Tiltak for organisert oppfølging av atferd som øker risiko for sykdom hos voksne

Notat fra Kunnskapssenteret Systematisk litteratursøk med sortering November 2012

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Nasjonalt kunnskapssenter for helsetjenesten Oslo, november 2012

Hovedfunn

I Norge har det blitt innført frisklivssentraler for å støtte endring av atferd og levevaner som innvirker på helsen. I rapport fra Kunnskapssenteret nr 12-2012 "Effekter av organisert oppfølging på atferd som øker risiko for sykdom hos voksne" har vi oppsummert studier som har tiltak med varighet tilsvarende én reseptperiode (10-14 uker) i frisklivssentraler. I dette notatet har vi listet sammendrag av studier som hadde kortere eller lengre tiltaksperiode enn studiene vi sammenfattet i rapporten over. Vi fant 7 systematiske oversikter og 70 primærstudier (87 publikasjoner) hvor tiltaket hadde en varighet kortere enn 10 uker eller lengre enn 14 uker.

Tiltakene var rettet mot:

Fysisk aktivitet

- 4 systematiske oversikter
- 21 primærstudier

Fysisk aktivitet og kosthold

• 29 primærstudier (41 publikasjoner)

Fysisk aktivitet, kosthold og tobakk

3 primærstudier

Fysisk aktivitet, kosthold, tobakk og alkohol

• 2 primærstudier (6 publikasjoner)

Kosthold

• 5 primærstudier (6 publikasjoner)

Tobakk

- 3 systematiske oversikter
- 5 primærstudier

Alkohol

5 primærstudier

Tittel:

Tiltak for organisert oppfølging av atferd som øker risiko for sykdom hos voksne

Publikasjonstype:

Systematisk litteratursøk med sortering

Systematisk litteratursøk med sortering er resultatet av å -søke etter relevant litteratur ifølge en søkestrategi og - eventuelt sortere denne litteraturen i grupper presentert med referanser og vanligvis sammendrag

Svarer ikke på alt:

- Ingen kritisk vurdering av studienes kvalitet
- Ingen analyse eller sammenfatning av studiene
- Ingen anbefalinger

Hvem står bak denne publikasjonen?

Kunnskapssenteret har gjennomført oppdraget etter forespørsel fra Helsedirektoratet

Når ble litteratursøket utført?

Søk etter studier ble avsluttet Juni 2012.

Key messages (English)

In Norway, 'frisklivssentraler' – 'healthy living centres' have been introduced to support change of behaviours that have significance for health. In Rapport fra Kunnskapssenteret Nr 12-2012 "Effects of organised follow-up on behaviour that may increase risk of disease in adults" we summarize studies with interventions comparable to one period of intervention in 'healthy living centres' (10-14 weeks). In this systematic reference list we have listed abstracts of studies that were excluded only due to the duration of the intervention. We found 7 systematic reviews and 70 primary studies (87 publications) where the intervention had a duration shorter than 10 weeks or longer than 14 weeks.

The interventions targeted: Physical activity

- 4 systematic reviews
- 21 primary studies

Physical activity and diet

• 29 primary studies (41 publications)

Physical activity, diet, and tobacco

• 3 primary studies

Physical activity, diet, tobacco, and alcohol

• 2 primary studies (6 publications)

Diet

5 primary studies (6 publications)

Tobacco

- 3 systematic reviews
- 5 primary studies

Alcohol

• 5 primary studies

3 Key messages (English)

Title:

Interventions for organised follow-up of behaviour that may increase risk of disease in adults.

Type of publication:

Systematic reference list

A systematic reference list is the result of a search for relevant literature according to a specific search strategy. The references resulting from the search are then grouped and presented with their abstracts.

Doesn't answer everything:

- No critical evaluation of study quality
- No analysis or synthesis of the studies
- No recommendations

Publisher:

Norwegian Knowledge Centre for the Health Services

Updated:

Last search for studies: June, 2012.

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Forord

Nasjonalt kunnskapssenter for helsetjenesten fikk i oppdrag fra Helsedirektoratet å oppsummere tilgjengelig forskning om effekter av organisert oppfølging på endring av helseatferd (fysisk aktivitet, kosthold, bruk av tobakk og/eller alkohol). Oversikten er tenkt som et dokumentasjonsgrunnlag for revidering av Helsedirektoratets *Veileder for kommunale frisklivssentraler*. Oppdraget omfattet tiltak med varighet tilsvarende én frisklivsperiode (10 til 14 uker) og er publisert i Rapport fra Kunnskapssenteret Nr 12-2012 "Effekter av organisert oppfølging på atferd som øker risiko for sykdom hos voksne". Dette systematiske litteratursøket med sortering lister studier med kortere eller lengre tiltaksperiode.

Prosjektgruppen har bestått av:

- Prosjektleder: forsker Eva Denison, Kunnskapssenteret
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Avdelingsdirektør Seksjonsleder Prosjektleder

Innledning

Rapport fra Kunnskapssenteret nr 12-2012 "Effekter av organisert oppfølging på av atferd som øker risiko for sykdom hos voksne" omfattet tiltak med varighet tilsvarende én frisklivsperiode (10-14 uker). I dette systematiske litteratursøket med sortering har vi listet sammendrag av studier som ble ekskludert kun på grunnlag av tiltakets varighet, det vil si studier hvor tiltaket var kortere enn 10 uker eller lengre enn 14 uker.

Metode

Litteratursøk, inklusjons- og eksklusjonskriterier, og utvelgelse av studier er beskrevet i Rapport fra Kunnskapssenteret Nr 12-2012. Studier (systematiske oversikter og primærstudier) som oppfylte alle inklusjonskriterier utenom varighet på tiltak ble satt på liste og sortert etter hvilken atferd tiltakene var rettet mot (fysisk aktivitet, kosthold, bruk av tobakk eller alkohol). Disse studiene med kortere eller lengre enn én periode (10-14 uker) på frisklivssentral er presentert i tabeller og med sammendrag.

Inklusjonskriterier

Studiedesign:

Vi søkte primært etter oversikter over systematiske oversikter, deretter søkte vi etter systematiske oversikter. For det tredje søkte vi etter primærstudier, herunder

- Randomiserte kontrollerte studier
- Klynge-randomiserte kontrollerte studier
- Kvasi-randomiserte kontrollerte studier
- Kontrollerte f
 ør- og etterstudier
- Avbrutte tidsserieanalyser

Populasjon: Voksne personer ≥ 18 år med risikofylt helseatferd (fysisk

aktivitet, kosthold, bruk av tobakk og/eller alkohol) eller økt risiko for sykdom, inklusive personer som allerede har en

diagnose.

Tiltak: 1) Organisert oppfølging over tid*, gitt individuelt eller i

gruppe, med hensikt å støtte endring av risikofylt helseatferd – tilsvarende den oppfølging som tilbys ved "frisklivssentral".

Et frisklivstilbud omfatter:

Motivasjonssamtale: samtale ved start for å kartlegge motivasjon og lage en individuell plan, deretter valg av

Tiltak for å fremme fysisk aktivitet:

Individuell veiledning

Gruppetrening i regi av frisklivssentral

Trening med lag/foreninger eller private aktører

Treningskontakt

Tiltak for å fremme røykeslutt:

Individuell veiledning

Røykesluttkurs (gruppebasert)

Røyketelefonen

www.slutta.no

Tiltak for å fremme sunt kosthold:

Individuell veiledning

Bra Mat for bedre helse-kurs (gruppebasert)

2) Organisert oppfølging over tid*, individuelt eller i gruppe, med hensikt å støtte endring av risikofylt helseatferd gitt av en enkeltstående tjenestetilbyder, f eks fysioterapeut, røykesluttkurs.

