Case management for persons with substance use disorders
(Protocol)

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Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

1) to evaluate the effectiveness of case management for persons with substance use disorders;
2) to determine whether and which aspects of this intervention influence its effectiveness.

Background

According to the World Health Organization, the prevalence of current alcohol dependence in the European Union is estimated to be between 3.8 (Germany) and 12.2% (Poland) of the adult population, while these percentages are around 7.7 and 9.3% in the United States and Canada respectively (WHO, 2004). Concerning illicit drug use, the most recent figures indicate that the prevalence of opiate abuse among persons from 15 to 64 years old is around 0.5% in most Western countries (EU, US, Canada and Australia) (UNODC, 2005). The prevalence of cocaine abuse is estimated around 1% in the European Union and Australia, but over 2% in Canada and around 3% in the US. The prevalence of amphetamine abuse is generally lower than 1%, but cannabis abuse rates over 10% in several large European countries, Canada, the US and Australia (UNODC, 2005).

Substance use disorders [SUD] are associated with a wide range of serious health, social and economic complications. The health status of alcohol and drug abusers is generally affected by their abuse (de Alba, Samet, & Saitz, 2004). Consequently, their life expectancy is often much lower than among the general population (Price, Risk, Murray, Virgo, & Spitznagel, 2001; Sørensen, Jepsen, Haastrup, & Juel, 2005; Wahren, Brandt, & Allebeck, 1997). People with alcohol or drug abuse are less likely to be working (Ettner, Frank, & Kessler, 1997) and alcohol addiction is associated with prematurely leaving the workforce (Romelsjo, Stenbacka, Lundberg, & Upmark, 2004). Housing, relational and judicial problems are also well documented among substance abusers. Drug and alcohol abuse further cause high costs due to frequent and multiple hospitalisations and treatment episodes (Xie, Rehm, Single, Robson, & Paul, 1998a, 1998b). Despite the multi-faceted and complex nature of substance abuse problems, few treatment programs are equipped to provide the expanded array of services necessary to meet clients’ diverse needs (Brindis & Theidon, 1997). Moreover, since substance abuse is increasingly recognised as a chronic and relapsing disorder (McLellan, 2002), ongoing support services and continuing care are necessary to assist clients in stabilizing and overcoming their problems.

The observation that many substance abusers have significant long-lasting problems in addition to abusing substances has been the main impetus for using case management as an enhancement and supplement to traditional substance abuse treatment services (Vanderplasschen, Rapp, Wolf, & Broekaert, 2004). Case management has a long and relatively successful history for the treatment and support of several mental health populations in the United States, Australia, Canada and several European countries (Burns, Fioritti, Holloway, Malm, & Rössler, 2001). From the mid-1980’s on, this intervention was adapted to work with persons with substance use disorders and has been
applied among several specific populations, such as dually diagnosed persons, chronic public inebriates and substance abusing mothers.

Case management is a client-centred strategy to improve the coordination and continuity of the delivery of services, especially for persons with multiple and complex needs. One of the first definitions has described this intervention as “that part of substance abuse treatment that provides ongoing supportive care to clients and facilitates linking with appropriate helping resources in the community” (Graham & Birchmore-Timney, 1989). Case management is usually characterized by its basic functions: assessment, planning, linking, monitoring and advocacy (SAMHSA, 2002). Despite the lack of a common definition and divergent practices from place to place, following models of case management are usually distinguished for working with substance abusers: 1) brokerage case management; 2) generalist/intensive case management; 3) assertive community treatment; 4) clinical case management; 5) strengths-based case management (Vanderplasschen et al., 2004).

