

2016



Cognitive therapies for increasing physical activity

Systematic review

Published by	The Norwegian Institute of Public Health
Title	Cognitive therapies for increasing physical activity
Norwegian title	Kognitive terapier for økt fysisk aktivitet
Editor-in-chief	Camilla Stoltenberg, Director-General
Authors	Eva Denison, project leder, <i>senior researcher</i> , The Norwegian Institute of Public Health Vigdis Underland, <i>researcher</i> , The Norwegian Institute of Public Health Annhild Mosdøl, <i>senior researcher</i> , The Norwegian Institute of Public Health Gunn Vist, <i>research director</i> , The Norwegian Institute of Public Health
ISBN	978-82-8082-755-5
Project number	11319
Publications type	Systematic review
Number of pages	44 (74 including appendices)
Commissioner	The Norwegian Directorate of Health
MeSH terms	Cognitive therapy, motor activity, life style.
Citation	Denison E, Underland V, Mosdøl A, Vist GE. Cognitive therapies for increasing physical activity. Report 2016. Oslo: The Norwegian Institute of Public Health, 2016.
Cover Photo	Colourbox.com

The Norwegian Institute of Public Health
Oslo, August 2016

Table of Content

TABLE OF CONTENT	3
KEY MESSAGES	5
EXECUTIVE SUMMARY	6
HOVEDBUDSKAP	9
SAMMENDRAG	10
PREFACE	13
INTRODUCTION	14
About this report	14
Physical activity	14
Cognitive therapies	15
Problem formulation for this systematic review	16
METHODS	17
Selection criteria	17
Literature search	18
Study selection	18
Assessment of quality of systematic reviews	18
Assessment of risk of bias in primary studies	18
Data extraction	19
Analyses	19
Rating of our confidence in the effect estimates	20
RESULTS	21
Description of the studies	22
Risk of bias in included studies	25
Effects of interventions: Cognitive therapies compared to no intervention or usual care	28
Effects of interventions: Cognitive therapies compared to an exercise or rehabilitation program only, when added to such a program	30
Effects of interventions: Cognitive therapies compared to exercise or rehabilitation	31
Effects of interventions: Cognitive therapies compared to health education	31
DISCUSSION	33
Main findings	33
The quality of the documentation	33

Strengths and limitations	33
How applicable are the results?	34
Agreement with other systematic reviews	36
Implications for practice	36
Research gaps	37
CONCLUSION	39
REFERENCES	40
APPENDIX	45
A. Glossary	45
B. Search strategy	45
C. Excluded studies	52
D. Characteristics of included studies	53
E. Risk of bias	65
F. Sensitivity analyses	70
G. GRADE evidence profiles	72

Key messages

Regular physical activity reduces the risk of heart disease, diabetes, and cancer. Cognitive therapies have documented effects in a number of health care settings but we do not know if cognitive therapies can increase physical activity.

We evaluated the effect of cognitive therapies on physical activity summarizing studies involving different patient groups and persons at risk of heart disease. Few studies had follow-up times beyond six months.

We found that:

- It is probable, based on moderate-quality evidence, that cognitive therapies lead to small to moderate increases in physical activity. This applies to comparisons with no intervention, usual care, or as an adjunct to exercise or rehabilitation programs.
- It is possible, based on low-quality evidence, that cognitive therapies has a similar effect on physical activity as health education has.
- The documentation is too sparse to conclude about the effect of cognitive therapies when directly compared to exercise or rehabilitation.

Title:
Cognitive therapies for increasing physical activity.

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.

Publisher:
The Norwegian Institute of Public Health.

Updated:
Last search for studies:
February 2015.

Peer review:
Liv Merete Reinart, research director, the Knowledge Centre in the Norwegian Institute of Public Health.
Marianne Klemp, research director, the Knowledge Centre in the Norwegian Institute of Public Health.

External peer review:
Roger Hagen, associate professor, Department of Psychology, the Norwegian University of Science and Technology.

Anders Hovland, associate professor, Department of Psychology, University of Bergen.

Bente Wold, professor, Department of Health Promotion and Development, University of Bergen.

Executive summary

Background

Insufficient physical activity is a major risk factor for several common diseases, for example heart disease, type 2 diabetes, and cancer. Conversely, regular physical activity reduces the risk of these diseases. Only about a third of Norwegian adults manage to accumulate enough weekly physical activity to achieve health benefits. Cognitive therapies have documented effects in a range of disorders, e.g. depression, anxiety, insomnia, and chronic pain, but we do not know if they are useful in promoting physical activity in adults.

The term cognitive therapies is used in this report and is understood to include cognitive behavioural therapies, which is a common use in Norway.

Objective

We carried out this systematic review to answer the question “What is the effect of cognitive therapies on physical activity in adults ≥ 18 years, compared to no intervention, usual care or another intervention?”

Method

We searched systematically in five electronic databases. In addition, we searched the reference lists of included studies. Two persons independently screened titles and abstracts, selected studies from 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 by random-effects meta-analyses and presented standardized mean differences and 95% confidence intervals. We carried out analyses to explore whether characteristics of the populations or the interventions, or the quality of the studies influenced the results. 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 means 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 means that the true effect may be substantially different from the estimate of the effect. Very low quality means 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 21 randomized controlled trials with 25 comparisons that fulfilled our inclusion criteria. Most of the studies included different patient groups, such as persons with cancer, type 2 diabetes, or coronary heart disease, while a third of the studies included sedentary but otherwise healthy persons. All studies but three were judged to have an unclear risk of bias, most commonly due to insufficient information on how allocation of participants to study groups was concealed.

We found a moderate effect of cognitive therapies on physical activity compared to no intervention or usual care, including receiving advice. The standardized mean change difference was 0.47 with a 95% confidence interval of 0.19 to 0.74. According to GRADE, we rated our confidence in the effect estimate as moderate. Other studies that compared cognitive therapies with no intervention or usual care reported their results as mean differences. Our confidence in the effect estimate was very low and we considered these data to be too uncertain to consider whether there was an effect or not.

We found a small to moderate effect of cognitive therapies on physical activity when added to exercise or rehabilitation programs compared to these programs alone. The standardized mean difference was 0.42 with a 95% confidence interval of 0.15 to 0.69. Our confidence in this effect estimate was moderate. The documentation is too sparse to conclude about the effect of cognitive therapies directly compared to exercise or rehabilitation.

Finally, we found that cognitive therapies might have a small effect similar to health education. The standardized mean difference was 0.14 with a 95% confidence interval of -0.14 to 0.42. Our confidence in this effect estimate was low.

In sensitivity analyses, the characteristics of the populations or interventions, or quality of the studies did not systematically influence the results across the comparisons.

Discussion

The studies included in this systematic review covered a range of adult populations, including both patients and sedentary but otherwise healthy persons. The interventions included basic elements of cognitive therapies such as goal-setting, development of skills to identify and handle maladaptive thoughts and behaviours, and relapse prevention. The interventions were delivered by several different categories of health professionals. There was great variation in the duration and frequency of the intervention given. These factors, explored in sensitivity analyses, did not seem to influence the results systematically, which supports the applicability of the results.

However, applicability may be limited by the fact that most studies used strict exclusion criteria meaning that, for example, persons with co-morbidities or mental health problems were excluded from participation. Thus, the results may not capture the effectiveness of cognitive therapies, i.e. if they work well in routine clinical practice. Another possible limitation pertains to the measurement of physical activity. All methods

to measure physical activity have their strengths and limitations. The most serious limitation related to the present results is the unknown ability of self-report questionnaires to detect change in physical activity from one point in time to another in a reliable way. Another limitation is that many different methods were used to measure physical activity across the studies. The consequence of this is that results that go into meta-analyses needed to be standardized, and the connection with the original measurement scales such as minutes per day, steps per day, or calories used is lost. We can only describe effects in terms of direction (to the 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. The lack of direct comparison of cognitive therapies with exercise or rehabilitation programs may limit the applicability of the results. We do not know the effect on physical activity of participating in either a cognitive therapy program or an exercise or rehabilitation program. Finally, few studies had follow-up beyond six months after the end of the intervention.

Research gaps include standardization of primary outcome measurements in physical activity, preferably organised as a task for international cooperation; follow-up results for at least 12 months after the end of the intervention; direct comparison of cognitive therapies with exercise or rehabilitation programs.

Conclusion

Cognitive therapies probably lead to a moderate increase in physical activity when they are compared to no intervention or usual care. When cognitive therapies are added to exercise or rehabilitation programs they probably lead to a small to moderate additional increase in physical activity compared to exercise or rehabilitation only. The follow-up times are short, up to six and nine months, respectively. Cognitive therapies may have a similar small effect on physical activity as health education, up to nine months post intervention.

Hovedbudskap

Regelmessig fysisk aktivitet reduserer risiko for hjerte- og kar-sykdom, diabetes og kreft. Kognitive terapier har dokumentert effekt innen en rekke områder, men vi vet ikke om kognitive te-rapier kan øke fysisk aktivitet.

Vi oppsummerte effekten av kognitive terapier i studier som involverer pasientgrupper og personer med risiko for hjerte- og karsykdom. Få studier hadde oppfølging mer enn seks måneder.

Vi fant at:

- Det er trolig, basert på dokumentasjon av middels kvalitet at kognitive terapier gir en liten til moderat økning av fysisk aktivitet. Dette gjelder når tiltaket er sammenlignet med ingen eller vanlig behandling eller som tillegg til trenings- og rehabiliteringsprogrammer.
- Det er mulig, basert på dokumentasjon av lav kvalitet at kognitive terapier har en lignende liten effekt på fysisk aktivitet som undervisning om helse.
- Kunnskapsgrunnlaget er altfor mangelfullt til å trekke konklusjoner om effekter av kognitive terapier direkte sammenlignet med trenings- og rehabiliteringsprogrammer.

Tittel

Kognitive terapier for økt fysisk aktivitet.

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 publikasjonen?

Folkehelseinstituttet har gjennomført denne systematiske oversikten på oppdrag fra Helsedirektoratet.

Når ble litteratursøket utført?

Søk etter studier ble avsluttet Februar 2015.

Eksterne fagfeller:

Roger Hagen, førsteamanuensis, Psykologisk institutt, Norges teknisk-naturvitenskapelige universitet.

Anders Hovland, førsteamanuensis, Institutt for klinisk psykologi, Universitetet i Bergen.

Bente Wold, professor, HEMIL-senteret, Universitetet i Bergen.

Sammendrag

Innledning

Utilstrekkelig fysisk aktivitet er en ledende risikofaktor for flere vanlige sykdommer som for eksempel hjerte- og karsykdom, type 2 diabetes, og kreft. Omvendt reduserer regelmessig fysisk aktivitet risiko for disse sykdommene. Kun en tredjedel av nordmenn har et ukentlig nivå av fysisk aktivitet som gir helsegevinst. Kognitive terapier har dokumentert effekt innen flere helseområder men vi vet ikke om de kan være til nytte for å fremme fysisk aktivitet hos voksne.

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

Formål

Vi utførte en systematisk oversikt for å svare på spørsmålet «Hva er effekten av kognitive terapier på fysisk aktivitet hos voksne ≥ 18 år, sammenlignet med ingen tiltak, vanlig behandling eller annet tiltak?»

Metode

Vi søkte systematisk etter litteratur i fem elektroniske databaser. I tillegg søkte vi i referanselister til inkluderte studier. To personer gikk uavhengig igjennom titler og sammendrag, valgte ut studier fra fulltekstartikler, og vurderte risiko for systematiske skjevheter i de inkluderte studiene. En person trakk ut data fra studiene og en annen person verifiserte datauttrekkingen. Vi oppsummerte resultatene med «random-effects» metaanalyser og presenterte standardiserte gjennomsnittsforskjeller og 95 % konfidensintervall. Vi undersøkte om egenskaper hos populasjonene eller tiltakene, eller kvaliteten på studiene påvirket resultatene. Vi vurderte tilliten til effektestimater 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 effektestimater ligger nær den sanne effekten. Middels kvalitet betyr at effektestimater 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 effektestimater. Svært lav kvalitet betyr at vi har svært liten tillit til at effektestimater ligger nær den sanne effekten.

Resultat

Vi fant ikke systematiske oversikter som besvarte vårt spørsmål. Vi fant 21 randomiserte kontrollerte forsøk med 25 sammenligninger som oppfylte våre inklusjonskriterier. Studiene inkluderte flere pasientgrupper som for eksempel personer med kreft, type 2 diabetes og hjerte- og karsykdom. En tredjedel av studiene inkluderte personer med lavt nivå av fysisk aktivitet, men som ellers var friske. Vi vurderte alle studier unnatt tre til å ha uklar risiko for systematiske skjevheter. I de fleste fall skyltes dette at det var utilstrekkelig informasjon om hvordan fordelingen av deltakere til ulike grupper ble skjult.

Vi fant en moderat økning av fysisk aktivitet når kognitive terapier ble sammenlignet med ingen tiltak eller vanlig behandling, inkludert råd. Den standardiserte gjennomsnittsforskjellen i forandring av fysisk aktivitet var 0,47 med et 95 % konfidensintervall på 0,19 til 0,74. Vi vurderte, ifølge GRADE, vår tillit til effektestimater som middels. Andre studier som sammenlignet kognitive terapier sammenlignet med ingen tiltak eller vanlig behandling rapporterte sine resultater som gjennomsnittsforskjeller. Vi vurderte vår tillit til effektestimater som svært lav. Dokumentasjonen i disse studiene er altfor usikker til å vurdere om det fantes en effekt.