* I dette notatet har vi samlet tiltak med varighet kortere enn 10 uker og lengre enn 14 uker. I rapporten "Effekter av organisert oppfølging på atferd som øker risiko for sykdom hos voksne" inkluderte vi tiltak med varighet mellom 10 og 14 uker.

Sammenligning:

Rådgiving (samtale med eller uten skriftlig informasjon) om helseatferd (fysisk aktivitet, kosthold, bruk av tobakk og/eller alkohol) fra helsepersonell uten organisert oppfølging utenfor legekontoret. Vi vil også sammenligne med ingen tiltak hvis det har vært tilfelle, eller med annen vanlig praksis slik det er beskrevet i studiene.

Utfall:

Primære utfall tilpasses risikoatferden som tiltaket er rettet mot: grad av fysisk aktivitet (f eks hyppighet, varighet, intensitet, etterlevelse til fysiske aktivitetsmål); kosthold (selvrapportert kosthold mht. mengde fett, fiber, frukt, fisk og grønnsaker); bruk av tobakk og/eller alkohol (f eks. andel deltakere som slutter å røyke, antall centiliter alkohol/uke). Utfall som sykelighet og dødelighet vil inkluderes. Sekundære utfall: pasientopplevde utfall (f eks helserelatert livskvalitet); kliniske utfall (f eks blodtrykk, glukoseverdier, kroppsmasseindeks (KMI), lipidverdier, kolesterolverdier, kondisjon, midjemål, lungefunksjonsverdier).

Resultat

Fra det omfattende søket som identifiserte 1088 unike referanser ble 24 inkludert og beskrevet i rapport 12-2012 som omfattet en frisklivsperiode. Vi fant i tillegg 7 systematiske oversikter og 70 primærstudier (87 publikasjoner) der tiltaksperioden var enten kortere eller lengre, disse er presentert i dette notatet. Mange studier var rettet mot flere atferder, vi har laget følgende kategorier hvor sammendragene presenteres:

- Fysisk aktivitet
- Fysisk aktivitet og kosthold
- Fysisk aktivitet, kosthold og tobakk
- Fysisk aktivitet, kosthold, tobakk og alkohol
- Tobakk
- Alkohol

Fysisk aktivitet

Systematiske oversikter

Vi fant 4 systematiske oversikter om effekter av tiltak for å fremme økt fysisk aktivitet. Tabell 1 beskriver kort populasjon, tema, utfall og varighet på tiltakene.

Tabell 1. Kort beskrivelse av systematiske oversikter om effekter av tiltak for å fremme økt fysisk aktivitet.

| Forfatter | Populasjon | Tema | Utfall | Varighet |
|--------------|---|---|---|--|
| Gourlan 2011 | Voksne med KMI ≥ 25 | Fysisk aktivitet | Fysisk aktivitet | 3 uker – 24 måneder, M 6 måneder |
| Murphy 2007 | Voksne med lav fysisk aktivitet | Effekt av gåturer på kondisjon, fedme og blodtrykk | Kondisjon KMI Blodtrykk | 8-104 uker, M 35 uker |
| Thomas 2006 | Voksne med type 2 diabetes | Trening | Kondisjon KMI, blodtrykk, kolesterolverdier, glukoseverdier, insulinverdier, livskvalitet | 8 uker – 1 år |
| Yates 2007 | Voksne med nedsatt glukosetoleranse | Fysisk aktivitet og nedsatt glukosetoleranse | Fysisk aktivitet Glukoseverdier | 1-6 år |

Gourlan MJ, Trouilloud DO, Sarrazin PG. Interventions promoting physical activity among obese populations: A meta-analysis considering global effect, long-term maintenance, physical activity indicators and dose characteristics. Obesity Reviews 2011;12(7):e633-e645.

Background As the benefits that regular physical activity (PA) have on obesity are well known, many interventions promote active lifestyle adoption among obese populations. This meta-analysis aims to determine (i) the global effect that interventions promoting PA among obese populations have on their PA behaviour; (ii) variations in the effect of interventions depending on the PA indicator used; (iii) the programme's dose characteristics and (iv) maintenance of the intervention effects after the intervention has ended. Methods A comprehensive search through databases and review articles was completed. Forty-six studies met the inclusion criteria. Calculations of effect size (Cohen's d) and a moderator analysis were conducted. Results The meta-analysis showed that interventions globally have an impact on the PA behaviour of obese populations (d = 0.44; 95% CI = 0.31, 0.57). The moderator analysis revealed that interventions of less than 6 months reported significantly larger effects than longer interventions. Moreover, the interventions had a stronger impact on the number of steps and the PA indexes (i.e. composite scores reflecting PA practice) than on other PA indicators. Finally, the analysis revealed that interventions succeed in maintaining PA behaviour after the intervention is over. However, relatively few studies addressed this issue (n = 9). <u>Conclusion</u> Despite global positive effects, further research is needed to determine the optimal dose for interventions and to evaluate the maintenance of intervention effects.

Murphy M, Nevill A, Murtagh E, Holder R. **The effect of walking on fitness, fatness, and resting blood pressure: a meta-analysis of randomised, controlled trials.** Preventive Medicine 2007;44:377-85.

Objective The purpose of this review was to perform a meta-analysis on walking intervention studies in order to quantify the magnitude and direction of walking-induced changes that may alter selected cardiovascular risk factors. Method Twenty-four randomised controlled trials of walking were assessed for quality on a three-point scale. Data from these studies were pooled and treatment effects (TEs) were calculated for six traditional cardiovascular risk variables: body weight, body mass index (BMI), percentage body fat, aerobic fitness (VO2 max in ml kg−1 min−1) and resting systolic and diastolic blood pressure. Weighted TEs were analysed using a random effects model with weights obtained using the inverse of the individual TE variances. Random effects models were used to investigate the influence of both study quality and exercise volume (<150 vs. ≥150 min week−1). Results Random

effects modelling showed that walking interventions increased VO2 max and decreased body weight, BMI, percent body fat and resting diastolic blood pressure in previously sedentary adults (p<0.05 for all). <u>Conclusion</u> The results of this study provide evidence that healthy but sedentary individuals who take up a programme of regular brisk walking improves several known risk factors for cardiovascular disease.

Thomas D, Elliott EJ, Naughton GA. **Exercise for type 2 diabetes mellitus.**Cochrane Database of Systematic Reviews: Reviews. In: Cochrane Database of Systematic Reviews 2006 Issue 3. Chichester (UK): John Wiley & Sons, Ltd; 2006.6

Background Exercise is generally recommended for people with type 2 diabetes mellitus. However, some studies evaluate an exercise intervention including diet or behaviour modification or both, and the effects of diet and exercise are not differentiated. Some exercise studies involve low participant numbers, lacking power to show significant differences which may appear in larger trials. Objectives To assess the effects of exercise in type 2 diabetes mellitus. Search strategy Trials were identified through the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE and manual searches of bibliographies. Selection criteria All randomised controlled trials comparing any type of well-documented aerobic, fitness or progressive resistance training exercise with no exercise in people with type 2 diabetes mellitus. Data collection and analysis Two authors independently selected trials, assessed trial quality and extracted data. Study authors were contacted for additional information. Any information on adverse effects was collected from the trials. Main results Fourteen randomised controlled trials comparing exercise against no exercise in type 2 diabeteswere identified involving 377 participants. Trials ranged from eight weeks to twelvemonths duration. Compared with the control, the exercise intervention significantly improved glycaemic control as indicated by a decrease in glycated haemoglobin levels of 0.6% (-0.6 %HbA1c, 95% confidence interval (CI) -0.9 to -0.3; P < 0.05). This result is both statistically and clinically significant. There was no significant difference between groups in whole body mass, probably due to an increase in fat free mass (muscle) with exercise, as reported in one trial (6.3 kg, 95% CI o.o to 12.6). There was a reduction in visceral adipose tissue with exercise (-45.5 cm², 95% CI -63.8 to -27.3), and subcutaneous adipose tissue also decreased. No study reported adverse effects in the exercise group or diabetic complications. The exercise intervention significantly increased insulin response (131 AUC, 95% CI 20 to 242) (one trial), and decreased plasma triglycerides (-0.25 mmol/L, 95% CI - 0.48 to -0.02). No significant difference was found between groups in quality of life (one trial), plasma cholesterol or blood pressure. Authors' conclusions The meta-analysis shows that exercise significantly improves glycaemic control and reduces visceral adipose tissue and plasma triglycerides, but not plasma cholesterol, in people with type 2 diabetes, even without weight loss.

