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Transparency of Outcome Reporting and Trial Registration of Randomized Controlled Trials in Top Psychosomatic and Behavioural Health Journals: A Systematic Review

Running Head: Outcome Reporting and Trial Registration

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#### Abstract

**Objective:** The most reliable evidence for evaluating healthcare interventions comes from welldesigned and conducted randomized controlled trials (RCTs). The extent that published RCTs reflect the efficacy of interventions, however, depends on the completeness and accuracy of published results. The CONSORT statement, initially developed in 1996, provides guidelines intended to improve the transparency of published RCT reports. A policy of the International Committee of Medical Journal Editors, initiated in 2005, requires clinical trials published in member journals to be registered in publicly accessible registries prior to patient enrolment. The objective of this study was to assess the clarity of outcome reporting, proportion of registered trials, and adequacy of outcome registration in RCTs published in top behavioural health journals.

**Method:** Eligible studies were primary or secondary reports of RCTs published in *Annals of Behavioural Medicine*, *Health Psychology*, the *Journal of Psychosomatic Research*, and *Psychosomatic Medicine* from January 2008 to September 2009. Data was extracted for each study on adequacy of outcome reporting and registration.

**Results:** Of 63 articles reviewed, only 25 (39.7%) had adequately declared primary or secondary outcomes, whereas 38 (60.3%) had multiple primary outcomes or did not define outcomes. Only 13 studies (20.6%) were registered. Only 1 study registered sufficiently precise outcome information to compare to published outcomes, and registered and published outcomes were discrepant in that study.

**Conclusion:** Greater attention to outcome reporting and trial registration by researchers, peerreviewers, and journal editors will increase the likelihood that effective behavioural health interventions are readily identified and made available to patients. **Keywords:** Methods; Review, Systematic; Randomized Controlled Trials at Topic; Behavioral Medicine; Psychosomatic Medicine,

Evidence-based approaches are increasingly emphasized in practice guidelines and healthcare policy (1-3), and psychological and behavioural treatments supported by strong evidence are more likely to be evaluated positively and implemented in clinical practice than at any time previously (4). The most reliable evidence for determining the efficacy of interventions comes from well-designed and conducted randomized controlled trials (RCTs) (5, 6), and highquality RCTs are prioritized in clinical guideline development (6). The extent to which published RCTs accurately reflect the efficacy of interventions, however, depends on the completeness and transparency of reports of results (5, 7, 8).

Prior to beginning a trial, a single primary outcome variable is generally identified to answer the main question addressed by the trial. Other secondary outcome variables are typically specified, as well (5, 9). In some cases, more than one primary outcome may be specified with appropriate statistical adjustment. However, this is not typically recommended due to the complexity of interpreting potentially contradictory results. All outcome definitions should specify *a priori* the measure and time point of interest.

Study publication bias occurs when the decision to publish or not publish study data depends on the results (10-12), and numerous studies have shown that published studies are significantly more likely to have positive results than non-published studies (10, 13-18). Withinstudy selective outcome reporting, on the other hand, relates to published studies and refers to the selection of outcomes to report based on statistical significance, including the prioritization of time points for analysis, selective reporting of a subset of measures, and data-driven selection or switching of primary outcomes compared to pre-study protocols (10, 19, 20). Comparisons of study protocols and published results have shown that significant outcomes are more likely to be reported than non-significant outcomes and that non-significant pre-specified primary outcomes

are sometimes replaced with statistically significant secondary outcomes that are identified as "primary" in published reports (10, 20-27).

Two important initiatives have emphasized the need to improve the transparency and completeness of RCT outcome specification and reporting, the Consolidated Standards of Reporting Trials (CONSORT) statement (28-30) and the International Committee of Medical Journal Editors (ICMJE) registration requirements for RCTs (31). CONSORT, which has been endorsed by most major medical journals and international editorial groups (31), provides a checklist of items that should be reported by RCT authors and used by peer reviewers, editors, and research consumers to critically review and interpret trial results (5). CONSORT specifies that authors of RCTs should report fully defined pre-specified primary and secondary outcome measures, including how and when they were assessed, and discourages multiple primary outcomes (30). The ICMJE trial registration policy (32) requires adequate pre-trial registration, including a priori specification of all primary and secondary trial outcomes with time of measurement, for all trials intended to affect clinical practice that began recruiting on or after July 1, 2005. Trials that were ongoing as of July 1, 2005 were required to have registered by September 13, 2005 (32). Examples of publicly accessible registries include ClinicalTrials.gov (33), the International Standard Randomized Controlled Trial Number Register (ISRCTN) (34), and region-specific registries, all of which can be accessed through the World Health Organization (WHO) registry search portal (35).

