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REPORT

A SYSTEMATIC REVIEW

Cognitive therapies targeting change in two or more health behaviours at the same time

Title Cognitive therapies targeting change in two or more health

behaviours at the same time: a systematic review

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samtidig: en systematisk oversikt

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Key messages

Physical inactivity, unhealthy diets or tobacco use increase risk of disease. Many people engage in two or more such unhealthy behaviours. Cognitive therapies may increase physical activity, but we do not know the effects of targeting two or more health behaviours at the same time.

We evaluated the effect of cognitive therapies targeting two or more lifestyle habits. The included studies involved different patient groups and sedentary and/or overweight persons. We included 14 randomised controlled trials, however few studies followed up the participants beyond four months.

We found that:

- Cognitive therapies, targeting two or more health behaviours at the same time, probably lead to small improvements in physical activity and dietary habits, compared to no intervention or usual care, based on moderate-quality evidence.
- We are uncertain whether cognitive therapies, when targeting two
 or more health behaviours at the same time, change physical
 activity, diet, or tobacco use compared to other interventions.

Title:

Cognitive therapies targeting change in two or more one health behaviours at the same time: a systematic review.

Type of publication: Systematic review

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Doesn't answer everything:

No health economic evaluation.

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Executive summary

Background

In 2013, 37% of all deaths in Norway could be attributed to behavioural risk factors, of which unhealthy diets, tobacco use, and physical inactivity were the most important. Many people engage in two or more of these unhealthy behaviours. Cognitive therapies are considered effective treatments for a range of disorders such as depression, anxiety, insomnia, and chronic pain. There are also documented effects of cognitive therapies when used to increase physical activity, but we do not know the effects of targeting two or more health behaviours at the same time.

In this report, the term cognitive therapies includes cognitive behavioural therapies.

Objective

Our objective was to answer the question "What is the effect of cognitive therapies to change two or more health behaviours in adults 18 years or older, compared to no intervention, usual care or another intervention?"

Method

We searched systematically in five electronic databases for systematic reviews and subsequently for primary studies. In addition, we searched the reference lists of included studies. Two reviewers independently screened titles and abstracts, selected studies based on full text publications, and assessed risk of bias in the included studies. One person extracted data from the studies and another person verified the data extraction. We summarized the results for each health behaviour by random-effects meta-analyses, presented as standardized mean differences or relative risk and 95% confidence intervals. We rated our confidence in the effect estimates using GRADE (Grading of Recommendations Assessment, Development and Evaluation) and presented the results in summary of findings tables. In the GRADE system, high quality means that we are very confident that the true effect is close to that of the estimate of the effect; moderate quality that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; low quality that the true effect may be substantially different from the estimate of the effect; and very low quality that the true effect is likely to be substantially different from the estimate of effect.

Results

We did not find any systematic reviews that could answer our question. We found 14 randomized controlled trials that fulfilled our inclusion criteria. Nine studies included sedentary and/or overweight persons. Five studies included different patient groups, such as persons with cancer, type 2 diabetes, or coronary heart disease. Twelve studies used cognitive therapies to alter physical activity and diet, while the remaining two studies focused on other behaviours. The control groups received either no intervention, usual care or other interventions, and the studies measured several behavioural outcomes. Few studies had follow-up times beyond four months after the end of the intervention. We judged 11 studies to have an unclear risk of bias, two studies to have a low risk of bias, and one study to have a high risk of bias.

We found small effects of cognitive therapies targeting physical activity and diet compared to no intervention or usual care.

- For physical activity, the standardized mean change difference based on nine studies with 1401 participants was 0.19 with a 95% confidence interval of 0.03 to 0.35, indicating increased physical activity. According to GRADE, we rated our confidence in the effect estimate as moderate.
- For diet based on types of foods or food groups consumed, the standardized mean change difference based on three studies with 562 participants was 0.23 with a 95% confidence interval of 0.06 to 0.39, indicating improved dietary quality. We rated our confidence in the effect estimate as moderate.
- For diet based on energy intake, the standardized mean change difference based on three studies with 588 participants was -0.19 with a 95% confidence interval of -0.38 to -0.03, indicating reduced energy intake. We rated our confidence in the effect estimate as moderate.

The results of cognitive therapies targeting physical activity and diet, or physical activity and tobacco use, as compared to other interventions were associated with large uncertainty. According to GRADE, we rated our confidence in the effect estimates as very low. Thus, we are uncertain whether cognitive therapies change these outcomes compared to other interventions.

Discussion

The study participants in this review were diverse and included both patients and healthy persons with risk factors such as overweight or a sedentary lifestyle. The interventions involved basic elements of cognitive therapies, such as goal setting and skills development related to self-regulation of behaviour, problem solving, and relapse prevention. Several different health professions delivered the interventions, with great variation in the duration and frequency of the therapy sessions.

The strict exclusion criteria applied in several of the studies, for example exclusion of persons with co-morbidities or mental health problems, may limit the applicability of the results. Our results may not capture how effective cognitive therapies targeting two health behaviours will be under routine clinical practice. Another possible limitation was that all studies except one measured the outcome as self-reported behaviours using questionnaires. Such methods are known to have limited ability to detect behavioural change from one point in time to another in a reliable way. Another limitation is that the studies used many different methods to measure the outcome, and therefore we had to standardise the scales for the meta-analyses. Thus, the connection with the original measurement scales, such as minutes per day of physical activity or units of fruit, is lost. We can only describe effects in terms of direction (advantage of the intervention or control group or showing little or no difference) and magnitude (small, moderate, or large). This makes it difficult to interpret the results. Finally, few studies had follow-up beyond four months post-intervention.

Research gaps include lack of studies targeting tobacco use together with other health behaviours, few studies comparing cognitive therapies to other interventions, lack of common outcomes measurements for heath behaviours, and lack of follow-up for at least 12 months post-intervention.

Conclusion

Cognitive therapies targeting at least two health behaviours at the same time probably lead to small short-term improvements in physical activity level and diet when they are compared to no intervention or usual care. Compared to other interventions, the evidence is too uncertain to indicate whether cognitive therapies targeting multiple behaviours at the same time change physical activity, diet, and tobacco use.

Hovedfunn (norsk)

En stor del av befolkningen har to eller flere levevaner som medfører økt risiko for sykdom, for eksempel fysisk inaktivitet, usunt kosthold eller bruk av tobakk. Kognitive terapier har dokumentert effekt på fysisk aktivitet, men vi kjenner ikke effekten av å arbeide med to eller flere levevaner samtidig.

Vi oppsummerte effekten av kognitive terapier på to eller flere levevaner i studier som involverer pasientgrupper og personer med lav fysisk aktiveter og/eller overvekt. Vi inkluderte 14 randomiserte kontrollerte studier. Få studier hadde oppfølging mer enn fire måneder.

Vi fant at:

- Kognitive terapier gir trolig en liten bedring av fysisk aktivitet og kosthold sammenlignet med ingen tiltak eller vanlig behandling, basert på dokumentasjon av middels kvalitet.
- Vi er usikre om kognitive terapier fører til endring av fysisk aktivitet, kosthold, eller bruk av tobakk sammenlignet med andre tiltak.

Tittel:

Kognitive terapier rettet mot endring av to eller flere levevaner samtidig: en systematisk oversikt.

Publikasjonstype:

Systematisk oversikt

En systematisk oversikt er resultatet av å

- innhente
- kritisk vurdere og
- sammenfatte relevante forskningsresultater ved hjelp av forhåndsdefinerte og eksplisitte metoder.

Svarer ikke på alt:

Ingen helseøkonomisk vurdering.

Hvem står bak denne rapporten?

Folkehelseinstituttet har gjennomført denne systematiske oversikten på oppdrag fra Helsedirektoratet.

Når ble litteratursøket utført?

Søk etter studier ble avsluttet November 2016.

Fagfeller:

Roger Hagen, førsteamanuensis, Psykologisk institutt, Norges teknisknaturviteskapelige universitet.

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Sammendrag (norsk)

Bakgrunn

I 2013 skyldtes 37 % av alle dødsfall i Norge risikofaktorer koblet til levevaner. De viktigste av disse var usunt kosthold, røyking og fysisk inaktivitet. En stor del av befolkningen har to eller flere av disse levevanene, som medfører økt risiko for sykdom. Kognitive terapier har dokumentert effekt innen flere helseområder, inkludert på fysisk aktivitet, men vi kjenner ikke effekten av å arbeide med tiltak rettet mot to eller flere levevaner samtidig.

Termen kognitive terapier som den brukes i denne rapporten inkluderer også kognitive atferdsterapier.

Formál

Vi utførte en systematisk oversikt for å svare på spørsmålet «Hva er effekten av kognitive terapier på forandring av to eller flere levevaner samtidig hos voksne 18 år eller eldre, sammenlignet med ingen tiltak, vanlig behandling eller annet tiltak?»

Metode

Vi søkte systematisk etter systematiske oversiktsartikler og senere etter primærstudier i fem elektroniske databaser. I tillegg søkte vi i referanselister til inkluderte studier. To personer gikk uavhengig igjennom titler og sammendrag, valgte ut studier basert på fulltekstartikler, og vurderte risiko for systematiske skjevheter i de inkluderte studiene. En person hentet ut data fra studiene og en annen person verifiserte datauttrekkingen. Vi oppsummerte resultatene med «random-effects» metaanalyser og presenterte standardiserte gjennomsnittsforskjeller og relativ risiko med 95 % konfidensintervall. Vi vurderte tilliten til effektestimatene med GRADE (Grading of Recommendations Assessment, Development and Evaluation) og presenterte resultatene i diagram og tabeller. I GRADE-systemet betyr høy kvalitet at vi har stor tillit til at effektestimatet ligger nære den sanne effekten. Middels kvalitet betyr at effektestimatet sannsynligvis nær den sanne effekten, men det er også en mulighet for at den kan være forskjellig. Lav kvalitet betyr at den sanne effekten kan være vesentlig

ulik effektestimatet. Svært lav kvalitet betyr at vi har svært liten tillit til at effektestimatet ligger nær den sanne effekten.

Resultat

Vi fant ikke systematiske oversikter som besvarte spørsmålet. Vi fant 14 randomiserte kontrollerte studier som tilfredsstilte våre inklusjonskriterier. De fleste studiene inkluderte personer med lavt fysisk aktivitetsnivå og/eller overvekt. Fem studier inkluderte pasientgrupper, for eksempel personer med kreft, type 2 diabetes eller hjerte- og karsykdom. Tolv studier evaluerte tiltak rettet mot fysisk aktivitet og kosthold. Få studier hadde oppfølging mer enn fire måneder etter avsluttet tiltak. Vi vurderte 11 studier til å ha uklar risiko for systematiske skjevheter, to studier til å ha lav risiko, og én studie til å ha høy risiko for systematiske skjevheter.

Vi fant at kognitive terapier hadde små effekter på fysisk aktivitet og kosthold sammenlignet med ingen tiltak eller vanlig behandling.

- For fysisk aktivitet var den standardiserte gjennomsnittsforskjellen for forandring 0.19 med 95 % konfidensintervall 0.03 til 0.35. Dette er basert på ni studier med til sammen 1401 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som middels.
- For kosthold basert på type matvarer var den standardiserte gjennomsnittsforskjellen for forandring 0.23 med 95 % konfidensintervall 0.06 til 0.39. Dette er basert på tre studier med til sammen 562 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som moderat.
- For kosthold basert på energiinntak var den standardiserte gjennomsnittsforskjellen for forandring -0.19 med 95 % konfidensintervall -0.38 til -0.03. Dette er basert på tre studier med 588 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som middels.

Resultatene for kognitive terapier rettet mot fysisk aktivitet og kosthold, og fysisk aktivitet og bruk av tobakk sammenlignet med andre tiltak var forbundet med stor usikkerhet. Vi vurderte, ifølge GRADE, vår tillit til effektestimatene som svært lav. Vi er usikre på om kognitiv terapi fører til endring av disse utfallene, sammenlignet med andre tiltak.

Diskusjon

Det var mange forskjellige deltakere i studiene som ble inkludert i denne systematiske oversikten. Det var både pasienter og ellers friske personer med lavt nivå av fysisk aktivitet og/eller overvekt. Tiltakene inneholdt grunnleggende elementer i kognitive terapier slik som målsetting, utvikling av ferdigheter til selvregulering, problemløsning, og forebygging av tilbakefall. Flere ulike typer helsepersonell ga tiltakene, og det var stor variasjon i varighet og hyppighet de kognitive terapiene som ble gitt.

Strenge eksklusjonskriterier, for eksempel at personer med flere sykdommer eller med problemer innen mental helse ble ekskludert, kan begrense anvendbarheten av resultatene. Det kan være at resultatene ikke fanger opp hvorvidt kognitive terapier rettet mot to eller flere levevaner samtidig virker når de brukes i vanlig klinisk praksis. En annen mulig begrensning er at måling av levevaner ble gjort med selvrapportering av endepunkter via spørreskjemaer i alle studier unntatt én. Muligheten for at spørreskjemaer fanger opp forandring fra et tidspunkt til et annet på en pålitelig måte er ukjent. En annen begrensning er at studiene målte levevaner på mange forskjellige måter og som en konsekvens måtte vi standardisere skalaene i meta-analysene. Koblingen til de opprinnelige måleskalaene som for eksempel minutter av fysisk aktivitet per dag, eller energiinntak gikk da tapt. Vi kan kun beskrive effekter i termer av retning (til fordel for tiltaks- eller kontrollgruppen, eller at resultatene fant liten eller ingen forskjell) og størrelsesorden (liten, moderat, eller stor effekt). Dette gjør det vanskelig å tolke resultatene. Få studier hadde oppfølging av resultater lenger enn fire måneder etter avsluttet tiltak, noe som også begrenser tolkning av disse studiene.

Vi identifiserte følgende forskningshull: mangel på studier hvor tiltaket også er rettet mot røyking, mangel på studier som sammenlignet kognitive terapier med andre tiltak, mangel på standardisering av utfallmål for levevaner, og mangel på oppfølging i det minste 12 måneder etter avsluttet tiltak.

Konklusjon

Kognitive terapier rettet mot to eller flere levevaner samtidig gir trolig en liten bedring av fysisk aktivitetsnivå og kosthold på kort sikt sammenlignet med ingen tiltak eller vanlig behandling. Det er usikkert om kognitiv terapi endrer fysisk aktivitet, kosthold og bruk av tobakk sammenlignet med andre tiltak.

