

review title

Contracts between patients and healthcare practitioners for improving patients' adherence to treatment, prevention and health promotion activities
(Bosch-Capblanch et al. 2008)

focus of the review

The aim of this Cochrane review was to examine the effects of contracts between patients and healthcare practitioners in relation to adherence, prevention and health promotion activities, by examining effects on:

- The health or behaviour changes outlined in the contract;
- Patient satisfaction; and
- Other relevant outcomes, such as behaviour and views of health provider, health status, harms, costs, or treatment denial due to the contract.

Contracts are a mutual formalised agreement between two health care participants (usually patient and health care practitioner) that certain behaviours will be adhered to.

key results of the review

What this review shows about contracts for improving adherence:

- Contracts, compared with control may improve adherence in some areas, such as substance addiction and selected self-care behaviours, but the effects of contracts are not consistently positive across all areas assessed.
- Contracts may also improve other outcomes such as knowledge, service use and selected treatment outcomes in some areas, but these effects are not uniform or consistently beneficial across all health treatment, prevention or health promotion areas assessed, and in some cases contracts have negative effects on outcomes.

What this review does not show about contracts for improving adherence:

- This review highlights gaps in the evidence in relation to the effects of contracts on other patient, professional and health system outcomes, particularly those related to shared decision-making and participation by patients and carers.

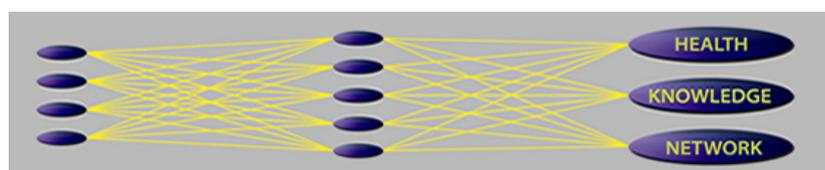
This Evidence bulletin is produced by the Centre for Health Communication and Participation, for Health Knowledge Network, with funding from Statewide Quality Branch, Department of Human Services, Victoria, Australia.

This bulletin summarises a recently published Cochrane systematic review

This page highlights key aspects of the review

Pages 2-5 summarise the review

The evidence table on pages 6-10 contains more detail of the review



Background to the review

Contracts can be any type of written or verbal agreement between two participants in the healthcare context that aim to improve patients' adherence to a course of treatment or recommended health promotion activities. Contracts between health care practitioners and patients are the most widely used.

Contracts have been used in a variety of health care contexts including smoking cessation, breast self-examination, hypertension, diabetes, for renal patients and for people with psychiatric conditions.

There is no single definition of contracts, however there are three features that characterise contracts when they are used as a strategy to improve adherence: contracts formalise the agreement between participants; contracts are mostly established between patients and their physicians; and contracts are usually between adults, although adolescents and children have also been involved. Contracts can also include a reward, or positive consequences contingent on positive behaviour as outlined in the contract.

Review authors discuss two relevant theoretical models. In a concordance model patients and practitioners are partners who contribute equally in decision making processes in relation to the contract. In a relationship model for contracts the literature suggests that responsibility for success of the contract lies primarily with the patient despite appearing to be based on a model of shared responsibility and decision making. The term adherence in its most restrictive sense is used in this review—meaning that what has been agreed to between health care practitioner and patient is actually done, regardless of the nature of their relationship.

Interventions to increase adherence tend to be complex—many different participants may be involved, and interventions combine various strategies. Review authors suggest that contracts may be more advantageous than other interventions that aim to improve adherence because they can be replicated easily, may be cheaper to implement than other more complex interventions, and provided that effective interventions are used

there may be health and psychological benefits for patients.

This review aims to evaluate the effectiveness of contract-based interventions in terms of adherence, across health conditions and contexts. Other reviews have assessed interventions to improve adherence or compliance in relation to specific health conditions.

Trials included in the review

The review included 30 randomised controlled trials (RCTs); involving 4,691 participants.

Interventions were directed to consumers, in various settings including specialised services (services for addictions, a geriatric centre and an optic centre), primary health care, hospital, and other settings (including substance abuse, weight loss and other community-based trials).

