real world" clinical practice [7-12]. Patients in routine clinical practice have been shown to differ from patients included in RCTs on a number of clinical features, like the severity of symptoms or the presence of co morbidity or suicidality. These clinical differences between RCT participants and daily practice patients are mainly caused by selection bias due to the use of eligibility criteria [13-17]. However, beyond the use of clinical eligibility criteria, there are other forms of (probably unintended) selection bias which might jeopardize the external validity (i.e. generalizability) of RCTs. Patients may be eligible, but still not willing to participate in RCTs for several reasons, for instance a preference for a treatment modality. Furthermore, due to recruitment and inclusion procedures, participants in RCTs might also differ importantly from "real life" patients with respect to sociodemographic and socioeconomic background [7].

Previous research in both general medicine and psychiatry has shown that socio-demographic and socioeconomic features influence the outcome of treatment. Lower socioeconomic status and increased age were associated with poorer treatment outcome and mortality in several medical conditions [18,19]. In psychiatry, several studies on the influence of age and gender on the outcome of antidepressant treatment showed a negative association with increased age and the male gender [20-26]. In three studies increased age was not associated with poorer treatment outcome of psychotherapy for depression [27-29], and in one study, male gender was associated with better treatment outcome in psychotherapy for depression [28]. In pharmacotherapy, being married and a better socioeconomic or employment status predicted better outcomes. In psychotherapy, employment had no influence [25-28,30-33]. Remarkably, level of education was predictive for outcome neither in pharmacotherapy nor in psychotherapy [20,23,27,33-37]. Furthermore, patients with different ethnic backgrounds seem to benefit equally from pharmacotherapy and psychotherapy, yet in certain ethnic minorities treatment adherence was found to be significantly worse [38-43].

As sociodemographic and socioeconomic features (SES features) may influence treatment results, clinicians should be able to compare their "real life" patients with the participants of the trials in order to assess the generalizability of the results of the trials to their own population. Therefore, the quality of the reporting of SES features in RCTs is

of importance. For this paper we reviewed the reporting of SES features in RCTs on major depression.

METHODS

Literature Review

Inclusion: We included peer reviewed publications of RCTs, published through 2007 in outpatients with a unipolar, non-psychotic depression according to DSM-III-R or DSM-IV (major depressive disorder MDD). Because we aimed to review the reporting of sociodemographic and socioeconomic features in RCTs usually selected for the development of guidelines for routine treatment, we excluded trials which a priori included only participants from specified subgroups like elderly or a specific ethnic minority. For the same reason, we also excluded augmentation trials, trials that focused on refractory depression, or trials limited to patients with a particular co morbid condition such as alcoholism, anxiety disorder, or medical illness. Furthermore, it was essential that the publication provided baseline information on sociodemographic and/or socioeconomic features. When there were several publications from the same trial, we included the report that provided the most detailed information on sociodemographic and/or socioeconomic features. When the reports on a trial provided the same information, we included the first report. We included trials written in English, since international guidelines for treatment of MDD are predominantly based on English literature.

Psychotherapy: We performed a Medline search for RCTs investigating psychotherapy (cognitive behavioral therapy and interpersonal therapy) for adult patients suffering from MDD. Furthermore, we performed an additional search in PsycInfo and checked the reference lists of included trials for other relevant studies as well as the database http://www.psychotherapyrcts.org. This website contains a database of RCTs and comparative studies examining the effect of psychotherapy on adult depression, collected by a group of researchers from the VU University in Amsterdam, the Netherlands, and Linköping University in Sweden. We selected the psychotherapy efficacy trials (PETs) in which outpatient treatment was investigated and in which either only individual cognitive behavioral therapy (CBT) or individual interpersonal therapy (IPT) was the intervention or control group, as these two treatments are usually incorporated in treatment guidelines.