Yates T, Khunti K, Bull F, Gorely T, Davies MJ. **The role of physical activity in the management of impaired glucose tolerance: a systematic review**. Diabetologia 2007;50:1116-26.

Background Although physical activity is widely reported to reduce the risk of type 2 diabetes in individuals with prediabetes, few studies have examined this issue independently of other lifestyle modifications. The aim of this review is to conduct a systematic review of controlled trials to determine the independent effect of exercise on glucose levels and risk of type 2 diabetes in people with prediabetes (IGT and/or IFG). Methods A detailed search of MEDLINE (1966–2006) and EMBASE (1980– 2006) found 279 potentially relevant studies, eight of which met the inclusion criteria for this review. Results All eight studies were controlled trials in individuals with impaired glucose tolerance. Seven studies used a multi-component lifestyle intervention that included exercise, diet and weight loss goals and one used a structured exercise training intervention. Four studies used the incidence of diabetes over the course of the study as anoutcome variable and four relied on 2-h plasma glucose as an outcome measure. In the four studies that measured the incidence of diabetes as an outcome, the risk of diabetes was reduced by approximately 50% (range 42–63%); as these studies reported only small changes in physical activity levels, the reduced risk of diabetes is likely to be attributable to factors other than physical activity. In the remaining four studies, only one reported significant improvements in 2-h plasma glucose even though all but one reported small to moderate increases in maximal oxygen uptake. Conclusion These results indicate that the contribution of physical activity independent of dietary or weight loss changes to the prevention of type 2 diabetes in people with prediabetes is equivocal.

Primærstudier

Vi fant 21 primærstudier om tiltak for å fremme økt fysisk aktivitet. Tabell 2 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 2. Kort beskrivelse av primærstudier om tiltak for å fremme økt fysisk aktivitet. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|------------------|-------------------------------------|---|-----------|
| DuVall 2004 | Voksne kvinner | Fysisk aktivitet | 2 måneder |
| Morgan 2010 | Frivillige voksne i befolkningen | Fysisk aktivitet, kolesterolverdier | 15 uker |
| Tessier 2000 | Eldre voksne med type 2 diabetes | Kondisjon, KMI, glukoseverdier, insulinverdier | 4 måneder |
| Tudor-Locke 2004 | Voksne med type 2 diabetes | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier, insulinverdier | 4 måneder |
| Fisher 2004 | Eldre voksne i | Fysisk aktivitet, | 6 måneder |

| | befolkningen | livskvalitet | |
|-----------------|--|--|-------------------------|
| Halbert 2000 | Eldre voksne i primærhelsetjeneste | Fysisk aktivitet, blodtrykk, vekt, kolesterolverdier, livskvalitet | 6 måneder (to sesjoner) |
| Harmdorf 1999 | Eldre kvinner | Fysisk aktivitet, KMI, blodtrykk | 6 måneder |
| Lee 2007 | Eldre voksne med høyt blodtrykk | Fysisk aktivitet, blodtrykk | 6 måneder |
| Moreau 2001 | Kvinner i/etter overgangsalderen | Fysisk aktivitet, KMI, blodtrykk, glukoseverdier, insulinverdier | 6 måneder |
| Nies 2003 | Voksne kvinner i befolkningen | Fysisk aktivitet | 6 måneder |
| Pekmezi 2009 | Latinas med overvekt eller fedme og fattige | Fysisk aktivitet | 6 måneder |
| Stewart 2001 | Eldre voksne | Energiforbruk | 6 måneder |
| Sundquist 2010 | Voksne kvinner, flyktninger, i primærhelsetjeneste | Kondisjon | 6 måneder |
| Wu 2011 | Kinesiske menn med risiko for type 2 diabetes | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 6 måneder |
| Hillsdon 2002 | Voksne i primærhelsetjeneste | Fysisk aktivitet | 34 uker |
| Dubbert 2002 | Eldre pasienter i primærhelsetjeneste | Fysisk aktivitet | 12 måneder |
| Keyserling 2002 | Voksne African-American kvinner | Fysisk aktivitet, energiinntak, kolesterolverdier, vekt | 12 måneder |
| Kinmoth 2008 | Voksne i primærhelsetjeneste | Energiforbruk, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 12 måneder (telefon) |
| Lamb 2002 | Eldre voksne i primærhelsetjeneste | Fysisk aktivitet, blodtrykk, kolesterolverdier | 12 måneder |
| Rejeski 2009 | Eldre voksne i befolkningen | Fysisk aktivitet | 12 måneder |
| Rimmer 2009 | African-American kvinner med fedme og funksjonsnedsettelse | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier | 12 måneder |

Du Vall C, Dinger M, Taylor L, Bemben D. **Minimal-contact physical activity interventions in women: a pilot study.** American Journal of Health Behavior 2004;28(3):280-6.

<u>Objective</u> To examine the impact of 3 minimal-contact lifestyle interventions on physical activity in women. <u>Methods</u> Fifty female volunteers were randomly assigned to one of 3 lifestyle physical activity interventions for 8 weeks. Subjects wore an accelerometer for a week at baseline and postintervention to objectively monitor their physical activity. <u>Results</u> Participants significantly increased their physical activity from baseline to postintervention; however, there was no significant difference in physical activity among the 3 intervention groups. <u>Conclusions</u> Results of this pilot study support the use of minimal-contact lifestyle interventions to promote physical activity in women

Morgan AL, Tobar DA, Snyder L. Walking toward a new me: the impact of prescribed walking 10,000 steps/day on physical and psychological wellbeing. Journal of physical activity & health 2010;7(3):299-307.

<u>Purpose</u> To determine whether individuals participating in a program designed to accumulate 10,000 steps/day demonstrate health, fitness and psychological benefits. Methods Sedentary individuals (22 F, 7 M; age 59.8 +/- 5.78 yr) were randomly assigned into a walking (W, n = 14) or control (C, n = 15) group. Following baseline assessment, the W group was given a daily plan to reach 10,000 steps/day within 3 weeks and asked to maintain this level for 12 weeks; the C group was asked to maintain their current activity. Participants were evaluated for cardiovascular endurance, resting and postexercise HR, functional ability, cholesterol, psychological well-being, and exercise self-efficacy before and following the 15-week program. Results Significant changes over time were noted between groups (G x T; P < .05) with the W group demonstrating improvements in postexercise HR (-6.51%), total cholesterol (TC: -7.74%), and personal growth (2.53%). While not statistically significant, the W group also demonstrated improvements in 6 min walk distance (2.32%), total/HDL ratio (-10.09%), 8 foot up-and-go time (-3.35%), chair stands (6.17%), flexibility (128%), and environmental mastery (4.54%). Conclusion A 15week program aimed at accumulating 10,000 steps/day improves cardiovascular performance and personal growth and also positively influences many variables that are indicators of health, fitness and psychological well-being.

Tessier D, Ménard J, Fülöp T, Ardilouze J, Roy M, Dubuc N, et al. **Effects of aerobic physical exercise in the elderly with type 2 diabetes mellitus.** Archives of Gerontology and Geriatrics 2000;31:121-32.