The brokerage model is a very brief approach to case management in which case workers attempt to help clients identify their needs and broker ancillary or supportive services, all in one or two contacts. Generalist or standard models utilize the commonly accepted functions of case management (assessment, planning, linking, monitoring, advocacy) and are characterized by a closer involvement between case manager and client. Similarly, intensive case management applies the same principles, usually with a smaller caseload and greater intensity of service provision. Assertive Community Treatment (ACT) consists of a “wrap-around set of services” and assumes a comprehensive role for a team of case managers by providing assertive outreach and direct counselling services, including skills-building, family consultations and crisis intervention. The clinical approach combines resources acquisition (case management) and clinical activities, which might include psychotherapy for clients and their families. Finally, strengths-based case management focuses on clients’ strengths, self-direction, and the use of informal help networks (as opposed to agency resources). It further stresses the primacy of the client-case manager relationship and applies an active form of outreach.

As opposed to case management for persons with (severe) mental illness (Zwarenstein, Stephenson, & Johnson, 2000), no meta-analysis has yet been published on the effectiveness of this intervention for persons with substance use disorders (Vanderplasschen, Wolf, Rapp, & Broekaert, in press). Therefore, the aim of this review is to examine the evidence for the effectiveness of case management for persons with substance use disorders and to identify which aspects of this intervention influence its effectiveness. Social, health and economic outcome measures will be included.

Objectives

The specific objectives of this review are:
1) to assess whether case management reduces substance use and improves quality of life compared with other forms of treatment, including “treatment as usual”, standard community treatment, other psychosocial interventions or waitlist controls;
2) to evaluate whether case management links patients with the services they need and whether this linkage is related to the effects of case management.
3) to study whether other potential mediating variables (e.g. length or model of case management, retention in treatment, use of pharmacotherapy) affect case management-outcomes.

Criteria for considering studies for this review

Types of studies

Randomized controlled trials that compare a specific case management model with “treatment as usual” or other forms of treatment.

Types of participants

Persons with substance use disorders (abuse or dependence of any substance). Studies including people with other mental disorders are eligible, if substance use disorders are present in the entire sample.

Types of intervention

Experimental intervention

Any model of case management (brokerage model, generalist/intensive case management, assertive community treatment, clinical case management, or strengths-based case management)

Control intervention

“Treatment as usual”, standard community treatment, other psychosocial interventions or waitlist controls

Types of outcome measures

Primary outcomes

Since case management is a comprehensive intervention with multiple aims, primary outcomes will be defined as the 7 problem areas covered by the Addiction Severity Index (ASI) (McLellan et al., 1985), extended with living situation. For each of the problem areas, some possible outcome measures are described below, which will not necessarily be measured by the Addiction Severity Index (ASI):

- Drug use (e.g., self-report, biological markers, problem severity measured by ASI, DAST or a similar scale)
- Alcohol use (e.g., self-report, biological markers, problem severity measured by ASI, AUDIT or a similar scale)
- Employment and income (e.g., number of days working, income from work, daily activities, problem severity measured by ASI)
- Physical health (e.g., number of days hospitalised for physical problems, SF-36 Health Questionnaire, problem severity measured by ASI)
• Legal status (e.g., number of days incarcerated, proportion of subjects charged for a (drug-related) offence, problem severity measured by ASI)
• Family/social relations (e.g., extent of the social network, burden for the family, problem severity measured by ASI)
• Mental health (e.g., Hamilton rating scale for depression, Beck depression inventory, Symptom Check List 90, problem severity measured by ASI)
• Living situation (e.g., number of days in own house, number of days in sheltered/protected living facility, housing stability)

In case an outcome measure is reported, a single effect size will be computed for each study, by averaging the effect sizes for each problem area.

Secondary outcomes
While primary outcomes can be mainly situated at the level of the individual, secondary outcomes rather relate to structural achievements:
• Treatment participation and retention
• Service utilization, not including case management services
• Rehospitalisation, including emergency room utilisation
• Satisfaction with the intervention received

If studies report outcomes over various time periods, these will be grouped into short (≤ 6 months) and medium-term outcomes (> 6 months).

Search strategy for identification of studies
Both electronic and manual searches will be undertaken to identify studies for this review.