Pharmacotherapy: Because of the large number of published antidepressant efficacy trials (AETs), we restricted our search to AETs published in journals from the top ten Impact Ranking psychiatric journals of 2005. By including only high impact factor journals, we expected to have a sample of trials with the most systematic manner of reporting SES features. The journals

were Archives of General Psychiatry; Molecular Psychiatry; American Journal of Psychiatry, Biological Psychiatry; Neuropsychopharmacology; Journal of Psychopharmacology; Journal of Clinical Psychiatry; Psychotherapy/Psychosomatics; the British Journal of Psychiatry and Sleep. We added Psychopharmacology Bulletin to our selection of journals, since AETs from this journal are frequently cited in literature on antidepressants. We excluded trials with experimental medication such as dexamethason or valproate.

Sociodemographic and socioeconomic features

For the included RCTs, we explored the sociodemographic and socioeconomic features of the intent-to-treat samples. If intent-to-treat data were missing we used the data of the completers. We determined the most frequently described features and their operationalisation. If the operationalisation of the sociodemographic and socioeconomic features in a study was not well defined, we tried to contact the authors for further information. We converted the reported SES features into dichotomous or trichotomous variables.

Statistics

Descriptive summary statistics (means, frequencies, percentages) were used to describe the baseline sociodemographic and socioeconomic features of the RCT patients. These procedures were performed in SPSS 16.0. As standard deviations for continuous variables (age) were often missing in trials, we corrected for sample size by dividing the sum of all "mean age x number of patients in a trial" by the total number of patients of all trials.

RESULTS

Review of sociodemographic and socioeconomic features used in RCTs

Based on our criteria and search strategy, we included 64 published RCTs; 45 AETs and 19 PETs. We found no PETs published after 2007 meeting our inclusion criteria, and therefore also limited the inclusion of AETs to those published before 2008. Table 1 shows a list of the included trials. The total number of patients who participated in these trials is 9694; 8838 patients in the AETs group and 856 patients in the PETs group. Table 2 provides an overview of the eight most frequently described sociodemographic and socioeconomic features that were used in the 64 studies. Remarkably, only three features were reported in at least half of the included trials: mean age (n=62, 96.9%), gender (n=63, 98.4%) and race or ethnicity (n=41, 64.1%). The operationalisation of sociodemographic and socioeconomic status, which varied greatly among the studies for some features, will be discussed below.

Table 1. List of included trials.

	Title of trial	First Author	Year of Publication	Journal
1	Comparative efficacy of CT and pharmacotherapy in the treatment of depressed outpatients	Rush	1977	Cognitive therapy and research
2	Differential symptom reduction by drugs and psychotherapy in acute depression	Dimascio	1979	Archives of General Psychiatry
3	The efficacy of CT in depression: a treatment using CT and pharmacotherapy, each alone and in combination	Blackburn	1981	British Journal of Psychiatry
4	Group versus individual cognitive therapy: a pilot study	Rush*	1981	Cognitive therapy and research
5	Comparative efficacy of behavioral and cognitive treatments of depression	Wilson	1983	Cognitive therapy and research
6	Cognitive therapy and pharmacotherapy: singly and together in the treatment of depression	Murphy	1984	Archives of General Psychiatry
7	Treatment of depression with cognitive therapy and amitriptyline	Beck	1985	Archives of General Psychiatry
8	Individual and group treatment of unipolar depression: comparison of treatment outcome and identification of predictors of successful treatment outcome	Teri	1986	Behavior Therapy
9	NIMH treatment of Depression Collaborative Research Program: General effectiveness of treatments	Elkin	1989	Archives of General Psychiatry
10	Cognitive therapy and pharmacotherapy for depression: singly and in combination	Hollon	1992	Archives of General Psychiatry
11	Responsivity to cognitive therapy as a function of treatment format and client personality dimensions	Zettle	1992	Journal of Clinical Psychology
12	A comparison of venlafaxine, trazodone and placebo in major depression	Cunningham	1994	Journal of Clinical Psychopharmacology
13	Dothiepin versus doxepin in major depression: results of a multicenter, placebo-controlled trial	Ferguson	1994	Journal of Clinical Psychiatry