The objective of this study was to assess the degree to which RCTs designed to improve health that were published in top psychosomatic and behavioural health journals (*Annals of Behavioural Medicine*, *Health Psychology*, *Journal of Psychosomatic Research*, and *Psychosomatic Medicine*), adequately registered and reported trial outcomes. Specific objectives

were to: (1) determine the proportion of recently published RCTs that clearly and appropriately declared outcomes as primary or secondary, and (2) assess the degree to which RCT outcomes were registered adequately, as well as whether there were discrepancies between registered and published outcomes.

### **METHODS**

#### **Article Selection**

We searched PubMed on October 31, 2009 to identify RCTs published between January 2008 and October 2009 in *Annals of Behavioural Medicine*, *Health Psychology*, *Journal of Psychosomatic Research*, or *Psychosomatic Medicine* (36) using the search limit of study type ("randomized controlled trial"). We also conducted a hand search of the titles/abstracts of all published articles in the 4 journals, searching for the words "random," "randomized," or "randomly," to identify potentially eligible RCTs not identified in the PubMed search.

Based on the definition used in a recent study of RCT registration in high-impact medical journal publications, (37), studies were included if they reported data from an RCT, defined as a comparative study with random assignment of participants, of an intervention intended to improve health. Studies that randomized participants into experimental conditions not intended to improve health (e.g., laughter versus mental stress conditions to assess arterial stiffness) or that primarily assessed intervention feasibility were excluded. Secondary analyses that reported on trial outcomes, including subgroup analyses, were included. Secondary analyses that tested mediational processes, used RCT data for cross-sectional analyses, or only analyzed control or treatment group data were excluded. Two reviewers assessed articles for eligibility, and disagreements were resolved by consensus.

#### **Data Extraction and Classification**

Two investigators independently extracted and entered relevant data into a standardized Excel<sup>©</sup> spreadsheet. Discrepancies were resolved by consensus.

#### **Objective 1 - Clearly and Adequately Declared Outcomes in Published Articles:**

Published articles were classified as reporting: (1) *primary*, (2) *multiple primary*, (3) *secondary*, or (4) *undefined* outcomes.

An article was classified as reporting a *primary* outcome if a single outcome was clearly and consistently defined as primary throughout the article or, alternatively, if a single primary outcome could be determined from the power analysis. Articles that measured a primary outcome variable at multiple time points in the context of a single repeated measures assessment were classified as reporting a single *primary* outcome. Studies that identified more than one variable as the primary outcome variable or that identified a single variable, but analyzed multiple time points without specification of primacy, were classified as reporting *multiple primary* outcomes. Studies classified as *primary* or *multiple primary* may have also reported secondary outcomes, but this was not recorded.

Studies were classified as reporting *secondary* outcomes if the authors clearly and consistently defined one or more outcomes as secondary and did not report any primary outcomes. Studies were also classified as reporting *secondary* outcomes if there was a clear statement indicating that the primary or main findings of the RCT had been reported in a previous article.

Studies that did not clearly define outcomes as being primary or secondary were classified as reporting *undefined* outcomes. Studies that noted the existence of a previous report, but did not classify outcomes from the previous or current report as primary or secondary, were

also classified as reporting *undefined* outcomes (e.g., a report of 12-month post-intervention outcomes with a previous report on 6-month outcomes).

Studies with *primary* or *secondary* outcomes were classified as having *adequately declared* outcomes, whereas studies with *multiple primary* or *undefined* outcomes were classified as having *inadequately declared* outcomes with one exception. For studies with *primary* outcomes, if a previous report was identified that designated a different trial outcome as *primary*, the current study was reclassified as reporting an *inadequately declared primary* outcome. To identify previous reports, one investigator reviewed references in the included RCT publication and searched PubMed and PsycInfo using author names and keywords.

*Objective 2 - Trial Registration:* We followed a procedure outlined by Mathieu et al. (37). First, we attempted to retrieve trial registration data, including the registration number, from each published article. If no registration information was listed in the published article, we contacted the corresponding author by email to determine if the trial had been registered and to obtain the registry name and number, if registered. If no response was received from the corresponding author after 3 contact attempts, each one week apart, we searched for the studies in multiple clinical trial registries, including ClinicalTrials.gov (33), ISRCTN (34), the WHO registry search portal (35), and the registries from the country of the first author (e.g., Netherlands Trial Register (38)). To identify registry records, we performed a search using key terms from the published article then attempted to match the principal investigator, funding source, intervention, control group, and design from the article to the registrations obtained in the search. If this did not uncover a registration number, the published article was coded as not registered. For both registered and unregistered trials, trial start and end dates or patient enrollment dates were extracted from the publication to determine if the trial should have been

registered per ICMJE policy. For registered trials, start and end dates were also extracted from the registration record. From the registration information, we determined the proportion of published RCTs that were registered versus not registered. We also assessed the proportion that were collecting data as of July 1, 2005 or later and should have been registered based on ICMJE requirements.