See: Drugs and Alcohol Group search strategy.

The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (on Silver Platter), EMBASE (on OVID), PsycINFO, LILACS and Toxibase will be searched using the following search strategies. There will be no language or publication year restrictions. The search strategy for EMBASE is described below:

Search strategy for EMBASE database:

1. exp Addiction/
2. exp Drug Abuse/
3. ((drug or substance) and (abuse$ or misuse$ or addict$ or dependen$))
4. 1 or 2 or 3
5. exp cocaine/ or exp cocaine derivative/
6. exp Diamorphine/
7. heroin.ti,ab.
8. *Opiate/
9. exp *Benzodiazepine derivative/ or benzodiazepine$.ti,ab.
10. exp *Amphetamine derivative/ or Amphetamine
11. exp alcohol/ or alcohol.ab,ti.
combined with the following search filter for retrieving RCTs. (For Medline, we will use the phases 1 & 2 of the Cochrane Sensitive Search Strategy for the identification of RCTs as published in Appendix 5b2, Cochrane Handbook for Systematic Reviews of Interventions)

31. random$.ab,ti.
32. placebo.ab,ti.
33. randomized controlled trial/
34. phase-2-clinical-trial/
35. phase-3-clinical-trial/
36. single blind procedure/
37. crossover procedure/
38. Latin square design/
39. exp PLACEBOS/
40. multicenter study/
41. controlled$.sh.
42. 30/40 OR
43. 30 and 42
44. limit 43 to human

In addition, the reference lists of retrieved studies, reviews, conference abstracts and grey literature will be scanned for other relevant (un)published studies. A search of the registry of trials will be done for identifying ongoing studies. If possible, authors of included studies and experts in the field in various countries will be contacted to find out if they know any other published or unpublished controlled trials that assess the effectiveness of case management for persons with substance disorders. Large research organizations (e.g. NIAAA, NIDA, NDARC, NAC) will be contacted for advice on their trials concerning case management.
Methods for the review

For conducting the review, two groups of researchers (one located in Belgium, referred to as the “S” group, and one located in Copenhagen and Lund, called the “N” group) will screen and rate the identified and selected studies independently from each other. Below, we indicate with N and S codes who will do the specific parts of the review.

1. Study selection (N + S)

Studies are eligible for selection if:

a. a specific model of case management is evaluated. Studies can be selected if the intervention is called case management in the report or article and/or consists of at least 4 of the 5 basic functions of case management as defined by an American consensus panel of experts (SAMHSA, 2002). As compared with other interventions, crucial and differential elements appear to be: monitoring and linking. If it remains unclear whether an intervention can be considered as case management according to our criteria, the original authors of the study will be contacted.

b. a randomised controlled design is used, in which groups are randomly assigned to the experimental and control group;

c. the sample consists of persons with substance use disorders;

d. at least one primary outcome measure, as defined in this protocol, is reported;

e. the randomisation concerns case management only. Trials in which the experimental and control group receive different treatments in other respects, e.g. different pharmacological interventions or differ with regard to being randomized to psychotherapy, inpatient treatment or other interventions that are not case management, will be excluded.

Two groups of two reviewers will screen the titles and abstracts of all papers initially identified by the electronic and hand searches, in order to reject studies that clearly do not meet the review’s inclusion criteria. Next, the full texts of all studies that were identified as potentially eligible will be studied. The two groups of reviewers will evaluate independently from each other whether a study should be included or not. In case of any disagreement, a third reviewer (R.C. Rapp) will be consulted.

All searches will include non-English literature as well. Studies with English abstracts will be assessed for inclusion applying the same strategy and criteria. If a study meets the inclusion criteria but is in a language which is not understood by any of the reviewers, the full text of the manuscript will be translated.