Objective The objective of this study was to determine the impact of an aerobic physical exercise program in the treatment of a group of elderly patients with type 2 diabetes mellitus (DM) in relation to metabolic control, physical capacity, quality of life (QOL) and attitudes toward diabetes. Methods Patients were randomly assigned to either an experimental (n_19) or a control (n=20) group. The following measurements were conducted at baseline and after week 16: glycosylated hemoglobin (hbA1c), fructosamine, 3 h oral glucose tolerance test, treadmill test (Balke–Naughton), and a questionnaire on QOL and attitudes toward DM. Results After the intervention, the experimental group showed a significant decrease of glucose excursion during the oral glucose tolerance test (OGTT) (area under the curve) (16.6 \pm 3.8 vs. 15.3 \pm 3.1, P<0.05) and an increase in total time on the treadmill (s) (423 \pm 207 vs. 471 \pm 230, P<0.0 5). An improvement in the attitudes toward DM was observed in the experimental group (P=0.01) but not in the control group. Female gender, higher body mass index and hbA1c were factors associated with a response to the intervention. Conclusions This study suggests that physical

exercise has significant effects on glucose excursion during an OGTT and exercise tolerance in elderly patients with type 2 DM.

Tudor-Locke C, Bell R, Myers A, Harris S, Ecclestone N, Lauzon N, et al. **Controlled outcome evaluation of the First Step Program: a daily physical activity intervention for individuals with type II diabetes.** International Journal of Obesity 2004;28:113-9.

Objective To conduct a randomised trial of a physical activity (PA) intervention, The First Step Program (FSP) for adults with type II diabetes. **Design** A 16-week intervention study and 24-week follow-up assessment. Participants A total of 47 overweight/obese, sedentary individuals (age 52.77 \pm 5.2 y; BMI 33.3 \pm 5.6 kg/m2) recruited through a diabetes education centre. Measurements Primary outcome: daily PA assessed by pedometer (steps/day). Secondary outcomes: anthropometric measures (weight, BMI, waist girth, hip girth); indicators of cardiovascular health (resting heart rate and blood pressure); glycemic control (fasting glucose, insulin, HbA1c, glucose concentration 120 min postglucose load); plasma lipid status (total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides). Results Relative to the CONTROL group, FSP participants increased their PA 43000 steps/day (approximately 30 min/day) during the intervention (P<0.0001). Waist and hip girth decreased (approximately 2-3 cm), but did not differ significantly between groups. Significant changes did not emerge for any of the other variables. Conclusions The FSP is a practical intervention that elicits an immediate and profound change in walking behaviour. Such change is an important 'first step' towards increasing the volume and/or intensity of PA necessary to improve longterm health outcomes in this largely sedentary and overweight or obese population. Relapse by 24 weeks indicates that other strategies such as booster sessions are needed to maintain lifestyle change. Further research must determine realistic and responsive health outcomes for this population that are achievable through practical, real-world programming.

Fisher J, Fuzhong L. A community-based walking trial to improve neighborhood quality of life in older adults: a multilevel analysis. Annals of Behavioral Medicine 2004;28(3):186-94.

<u>Background</u> Few studies have considered the neighborhood as a context in which to examine the physical activity and quality of life relationship. Purpose: The goal of this study was to evaluate the effects of a neighborhood walking program on quality of life among older adults. It was designed as a randomized trial involving a multilevel design with neighborhoods corresponding to primary sampling units and residents to secondary units. <u>Methods</u> Five hundred eighty-two community dwelling senior residents (65 years of age or older) in neighborhoods in the northeast

metropolitan area of Portland, Oregon, were recruited through telephone, direct mail, and referrals. The walking intervention was delivered at the neighborhood level. Neighborhoods (N=56) were randomly assigned to a 6-month, 3 times per week, leader-led walking group activity (n = 28) or an information-only control group (n = 28). Primary outcome measures includedSF 12 (Physical, Mental summary scores) and life satisfaction (SWLS); the secondary outcome measure was neighborhood walking activity, assessed at baseline, 3 months, and 6 months of the study period. Results Compared to the control neighborhoods, results from multilevel, longitudinal analyses indicated significant improvements in the primary outcomes of SF-12 Physical (p < .05), SF-12 Mental (p < .05) summary scores, and SWLS (p<.05), over the course of the 6-month intervention. A significant increase was also observed in the secondary outcome of walking activity (p < .05). Conclusions Implementing a neighborhood-based walking program of low to moderate intensity is feasible and beneficial for promoting quality of life among senior residents at a community level.

Halbert J, Silagy C, Finucane P, Withers R, Hamdorf P. **Physical activity and** cardiovascular risk factors: effect of advice from an exercise specialist in **Australian general practice.** The Medical Journal of Australia 2000;173:84-7.

Objective To determine whether provision of individualised physical activity advice by an exercise specialist in general practice is effective in modifying physical activity and cardiovascular risk factors in older adults. Design Randomised controlled trial of individualised physical activity advice, reinforced at three and six months (intervention) versus no advice (control). Setting Two general practices in Adelaide, South Australia, 1996. Participants 299 adults aged 60 years or more who were healthy, sedentary and living in the community. Main outcome measures Changes to physical activity (frequency and duration of walking and vigorous exercise), selected cardiovascular risk factors (blood pressure, body weight, serum lipid levels) and quality of life over 12 months. Results Self-reported physical activity increased over the 12 months in both groups (P < 0.001). The increase was greater for the intervention than the control group for all measures except time spent walking (P <0.05). More intervention than control participants increased their intention to exercise (P < 0.001). Serum levels of total and low-density lipoprotein cholesterol and triglycerides fell significantly over the 12 months to a similar extent in the two groups. No other significant changes in cardiovascular risk factors were seen. Quality-of-life scores decreased over the 12 months. The decrease was significantly greater among intervention than control women, but not men, for emotional wellbeing (P = 0.02), physical well-being (P = 0.04) and social functioning (P = 0.04). <u>Discussion</u> Provision of general practice-based physical activity advice reinforced three-monthly produced a sustained increase in self-reported physical activity. However, there were no associated changes in clinical measures of cardiovascular risk factors and minimal changes in quality-of-life measures.

Harmdorf P, Penhall R. Walking with its training effects on the fitness and activity patterns of 79-91 year old females. Australian and New Zealand Journal of Medicine 1999;29:22-8.

Background Information is lacking about the physiological and psychosocial effects of exercise among very old persons. Aim: To investigate the effect of a twice-weekly, six-month progressive walking programme on 38 healthy women in their ninth decade, for evidence of the benefits of exercise. Methods Aerobic fimess, blood pressure, skinfold thickness and habitual activity patterns were studied in a randomised controlled trial. Women were chosen, as this is a group of increasing demographic importance for which studies are lacking. Results The training group and control group were not significantly different at baseline. However, after six months of progressive exercise the training group showed lower resting (p<0.05) and working (p<0.005) heart rates compared with non-exercising controls. ANCOVA analyses indicated higher scores for the training group compared with the control group for Maximum Current Activity and Normative Impairment Index (both p < 0.001), which are both components of the Habitual Activity Profile. Morale also significantly improved within the training group (p<0.01). Conclusions These data show the trainability of very old women and the positive impact a low frequency, progressive exercise programme can have on cardiorespiratory fitness and daily living activity patterns. Such improvements are likely to be indicative of an enhanced outlook for independence.

Lee L, Arthur A, Avis M. Evaluating a community-based walking intervention for hypertensive older people in Taiwan: a randomized controlled trial. Preventive Medicine 2007;44:160-6.