The majority of trials included in the review involved adults; while a few included trials involved adolescents, college students, girls aged 5 to 12, or children.

Trials were undertaken in the USA (26 trials), the UK (2), in Canada (1) and Australia (1).

Description of interventions

Review authors included any contract-based intervention aimed at improving patients' adherence to treatment, prevention or health promotion activities. Interventions could have the following characteristics:

- A verbal or written agreement;
- Specifying at least one treatment, prevention or health promotion activity, and a commitment of adherence;
- An agreement between healthcare providers or services and patients/carers; between patients and their carers; or patients with themselves.
- They could be delivered as a single intervention or as part of a multifaceted intervention;

- Interventions could apply to any activity or group of activities involved in managing patients, including diagnostic procedures, therapeutic regimes, rehabilitation approaches, general health advice or referral instructions; could include explicit rewards; and could include self-management as long as the approach involved some form of contract.

Contract interventions were compared with no intervention or routine care (aiming to improve adherence). The control groups consisted of routine care; or non-routine care such as counselling, education or instruction; group support or treatment.

Description of outcomes

Primary outcomes of interest to review authors were:

- Patients' adherence or change in behaviour related to adherence (eg. patients' adherence to a treatment regime, to undertake a diagnostic procedure, to take part in a health promotion activity, health care practitioners' adherence to the agreed commitment).

Secondary outcomes included:

- Patients' actual involvement in the contractual process, and the degree of shared decision making in relation to treatment options;
- Outcomes of agreed aims for patients and practitioners;
- Practitioner observance of contractual terms and process;
- Health status measures;
- Harms;
- Cost or saving by patient, practitioner or service.

What the review shows: summary of key findings:

Some evidence from trials

Addictions

There is **some evidence** from trials of a significant effect in favour of contracts with respect to:

Continuous abstinence at time periods of 90 days and longer (to 180 days) (1 trial, 102 participants), and negative urinalysis at 9 weeks and 18 months post-treatment (1 trial, 353 participants);

Substance-free samples for benzodiazepines (1 trial, 45 participants) and marijuana (1 trial, 48 participants), but **insufficient evidence** to decide between groups in terms of other tested samples (alcohol, barbiturates, amphetamine, cocaine);

Participants attending **selected aftercare sessions** (sessions 1, 3, 4, and 6 of 8 sessions) (1 trial, 50 participants), but **insufficient evidence** to decide between groups in terms of mean number sessions attended or number attending at least one aftercare session.

There is **some evidence** from trials of:

A significant decrease in the number of **cigarettes smoked** up to 6 months, but this effect was not found at 12 months (1 trial, 27 participants).

A significantly higher **discharge rate** with **contingency contracts** (as contract intervention included discharge for continuous positive urinalysis). There was also some evidence that those participants in the contract group were significantly fewer months out of treatment before readmission (1 trial, 353 participants).

Weight control

There is **some evidence** from trials of:

A significant effect of contracts on weight loss: 2 trials of 3 reported significantly **more weight loss** when contracts were compared with minimal or routine care;

A significant effect of **supervised exercise** in comparison with contracts for weight loss (1 trial, 28 participants).

Diabetes care

There is **some evidence** from trials of:

A significant effect in favour of **education** (control) compared with contracts on knowledge of diabetes care (1 trial, 50 participants);

A significant effect of contracts on some measures of **adherence to lower limb care** (physician-documented ulcers, pulse examination, dry or cracked skin and

calluses or corns) (1 trial, 383 participants) but **insufficient evidence** to decide between groups for other foot care outcomes.

Tuberculosis care

There is **some evidence** from trials of:

A significant effect of contracts on **returning** for skin test reading (1 trial, 1946 participants);

A significant effect of contracts when combined with counselling, compared with contracts alone, on **completion of treatment** (1 trial, 390 participants).

Depression

There is **some evidence** from trials of a significant effect of contracts on improvement in **target behaviours** up to 3 months follow-up, and reduction in negative reactions at the end of treatment (1 trial, 20 participants).

Acute bacterial infections

There is **some evidence** from trials of a significant effect of contracts on **adherence to antibiotic treatment** assessed by pill count (1 trial, 60 participants).