Using a method described by Mathieu et al. (37), registered studies were classified as having adequately or inadequately registered outcomes. Adequately registered studies had to meet two criteria, based on ICJME policy. First, studies that were ongoing as of July 1<sup>st</sup>, 2005 had to be registered prior to September 13<sup>th</sup>, 2005 and prior to trial completion. If studies were registered after trial completion, we excluded them from this assessment because post-hoc registrations are not useful for comparing *a priori* registered outcomes to published outcomes. Studies that started after July 1<sup>st</sup>, 2005 must have been registered before participant enrollment began. Second, studies had to specify one or more outcome variables in the registry with a clear description and time frame of assessment. For articles classified as having *adequately declared* primary outcomes in the publication, only the registered primary outcomes were assessed. For articles classified as having adequately declared secondary outcomes, only the registered secondary outcomes were assessed. If the outcomes were not registered on time or not clearly described with a time frame of assessment, the registered RCT was classified as having inadequately registered outcomes. If there were changes in the study registration records, we included only the information updated prior to trial completion. If more than one primary or secondary outcome was registered, the RCT had *adequately registered* outcomes if all were clearly described with a time frame of assessment.

#### RESULTS

### Article Selection

A total of 165 articles were identified for initial review, of which 81 were excluded at the title/abstract level, leaving 84 articles for full-text review. Twenty-one articles were excluded after full-text review, leaving 63 articles for inclusion in analyses (Figure 1): 18 from *Annals of Behavioural Medicine*, 23 from *Health Psychology*, 13 from the *Journal of Psychosomatic Research*, and 9 from *Psychosomatic Medicine*. Characteristics of included articles (39-101), along with outcome and registration classifications, are found in the Appendix.

#### **Objective 1: Clearly and Adequately Declared Outcomes in Published Articles**

Only 25 of 63 articles (39.7%) were classified as having *adequately declared* outcomes, including 9 (14.3%) with *adequately declared primary* outcomes and 16 (25.4%) with *adequately declared secondary* outcomes. Of the 38 articles (60.3%) that had *inadequately declared* outcomes, 15 (23.8%) declared *multiple primary* outcomes without appropriate statistical adjustment, 21 (33.3%) had *undefined* outcomes, 1 (1.6%) reported a previously published primary outcome without indicating this in the article, and 1 (1.6%) declared a *primary* outcome, but a previous report from the same RCT declared a different *primary* outcome (Table I). The proportion of *adequately declared* outcomes was similar across journals, and there were no statistically significant differences (p < .05) between journals.

#### **Objective 2: Trial Registration**

Data on registration requirement, based on ICMJE guidelines, and actual registration status of reviewed RCT articles are shown in Table II. Of the 63 articles reviewed, 13 (20.6%) reported on registered RCTs, and 50 (79.4%) on unregistered RCTs. Only 1 of the 13 articles reporting on a registered RCT provided registration information in the publication. Based on trial start and end dates or patient enrollment dates reported in the published articles, 13 (20.6%) articles reported on RCTs that should have been registered based on ICMJE policy, and 18 (28.6%) reported on RCTs that were not required to be registered. The remaining 32 articles (50.8%) reported insufficient information in the publications to assess when the trials were conducted and whether these trials should have been registered.

Based on study start and end dates provided in the registries, 8 of the 13 articles reporting on registered RCTs were required to be registered: 1 did not register the trial end date, but was not required to be registered according to the dates in the published article, and 4 were not required to be registered, but were registered after trial completion.

Of the 8 articles required to be registered and registered prior to trial completion, 3 reported *adequately declared primary* outcomes in the published article, 4 reported *adequately declared secondary* outcomes, including 2 articles reporting on the same RCT (84, 97), and 1 reported *inadequately declared* outcomes. Only 1 of the 8 articles, however, was from an RCT that had *adequately registered* outcomes, which permitted comparison to published outcomes (99). The 1 *adequately registered* trial registered 2 primary outcomes. The published article (99) from the trial, however, only reported 1 statistically significant, *adequately declared primary* outcome. The doctoral dissertation upon which the published article was based (102), on the other hand, described both registered outcomes, including a non-significant outcome that was omitted from the publication.