2. Quality rating (N + S)

The methodological quality will be evaluated using the Methodological Quality Scale (MQS) developed by Miller and co-workers (Miller & Wilbourne, 2002). This quality rating scale consists of 12 items, covering various methodological aspects of a clinical trial: method of allocation, means for quality control, follow-up rate, follow-up length, type of follow-up contact, use of collateral information, objective verification of the data, inclusion
of treatment dropouts in the analyses, dealing with attrition, use of independent interviewers, statistical analyses are appropriate, application of a multi-site design (cf. table 1).
### Table 1: Overview of methodological items included in the Methodological Quality Scale (MQS) (Miller & Wilbourne, 2002)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Group allocation</strong></td>
<td>4 true randomization</td>
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<td></td>
<td>3 within-subject counter-balanced</td>
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<td></td>
<td>2 case control/matching</td>
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<td></td>
<td>1 quasi-experimental design; arbitrary/sequential assignment</td>
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<td></td>
<td>0 violated randomization or non-equivalent groups</td>
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<tr>
<td><strong>Quality control</strong></td>
<td>1 treatment standardized by manual, specific training, …</td>
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<tr>
<td></td>
<td>0 no standardization specified</td>
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<tr>
<td><strong>Follow-up rate</strong></td>
<td>2 85%–100% of follow-ups completed</td>
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<td></td>
<td>1 70%–84.9% of follow-ups completed</td>
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<td></td>
<td>0 &lt; 70% of follow-ups completed or follow-up length &lt; 3 months</td>
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<tr>
<td><strong>Follow-up length</strong></td>
<td>2 12 months or longer</td>
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<td></td>
<td>1 6.0–11.9 months</td>
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<tr>
<td></td>
<td>0 6 months or unspecified</td>
</tr>
<tr>
<td><strong>Contact</strong></td>
<td>1 personal or telephone contact for 70% of completed follow-ups</td>
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<tr>
<td></td>
<td>0 questionnaire, unspecified, or &lt; 70% of follow-ups contacted in person or by</td>
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<tr>
<td></td>
<td>phone</td>
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<tr>
<td><strong>Collaterals</strong></td>
<td>1 collaterals (e.g., the client’s significant others) interviewed in 50% of</td>
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<td>the cases</td>
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<tr>
<td></td>
<td>0 no collateral verification in most cases, or unspecified</td>
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<tr>
<td><strong>Objectivity</strong></td>
<td>1 objective verification (records, serum, breath, etc.) in 50% of the cases</td>
</tr>
<tr>
<td></td>
<td>0 no objective verification in most cases, or unspecified</td>
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<tr>
<td><strong>Dropout</strong></td>
<td>1 treatment dropouts included in at least some outcome data (e.g., intent to</td>
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<td>treat analysis; compared on dependent variable, etc.)</td>
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<td>0 treatment dropouts not discussed or not accounted for (e.g., excluded non-</td>
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<td></td>
<td>completers from all analyses)</td>
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<tr>
<td><strong>Attrition</strong></td>
<td>1 cases lost to follow-up enumerated and considered in outcome reporting</td>
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<td>(e.g., counted as failures, compared with non-attrition cases on prior</td>
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<td></td>
<td>characteristics)</td>
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<tr>
<td></td>
<td>0 lost cases not enumerated or merely enumerated but not considered in</td>
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<td></td>
<td>outcome</td>
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<tr>
<td><strong>Independence</strong></td>
<td>1 follow-up done by independent interviewer</td>
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<td></td>
<td>0 follow-up non-blind, unspecified, or questionnaire only</td>
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<tr>
<td><strong>Data-analyses</strong></td>
<td>1 acceptable statistical analyses of group differences</td>
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<tr>
<td></td>
<td>0 no statistical analyses, inappropriate analyses, or unspecified</td>
</tr>
<tr>
<td><strong>Multi-site design</strong></td>
<td>1 parallel replications at two or more sites with separate research teams</td>
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<tr>
<td></td>
<td>0 single site or comparison of sites offering different treatments</td>
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</tbody>
</table>

In addition, allocation concealment will be rated according to the standard Cochrane rating system. This system rates allocation concealment as follows: a) low risk of bias; b) unclear; c) high risk; d) no allocation concealment) (Clarke & Oxman, 2002). These ratings will be supplemented with additional information that is particularly relevant for case management, i.e., the degree of linkage, advocacy, pre-treatment assessment, and monitoring in “standard treatment”.
The quality ratings will be conducted independently by the two teams and will be used in the mediator analyses.