Hypertension

There is **some evidence** from trials of a significant effect of contracts on:

Treatment continuation (1 trial, 115 participants).

Knowledge of hypertension care issues (1 trial, 115 participants) and patient views on health care (patient active orientation scores) (1 trial, 91 participants).

There is **some evidence** from trials in favour of the **group relaxation** without contracts (control) compared with group relaxation with contracts for adherence to relaxation practices (1 trial, 50 participants).

Arthritis

There is **some evidence** from trials of a significant effect of contracts on **self-reported practice of joint protection**, and goals set for joint protection, but this benefit was found only in phase I (with no significant effects after trial arm cross-over).

Phobia

There is **some evidence** from trials of a significant effect of control group compared with contracts on number of **desensitisation sessions** attended and time taken to study materials (1 trial, 24 participants).

Promotion of health diet/exercise

There is **some evidence** from trials of a significant effect of contracts on **fibre and salt intake** (1 trial, 64 participants).

What the review does not show

Insufficient evidence from trials

There is **insufficient evidence** from trials to decide between contracts and control with respect to (all of the following conditions/outcomes):

Addictions

- Proportion of participants with **substance-free samples** at 120 days;
- **Smoking abstinence** (proportion of participants abstinent, period of time abstinent);
- **Satisfaction, perceptions** of the treatment programme, ability to solve problems, dispensation of medication, or healthcare costs.

Diabetes care

- **Weight loss**, or reductions in **fasting blood glucose** or HbA1c levels.

Tuberculosis care

- **Treatment completion** when compared with either counselling or routine care.

Acute bacterial infections

- **Self-reported medication adherence** or participants needing additional prescriptions.

Hypertension

- **Blood pressure** changes.

Acne

- **Adherence** to treatment and **numbers of acne lesions**.

Arthritis

- **Knowledge** or health outcomes.

Summary of
the review
continued...

See the evidence
table and
key to results
on pages 6-10

Insufficient evidence from trials *continued...*

Breast self-examination

- Adherence, assessed as **frequency of breast examination** or frequency of prompting by partners to perform examination.

Asthma

- Adherence to PEFR monitoring or **number of asthma episodes** experienced.

Contact lens care

- Any behavioural outcomes (eg **handwashing**).

Promotion of health diet/exercise

- Fat or **sweet intake**, use of **stress management** techniques or practice of flexibility exercises.

Weight control

- None of studies assessed adherence or behaviour change related to adherence.

Harms and adverse effects

Authors note that none of the included studies reported outcomes related to adverse effects or ethical issues.

Conclusions

While some contract-based strategies, alone or in combination with other strategies, may be associated with improved adherence and health outcomes for patients, it is considered that the effects are small compared to the effort they require.

Forwarding

You are welcome to forward this bulletin on to any interested colleagues—individuals, organisations or networks.

Contacting us

Health Knowledge Network,
Centre for Health Communication and
Participation, AIPC,
La Trobe University, Bundoora, VIC 3078
Helen Dilkes, Research Officer
Ph: 03 9479 5730
hkn@latrobe.edu.au

Recommendations from authors

Authors recommend that further well-designed and clearly reported randomised trials be conducted to assess the effectiveness of contracts on adherence and other patient-centred outcomes in the context of treatment, prevention and health promotion. Trials could usefully be conducted in a range of additional health treatment and prevention areas such as the use of contracts in managing opioids for chronic pain relief; and in health areas in which adherence is particularly problematic.

Authors highlight the need for future trials to include clear descriptions of the contract intervention, as well as the control group and any co-interventions delivered concurrently with the contract. Trials should be designed to explicitly assess the contribution of the contract intervention separately and together with other intervention components. Trials should also explore the different aims and features of contracts and their effectiveness.

Authors recommend that future trials assess and report a range of outcomes relevant to patients, such as patients' participation in the contractual process, and the degree of shared decision-making, acceptability and satisfaction. Trials should also assess potential harms associated with the use of contracts, such as reduced adherence, drops in retention rates of trials and the degree to which patients report breaches of the contract's terms.