Objective To study the effect of a community-based walking intervention on blood pressure among older people. Method The study design was a randomized controlled trial conducted in a rural area of Taiwan between October 2002 and June 2003. A total of 202 participants aged 60 years and over with mild to moderate hypertension was recruited. Participants randomized to the intervention group (n=102) received a six-month community-based walking intervention based on self-efficacy theory. A public health nurse provided both face-to face and telephone support designed to assist participants to increase their walking. Control group participants (n=100) received usual primary health care. Primary outcome was change in systolic blood pressure and secondary outcomes were exercise self-efficacy, self-reported walking and diastolic blood pressure. Results At six-month follow-up the mean change in systolic blood pressure was a decrease of 15.4 mmHg and 8.4 mmHg in the intervention and control group, respectively. The difference in mean change between the two groups was -7.0 mmHg (95% CI, -11.5 to -2.5

mmHg, p=0.002). Improvement in exercise self-efficacy scores was greater among intervention group participants (mean difference 1.23, 95% CI, 0.5 to 2.0, p=0.001). Intervention group participants were more likely to report walking more (p<0.0005) but no differences were observed in diastolic blood pressure (p=0.19). <u>Conclusions</u> Among hypertensive older people, a six-month community-based walking intervention was effective in increasing their exercise self-efficacy and reducing systolic blood pressure.

Moreau K, Degarmo R, Langley J, McMahon C, Howley E, Basset D, et al. **Increasing daily walking lowers blood pressure in postmenopausal women.** Medicine & Science in Sports & Exercise 2001;33(11):1825-31.

Purpose The American College of Sports Medicine and the Centers for Disease Control and Prevention (ACSM-CDC) recommend 30 min of daily moderateintensity physical activity for health; however, the effectiveness of this recommendation in lowering blood pressure (BP) in hypertensives is unclear. The present study tested the hypothesis that walking activity following the ACSM-CDC physical activity recommendation would lower BP in postmenopausal women with high BP. Methods Resting BP was measured in 24 postmenopausal women with borderline to stage 1 hypertension at baseline, 12 wk, and 24 wk. Fifteen women in the exercise (EX) group walked 3 km/day above their daily lifestyle walking, whereas 9 women in the control (CON) group did not change their activity. Walking activity was self-measured with a pedometer in both groups. Results Resting systolic BP was reduced in the EX group after 12 wk by 6 mm Hg (P < 0.005) and was further reduced by 5 mm Hg at the end of 24 wk (P < 0.005). There was no change in diastolic BP with walking. The CON group experienced no change in BP at either 12 or 24 wk. Body mass was modestly reduced by 1.3 kg in the EX group after 24 wk (P < 0.05); however, it was not correlated with the change in BP. There were no changes in selected variables known to impact BP including percent body fat, fasting plasma insulin, or dietary intake. Conclusion In conclusion, a 24-wk walking program meeting the ACSM-CDC physical activity recommendation is effective in lowering systolic BP in postmenopausal women with borderline to stage 1 hypertension.

Nies M, Chruscial H, Hepworth J. An intervention to promote walking in sedentary women in the community. American Journal of Health Behavior 2003;27(5):524-35.

<u>Objective</u> To evaluate a telephone counseling intervention that was designed to help sedentary women begin and maintain a walking program. <u>Methods</u> Females (N = 197) were randomly assigned to either an intervention, attention control, or no-attention control group. Assessments were made at baseline and 6 months. <u>Results</u>

Women in the intervention group reported more time walked each day than did control women (P < .05). The intervention worked equally for African American and European American women as well as for different income groups. <u>Conclusion</u> Overall, a counseling intervention via telephone appears to be a good way to help women begin a walking program

Pekmezi D, Neighbors C, Lee C, Gans K, Bock B, Morrow K, et al. **A culturally adapted physical activity intervention for Latinas.** American Journal of Preventive Medicine 2009;37(6):495-500.

Background In the U.S., Latinos report particularly high levels of inactivity and related chronic illnesses and are in need of intervention. Thus, the purpose of the current study was to culturally and linguistically adapt an empirically supported, individually tailored physical activity print intervention for Latinos and then conduct an RCT of the modified program. Design An RCT was conducted. Setting/participants The sample included 93 overweight/obese (80%) Latinas with low income and acculturation. Intervention Data were collected in 2007-2008 and analyzed by intent-to-treat in 2009. Participants were randomly assigned to either (1) a culturally and linguistically adapted physical activity intervention (Seamos Activas) or (2) a wellness contact control condition. Main outcome measures Selfreport physical activity, as measured pre- and post-intervention (6 months, 87% retention) by the 7-Day Physical Activity Recall. Results Moderate-intensity (or greater) physical activity increased from an average of 16.56 minutes/week (SD = 25.76) at baseline to 147.27 (SD = 241.55) at 6 months in the intervention arm (n = 45), and from 11.88 minutes/week (SD = 21.99) to 96.79 (SD = 118.49) in the wellness contact control arm (n = 48). No between-group differences were seen in overall physical activity. Intervention participants reported significantly greater increases in cognitive (F [1, 91] = 9.53, p = 0.003) and behavioral processes of change (F [1, 91] = 8.37, p = 0.005) and available physical activity supplies and equipment at home (F [1, 91] = 4.17, p = 0.04) than control participants. Conclusions Results supported the hypothesized feasibility, acceptability, and preliminary efficacy of individually tailored physical activity print interventions among Latinas. Although more research is needed to corroborate these findings, such high-reach, low-cost approaches have great potential to positively affect public health.

Stewart A, Verboncoeur C, McLellan B, Gillis D, Rush S, Mills K, et al. **Physical activity outcomes of CHAMPS II: a physical activity promotion program for older adults.** Journal of Gerontology: MEDICAL SCIENCES 2001;56A(8):M465-M470.

<u>Background</u> Despite well-known benefits of physical activity for older adults, about two thirds are underactive. Community-based programs are needed to facilitate

increased physical activity. We examine the effectiveness of CHAMPS II, an inclusive, choice-based physical activity promotion program to increase lifetime physical activity levels of seniors. CHAMPS guided participants to choose activities that took into account their health, preferences, and abilities. It offered information on ways for them to exercise safely, motivate themselves, overcome barriers, and develop a balanced exercise regimen. Methods A 1-year randomized controlled trial was conducted with physically underactive seniors in a multispecialty group practice. Changes in self-reported physical activity by group were evaluated using ANCOVA, controlling for age and sex. Results Of 173 randomized subjects, 164 (95%) completed the trial. Subjects were aged 65 to 90 years (M = 74, SD = 6); 66% were female. The intervention group increased estimated caloric expenditure by 487 calories/week in moderate (or greater) intensity activities (MET \geq 3.0; p < .001) and by 687 calories/week in physical activities of any intensity (p < .001). Control group changes were negligible. Between-group analyses found that the changes were significantly different in both measures (p values < .05). Overweight persons especially benefited from this program. The program was as effective for women, older adults (75+), and those who did not set aside time to exercise at baseline. Conclusions The program led to meaningful physical activity increases. Individually tailored programs to encourage lifestyle changes in seniors may be effective and applicable to health care and community settings.

Sundquist J, Hagstromer M, Johansson SE, Sundquist K. **Effect of a primary health-care-based controlled trial for cardiorespiratory fitness in refugee women.** BMC Fam Pract 2010;11:55.

<u>Background</u> Refugee women have a high risk of coronary heart disease with low physical activity as one possible mediator. Furthermore, cultural and environmental barriers to increasing physical activity have been demonstrated. The aim of the study was to evaluate the combined effect of an approximate 6-month primary health care- and community-based exercise intervention versus an individual written prescription for exercise on objectively assessed cardiorespiratory fitness in low-active refugee women. Methods A controlled clinical trial, named "Support for Increased Physical Activity", was executed among 243 refugee women recruited between November 2006 and April 2008 from two deprived geographic areas in southern Stockholm, Sweden. One geographic area provided the intervention group and the other area the control group. The control group was on a higher activity level at both baseline and follow-up, which was taken into consideration in the analysis by applying statistical models that accounted for this. Relative aerobic capacity and fitness level were assessed as the two main outcome measures. Results The intervention group increased their relative aerobic capacity and the percentage with an acceptable fitness level (relative aerobic capacity > 23 O2ml•kg•min) to a greater extent than the control group between baseline and the 6-month follow-up, after adjusting for possible confounders (P = 0.020). Conclusions A combined primary

health-care and community-based exercise programme (involving non-profit organizations) can be an effective strategy to increase cardiorespiratory fitness among low-active refugee women.