## DISCUSSION

Trial outcomes were *adequately declared* in only 40% of recently published RCTs from 4 leading psychosomatic and behavioural health journals. Trial registration rates were also low for RCTs published in these journals, and when trials were registered they were typically not

registered with enough information to be able to compare registered and published outcomes. Of the 8 registered trials that should have been registered based on ICJME policy, only 1 study registered outcomes with sufficient information to compare registered and published outcomes, and that study published a statistically significant registered primary outcome without mentioning a registered primary outcome that was not statistically significant.

A recent study of all primary reports of RCTs indexed in PubMed in December 2006 found that 53% properly defined a primary outcome variable (103), which is somewhat higher than the 40% found in the current study based on both primary and secondary outcome reports. A previous study reviewed primary reports of behavioural health RCTs published from January 2000 through July 2003 in the *Journal of Consulting and Clinical Psychology, Annals of Behavioral Medicine*, and *Health Psychology* and found that 58% specified a primary outcome (4). However, studies were counted as having specified a primary outcome if it was done explicitly or implicitly, if 1-3 dependent variables were identified as primary, and whether or not a specific time point was specified. Regarding trial registration, Mathieu et al. (37) found that 46% of 323 trials published in high-impact medical journals were registered before trial completion with clearly specified primary outcomes. This may appear low, but is much higher than in the present study (1 of 63 trials), which used the same methodology.

A 2003 report from a Committee of the Society of Behavioral Medicine urged behavioural medicine researchers to utilize CONSORT guidelines (104). *Health Psychology* has required authors of reports on RCTs to submit completed CONSORT checklists since 2003 (105), and *Annals of Behavioral Medicine* and *Psychosomatic Medicine* have recommended that authors adhere to CONSORT guidelines since 2002 (106) and 2003 (107), respectively. The *Journal of Psychosomatic Research* has not yet included CONSORT in its author instructions.. Results from this study suggest that adequacy of outcome reporting is generally similar across these journals, although somewhat lower for *Health Psychology* than the others. This would seem to contradict reporting practices from the overall medical literature where RCTs that are reported in journals that have adopted CONSORT provide more complete reporting than those from non-adopters (103, 108). On the other hand, the small number of studies from each journal reviewed made it impossible to confidently draw conclusions regarding the performance of any particular journal.

Consistent with recommendations in the general medical literature that CONSORTadopting journals should be more proactive in the enforcement of CONSORT guidelines (108), we recommend that behavioural medicine and psychosomatic research journals require authors to submit a CONSORT checklist with RCTs and require reviewers to address the degree to which CONSORT items are adequately reported. In addition, increased emphasis is needed on education about the importance of clear and precise outcome reporting. For instance, authors of systematic reviews and meta-analyses should be encouraged to address outcome reporting in quality assessments of included studies. The Cochrane Collaboration's tool for assessing risk of bias (109) includes a rating for selective outcome reporting, and studies with poor outcome declaration should be flagged for being at risk of selectively reporting outcomes (110).

In a similar vein, efforts to improve trial registration should include both increased education and mechanisms that explicitly downgrade confidence in non-registered or poorly registered trials. The Cochrane Collaboration's risk assessment tool stipulates that unregistered studies be classified as "no" or "unclear" in terms of being free of selective reporting bias, whereas registered studies that publish outcomes consistent with those registered are rated as being free of this bias (109).

We recommend that behavioural medicine and psychosomatic journals also adopt a policy of clinical trial registration. Of the journals included in the current review, only *Annals of Behavioral Medicine* has implemented a clinical trial registration policy. This is an important first step. However, the trial registration policy adopted by *Annals of Behavioral Medicine* in October 2009 (111) does not address potential differences between primary and secondary outcome registration and publication. This is an important issue since a substantial proportion of articles on RCTs published in *Annals of Behavioural Medicine*, *Health Psychology, Journal of Psychosomatic Research*, and *Psychosomatic Medicine* report on secondary outcomes.

CONSORT does not preclude publication of exploratory analyses, which may be less reliable than pre-specified analyses, but stipulates that a clear distinction be made between prespecified and exploratory analyses. It would seem reasonable for behavioural medicine and psychosomatic journals to implement an across-the-board registration requirement for publication of primary outcomes from RCTs. For secondary outcomes, it might make sense to publish unregistered outcome analyses, but to require authors to clearly define them as either (1) registered, pre-specified secondary outcomes with the registration information provided, or (2) post-hoc/exploratory outcomes with a specific statement in the article about the potential limitations of such analyses.