Table of contents

KEY MESSAGES	Z
EXECUTIVE SUMMARY	3
HOVEDFUNN (NORSK)	6
SAMMENDRAG (NORSK)	7
TABLE OF CONTENTS	10
PREFACE	12
OBJECTIVE	13
INTRODUCTION	14
About this report	14
Health behaviours	14
Cognitive therapies	16
METHODS	18
Literature search	18
Inclusion criteria	18
Exclusion criteria	19
Study selection	19
Assessment of quality of systematic reviews	19
Assessment of risk of bias in primary studies	19
Data extraction	20
Analyses	20
Rating of our confidence in the effect estimates	21
RESULTS	22
Description of the included studies	23
Risk of bias in included studies	26
Effects cognitive therapies targeting physical activity and dietary habits	s compared to
no intervention or usual care	28
Effects of cognitive therapies targeting dietary habits and tobacco use of	ompared to
no intervention or usual care	31
Effects of cognitive therapies targeting physical activity and dietary hab	oits compared
to other interventions	33

Effects of cognitive therapies targeting physical activity habits and tobacco use	
compared to other interventions	35
DISCUSSION	37
Main findings	37
The quality of the documentation	38
Strengths and limitations	38
How applicable are the results?	39
Agreement with other systematic reviews	40
Implications for practice	41
Research gaps	42
CONCLUSION	44
REFERENCES	45
APPENDIX	50
A. Search strategy	50
B. Excluded studies	53
C. Characteristics of included studies	56
D. Risk of bias	64
E. GRADE evidence profiles	67
F. Studywise results	73

Preface

The Knowledge Centre in the Norwegian Institute of Public Health carried out a systematic review of the effects of cognitive therapies for changing health behaviours related to physical activity, diet, and tobacco use. This report is the second of three and presents the findings concerning effects of cognitive therapies targeting two or more health behaviours. The Norwegian Directorate of Health commissioned the systematic review.

The project group consisted of:

Project leader: Eva Denison, senior researcher.

Vigdis Underland, researcher.

Annhild Mosdøl, senior researcher.

Gyri Hval Straumann, research librarian.

All at the Knowledge Centre for the Health Services in the Norwegian Institute of Public Health

We thank Rigmor C Berg, research director at the Knowledge Centre in the Norwegian Institute of Public Health, who was the project leader in the initial stages of the project. We also thank Atle Fretheim, research director at the Knowledge Centre in the Norwegian Institute of Public Health, and Liv Merete Reinar, research director at the Knowledge Centre in the Norwegian Institute of Public Health, for reviewing and commenting on a draft of the report. Finally, we thank the reviewers Roger Hagen, associate professor, Department of Psychology, the Norwegian University of Science and Technology, and Anders Hovland, associate professor, Department of Psychology, University of Bergen.

All authors and reviewers declare that they have no conflicts of interest.

Signe Flottorp Gunn E Vist Eva Denison

Acting head of department Research director Project leader

Objective

Our objective was to answer the question "What is the effect of cognitive therapies to change two or more health behaviours in adults 18 years or older, compared to no intervention, usual care or another intervention?"

Introduction

About this report

This is the second in a series of three reports, based on a systematic search, of the effects of cognitive therapies when used to change health behaviours. In this report, we present the results concerning effects of cognitive therapy interventions designed to change more than one health behaviour at the same time, e.g. both diet and physical activity. The first report presented the results concerning effects of cognitive therapies in increasing physical activity (1), and the third report will present the results concerning effects of cognitive therapies in reducing tobacco use.

Because we have chosen to write three reports as "stand-alone" documents, some chapters are very similar in all three reports. This applies particularly to the introduction, methods and some parts of the discussion.

There is some disagreement in Norway about the terminology concerning the intervention in this report series. The term "cognitive therapies" commonly includes "cognitive behavioural therapies" (2), and the commission by the Norwegian Directorate of Health concerned cognitive therapies in this sense, i.e. with a behavioural component. We will use the term "cognitive therapies" throughout the text also when included studies and other literature we may refer to use the term "cognitive behavioural therapies". We are aware that researchers and practitioners may disagree with this use of terminology.

Health behaviours

Behavioural risk factors for non-communicable disease

Non-communicable diseases such as cardiovascular diseases, cancers, and chronic respiratory diseases accounted for an estimated 67% of deaths globally in 2008. These diseases share four behavioural (or lifestyle) risk factors: tobacco use, physical inactivity, unhealthy diet, and harmful alcohol use (3). Ischemic heart disease, stroke, and lung cancer contributes most to years of life lost in Western European countries (4). In 2013, 37% of all deaths in Norway could be attributed to behavioural risk factors, of which unhealthy diet, tobacco use, and physical inactivity were the most important. Metabolic risk factors, such as high blood pressure, high body

mass index, high blood glucose, and high levels of total cholesterol contributed to 30% of all deaths. The analyses adjusted for overlap within and between the behavioural and metabolic factors (5).

Engaging in more than one health behaviour related to non-communicable diseases

A large proportion of the population engages in two or more unfavourable health behaviours, i.e. tobacco use, physical inactivity, unhealthy diet, and harmful alcohol use (3).

For example, a Dutch study showed that adherence to five preventive health behaviours (non-smoking, moderate alcohol use, fruit consumption, vegetable consumption and physical exercise) formed three clusters: a healthy, a non-healthy, and a poor nutrition cluster. The pattern was replicated in groups with low, moderate, and high educational background. The high education group scored better on all behaviours, whereas the low education group scored worst (6). An Irish population study defined six clusters: former smokers, temperate, physically inactive, healthy lifestyle, multiple risk factor, and mixed lifestyle. Men aged 18-29 years, in the lower social classes, were most likely to adopt unhealthy lifestyle patterns, while women from the higher social classes and aged over 65 years were most likely to be in the healthy lifestyle cluster (7).

A systematic review on smoking, nutrition, alcohol, and physical activity identified 56 relevant studies where a majority (81%) of studies reported a "healthy" cluster characterized by an absence of risk factors. More than half of the studies reported a clustering of alcohol with smoking, and half reported clustering of all four risk factors. Males and those with greater social disadvantage showed riskier patterns of behaviours (8). Another systematic review including only studies from the United Kingdom, found that alcohol misuse and smoking was the most commonly identified risk behaviour cluster. Socio-economic status was the strongest predictor of engaging in multiple risk behaviours (9).

The studies described above have all taken a clustering approach to data analysis and interpretation of the results. In line with epidemiological research, multiple health behaviours may be viewed as either co-occurring or clustered. Co-occurrence implies that multiple behaviours are independent of each other, whereas clustering implies either co-occurrence of behaviours beyond what may be expected from probability rules, or underlying patterns of association between behaviours (10). The terms are often used interchangeably, but they are conceptually and methodologically distinct and should be used consistently, especially as they may imply different approaches to interventions (11).

Interventions to change multiple health behaviours

Multiple health behaviour change interventions are efforts to promote two or more health behaviours at the same time. Such interventions may target populations or individuals (12). A systematic scoping review of interventions targeting multiple risk behaviours in adults showed that the most commonly targeted combination was diet and physical activity. The focus of most interventions was prevention or reduction of risk for chronic disease or health promotion. Most interventions had multiple components including education, advice, counselling, skills training, and incentives (13). A systematic review concluded that multifactorial interventions in primary health care did not change or reduce cardiovascular mortality or clinical events in general populations (14). A more recent overview of systematic reviews concluded that multifactorial interventions in primary health care improve cardiovascular risk factors and have a small but potentially important effect on mortality. The interventions seemed more effective in the at-risk populations and when carried out at a high level of intensity (15). A recent systematic review investigating the relative efficacy of simultaneous and sequential approaches to multiple health behaviour change suggested that simultaneous and sequential approaches were equally efficacious. However, the limited number of studies and heterogeneity between the studies constrained the conclusions that could be drawn (16).

Cognitive therapies

Cognitive therapies are psychological treatments that address the interactions between thoughts, emotions, and behaviour. Cognitive therapies include several treatments and practices (17) which share fundamental propositions, e.g. that our cognitions/what we think affects what we feel and how we choose to act/behave, and that desired behaviour change may be affected through changes in our cognitions (18). A range of disorders is treated using cognitive therapies, of which the majority is psychiatric disorders, e.g. major depressive disorder, generalized anxiety disorder, panic disorder, and phobias. Psychological problems, such as couple and family problems, and medical problems with psychological components, such as chronic pain, tinnitus, and insomnia are also treated using cognitive therapies (19).

Cognitive therapies are usually limited to between 10 and 20 sessions. The interventions focus on current problems and follow a structured style including problem description, goal setting, collection of data for analysis of the problem, a specific problem formulation, development of skills relevant to the problem, and relapse prevention (17). Techniques used in cognitive therapies include, for example, Socratic questioning to understand clients' perspectives and help them work out solutions to their problems, using logs for self-monitoring of thoughts, emotions, beliefs, and behaviours, graded task assignments, graded exposure, relaxation techniques, and roleplay (19).

Health personnel with a primary professional qualification other than psychology may deliver cognitive therapies given sufficient training, acquired through post-qualification courses. Roth and co-workers described a model of competences to deliver cognitive therapies, regardless of primary professional qualification, (20) which comprises:

- generic competencies in psychological therapy
 - competences needed to relate to people and to carry out any form of psychological intervention
- basic cognitive and behavioural competencies
 - o basic competencies used in most cognitive therapies
- specific cognitive and behavioural therapy techniques
 - specific techniques employed in most behavioural and cognitive therapies
- problem-specific skills
 - competencies needed to deliver a treatment package for a specific problem formulation
- metacompetences
 - competences used to work across all levels and to adapt cognitive therapies to each individual patient

In Norway, the health authorities recommend cognitive therapies for a range of mental health disorders and for coping with somatic disorders (21). The Norwegian Association for Cognitive Therapy holds 2-4 semester post-qualification courses in cognitive therapies for psychologists and physicians, and for health- and social welfare personnel with at least a bachelor degree.

The knowledge base of cognitive therapies

Cognitive therapies are widely researched. A review from 2012 included 269 meta-analyses published from 2000 through September 2011 (22). The authors divided the included meta-analyses into 17 disorder- or population categories. Categories with 10 or more meta-analyses were disorders in children (n=66), anxiety disorders (n=48), depression (n=35), chronic medical conditions (n=23), addictions (n=18), schizophrenia or psychosis (n=18), chronic pain or fatigue (n=15), bipolar disorder (n=10), and disorders in elderly adults (n=10). The review appeared to focus solely on "disorders" and no categories concerned health behaviours such as physical activity, diet or tobacco use (22).

The results of recently published systematic reviews suggest that cognitive therapies are effective for the treatment of adult depressive disorders (23, 24), social anxiety disorders (25), insomnia (26, 27), chronic pain (28), and subacute and chronic neck pain (29) when compared to no treatment or usual treatment. The evidence for cognitive therapies compared to other treatment seems to be limited (23, 28, 29). We have not found systematic reviews investigating effects of cognitive therapies on change of multiple health behaviours.

Methods

We carried out a systematic review according to the Cochrane Handbook for Systematic Reviews of Interventions (30).

Literature search

We searched systematically in the following electronic databases:

- The Cochrane Controlled Trials Register (CENTRAL)
- Cinahl
- MEDLINE (Ovid)
- Embase (Ovid)
- PsycINFO (Ovid)

Research librarian Gyri Hval Straumann planned and carried out the searches. We initially searched for systematic reviews, without finding relevant publications. The search strategy, presented in Appendix A, was last updated in November 2016. It was adapted to primary studies and was peer-reviewed by another research librarian. We searched simultaneously for studies evaluating effects of cognitive therapies for change of different health behaviours, i.e. physical activity, diet, and tobacco use. This report presents the results for studies where cognitive therapies were used to target two or more behaviours at the same time, e.g. physical activity *and* diet, in the same program. We read the reference lists of included studies in addition to searching in the electronic databases.

Inclusion criteria

Study design: Systematic reviews of high quality.

Randomised controlled trials.

Cluster-randomised controlled trials.

Population: Adults 18 years or older.

Intervention: Cognitive therapies aiming to change any combination of two or

more of the following behaviours: physical activity, diet, to-

bacco use.

Comparison: No intervention or other intervention.

Outcomes: Primary outcomes: Measures of physical activity, diet, or to-

bacco use.

Secondary outcomes: Relevant physiological or clinical out-

comes related to the health behaviours in question.

Language: No restrictions in the literature search. The project group read

publications in English, French, and Scandinavian languages and considered publications in other languages for translation.

Exclusion criteria

• Abstracts and other publication formats that do not convey full information from a study.

- Systematic reviews published before 2009.
- Systematic reviews or primary studies describing
 - o interventions without a behavioural component
 - interventions that are web-based or otherwise oriented towards self-help
 - interventions based only on mindfulness or motivational interviewing
 - interventions designed to help persons cope with disease or illness.

Study selection

We (ED and VU, ED and AM) independently screened titles and abstracts. Two of us (ED and VU) independently selected studies from full text publications. We based our selection on consensus and consulted a third author (GEV) to solve disagreements.

Assessment of quality of systematic reviews

We had planned to assess the quality of any included systematic reviews with a checklist based on the EPOC Checklist for Refereeing Protocols for Reviews (31).

Assessment of risk of bias in primary studies

We (ED and VU) independently assessed risk of bias by sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias (32). We based our final assessment on consensus and consulted a third author (GEV) to solve disagreements.

Data extraction

We had planned to extract the following data from any systematic reviews, using a data extraction form: authors and year of publication, topic, number of relevant studies included, study design and methodological quality of included studies, number of participants in the included studies, intervention, who carried out the intervention, comparison(s), outcomes, and results.

One author (ED) extracted the following data from included primary studies, using a data extraction form: authors and year of publication, topic, study design, country, population details, intervention details, comparison(s), outcomes, and length of follow-up, attrition, descriptive dichotomous and continuous data, measures and estimates of effect. When more than one effect estimate was reported for primary outcomes, we chose the estimates that in our judgment best reflected the outcomes in general terms. For example, we chose minutes of physical activity per week rather than minutes spent in leisure activities, or total calorie intake per day or week rather than calories coming from sugar. Another author (VU) verified the extracted data against the full text publications.