Wu Y, Hwang C, Chen C, Chuang L. **Home-based exercise for middle-aged Chinese at diabetic risk: a randomized controlled trial.** Preventive Medicine 2011;52:337-43.

Objective To evaluate short- (3 months) and long-term (9 months) effects of homebased exercise on adiponectin, exercise behavior and metabolic risk factors in middle-aged adults at diabetic risk. Methods One hundred and thirty-five middleaged adults (38 men, 97 women) with at least one diabetic risk factor were randomly assigned to either a home-based exercise group (Ex-group) or a usual care group (Cgroup). Outcome measures included plasma adiponectin, exercise self-efficacy, physical activity, and metabolic risk factors, as follows: insulin levels, insulin resistance by homeostasismodel assessment (HOMA-IR), physical fitness, and components of metabolic syndrome. This study was conducted in metropolitan Taipei from 2004 to 2005. Results The Ex-group had improvements in exercise selfefficacy (+2.5, p = 0.01), body mass index (BMI) (-0.6 kg/m2, p < 0.001) and flexibility (+2.4 cm, p < 0.001) at 3-month follow-up and maintained BMI and flexibility at 9-month follow-up. The Ex-group exhibited significantly increased physical activity while the Cgroup exhibited decreased physical activity at 9-month follow-up (p < 0.001). No intervention effect was found on adiponectin (p=0.64) or other outcome measures over time. Conclusions Home-based exercise did not improve adiponectin levels, but significantly improved exercise behavior, and certain metabolic risk factors, with the effects maintained for 9-months in subjects with type 2 diabetic risk.

Hillsdon M, Thorogood M, White I, Foster C. **Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care.** International Journal of Epidemiology 2002;31:808-15.

<u>Background</u> Over the last 10 years 'exercise referral schemes' have been popular even though the evidence for effectiveness of any one-to-one intervention in primary care is deficient. We report the results of a primary care based one-to-one intervention that compared the effect of two communication styles with a no-intervention control group on self-reported physical activity at 12 months. <u>Methods</u> In all, 1658 middle-aged men and women were randomly assigned to 30 minutes of brief negotiation or direct advice in primary care or a no-intervention control group. The main outcome was self-reported physical activity at 12 months. Secondary outcome measures included change in blood pressure and body mass index. <u>Results</u>

Intention-to-treat analysis revealed no significant differences in physical activity between groups. Brief negotiation group participants who completed the study increased their physical activity significantly more than controls. There was no change in body mass index in any group. The brief negotiation group produced a greater reduction in diastolic blood pressure than direct advice. Conclusion If patients whose health may benefit from increased physical activity seek advice in primary care, 20-30 minutes of brief negotiation to increase physical activity is probably more effective than similar attempts to persuade or coerce. However, blanket physical activity promotion in primary care is not effective. The most effective way of increasing physical activity in primary care has yet to be determined

Dubbert P, Cooper K, Kirchner K, Meydrech E, Bilbrew D. **Effects of nurse counseling on walking for exercise in elderly primary care patients.**Journal of Gerontology: MEDICAL SCIENCES 2002;57A(11):M 733-M 740.

Background Counseling sedentary primary care patients can increase physical activity, but whether this approach will increase exercise and fitness in elderly adults with chronic diseases remains to be determined. Methods After receiving individualized nurse counseling to begin a program of walking for health, 60- to 80yearold primary care patients were randomized to one of three levels of telephone contacts over 10 months: (i) 20 nurseinitiated calls, (ii) 10 nurse-initiated calls plus 10 motivational calls programmed through an automated phone calling system, or (iii) no program-initiated phone contacts. Self-reported (diary) walking adherence was the primary outcome; other activity, social support, health quality of life, and measured walking performance, mobility, and body mass index and girths were also assessed during the initiation (months 1-6) and maintenance (months 7-10) phases of the trial. Results Average adherence for the 181 participants to the goal of walking at least 20 minutes on 3 or more days per week was 44% for initiation and 42% for maintenance. Participants receiving the combination of nurse-initiated personal and automated phone calls walked significantly more frequently than those with no phone contacts. Fitness improved in all three groups; changes were generally correlated with self-reported walking. Having a companion was associated with more frequent walking. Perceived quality of physical and mental health did not change. Conclusions Simple and relatively inexpensive nurse contacts can motivate elderly primary care patients to walk for exercise, and this activity is associated with measurable health benefits.

Keyserling T, Samuel-Hodge C, Ammerman A, Henríques-Roldán C, Elasy T, Skelly A, et al. **A randomized trial of an intervention to improve self-care behaviors of African American women with type 2 diabetes.** Diabetes Care 2002;25(9):1576-83.

Objective To determine whether a culturally appropriate clinic- and communitybased intervention for African-American women with type 2 diabetes will increase moderate-intensity physical activity (PA). Research design and methods In this randomized controlled trial conducted at seven practices in central North Carolina, 200 African-American women, > or =40 years of age with type 2 diabetes, were randomized to one of three treatment conditions: clinic and community (group A), clinic only (group B), or minimal intervention (group C). The clinic-based intervention (groups A and B) consisted of four monthly visits with a nutritionist who provided counseling to enhance PA and dietary intake that was tailored to baseline practices and attitudes; the community-based intervention (group A) consisted of three group sessions and 12 monthly phone calls from a peer counselor and was designed to provide social support and reinforce behavior change goals; and the minimal intervention (group C) consisted of educational pamphlets mailed to participants. The primary study outcome was the comparison of PA levels between groups assessed at 6 and 12 months by accelerometer, which was worn while awake for 7 days. Results Totals of 175 (88%) and 167 (84%) participants completed PA assessment at 6 and 12 months, respectively. For comparison of PA, the P value for overall group effect was 0.014. Comparing group A with C, the difference in the average adjusted mean for PA was 44.1 kcal/day (95% CI 13.1-75.1, P = 0.0055). Comparing group B with C, the difference in the average adjusted mean was 33.1 $\frac{\text{kcal}}{\text{day}}$ (95% CI 3.3-62.8, P = 0.029). The intervention was acceptable to participants: 88% were very satisfied with clinic-based counseling to enhance PA, and 86% indicated that the peer counselor's role in the program was important. Conclusions The intervention was associated with a modest enhancement of PA and was acceptable to participants.

Kinmonth A, Wareham N, Hardeman W, Sutton S, Prevost T, Fanshawe T, et al. **Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial.** Lancet 2008;371:41-8.

Background Declining physical activity is associated with a rising burden of global disease. Efforts to reverse this trend have not been successful. We aimed to assess the efficacy of a facilitated behavioural intervention to increase the physical activity of sedentary individuals at familial risk of diabetes. Methods We enrolled 365 sedentary adults who had a parental history of type 2 diabetes. They were recruited from either diabetes or family history registers at 20 general practice clinics in the UK. Eligible participants were randomly assigned to one of two intervention groups, or to a comparison group. All participants were posted a brief advice leaflet. One intervention group was offered a 1-year behaviour-change programme, to be delivered by trained facilitators in participants' homes, and the other the same programme by telephone. The programme was designed to alter behavioural determinants, as defined by the theory of planned behaviour, and to teach

behaviour-change strategies. The principal outcome at 1 year was daytime physical activity, which was objectively measured as a ratio to resting energy expenditure. Analysis was by intention to treat. Findings Of 365 patients, we analysed primary endpoints for 321 (88%) for whom we had data after 1 year of follow-up. At 1 year, the physical-activity ratio of participants who received the intervention, by either delivery route, did not differ from the ratio in those who were given a brief advice leafl et. The mean diff erence in daytime physical-activity ratio, adjusted for baseline, was -0.04 (95% CI -0.16 to 0.08). The physical-activity ratio did not diff er between participants who were delivered the intervention face-to-face or by telephone (mean diff erence -0.05; 95% CI -0.19 to 0.10). Interpretation A facilitated theory-based behavioural intervention was no more effective than an advice leaflet for promotion of physical activity in an at-risk group; therefore health-care providers should remain cautious about commissioning behavioural programmes into individual preventive health-care services.