Vi fant en liten til moderat økning av fysisk aktivitet når kognitive terapier ble gitt i tillegg til trenings- eller rehabiliteringsprogram og sammenlignet med å kun gjennomgå disse programmene. Den standardiserte gjennomsnittsforskjellen var 0,42 med et 95 % konfidensintervall på 0,15 til 0,69. Vi vurderte vår tillit til effektestimater til middels. Kunnskapsgrunnlaget er altfor mangelfullt til å trekke konklusjoner om effekter av kognitive terapier direkte sammenlignet med trenings- og rehabiliteringsprogrammer.

Til slutt fant vi at kognitive terapier muligens har en lignende liten effekt på fysisk aktivitet som undervisning om helse. Den standardiserte gjennomsnittsforskjellen var 0,14 med et 95 % konfidensintervall på -0,14 til 0,42. Vi vurderte vår tillit til effektestimater til lav.

Egenskaper hos populasjonene eller tiltakene påvirket ikke resultatene systematisk sett over alle sammenligningene.

Diskusjon

Studiene som ble inkludert i denne systematiske oversikten dekket flere populasjoner av voksne, både pasienter og friske personer med lavt nivå av fysisk aktivitet. Tiltakene inneholdt grunnleggende elementer i kognitive terapier så som målsetting, utvikling av ferdigheter til å identifisere og håndtere maladaptive tanker og handlingsmønstre, og forebygging av tilbakefall. Tiltakene ble gitt av flere kategorier av helsepersonell. Det var stor variasjon i varighet og hyppighet av tiltakene. Det så ikke ut til at disse faktorene påvirket resultatene på en systematisk måte, noe som støtter anvendbarheten av resultatene.

Anvendbarheten av resultatene kan være begrenset av at de fleste studiene hadde strenge eksklusjonskriterier. Det betyr at, for eksempel, personer med flere sykdommer eller problemer innen mental helse ble ekskludert. Derfor kan det være at resultatene ikke fanger opp hvorvidt kognitive terapier er effektive, det vil si om de virker for å fremme fysisk aktivitet når de brukes i vanlig klinisk praksis. En annen mulig begrensning har å gjøre med måling av fysisk aktivitet. Alle metoder for å måle fysisk aktivitet har styrker og begrensninger. Den mest alvorlige begrensningen er at muligheten for at spørreskjemaer fanger opp forandring av fysisk aktivitet fra et tidspunkt til et annet på en pålitelig måte er ukjent. Ytterligere en begrensning er at studiene målte fysisk aktivitet på mange forskjellige måter. Konsekvensen av dette er at resultatene som går inn i metaanalyser må standardiseres, og koblingen til de opprinnelige måleskalaene som for eksempel minutter per dag, skritt per dag, eller kaloriforbruk går tapt. Vi kan kun beskrive effekter i termer av retning (til fordel for tiltaks- eller kontrollgruppen, eller at resultatene viser liten eller ingen forskjell) og størrelsesorden (liten, moderat, eller stor effekt). Dette gjør det vanskelig å tolke resultatene. Mangel på direkte sammenligning mellom kognitive terapier og trenings- eller rehabiliteringsprogrammer kan også begrense anvendbarheten av resultatene. Vi kjenner ikke effekten av å delta i enten kognitiv terapi eller et trenings- eller rehabiliteringsprogram. Få studier hadde oppfølging av resultater lenger enn seks måneder, noe som også kan begrense tolkning av disse studiene.

Identifiserte forskningshull inkluderer mangel på standardisering av hvordan fysisk aktivitet skal måles. Dette er en oppgave for internasjonalt samarbeid. Videre er det behov for studier med oppfølging av resultatene minst 12 måneder etter avsluttet behandling. Det er også behov for studier med direkte sammenligning mellom kognitive terapier og trenings- eller rehabiliteringsprogrammer.

Konklusjon

Kognitive terapier fører trolig til en moderat økning av fysisk aktivitet sammenlignet med ingen tiltak eller vanlig behandling. Når kognitive terapier gis i tillegg til trenings- og rehabiliteringsprogrammer fører de trolig til en liten til moderat økning av fysisk aktivitet sammenlignet med kun å delta i trenings- og rehabiliteringsprogrammer. Oppfølgingsperiodene i disse sammenligningene er korte, henholdsvis opptil seks og ni måneder. Kognitive terapier har muligens liten eller ingen effekt på fysisk aktivitet sammenlignet med undervisning om helse. Dokumentasjonen fra fire studier hvor kognitive terapier sammenlignes med ingen tiltak eller vanlig behandling og hvor resultatene er basert på gjennomsnittsforskjeller er altfor usikre for å vurdere om tiltaket har effekt.

Preface

The Knowledge Centre in the Norwegian Institute of Public Health carried out a systematic review of the effects of cognitive therapies for changing life style habits related to physical activity, diet, and tobacco use. This report is the first of three and presents the findings concerning effects of cognitive therapies for increasing physical activity. The Norwegian Directorate of Health commissioned the systematic review.

The report is intended to assist decision makers in the health services to make informed decisions that can improve the quality of health services. The findings should be seen in conjunction with experience-based knowledge, client knowledge, and the context before making a decision about the intervention.

The project group consisted of:

Project leader: Eva Denison, senior researcher, the Knowledge Centre in the Norwegian Institute of Public Health.

Vigdis Underland, researcher, the Knowledge Centre in the Norwegian Institute of Public Health.

Annhild Mosdøl, senior researcher, the Knowledge Centre in the Norwegian Institute of Public Health.

Gyri Hval Straumann, research librarian, the Knowledge Centre 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 Marianne Klemp, research director at the Knowledge Centre in the Norwegian Institute of Public Health, and Liv Merete Reinart, 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, Anders Hovland, associate professor, Department of Psychology, University of Bergen, and Bente Wold, professor, Department of Health Promotion and Development, University of Bergen.

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

Signe Flottorp

Acting head of department

Gunn E Vist

Research director

Eva Denison

Project leader

Introduction

About this report

This is the first report in a series of three concerning the effects of cognitive therapies on change of lifestyle habits. The theme of this report is physical activity. The second report will review effects of cognitive therapies used to change more than one habit, e.g. both diet and physical activity. The third report will concern effects of cognitive therapies in reducing tobacco use.

The Norwegian Directorate of Health is the commissioner of the systematic review on which the reports are based. There is some disagreement in Norway about terminology concerning the intervention. The term “cognitive therapies” commonly includes cognitive behavioural therapies (1), and the commission concerned cognitive therapies in this sense. We are aware that this position is not endorsed by all. We will use the term cognitive therapies throughout the text even when included studies and other literature we may refer to use the term cognitive behavioural therapies.

Physical activity

Insufficient physical activity is the fourth leading risk factor for global mortality with an estimated 6% of global deaths. Approximately 21–25% of breast and colon cancer burden, 27% of diabetes burden and approximately 30% of ischaemic heart disease burden is attributed to insufficient physical activity. Conversely, participation in regular physical activity reduces the risk of coronary heart disease and stroke, diabetes, hypertension, colon cancer, breast cancer and depression. Physical activity is also fundamental to energy balance and weight control (2).

Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure (3). Duration, frequency, and intensity are basic behavioural dimensions of physical activity (4, 5). These dimensions are used in international recommendations of physical activity (2). Currently, adults 18-64 years old are recommended to do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity. Muscle-strengthening activities should be done involving major muscle groups on two or more days a week. (2).

In Norway, recent population-based data suggest that only 32% of adults are physically active in accordance with current recommendations. This figure may overestimate the physical activity level in the population due to a relatively high proportion of participants with high socio-economic status (6). The Norwegian health authorities promote increased physical activity in the population through policy documents and campaigns. The Directorate of Health issues national guidelines and supports the development of municipal 'healthy lifestyle' centres (in Norwegian, frisklivssentraler). These are organisations at the primary health care level and run by health care personnel. The centres offer a structured, but flexible program for counselling and organised follow-up of behaviours that may increase risk of disease in adults, including lack of physical activity (7).

Cognitive therapies

Cognitive therapies are psychological treatments that address the interactions between thoughts, emotions, and behaviour. Cognitive therapies include several treatments and practices (8) 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 (9). A range of disorders is treated by 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 by cognitive therapies (10).

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 (8). 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 role-play (10).

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, (11) 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
 - 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 (12). 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 a bachelor's 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 (13). 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 lifestyle habits such as physical activity (13).

The results of recently published systematic reviews suggest that cognitive therapies are effective for the treatment of adult depressive disorders (14, 15), social anxiety disorders (16), insomnia (17, 18), chronic pain (19), and subacute and chronic neck pain (20) when compared to no treatment or usual treatment. The evidence for cognitive therapies compared to other treatment seems to be limited (14, 19, 20). We have not found systematic reviews covering cognitive therapies for physical activity.

Problem formulation for this systematic review

We carried out this systematic review to answer the question "What is the effect of cognitive therapies on physical activity in adults ≥ 18 years, compared to no intervention, usual care or another intervention?"

Methods

We carried out a systematic review according to the Cochrane Handbook for Systematic Reviews of Interventions (21).

Selection criteria

Study design:

Systematic reviews of high quality.

Randomised controlled trials.

Cluster-randomised controlled trials.

Non-randomised controlled studies.

Interrupted time-series analyses with at least three measurements both before and after the intervention, and with a clearly defined point in time when the intervention was introduced.

Population: Adults ≥ 18 years.

Intervention: Cognitive therapies aiming to increase physical activity.

Comparison: No intervention, usual care or other intervention.

Outcome: Primary outcome: physical activity.

Secondary outcomes: relevant physiological or clinical outcomes related to physical activity.

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
 - interventions without a behavioral 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.

Literature search

We searched systematically in the following electronic databases:

- The Cochrane Database of Systematic Reviews (CDSR)
- Database of Abstracts of Reviews of Effects (DARE)
- MEDLINE (Ovid)
- Embase (Ovid)
- PsycINFO (Ovid)

Research librarian Gyri Hval Strauman planned and carried out the searches. We initially searched for systematic reviews, without finding relevant publications. The search strategy, presented in Appendix 2, 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 several lifestyle habits, i.e. physical activity, diet, and tobacco use. This report presents the results for studies on physical activity. We read the reference lists of included studies in addition to searching in the electronic searches.

Study selection

Two persons (ED and VU, ED and AM) independently screened titles and abstracts. Two persons (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 (22).

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 (23). 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 a primary outcome, we chose the estimate that in our judgment best reflected the outcome in general terms, e.g. minutes of physical activity per week rather than minutes spent in leisure activities. 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 (24). We went through the following steps to synthesize the data: We first sorted the studies by comparison (against no intervention/usual care or other intervention) and outcome. Using the software Review Manager 5.3, (25) we then carried out random-effects meta-analyses for each outcome presenting standardized mean differences (SMD) and 95% confidence intervals for continuous data, with separate meta-analyses for studies that reported mean difference and studies that reported mean change difference (see explanation below). Finally, we carried 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 (26) 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 all 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 (27). 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 (28). 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 evaluating effects of cognitive therapies for change of several lifestyle habits, resulted in 4020 references after duplicate control. In addition, we identified three publications by searching reference lists of included publications. From 4023 references, we excluded 3914 references that were judged irrelevant based on title and abstract. We selected 83 full text reports for evaluation in two forthcoming reports. We evaluated 26 publications in full text for this report and excluded five studies based on inclusion- and exclusion criteria. The five excluded studies are presented in the Appendix, Table C1. We included 21 studies.

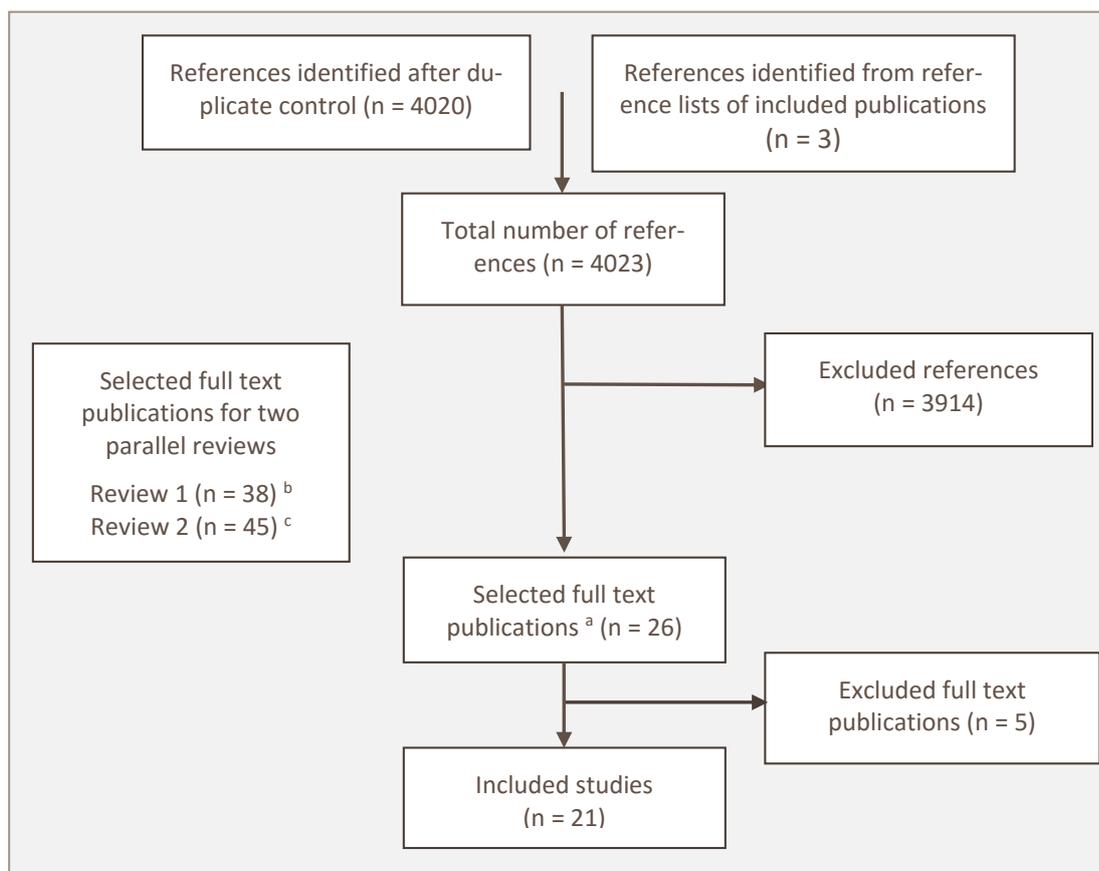


Figure 1. Flow chart of the citations reviewed in the systematic review.