	Title of trial	First Author	Year of Publication	Journal
14	A double-blind comparison of nefazodone, imipramine, and placebo in major depression	Fontaine	1994	Journal of Clinical Psychiatry
15	Comparison of venlafaxine and imipramine in the acute treatment of major depression in outpatients	Schweizer	1994	Journal of Clinical Psychiatry
16	Is baseline agitation a relative contraindication for a selective serotonin reuptake inhibitor: A comparative trial of fluoxetine versus imipramine	Tollefson	1994	Journal of Clinical Psychopharmacology
17	Comparison of bupropion and trazodone for the treatment of major depression	Weisler	1994	Journal of Clinical Psychopharmacology
18	A double-blind multicenter trial comparing sertraline and fluoxetine in outpatients with major depression	Bennie	1995	Journal of Clinical Psychiatry
19	A Double-blind comparison of org 3770, amitriptyline, and placebo in major depression	Bremner	1995	Journal of Clinical Psychiatry
20	Sertraline safety and efficacy in major depression: a double-blind fixed-dose comparison with placebo	Fabre	1995	Biological Psychiatry
21	Cognitive behavior therapy, relaxation training, and tricyclic antidepressant medication in the treatment of depression	Murphy	1995	Psychological reports
22	A multicenter double-blind comparison of nefazodone and paroxetine in the treatment of outpatients with moderate-to-severe depression	Baldwin	1996	Journal of Clinical Psychiatry
23	Fluvoxamine maleate in the treatment of depression: A single-center, double-blind, placebo-controlled comparison with imipramine in outpatients	Claghorn	1996	Journal of Clinical Psychopharmacology
24	Responders to antidepressant drug treatment: a study comparing nefazodone, imipramine, and placebo in patients with major depression	Cohn	1996	Journal of Clinical Psychiatry
25	An open-label trial of nefazodone in high co morbidity panic disorder	DeMartinis	1996	Journal of Clinical Psychiatry
26	Nefazodone versus sertraline in outpatients with major depression: focus on efficacy, tolerability, and effects on sexual function and satisfaction	Feiger	1996	Journal of Clinical Psychiatry

	Title of trial	First Author	Year of Publication	Journal
27	A double-blind comparison of gepirone extended release, imipramine, and placebo in the treatment of outpatient major depression	Feiger	1996	Psychopharmacology Bulletin
28	A comparison of fluvoxamine and fluoxetine in the treatment of major depression	Rapaport	1996	Journal of Clinical Psychopharmacology
29	Zalospirone in major depression: A placebo-controlled multicenter study	Rickels	1996	Journal of Clinical Psychopharmacology
30	A double-blind trial of low- and high-dose ranges of gepirone-ER compared with placebo in the treatment of depressed outpatients	Wilcox	1996	Psychopharmacology Bulletin
31	Double-blind comparison of bupropion sustained release and sertraline in depressed outpatients	Kavoussi	1997	Journal of Clinical Psychiatry
32	A double-blind comparison of fluvoxamine and paroxetine in the treatment of depressed outpatients	Kiev	1997	Journal of Clinical Psychiatry
33	A double-blind, placebo-controlled study comparing the effects of sertraline versus amitriptyline in the treatment of major depression	Lydiard	1997	Journal of Clinical Psychiatry
34	Factors that influence the outcome of placebo-controlled antidepressant clinical trials	Niklson	1997	Psychopharmacology Bulletin
35	Desipramine versus phenelzine in recurrent unipolar depression: Clinical characteristics and treatment response	Swann	1997	Journal of Clinical Psychopharmacology
36	Efficacy and tolerability of once-daily venlafaxine extended release (XR) in outpatients with major depression	Thase	1997	Journal of Clinical Psychiatry
37	Once- versus twice- daily venlafaxine therapy in major depression: a randomized, double-blind study	Amsterdam	1998	Journal of Clinical Psychiatry
38	A double-blind, randomized trial of sertraline and imipramine	Keller	1998	Journal of Clinical Psychiatry
39	A Canadian multicenter study of three fixed doses of controlled-release ipsapirone in outpatients with moderate to severe major depression	Lapierre	1998	Journal of Clinical Psychopharmacology
40	Factors that influence the outcome of placebo-controlled antidepressant clinical trials	Rudolph	1998	Psychopharmacology Bulletin