Lamb S, Bartlett H, Ashley A, Bird W. Can lay-led walking programmes increase physical activity in middle-aged adults? A randomised controlled trial. Journal of Epidemiology and Community Health 2002;56:246-52.

Study objective To compare health walks, a community based lay-led walking scheme versus advice only on physical activity and cardiovascular health status in middle aged adults. <u>Design</u> Randomised controlled trial with one year follow up. Physical activity was measured by questionnaire. Other measures included attitudes to exercise, body mass index, cholesterol, aerobic capacity, and blood pressure. Setting Primary care and community. Participants 260 men and women aged 40-70 years, taking less than 120 minutes of moderate intensity activity per week. Main <u>results</u> Seventy three per cent of people completed the trial. Of these, the proportion increasing their activity above 120 minutes of moderate intensity activity per week was 22.6% in the advice only and 35.7% in the health walks group at 12 months (between group difference =13% (95% CI 0.003% to 25.9%) p=0.05). Intention to treat analysis, using the last known value for missing cases, demonstrated smaller differences between the groups (between group difference =6% (95% CI -5% to 16.4%)) with the trend in favour of health walks. There were improvements in the total time spent and number of occasions of moderate intensity activity, and aerobic capacity, but no statistically significant differences between the groups. Other cardiovascular risk factors remained unchanged. Conclusions There were no significant between group differences in self reported physical activity at 12 month follow up when the analysis was by intention to treat. In people who completed the trial, health walks was more effective than giving advice only in increasing moderate intensity activity above 120 minutes per week.

Rejeski WJ, Marsh AP, Chmelo E, Prescott AJ, Dobrosielski M, Walkup MP, et al. **The Lifestyle Interventions and Independence for Elders Pilot (LIFE-P): 2-year follow-up.** Journals of Gerontology Series A-Biological Sciences and Medical Sciences 2009;64(4):462-7.

<u>Background</u> It is well recognized that physical activity (PA) is important for older adults; yet, clinicians remain pessimistic about the ability of older adults with compromised function to adhere to long-term treatment and to maintain behavior change once treatment has been terminated. Methods We examined the functional status of older adults at a field center (Wake Forest University) 2 years after completing 12 months of treatment in the Lifestyle Interventions and Independence for Elders Pilot study. At baseline, participants were randomized to either a PA or a successful aging (SA) control group. Outcome measures included an interview assessment of PA, the Short Physical Performance Battery (SPPB), and performance on a 400-m self-paced walking test. Results Two years after the formal intervention had ended, participants who were originally in the PA group continued to engage in more minutes of moderate PA and tended to have better SPPB and walking speed than those in the SA group (effect sizes [ES]: SPPB = 0.40, walking speed = 0.37). Seven (12.7%) participants in the PA group failed the 400-m walk at the 36-month follow-up assessment, whereas this number was 11 (21.6%) in the SA group. Conclusion Older adults who have compromised physical function are able to sustain some of the benefits derived from participating in structured PA 2 years after supervised treatment has been terminated.

Rimmer J, Rauworth A, Wang E, Heckerling P, Gerber B. A randomized controlled trial to increase physical activity and reduce obesity in a predominantly African american group of women with mobility disabilities and severe obesity. Preventive Medicine 2009;48:473-9.

Objective This randomized controlled trial tested a tailored, telephone-based physical activity coaching intervention for a predominantly African American group of women with severe obesity and mobility disability. Methods We recruited 92 clinic patients from the University of Illinois at Chicago Medical Center referred by their physicians during 2004–2007 and randomized participants to one of three groups – awareness (informational brochure, no coaching), lower support (phone coaching only) and higher support (phone coaching plus monthly exercise support group) – to determine the efficacy of a tailored coaching intervention on key health outcomes, which included body weight and body mass index, blood pressure, cholesterol, physical activity (barriers and self-reported activity), movement and mobility, general health, and social support. Results The higher support group had the greatest reduction in Body Mass Index (BMI) (7.4%) compared with a 0.2% and 1.6% increase in BMI for the lower support and awareness groups, respectively (p < .01). Both the higher and lower support groups had a greater increase in physical

activity scores (39% and 30%, respectively) compared with a decline of 13% in the awareness group (p < .05). Conclusion Providing phone-based coaching and monthly in-person exercise support group sessions appear to be an effective approach for reducing body weight and increasing physical activity among severely obese, disabled adults residing in difficult social environments.

Fysisk aktivitet og kosthold

Vi fant 29 primærstudier (41 publikasjoner) om tiltak for å fremme økt fysisk aktivitet og sunnere kosthold. Tabell 3 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 3. Kort beskrivelse av primærstudier om tiltak for å fremme økt fysisk aktivitet og sunnere kosthold. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|--------------------|--|--|-----------|
| Holtrop 2002 | Voksne kvinner med type 2 diabetes | Fysisk aktivitet, kosthold, KMI, glukoseverdier | 6 uker |
| Yancey 2006 | Voksne Afrikansk-Amerikanske friske kvinner | Fysisk aktivitet, KMI | 2 måneder |
| Dale 2009 | Voksne med overvekt og insulinresistens | Kondisjon, energiinntak, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 4 måneder |
| McAuley 2002 | Frivillige voksne i befolkningen | Kondisjon, energiinntak, KMI, blodtrykk, kolesterolverdier, glukoseverdier, insulinverdier | 4 måneder |
| Oldroyd 2001 | Voksne med nedsatt glukosetoleranse | Fysisk aktivitet, energiinntak, KMI, blodtrykk, kolesterolverdier, glukoseverdier, insulinverdier | 18 uker |
| Agurs-Collins 1997 | Eldre med Afrikansk- Amerikansk herkomst | Fysisk aktivitet, kosthold, blodtrykk, kolesterolverdier, glukoseverdier, vekt | 6 måneder |
| Clark 2004 | Voksne med type 2 diabetes | Fysisk aktivitet, kosthold, KMI, kolesterolverdier, glukoseverdier | 6 måneder |
| Greaves 2008 | Pasienter i primærhelsetjeneste, BMI ≥ 28 | Fysisk aktivitet, kosthold | 6 måneder |
| Hardcastle 2008 | Pasienter i primærhelsetjeneste | Fysisk aktivitet, kosthold, KMI, blodtrykk, kolesterolverdier | 6 måneder |
| Hayashi 2010 | Eldre kvinner uten/med lav helseforsikring (USA) | Fysisk aktivitet, kosthold, KMI, blodtrykk, kolesterolverdier, 10 år risiko for hjerte- og karsykdom | 6 måneder |
| Sartorelli 2005 | Voksne med BMI 24-35 | Fysisk aktivitet, energiinntak, KMI, blodtrykk, glukoseverdier, kolesterolverdier | 6 måneder |