Analyses

We had planned to present the results reported in included systematic reviews by interventions and comparisons. We also planned to present outcomes based on length of follow-up: short-term from post intervention to six months post intervention; medium-term from more than six months to one-year post intervention; long-term, more than one-year post intervention.

In synthesizing the results from the included primary studies, we adopted a broad approach assuming that cognitive therapies are used in different populations and contexts, are of varying length and intensity, and are given by a range of health professionals. We further assumed that the generalizability and usefulness of the results would increase by synthesizing studies that covered different populations, settings and modes of delivery (33). We went through the following steps to synthesize the data: We first sorted the studies by primary outcomes targeted by the intervention and then by comparison (against no intervention/usual care or other intervention). Using the software Review Manager 5.3, (34), we then carried out random-effects meta-analyses for each outcome. We present relative risk and 95% confidence intervals for dichotomous data and standardized mean differences (SMD, described below) and 95% confidence intervals for continuous data. We carried out separate meta-analyses for studies that reported mean difference and studies that reported mean change difference (see explanation below). We planned to carry out sensitivity analyses to examine the robustness of the obtained results for each comparison. We specified, a priori, the following characteristics: health status (patient group or

healthy persons with risk factors for cardiovascular disease), duration of the intervention, profession of person(s) delivering the intervention, and risk of bias in the included studies. We interpreted the effect estimates based on SMD according to Cohen (35) who suggested the following (arbitrary) definitions: small effect = 0.2, medium effect = 0.5 and large effect = 0.8.

The standardized mean difference (SMD) is used as a summary statistic in meta-analysis when studies assess the same outcome but measure it in different ways. Before the results are combined in the meta-analysis they are standardized to a uniform scale. Thus, the intervention effect in each study is described relative to the observed variability (standard deviation) in that study. Study results representing mean difference and mean change difference should not be combined in the same meta-analysis using standardized mean differences (36). Therefore, we have carried out separate analyses within the same comparison (with no intervention or usual care).

Rating of our confidence in the effect estimates

We used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to rate our confidence in the effect estimates for critical outcomes and comparisons within each topic. The domains rated in the GRADE approach are study limitations, indirectness, inconsistency, imprecision, publication bias, and magnitude of effect, dose-response gradient, and plausible confounding affecting confidence in estimated effects (37). ED and VU carried out the GRADE ratings together, discussing issues and arriving at consensus. We consulted a third author (GEV) to solve uncertainties.

The ratings are defined as follows:

High quality: We are very confident that the true effect is close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Results

Results of the literature search

We did not identify relevant systematic reviews in the initial search. The adapted search in electronic databases, designed to identify primary studies, resulted in 6538 references after duplicate control. In addition, we identified two relevant publications by searching reference lists of included publications. From 6540 references, we excluded 6427 references that were judged irrelevant based on title and abstract. We selected 71 full text reports for evaluation in the two other reports in this series. We evaluated 42 publications in full text for this report and excluded 28 studies based on inclusion- and exclusion criteria. The 28 excluded studies are presented with the reason for exclusion in the Appendix, Table B1. We included 14 studies.

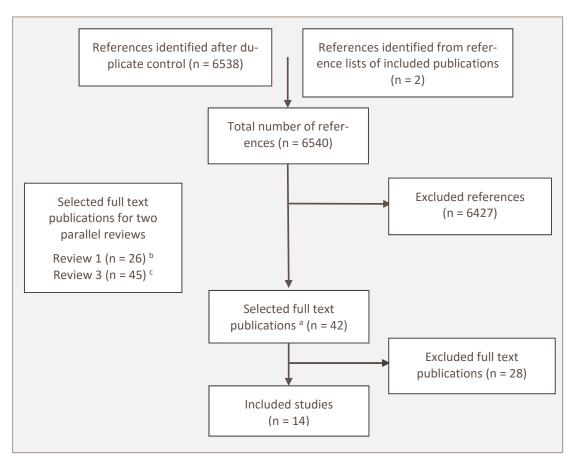


Figure 1. Flow chart of the citations reviewed in the systematic review.

- ^a References relevant to the present systematic review.
- ^b References relevant to a previous report on physical activity (1).
- ^c References relevant to a future report on tobacco use.

Description of the included studies

We included 14 randomised controlled trials with 2 434 participants. Seven studies were from the USA, three were from Australia, two were from Great Britain, and one each from The Netherlands and Sweden. Twelve studies evaluated an intervention that targeted physical activity and dietary habits. Six of these studies included adults who were overweight or obese according to BMI criteria (38). Five studies included persons with type 2 diabetes, type 2 diabetes or hypertension, rheumatoid arthritis, coronary heart disease, or survivors of breast cancer. One study included persons with mild to moderate intellectual disabilities. One study evaluated an intervention that targeted tobacco use and dietary habits in weight-concerned adult female smokers, and one study evaluated an intervention that targeted tobacco use and physical activity habits in adults with type 2 diabetes. Most interventions included one or more of the following cognitive or cognitive-behavioural content: goal-setting, selfefficacy, self-monitoring, self-management, self-regulation, problem solving, coping skills, cognitive restructuring, and relapse prevention. Two studies evaluated interventions based on an acceptance and commitment approach. Ten studies compared the intervention to no intervention or usual care, and two to education. Two studies had two intervention arms in addition to controls. The primary outcomes, physical activity and diet, were conceptualized in several ways, e.g. as minutes, hours or days of physical activity per week, steps per day, fruit and vegetable consumption, total fat intake, or healthy eating. Tobacco use was conceptualized as either number of cigarettes per day or abstinence rate. Four studies had follow-up at the end of the intervention, and seven studies had follow-up 8 months or more after the intervention. One study that did not report duration of the intervention had follow-up 12 months after start of the study. (Table 1).

Table 1. General description of the included studies, ordered by comparison.

Study ID; country	Population	Intervention content	Comparison	Primary out- come(s)	Length of follow-up				
Cognitive th	Cognitive therapies targeting physical activity and dietary habits compared to no intervention/usual care								
Ash (39) Australia	Adults ≥ 18; BMI ≥ 27; N = 191	Knowledge and skills develop-	Advice	PA: % sufficiently active	10 months post interven-				
		ment; self-effi- cacy; relapse pre- vention		Diet: not reported	tion				
Bergström (40) A	Adults 20-66;	Knowledge and	Usual care	PA: steps/day	4 months post intervention				
Sweden	mild to moderate intellectual disa- bilites; N = 130	skills develop- ment; self-effi- cacy; environment improvement		Diet: number of food groups/day					
Burke (41)	Adults 40-70;	Goal setting; self-	Usual care	PA: minutes/week	End of inter-				
Australia	BMI >25; N = 241	regulation; social support		Diet: energy intake	vention				

Eakin (42) Australia	Adults ≥ 30; type 2 diabetes or hy- pertension; N = 434	4 A's approach: advice, assess, assist, arrange; based on social cognitive theory	Usual care	PA: minutes/week Diet: total fat intake	End of intervention
Fletcher (43) USA	Adults ≥18; cur- rent or past over- weight; N = 72	Acceptance and commitment therapy workshop organised around 10 principles	No intervention	PA: MET- minutes/week Diet: fruit and veg- etable consumption	3 months post intervention
Hinderliter (44) USA	Adults > 35; BMI 25-39; sedentary; N = 144	Awareness training; self-monitoring	Usual care	PA: % exercising ≥ 3 times/week Diet: dietary intake	8 months post interven tion
John (45) UK	Adults > 18; diagnosis of RA; N = 110	Goal setting: skills development	No intervention	PA: MET- minutes/week Diet: fruit and veg- etable consumption	4 months post interven tion
Kattermann (46) USA	Students 18-30; BMI 23-30; N = 58	Based on ac- ceptance princi- ples; goal-setting: self-monitoring	No intervention	PA: fre- quency/week Diet: not reported	End of intervention
Mefferd (47) USA	Breast cancer surviviors ≥ 18; N = 85	Goal-setting; self- monitoring; cogni- tive restructuring; self-regulation	No intervention	PA: hours/week Diet: not reported	End of intervention
Murphy (48) USA	Adults <75; admitted to hospital for coronary heart disease; N = 275	Cognitive restruc- turing; self-regula- tion; relapse pre- vention	Usual care	PA: minutes/week Diet: dietary fat in- take	10 months post interver tion
Steed (49) UK	Adults < 75; type 2 diabetes; N = 124	Goal-setting; self- monitoring; self- management; problem solving	Usual care	PA: days/week Diet: days/week	3 months post interver tion
Cognitive t	herapies targeting o	lietary habits and tol	bacco use compare	ed to no intervention/us	ual care
Sallit (50) USA	Female weight- concerend smok- ers ≥19 yr; N = 216	Cognitive restruc- turing; goal-set- ting; self-regula- tion; relapse pre- vention	No intervention	Diet: healthy eating Tobacco use: num- ber of cigarettes per day	9 months post interven tion
Cognitive	therapies targeting	physical activity an	d dietary habits coi	mpared to other interve	entions
Annesi (51) USA	Adults 34-55; BMI 35-50; N = 200	Goal setting; self- monitoring; cogni- tive restructuring; relapse prevention	Education	PA: METs/week Diet: fruit and veg- etable consumption	3 months post interven tion
Ash (39) Australia	Adults ≥ 18; BMI ≥ 27; N = 191	Knowledge and skills develop- ment; self-effi- cacy; relapse pre- vention	Individual diet prescription	PA: % sufficiently active Diet: not reported	10 months post interver tion
Hinderliter (44) USA	Adults > 35; BMI 25-39; sedentary; N = 144	Awareness train- ing; self-monitor- ing	Diet only	PA: % exercising ≥ 3 times/week	8 months post intervention

Diet: dietary intake						
Cognitive therapies targeting physical activity habits and tobacco use compared to other interventions						
Welschen (52)	Adults 18-75;	Goal-setting; pro-	Diabetes care	PA: minutes/day	12 months	
The Netherlands	rlands type 2 diabetes; N = 154	blem solving	system	Tobacco use: abstinence rate	post base- line ^a	

^a Duration of the intervention was not reported.

Participants

We describe the participants in each study further in the Appendix, Table C1. The age of the participants ranged between 22 and 61 years with a mean age across studies of 50 years. Three studies included women only. There was a mean of 57% women across the remaining studies, with a range from 13% to 83%. Twelve studies reported the ethnicity of the participants. The mean percentage of participants reported as Caucasian across 10 studies was 76%, with a range of 49% to 97%. The percentage of participants who had college education or more, reported in six studies, varied between 14% and 65% with a median value of 46%. One study reported that mean length of education was 11 years. Other characteristics, such as civil and economic status, were sparsely reported

Interventions and comparisons

The 12 studies that targeted physical activity and dietary habits, compared the intervention either to no intervention/usual care (often including advice), or they compared the intervention to other interventions. These were education or diet prescriptions. The study that targeted diet and tobacco use compared the intervention to no intervention, and the study that targeted physical activity and tobacco use compared the intervention to another intervention, a diabetes care system.

The interventions that targeted physical activity and diet as <u>compared to no intervention</u> (n = 4), or <u>usual care</u> (n = 7) were mainly delivered in a group format. Ten out of 12 studies used this format. One study used a combination of group and individual sessions, and one study had only individual sessions by phone. The duration of the interventions ranged from one day to 52+ weeks with a median duration of 16 weeks. Session length, reported in eight studies, varied between 18 minutes and six hours with a median length of 90 minutes. Health professionals with education in nutrition gave the intervention in five studies. The intervention was given by either health ambassadors and caregivers, "trained staff", "facilitators", psychologist and nurse, or rheumatology researchers in five studies. One study did not state who gave the intervention. Goal setting, self-monitoring, problem solving and skills development were the most common elements of the intervention content across studies. See Appendix, Table C2 for details of each study.

The intervention that targeted diet and targeted tobacco use as <u>compared to no intervention</u> was delivered in a group format and lasted for 12 weeks, session length

was 60 minutes. A nutritionist gave the intervention that included goal setting, self-monitoring, development of self-efficacy and skills, and stimulus control. See Appendix, Table C2 for details of the study.

The interventions that targeted physical activity and diet as <u>compared to other interventions</u> (education [n=1] or diet prescriptions [n=2]) were all three delivered in a group format. The duration of the intervention was eight, 12, and 16 weeks, respectively. Session length was 60 and 90 minutes, respectively, in two studies and one study did not report session length. Health professionals with education in nutrition gave the intervention in two studies and in one study, certified YMCA wellness leaders delivered the intervention. The interventions included goal setting, self-monitoring, skills development, and relapse prevention. See Appendix, Table C2 for details of each study.

The intervention that targeted physical activity and tobacco use as <u>compared to another intervention</u> was delivered individually by dieticians and diabetes nurses. Duration of the intervention was not reported, but session length was stated to be 30 minutes. The main components were goal setting and problem solving. See Appendix, Table C2 for details of the study.

Outcomes

The primary outcomes physical activity and diet were conceptualized and measured in several ways. Regarding physical activity, seven studies measured duration, e.g. minutes or hours per week, two studies measured frequency, two studies measured achievement of pre-set goals, one study measured energy expenditure, and one study measured steps per day. All studies but one measured the outcome by self-report. The one study measured steps per day using a pedometer. Regarding diet, seven studies measured aspects of dietary intake, e.g. fruit and vegetable consumption, fat intake and energy intake, two studies measured qualitative aspects of the dietary intake such as food groups consumed or "healthy eating". Three studies did not report dietary intake data. All studies measured diet by self-report. Tobacco use was measured by number of cigarettes smoked per day in one study and by abstinence rate in one study. Both studies employed self-report without biochemical validation. See Appendix, Table C3 for details of each study.

The secondary outcomes reported in the studies, as defined by our inclusion criteria, are shown in the Appendix, Table C4.

Risk of bias in included studies

We judged 11 studies to have an unclear risk of bias, two studies to have a low risk of bias, and one study to have a high risk of bias (Figure 2). The rating of "unclear" was primarily due to lack of information concerning random sequence generation and

allocation concealment, and to uncertainty of consequences of non-blinding of participants and personnel and outcome assessment (32). Figure 2 shows our rating in each domain by study. Appendix, Table D1, presents support for our judgment of risk of bias for each study.