Forwarding
bulletins

Bulletins
available
online

Funding

Bulletins on Health Knowledge Network website:
www.latrobe.edu.au/cochrane/HKN/HKNBulletins.html

Funding

Evidence bulletins are provided by the Centre for Health Communication and Participation for Health Knowledge Network with funding from Statewide Quality Branch, Department of Human Services, Victoria, Australia.

A Victorian
Government
initiative 

Full citation for the review:

Bosch-Capblanch X, Abba K, Prictor M, Garner P. Contracts between patients and healthcare practitioners for improving patients' adherence to treatment, prevention and health promotion activities. *Cochrane Database of Systematic Reviews* 2007, Issue 2.

Art. No.: CD004808. DOI: 10.1002/14651858.CD004808.pub3

Link to review in The Cochrane Library: www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004808/frame.html

This table is part of an overview of the review created by Dr Rebecca Ryan, at The Consumers & Communication Review Group, La Trobe University. It contains detailed data extracted from the review. The summary on the previous pages of this EVIDENCE bulletin draws on content from both this table and the review. This table uses standardised wording developed by the Review Group. A key to this wording follows the table and should be used to interpret the data.

Review title: Contracts between patients and healthcare practitioners for improving patients' adherence to treatment, prevention and health promotion activities

Authors: Bosch-Capblanch X, Abba K, Prictor M, Garner P.

Description of main features

Aim: To examine the effects of contracts between patients and healthcare providers on patients' adherence to treatment, prevention and health promotion activities, the health or behaviour changes outlined in the contract, patient satisfaction, and other relevant outcomes, such as behaviour and views of health provider, health status, harms, costs, or treatment denial due to the contract.

Trial design:
RCT.

Participants:
Included: Any person (patient), or their carers, undergoing treatment, diagnostic testing, or participating in any health promotion or illness prevention activity. Providers (practitioners) were also eligible, including any clinician, nurse, or other health care worker involved in the provision of screening, diagnostic, therapeutic, preventative or health promotion activity.
Excluded: None stated.

Interventions:
Included: Interventions including a contract aiming to improve patients' adherence to treatment, prevention or health promotion activities. Contracts included any statement (written or verbal) specifying at least one treatment, prevention or health promotion activity and a commitment of adherence to this activity. Contracts were eligible if occurring between healthcare providers or services and patients/carers, between patients and carers, or between patients. Eligible interventions could involve contracts delivered as a single intervention or as part of a multifaceted intervention, as long as the contract was not provided to the control group. Eligible contracts could apply to any activity or group of activities involved in managing patients, including diagnostic procedures, therapeutic regimens, rehabilitation approaches, general health advice or referral instructions; could include explicit rewards; and could include self-management as long as the approach involved some form of contract.
Excluded: Studies comparing one form of contract with another.

Comparison arms:
Contract interventions versus no intervention or routine care (including any other type of intervention(s) aiming to improve adherence). Control groups consisted of routine care (14 trials); or of non-routine care such as counselling, education or instruction (8); group support or treatment (5); training (5); or others (3).

Outcomes:
Included: Patient adherence or change in adherence-related behaviours (such as treatment adherence, attendance, duration of participation, consistency with agreed targets); patient participation in the contractual process and the degree of shared decision-making; outcomes of agreed aims stated in contracts; patient satisfaction; healthcare providers' observance of the contract's terms and assessment of the contracting process; health status outcomes relevant to the contract purpose; harms associated with adherence; costs; treatment denial or deferral; utilisation of health services.

Number of trials included: 30

Types of trials included: RCT

Number of participants included: 4,691

Meta-analysis performed: Yes; narrative synthesis also performed as appropriate for heterogeneous interventions, populations and outcomes.

Review methods: Standard Cochrane Collaboration review methods were used, including the following: *a priori* research design provided; extensive searching, including searching for unpublished studies; selection criteria were specified in advance and applied; list of included and excluded studies provided; quality criteria for assessment of included studies were reported and applied; methods of analysis were reported; conflict of interest stated.