^a References relevant to the report on physical activity.

^b References relevant to a future report on diet and physical activity.

^c References relevant to a future report on tobacco use.

Description of the studies

Included studies

We did not identify systematic reviews that could answer our research question. Although we searched for observational studies as well, only randomised controlled trials were found. We included 21 primary studies with 25 comparisons. These randomised controlled trials included 3 559 participants. Twelve studies were from USA, three were from Germany, and two each were from Belgium, Canada, and The Netherlands. The intervention was given to adult patients in 14 studies, e.g. persons with cancer, type 2 diabetes, or coronary heart disease. In the remaining seven studies the participants were healthy, sedentary adults. All interventions included one or more of the following cognitive or cognitive-behavioural content: goal-setting, self-efficacy, self-monitoring, self-management, self-regulation, problem solving, coping skills, cognitive restructuring, and relapse prevention. Eleven studies compared the intervention to no intervention or usual care, nine as an adjunct to exercise or rehabilitation programs, and five to health education. Four studies had two intervention arms in addition to control. The primary outcome physical activity was conceptualized in a range of ways, e.g. duration/time unit, aerobic capacity and energy expenditure. Nine studies had follow-up at the end of the intervention only, and the remaining studies had follow-up ranging from three to nine months after the intervention. (Table 1).

Table 1. General description of the included studies.

Study ID; country	Population	Intervention content	Comparison	Outcome	Length of follow-up
Berry (29) USA	Adults mean age 66; COPD; N = 176	Goal-setting; skills training; self-regulation; exercise program	Exercise program	Energy expenditure	End of intervention
Brawley (30) Canada	Adults 65-70; sedentary; N = 60	Goal-setting; self-monitoring; problem solving; relapse prevention; exercise program	1. Exercise program 2. No intervention	Minutes/week	3 months post intervention
Calfas (31) USA	University students 18-29; N = 338	Self-efficacy; self-management	Health education	Hours/week	End of intervention
Christiansen (32) Germany	Adults 27-63; back pain; N = 75	Problem solving; exercise program	Exercise program	Physical capacity	3 months post intervention
Cramp (33) USA	Post-natal women mean age 31; sedentary; N = 57	Self-monitoring; self-regulatory skills development; exercise program	Exercise program	Minutes/week	End of intervention
De Greef (34) Belgium	Adults 35-75; type 2 diabetes; N = 41	Goal setting; self-monitoring; self-efficacy; relapse prevention	Usual care	Minutes/day	9 months post intervention
De Greef (35) Belgium	Adults 35-75; type 2 diabetes; BMI 25-35;	Goal setting; self-monitoring; self-efficacy;	Usual care	Steps/day	6 months post intervention

	N = 92	problem solving; relapse prevention			
Dunn (36) USA	Adults 35-60; sedentary; N = 237	Behavioural skills development; problem solving; exercise program	Exercise program	Energy expenditure	End of intervention (24 mo post bl)
Houle (37) Canada	Adults < 80; hospitalized for acute coronary syndrome; N = 65	Self-monitoring; self-efficacy	Usual care	Steps/day	End of intervention
Kirk (38) USA	Adults mean age 57; type 2 diabetes; N = 70	Counselling based on stages of change	Advice	Accelerometer counts/week	3 months post intervention
May (39) The Netherlands	Adults ≥18; cancer diagnosis; N = 147	Self-management skills development; problem solving; exercise program	Exercise program	Points based on frequency	End of intervention
McDermott (40) USA	Adults ≥ 65; peripheral artery disease; N = 194	Goal-setting; self-monitoring; self-management	Health education	Accelerometer units/week	End of intervention
Perna (41) USA	Adult women 21-75; recent diagnosis of breast cancer, stage 0, I, II or IIIA; N = 51	Goal-setting; behavioural skills development; self-monitoring; problem solving	Information control	Points based on frequency	End of intervention
Prinsen (42) The Netherlands	Adults 18-65; severely fatigued cancer survivors; N = 64	Self-regulation	No intervention	Actometer score/12 days	3 months post intervention
Rejeski (43) USA	Adults 50-80; at risk for or with cardiovascular disease; N = 147	Self-monitoring; self-regulation; cardiac rehabilitation	Cardiac rehabilitation	Peak MET level	3 months post intervention
Rogers (44) USA	Adult women 18-70; stage I, II or IIIA breast cancer; N = 41	Self-monitoring; self-management	Usual care	Minutes/week	3 months post intervention
Schneider (45) USA	Adults mean age 71; sedentary; N = 349	Goal-setting; cognitive restructuring; exercise	1. Exercise + health promotion 2. Exercise only	MET-hours/week	9 months post intervention
Simons-Morton (46) USA	Adults 35-75; sedentary; N = 581	Goal-setting; problem solving; reinforcement; social support	Advice	Aerobic capacity	End of intervention (24 mo post bl)
Sniehotta (47) Germany	Adults mean age 58; coronary heart disease; N = 240	Coping skills development; exercise program	1. Usual care 2. Exercise program	Minutes/week	2 months post intervention
Stadler (48) Germany	Adult women 30-50; N = 400	Self-regulation	Advice	Minutes/week	4 months post intervention

Taylor (49) USA	Adult men mean age 69; prostate cancer; N = 134	Goal-setting; cognitive restructuring; problem solving	1. Educational support program 2. Usual care	Energy expenditure	6 months post intervention
-----------------	---	--	--	--------------------	----------------------------

COPD = chronic obstructive pulmonary disease; BMI = body mass index; MET = metabolic equivalent (a measure of the energy cost of physical activity).

Participants

We describe the participants in each study further in the Appendix, Table D1. Summarised, the mean age of the participants ranged from 24 to 72 years, with a mean across studies of 55 years. Three studies had only female participants and one study had only male participants. The percentage of female participants in the remaining studies ranged from 18% to 84%, with a mean percentage of 49%. Eight studies reported ethnicity of the participants. The percentage of participants reported as Caucasian ranged from 47% to 93%, with a mean of 72%. Ten studies reported level of education. Although this was not reported in a consistent way, the percentage reported to have college- or longer education ranged from 34% to 83% (based on seven studies). Three studies reported years of education as either having a mean of 15 years, as 55% having more than 10 years, and as 35% having 12-13 years, respectively. Eight studies reported civil status. The percentage of participants who were married or living with a partner ranged from 37% to 98% with a mean of 74%. Only a few studies reported employment status and income level.

Interventions and comparisons

The interventions were compared to either a) no intervention or usual care (which often also included advice), b) to an exercise or rehabilitation program only, when added to such a program, or c) to health education. In the following, we describe the interventions within each of these comparisons.

Eleven studies compared the interventions to no intervention (n = 2) or usual care (n = 5, also including advice n = 4). The intervention was given in a group format in two studies, in a combined group and individual format in four studies, and in an individual format in five studies. The duration of the interventions ranged from 12 weeks to 24 months with a median duration of 24 weeks. The frequency of intervention sessions ranged from three per week to bimonthly. Session length ranged from 30 minutes to 120 minutes with a median length of 50 minutes. Psychologists gave the intervention in four studies, together with a physical educator in three of these. An exercise specialist, a clinical nurse specialist, “trained research assistants”, and a health educator gave the intervention in four studies, respectively. Three studies did not report who gave the intervention. Goal setting, self-monitoring, problem-solving, skills development, and relapse prevention were the most common elements of the intervention content across studies. See Appendix, Table D2 for details of each study

Eight studies compared the effect of adding cognitive therapies to an exercise or rehabilitation program (the intervention) to the same exercise or rehabilitation program on its own. One study compared the intervention directly to an exercise program. The in-

intervention was given in a group format in three studies, in a combined group and individual format in five studies, and in an individual format in one study. The duration of the interventions ranged from three weeks to 24 months with a median duration of 12 weeks. The duration of the interventions ranged from 15 minutes to 120 minutes. A median value for duration may not be useful because several studies reported a range for duration, e.g. 15-60 minutes. Psychologists gave the intervention in two studies. Exercise specialists gave the intervention in four studies. “Group facilitators” gave the intervention in one study, and two studies did not report who gave the intervention. Goal setting, self-monitoring, and problem solving were the most common elements of the intervention content across studies. See Appendix, Table D3 for details of each study

Five studies compared the interventions to health education. The intervention was given in a group format in four studies and in a combined group and individual format in one study. The duration of the interventions ranged from one session to 24 months, the remaining three studies reported durations of 12 weeks (one study) and 24 weeks (two studies). Session length ranged from 60 to 110 minutes in four studies and was not reported in one study. Goal setting and self-monitoring were the most common elements of the intervention content across studies. Trained “facilitators” or “counsellors” gave the intervention in four studies. One study did not report who gave the intervention. The intervention was compared to health education of various formats. All studies used a similar amount of contact as the intervention group, and typically provided lectures on health topics. See appendix, Table D4 for details of each study

Outcomes

The studies conceptualized and measured the primary outcome physical activity in different ways. Eight studies measured duration, e.g. minutes or hours per week, two studies measured frequency, reported as points, and three studies measured energy expenditure. Twelve studies measured the outcome by self-report while six studies measured physical activity by pedometer or accelerometer, reported as steps per day, or counts per time unit. Three studies measured physical capacity, a correlate of physical activity, by treadmill test or ergometer test. See Appendix, Table D5 for details of each study

The secondary outcomes reported in the studies, as defined by our inclusion criteria, are shown in the Appendix, Table D6.

Risk of bias in included studies

We judged 18 studies to have an unclear risk of bias and three studies to have a low risk of bias (Figures 2 and 3). 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 (Figure 2) (ref). Figure 3 shows our rating in each domain by study. Appendix, Table E1, presents support for our judgment of risk of bias for each study.

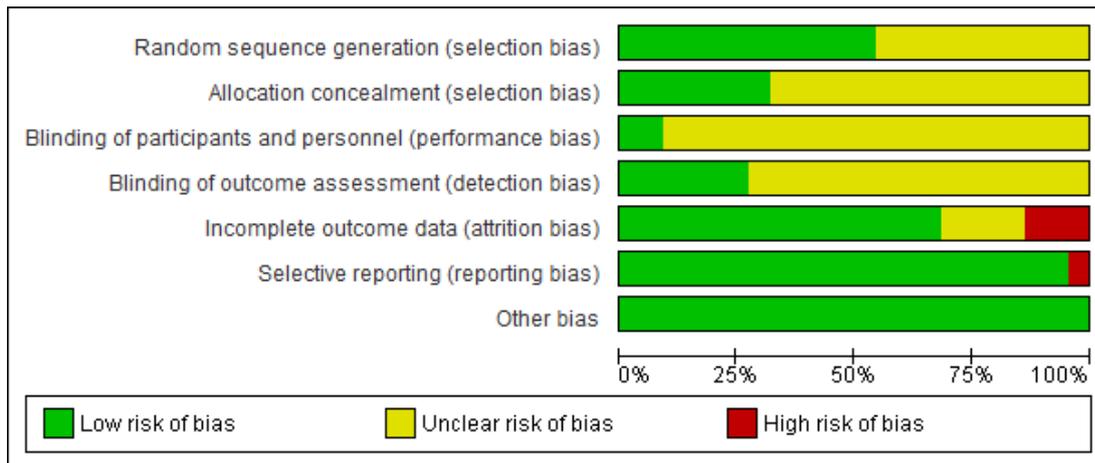


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Berry 2010	+	?	?	?	-	+	+
Brawley 2000	?	?	?	?	?	-	+
Calfas 2000	?	?	?	?	+	+	+
Christiansen 2010	?	?	+	?	+	+	+
Cramp 2006	?	?	?	?	?	+	+
De Greef 2010	?	+	?	+	+	+	+
De Greef 2011	?	?	+	+	+	+	+
Dunn 1999	?	?	?	?	+	+	+
Houle 2011	+	?	?	+	+	+	+
Kirk 2004	?	+	?	+	?	+	+
May 2008	+	?	?	?	+	+	+
McDermott 2013	+	?	?	?	+	+	+
Perna 2010	+	+	?	?	+	+	+
Prinsen 2013	+	+	?	+	-	+	+
Rejeski 2003	?	?	?	?	+	+	+
Rogers 2009	+	+	?	+	+	+	+
Schneider 2008	+	?	?	?	+	+	+
Simons-Morton 2001 men	+	+	?	?	+	+	+
Simons-Morton 2001 women	+	+	?	?	+	+	+
Sniehotta 2005	?	?	?	?	?	+	+
Stadler 2009	+	?	?	?	+	+	+
Taylor 2006	+	?	?	?	-	+	+

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Effects of interventions: Cognitive therapies compared to no intervention or usual care

Figures 4 and 5 show the physical activity results for the studies comparing cognitive therapies to no intervention or usual care. The six studies shown in Figure 4 re-reported mean change difference as the effect measure while the five studies shown in Figure 5 reported mean difference. By coincidence, the studies reporting mean change difference measured physical activity by pedometer or accelerometer, while the studies reporting mean difference used self-report questionnaires to measure the outcome. One study, Brawley (30) in Figure 5, did not report data concerning this comparison.