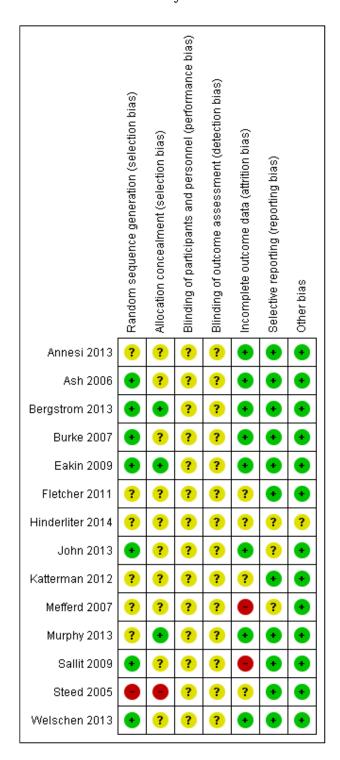


Figure 2. Risk of bias summary: our judgements about each risk of bias item for each included study.

Effects of cognitive therapies targeting physical activity and dietary habits compared to no intervention or usual care

We first show the results for outcomes related to physical activity (n=9), then for dietary outcomes (n=3).

Figures 3 and 4 show the effect measured on <u>physical activity</u> in the studies comparing cognitive therapies to no intervention or usual care. The nine studies shown in Figure 3 reported mean change difference as the effect measure while the two studies shown in Figure 4 reported relative risk. One study, John (45) in Figure 3, with 110 participants in total is not contributing to the meta-analysis. The authors stated that there was no statistical difference between the intervention and control group.

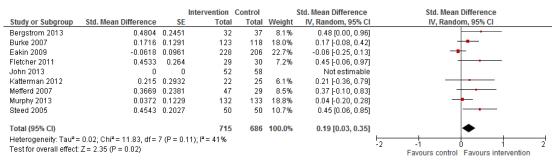


Figure 3. Effects of cognitive therapies compared to no intervention or usual care on physical activity in studies reporting mean change difference. Follow-up 0-10 months. SE = standard error, CI = confidence interval.

	Interver	ntion	Conti	rol		Risk Ratio	Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	I M-H, Random, 95% CI	
Ash 2006	10	28	10	24	59.2%	0.86 [0.43, 1.70]	ıj — — — — — — — — — — — — — — — — — — —	
Hinderliter 2014	9	40	3	37	40.8%	2.77 [0.81, 9.47]	i -	+
Total (95% CI)		68		61	100.0%	1.38 [0.43, 4.45]		
Total events	19		13					
Heterogeneity: Tau² =	0.48; Chi	= 2.85	, df = 1 (F	P = 0.09	9); I² = 659	%	0.2 0.5 1 2	Į.
Test for overall effect:	Z = 0.55 (P = 0.58	3)				Favours control Favours intervention	5

Figure 4. Effects of cognitive therapies compared to no intervention or usual care on physical activity in studies reporting relative risk. Follow-up 12 months. CI = confidence interval.

Figures 5 and 6 show the effect measured on <u>dietary aspects</u>. We categorized the interventions to focus on either promotion of a healthy diet or a reduction of energy intake. The three studies shown in Figure 6 promoted a healthy diet and reported mean change difference as the effect measure. The three studies shown in Figure 7 promoted a reduction of energy intake and reported mean difference as the effect measure.

				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Std. Mean Difference	SE	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Bergstrom 2013	0.1592	0.2471	11.8%	0.16 [-0.33, 0.64]	
Eakin 2009	0.2646	0.0964	77.6%	0.26 [0.08, 0.45]	
Fletcher 2011	0.0356	0.2604	10.6%	0.04 [-0.47, 0.55]	
Total (95% CI)			100.0%	0.23 [0.06, 0.39]	•
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.77$, $df = 2$ (P = 0.68); I		3); I² = 0%		, , , , , , , , , , , , , , , , , , , 	
Test for overall effect:	Z = 2.68 (P = 0.007)				-2 -1 U 1 2 Favours control Favours intervention

Figure 5. Effects of cognitive therapies compared to no intervention or usual care on healthy diet in studies reporting mean change difference. Follow-up 0-3 months. SE = standard error, CI = confidence interval.

	Inte	rventi	on	C	ontrol			Std. Mean Difference		Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Random, 95% CI	
Burke 2007	6.74	2.22	123	7.09	2.22	118	41.1%	-0.16 [-0.41, 0.10]			
Hinderliter 2014	1,806	550	40	1,873	669	37	13.1%	-0.11 [-0.56, 0.34]			
Murphy 2013	15.9	7	135	17.59	7	135	45.8%	-0.24 [-0.48, -0.00]		-	
Total (95% CI)			298			290	100.0%	-0.19 [-0.35, -0.03]		•	
Heterogeneity: Tau ² =	0.00; C	hi² = 0	.36, df:	= 2 (P =	0.83);	l ² = 0%			<u> </u>	- 1 	
Test for overall effect:	Z = 2.29	$\theta (P = 0)$	0.02)						-2 F	avours intervention Favours control	2

Figure 6. Effects of cognitive therapies compared to no intervention or usual care on energy intake in studies reporting mean difference. Follow-up 10-12 months. SD = standard deviation, CI = confidence interval.

Steed et al (49) measured effect of cognitive therapy on dietary aspects (healthy diet) as mean difference. The results showed that the groups were similar, three months after the end of the intervention. John et al (45) did not report data. The authors stated that there was no difference between the intervention group and the control group.

Table 2 presents the effect estimates from Figures 3-6 and the stand-alone studies along with our GRADE assessments concerning the quality of the evidence. The GRADE evidence profile is presented in the Appendix, Table E1.

The uncertainty due to the unclear risk of bias in most of the included studied resulted in downgrading for most of the outcomes. The studies were small with few participants and the resulting wide confidence intervals further reduced our confidence in the results. Additionally, heterogeneity in results across studies reduced our confidence for one of the outcomes.

Table 2. Summary of findings table and evidence for effects of cognitive therapies targeting physical activity and dietary aspects compared to no intervention or usual care on behavioural outcomes.

Cognitive therapies targeting physical activity and dietary aspects compared to no intervention/usual care on behavioural outcomes

Patient or population: Persons who may benefit from change in health behaviours

Setting: Primary health care

Intervention: Cognitive therapies targeting both physical activity and dietary aspects

Comparison: No intervention/usual care

Outcomes	Impact	№ of parti- cipants (studies)	Quality of the evidence (GRADE)
Physical activity, assessed with: self-report/pe- dometer/accelerometer follow up: range 0 to 10 months	The standardized mean change difference was 0.19 (0.03, 0.35) to the advantage of the intervention group. One study (n=110) did not report data, only that "there was no statistical difference between the intervention and control group".	1401 (9 RCTs)	⊕⊕⊕O MODERATE ¹
Physical activity, assessed with: self-report follow up: 12 months	The relative risk was 1.38 (0.43, 4.45).	161 (2 RCTs)	⊕OOO VERY LOW 1,3,4
Healthy diet, assessed with: self-report follow up: range 0 to 3 months	The standardized mean change difference was 0.23 (0.06, 0.39) to the advantage of the intervention group.	562 (3 RCTs)	⊕⊕⊕O MODERATE⁵
Healthy diet, assessed with: self-report follow up: range 3 to 9 months	The standardized mean difference based on one of two studies (n=100) was 0.11 (-0.28, 0.51). One study (n=110) did not report data, only that there was no statistical difference between the intervention and control group.	210 (2 RCTs)	⊕OOO VERY LOW 1,2,4
Energy intake, assessed with: self-report follow up: range 10 to 12 months	The standardized mean difference was -0.19 (-0.35, -0.03) to the advantage of the intervention group.	588 (3 RCTs)	⊕⊕⊕O MODERATE ¹

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- 1. Overall unclear risk of bias.
- 2. 2 small studies with 210 participants.
- 3. I-square 65%
- 95% confidence interval includes both considerable benefit and sizeable negative outcome.
- 5. The outcome was assessed with self-report.

We judged the quality of the evidence of effect to be moderate for physical activity in the studies where the results were reported as mean change difference and very low for physical activity in the studies where the results were reported as relative risk. A moderate rating of the quality of the evidence of effect indicates our assessment that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. A very low rating of the quality of the evidence of effect indicates that we have very little confidence in the effect estimate. Hence, for physical activity based on relative risk we think that the true effect is likely to be substantially different from the estimate of effect.

We judged the quality of the evidence of effect to be moderate for healthy diet in the studies where the results were reported as mean change difference and very low for healthy diet in the studies where the results were reported as mean difference.

We judged the quality of the evidence of effect to be moderate for energy intake.

These results show the effect of cognitive therapies targeting both physical activity and dietary aspects as compared to no intervention or usual care. We found that:

- Cognitive therapies probably lead to a small increase in physical activity, up to 10
 months after the end of the intervention. We are uncertain whether the
 intervention changes physical activity 12 months after the intervention.
- Cognitive therapies probably lead to a small increase in aspects of a healthy diet, up to three months after the end of the intervention. We are uncertain whether the intervention changes diet three to nine months after the intervention.
- Cognitive therapies probably lead to a small reduction of energy intake, 10 to 12 months after the end of the intervention.

We provide a description of the results in each study, based on the standardized mean difference and relative risk data from the meta-analyses (Appendix, Table F1).

Effects of cognitive therapies targeting dietary habits and tobacco use compared to no intervention or usual care

The evidence in this comparison is based on one study.

Sallit et al (50) reported results for therapy targeting dietary habits and tobacco use. The results showed that the intervention group improved their diet and reduced tobacco use compared to the control group. The standardized mean difference was 0.87 (95% CI 0.50, 1.23) for diet and -0.37 (95% CI -0.72, -0.01) for tobacco use.

Table 3 presents the effect estimates along with our GRADE assessments concerning the quality of the evidence of effect. The GRADE evidence profile is presented in the Appendix, Table E2.

Uncertainty due to study limitations in the included study resulted in downgrading for both outcomes. The study had few participants and included only females. Additionally, there was a low response rate and only completers were analysed.

Table 3. Summary of findings table and evidence for effects of cognitive therapies on diet and tobacco use compared to no intervention or usual care on behavioural outcomes.

Cognitive behavioural therapies targeting diet and tobacco use compared to no intervention/usual care on behavioural outcomes

Patient or population: Persons who may benefit from change in health behaviours

Setting: Primary health care

Intervention: Cognitive therapies, targeting both diet and tobacco use

Comparison: No intervention or usual care

Outcomes	Impact	№ of parti- cipants (studies)	Quality of the evidence (GRADE)
Healthy diet assessed with: self-report follow up: 9 months	The standardized mean difference was 0.87 (0.50, 1.23) to the advantage of the intervention group.	128 (1 RCT)	⊕⊖⊖⊖ VERY LOW 1,2,3
Number of cigarettes smoked per day assessed with: self-report without biochemical validation follow up: 9 months	The standardized mean difference was -0.37 (-0.72, -0.01) to the advantage of the intervention group.	128 (1 RCT)	⊕⊖⊖⊖ VERY LOW 1,2,3

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- 1. Unclear risk of bias, incomplete outcome data; per protocol analysis; 60% response rate
- 2. Female participants only
- 3. One small study with 128 participants.

We judged the quality of the evidence of effect to be very low for both outcomes. This indicates that we have very little confidence in the effect estimate. Hence, for both healthy diet and number of cigarettes smoked per day we assume that the true effect can be substantially different from the estimate of effect.

We found that:

• We are uncertain whether the intervention changes diet or tobacco use nine months after the intervention, as compared to no intervention or usual care.

Effects of cognitive therapies targeting physical activity and dietary habits compared to other interventions

The interventions in this comparison used cognitive therapies to target changes in physical activity and diet. Three studies were included in this comparison.

Figure 7 shows the effect measured on <u>physical activity</u> in two studies comparing cognitive therapies to other interventions. The studies shown in Figure 9 reported the effect estimate as relative risk.



Figure 7. Effects of cognitive therapies compared to other interventions on physical activity in studies reporting relative risk. Follow-up 8-10 months. CI = confidence interval.

Annesi et al (51) compared the intervention to education about nutrition, three months after the end of the intervention. The standardized mean difference <u>in physical activity</u> between the two interventions was 0.25 (95% CI -0.02, 0.53).

Annesi et al (51) also evaluated the effect of their intervention on <u>diet</u>, <u>defined as a "healthy diet"</u>. The standardized mean difference between the two interventions was 0.10 (95% CI -0.17, 0.38).

Hinderliter et al (44) compared the intervention to education about dietary approaches to stop hypertension, eight months after the end of the intervention. The standardized mean difference in <u>energy intake</u> between the two interventions was 0.06 (95% CI -0.39, 0.50).

Table 4 presents the effect estimates along with our GRADE assessments concerning the quality of the evidence of effect. The GRADE evidence profile is presented in the Appendix, Table E3.

Uncertainty due to unclear risk of bias in the included studies resulted in downgrading for all outcomes. There was only one or two studies per outcome and the studies had few participants and wide confidence intervals. This further reduced our confidence in the effect estimates.

Table 4. Summary of findings table and evidence for effects of cognitive therapies targeting physical activity and diet compared to other interventions on health behaviours.

Cognitive behavioural therapies targeting physical activity and diet compared to other interventions on behavioural outcomes

Patient or population: Persons who may benefit from change in health behaviours

Setting: Primary health care

Intervention: Cognitive therapies targeting both physical activity and diet

Comparison: Other intervention

Outcomes	Impact	№ of participants (studies)	Quality of the evidence (GRADE)
Physical activity assessed with: Self-report follow up: range 8 to 10 months	The relative risk was 1.09 (0.71, 1.67).	151 (2 RCTs)	⊕○○○ VERY LOW 1,2
Physical activity assessed with: Self-report follow up: 3 months	The standardized mean difference was 0.25 (-0.02, 0.53).	200 (1 RCT)	⊕○○○ VERY LOW ^{3,4}
Healthy diet assessed with: Self-report follow up: 3 months	The standardized mean difference was 0.10 (-0.17, 0.38).	200 (1 RCT)	⊕○○○ VERY LOW 3,5
Energy intake assessed with: Self-report follow up: 8 months	The standardized mean difference was 0.06 (-0.39, 0.50).	76 (1 RCT)	⊕○○ VERY LOW ^{2,3}

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- 1. Overall unclear risk of bias.
- 2. One small study with 76 participants. The 95% CI includes both negative effect and large effect.
- 3. Unclear risk of bias.
- 4. One small study with 200 participants. The 95% CI includes both negative effect and large effect.
- 5. One small study with 200 participants.