3. Extraction (N + S)

The data extraction will be done independently by both teams. All relevant data on all outcome measures reported will be extracted. For all extracted data, the following information will be coded:

1. Any relevant data for each of the outcome areas described above: For instance, concerning alcohol use: if a study reports the AUDIT, the ASI alcohol severity, and the percentage of abstinent days for each subject, data that allow to compute effect sizes will be registered for each indicator. Data should include either means or standard deviations for both the control and experimental group, a proportion for both the control and experimental group or statistics that allow to calculate an effect size, such as a univariate F-statistic, t-statistic or a $\chi^2$-statistic with only one degree of freedom. For each outcome measure, data will be reported on the degree of change in the experimental and comparison group.

2. Report of any references concerning the validity and reliability of outcome measures: The purpose of this coding is to assess whether outcome measures are likely to be reliable and valid. Lack of such references may not necessarily exclude an outcome measure from the analyses, but each outcome measure that has not been published will be evaluated by the team. Self-report measures such as questionnaires or interviews that have not been published will generally not be included in the analyses.

3. Sample characteristics: the type of substance(s) used and, eventually, the type of co-morbidity will be registered.

4. Service characteristics: This includes information concerning the model of case management, caseload, monitoring of the quality of the intervention, the integration of case management in the network of services.

5. Data omission: We will screen whether or not there is any indication that data were omitted for reporting (e.g., urine specimens were taken for several drugs, but only the effect sizes for one drug were reported; ASI interviews were conducted, but only one composite score was reported). The purpose of this coding is to assess the possible impact of reporting bias on the results.

6. Proportion of eligible subjects who actually entered the study: For, the lower the proportion of eligible subjects who entered the study, the lower the experiment’s external validity.

All effects reported will be included in the meta-analysis. When data were omitted in a publication about a study, the authors of the original study will be contacted to retrieve additional data.

4. Analysis (N)

Analyses will be conducted separately for each outcome measure. In case multiple indicators are reported that are relevant for a single outcome measure (e.g., days abstinent from alcohol, days of heavy drinking, proportion of abstinent subjects), a within-study meta-analysis will be performed to derive a single effect size for each outcome measure for each study. If feasible, measures with unknown or unsatisfactory
psychometric properties will be dropped from such analyses. Exceptions will be: data from registers (e.g., criminal justice records, number of hospital admissions), and data related to persons’ living situation (e.g., homeless status, living in temporary accommodation).

Because the goal of case management is stabilisation and improvement of clients’ situation rather than (necessarily) recovery, we will report effect sizes as standardized mean differences.

All effect sizes will be calculated separately during and after treatment (6-12 months follow-up).

In case of missing data, analyses will be conducted based on the sample size at the follow-up point for which data are present. Random effect models will be used to produce aggregate effect sizes.

For continuous measures, standardized mean differences will be used as effect sizes with Hedges’ correction (Clarke & Oxman, 2002). For dichotomous measures, odds ratios will be used as effect sizes. If a dichotomous measure is reported in a study for an outcome measure that is generally reported as continuous in the analyses, odds ratios will be transformed into Hedges’ $g$ using the formula:

$$g = 2 \times \sqrt{\chi^2/(N-\chi^2)}$$

in which $\sqrt{}$ is the square root, $\chi^2$-the difference between the two proportions, N the number of subjects in the analysis.