	Title of trial	First Author	Year of Publication	Journal
41	Randomized, double-blind comparison of venlafaxine and fluoxetine in outpatients with major depression	Silva	1998	Journal of Clinical Psychiatry
42	Mirtazapine: Efficacy and tolerability in comparison with fluoxetine in patients with moderate to severe major depressive disorder	Wheatley	1998	Journal of Clinical Psychiatry
43	Multicenter, placebo-controlled, fixed-dose study of citalopram in moderate-to-severe depression	Feighner	1999	Journal of Clinical Psychiatry
44	Treatment of atypical depression with cognitive therapy or phenelzine	Jarrett	1999	Archives of General Psychiatry
45	Mirtazapine compared with paroxetine in major depression	Benkert	2000	Journal of Clinical Psychiatry
46	Randomized, double-blind comparison of venlafaxine and sertraline in outpatients with major depressive disorder	Mehtonen	2000	Journal of Clinical Psychiatry
47	Placebo-controlled comparison of the selective serotonin reuptake inhibitors citalopram and sertraline	Stahl	2000	Biological Psychiatry
48	Efficacy and response time to sertraline versus fluoxetine in the treatment of unipolar major depressive disorder	Suri	2000	Journal of Clinical Psychiatry
49	Duloxetine, 60mg once daily, for major depressive disorder: a randomized double-blind placebo-controlled trial	Detke	2002	Journal of Clinical Psychiatry
50	Efficacy and tolerability of controlled-release and immediate-release paroxetine in the treatment of depression	Golden	2002	Journal of Clinical Psychiatry
51	Duloxetine in the treatment of major depressive disorder: a double-blind clinical trial	Goldstein	2002	Journal of Clinical Psychiatry
52	Outcomes of patients completing and not completing cognitive therapy for depression.	Cahill	2003	British Journal of Clinical Psychology
53	Comparing Effectiveness of Process Experiential with CBT in the treatment of depression	Watson	2003	Journal of Consulting and Clinical Psychology
54	A double-blind comparison of escitalopram and venlafaxine extended release in the treatment of major depressive disorder	Bielski	2004	Journal of Clinical Psychiatry

	Title of trial	First Author	Year of Publication	Journal
55	Duloxetine in the treatment of depression: a double-blind placebo-controlled comparison with paroxetine	Goldstein	2004	Journal of Clinical Psychopharmacology
56	Effectiveness of low doses of paroxetine controlled release in the treatment of major depressive disorder	Trivedi	2004	Journal of Clinical Psychiatry
57	Cognitive therapy vs medications in the treatment of moderate to severe depression	Derubeis	2005	Archives of General Psychiatry
58	Randomized trial of sertraline versus venlafaxine XR in major depression: efficacy and discontinuation symptoms	Sir	2005	Journal of Clinical Psychiatry
59	Efficacy and tolerability of reboxetine compared with citalopram: a double-blind study in patients with major depressive	Langworth	2006	Journal of Clinical Psychopharmacology
60	A randomized, double-blind, active-control study of sertraline versus venlafaxine XR in major depressive disorder	Shelton	2006	Journal of Clinical Psychiatry
61	Self-system therapy as an intervention for self-regulatory dysfunction in depression: a randomized comparison with cognitive therapy	Strauman	2006	Journal of Consulting and Clinical Psychology
62	Attachment as moderator of treatment outcome in major depression: a RCT of IPT versus CBT	McBride	2006	Journal of Consulting and Clinical Psychology
63	Combination treatment for acute depression is superior only when psychotherapy is added to medication	Blom	2007	Psychotherapy and Psychosomatics
64	RCT of interpersonal psychotherapy and cognitive-behavioural therapy for depression	Luty	2007	British Journal of Psychiatry

Table 2. Reporting of sociodemographic/socioeconomic features in RCTs.