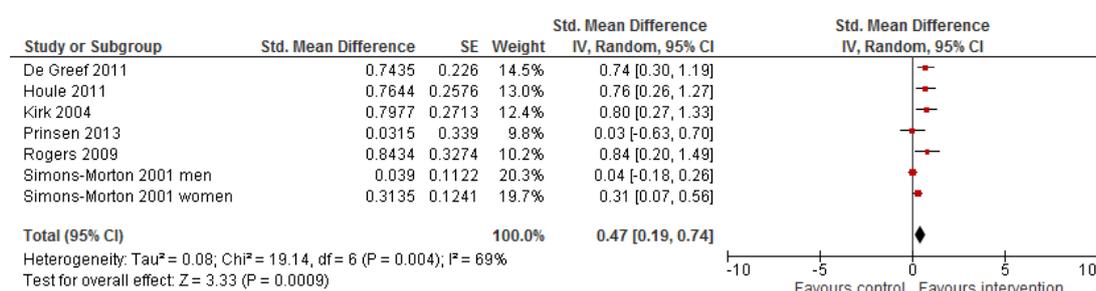


Figure 4. Effects of cognitive therapies compared to no intervention or usual care on physical activity in studies reporting mean change difference. SE = standard error, CI = confidence interval.

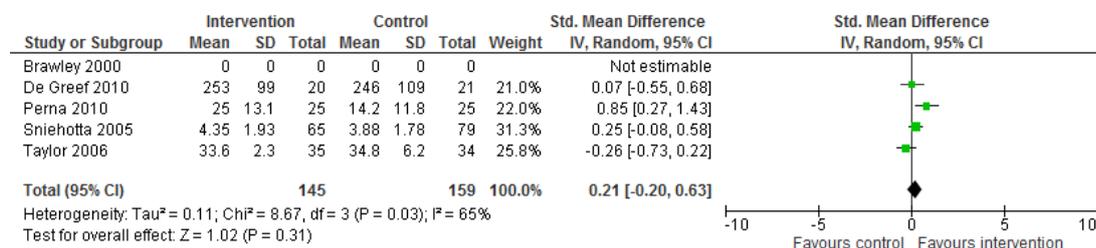


Figure 5. Effects of cognitive therapies compared to no intervention or usual care on physical activity in studies reporting mean difference. SD = standard deviation, CI = confidence interval.

We carried out sensitivity analyses to explore whether the results of the meta-analyses were robust to the broad approach we took in synthesizing studies representing different populations and contexts, interventions of varying length and intensity, given by a range of health professionals, and varying risk of bias. The results of the sensitivity analyses are shown in the Appendix, Table F1, and text.

Table 2 presents the effect estimates from Figures 4 and 5 along with our GRADE assessments concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table G1

Table 2. Summary of findings table and documentation for effects of cognitive therapies compared to no intervention or usual care on physical activity.

Cognitive therapies compared to no intervention/usual care for physical activity.			
Patient or population: Persons who may benefit from change of lifestyle habits Setting: Primary health care Intervention: Cognitive therapies Comparison: No intervention/usual care			
Outcomes	Impact	№ of participants (studies)	Quality of the evidence (GRADE)
Physical activity , mean change difference assessed with: pedometer/accelerometer follow-up: range 0 to 6 months	The standardized mean change difference was 0.47 [0.19, 0.74] to the advantage of the intervention group.	875 (6 RCTs)	⊕⊕⊕○ MODERATE ¹
Physical activity , mean difference assessed with: self-report follow-up: range 0 to 6 months	The standardized mean difference was 0.21 [-0.20, 0.63].	304 (4 RCTs)	⊕○○○ VERY LOW ^{1,2}

1. Overall unclear risk of bias.
2. I-square 65%, non-overlapping confidence intervals and the 95% confidence interval ranges from no effect to large effect.

We judged the quality of the documentation 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 mean difference. A moderate rating of the quality of the documentation indicates our assumption 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 documentation indicates that we have very little confidence in the effect estimate. Hence, for physical activity based on mean difference we assume that the true effect is likely to be substantially different from the estimate of effect.

We found that:

- Cognitive therapies probably lead to a moderate increase in physical activity, based on mean change differences, up to six months after end of the intervention.
- The documentation from four studies based on mean differences is too uncertain to consider whether cognitive therapies change physical activity, up to six months after end of the intervention.

Effects of interventions: Cognitive therapies compared to an exercise or rehabilitation program only, when added to such a program

Figure 6 illustrates the results for the studies comparing cognitive therapies to an exercise or rehabilitation program only, when added to such a program.

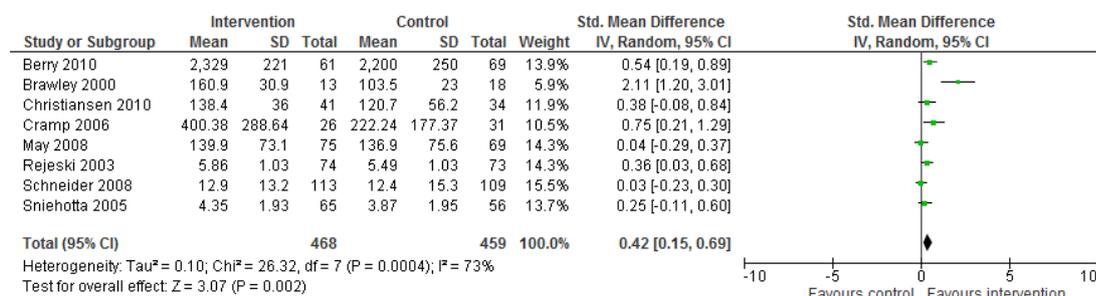


Figure 6. Effects of cognitive therapies compared to exercise or rehabilitation on physical activity. SD = standard deviation, CI = confidence interval.

We carried out sensitivity analyses to explore whether the results of the meta-analyses were robust to the broad approach we took in synthesizing studies representing different populations and contexts, interventions of varying length and intensity, given by a range of health professionals, and varying risk of bias. The results of the sensitivity analyses are shown in the Appendix, Table F2, and text.

Table 3 presents the effect estimates shown in Figure 6 along with our GRADE assessments concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table G2.

Table 3. Summary of findings table and documentation for effects of cognitive therapies compared to an exercise or rehabilitation on physical activity only, when added to such a program.

Cognitive therapies for physical activity compared to an exercise or rehabilitation program only, when added to such a program.			
Patient or population: Persons who may benefit from change of lifestyle habits			
Setting: Primary health care			
Intervention: Cognitive therapies added to exercise or rehabilitation			
Comparison: Exercise or rehabilitation only			
Outcomes	Impact	№ of participants (studies)	Quality of the evidence (GRADE)
Physical activity , mean difference assessed with: self-report follow-up: range 0 to 9 months	The standardized mean difference was 0.42 [0.15, 0.69] to the advantage of the intervention group.	927 (8 RCTs)	⊕⊕⊕⊕ MODERATE ¹

1. Overall unclear risk of bias.

We judged the quality of the documentation to be moderate. A moderate rating of the quality of the documentation indicates our assumption 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.

The documentation in Table 5 shows the result of cognitive therapies compared to an exercise or rehabilitation program when added to such a program.

We found that:

- Cognitive therapies added to an exercise or rehabilitation program probably give a small to moderate extra increase in physical activity up to nine months after end of the intervention.

Effects of interventions: Cognitive therapies compared to exercise or rehabilitation

One study (36) compared cognitive therapy to a structured, supervised exercise program. The results showed that both the intervention group and the control group had increased their energy expenditure to a similar degree at the end of the intervention. The standardized mean difference was 0.11 (95% CI -0.17, 0.40).

We found that:

- There is insufficient documentation to conclude about the effects of cognitive therapies compared to exercise or rehabilitation.

Effects of interventions: Cognitive therapies compared to health education

Figure 7 illustrates the results for the studies comparing cognitive methods to health education.

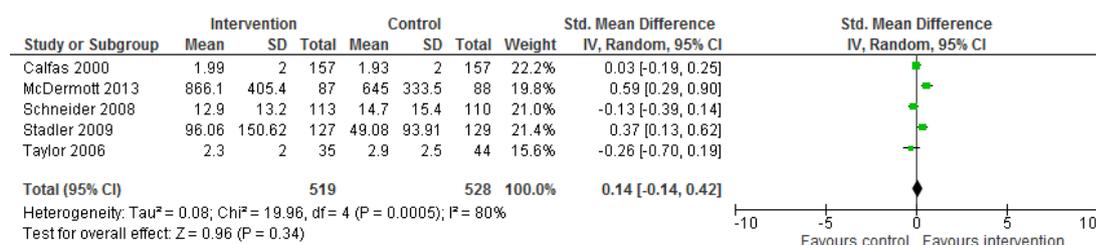


Figure 7. Effects of cognitive therapies compared to health education on physical activity. SD = standard deviation, CI = confidence interval.

We carried out sensitivity analyses to explore whether the results of the meta-analyses were robust to the broad approach we took in synthesizing studies representing different populations and contexts, interventions of varying length and intensity, given by a range of health professionals, and varying risk of bias. The results of the sensitivity analyses are shown in Appendix F.

Table 4 presents the effect estimates shown in Figure 7 along with our GRADE assessments concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table G3.

Table 4. Summary of findings table and documentation for effects of cognitive therapies compared to health education on physical activity.

Cognitive therapies compared to health education for physical activity			
Patient or population: Persons who may benefit from change of lifestyle habits Setting: Primary health care Intervention: Cognitive therapies Comparison: Health education			
Outcomes	Impact	№ of participants (studies)	Quality of the evidence (GRADE)
Physical activity, mean difference assessed with: self-report follow up: 0 to 9 months	The standardized mean difference was 0.14 (95% CI -0.14, 0.42).	1047 (5 RCTs)	⊕⊕○○ LOW ^{1,2}

1. Overall unclear risk of bias.
2. I-square 80%, unexplained.

We judged the quality of the documentation to be low. A low rating of the quality of the documentation indicates that our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

The documentation in Table 7 shows the result of cognitive therapies compared to health education.

We found that:

- Cognitive therapies may have a similar effect on physical activity up to nine months after end of the intervention.

Discussion

Main findings

The main findings in this systematic review

The main findings in this systematic review were that cognitive therapies:

- probably give a moderate increase in physical activity measured by pedometer or accelerometer, up to six months after the intervention, compared to no intervention or usual care (Table 2),
- probably give a small to moderate extra increase in physical activity up to nine months after the intervention, when added to and compared to exercise or rehabilitation only (Table 3),
- may have a similar effect on physical activity up to nine months after the intervention, compared to health education (Table 4).

The documentation is too sparse to conclude about the effects of cognitive therapies directly compared to exercise or rehabilitation.

The quality of the documentation

We included 21 primary studies with 25 study arms. All were randomised controlled trials and included 3 559 participants in total. We judged 18 studies to have an unclear risk of bias and three studies to have a low risk of bias. Ten studies had insufficient information concerning the random sequence generation and 15 studies did not report how allocation to study groups was concealed. Fifteen studies used self-report questionnaires as outcome measures.

Strengths and limitations

Strengths of systematic reviews are that they seek to answer a specific question; 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.

Although we looked for several non-randomized study designs, 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 question about effect 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.

Difficulties in recruiting participants may lead to small studies and potentially to wide confidence intervals in meta-analysis results. The effect estimate for the intervention compared to no intervention or usual care, measured by self-report, has a 95% confidence interval that includes both no effect and large effect. Here, the effect estimate was based on 304 participants in four studies, which is regarded as a small population.

We had decided *a priori* that when studies reported more than one measure of physical activity, we would choose the one that best reflected the outcome in general terms. This may have introduced bias, because of different results for e.g. vigorous physical activity but not for total physical activity, or vice versa. However, we consistently describe the most general level of physical activity reported in the studies.

How applicable are the results?

The question we aimed to answer in this systematic review was quite broad: “What is the documented effect of cognitive therapies on change of physical activity?” We summarized the results across different populations and contexts, varying length and intensity of the intervention, different comparisons, and a range of health professionals.