Several limitations should be considered when interpreting the results of this study. First, the time period of the study was relatively short, and the sample of reviewed RCTs was small, which may reduce the precision of estimated rates of adequate outcome reporting and registration. Related to this, the number of RCTs reviewed from each journal was not large enough to draw reliable conclusions about outcome reporting or trial registration in individual journals. Second, although CONSORT requires that trial start and end dates be reported, this

information was only provided in 50% of articles, which limited our ability to determine whether many RCTs were required to be registered. Third, only RCTs published in *Annals of Behavioural Medicine*, *Health Psychology*, *Journal of Psychosomatic Research*, and *Psychosomatic Medicine* were included. It is not known to what degree study results and conclusions would apply to other related journals or to behavioural health and psychosomatic RCTs that are published in medicine or psychiatry journals, which may be of better quality.

In conclusion, increasing the accessibility of behavioural health and psychosomatic interventions depends on establishing a robust evidence base for clinical efficacy. This requires complete and transparent reporting of clinical trials. We encourage behavioural health and psychosomatic researchers, peer-reviewers, and journal editors to work in concert to improve trial reporting and registration so that effective behavioural health and psychosomatic interventions are more readily identified and so that those that work are made available to patients. Conflicts of Interest: None to declare

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# **Figure 1: Article Selection**



	Annals of		Journal of		
	Behavioural	Health	Psychosomatic	Psychosomatic	All Journals
	Medicine	Psychology	Research	Medicine	(n, % of total)
Adequately declared outcomes:	8 (44.4%)	7 (30.4%)	6 (46.2%)	4 (44.4%)	25 (39.7%)
Primary	3	4	1	1	9 (14.3%)
Secondary	5	3	5	3	16 (25.4%)
Inadequately declared outcomes:	10 (55.6%)	16 (69.6%)	7 (53.8%)	5 (55.6%)	38 (60.3%)
Primary (undeclared previous report)	0	2	0	0	2 (3.2%)
Multiple primary	7	3	3	2	15 (23.8%)
Undefined	3	11	4	3	21 (33.3%)
Total	18 (100%)	23 (100%)	13 (100%)	9 (100%)	63 (100%)

# Table I: Outcome Declaration in Published Randomized Controlled Trials

	Annals of		Journal of		
	Behavioural	Health	Psychosomatic	Psychosomatic	All Journals
	Medicine	Psychology	Research	Medicine	(n, % of total)
Unregistered RCT Publications	16 (88.9%)	19 (82.6%)	10 (76.9%)	5 (55.6%)	50 (79.4%)
Registration required (according to ICMJE)	4	2	0	2	8 (12.7%)
Registration not required (according to ICMJE)	6	3	3	2	14 (22.2%)
Cannot assess registration requirement	6	14	7	1	28 (44.4%)
<b>Registered RCT Publications</b>	2 (11.1%)	4 (17.4%)	3 (23.1%)	4 (44.4%)	13 (20.6%)
Registration required (according to ICMJE)	2	1	0	2	5 (7.9%)
Registration not required (according to ICMJE)	0	0	2	2	4 (6.3%)
Cannot assess registration requirement	0	3	1	0	4 (6.3%)
Total	18 (100%)	23 (100%)	13 (100%)	9 (100%)	63 (100%)

# Table II: Registration of Published RCTs and Registration Requirement Based on Dates in Published Articles

# Appendix

		Published Outcomes		<b>Trial Registration</b>		tion
		Adequate/		Adequate/		
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Annals of Beh	avioral Medicine					
Ockene	To determine the effect at 48 months of a physician- and nurse practitioner-delivered screening and	Undefined	Inadequately	Not registered	N/A	N/A
2009 (41)	brief patient-centered intervention to reduce alcohol consumption among high-risk drinkers		declared			
Ditto	To examine the psycho-physiological effects of applied tension during blood donations	Secondary	Adequately	Not registered	N/A	N/A
2009 (42)			declared			
Manne	To evaluate the efficacy of 2 tailored interventions and a generic print intervention to increase	Primary	Adequately	Registered§	Inadequately	ClinicalTrials.gov
2009 (43)	screening adherence in colorectal cancer		declared		registered	NCT00352638
Lillis	To evaluate the effect of a 1-day mindfulness and acceptance-based workshop on reducing obesity-	Multiple	Inadequately	Not registered	N/A	N/A
2009 (44)	related stigma and psychological distress	primary	declared			
Kalichman	To test the efficacy of a brief single session HIV-alcohol risk-reduction intervention	Multiple	Inadequately	Not registered	N/A	N/A
2008 (40)		primary	declared			
Resnicow	To test the efficacy of 2 school-based approaches to adolescent smoking prevention (life skills	Primary	Adequately	Not registered	N/A	N/A
2008 (45)	training and harm minimization) in South-African youth		declared			
Smiley-Oyen	To evaluate the effects of an exercise program on cognitive tasks requiring executive control among	Secondary	Adequately	Not registered	N/A	N/A
2008 (46)	older adults		declared			