Sociodemographic/ socioeconomic characteristic	Number of trials reporting on the feature (%)
Age (mean)	62 (96.9%)
Gender	63 (98.4%)
Race/ethnicity	41 (64.1%)
Marital status	23 (35.9%)
Employment status	12 (18.8%)
Education	17 (26.6%)
Income	3 (4.7%)
SES	3 (4.7%)

Age

Sixty-two (97%) trials reported a mean age for their study population. Of the two trials who did not report a mean age, one trial divided the population in age categories (<30, 30–39, >39 years of age). The mean age of the participants in RCTs was 41 years. The AET participants had a mean age of 41 years, the PETs participants of 37 years.

Gender

There were 63 trials (98%) that described the distribution of the population by gender. Patients were predominantly female (62% woman versus 38% man). In AETs 61% of the patients were women. In the PETs 72% of the participants were female.

Race and ethnicity

There were 41 trials (64%) that reported race or ethnicity of the study population. Of these trials, two only gave a short description of race, for example: predominantly Caucasian. The other 39 studies used 16 different ways to define race/ethnicity. The most frequently used definition of race was white/non-white. Seventeen of the 39 trials used this definition (44%). Furthermore, the following descriptions were used: European; (non) Caucasian; Hispanic or Latino; African-descent or African American or Black; Asian or Oriental; Middle Eastern; Other Ethnicity. We converted the reported information on race or ethnicity into the dichotomous variable white/non-white. We considered Hispanic as "white", since two out of three authors of the RCTs, who we contacted, responded that they had considered Hispanic as "white". Latino, European and Caucasian are also considered to be "white" [44-46]. For this analysis, we considered "non-Caucasian, African descent, African American, black, Asian, middle Eastern, Oriental and other" as "non-white". Patients in AETs and PETs were predominantly white. The percentage of patients considered "non-white" in the AETs group was 11%. In the PETs this percentage was 15%.

Marital status

Twenty-three trials (36%) reported the marital status of their patients. Fourteen different definitions were used to describe the marital status. The most frequently used definition, which was used, only four times, was: married/not-married. We dichotomised marital status into "married/cohabitating" – "not married". In the RCT population 45% of the participating patients were married/cohabitating. Of the patients participating in AETs 46% was married/cohabitating. In PETs, 43% of the participants were married/cohabitating.

Employment

Only twelve (19%) trials reported information on employment status. Seven different types of definition were used to define employment status. The two most commonly used ways of reporting were: "employed-unemployed" (25%) and "percentage employed participants" (25%). We converted all reported information on employment status into: "paid work" – "non-paid work". We considered the subcategories "unemployed", "homemaker", "house person", "housewife", "student" and "retired" as "non-paid work". One trial [47] reported categorical information on employment status, which could not be converted into the dichotomous variable "paid work"- "non-paid work." The percentage of people with paid work in AETs was 59% and in PETs 66%.

Education

Seventeen trials (27%) reported information on educational level. Approximately half of these trials described the educational level by years of education (n=9). The other half described the educational level by means of categories (n=7). One trial used both ways to describe the educational level. All seven trials describing the educational level by means of categories used different definitions. We converted the reported information on educational level of all trials into a trichotomous variable: high school or less – some college education – college graduate or more. Two trials reported information that could not be converted into a trichotomous variable. This exclusion resulted in too few trials (n=5) to reliably estimate the educational level of the RCT population.

Socioeconomic status

Only three trials (5%) reported socioeconomic status (SES). Two trials used the Hollingshead and Redlich's two-factor index of social position. This index refers a person's social class to that of his family and is determined with reference to the education and occupation of the family head plus the location of the family place of residence. Five class levels are distinguished, with level five being the lowest class and level one the highest [48]. One trial used the Blishen index [49] to describe the social economic status. This index is based on the Canadian Census and uses 514 occupational categories according to the Canadian

Classification and Dictionary of Occupations. Indicators of prevailing education and income levels are derived for each occupational category. A lower index indicates a lower SES.

Income

Only three trials (5%) reported information on income. Two trials reported income/year as a continuous variable (amount of money/year), one trial reported income as a categorical variable (<8.000, 8.000–16.000, >16.000 US Dollar per year). Too few selected trials reported on income to estimate the income of the RCT population.