A number of circumstances related to the populations, comparisons, and outcomes limits the applicability of the results:

- Extensive exclusion criteria possibly leading to under-representation of persons with co-morbidities.
- Possible under-representation of persons of non-Caucasian origin and persons with a low education level.
- Insufficient documentation of cognitive therapies compared to supervised exercise or rehabilitation.
- Shortcomings of methods to measure physical activity, most importantly unknown responsiveness of self-report questionnaires.
- Large variation of measurement methods across studies resulting in standardized population estimates that are difficult to interpret.

Some circumstances related to the intervention may support the applicability of the results:

- The interventions commonly included basic elements of cognitive therapies, such as goal-setting, self-efficacy, self-monitoring, self-management, self-regulation, problem solving, coping skills, cognitive restructuring, and relapse prevention.
- Sensitivity analyses generally suggested that the results were robust to variation in health status, duration of the intervention, and profession delivering the intervention.

All included studies had extensive exclusion criteria. Thus it is plausible that the results in this systematic review indicate whether or not the intervention has an effect but not whether it is effective (i.e. works in routine clinical circumstances). 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 and had a high education level. 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 (6). This pattern is similar to our findings and suggests that our conclusions are interpreted with caution regarding disadvantaged populations.

All interventions included common and basic elements of cognitive therapies that may target a range of populations (9). There was considerable variation in duration and frequency of the interventions, in light of which the findings are surprisingly homogeneous. The same can be said about the variation in profession of those who delivered the interventions. The sensitivity analyses suggest that the pre-specified characteristics (health status, duration of the intervention, profession delivering the intervention, and risk of bias) did not systematically influence the findings across the comparisons. Due to the small amount of studies in each meta-analysis (< 10) the results should be interpreted with caution. Differences may have gone undetected due to few studies, and hence low power in the sensitivity analyses.

The intervention was compared to no intervention or usual care including advice, or to exercise or rehabilitation as an adjunct to such programmes, and to health education. Only one of nine studies compared the intervention directly to an exercise or rehabilitation program. Thus, there is a lack of data concerning effects of cognitive therapies directly compared to exercise or rehabilitation programs.

The primary outcome, physical activity, is commonly measured along the dimensions duration, frequency, and intensity (3). From these, energy expenditure, which is the cost of physical activity, can be calculated (5). These dimensions are usually measured by self-report questionnaire, which was the case in 15 of the 25 study arms included in this systematic review. A serious problem affecting self-report questionnaires is that their responsiveness is unknown (50). Thus, it is uncertain whether changes in physical activity were reliably detected in the studies using questionnaires. Motion sensors such as pedometers and accelerometers were used in seven comparisons. While these represent objective measurement of physical activity (as long as the data are directly downloaded into software for analysis), motion sensors may underestimate the

amount of activity because they do not register all types of movement (5). Physical capacity is often used as a proxy of physical activity (4). This outcome was used in three study arms. Although physical capacity is deemed a reliable correlate of physical activity, it is not a direct measure of the behavioural aspects of physical activity (4).

Apart from the shortcomings of the methods themselves to measure physical activity, 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 population 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, or large). It is not possible to refer back to dimensions of physical activity such as duration, frequency, and intensity from these standardized effect estimates, only to a broad category of “physical activity”.

Agreement with other systematic reviews

We did not identify systematic reviews that could answer our research question through our systematic literature search. Recent systematic reviews have summarized the effect of other interventions to increase physical activity in adults (51, 52, 53). The interventions were exercise referral schemes (51), physical activity promotion based in primary care (52), and organized follow-up of physical activity (53). The reviews reported small to moderate effects of the interventions while acknowledging uncertainty of the results due to methodological problems in the included studies. Our results concerning cognitive therapies show similar magnitude and direction of effects in two of the comparisons (no intervention or usual care, and added to exercise or rehabilitation programs). Methodological concerns of the included studies in the present review include, as described above, uncertainty regarding allocation concealment and measurement of physical activity.

Implications for practice

The findings in this systematic review suggest that cognitive therapies probably can help patients and persons with risk factors for cardiovascular disease to achieve small to moderate increases in physical activity, when compared to no treatment or usual care, or when added to exercise or rehabilitation programs.

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

A range of professionals such as psychologists, exercise specialists (including physical therapists), nurses, social workers, and health educators gave the interventions. The profession of providers did not seem to influence the effect estimates in our analyses. It appears that associations between therapist competence and outcomes of cognitive

therapies are little explored (54). 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 (11, 54). 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 the intervention in practice will be dependent on both the level of competency required 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

This systematic review reports effects of cognitive therapies on physical activity in adults ≥ 18 years. The included studies were all randomised controlled trials and comprised healthy adults possibly at risk of cardiovascular disease as well as several patient groups. The interventions were carried out in individual-, group-, and combinations of individual and group formats. The length of the interventions varied between one session and two years. The content of the interventions reflect basic elements of cognitive and cognitive behavioural therapies.

We identified the following research gaps:

- A direct comparison with supervised exercise or rehabilitation is lacking. Eight of nine studies comparing the intervention to exercise or rehabilitation programs evaluated the effect of the intervention as an adjunct to such programs.
- Only two studies had follow-up beyond six months post intervention.
- A standard for measurement of physical activity is evidently lacking in this research field. Measurements included duration, frequency, and intensity, using self-report questionnaires, motion sensors, or tests of physical capacity. Such variation of measurement methods induces problems when pooling studies, making the combined estimates difficult to interpret.

Implications for future research:

- Direct comparisons with supervised exercise or rehabilitation are needed.
- Studies should allow for follow-up of at least 12 months post intervention.
- Core outcome sets (55) should be developed for future use in studies evaluating effects of interventions on physical activity. 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.

Conclusion

We carried out a systematic review of 21 randomized controlled trials with 25 comparisons. We synthesized the results quantitatively, adopting 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. The results were, overall, robust to such differences.

Based on the results and our rating of the quality of the documentation, we conclude that:

- Cognitive therapies probably lead to a moderate increase in physical activity compared to no intervention or usual care, up to six months after the end of the intervention. This documentation is based on reported mean change differences.
- The documentation from four studies based on reported mean differences is too uncertain to consider whether cognitive therapies increase physical activity compared to no intervention or usual care.
- Cognitive therapies added to exercise or rehabilitation programs probably lead to a small to moderate extra increase in physical activity compared to exercise or rehabilitation only. The length of follow-up in these studies was up to nine months post intervention.
- The documentation is too sparse to conclude about the effect of cognitive therapies directly compared to exercise or rehabilitation.
- Cognitive therapies may have a similar effect on physical activity to health education, up to nine months post intervention.

References

1. Norsk Forening for Kognitiv Terapi. (*The Norwegian Association for Cognitive Therapies.*) Available from: <http://www.kognitiv.no/kognitiv-terapi/>. Accessed April 28 2016
2. World Health Organization: Global recommendations on physical activity for health. Geneva: WHO Press; 2010.
3. Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: Definitions and distinctions for health-related research. *Public Health Rep* 1985;100:126-31.
4. Lagerros Y, Lagiou P. Assessment of physical activity and energy expenditure in epidemiological research of chronic diseases. *Eur J Epidemiol.* 2007;22:353-62.
5. Warren J, Ekelund U, Bessond H, Mezzani A, Geladas N, Vanheesh L. Assessment of physical activity – a review of methodologies with reference to epidemiological research: a report of the exercise physiology section of the European Association of Cardiovascular Prevention and Rehabilitation. *Eur J Cardiovasc Prev Rehabil* 2010. 17: 127-39.
6. Hansen B, Anderssen S, Steene-Johannessen J, Ekelund U, Nilsen A, Dehli Andersen I, et al. Fysisk aktivitet og sedat tid blant voksne og eldre i Norge - Nasjonal kartlegging 2014-2015. (*Physical activity and sedentary time among adults and older adults in Norway – National survey 2014-2015.*) Oslo, Helsedirektoratet, 2015.
7. Veileder for kommunale frisklivssentraler – Etablering og organisering. (*Instructions for municipal health living centres – establishment and organization.*) Oslo, Helsedirektoratet, 2013.
8. Somers J. Cognitive behavioural therapy. Core information document. British Columbia Ministry of Health.2007. Available from: http://www.health.gov.bc.ca/library/publications/year/2007/MHA_CognitiveBehaviouralTherapy.pdf. Accessed April 28 2016.

9. Dobson S, Dozois D. Historical and philosophical bases of the cognitive-behavioral therapies. In: Handbook of cognitive behavioural therapies, 2nd ed. Ed. Dobson K. New York: The Guilford Press; 2001.
10. Judith S Beck. Cognitive behavior therapy: basics and beyond. 2nd ed. New York: The Guilford Press; 2011.
11. Roth A, Pilling S. The competences required to deliver effective cognitive and behavioural therapy for people with depression and with anxiety disorders. Improving Access to Psychological Therapies (IAPT) Programme. 2007. Department of health. Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_078535.pdf. Accessed April 28 2016.
12. Guidelines concerning cognitive therapies. Available from: <https://helsedirektoratet.no/retningslinjer/>. Accessed April 28 2016.
13. Hofman S, Asaani A, Vonk I, Sawyer A, Fang A. The Efficacy of Cognitive Behavioral Therapy: A Review of Metaanalyses. Cognit Ther Res 2012;36:427-440.
14. Cuijpers P, Berking M, Andersson G, Quigley L, Kleiboer A, Dobson K. A meta-analysis of cognitive-behavioural therapy for adult depression alone, and in comparison with other treatments. Can J Psychiatry 2013;58:376-385.
15. Linde K, Sigterman K, Kriston L, Rücker G, Jamil S, Meissner K, et al. Effectiveness of psychological treatments for depressive disorders in primary care: systematic review and meta-analysis. Ann Fam Med 2015;13:56-68.
16. Mayo-Wilson E, Dias S, Mavranouzouli I, Clark D, Ades A, Pilling S. Psychological and pharmacological interventions for social anxiety disorder in adults: a systematic review and network meta-analysis. Lancet Psychiatry 2014;1:368-76.
17. Trauer J, Qian M, Doyle J, Rajaratnam S, Cunnington D. Cognitive behavioral therapy for chronic insomnia. A systematic review and meta-analysis. Ann Intern Med. 2015;163:191-204.
18. Wu J, Appleman E, Salazar R, Ong J. Cognitive behavioral therapy for insomnia comorbid with psychiatric and medical conditions. A meta-analysis. JAMA Intern Med. 2015;175(9):1461-1472.
19. Williams ACDC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database of Systematic Reviews 2012;(11):CD007407.
20. Monticone M, Cedraschi C, Ambrosini E, Rocca B, Fiorentini R, Restelli M, et al. Cognitive-behavioural treatment for subacute and chronic neck pain. Cochrane Database of Systematic Reviews 2015;(5):CD010664.
21. Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.
22. EPOC Checklist for Refereeing Protocols for Reviews. EPOC, Effective Practice and Organisation of Care group, Guide for review authors. Available from: www.epoc.cochrane.org.

23. Higgins JPT, Altman DG, Sterne JAC (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.
24. Gøtzsche P. Why we need a broad perspective on meta-analysis. It may be crucially important for patients. *BMJ* 2000;321:585-586.
25. Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.
26. Cohen J. *Statistical power analysis for the behavioral sciences*, 2nd ed. New York: Lawrence Erlbaum Associates, Publishers; 1988.
27. Deeks JJ, Higgins JPT, Altman DG (editors). Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.
28. Balshem H, Helfand M, Schünemann H, Oxman A, Kunze R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clinl Epidemiol* 2011;64:401-406.
29. Berry M, Rejeski J, Miller M, Adair N, Lang W, Foy C, et al. A lifestyle activity intervention in patients with chronic obstructive pulmonary disease. *Respir Med* 2010;104:829-839.
30. Brawley L, Rejeski J, Lutes L. a group-mediated cognitive-behavioral intervention for increasing adherence to physical activity in older adults. *J Appl Biobehav Res* 2000;5:47-65.
31. Calfas K, Sallis J, Nichols J, Sarkin J, Johnson M, Caparosa S, et al. Project GRAD: Two-year outcomes of a randomized controlled physical activity intervention among young adults. *Am J Prev Med* 2000;18:28-37.
32. Christiansen S, Oettingen G, Dahme B, Klinger R. A short goal-pursuit intervention to improve physical capacity: A randomized clinical trial in chronic back pain patients. *Pain* 2010;149:444-452.
33. Cramp A, Brawley L. Moms in motion: a group-mediated cognitive-behavioral physical activity intervention. *Int J Behav Nutr Phys Act* 2006, 3:23.
34. De Greef K, Deforche B, Tudor-Locke C, De Bourdeaudhuij I. A cognitive-behavioural pedometer-based group intervention on physical activity and sedentary behaviour in individuals with type 2 diabetes. *Health Educ* 2010;25:724-736.
35. De Greef K, Deforche B, Ruige J, Buckaert J, Tudor-Locke C, Kaufman JM, De Bourdeaudhuij I. the effects of a pedometer-based behavioral modification program with telephone support on physical activity and sedentary behavior in type 2 diabetes patients. *Patient Educ Couns* 2011;84:275.279.
36. Dunn A, Marcus B, Kampert J, Garcia M, Kohl H, Blair S. Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness. *JAMA* 1999;281:327-334.
37. Houle J, Doyon O, Vadeboncoeur N, Turbide G, Diaz A, Poirier P. Innovative program to increase physical activity following an acute coronary syndrome: randomized controlled trial. *Patient Educ Couns* 2011;85:e237-e244.