Quality:

Included trials: Rated against eight distinct quality criteria, as follows: method and adequacy of randomisation; adequacy of allocation concealment; blinding of each of participants, providers and outcomes assessors; comparability of groups on measurements at baseline; degree of loss to follow-up; and adequacy of consumer participation. Authors note that most included trials were of poor design, were poorly reported, or both. None of the included studies met all quality criteria: all were rated as inadequate on at least 3/8 criteria. Randomisation method was appropriately reported in 3/30 trials; 2/30 reported adequately concealed allocation; 16/24 trials reporting baseline data reported no differences in measurements; provider blinding was adequate in 4/30 trials and not done in 4/30; participant blinding was adequate in 3/30 trials; outcome assessor blinding was done adequately in 6/30 trials, not done in 1/30; loss to follow-up was adequate (<20%) in 19 trials; no trials reported consumer participation in design, implementation or interpretation of the research.

Review AMSTAR rating (out of possible 11): 10 - high quality review.

Comments: The review methods adequately met all items of the AMSTAR checklist with the exception of the item evaluating assessment of publication bias: the likelihood of publication bias was not explicitly addressed by the review.

Setting: *Country:* USA (26 trials), UK (2), Canada (1) and Australia (1). *Intervention:* Variable, including the following: specialised services (7 trials; including clinics providing specialist care for addictions, a geriatric centre and an optical centre); primary health care (5); hospital (2); other settings (9; including programmes established for substance abuse, weight loss and other community-based trials); or setting not stated (7). Included trials spanned a range of health areas, including: addictions (10 trials); hypertension (4); weight control (3); and others (13; including diabetes, TB, acute antibiotic therapy, asthma, depression and rheumatoid arthritis).

Recipient: Interventions directed to the consumer.

Provider: Contracts were established predominantly between two parties: 17/30 studies examined contracts between two parties - between participants and healthcare providers (7 trials), between participants and carers, peers or significant others (9 trials) or between healthcare providers and carers (1 trial). Four included trials assessed contracts involving three parties (patients, carers and healthcare providers); another two trials assessed the effects of a self-contract. In the remaining trials (7/30) the parties involved in establishing the contracts were not reported.

Format: The contract interventions were delivered in written format in 25/30 included trials. In the remaining 5 trials the format of contracts was not stated. Incentives were attached to contracts in 21/30 included trials. Incentives were variable and included monetary (total or partial) reimbursements, tokens or gifts, rewards, special activities and changes in medication (methadone) dosages. Terms of the contract interventions were also variable: these included behavioural changes (such as stopping/ decreasing substance abuse, exercising, changing eating habits); monitoring of specified activities/ behaviours (such as clinical parameters, pain, setting goals for child weight loss, limiting and monitoring alcohol intake); and other terms such as attending sessions, working on a manual for phobia desensitisation, and following written instructions. Contract interventions had one or more co-interventions delivered with them in 25/30 trials: these included counselling/ education/ instruction (18 trials); skill or behavioural training (11 trials); reminders (4 trials); group support/ treatment (2 trials); monitoring of medication taken/ problems related to medication (2 trials); and goal setting (1 trial).