The sociodemographic and socioeconomic features of the RCT participants are described in table 3.

Table 3. Sociodemographic/socioeconomic features of RCT participants.

	RCT (n=64)	**AET (n=45)**	**PET (n=19)**
Age (years)	41	41	37
Gender (% female)	62	61	72
Ethnicity (% "non-white")	11	11	15
Marital status (% married/cohabitating)	45	46	43
Employment status (% employed)	61	59	66
Educational level	Reported only in 8% of included trials	-	-
Socioeconomic status	Reported only in 5% of included trials	-	-
Income	Reported only in 5% of included trials	-	-

DISCUSSION

To our knowledge, this is the first review on the reporting and operationalisation of sociodemographic and socioeconomic features of participants in antidepressant efficacy trials (AET) and psychotherapy efficacy trials (PET) in major depression.

Remarkably, we found that in RCTs the reporting and operationalisation of sociodemographic and socioeconomic features turned out to be very diverse and for socioeconomic variables often very limited, even in the high impact factor journals. Only age, gender and race were reported in the majority of studies. All other features were reported in less than 40% of the trials and often operationalised in very different ways. The lack of standardisation in defining sociodemographic and socioeconomic variables and their insufficient reporting in RCTs may be explained by the fact that interest in the relation of social economic status and treatment outcome is relatively young. Only recently, RCTs have

been carried out in specific populations like low-income women [50] and ethnic minorities [51,52]. RCTs in specific subgroups is one way to address the influence of socioeconomic features on treatment outcome in MDD, yet more interest for SES features in "general" trials is needed, since guidelines are based on results from these trials. Furthermore, our findings suggest that there are differences between AET participants and PET participants with respect to several sociodemographic and socioeconomic features. In meta-analyses results from AETs and PETs are often directly compared, without controlling for SES features as marital status, educational level, employment status etc., since these features are not reported in trials. SES features are known to influence outcome, and therefore one risks to introduce confounders in the comparison between AETs and PETs. Several factors may explain differences in the SES features between participants in AETs and PETs, for example patients' preferences for certain types of treatment, or the use of specific eligibility criteria in AETs, like the exclusion of women who are pregnant or do not use contraceptives.
Both clinical practice and scientific research would benefit from uniform reporting of a standard set of SES features. In this way, estimation of the generalizability of results of RCTs to daily practice, comparison between RCTs and future research on the influence of SES features on outcome is facilitated.

There are some limitations to our study to consider. We performed a restricted search for AET's, which may not fully represent the available literature. However, the fact that we found significant underreporting of SES features in the AETs from the included high impact factor journals suggests that that underreporting of SES features in AETs in the whole body literature might be even worse. On the other hand, we found no association between the impact factor of the journal and the reporting of sociodemographic features.

We only included RCTs published till 2008, as we did not find PETs after 2007 that met our selection-criteria. It is possible that the reporting of sociodemographic and socioeconomic features has improved after 2007. We examined a sample of AETs published after 2007 [53-59] that met our exclusion criteria. In these studies published after 2007 we found a similar variety of reporting. Finally, it is important to note that when discussing the generalizability of results of RCTs to daily practice, one might easily overlook the fact that RCTs are explicitly designed to provide relative outcomes (differences between active treatment and placebo), rather than absolute effects of treatment. However, as treatment guidelines are based on the results from RCTs and used in daily practice, where the absolute treatment effect is far more important than the relative effect, it is very important for clinicians to know to what extent RCT participants resemble their "real life" patients.

CONCLUSIONS

Previous research has shown that SES features of patients can influence treatment outcome in depression. RCTs for treatments of depression do not adequately report on SES features. A uniform reporting of a standard set of sociodemographic and socioeconomic features is recommendable; especially on those features that are already known to be associated with treatment outcome (age, gender, marital and employment status). This would facilitate comparisons not only within the body of RCTs, but especially of RCT populations with 'real-life' populations, which would clearly benefit daily practice and guideline development.

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