38. Kirk A, Mutrie N, MacIntyre P, Fisher M. Promoting and maintaining physical activity in people with type 2 diabetes. *Am J Prev Med* 2004;27:289–296.
39. May A, van Weert E, Korstjens I, Hoekstra-Weebers J, van der Schans C, Zonderland M, et al. Improved physical fitness of cancer survivors: A randomised controlled trial comparing physical training with physical and cognitive-behavioural training. *Acta Oncol* 2008;47:825-834.
40. McDermott M, Liu K, Guralnik J, Criqui M, Spring B, Tian L, et al. Home-based walking exercise intervention in peripheral artery disease. A randomized clinical trial. *JAMA* 2013;31:57-65.
41. Perna F, Craft L, Freund K, Skrinar G, Stone M, Kachnic L, et al. The effect of a cognitive behavioral exercise intervention on clinical depression in a multiethnic sample of women with breast cancer: a randomized controlled trial. *International J Sport Exer Psychol* 2010;8:36-47.
42. Prinsen H, Bleijenberg G, Heijmen L, Zwarts M, Leer J, Heershap A, et al. The role of physical activity and physical fitness in postcancer fatigue: a randomized controlled trial. *Support Care Cancer* 2013;21:2279–2288.
43. Rejeski J, Brawley L, Ambrosius W, Brubaker P, Focht B, Foy C, et al. Older adults with chronic disease: benefits of group-mediated counseling in the promotion of physically active lifestyles. *Health Psychol* 2003;22:414–423.
44. Rogers L, Hopkins-Price P, Vicari S, Markwell S, Pamentier R, Courneya K, et al. Physical activity and health outcomes three months after completing a physical activity behavior change intervention: persistent and delayed effects. *Cancer Epidemiol Biomarkers Prev* 2009;18:1410–8.
45. Schneider J, Cook J, Douglas L. Cognitive-behavioral therapy, exercise, and older adults' quality of life. *West J Nurs Res* 2008;30:704-723.
46. Simons-Morton D, Blair S, King A, Morgan T, Applegate W, O'Toole M, et al. effects of physical activity counselling in primary care. The activity counselling trial: a randomized controlled trial. *JAMA* 2001;286: 677-687.
47. Sniehotta F, Scholz U, Schwarzer R, Fuhrmann B, Kiwus U, Völler H. Long-term effects of two psychological interventions on physical exercise and self-regulation following coronary rehabilitation. *Int J Behav Med* 2005;12:244–255.
48. Stadler G, Oettingen G, Gollwitzer P. Physical activity in women effects of a self-regulation intervention. *Am J Prev Med* 2009;36:29–34.
49. Taylor C, Demoor C, Smith M, Dunn A, Basen-Engquist K, Nielsen I, et al. Active for life after cancer: a randomized trial examining a lifestyle physical activity program for prostate cancer patients. *Psychooncology* 2006;15:847–862.a
50. van Poppel M, Chinapaw M, Mokkink L, van Mechelen W, Terwee C. physical activity questionnaires for adults. A systematic review of measurement properties. *Sports Med* 2010;40:565-600.
51. Pavey T, Taylor A, Hillsdon M, Anokye N, Campbell J, Foster C, et al. effect of exercise referral schemes in primary care on physical activity and improving health outcomes: systematic review and meta-analysis. *BMJ* 2011;343:d6462.
52. Orrow g, Kinmonth A-L, Sanderson S, Sutton S. Effectiveness of physical activity promotion based in primary care: systematic review and meta-analysis of randomised controlled trials. *BMJ* 2012;344:e1389.

53. Denison E, Vist G, Underland V, Berg RC. Interventions aimed at increasing physical activity by including organised follow-up: a systematic review of effect. *BMC Fam Pract* 2014;15:120.
54. 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.
55. 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. Glossary

Cognitive therapies	Psychological treatments that address the interactions between thoughts, emotions, and behaviour. In this report the term cognitive therapies includes cognitive behavioural therapies.
Physical activity	Any bodily movement produced by skeletal muscles that result in energy expenditure.

B. Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Dato for søk: 21.01.2015

- 1 exp Life Style/ (72713)
- 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

Dato for søk: 22.01.2015.

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

Dato for søk: 22.01.2015.

- 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)
- 14 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

Dato for søk: 22.01.2015.

#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 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*)	6337
#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 mindfulness) near/3 (therap* or treatment*)) or (third adj wave) or cbt)	11768
#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**Dato for søk: 22.01.2015**

S30	S17 AND S21 AND S28 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 "acceptance and commitment" or mindfulness) N3 (therap* or treatment*)) or (third adj wave) or cbt))	5,868
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

C. Excluded studies

Five studies were excluded due to exclusion criteria after reading full text publications (Table C1).

Table C1. Excluded studies.

Study	Reason for exclusion
De Cocker KA, De Bourdeaudhuij IM, Cardon GM. The effect of pedometer use in combination with cognitive and behavioral support materials to promote physical activity. <i>Patient Educ Couns</i> 2008;70(2):209-214.	The intervention consisted only of self-help materials that were sent to the participants.
Farran CJ, Rajan KB, McCann JJ, Castro C, King A. An individualized physical activity intervention for family caregivers of persons with dementia: A randomized controlled trial. <i>Alzheimer's and Dementia</i> 2014;10:P163-P164.	Not a study published in full text format.
Gielissen MF, Wiborg JF, Verhagen CA, Knoop H, Bleijenberg G. Examining the role of physical activity in reducing postcancer fatigue. <i>Support Care Cancer</i> 2012;20(7):1441-1447.	Outcomes corresponding to the inclusion criteria not reported.
Mancuso CA, Choi TN, Westermann H, Wenderoth S, Holtenberg JP, Wells MT, et al. Increasing physical activity in patients with asthma through positive affect and self-affirmation: a randomized trial. <i>Arch Intern Med</i> 2012;172(4):337-343.	The control condition was very similar to the intervention.

Segura Orti E, Donaghy M. A cognitive-behavioural intervention to increase adherence of adult women exercisers. *Advances in physiotherapy* 2004. p. 84-92.

Outcomes corresponding to the inclusion criteria not reported.

D. Characteristics of included studies

Participants

Table D1. Description of the participants.

Study ID	Country	Mean age	% women	Ethnicity	Education	Other
Berry 2010	USA	66	46			
Brawley 2000	Canada	70	63			

Christiansen 2010	Germany	48	62	85% German	71 % "high level of education"	76% married
Calfas 2000	USA	24	56	64% Caucasian		87% full time students
Cramp 2006	USA	32	100			98% married
De Greef 2010	Belgium	Majority 55-75	32		71 % "high level of education"	76% married
De Greef 2011	Belgium	62	31			
Dunn 1999	USA	46	50			
Houle 2011	Canada	59	22		34 % ≥ college	25% < \$ 30,000 CAN/year
Kirk 2004	UK	58	50			
May 2008	The Netherlands	49	84		37 % "high" education level	72 % married or living with partner
McDermott 2013	USA	70	50	47% Caucasian		
Perna 2010	USA	51	100	55% Caucasian		37% married or living with partner
Prinsen 2013	The Netherlands	50	51			
Rejeski 2003	USA	64	48			21% < \$ 25,000/year
Rogers 2009	USA	53	100	93% Caucasian	Mean 15 years	22% < \$ 35,000/year
Schneider 2008	USA	72	76	86% Caucasian	36% ≥ college	
Simons-Morton 2001	USA	51	45	71 % Caucasian or Asian or "other"	83% ≥ college	79% employed
Sniehotta 2005	Germany	58	18		35% 12-13 years	80% married or living with partner
Stadler 2009	Germany	41	100		55% ≥ 10 years	73% married or living with partner
Taylor 2006	USA	69	0	73% Caucasian	49% ≥ college	83% married or living with partner

Interventions and comparisons

Table D2. Description of the interventions compared to no intervention or usual care, including advice.

Study ID	Mode; duration; frequency; session length	Provider	Intervention content	Comparison
Brawley 2000	Group and individual; 24 weeks; 1/week for 12 weeks, then phone contact; 120 minutes first 12 weeks	Exercise-certified leaders trained to work with the elderly	1) 12 weeks of Standard physical activity program: 2 weekly 1.5-hour sessions first 3 weeks, then weekly for 9 weeks. 30 minutes educational lecture on various health-related topics + 1-hour exercise: 5-10 minutes warm-up, walking, 5-10 minutes cool-down; 30 minutes cognitive-behavioral skills and group interaction skills: group identity, self-monitoring, goal setting, planning of home-based exercise, specific goals for increasing active time, self-reinforcement, be more systematic in self-monitoring and goal-setting, personal home-based approaches to active lifestyle, problem-solving, relapse prevention, reinforcement 2) 12 weeks of gradually decreasing phone support for home-based activity.	Waitlist + visit center every other week for a 1-hour lecture/group interaction on various health topics.
De Greef 2010	Group; 12 weeks; 5/8 weeks + 1 booster session; 90 minutes	Physical educator and clinical psychologist	Risks of sedentary lifestyle; goal setting and self-monitoring skills, self-efficacy to set up action plan; self-efficacy to deal with barriers, negative thoughts, change habits; relapse prevention; social cues, long-term action plan, goal achievement; booster session .	Usual care.
De Greef 2011	Individual; 24 weeks; 8/24 weeks; 1 face-to-face, 7 by phone; 30 minutes + 7 x 20 minutes	Psychologist	Face-to-face session including MI; a pedometer; phone support: goal setting, self-monitoring, self-efficacy, benefits, decisional balance, problem-solving strategies, social support, relapse prevention; pedometer diary to track progress.	Usual care.
Houle 2011	Individual; 52 weeks; 7/52 weeks: 1 phone call + 6 face-to-face; 30-60 minutes	Clinical nurse specialist	Pedometer administered in hospital + instructions on use and self-monitoring; verbal persuasion, physiological states, vicarious experience, performance accomplishments.	Usual care standard at discharge from hospital: advice regarding physical activity, diet and medication. In addition, access to center-based cardiac rehabilitation program or health professional, e.g.

				nutritionist, exercise specialist or psychologist, without systematic reference.
Kirk 2004	Individual; 36 weeks; 4/36 weeks: 2 face-to-face, 2 phone; 30 minutes	Trained research assistants	Stage of change confirmed, current physical activity level assessed; benefits, barriers and costs of becoming more active, suitable activities, social support, goal setting; relapse prevention and maintenance of physically active lifestyle.	Advice by a leaflet "Exercise and your diabetes", approved by Diabetes UK. The leaflet covered the following topics: why exercise how much exercise to do, getting started, and exercise and diabetes.
Perna 2010	Group and individual by phone or mail; 12 weeks; 3/week during week 1-4, then 1/week; Week 1-4; 45-60 minutes, then N/R	Exercise specialist and clinical psychologist	Counselling in hospital addressing exertion cues and behavioral strategies to identify appropriate training zones, thereafter weekly contact by phone or mail addressing goal setting, behavioral skills, self-monitoring, problem solving.	45-minutes information session with individualised feedback on physical assessment and a brochure describing potential physical and psychological benefits of exercise and their relevance to breast cancer.
Prinsen 2013	Individual; 24 weeks; Mean 12; 50 minutes	N/R	Focus on 6 perpetuating factors of post cancer fatigue: insufficient coping with the experience of cancer, fear of disease recurrence, dysfunctional cognitions concerning fatigue, dysregulation of sleep, dysregulation of activity, low social support and negative social interactions; individually tailored physical activity program; physical activity eventually replaced by other activities.	Wait list for 6 months and received the intervention outside of the study.
Rogers 2009	Group and individual; 12 weeks; 21/12 weeks; N/R	Exercise specialist and clinical psychologist	Social support, personal behavioral plan to facilitate regular exercise participation, group counselling: overcoming exercise barriers, emotional coping, exercise benefits and importance; exercise sessions: improve task self-efficacy, self-monitoring with daily activity log, overcoming exercise barriers; individual exercise counselling: reinforcement of self-monitoring, use of behavioral modification plan, exercise benefits, reinforcement for reaching goal, update of exercise prescription.	Written materials about physical activity available through the American Cancer Society.
Simons-Morton 2001	Group and individual; 24 months; Bi-weekly/6 weeks; monthly after 6 weeks; negotiated after 12 months; 60 minutes	Health educator	Goals and plans evaluation of physical activity goals, problem solving, planning for future barriers, reinforcement, social support; behavioral skills to adopt and maintain physical activity.	Physician advice based on national physical activity recommendations. Health educator provided existing educational materials on physical activity, answered questions about the recommendations

				made by the physician. The advice was limited to type and amount of physical activity.
Sniehotta 2005	Individual by mail; 6 weeks; 1/week; Session diary	N/R	Planning (1 face-to-face session during last week of rehab), booklet with 2 planning sheets for coping plans and action plans, instruction in planning booklet, e.g. when, where and how (action); write down plans, e.g. coping with obstacles or barriers, realization of plan, optimism about adherence over next week, possibility to modify plan, sending diary back to research team.	Usual care following coronary rehabilitation.
Taylor 2006	Group; 24 weeks; 21/24 weeks; 90 minutes	N/R	Self-efficacy and cognitive-behavioral skills to adopt and maintain physical activity of moderate intensity on most weekdays; self-monitoring, goal-setting, problem solving to overcome barriers, cognitive restructuring, self-reward; skills were practiced in sessions and assigned as homework; tracing of daily physical activity.	Usual care.