		Published Outcomes		<b>Trial Registration</b>		
		Adequate/		Adequate/		
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Milne	To examine the effects of structured exercise program on motivational variables in breast cancer	Secondary	Adequately	Not registered	N/A	N/A
2008 (47)	survivors		declared			
Werch	To examine the efficacy of a brief image-based multiple-behaviour intervention for influencing risk	Undefined	Inadequately	Not registered	N/A	N/A
2008 (48)	behavior in college students		declared			
D'Souza	To compare the effects of relaxation training and written emotional disclosure on headaches in	Multiple	Inadequately	Not registered	N/A	N/A
2008 (39)	college students	primary	declared			
Maddison	To examine the effectiveness of a behavioural modeling intervention on peak VO2 and self-efficacy	Multiple	Inadequately	Not registered	N/A	N/A
2008 (49)	in people with chronic heart failure	primary	declared			
Latimer	To assess whether tailoring messages on fruit and vegetable intake increased their persuasiveness	Undefined	Inadequately	Not registered	N/A	N/A
2008 (50)			declared			
Lutes	To examine the efficacy of program to change diet and physical activity to increase weight loss and	Multiple	Inadequately	Not registered	N/A	N/A
2008 (51)	weight maintenance	primary	declared			
Nyklíček	To test the effects of mindfulness-based stress reduction on psychological well-being	Primary	Adequately	Not registered	N/A	N/A
2008 (52)			declared			
Dritsa	To evaluate the efficacy of a home-based exercise intervention in reducing physical and mental	Secondary	Adequately	Not registered	N/A	N/A
2008 (53)	fatigue in post-partum depressed women		declared			

		Published Outcomes		<b>Trial Registration</b>		tion
			Adequate/ Inadequate		Adequate/ Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Oenema	To evaluate the short-term efficacy (1 month) of an internet-delivered, computer-tailored lifestyle	Multiple	Inadequately	Not registered	N/A	N/A
2008 (54)	intervention targeting saturated fat intake, physical activity (PA), and smoking cessation	primary	declared			
Resnicow	To test the effect of a tailored paper-based intervention to increase fruit and vegetable intake in	Multiple	Inadequately	Not registered	N/A	N/A
2008 (55)	African Americans	primary	declared			
Vallance	To examine the effects of a physical activity behaviour change intervention on theory of planned	Secondary	Adequately	Registered§	Inadequately	ClinicalTrials.gov
2008 (56)	behavior variables in breast cancer survivors		declared		registered	NCT00221221
Health Psycho	blogy					
Resnicow	To test whether tailoring a print-based fruit and vegetable behaviour change intervention would	Primary	Adequately	Not registered	N/A	N/A
2009 (57)	enhance impact		declared			
Montgomery	To test the effectiveness of a psychological intervention combining cognitive-behavioural therapy	Undefined	Inadequately	Not registered	N/A	N/A
2009 (58)	and hypnosis to treat radiotherapy-related fatigue		declared			
Hall	To test a brief smoking cessation intervention for women attending cervical smear tests on intention	Primary	Inadequately	Not registered	N/A	N/A
2009 (59)	to stop smoking		declared <sup>+</sup>			
Vogt	To evaluate three theory-based interventions aimed at increasing physician recommendations of	Primary	Adequately	Not registered	N/A	N/A
2009 (60)	smoking cessation services		declared			

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		Published Outcomes		Trial Registration		tion
		Adequate/			Adequate/	
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Safren	To evaluate cognitive-behavioural therapy to increase adherence and reduce depression among	Multiple	Inadequately	Not registered	N/A	N/A
2009 (61)	individuals with HIV	primary	declared			
Schwartz	To test the impact of a decision aid on breast cancer patients' decisions about risk management	Undefined	Inadequately	Not registered	N/A	N/A
2009 (62)	strategies		declared			
Armitage	To see whether stages of change are useful to target a brief intervention to reduce smoking	Undefined	Inadequately	Not registered	N/A	N/A
2008 (63)			declared			
Carey	To evaluate 2 brief interventions to increase rapid HIV testing among sexually transmitted disease	Primary	Adequately	Registered§	Inadequately	ClinicalTrials.gov
2008 (64)	clinic patients who initially declined testing		declared		registered	NCT00183573
Glasgow	To evaluate the effectiveness, along with moderators and mediators of a smoking reduction program	Undefined	Inadequately	Not registered	N/A	N/A
2008 (65)			declared			
Norman	To evaluate the impact of a classroom-based, web-assisted tobacco intervention for smoking	Multiple	Inadequately	Not registered	N/A	N/A
2008 (66)	prevention and cessation in adolescents	primary	declared			
Albarracín	To evaluate an intervention to increase participation in HIV-prevention interventions by infrequent	Primary	Inadequately	Not registered	N/A	N/A
2008 (67)	condom users		declared <sup>+</sup>			
Armitage	To test a brief implementation intention intervention to reduce smoking	Primary	Adequately	Not registered	N/A	N/A
2008 (68)			declared			