We judged the quality of the evidence of effect to be very low for all outcomes. A very low rating of the quality of the evidence indicates that we have very little confidence in the effect estimate.

We found that the evidence is too uncertain to estimate whether cognitive therapies targeting physical activity and diet, compared to other interventions, change:

- physical activity, eight to ten months after end of the intervention.
- physical activity, three months after end of the intervention.
- diet, three months after end of the intervention.
- energy intake, three months after end of the intervention.

We provide a description of the results in each study, based on the standardized mean difference and relative risk data from the meta-analyses (Appendix, Table F2).

Effects of cognitive therapies targeting physical activity habits and tobacco use compared to other interventions

The evidence in this comparison is based on one study.

The intervention in this comparison targeted physical activity and tobacco use. Welschen et al (52) reported results for physical activity and tobacco use, three months after the end of the intervention. The standardized mean difference was 0.20 (95% CI -0.13, 0.52) for physical activity, and the relative risk was 0.72 (95% CI 0.33, 1.54) for tobacco use.

Table 5 presents the effect estimates along with our GRADE assessments concerning the quality of the evidence of effect. The GRADE evidence profile is presented in the Appendix, Table E4.

Uncertainty due to unclear risk of bias in the included study resulted in downgrading for all outcomes. There was only one study with few participants and wide confidence intervals. This further reduced our confidence in the effect estimates.

Table 5. Summary of findings table and evidence for effects of cognitive therapies targeting physical activity and tobacco use compared to other interventions on health behaviours.

Cognitive behavioural therapies targeting physical activity and tobacco use compared to other intervention on behavioural outcomes

Patient or population: Persons who may benefit from change in health behaviours

Setting: Primary health care

Intervention: Cognitive therapies targeting both physical activity and tobacco use

Comparison: Other intervention

Outcomes	Impact	№ of parti- cipants (studies)	Quality of the evidence (GRADE)
Physical activity assessed with: Self-report follow up: 12 months	The standardized mean difference was 0.20 (-0.13, 0.52).	143 (1 RCT)	⊕○○○ VERY LOW 1,2
Tobacco use assessed with: Self-report without biochemical validation follow up: 12 months	The relative risk was 0.72 (0.33, 1.54).	131 (1 RCT)	⊕○○ VERY LOW ^{1,3}

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- 1. Unclear risk of bias.
- 2. One small study with 143 participants. The 95% CI includes both negative effect and large effect.
- 3. One small study with 131 participants. The 95% CI includes both negative effect and large effect.

We judged the quality of the evidence of effect to be very low for both outcomes. A very low rating of the quality of the documentation indicates that we have very little confidence in the effect estimate.

We found that:

- We are uncertain whether the intervention changes physical activity 12 months after the start of the study as compared to other interventions.
- We are uncertain whether the intervention changes tobacco use 12 months after the start of the study as compared to other interventions.

Discussion

Main findings

The main findings in this systematic review were that:

- 1) Cognitive therapies targeting physical activity and dietary habits compared to no intervention or usual care:
- probably lead to a small increase in physical activity, up to 10 months after the end of the intervention, but we are uncertain if physical activity is altered after 12 months after the intervention,
- probably lead to a small increase in healthy diet, up to three months after the
 end of the intervention, but we are uncertain if diet is altered four to nine
 months after the intervention,
- probably lead to a small reduction of energy intake, 10 to 12 months after the end
 of the intervention, compared to no intervention or usual care.
- 2) We are uncertain whether cognitive therapies targeting diet and tobacco use change these outcomes nine months after the intervention, as compared to no intervention or usual care.
- 3) We are uncertain whether cognitive therapies targeting physical activity and diet, compared to other interventions, change:
- physical activity, three months after the end of the intervention, and eight to ten months after the end of the intervention,
- diet three months after end of the intervention.
- energy intake three months after the end of the intervention.
- 4) We are uncertain whether cognitive therapies targeting physical activity and tobacco use change these outcomes 12 months after the start of the study, as compared to other interventions.

The quality of the evidence

We included 14 randomised controlled trials including 2 434 participants. We judged 11 studies to have an unclear risk of bias, two to have a low risk of bias, and one study to have a high risk of bias. Five studies had insufficient information concerning the random sequence generation and 10 studies did not report how allocation to study groups was concealed. All studies but one measured physical activity by self-report, and all studies measured diet and tobacco use by self-report. The trials were small and there were several outcomes with only one study, resulting in wide confidence intervals.

Strengths and limitations

Systematic reviews seek to answer specific questions; they have clear inclusion criteria, and the methods are described *a priori* in a protocol for transparency. They are based on systematic literature searches in electronic databases and other relevant sources, and describe the uncertainty of the summarized results. The methodology, including independent study selection and assessment of risk of bias by two or more researchers, ensures that a body of evidence is summarized in a systematic and unbiased way. Potential limitations are the possibility that not all relevant studies are identified by the literature search, because of the search strategy, or because they were not published at the time of the search. Another limitation is that systematic reviews go out of date unless regularly updated.

The studies included in this systematic review are all randomised controlled trials. This is the preferred study design to answer research questions about effects of interventions. One potential limitation, that is more relevant to the selection of participants than to the study design *per se*, is the exclusion of persons whose medical or mental condition may limit their benefit from the intervention or confound the results. Compared to our previous report in cognitive therapies for behavioural change (1), we found less rigorous exclusion criteria in these studies, but co-morbidity was still the most common exclusion criterion.

Only few studies compared cognitive therapies with other interventions for lifestyle change, and some outcomes could not be included in the meta-analyses. Thus, there is limited information about how effective cognitive therapies are as compared to other relevant interventions. Due to the small amount of studies in each meta-analysis, it was not considered sensible to perform the planned sensitivity analyses.

We had decided *a priori* that when studies reported more than one measure of physical activity, diet, or tobacco use we would choose the one that best reflected the outcome in general terms. This may have introduced bias, because of different results when considering e.g. vigorous physical activity chosen over total physical activity,

or vice versa. However, we consistently describe outcomes for the most general level of physical activity, diet or tobacco use reported in the studies.

Several options for reporting results from studies that target more than one behaviour have been suggested. These include reporting each behaviour individually, combining change scores, creating an index, applying special formulas, and using overarching measures of change (53). None of the included studies attempted to combine or use index scores, or use formulas or overarching measures of change. Because of the diversity of outcome measurements, we found it difficult to combine scores in a meaningful way, and thus chose to report outcomes for each behaviour separately. This approach may obscure the impact of the intervention on the targeted behaviours as a whole. The tables provided in the Appendix (Tables F1 and F2) describe the results for both behaviours in each study. The tables show that only one study (50) reported change of both the targeted behaviours.

How applicable are the results?

The question we aimed to answer in this systematic review was "What is the effect of cognitive therapies on change of two or more health behaviours?" We summarized the results across different populations and contexts, varying length and intensity of the intervention, different comparisons, and a range of health professionals.

The factors limiting or supporting the applicability of the results are generally the same as those discussed in our previous report (1). The main limiting factors of the findings presented in this review were:

- Extensive exclusion criteria regarding co-morbidity, probably leading to underrepresentation of persons with co-morbidities.
- Possible under-representation of persons of Non-Western origin and persons with a low education level.
- All studies but one employed self-report measures to measure the outcomes.
- Large variation of measurement methods across studies resulting in standardized population estimates that are difficult to interpret.

All included studies had extensive exclusion criteria related to co-morbidity. Thus it is plausible that the results in this systematic review tell us more about how well the intervention works under ideal circumstances, and less about how effective it may be in routine clinical practice. This may be most relevant in the case of persons with co-morbidities. Further, disadvantaged populations may be under-represented in the research we summarized. The socio-demographic data presented in the Appendix, Table D1, indicate that the participants were mainly of Caucasian origin. Educational level was reported in half of the studies, with a median value of 45.5% having college education or more. We judge this figure to be uncertain, due to lack of information in half of the studies. In the most recent study on the level of physical activity in the

Norwegian population, the authors indicated that persons with a high socioeconomic status were over-represented, and immigrants from Non-Western countries were under-represented (54). The finding concerning ethnicity is similar to our findings and suggests that our conclusions be interpreted with caution regarding populations from non-western countries.

Collecting outcomes data on physical activity, diet, or tobacco use by self-report is a feasible and non-expensive method, whether by questionnaire, diary or interview (55, 56, 57). Self-reports may be influenced by e.g. social desirability that may result in over- or underestimation of actual behaviour (58, 59, 60). A serious problem affecting self-report questionnaires assessing physical activity and diet in adults is that their responsiveness is unknown (58, 61). Thus, it is uncertain whether changes in physical activity and diet were reliably detected in the studies using questionnaires. Self-reported tobacco use underestimates true tobacco use when compared to biochemical validation by cotinine levels in either saliva, serum, or urine (60). The two studies that targeted tobacco use employed self-report without biochemical validation, results from these studies should be viewed with caution.

Apart from the shortcomings of the methods themselves to measure physical activity, diet, and tobacco use, the variation of methods used in the included studies have consequences for the synthesis and interpretation of the results. Due to the many different response formats and scale formats, we summarized the data by standardizing all effect estimates. The ensuing estimate is interpreted in terms of direction (in favour of the intervention or control group, or suggesting no or little difference between the groups) and magnitude of the effect (small, medium, large, or uncertain). It is not possible to refer back to e.g. minutes of physical activity per week, amount of vegetables consumed each day, or number of cigarettes smoked per day. This may lead to difficulties in interpreting the results.

The main supporting factors of applicability in the present review were:

- All interventions included common and basic elements of cognitive therapies that may target a range of populations.
- There was considerable variation in duration and frequency of the interventions, in light of which the findings are surprisingly homogeneous. It is however not possible to draw conclusions about aspects of content, frequency or duration based on these findings. That would require larger sets of studies for each comparison.
- There was considerable variation in profession of those who delivered the interventions.

Agreement with other systematic reviews

We did not identify systematic reviews that could answer our research question through our systematic literature search. A review "Are interventions for low-income groups effective in changing healthy eating, physical activity and smoking behaviours? A systematic review and meta-analysis" by Bull and co-workers (62) appeared by its title to answer the same question. However, the review included studies that could target a single behaviour or multiple behaviours in any combination, and only six of 35 studies evaluated interventions that targeted multiple behaviours. Studies were included if the intervention targeted a change in smoking, eating, and/physical activity behaviour, not specifying cognitive therapies. Eight studies seemed to involve motivational interviewing (which was excluded in our review by request of the commissioner). The results showed small improvements of diet, physical activity, and smoking at the end of the intervention, with maintained effects up to 12 months after baseline for diet only.

Implications for practice

Our findings suggest that cognitive therapies targeting physical activity and dietary habits at the same time probably can help patients and sedentary and/or overweight persons to achieve small increases in physical activity, small improvements of dietary quality, and small reductions of energy intake compared to no treatment or usual care.

Most studies included basic elements of cognitive therapies such as goal setting and development of skills related to self-regulation of behaviour, problem solving, and relapse prevention.

"Health ambassadors" and caregivers, "trained staff", "facilitators", psychologists, nurses, rheumatology researchers, nutritionists, health professionals with education in nutrition, and certified YMCA wellness leaders gave the interventions. Associations between therapist competence and outcomes of cognitive therapies appear to be little explored (63). However, the training and competence to deliver an intervention as intended may be a more important issue than the label of the profession. Competence includes the ability to establish a therapeutic relationship, to provide basic and specific treatment, and to work with specific populations, e.g. ethnic minorities or patient groups (20, 63). It is plausible that those who delivered the intervention in the included studies had more training than can be expected in routine care.

Costs of implementing such an intervention in practice will be dependent on both the level of competency required to deliver it and the extent of treatment chosen. The findings in this systematic review cannot give answers to questions about costs.

Evidence-based health services entail integration of research-based knowledge with clinical expertise and patient values while also taking into account contextual factors. The findings in this systematic review should therefore be seen in conjunction

with experience-based knowledge, client knowledge, and the context before making a decision about the intervention.

Research gaps

We report effects of cognitive therapies targeting two or more of the health behaviours (physical activity, diet, tobacco use) in adults 18 years or older. All included studies were randomised controlled trials and comprised healthy adults possibly at risk of cardiovascular disease, and several patient groups. The interventions were mainly carried out in a group format. The length of the interventions varied between one day and more than 52 weeks. The content of the interventions reflect basic elements of cognitive and cognitive behavioural therapies.

We identified the following research gaps:

- There were only two studies using cognitive therapies to target tobacco use in combination with either physical activity or diet. We did not identify studies that targeted and reported results for all three behaviours at the same time.
- There were only four studies comparing cognitive therapies for behavioural change with other types of relevant interventions, while there were 12 studies with no intervention or usual care.
- Only four studies had follow-up beyond four months after the end of the intervention.
- There was a great variation in measurement methods, which induces problems when pooling studies, making the combined estimates difficult to interpret. Measurements of
 - physical activity included duration, frequency, and intensity, using selfreport questionnaires in all studies but one that used pedometers,
 - diet included dietary intake, e.g. fruit and vegetable consumption, fat intake and energy intake, and qualitative aspects of the dietary intake such as food groups consumed or "healthy eating",
 - tobacco use included number of cigarettes smoked per day and abstinence rate.

Implications for future research:

- Researchers may find good guidance from the emerging literature on cooccurrence and clustering of health behaviours when designing intervention studies targeting multiple behaviours.
- There is a need for studies that compare cognitive therapies with other interventions.
- Studies should allow for follow-up of at least 12 months post intervention.
- Core outcome sets (64) should be developed for future use in studies evaluating
 effects of interventions on physical activity, diet, and tobacco use. The COMET
 (Core Outcome Measures in Effectiveness Trials) Initiative (http://www.comet-initiative.org/) provides a good starting point for such work. This would be a task
 for international cooperation.
 - o In this particular research field, it may also be relevant to develop consensus on how to evaluate and report results of interventions

targeting more than one health behaviour, e.g. reporting each behaviour individually, combining change scores, creating indexes, applying special formulas, or using overarching measures of change (53).

Conclusion

Cognitive therapies targeting physical activity and diet compared to no intervention or usual care probably lead to a short term small increase in physical activity, a small increase in achieving a healthy diet, and a small reduction of energy intake. We are uncertain if cognitive therapies targeting diet and tobacco use change these outcomes nine months after the intervention, as compared to no intervention or usual care.