Table D3. Description of the interventions compared to exercise or rehabilitation programs only, when added to such programs.

Study ID	Mode; duration; frequency; session length	Provider	Intervention content	Comparison
Berry 2010	Group and individual; 48 weeks; 36/48 weeks; 15-60 minutes	N/R	<p>Exercise program: 3x1 hour/week for 12 weeks. Brief warm-up, 30-35 minutes of walking at a rating of perceived dyspnoea of 3-5 on the Borg scale, 10-15 minutes of strength training using elastic rubber bands, and a brief cool-down.</p> <p>Gradual weaning of participants from dependency of staff toward independent promotion and self-regulation of physical activity at home; group dynamics to a) promote independent physical activity b) teach and practice within group c) commitment to independent exercise d) weaning from group; 4 different types of contact 1) center-based exercise/group sessions 2) center-based exercise training sessions 3) 30 minutes of individual sessions to review ability to sustain independent physical activity 4) 15 min individual phone contact to review independent physical activity; encouragement to increase home-based training as center-based training was reduced; goal setting for pa into daily life.</p>	<p>Exercise program same as intervention group, 3x1 hour/week for 12 weeks. Thereafter encouragement to continue exercising. Information on community sites that conducted similar programs.</p>
Brawley 2000	Group and individual; 24 weeks; 1/week for 12 weeks, then phone contact; 120 minutes first 12 weeks	Exercise-certified leaders trained to work with the elderly	<p>1) 12 weeks of Standard physical activity program: 2 weekly 1.5-hour sessions first 3 weeks, then weekly for 9 weeks. 30 minutes educational lecture on various health-related topics + 1-hour exercise: 5-10 minutes warm-up, walking, 5-10 minutes cool-down; 30 minutes cognitive-behavioral skills and group interaction skills: group identity, self-monitoring, goal setting, planning of home-based exercise, specific goals for increasing active time, self-reinforcement, be more systematic in self-monitoring and goal-setting, personal home-based approaches to active lifestyle, problem-solving, relapse prevention, reinforcement 2) 12 weeks of gradually decreasing phone support for home-based activity.</p>	<p>Same exercise program and information as the intervention group.</p>

Christiansen 2010	Group and individual; 3 weeks; back pain program: 30 hours/week; cognitive-behavioral sessions: 2/3 weeks; 30 minutes	Trained psychologist	3-week outpatient back pain program: intensive, daily 8 a.m. – 5 p.m. supervised exercise therapy; information about pain and the interaction between the psychological and somatic factors of pain. 1st session) mental contrasting strategy, positive aspects obstacles regarding increasing physical activity; 2nd session) identify beneficial behaviors; problem solving regarding obstacles; implementation intentions regarding desired behaviour.	Same exercise program and information as the intervention group.
Cramp 2006	Group and individual by phone; 8 weeks; 8 exercise sessions +6 cognitive-behavioural sessions/4 weeks; 1 phone contact/4 weeks; 75 + 20 minutes; 10 minutes	Certified fitness instructor supervised exercise; cognitive-behavioral sessions N/R	Supervised center-based exercise 4 weeks and participant-managed home-based 4 weeks. Supervised: warm-up, cardiovascular (aerobic) and strength training, cool down and flexibility. Log book. Home-based: implement learned exercises home-based exercise regime. Log book. Self-monitoring; home-based exercise, self-monitoring; develop self-regulatory skills, overcome post-natal specific barriers to self-managed physical activity; practise of skills at home; increasingly greater self-regulation practised each week to wean from dependency on group and instructor; review of self-management.	Same center-based and home-based exercise program as the intervention group.
May 2008	12 weeks; Group; 2/week physical activity sessions; 1/week cognitive-behavioral session; 120 minutes	Physical therapist; psychologist + social worker	Physical training 2/week for 2 hours, based on principles for self-management, use of heart monitors, the Borg scale for dyspnoea and training logs. Bicycle training 30 minutes, muscle strength training 30 minutes, group sport 60 minutes. From week 6 also home-based walking program. Information about stress relaxation, fatigue, exercise physiology; self-management skills, problem orientation definition and formulation, goal setting, generation of alternative solutions, decision making, solution implementation, recapitulation and practice of self-management process, anticipation to future functioning.	Same exercise program as the intervention group.
Rejeski 2003	36 weeks; Group and individual by phone; Total of 36 hours/36 weeks; Exercise: 60 minutes; counselling: 20-25 minutes	Certified and trained exercise leaders	Month 1-3: exercise; self-monitoring, managing barriers and lapses in physical activity, environmental cues, recognize signs of relapse, dealing with relapse, plan for independent physical activity; month 4-9: home-based phase, booster sessions, phone contact, progress of program, activity card.	3 days/week for 3 months: warm-up (5 minutes), aerobic exercises (30-35 minutes), upper extremity strength training (15-20 minutes), cooldown including stretching exercises (5 minutes).

Schneider2008	12 weeks; Group; wks 1-2: 3/week exercise only, weeks 3-12: 1/week exercise + 8/10 weeks cognitive-behavioral sessions; Exercise: 60 minutes; cognitive-behavioral sessions: 60-75 min	Physical educator; "licensed professional counselor"	<p>Exercise training: warm-up 5-10 minutes, strength training using resistance bands 40-45 minutes, and cool down.</p> <p>Recognize and modify negative interpretations of exercise, stressing understanding of thoughts and their effects on behavior: goal setting and review, lifestyle review, motivation and exercise maintenance.</p>	Same exercise program as the intervention group
Sniehotta 2005	6 weeks; Individual by mail; 1/week; Session diary	N/R	<p>Cardiac rehabilitation: guided exercise sessions (bicycle ergometer training, walking or Nordic walking), gymnastic exercises.</p> <p>Planning (1 face-to-face session during last week of cardiac rehabilitation), booklet with 2 planning sheets for coping plans and action plans, instruction in planning booklet, e.g. when, where and how (action); write down plans, e.g. coping with obstacles or barriers, realization of plan, optimism about adherence over next week, possibility to modify plan, sending diary back to research team.</p>	Same 3-4 week cardiac rehabilitation program as the intervention group + diary.

Table D4. Description of the intervention compared to exercise or rehabilitation.

Study ID	Mode; duration; frequency; session length	Provider	Intervention content	Comparison
Dunn 1999	24 months; Group; 16/16 weeks, 4/8 weeks, 11/18 months; 60 minutes	"Group facilitators"	Goal to accumulate at least 30 min of moderate-intense physical activity on most days/week; cognitive-behavioral strategies related to physical activity behaviour: problem-solving approach, weekly home assignments; activities and reinforcement of cognitive-behavioral skills.	Structured, supervised exercise program: 6 months intense program, up to 5 days/week, 18 months maintenance with quarterly group activities. First 3 weeks intense program 50%-80% of maximal aerobic power for 20-60 minutes then individualised program with choice of aerobic exercise.

Table D5. Description of the interventions compared to health education.

Study ID	Mode; duration; frequency; session length	Provider	Intervention content	Comparison
Calfas 2000	Group and individual by phone and mail; 15 weeks + 72 weeks; 1/week for 15 weeks; 1/month for 18 months; 15 weeks: 50 + 110 minutes, 18 months: 5-10 minutes	Faculty member, peer health facilitator, trained by research team	2 year program; pre-graduation intervention: 1-semester, 2-unit course weekly faculty-led lectures, peer-led labs, 15 weekly 50-min lectures based on the trans-theoretical model and social cognitive theory 1) self-efficacy 2) social support 3) outcome expectations 4) barriers to changing behavior 5) enjoyment om behavior 6) experiential and behavioral processes of change, weekly 110-min lab led by peer health facilitators including supervised physical activity, personal application of behavioral management strategies including discussion of goals and homework assignments, transition issues were addressed in both lectures and labs: how to continue exercising; follow-up intervention: monthly mailed materials with	2-hour lecture weekly for 15 weeks covering general health topics with emphasis on knowledge acquisition.

			follow-up phone calls reflecting content of mail, decreasing toward end of period, each call 5-10 minutes following script: review behavioral skills topic, set new physical activity goal, anticipate upcoming risks for relapse, problem solving; after first 6 months of follow-up "prompt calls".	
McDermott 2013	24 weeks; Group; 1/week; 90 minutes	Trained "facilitator"	Based on social cognitive theory, group dynamics and self-regulation; walking around indoor track; benefits of walking exercise, goal setting, self-monitoring, pain management during exercise; encouragement to walk 5 days/week up to 50 minutes per session.	Weekly 60-minute group sessions with other patients with peripheral artery disease. Topics included management of hypertension, cancer screening, and vaccinations.
Schneider2008	12 weeks; Group; wks 1-2: 3/week exercise only, weeks 3-12: 1/week exercise + 8/10 weeks cognitive-behavioral sessions; Exercise: 60 minutes; cognitive-behavioral sessions: 60-75 min	Physical educator; "licensed professional counselor"	Exercise training: warm-up 5-10 minutes, strength training using resistance bands 40-45 minutes, and cool down. Recognize and modify negative interpretations of exercise, stressing understanding of thoughts and their effects on behavior: goal setting and review, lifestyle review, motivation and exercise maintenance.	10 weeks of exercise training, 3/week for the first 2 weeks, then 1/week for 8 weeks. Warm-up 5-10 minutes, strength training using resistance bands 40-45 minutes, and cool down. 8 60-75 minute sessions on health promotion topics, e.g. alcoholism, depression, stress management. No discussion of exercise.
Stadler 2009	1 session; Group; 1 session; N/R	"Trained female interventionist"	Health education leaflet on importance of physical activity; knowledge self-check; discussion among group members on answers to self-check; self-regulation techniques concerning reaching physical activity goal.	Health education leaflet on importance of regular physical activity and its positive effects, knowledge self-check, discussion of self-check results in a group setting. Diary to record physical activity.
Taylor 2006	24 weeks; Group; 21/24 weeks; 90 minutes	N/R	Self-efficacy and cognitive-behavioral skills to adopt and maintain physical activity of moderate intensity on most weekdays; self-monitoring, goal-setting, problem solving to overcome barriers, cognitive restructuring, self-reward; skills were practiced in sessions and assigned as homework; tracing of daily physical activity.	Educational support program: 16 weekly and 4 bi-weekly 90-minute small group sessions in 24 weeks. Prostate cancer-specific topics were covered, including e.g. diet and prostate cancer, side effects of androgen-ablation, sexuality.

Outcomes

Primary outcomes

Table D5. Primary outcomes and measurement methods.

Study ID	Outcome	Measurement method
<i>Studies comparing the intervention with no intervention or usual care</i>		
Brawley 2000	Minutes/week	7-day physical activity recall by interview
De Greef 2010	Minutes/day	Accelerometer
De Greef 2011	Steps/day	Pedometer
Houle 2011	Steps/day	Pedometer
Kirk 2004	Accelerometer counts/week	Accelerometer
Perna 2010	Points based on frequency	Godin Leisure Time Exercise Questionnaire (LTEQ) questionnaire
Prinsen 2013	Actometer score/12 days	Actometer
Rogers 2009	Minutes/week	Accelerometer
Simons-Morton 2001	Aerobic capacity	Treadmill test
Sniehotta 2005	Minutes/week	Kaiser Physical Activity Survey adapted to characteristics of a cardiac patient sample
Taylor 2006	Energy expenditure	7-day physical activity recall
<i>Studies comparing the intervention with an exercise or rehabilitation program only, when added to such a program</i>		
Berry 2010	Energy expenditure	Community Health Activities Model Program for Seniors (CHAMPS) questionnaire
Brawley 2000	Minutes/week	7-day physical activity recall by interview
Christiansen 2010	Physical capacity	Ergometer test
Cramp 2006	Minutes/week	7-day physical activity recall by questionnaire
Dunn 2009	Energy expenditure	7-day physical activity recall by interview
May 2008	Points based on frequency	Physical Activity Scale for the Elderly (PASE) questionnaire
Rejeski 2003	Peak MET level	Treadmill test
Schneider 2008	MET-hours/week	Questions from the Modifiable Activity Questionnaire tailored to activities frequently engaged in by older adults
Sniehotta 2005	Minutes/week	Kaiser Physical Activity Survey adapted to characteristics of a cardiac patient sample
<i>Studies comparing the intervention with health education</i>		
Calfas 2000	Hours/week	7-day physical activity recall by interview
McDermott 2013	Accelerometer units/week	Accelerometer
Schneider 2008	MET-hours/week	Questions from the Modifiable Activity Questionnaire tailored to activities frequently engaged in by older adults
Stadler 2009	Minutes/week	7-day behavioral diary modeled after the Bouchard Three-Day Physical Activity Record
Taylor 2006	Energy expenditure	7-day physical activity recall

Secondary outcomes

Table D6. Secondary outcomes reported in the included studies.