		Published Outcomes		<b>Trial Registration</b>		
			Adequate/		Adequate/	
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Haskard	To assess the effects of a communication and partnership training program on physicians and	Undefined	Inadequately	Not registered	N/A	N/A
2008 (69)	patients		declared			
Pischke	To test effects of a 1-year lifestyle intervention for coronary heart disease on psychosocial risk	Secondary	Adequately	Registered	N/A	ClinicalTrials.gov
2008 (70)	factors		declared	Post-hoc <sup>§</sup>		NCT00000471
Sullivan	To test whether forming implementation intentions is an effective strategy for attaining health goals	Undefined	Inadequately	Not registered	N/A	N/A
2008 (71)			declared			
Alschuler	To test whether a psychological screen improved detection of behavioural problems and increased	Multiple	Inadequately	Not registered	N/A	N/A
2008 (72)	treatment	primary	declared			
Schumann	To evaluate a smoking intervention based on the transtheoretical model	Undefined	Inadequately	Not registered	N/A	N/A
2008 (73)			declared			
Barrera	To evaluate the effects and conduct mediational analyses of a 24-month lifestyle intervention for	Undefined	Inadequately	Registered	N/A	ClinicalTrials.gov
2008 (74)	post-menopausal women diagnosed with type-2 diabetes on physical activity and fat consumption		declared	Post-hoc <sup>§</sup>		NCT00142701
Koenig	To compare the efficacy of a multi-component social support intervention on medication adherence	Undefined	Inadequately	Not registered	N/A	N/A
2008 (75)	among HIV-infected patients initiating antiretroviral therapy		declared			
de Wit	To compare the effects of different persuasive evidence in promoting the acceptance of personal	Undefined	Inadequately	Not registered	N/A	N/A
2008 (76)	health risk in men who have sex with men		declared			

		Publishe	Published Outcomes Trial Registration		tion	
			Adequate/		Adequate/	
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
McQueen	To examine predictors of perceived susceptibility to breast cancer in a sample of veteran women	Secondary	Adequately	Not registered	N/A	N/A
2008 (77)	who participated in a behavioural intervention to increase regular mammography screening		declared			
Ward	To test the efficacy of an intervention based on theories of cognitive representations of illness and	Undefined	Inadequately	Not registered	N/A	N/A
2008 (78)	processes of conceptual change to decrease cancer pain		declared			
Williamson	To test whether intentional dietary restriction would be associated with eating disordered symptoms	Secondary	Adequately	Registered§	Inadequately	ClinicalTrials.gov
2008 (79)			declared		registered	NCT00099151
Journal of Ps	ychosomatic Research					
Werrij	To test the effect of adding cognitive therapy to a standard dietetic treatment for obesity on relapse	Undefined	Inadequately	Not registered	N/A	N/A
2009 (80)	prevention		declared			
Dritsa	To determine moderators of the effects of a home-based exercise intervention for postpartum women	Secondary	Adequately	Not registered	N/A	N/A
2009 (81)	on mental and physical fatigue		declared			
Broadbent	To assess the effect of a brief in-hospital illness perception intervention for myocardial infarction	Multiple	Inadequately	Not registered	N/A	N/A
2009 (83)	patients and spouses on spouses' illness perceptions and anxiety	primary	declared			
Broadbent	To determine the effect of a brief in-hospital illness perception intervention for myocardial	Multiple	Inadequately	Not registered	N/A	N/A
2009 (82)	infarction patients and spouses on return to work	primary	declared			