We are uncertain whether cognitive therapies targeting physical activity and diet, compared to other interventions, change physical activity, diet, or energy intake. We are uncertain whether cognitive therapies targeting physical activity and tobacco use change these outcomes compared to other interventions.

We do not know the long-term effects of cognitive therapies targeting two health behaviours at the same time.

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- 63. Ehde D, Dillworth T, Turner J. Cognitive-behavioral therapy for individuals with chronic pain. Efficacy, innovations, and directions for research. Am Psychol. 2014;69:153-166.
- 64. Williamson P, Altman D, Blazeby J, Clarke M, Devane D, Gargon E, et al. Developing core outcome sets for clinical trials: issues to consider. Trials 2012;13:132.

Appendix

A. Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present Search date: 21.01.2015; 10.11.2016.

```
1 exp Life Style/ (72713)
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- 2 exp Attitude to Health/ (334568)
- 3 Health Behavior/ (39668)
- 4 exp "tobacco use"/ (131734)
- 5 exp food habits/ (27313)
- 6 motor activity/ (87607)
- 7 exp sports/ (146409)
- 8 exp physical fitness/ (24049)
- 9 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or running or jogging or swimming or walking or skiing or cycling or climbing or smok* or tobacco* or cigarette*).ti,ab. (1171572)
- 10 or/1-9 (1677282)
- 11 Cognitive Therapy/ (18881)
- 12 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (21320)
- 13 cognitive method*.ti,ab. (86)
- 14 cognitive approach*.ti,ab. (474)
- 15 or/11-14 (30687)
- 16 10 and 15 (6294)
- 17 randomized controlled trial.pt. (419601)
- 18 controlled clinical trial.pt. (90951)
- 19 random*.mp. (1024672)
- 20 (trial or effect).ti. (908946)
- 21 or/17-20 (1832124)
- 22 16 and 21 (2596)
- 23 (2005* or 2006* or 2007* or 2008* or 2009* or 2010* or 2011* or 2012* or 2013* or 2014* or 2015*).dp,ed,yr. (10667000)
- 24 22 and 23 (2089)

Database: Embase 1974 to 2015 January 21 Search date: 22.01.2015; 10.11.2016.

- 1 lifestyle/ (84077)
- 2 attitude to health/ (88855)
- 3 health behavior/ (49903)
- 4 smoking/ (218061)
- 5 smoking cessation/ (43646)

- 6 exp feeding behavior/ (140549)
- 7 physical activity/ (98860)
- 8 exp sport/ (117791)
- 9 fitness/ (32426)
- 10 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or smok* or tobacco* or cigarette*).ti,ab. (1306639)
- 11 or/1-10 (1679644)
- 12 exp cognitive therapy/ (40217)
- 13 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (31912)
- 14 cognitive approach*.ti,ab. (666)
- 15 cognitive method*.ti,ab. (137)
- 16 or/12-15 (53550)
- 17 randomized controlled trial/ (397419)
- 18 controlled study/ (4826117)
- 19 random*.mp. (1227798)
- 20 (trial or effect).ti. (1095944)
- 21 or/17-20 (6205218)
- 22 10 and 16 and 21 (2170)
- 23 (2010* or 2011* or 2012* or 2013* or 2014* or 2015*).dd,dp,yr. (9081521)
- 24 22 and 23 (1325)

Database: PsycINFO 1806 to January Week 4 2015 Search date: 22.01.2015; 10.11.2016.

- 1 exp lifestyle/ (9547)
- 2 health attitudes/ (8976)
- 3 health behavior/ (20406)
- 4 tobacco smoking/ (25908)
- 5 smoking cessation/ (10628)
- 6 eating behavior/ (9233)
- 7 physical activity/ (12759)
- 8 exp sports/ (20158)
- 9 exp PHYSICAL FITNESS/ (3569)
- 10 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or running or jogging or swimming or walking or skiing or cycling or climbing or smok* or tobacco* or cigarette*).ti,ab. (218315)
- 11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (250241)
- 12 exp cognitive behavior therapy/ (14743)
- 13 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (32203)
- cognitive method*.ti,ab. (224)
- 15 cognitive approach*.ti,ab. (2225)
- 16 12 or 13 or 14 or 15 (37089)
- 17 11 and 16 (3189)
- 18 control:.tw. (551728)
- 19 random:.tw. (151568)
- 20 exp treatment/ (644895)
- 21 18 or 19 or 20 (1168682)
- 22 17 and 21 (2829)

Database: Central

Search date: 22.01.2015; 10.11.2016.

#1	MeSH descriptor: [Life Style] explode all trees	3540
#2	MeSH descriptor: [Attitude to Health] explode all trees	29503
#3	MeSH descriptor: [Health Behavior] explode all trees	17682
#4	MeSH descriptor: [Smoking Cessation] explode all trees	100
#5	MeSH descriptor: [Smoking] explode all trees	136
#6	MeSH descriptor: [Food Habits] explode all trees	2000
#7	MeSH descriptor: [Motor Activity] explode all trees	19602
#8	MeSH descriptor: [Sports] explode all trees	123973
#9	MeSH descriptor: [Physical Fitness] explode all trees	54522
#10	((life next style*) or lifestyle* or (health* near/3 (behavio* or attitude*)) or	6337
	nutrit* or diet* or food* of feed* or eating or meal or meals or (physical*	
	near/3 (exercis* or activ* or fitness)) or smok* or tobacco* or cigarette*)	
#11	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10	13669
#12	MeSH descriptor: [Cognitive Therapy] explode all trees	93
#13	(((cognitive or metacognitive or "acceptance and commitment" or mindful-	11768
	ness) near/3 (therap* or treatment*)) or (third adj wave) or cbt)	
#14	cognitive next (method* or approach*)	11768
#15	MeSH descriptor: [Sports] explode all trees	2446
#16	MeSH descriptor: [Physical Fitness] explode all trees	153875
#17	#12 or #13 or #14 or #15 or #16	13804
#18	#11 and #17 in Trials	2489

Database: Cinahl

Search date: 22.01.2015; 10.11.2016.

	S17 AND S21 AND S28	
S30	Limiters - Exclude MEDLINE records	111
S29	S17 AND S21 AND S28	735
S28	S22 OR S23 OR S24 OR S25 OR S26 OR S27	195,853
S27	TI random* OR AB random*	124,876
S26	(MH "Intervention Trials")	5,925
S25	(MH "Clinical Trials")	84,174
S24	(MH "Randomized Controlled Trials")	25,467
S23	PT clinical trial	52,808
S22	PT randomized controlled trial	30,658
S21	S18 OR S19 OR S20	11,637
S20	TI (cognitive W0 (method* or approach*)) OR AB (cognitive W0 (method* or approach*))	140
S19	TI ((((cognitive or metacognitive or "acceptance and commitment" or mindfulness) N3 (therap* or treatment*)) or (third adj wave) or cbt)) OR AB ((((cognitive or metacognitive or metacogniti	5,868

"acceptance and commitment"	or mindfulness) N3 (therap*	or treatment*)) or (third adj
wave) or cbt))		

	wave, or only,	
S18	(MH "Cognitive Therapy+")	8,996
S17	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16	490,440
S16	(MH "Attitude to Health")	18,295
S15	(MH "Life Style+")	113,298
S14	((life W0 style*) or lifestyle* or (health* N3 (behavio* or attitude*)) or nutrition* or diet* or food* or feed* or eating or meal or meals or ((physical or motor) N3 (activ* or exercis* or fitness)) or physical conditioning or running or jogging or swimming or walking or cycling or climbing or skiing or smok* or tobacco* or cigarette*)	405,475
S13	(MH "Snow Skiing+")	337
S12	(MH "Cycling")	4,843
S11	(MH "Walking")	11,151
S10	(MH "Running+")	6,690
S9	(MH "Swimming")	2,004
S8	(MH "Physical Activity")	19,829
S7	(MH "Exercise+")	56,422
S6	(MH "Motor Activity")	4,291
S5	(MH "Eating Behavior+")	15,426
S4	(MH "Smoking Cessation Programs")	1,463
S3	(MH "Smoking Cessation")	11,086
S2	(MH "Smoking")	30,112
S1	(MH "Tobacco")	4,253

B. Excluded studies

Twenty-eight studies were excluded due to exclusion criteria after reading full text publications (Table B1).

Table B1. Excluded studies.

Study	Reason for exclusion
Annesi JJ, Howton A, Johnson PH, Porter KJ. Pilot testing a cognitive-behavioral protocol on psychosocial predictors of exercise, nutrition, weight, and body satisfaction changes in a college-level health-related fitness course. Journal of American college health: J of ACH 2015;63(4):268-278.	Pilot study.
Borkoles E, Polman R. Lifestyle intervention programmes for clinically obese clients: Need for psychological and physical profiling. Obesity Research and Clinical Practice 2013;7:e70.	Conference abstract.

Brown DMY, Bray SR, Beatty KR, Kwan MYW. Healthy active living: A residence community-based intervention to increase physical activity and healthy eating during the transition to first-year university. Journal of American College Health, 62:4, 234-242.

Not a randomised controlled trial. Population not adults \geq 18 years.

Crespo N, Rubio V, Casado M, Campo C. Anciedad y Estrés, 2005;11:27-35. Influencia sobres los niveles des preción arterial de una intervnción conductual y educative dirigida al control del estrés y la modificación de habitós de una muestra de hipertensos.

Not a randomised controlled trial.

DeLucia JL, Kalodner CR. An individualized cognitive intervention: does it increase the efficacy of behavioral interventions for obesity? Addict Behav1990. p. 473-479.

This study examined the effectiveness of the addition of a cognitive intervention to a behavioural intervention.

Dennis KE, Pane KW, Adams BK, Qi BB. The impact of a shipboard weight control program. Obes Res1999. p. 60-67.

The study did not have behavioural outcomes.

Filipa P, Maroco J, Leal I. An 8-week individual cognitive-behavioural intervention for weight loss: Outcomes of a controlled study with portuguese middleaged women. Climacteric 2014;17:82.

Conference abstract. The intervention targeted diet only.

Gerstel E, Pataky Z, Busnel C, Rutschmann O, Guessous I, Zumwald C, et al. Impact of lifestyle intervention on body weight and the metabolic syndrome in home-care providers. Diabetes Metab 2013;39(1):78-84.

Not a randomised controlled trial.

Gohner W, Schlatterer M, Seelig H, Frey I, Berg A, Fuchs R. Two-year follow-up of an interdisciplinary cognitive-behavioral intervention program for obese adults. The Journal of Psychology: Interdisciplinary and Applied 2012;146(4):371-391.

Not a randomised controlled trial.

Kajaste S, Brander PE, Telakivi T, Partinen M, Mustajoki P. A cognitive-behavioral weight reduction program in the treatment of obstructive sleep apnea syndrome with or without initial nasal CPAP: a randomized study. Sleep Med 2004. p. 125-131. All participants received cognitive behavioural therapy.

Miller CK, Kristeller JL, Headings A, Nagaraja H. Comparison of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes: A randomized controlled trial. Health Education & Behavior 2014, Vol. 41(2) 145–154

The intervention was based on mindfulness only and diet only.

Muggia C, Falchi AG, Michelini I, Montagna E, De Silvestri A, Grecchi I, et al. Brief group cognitive behavioral treatment in addition to prescriptive diet versus standard care in obese and overweight patients. A randomized controlled trial. e-SPEN Journal 2014;9(1):e26-e33.

The intervention targeted diet only.

Munsch S, Biedert E, Keller U. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. Swiss Med Wkly 2003. p. 148-154.

The study did not have behavioural outcomes.

Murphy B, Higgins R, Worcester M, Elliott P, Navaratnam H, Mitchell F, et al. Group cognitive behaviour therapy for cardiac patients: Results of a randomised controlled trial. Heart Lung and Circulation 2010;19:S242. Conference abstract.

Olvera N, Bush JA, Sharma SV, Knox BB, Scherer RL, Butte NF. BOUNCE: a community-based mother-daughter healthy lifestyle intervention for low-income Latino families. Obesity 2010;18 Suppl 1:S102-104.

The intervention targeted mother-daughter dyads.

Pakiz B, Flatt SW, Bardwell WA, Rock CL, Mills PJ. Effects of a weight loss intervention on body mass, fitness, and inflammatory biomarkers in overweight or obese breast cancer survivors. Int J Behav Med 2011;18(4):333-341.

The objective was not to evaluate effects of cognitive therapies.

Perkins KA, Marcus MD, Levine MD, D'Amico D, Miller A, Broge M, et al. Cognitive-behavioral therapy to reduce weight concerns improves smoking cessation outcome in weight-concerned women. J Consult Clin Psychol2001. p. 604-613.

Either "behavioural weight control" or "cognitive-behavioural weight control" treatment given in addition to "standard cognitive behavioural therapy smoking cessation counselling" for all participants.

Rapoport L, Clark M, Wardle J. Evaluation of a modified cognitive-behavioural programme for weight management. International journal of obesity and related metabolic disorders: journal of the International Association for the Study of Obesity2000. p. 1726-1737.

Two variants of cognitive behavioural therapy were evaluated.

Rodriguez-Hernandez H, Morales-Amaya UA, Rosales-Valdez R, Rivera-Hinojosa F, Rodriguez-Moran M, Guerrero-Romero F. Adding cognitive behavioural treatment to either low-carbohydrate or low-fat diets: differential short-term effects. Br J Nutr 2009;102(12):1847-1853.

The study did not have behavioural outcomes.

Share BL, Naughton GA, Obert P, Peat JK, Aumand EA, Kemp JG. Effects of a Multi-Disciplinary Lifestyle Intervention on Cardiometabolic Risk Factors in Young Women with Abdominal Obesity: A Randomised Controlled Trial. PLoS One 2015;10(6):e0130270.

The intervention comprised other elements than cognitive therapy.

Stahre L, Hällström T. A short-term cognitive group treatment program gives substantial weight reduction up to 18 months from the end of treatment. A randomized controlled trial. Eating and weight disorders 2005. p. 51-58.

The intervention targeted diet only. The study did not have behavioural outcomes.

Stahre L, Tarnell B, Hakanson CE, Hallstrom T. A randomized controlled trial of two weight-reducing short-term group treatment programs for obesity with an 18-month follow-up. Int J Behav Med 2007;14(1):48-55.

The intervention targeted diet only. The study did not have behavioural outcomes.

Stevens VJ, Corrigan SA, Obarzanek E, Bernauer E, Cook NR, Hebert P, et al. Weight loss intervention in phase 1 of the Trials of Hypertension Prevention. The TOHP Collaborative Research Group. Arch Intern Med 1993. p. 849-858.

The study did not have behavioural outcomes.

Swencionis C, Wylie-Rosett J, Lent MR, Ginsberg M, Cimino C, Wassertheil-Smoller S, et al. Weight change, psychological well-being, and vitality in adults participating in a cognitive-behavioral weight loss program. Health Psychol 2013;32(4):439-446.

All groups received cognitive-behavioural treatment. Different intensities were evaluated.

Tanco S, Linden W, Earle T. Well-being and morbid obesity in women: A controlled therapy evaluation. Int J Eat Disord 1998;23(3):325-339.