*Full text of paper about AMSTAR: http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=17302989&ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Intervention	Results of review
<p>Contracts versus control (routine or non-routine care)</p>	<p><u>Addictions</u></p> <p>Some evidence from trials: of a significant effect in favour of contracts with respect to continuous abstinence at time periods of 90 days and longer (to 180 days) (1 trial, 102 participants), and negative urinalysis at 9 weeks and 18 months post-treatment (1 trial, 353 participants).</p> <p>Some evidence from trials: of a significant effect in favour of contracts with respect to substance-free samples for benzodiazepines (1 trial, 45 participants) and marijuana (1 trial, 48 participants), but insufficient evidence to decide between groups in terms of other tested samples (alcohol, barbiturates, amphetamine, cocaine).</p> <p>Some evidence from trials: of a significant effect in favour of contracts with respect to participants attending selected aftercare sessions (sessions 1, 3, 4, and 6 of 8 sessions) (1 trial, 50 participants), but insufficient evidence to decide between groups in terms of mean number sessions attended or number attending at least one aftercare session.</p> <p>Insufficient evidence from trials to decide between contracts and control with respect to proportion of participants with substance-free samples at 120 days.</p> <p>Insufficient evidence from trials to decide between contracts and control with respect to smoking abstinence (proportion of participants abstinent, period of time abstinent).</p> <p>Some evidence from trials: of a significant decrease in the number of cigarettes smoked up to 6 months, but this effect was not found at 12 months (1 trial, 27 participants).</p> <p>Some evidence from trials: of a significantly higher discharge rate with contingency contracts (as contract intervention included discharge for continuous positive urinalysis). There was also some evidence that those participants in the contract group were significantly fewer months out of treatment before readmission (1 trial, 353 participants).</p> <p>Insufficient evidence from trials: to decide between contract and control with respect to satisfaction, perceptions of the treatment programme, ability to solve problems, dispensation of medication, or healthcare costs.</p> <p><u>Weight control</u></p> <p>Insufficient evidence in relation to measurement: none of the studies evaluating weight control with contract-based interventions assessed adherence or behaviour change related to adherence.</p> <p>Some evidence from trials: of a significant effect of contracts on weight loss: 2 trials of 3 reported significantly more weight loss when contracts were compared with minimal or routine care.</p> <p>Some evidence from trials: of a significant effect of supervised exercise in comparison with contracts for weight loss (1 trial, 28 participants).</p> <p><u>Diabetes care</u></p> <p>Some evidence from trials: of a significant effect in favour of education (control) compared with contracts on knowledge of diabetes care (1 trial, 50 participants).</p> <p>Some evidence from trials: of a significant effect of contracts on some measures of adherence to lower limb care (physician-documented ulcers, pulse examination, dry or cracked skin and calluses or corns) (1 trial, 383 participants) but insufficient evidence to decide between groups for other foot care outcomes.</p> <p>Insufficient evidence from trials to decide between contracts and control with respect to weight loss, or reductions in fasting blood glucose or HbA1c levels.</p> <p><u>Tuberculosis care</u></p> <p>Some evidence from trials: of a significant effect of contracts on returning for skin test reading (1 trial, 1946 participants).</p> <p>Some evidence from trials: of a significant effect of contracts when combined with counselling, compared with contracts alone, on completion of treatment (1 trial, 390 participants).</p> <p>Insufficient evidence from trials to decide between contracts alone and control with respect to treatment completion when compared with either counselling or routine care.</p> <p><u>Depression</u></p> <p>Some evidence from trials: of a significant effect of contracts on improvement in target behaviours up to 3 months follow-up, and reduction in negative reactions at the end of treatment (1 trial, 20 participants).</p>

Intervention	Results of review
<p>Contracts versus control (routine or non-routine care)</p>	<p><u><i>Acute bacterial infections</i></u> Some evidence from trials: of a significant effect of contracts on adherence to antibiotic treatment assessed by pill count (1 trial, 60 participants). Insufficient evidence from trials to decide between contracts and control with respect to self-reported medication adherence or participants needing additional prescriptions.</p> <p><u><i>Hypertension</i></u> Some evidence from trials: of a significant effect of contracts on treatment continuation (1 trial, 115 participants) Some evidence from trials: in favour of the group relaxation without contracts (control) compared with group relaxation with contracts for adherence to relaxation practices (1 trial, 50 participants). Some evidence from trials: of a significant effect of contracts on knowledge of hypertension care issues (1 trial, 115 participants) and patient views on health care (patient active orientation scores) (1 trial, 91 participants). Insufficient evidence from trials to decide between contracts and control with respect to blood pressure changes.</p> <p><u><i>Acne</i></u> Insufficient evidence from trials to decide between contracts and control with respect to adherence to treatment and numbers of acne lesions.</p> <p><u><i>Arthritis</i></u> Some evidence from trials: of a significant effect of contracts on self-reported practice of joint protection, and goals set for joint protection, but this benefit was found only in phase I (with no significant effects after trial arm cross-over). Insufficient evidence from trials to decide between contracts and control with respect to knowledge or health outcomes.</p> <p><u><i>Breast self-examination</i></u> Insufficient evidence from trials to decide between contracts and control with respect to adherence, assessed as frequency of breast examination or frequency of prompting by partners to perform examination.</p> <p><u><i>Asthma</i></u> Insufficient evidence from trials to decide between contracts and control with respect to adherence to PEFr monitoring or number of asthma episodes experienced.</p> <p><u><i>Contact lens care</i></u> Insufficient evidence from trials to decide between contracts and control with respect to any behavioural outcomes (<i>eg</i> handwashing).</p> <p><u><i>Phobia</i></u> Some evidence from trials: of a significant effect of control group compared with contracts on number of desensitisation sessions attended and time taken to study materials (1 trial, 24 participants).</p> <p><u><i>Promotion of healthy diet/ exercise</i></u> Some evidence from trials: of a significant effect of contracts on fibre and salt intake (1 trial, 64 participants). Insufficient evidence from trials to decide between contracts and control with respect to fat or sweet intake, use of stress management techniques or practice of flexibility exercises.</p> <p><u><i>Harms and adverse effects:</i></u> Authors note that none of the included studies reported outcomes related to adverse effects or ethical issues.</p>