		Published Outcomes		Trial Registration			
			Adequate/		Adequate/		
			Inadequate		Inadequate	Registry	
First Author		Reported	Outcome	Registration	Outcome	Name and	
Year	Purpose	Outcomes	Reporting	Status	Registration	Number	
Saab*	To assess the impact of cognitive behavioural group training on event-free survival in patients with	Secondary	Adequately	Registered§	Inadequately	ClinicalTrials.gov	
2009 (84)	myocardial infarction		declared		registered	NCT00000557	
Conradt	To test the effects of a consultation using genetic information about obesity on weight loss goals,	Undefined	Inadequately	Registered	N/A	ClinicalTrials.gov	
2009 (85)	self-blame about eating, and weight-related coping in obese individuals		declared	Post-hoc§		NCT00389246	
Bormann	To test the effects of a spiritually-based mantram intervention on faith/assurance and average	Secondary	Adequately	Registered	N/A	ClinicalTrials.gov	
2009 (86)	salivary cortisol levels among HIV-infected individuals		declared	Not required§		NCT00057538	
Antoni	To test the effects of a cognitive behavioural stress management intervention on life stress and	Undefined	Inadequately	Not registered	N/A	N/A	
2008 (87)	cervical neoplasia in HIV+ minority women		declared				
Creed	To conduct a subgroup analysis to assess the relationship between baseline somatisation scores and	Secondary	Adequately	Not registered	N/A	N/A	
2008 (88)	effects of an intervention for patients with severe irritable bowel syndrome on health status and cost		declared				
Axford	To identify factors that may limit the effectiveness of a patient education program for knee	Secondary	Adequately	Not registered	N/A	N/A	
2008 (89)	osteoarthritis patients		declared				
Molton	To determine the effect of a 10-week group-based cognitive behavioural stress management	Undefined	Inadequately	Not registered	N/A	N/A	
2008 (90)	intervention for men recovering from radical prostectomy		declared				
Barlow	To examine the effect of a training and support program on general and parental self-efficacy for	Multiple	Inadequately	Not registered	N/A	N/A	
2008 (91)	managing psychosocial well-being of children with disabilities	primary	declared				

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		Published Outcomes     Trial Registration       Adequate/     Adequate/		tion		
				Adequate/		
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
Bieber	To test whether a shared decision making intervention improved communication between	Primary	Adequately	Not registered	N/A	N/A
2008 (92)	fibromyalgia patients and their physicians		declared			
Psychosomatic	c Medicine					
Thornton	To test whether a psychological intervention reduced depression-related symptoms and	Secondary	Adequately	Not registered	N/A	N/A
2009 (93)	inflammation markers among cancer patients		declared			
Bygren	To test the effects of attending cultural events on health	Multiple	Inadequately	Not registered	N/A	N/A
2009 (94)		primary	declared			
Holt-Lunstad	To test the effects of a 4-week support intervention (warm touch enhancement) on physiological	Undefined	Inadequately	Not registered	N/A	N/A
2008 (95)	stress systems linked to important health outcomes		declared			
Phillips	To test the effect of a 10-week cognitive-behavioural stress management intervention on serum	Undefined	Inadequately	Not registered	N/A	N/A
2008 (96)	cortisol and relaxation indicators in women who underwent treatment for nonmetastatic breast		declared			
	cancer					
Trockel <sup>*</sup>	To test the effect of cognitive behaviour therapy for depression and/or low perceived social support	Secondary	Adequately	Registered§	Inadequately	ClinicalTrials.gov
2008 (97)	on smoking behaviour in post-myocardial infarction patients		declared		registered	NCT00000557
Korstjens	To compare the effects of a combined physical and cognitive-behavioural training intervention with	Multiple	Inadequately	Registered§	Inadequately	ISRCTN
2008 (98)	physical training alone on quality of life in cancer patients	primary	declared		registered	ISRCTN6853011

		Published Outcomes		Trial Registration		tion
			Adequate/		Adequate/	
			Inadequate		Inadequate	Registry
First Author		Reported	Outcome	Registration	Outcome	Name and
Year	Purpose	Outcomes	Reporting	Status	Registration	Number
van Kessel	To assess the efficacy of an 8-week cognitive behaviour therapy intervention on fatigue for multiple	Primary	Adequately	Registered <sup>‡</sup>	Adequately	ACTRN
2008 (99)	sclerosis patients		declared		registered	012605000209695
Kundermann	To investigate the short-term effects of sleep deprivation therapy on symptoms of depression and	Undefined	Inadequately	Not registered	N/A	N/A
2008 (100)	pain processing		declared			
Rabe	To investigate the effect of cognitive behavioural therapy on neural processes for patients with post-	Secondary	Adequately	Registered	N/A	ISRCTN
2008 (101)	traumatic stress disorder after severe motor vehicle accidents		declared	Post-hoc <sup>§</sup>		ISRCTN66456536

ACTRN = Australian New Zealand Clinical Trials Registry; ISRCTN = International Standard Randomized Controlled Trial Number Register; N/A = Not Applicable. \* Articles reported findings from the same RCT.

<sup>+</sup>Articles clearly declared primary outcomes, but previous reports on the same RCTs contradicted the current declarations of primary outcomes.

<sup>‡</sup>Registry name and number were reported in the article.

<sup>§</sup>Registry name and number were not reported in the article.