One group received "behavioural therapy" and one group received "cognitive therapy" but both included elements in cognitive behavioral therapy, and difficult to compare to control.

Werrij MQ, Jansen A, Mulkens S, Elgersma HJ, Ament AJ, Hospers HJ. Adding cognitive therapy to dietetic treatment is associated with less relapse in obesity. J Psychosom Res 2009;67(4):315-324.

The study did not have behavioural outcomes.

Woo J, Sea MM, Tong P, Ko GT, Lee Z, Chan J, et al. Effectiveness of a lifestyle modification programme in weight maintenance in obese subjects after cessation of treatment with Orlistat. J Eval Clin Pract 2007;13(6):853-859.

Not enough information on the intervention.

Xue F, Yao W, Lewin RJ. A randomised trial of a 5 week, manual based, self-management programme for hypertension delivered in a cardiac patient club in Shanghai. BMC Cardiovasc Disord 2008;8:10.

The intervention focused on reduction of blood pressure, and comprised other elements than cognitive therapy.

C. Characteristics of included studies

Participants

Table C1. Description of the participants.

Study ID	Country	Mean age	% women	Ethnicity	Education	Other
Cognitive	therapies targe	ting physical a	activity and di	ietary habits comp	ared to no interver	ntion/usual care
Ash 2006	Australia	48	73			
Bergström 2013	Sweden	36	58	86% born in Sweden		
Burke 2007	Australia	56	56			
Eakin 2009	Australia	58	61	91% Caucasian	45% ≥ high school graduate	71% married or liv- ing with partner, 36 % retired
Fletcher 2011	USA	52	83	89% Caucasian		
John 2013	UK	61	73	97% Caucasian	Mean 11 years	72% retired
Kattermann 2012	USA	22	100	62% Caucasian	43% graduate program	86% full time students

Mefferd 2007	USA	57	100	93% Caucasian	65% ≥ college	
Murphy 2013	Australia	59	13	61% born in Australia		79% living with partner
Steed 2005	UK	60	29	49% Caucasian		
Cogniti	ive therapies tar	geting dieta	ary habits and	l tobacco use compar	ed to no intervent	tion/usual care
Sallit 2009	USA	35	100	72% Caucasian	52% ≥ college	42% < \$ 50,000/year
Cogn	itive therapies ta	argeting ph	ysical activity	and dietary habits co	mpared to other i	interventions
3	,	0 0, .	,	, , , , , , , , , , , , , , , , , , ,	,	
	USA	44	81	52% Caucasian	<u>′</u>	«Most middle class»
Annesi 2013	-			•	<u>, </u>	«Most middle
Annesi 2013 Ash 2006 Hinderliter	USA	44	81	•	46% ≥ college	«Most middle
Annesi 2013 Ash 2006 Hinderliter 2014	USA Australia USA	44 48 52	81 73 67	52% Caucasian	46% ≥ college	«Most middle class» 26% < \$ 50,000/year

Interventions and comparisons

Table C1. Description of the interventions and comparisons.

Study ID	Mode; Duration; Frequency; Session length	Provider	Intervention content	Comparison
	Соц	gnitive therapies targ	geting physical activity and dietary habits compared to no interve	ention/usual care
Ash 2006	Group; 8 weeks; 6 weekly + 1 at 8 weeks; 90 minutes	Dietician + nut- rition staff	Nutrition booklet based on CBT principles; knowledge and skill development, relapse prevention; focus on improving self-concept, self-efficacy and skills.	Nutrition resource booklet based on cognitive behavioural therapy principles only.
Bergström 2013	Group; 52+ weeks; Health ambassadors: 6 network meetings; care- givers: 10 sessions; res- idents: 10 sessions; Health ambassador: 180 min; caregiver: 90 min; resident: N/R	Health ambassa- dor; caregiver	Program targeting residents' knowledge, skills, preferences, self-efficacy; improvement of social and physical environment: three components 1) health ambassador in each residence 2) study circle for caregivers 3) health course for residents, 10 sessions.	Community residences continued to work as usual: residents had support from staff in their everyday lives, possibility to cook, but also opportunities for having dinner together, either every evening or a few evenings per week.
Burke 2007	Group and individual; 16 weeks + 52 weeks; 6/16 weeks; 6+6/52 weeks; N/R	Dietician	Program including 6 interactive group workshops, 5 printed modules: self-directed change encouraged by emphasis on barriers, costs and benefits of healthy lifestyle, goal setting, time management; nutritional and physical activity goals; social support by attendance of partner; 1 year follow-up: regular phone contact to report blood pressure, 6 individual appointments to measure weight and blood pressure, 6 group sessions to discuss individual progress: 2/month for first month, monthly for 2 months, then 1/3 months.	Usual care including publications from the National Heart foundation and the Health department of Western Australia.
Eakin 2009	Individual by phone; 52 weeks; 18/52 weeks; Mean 18 minutes/call	Master level grad- uates in nutrition	Workbook + pedometer: calls went from weekly to bi-weekly to monthly; followed 4a's assess advice, assist, arrange, content was based on social cognitive theory.	Usual care including brief feedback on assessment results and brochures on a variety of health topics such as

				physical activity and diet, and a newsletter with general health tips.
Fletcher 2011	Group; 1 day; 1 session only; 6 hours	"Trained staff"	Workshop based on acceptance and commitment therapy; 10 components: framing the problem, values, barriers, reason-giving, control is the problem, acceptance, distress tolerance, defusion and mindfulness, self-stigma, stand and declare a commitment.	Waitlist control group that was given the option to attend the workshop after completing 3-month follow-up.
Hinderliter 2014	Group; 16 weeks; 1/week diet; 1/week CB weight loss intervention;	Nutritionist	DASH (Dietary Approaches to Stop Hypertension) diet: weekly meetings with nutritionist in small group sessions to discuss the diet and receive feedback on adherence to the diet.	Usual care including information about behavioural strategies to lose weight.
	3/week exercise; 45 minute exercise sessions, otherwise N/R		How to buy and prepare appropriate foods; appetite awareness training, self-monitoring to identify cues to guide eating behaviour; supervised exercise.	
John 2013	Group; 8 weeks; 5/8weeks; 150 minutes	Rheumatology researcher	Meeting weeks 1-4 and 8; practice in weeks 5-7; explore beliefs about cardiovascular disease, challenge ways of thinking, specify individual behaviour change, graded goal setting, coping skills.	Waitlist control group that was given the option to attend the intervention program after completing 6-month follow- up.
Katterman 2012	Group; 12-16 weeks; 8/12-16 weeks; 75 minutes	"Facilitator"	Self-monitoring, goal setting, major acceptance-based constructs: creative helplessness, limits of control, willingness, defusion, committed action, experiential acceptance, mindfulness.	No intervention beyond assessments.
Mefferd 2007	Group and individual by phone; 16 weeks; 1/week; N/R	N/R	Weekly group sessions + individual phone calls 4/week first 2 weeks, then 1/week; group sessions: self-monitoring, realistic goal setting, cognitive restructuring; self-monitoring with food diaries and exercise logs, negative and positive thoughts and feelings; phone calls reviewed physical activity and food choices + feedback to develop sub-goals and goals; physical activity component: promoting regular planned aerobic exercise, overall long-term goal 1 hr/day of moderate to vigorous physical activity; goal of dietary guidance was deficit of 500-1000 kcal/day + promotion of fibre, fruit and vegetables, and adequate protein.	Waitlist.
Murphy 2013	Group; 8 weeks; 1/week; 90 minutes;	Psychologist and nurse	Intervention modules addressed physical activity, diet, medication adherence, smoking cessation, depression, anxiety, anger, and social support; within each module: exercises to identify, chal-	Usual medical care.

			lenge and change unhelpful thoughts and faulty beliefs (cognitions) associated with risk factors and negative emotions; cognitive-behavioural and motivational interviewing tools used to help construct action plans for implementing health behaviours including goal setting, identifying motivators for change, resources, barriers, rewards, relapse-prevention strategies; intervention was manualized.	
Steed 2005	Group; 5 weeks; 1/week; 150 minutes	Diabetes specialist nurse and dietician	Self-monitoring and self-management, benefits and barriers + problem solving for each behaviour, challenging of beliefs, goal setting, program was manual driven.	Usual care.
		Cognitive therapies to	argeting dietary habits and tobacco use compared to no interven	tion/usual care
Sallit 2009	Group; 12 weeks; 1/week; 60 minutes	Nutritionist	Each session included nutrition info on a topic related to healthful eating + one or more activities to promote self-efficacy for weight loss: mastery experience, vicarious experience, social persuasion, physiological states; strategies included self-monitoring, goal setting, stimulus control for modification of eating behaviour, cognitive restructuring techniques, stress management, social support.	No intervention beyond assessments.
		Cognitive therapies	targeting physical activity and dietary habits compared to other	interventions
Annesi 2013	Group; 12 weeks; 6/12 weeks; 60 minutes	Certified YMCA wellness leaders	Setting caloric goals, logging daily food and calorie intake, regular self-weighing, cognitive restructuring, relapse prevention training, cues to overeating; mood enhancement strategies: deep breathing, abbreviated progressive muscle relaxation.	6 1-hour group sessions of nutrition information from start of month 2 through month 4. Instruction in understanding macronutrients, use of the US Food guide Pyramid, and menu planning. YMCA wellness leaders led sessions.
Ash 2006	Group; 8 weeks; 6 weekly + 1 at 8 weeks; 90 minutes	Dietician + nut- rition staff	Nutrition booklet based on CBT principles; knowledge and skill development, relapse prevention; focus on improving self-concept, self-efficacy and skills.	Nutrition resource booklet based on cognitive behavioural therapy principles. Individualised weekly contact with a dietician for 8 weeks: nutrition assessment, provision of an individualised diet prescription (aiming to achieve weight loss of 0.5-1.0 kg/week), and an exercise prescription (23-30 minutes of accumulated exercise most days of the week). Monthly follow-up visits from week 8 to 6 months.

Hinderliter 2014	Group; 16 weeks; 1/week diet; 1/week CB weight loss intervention; 3/week exercise; 45 mi- nute exercise sessions, otherwise N/R	Nutritionist	DASH (Dietary Approaches to Stop Hypertension) diet: weekly meetings with nutritionist in small group sessions to discuss the diet and receive feedback on adherence to the diet. How to buy and prepare appropriate foods; appetite awareness training, self-monitoring to identify cues to guide eating behaviour; supervised exercise.	DASH (Dietary Approaches to Stop Hypertension) diet only: 16 weekly meetings with nutritionist in small group sessions to discuss the diet and receive feedback on adherence to the diet.
	Co	ognitive therapies tar	geting physical activity habits and tobacco use compared to oth	er interventions
Welschen 2013	Individual; N/R; 3-6/? weeks; 30 minutes	Trained dieticians and diabetes nurses	Problem-solving treatment used to set achievable goals for behaviour change: problem definition, goal setting, generating solution, implementing solution, evaluation of the outcome of the solution; the treatment was manualized.	Diabetes Care system including managed diabetes care by yearly assessments and visits to a dietician and a diabetes nurse to receive information and education. A standardized protocol according to the Guidelines of the Dutch college of General Practitioners was used.

Outcomes

Primary outcomes

Table C2. Primary outcomes and measurement methods.

Study ID	Outcomes	Measurement methods
Cognitive the	erapies targeting physical activity and d	ietary habits compared to no intervention/usual care
Ash 2006	PA: % sufficiently active	PA: The International Physical Activity Questionnaire
Bergström 2013	PA: steps/day	PA: pedometer
	Diet: number of food groups/day	Diet: 3-day photo diary
Burke 2007	PA: minutes/week	PA: 7-day physical activity recall by interview
	Diet: energy intake	Diet: 3-day food record
Eakin 2009	PA: minutes/week	PA: Active Australia Questionnaire
	Diet: total fat intake	Diet: Food frequency questionnaire
Fletcher 2011	PA: MET-minutes/week	PA: The International Physical Activity Questionnaire
	Diet: fruit and vegetable consumption	Diet: self-report (no further description)
Hinderliter 2014	PA: % exercising ≥ 3 times/week	PA: self-report (adherence to program)
	Diet: dietary intake	Diet: 4-day food diary
John 2013	PA: MET-minutes/week	PA: The International Physical Activity Questionnaire
	Diet: fruit and vegetable consumption	Diet: food questionnaire
Kattermann 2014	PA: frequency/week	PA: physical activity history questionnaire
Mefferd 2007	PA: hours/week	PA: 7-day physical activity recall by interview
Murphy 2013	PA: minutes/week	PA: Active Australia Questionnaire
	Diet: dietary fat intake	Diet: The Short Fat questionnaire
Steed 2005	PA: days/week Diet: days/week	PA and diet: The Revised Summary of Self-Care Diabetes Activities
Cognitive to	herapies targeting dietary habits and to	bacco use compared to no intervention/usual care
Sallit 2009	Tobacco: number of cigarettes	Tobacco: self-report of cigarettes/day
	smoked Diet: healthy eating	Diet: The Healthy Eating Index
Cognitive	, ,	d dietary habits compared to other interventions
Annesi 2013	PA: METS/week Diet: fruit and vegetable consumption	PA: Godin Leisure Time Exercise Questionnaire (LTEQ) questionnaire
		Diet: scale based on US food pyramid
Ash 2006	PA: % sufficiently active	PA: The International Physical Activity Questionnaire
Hinderliter 2014	PA: % exercising ≥ 3 times/week	PA: self-report (adherence to program)
	Diet: dietary intake	Diet: 4-day food diary

Cognitive therapies targeting physical activity habits and tobacco use compared to other interventions							
Welschen 2015	Tobacco: abstinence rate	Tobacco: single item yes/no					
	PA: minutes/day	PA: The Short Questionnaire to Assess Health Enhancing Physical Activity					

Secondary outcomes

Table C3. Secondary outcomes.

Study ID	Secondary outcomes ^a
Annesi 2013	Weight.
Ash 2006	Weight, body mass index, waist circumference.
Bergström 2013	Weight, body mass index, waist circumference.