Study ID	Secondary outcomes ^a
<i>Studies comparing the intervention with no intervention or usual care</i>	
Brawley 2000	Aerobic capacity.
De Greef 2010	Body weight and height, blood pressure, HbA1c, total cholesterol.
De Greef 2011	Waist circumference, weight, body mass index, HbA1c, fasting glucose, lipid profile (Reported in Van Dyck 2013)
Houle 2011	Waist circumference, blood pressure, resting heart rate, lipid profile, fasting blood glucose.
Kirk 2004	None.
Perna 2010	None.
Prinsen 2313	Physical fitness, functional impairment.
Rogers 2009	Physical fitness.
Simons-Morton 2001	None.
Sniehotta 2005	None.
Taylor 2006	Body mass index, waist circumference, hip circumference, waist-to-hip ratio.
<i>Studies comparing the intervention with an exercise or rehabilitation program only, when added to such a program</i>	
Berry 2010	Physical function, self-reported disability, exercise capacity, pulmonary function.
Brawley 2000	Aerobic capacity.
Christiansen 2010	None.
Cramp 2009	None.
Dunn 1999	Body fat, weight, lipid profile, blood pressure.
May 2008	Muscle strength.
Rejeski 2003	None.
Schneider 2008	None.
Sniehotta 2005	None.
<i>Studies comparing the intervention with health education</i>	
Calfas 2000	None.
McDermott 2013	6-minute walk distance, self-reported walking distance, walking speed, stair climbing.
Schneider 2008	None.
Stadler 2009	None.
Taylor 2006	Body mass index, waist circumference, hip circumference, waist-to-hip ratio.

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

E. Risk of bias

Table E1. Support for judgment of risk of bias.

Study ID	Bias	Judgment	Support for judgment
Berry 2010	Random sequence generation	Low risk	Web-based randomization application was used.
	Allocation concealment	Unclear risk	Stated that only statisticians were unblinded to randomization scheme but no description of procedure to conceal allocation.
	Blinding of participants and personnel	Unclear risk	Patients blinded, personnel not blinded.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	High risk	Loss to follow-up 30% in intervention group and 21% in control group, not accounted for
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Brawley 200	Random sequence generation	Unclear risk	"Randomly assigned", no further description.
	Allocation concealment	Unclear risk	No info.
	Blinding of participants and personnel	Unclear risk	No info.
	Blinding of outcome assessment	Unclear risk	No info.
	Incomplete outcome data	Unclear risk	Number of n/group at start not found.
	Selective reporting	High risk	Control group not reported on physical activity (reports on the two intervention groups available).
	Other bias	Low risk	Not found.
Calfas 2000	Random sequence generation	Unclear risk	No info.
	Allocation concealment	Unclear risk	No info.
	Blinding of participants and personnel	Unclear risk	Not possible to blind.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	93% of participants in follow-up.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Christiansen 2010	Random sequence generation	Unclear risk	The procedure was not described.
	Allocation concealment	Unclear risk	The procedure was not described.
	Blinding of participants and personnel	Low risk	Not possible, objective outcome (ergometer test).
	Blinding of outcome assessment	Unclear risk	No info.
	Incomplete outcome data	Low risk	ITT + imputation by last value carried forward.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.

Cramp 2006	Random sequence generation	Unclear risk	Procedure not described.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Unclear risk	Per protocol analysis, 85% in intervention group and 89% in control group.
	Selective reporting Other bias	Low risk Low risk	Not found. Not found.
De Greef 2010	Random sequence generation	Unclear risk	Procedure not described.
	Allocation concealment	Low risk	Sealed opaque envelopes were used.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Low risk	Accelerometer data.
	Incomplete outcome data	Low risk	ITT + imputation by baseline values carried forward.
	Selective reporting Other bias	Low risk Low risk	Not found. Not found.
De Greef 2011	Random sequence generation	Unclear risk	Procedure not described.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Low risk	Not possible. Pedometer data used.
	Blinding of outcome assessment	Low risk	Outcome assessed by pedometer.
	Incomplete outcome data	Low risk	ITT in all analyses.
	Selective reporting Other bias	Low risk Low risk	Not found. Not found.
Dunn 1999	Random sequence generation	Unclear risk	Procedure not described.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	ITT + imputation by last value carried forward.
	Selective reporting Other bias	Low risk Low risk	Not found. Not found.
Houle 2011	Random sequence generation	Low risk	A randomization table was used.
	Allocation concealment	Unclear risk	Procedure not sufficiently described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Low risk	Blinded pedometer used.
	Incomplete outcome data	Low risk	ITT + linear mixed model assumed to account for missing data.
	Selective reporting Other bias	Low risk Low risk	Not found. Not found.
Kirk 2004	Random sequence generation	Unclear risk	Only says "random assignment".

	Allocation concealment	Low risk	"..using consecutively numbered sealed envelopes."
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Low risk	Accelerometer used to measure outcome.
	Incomplete outcome data	Unclear risk	ITT but no imputation for loss to follow-up, 14% in intervention group and 17% in control group.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
May 2008	Random sequence generation	Low risk	Determined by randomization list.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome + ergometer test uncertain if blinded.
	Incomplete outcome data	Low risk	ITT + imputation of missing values.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
McDermott 2013	Random sequence generation	Low risk	Randomized by computer.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	ITT, 91% in intervention group and 93% in control group at follow-up.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Perna 2010	Random sequence generation	Low risk	Random number sequence table.
	Allocation concealment	Low risk	Assignment was concealed by project director.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	ITT + imputation of missing data using regression modeling.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Prinsen 2013	Random sequence generation	Low risk	Sequence prepared by statistical adviser.
	Allocation concealment	Low risk	Sealed numered envelopes.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Low risk	Actigraph used to measure outcome.
	Incomplete outcome data	High risk	Completers only analyzed. 46% in intervention group and 100% in control group.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Rejeski 2003	Random sequence generation	Unclear risk	Procedure not described.

	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome/insufficient information to conclude if treadmill test blinded.
	Incomplete outcome data	Low risk	ITT + 82% in intervention group and 92% in control group.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Rogers 2009	Random sequence generation	Low risk	Computer-generated numbers.
	Allocation concealment	Low risk	Opaque sealed envelopes.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Low risk	Accelerometer was used to measure outcome.
	Incomplete outcome data	Low risk	ITT + 95% in both groups.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Schneider 2008	Random sequence generation	Low risk	Computer-generated sequence.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	94% in intervention group and 93% in control group, mixed model approach to handle missing data.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Simons-Morton 2010	Random sequence generation	Low risk	Computer-generated sequence.
	Allocation concealment	Low risk	Allocation by coordination center, physicians masked.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	ITT, 2 imputation methods.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Sniehotta 2005	Random sequence generation	Unclear risk	Procedure not described.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Unclear risk	Insufficient information, only total 200/240 = 83%.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Stadler 2009	Random sequence generation	Low risk	Computer-generated sequence.

	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	Low risk	95% in intervention group and 97% in control group.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.
Taylor 2006	Random sequence generation	Low risk	Minimization procedure.
	Allocation concealment	Unclear risk	Procedure not described.
	Blinding of participants and personnel	Unclear risk	Not possible.
	Blinding of outcome assessment	Unclear risk	Self-reported outcome.
	Incomplete outcome data	High risk	Completers only, 76% in intervention group and 92% in control group.
	Selective reporting	Low risk	Not found.
	Other bias	Low risk	Not found.

F. Sensitivity analyses

Cognitive therapies compared to no intervention or usual care

In the studies reporting mean change difference (Figure 4), the effect estimate may be influenced by health status and risk of bias (Table F1). The effect estimate remained in favour of the intervention for the patient groups but not for healthy persons. Likewise, the effect estimate remained in favour of the intervention in the studies assessed as having an unclear risk of bias but not in the studies assessed as having a low risk of bias. The duration of the intervention and the profession of the person(s) delivering the intervention did not alter the direction of the effect estimate.

Table F1. Results of the sensitivity analyses in studies reporting mean change difference.

Study characteristic	SMD (95% CI)
Health status	
Patient group	0.68 (0.43, 0.93)
Healthy with risk factor(s) for CVD	0.17 (-0.10, 0.44)
Duration of the intervention	
12 weeks	0.57 (0.12, 1.03)
36+ weeks	0.41 (0.07, 0.74)
Profession of person(s) delivering intervention	
Psychologist + exercise specialist	0.78 (0.41, 1.14)
Nurse/research assistant/health educator	0.35 (0.06, 0.65)
Risk of bias	
Unclear	0.64 (0.34, 0.94)
Low	0.29 (-0.04, 0.62)

SMD = standardized mean difference; CVD = cardiovascular disease

In the studies reporting mean difference (Figure 5), the effect estimate was not influenced by health status, duration of the intervention or the profession of the person(s) delivering the intervention. These characteristics did not explain the statistical heterogeneity. When we synthesised studies assessed as having an unclear risk of bias the direction of the effect estimate did not change but statistical heterogeneity was reduced (from an I^2 of 65% to 35%). The study assessed as having a low risk of bias (Perna, 41) was the only study in which the effect estimate was in favour of the intervention (0.85 [0.27, 1.43])

Cognitive therapies compared to an exercise or rehabilitation program only, when added to such a program

The effect estimate may be influenced by duration of the intervention (Table F2). The effect estimate remained in favour of the intervention for the studies of shorter or longer duration than 12 weeks but not for the studies with a duration of 12 weeks. The effect estimate remained in favour of the intervention when studies were synthesised separately with regard to health status and profession of person(s) delivering the intervention. All studies were assessed to have an unclear risk of bias.

Table F2. Results of the sensitivity analyses.

Characteristic	Effect estimate (95% CI)
Health status	
Patient group	0.29 (0.07, 0.51)
Healthy with risk factor/s for CVD	0.50 (0.08, 0.91)
Duration of the intervention	
< 12 weeks	0.40 (0.13, 0.67)
12 weeks	0.55 (-0.18, 1.27)
36+ weeks	0.32 (0.07, 0.57)
Profession of person(s) delivering intervention	
Psychologist/counsellor/exercise specialist	0.32 (0.02, 0.63)
Profession not reported	0.47 (0.20, 0.74)

CVD = cardiovascular disease

Cognitive therapies compared to health education

The effect estimate was not influenced by any of the pre-determined study characteristics, and none of the sensitivity analyses explained the statistical heterogeneity.

G. GRADE evidence profiles

Table G1. GRADE evidence profile for cognitive therapies compared to no intervention or usual care.

Author(s): Eva Denison, Vigdis Underland

Date: 02.02.2016

Question: Cognitive therapies compared to no intervention/usual care for physical activity

Setting: Primary health care

Bibliography: De Greef 2010, De Greef 2011, Houle 2011, Kirk 2004, Perna 2010, Prinsen 2013, Rogers 2009, Simons-Morton 2001, Sniehotta 2005, Taylor 2006

Quality assessment							Impact	Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Physical activity (assessed with: pedometer/accelerometer)									
6	randomised trials	serious ¹	not serious	not serious	not serious	none	The standardized mean change difference was 0.47 [0.19, 0.74] to the advantage of the intervention group.	⊕⊕⊕○ MODERATE	CRITICAL
Physical activity (assessed with: Self-report)									
4	randomised trials	serious ¹	serious ²	not serious	serious ³	none	The standardized mean difference was 0.21 [-0.20, 0.63].	⊕○○○ VERY LOW	CRITICAL

1. Overall unclear risk of bias.
2. I-square 65%, non-overlapping confidence intervals.
3. The 95% confidence interval ranges from no effect to large effect.

Table G2. GRADE evidence profile for cognitive therapies compared to exercise or rehabilitation programs only, when added to such programs.

Author(s): Eva Denison, Vigdis Underland

Date: 02.02.2106

Question: Cognitive therapies physical activity compared to an exercise or rehabilitation program when added to such a program

Setting: Primary health care

Bibliography: Berry 2010, Brawley 2000, Christiansen 2010, Cramp 2006, May 2008, Rejeski 2003, Schneider 2008, Sniehotta 2005

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapies	Exercise or rehabilitation	Relative (95% CI)	Absolute (95% CI)		
Physical activity (assessed with: Self-report)												
8	randomised trials	serious ¹	not serious	not serious	not serious	none	468	459	-	SMD 0.42 SD higher (0.15 higher to 0.69 higher)	⊕⊕⊕○ MODERATE	CRITICAL

CI: Confidence interval; SMD: Standardised mean difference

1. Overall unclear risk of bias.

Table G3. GRADE evidence profile for cognitive therapies compared to health education.

Author(s): Eva Denison, Vigdis Underland

Date: 21.12.2015

Question: Cognitive therapies compared to health education for physical activity

Setting: Primary health care

Bibliography: McDermott 2013, Calfas 200, Schneider 2008, Stadler 2009, Taylor 2006

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapies	health education	Relative (95% CI)	Absolute (95% CI)		
Physical activity (assessed with: Self-report)												
5	randomised trials	serious ¹	serious ²	not serious	not serious	none	519	528	-	SMD 0.14 higher (0.14 lower to 0.42 higher)	⊕⊕○○ LOW	CRITICAL

CI: Confidence interval; SMD: Standardised mean difference

1. Overall unclear risk of bias.
2. I-square 80%

www.fhi.no

Utgitt av Folkehelseinstituttet
August 2016
Postboks 4404 Nydalen
NO-0403 Oslo
Telefon: 21 07 70 00
Rapporten lastes ned gratis fra
Folkehelseinstituttets nettsider www.fhi.no