The table on this page presents the standardised wording that should be used to interpret the data in the results section of the EVIDENCE table on the previous pages.

SUMMARY STATEMENT	TRANSLATION
<p><i>Sufficient evidence from trials</i></p>	<p>Evidence to support conclusions about the effect of the intervention(s) in relation to a specific outcome(s). This includes evidence of an effect in terms of:</p> <ul style="list-style-type: none"> • benefit or • harm. <p>Statistically significant results are considered to represent sufficient evidence to support conclusions, but a judgement of 'sufficient evidence' is also based on the number of trials/ participants included in the analysis for a particular outcome.</p> <p>A grading of 'sufficient evidence' is often based on meta-analysis producing a statistically significant pooled result that is based on a large number of included trials/ participants.</p> <p>This judgement may also be made based on the number of trials and/or trial participants showing a statistically significant result - for example (in a narrative synthesis) a result where 12 trials of a total of 14 for a specific outcome showed a statistically significant effect of an intervention would be considered to represent 'sufficient evidence.'</p>
<p><i>Some evidence from trials</i></p>	<p>Less conclusive evidence to make a decision about the effects of a particular intervention(s) in relation to a specific outcome(s).</p> <p>This may be based on narrative syntheses of review results. In this case, the result is qualified according to the findings of the review - for example, 'some evidence (5 trials of 9) reported a positive effect of'</p> <p>{This would be based on a more equivocal set of results than those obtained for 'sufficient evidence' above. For example, while 12/14 statistically significant trials would be classed as 'sufficient evidence', 5/9 statistically significant trials is more equivocal and would be classed as 'some evidence.'}</p> <p>This may also be based on a statistically significant result obtained in a small number of trials; or a statistically significant result obtained from trials with a small number of participants.</p>
<p><i>Insufficient evidence from trials</i></p>	<p>Not enough evidence to support conclusions about the effects of the intervention(s) on the basis of the included trials. This should be interpreted as 'no evidence of effect', rather than 'evidence of no effect'.</p> <p>Statistically non-significant results are considered to represent insufficient evidence.</p> <p>Where the number of trials is small, and/or the number of participants included in the trials is small, 'insufficient evidence' might reflect underpowering of the included trials to be able to detect an effect of the intervention.</p> <p>Where the number of trials is large, and/or the number of participants included in these trials is large, 'insufficient evidence' may reflect underlying ineffectiveness of the intervention to affect the outcomes being examined.</p>
<p><i>Insufficient evidence in relation to measurement</i></p>	<p>Not enough evidence to support conclusions about the effects of the intervention due to a lack of reporting on the specified outcomes.</p> <p>This can be the result of :</p> <p>(i) the review electing not to report on a particular outcome, or set of outcomes, despite being reported by the included trials; or</p> <p>(ii) the review was not able to report on the outcome, as data for the outcome was not reported by the included trials. Note: used for reporting against outcomes only.</p>
<p><i>N/A</i></p>	<p>Not applicable to the outcome category of interest. Note: used for reporting against outcomes only.</p>