Burke 2007	Weight, body mass index, waist circumference, fasting glucose, insulin, lipids.
Eakin 2009	None.
Fletcher 2011	Weight, body mass index.
Hinderliter 2014	Blood pressure, weight.
John 2013	Body mass index, blood pressure, lipid profile.
Kattermann 2014	Weight, body mass index.
Mefferd 2007	Weight, body mass index, waist circumference, lipid profile.
Murphy 2013	Blood pressure, lipid profile.
Steed 2005	HbA1c.
Sallit 2009	None.
Welschen 2015	Weight, body mass index, blood pressure, fasting glucose, HbA1c, lipid profile.

^aAs defined in this systematic review: relevant physiological or clinical outcomes related to physical activity and diet. HbA1c = a measure of three month average concentration of glucose in blood plasma.

D. Risk of bias

Table D.1 Support for judgment of risk of bias.

Study ID	Bias	Judgment	Support for judgment
Annesi	Random sequence genera-	Unclear	"Randomly assigned" without further descrip-
2013	tion		tion.
	Allocation concealment	Unclear Unclear	Not found.
	Blinding of participants and personnel	Ulicieal	"Instructors were blind to the purposes of the research". Participants not blinded.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Intention-to-treat analysis with imputation of missing data (14%).
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Ash 2006	Random sequence generation	Low	"Random number table".
	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Intention-to-treat analysis with imputation of missing data
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Bergström 2013	Random sequence generation	Low	Cluster-RCT: districts drawn from a basket.
	Allocation concealment	Low Unclear	Sealed opaque envelopes. Not possible to blind.
	Blinding of participants and personnel	Unclear	Not possible to billia.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Multi-level intention-to-treat analysis.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Burke 2007	Random sequence generation	Low	"Computer-generated random numbers".
	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Intention-to-treat analysis with imputation of missing data.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Eakin 2009	Random sequence generation	Low	Computer-generated cluster randomization.
	Allocation concealment	Low	GPs and staff not informed of allocation until completion of screening list.

	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Intention-to-treat analysis with baseline values carried forward and adjustment for clustering.
	Selective reporting Other bias	Low Low	Not found. Not found.
Fletcher 2011	Random sequence genera-	Unclear	"Participants were randomly assigned to"
2011	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data	Unclear	Intervention group 19% missing data, control group 17%. Mixed methods model, all data used "fits well with intention-to-treat analysis".
	Selective reporting Other bias	Low Low	Not found. Not found.
Hinderliter 2014	Random sequence generation	Unclear	"Were randomized"
	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data	Unclear	Intention-to-treat analysis, 15% loss to 1-year follow up.
	Selective reporting Other bias	Low Low	Not found. Not found.
John 2013	Random sequence genera-	Low	"Computer-generated random sequence."
	Allocation concealment	Unclear	Randomization list applied by independent team member, but no info on concealment.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data Selective reporting	Low Unclear	Intention-to-treat analysis, 89% response. Data not reported, only "no difference between groups".
	Other bias	Low	Not found.
Katterman 2012	Random sequence generation	Unclear	"Were randomized"
	Allocation concealment	Unclear	Not found.
	Blinding of participants and	Unclear	Not possible to blind.
	personnel Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data	Unclear	Completers only, 81% response.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Mefferd 2007	Random sequence genera-	Unclear	Not found.
	Allocation concealment	Unclear	Not found.

	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	High	Completers only, 89% response, all drop-outs in intervention group.
	Selective reporting	Unclear	Data not reported, only "difference was not
	Other bias	Low	statistically significant". Not found.
Murphy	Random sequence genera-	Unclear	Not found.
2013	tion Allocation concealment	Low	Sequence obtained from other department af-
	Blinding of participants and	Unclear	ter baseline measurement. Not possible to blind.
	personnel Blinding of outcome assess-	Unclear	Self-reported data.
	ment Incomplete outcome data	Low	Intention-to-treat with last value carried for-
			ward.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Sallit 2009	Random sequence generation	Low	"Computer-generated sequence".
	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data	High	Completers only, 60% response.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Steed 2005	Random sequence genera- tion	High	"By allocating participants alternately to"
	Allocation concealment	High	Not concealed, see above.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assessment	Unclear	Self-reported data.
	Incomplete outcome data	Unclear	Intention-to-treat analysis, imputation by group mean 83% response.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Welschen 2013	Random sequence genera-	Low	"Computer-generated sequence".
* : *	Allocation concealment	Unclear	Not found.
	Blinding of participants and personnel	Unclear	Not possible to blind.
	Blinding of outcome assess- ment	Unclear	Self-reported data.
	Incomplete outcome data	Low	Intention-to-treat analysis, 93% response.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.

E. GRADE evidence profiles

Table E1. GRADE evidence profile for cognitive therapies targeting physical activity and diet compared to no intervention or usual care on behavioural outcomes.

Author(s): Eva Denison, Vigdis Underland

Date: 02.02.2016

Question: Cognitive therapies targeting physical activity and diet compared to no intervention/usual care on behavioural outcomes

Setting: Primary health care

Bibliography: Ásh 2006, Bergström 2013, Burke 2007, Eakin 2009, Fletcher 2011, Hinderliter 2014, John 2013, Katterman 2012, Mefferd 2007, Murphy 2013, Steed 2005.

	Quality assessment						lt	0.47	I	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	- Impact	Quality	Importance	
Physical activity, m	Physical activity, mean change difference (assessed with: self-report/pedometer/accelerometer)									
9	randomised trials	serious ¹	not serious	not serious	not serious	none	The standardized mean difference was 0.19 (0.03, 0.35) to the advantage of the intervention group	⊕⊕⊕O MODERATE	CRITICAL	
Physical activity, re	elative risk (follow up: 12 i	months; assessed w	ith: self-report)							
2	randomised trials	serious 1	serious ³	not serious	serious ⁴	none	The relative risk was 1.38 (0.43, 4.45).	⊕OOO VERY LOW	CRITICAL	
Healthy diet, mean	n change difference (asse	ssed with: self-repor	t)	<u> </u>	,				•	
3	randomised trials	not serious ⁵	not serious	not serious	not serious	none	The standardized mean difference was 0.23 (0.06, 0.39).	⊕⊕⊕O MODERATE	CRITICAL	
Healthy diet, mean	n difference (follow up: rar	nge 4 months to 9 m	onths; assessed with:	Self-report)	1	1	,			
3	randomised trials	serious 1	serious	not serious	serious ²	none	The standardized mean difference based on two of three studies was 0.49 (-0.24, 1.23).	⊕OOO VERY LOW	CRITICAL	
Energy intake, mea	an difference (follow up: r	ange 10 months to 1	12 months; assessed w	rith: self-report)	,				_	
2	randomised trials	serious ¹	not serious	not serious	not serious	none	The standardized mean difference was -0.19 (-0.35, -0.03) to the advantage of the intervention group.	⊕⊕⊕O MODERATE	CRITICAL	

CI: Confidence interval; SMD: Standardised mean difference

- Overall unclear risk of bias.
- 2 small studies with a total of 210 participants.
- Similar sources with a total of 2 to participants.
 I-square 65%
 95% confidence interval includes no effect and very large effect.
 The outcome was assessed with self-report.

Table E2. GRADE evidence profile for cognitive therapies targeting diet and tobacco use compared to no intervention or usual care on behavioural outcomes.

Author(s): Eva Denison, Vigdis Underland **Date**: 23.11.2016

Question: Cognitive therapies targeting diet and tobacco use compared to no intervention or usual care on behavioural outcomes Setting: Primary health care
Bibliography: Sallit 2009

Quality assessment									
№ of stu- dies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Quality	Importance
Healthy diet (follow up: 9 months; assessed with: self-report)									
1	randomised tri- als	very serious ^a	not serious	serious ^b	serious °	none	The mean difference was 0.87 (0.50, 1.23) to the advantage of the intervention group.	⊕○○○ VERY LOW	CRITICAL
Number of cig	garettes smoked pe	er day (follow up: 9 mo	onths; assessed with:	self-report without biod	chemical validation)				
1	randomised tri- als	very serious ^a	not serious	serious ^b	serious °	none	The mean difference was -0.37 (-0.72, -0.01) to the advantage of the intervention group.	⊕⊖⊖⊖ VERY LOW	CRITICAL

a. Unclear risk of bias, icomplete outcome data; per protocol analysis; 60% response rate

b. Female participants only
c. One small study with 128 participants.

Table E3. GRADE evidence profile for cognitive therapies targeting physical activity and diet compared to other interventions on behavioural outcomes.

Author(s): Eva Denison, Vigdis Underland

Date: 30.11.2016

Question: Cognitive therapies targeting physical activity and diet compared to other interventions on behavioural outcomes

Setting: Primary health care

Bibliography: Annesi 2013, Ash 2006, Hinderliter 2014

			Quality as	ssessment					
№ of stu- dies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Quality	Importance
Physical activ	vity (follow up: rang	e 8 to 10 months; ass	sessed with: Self-repor	rt)					
2	randomised tri- als	serious a	not serious	not serious	very serious ^b	none	The relative risk was 1.09 (0.71, 1.67).	⊕⊖⊖ VERY LOW	CRITICAL
Physical activ	rity (follow up: rang	e 3 months to 3 mont	hs; assessed with: Se	lf-report)					
1	randomised tri- als	serious °	not serious	not serious	very serious ^d	none	The standardized mean difference was 0.25 (-0.02, 0.53).	⊕⊖⊖ VERY LOW	CRITICAL
Healthy diet (follow up: range 3	months to 3 months; a	assessed with: Self-re	port)					
1	randomised tri- als	serious °	not serious	not serious	serious e	none	The standardized meand difference was 0.10 (-0.17, 0.38).	⊕⊖⊖ VERY LOW	CRITICAL
Energy intake	(follow up: range	8 months to 8 months	; assessed with: Self-	report)					
1	randomised tri- als	serious °	not serious	not serious	very serious ^b	none	The standardized mean difference was 0.06 (-0.39, 0.50).	⊕⊖⊖ VERY LOW	CRITICAL

a. Overall unclear risk of bias.b. One small study with 76 participants. The 95% CI includes both no effect and large effect.

c. Unclear risk of bias.

d. One small study with 200 participants. The 95% CI includes both no effect and large effect.

e. One small study with 200 participants.

Table E4. GRADE evidence profile for cognitive therapies targeting physical activity and tobacco use compared to other interventions on behavioural outcomes.

Author(s): Eva Denison, Vigdis Underland

Date: 30.11.2016

Question: Cognitive therapies targeting physical activity and tobacco use compared to other interventions for behavioural outcomes

Setting: Primary health care Bibliography: Welschen 2014

Quality assessment									
№ of stu- dies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Quality	Importance
Physical activ	vity (follow up: rang	e 12 months to 12 mo	onths; assessed with:	Self-report)					
1	randomised tri- als	serious a	not serious	not serious	very serious ^b	none	The relative risk was 0.20 (-0.13, 0.52)	⊕⊖⊖ VERY LOW	
Tobacco use	(follow up: range 1	2 months to 12 month	ns; assessed with: Sel	f-report without bioche	emical validation)				
1	randomised tri- als	serious a	not serious	not serious	very serious °	none	The relative risk was 0.72 (0.33, 1.54).	⊕⊖⊖ VERY LOW	

a. Unclear risk of bias.

b. One small study with 143 participants. The 95% CI includes both no effect and large effect.

c. One small study with 131 participants. The 95% CI includes both no effect and large effect.

F. Studywise results

Compared to no intervention or usual care

Table F1. Description of the results in each study based on the standardized mean difference and relative risk data from the meta-analyses.

Study ^a	Outcome 1	SMD (95% CI)	RR (95% CI)	Outcome 2	SMD (95% CI)
Bergström 2013	Physical activity	0.48 (0.00, 0.96)		Diet - healthy	0.16 (-0.33, 0.64)
Burke 2007	Physical activity	0.17 (-0.08, 0.42)		Diet – energy intake	-0.16 (-0.41, 0.10)
Eakin 2009	Physical activity	-0.06 (-0.25, 0.13)		Diet – healthy	0.26 (0.08, 0.45)
Fletcher 2011	Physical activity	0.45 (-0.06, 0.97)		Diet - healthy	0.04 (-0.47, 0.55)
Hinderliter 2014	Physical activity		2.77 (0.81, 9.47)	Diet – energy intake	-0.11 (-0.56, 0.34)
Murphy 2013	Physical activity	0.04 (-0.20, 0.28)		Diet – fat intake	-0.24 (-0.48, - 0.00)
Sallit 2009	Tobacco use	-0.37 (-0.72, - 0.01)		Diet - healthy	0.87 (0.50, 1.23)
Steed 2005	Physical activity	0.45 (0.06, 0.85)		Diet – healthy	0.11 (-0.28, 0.51)

^a Another three studies targeted physical activity and diet, but reported data on physical activity outcomes only, a fourth study targeted physical activity and diet did not report any outcome data. SMD = standardized mean difference; RR = relative risk; CI = confidence interval.

Compared to other interventions

Table F2. Description of the results in each study based on the standardized mean difference and relative risk data from the meta-analyses.

Study	Outcome 1	SMD (95% CI)	RR (95% CI)	Outcome 2	SMD (95% CI)	RR (95% CI)
Annesi 2013	Physical activity	0.25 (-0.02, 0.53)		Diet – healthy	0.10 (-0.17, 0.38)	
Hinderliter 2014	Physical activity		0.90 (0.40, 2.02)	Diet – energy intake	0.06 (-0.39, 0.50)	
Welschen 2015	Physical activity	0.20 (-0.13, 0.52)		Tobacco – absti- nence rate		0.72 (0.33, 1.54)

 $SMD = standardized \ mean \ difference; \ RR = relative \ risk; \ CI = confidence \ interval.$