A reporting or publication bias is a potential source of uncertainty in any meta-analysis. A publication bias emerges, when several indicators reflecting the same construct are measured, but only the statistically significant effects are reported. This will lead to an inflated effect size, although data are available for meta-analysis. We will note whether data have been omitted to make sure that we attempt to retrieve unpublished data. To establish reasonable boundaries on this file drawer problem, we will calculate the number of unavailable (filed or future) studies averaging null results that would reduce our findings to a non-significant level (Rosenthal, 1991, p. 104).

Moderator analyses will be conducted if Q-tests indicate significant heterogeneity. We will do so by subdividing the effect size groupings (outcome areas) further using categorical moderators.

In order to identify possible factors influencing the results, we have planned a series of subgroup analyses. We will perform the following subgroup analyses for primary outcomes:

1. Model of case management used: brokerage model, generalist/intensive case management, assertive community treatment, clinical case management, or strengths-based case management.

2. Use of pharmacological treatment: trials in which all participants receive opiate agonist treatment (e.g., methadone, buprenorphine or LAAM) vs. studies in which none or only some of the participants receive opiate agonist treatment. Opiate agonist treatment differs from other interventions for substance abusers in a number of ways, including a much higher retention. If effects are found in the presence of opiate agonist treatment programs that would indicate that case management can be successfully implemented
in such programs. If effects are found in medication free programs, case management can be successfully implemented in such programs.

3. Degree of co-occurring mental illness: studies of substance abusers with serious mental illness will be compared with studies including substance abusers without serious mental illness, since various studies on case management have focused on so-called “dually diagnosed patients”.

4. Role of retention and linkage: studies with high effects on retention and linkage \((d>=0.4)\) vs. studies with low effects on retention and linkage \((d<0.4)\). If high retention and linkage is associated with greater effect sizes, it indicates that the effects of case management are mediated through linkage and retention.

5. Degree of change in substance use in the control group (“placebo” response): studies with great improvement in the control group concerning substance use outcomes \((d>=0.4\) for pre/follow-up) vs. studies with little improvement in the control group on such outcomes \((d<0.4\) for pre/follow-up). A high degree of change in the control group can be due to client characteristics (e.g., clients entering treatment at a moment when their problems peaked), or the quality of the services received. In either case, a high degree of change in the control group is likely to mask true effects of case management (Nunes & Levin, 2004).

6. Type of comparison group: studies that compare case management with “treatment as usual” vs. studies that compare it with other viable interventions. While case management may be more effective than referral to regular community or standard services, it may not be differentially more effective than psychotherapy or behavioural interventions, such as contingency management or cognitive-behavioural therapy (Burke, Arkowitz, & Menchola, 2003).

7. High vs. low proportion of eligible patients entering the study, based on a “median split”: if studies that reported a high proportion of eligible patients entering the study found lower effects, it would indicate that case management is difficult to deliver in “real-world situations”, in which agencies are required to provide treatment to patients with multiple and complex problems.

8. Quality of the study: comparison of high and low quality studies (low MQS <10 vs. high MQS ≥10). A number of reviews have found an inverse relation between the quality of the study and the observed effect size in the literature concerning substance abuse (e.g. Burke et al., 2003; Stanton & Shadish, 1997).

While moderator analyses cannot provide definitive answers to questions about differential effectiveness, they may suggest whether methodological features such as study quality have impacted the observed results (Hesse, 2004; Nunes & Levin, 2004).

The results of the meta-analysis will be reported in RevMan forest plots.

**Potential conflict of interest**

Richard C. Rapp is first author and co-author of a number of RCT’s on case management. He will participate as third reviewer in the selection phase and will only be consulted in case of doubt. He will not be involved in the quality rating, data-extraction and data-analysis. He will be involved in the review process for detecting and reclaiming relevant
studies and for contacting case management-experts who are mainly situated in the United States. Other authors have no known conflicts of interest.

Sources of support

External sources of support

The Campbell Collaboration has agreed to pay for travel expenses in connection with meetings necessary for performing this review.

Internal sources of support

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References