| Stoddard 2004 | Eldre kvinner uten/med lav | Fysisk aktivitet, kosthold, | 6 måneder |
|---|---|---|---|
| | helseforsikring (USA) | blodtrykk, kolesterolverdier | |
| Diabetes Prevention Program Research | Voksne med type 2 diabetes | Fysisk aktivitet, kaloriinntak, sykelighet, | 6 måneder + ytterligere oppfølging |
| Group 2002 ^a Goldberg 2009 ^a | Voksne med type 2 diabetes | Risiko for hjerte- og | 6 måneder + |
| Molitch 2003a | Voksne med type 2 diabetes | karsykdom Fysisk aktivitet, | ytterligere oppfølging 6 måneder + |
| Orchard 2005 ^a | Voksne med type 2 diabetes og det metabolske syndrom | kaloriinntak, sykelighet Utvikling av det metabolske syndrom | ytterligere oppfølging 6 måneder + ytterligere oppfølging |
| Eriksson 2006 ^b | Voksne med høyt blodtrykk, dyslipidemi, type 2 diabetes, fedme | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 9 måneder |
| Eriksson 2009 ^b | Voksne med høyt blodtrykk, dyslipidemi, type 2 diabetes, fedme | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 9 måneder |
| Eriksson 2010 ^b | Voksne med høyt blodtrykk, dyslipidemi, type 2 diabetes, fedme | Kostnadseffektivitet, livskvalitet | 9 måneder |
| Kulzer 2009 | Voksne i primærhelsetjeneste med BMI ≥ 26 og prediabetes | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier | 10 måneder |
| Eiben 2006 | Unge voksne kvinner | Fysisk aktivitet, kosthold | 12 måneder |
| Parra-Medina 2010 | "Underserved" Afrikansk- Amerikanske kvinner | Fysisk aktivitet, energiinntak | 12 måneder |
| Pi-Sunyer 2007° | Voksne med type 2 diabetes og BMI>25 | Kondisjon, vekt, risikofaktorer for hjerte- og karsykdom | 12 måneder |
| Racette 2001 | Afrikansk-Amerikanske voksne med BMI>27 og nedsatt glukosetoleranse | Fysisk aktivitet, energiinntak, vekt, glukoseverdier, insulinverdier, kolesterolverdier | 12 måneder |
| Wadden 2009 ^c | Voksne med type 2 diabetes og BMI>25 | Kondisjon, vekt, risikofaktorer for hjerte- og karsykdom | 12 måneder |
| Wing 2010° | Voksne med type 2 diabetes og BMI>25 | Kondisjon, vekt, risikofaktorer for hjerte- og karsykdom | 12 måneder |
| Lindström 2003 ^d | Voksne i befolkningen | Fysisk aktivitet, energiinntak, KMI, kolesterolverdier, glukoseverdier | > 12 måneder |
| Lindström 2006 ^d | Voksne i befolkningen | Fysisk aktivitet, energiinntak, KMI, kolesterolverdier, glukoseverdier, sykelighet | > 12 måneder |
| Tuomilehto 2001 ^d | Voksne i befolkningen | Fysisk aktivitet, energiinntak, KMI, kolesterolverdier, glukoseverdier, sykelighet | > 12 måneder |
| Uusitupa 2000 ^d | Voksne i befolkningen | Fysisk aktivitet, energiinntak, KMI, kolesterolverdier, glukoseverdier, sykelighet | > 12 måneder |
| Uusitupa 2003 ^d | Voksne i befolkningen | KMI, kolesterolverdier, glukoseverdier, sykelighet | > 12 måneder |
| Uusitupa 2009 ^d | Voksne i befolkningen | KMI, kolesterolverdier, glukoseverdier, sykelighet | > 12 måneder |

| Uusitupa 1996 | Voksne med nydiagnostisert type 2 diabetes | Vekt, kolesterolverdier, glukoseverdier, insulinverdier | 15 måneder |
|-------------------------|--|---|------------|
| Elmer 2006 ^e | Voksne med høyt blodtrykk | Fysisk aktivitet, energiinntak, blodtrykk, vekt | 18 måneder |
| Marutur 2009e | Voksne med høyt blodtrykk | 10 år risiko for hjerte- og karsykdom | 18 måneder |
| Stolley 2008 | Voksne Afrikansk-Amerikanske kvinner med BMI 30-50 | Fysisk aktivitet, energiinntak | 18 måneder |
| Ketola 2001 | Voksne i primærhelsetjeneste | Fysisk aktivitet, KMI, blodtrykk, kolesterolverdier, glukoseverdier, risiko for hjerte- og karsykdom | 2 år |
| Roumen 2008 | Voksne med økt risiko for nedsatt glukosetoleranse | Kondisjon, energiinntak, KMI, blodtrykk, glukoseverdier, insulinverdier, kolesterolverdier | 3 år |
| Sakane 2011 | Voksne med nedsatt glukosetoleranse | Fysisk aktivitet, energiinntak, KMI, glukoseverdier, insulinverdier, sykelighet | 3 år |
| Penn 2009 ^f | Voksne i primærhelsetjeneste med BMI > 25 og over 40 år | Fysisk aktivitet, energiinntak, sykelighet | 5 år |
| Pan 1997 | Voksne med nedsatt glukosetoleranse | Fysisk aktivitet, energiinntak, sykelighet | 6 år |

^a Diabetes Prevention Program; ^b Björknäs studien; ^c LOOK AHEAD studien; ^d Finnish Diabetes Prevention Study; ^e PREMIER studien; ^f European Diabetes Prevention Study

Holtrop JS, Hickner J, Dosh S, Noel M, Ettenhofer TL. "Sticking to it -- diabetes mellitus": a pilot study of an innovative behavior change program for women with type 2 diabetes. AM J HEALTH EDUC 2002;33(3):161-6.

Background The goal of this project was to evaluate an innovative educational program for women with type 2 diabetes facilitated by trained lay health advisors from the local university extension service. Methods The program focused on adherence to behaviors recommended to achieve optimal blood glucose control. We evaluated whether primary care physicians would refer to this program, whether the program would reach diabetic women in rural areas, and whether the program improved health behaviors and glycemic control. Women over 40 with type 2 diabetes were recruited through their primary care physician's offices. Eligible participants were randomly assigned to intervention (program) or control (usual care) groups. The six-session educational program focused on encouraging behavior change through instructor and group support, learning specific behavior change skills, and developing a confident attitude about self-management of diabetes. Physicians supported referral to the program, and the utilization of a lay health advisor for delivery of the program in rural areas was feasible. Results At 6-month follow-up the mean change in hemoglobin Alc and body mass index did not differ significantly between the intervention (n=67) and control (n=65) groups. However, participants felt better about their ability to control their diabetes and demonstrated an improvement in behaviors related to control

Yancey AK, McCarthy WJ, Harrison GG, Wong WK, Siegel JM, Leslie J. Challenges in improving fitness: results of a community-based, randomized, controlled lifestyle change intervention. Journal of Women's Health (15409996) 2006;15(4):412-29.

Objective This study tested the efficacy of an 8-week culturally targeted nutrition and physical activity intervention on body composition. Methods A randomized, attention-controlled, two-group trial was conducted in a black-owned commercial gym with a sample of 366 predominantly healthy, obese African American women. A free 1-year membership to the study site gym was provided to participants in both groups. Data were collected at baseline, 2, 6, and 12 months. Results Sample retention at 1 year was 71%. Between-group longitudinal analysis including only participants with complete data revealed a trend toward weight stability in the intervention group at 2 months compared with controls (+ 0.05 kg/m^2 , p = 0.75; + 0.32 kg/m2, p = 0.08, respectively), disappearing at 12 months (+ 1.37 kg/m2, p = 0.0001; + 1.02 kg/m2, p = 0.001, respectively). Within-group analysis demonstrated that intervention and control participants' fitness (1-mile run-walk) improved by 1.9 minutes (p = 0.0001) and 2.3 minutes (p = 0.0001), respectively, at 12 months. Mixed model regression analyses demonstrated a significant main effect of the intervention on fitness (p = 0.0185) and a marginally significant effect on body mass index (BMI) (p = 0.057), at 2 months, disappearing by 6 months. By 12 months, however, the controls exhibited a significant advantage in waist circumference stability compared with intervention participants (+ 1.1 cm, p = 0.2763; + 2.1 cm, p = 0.0002, respectively). <u>Conclusions</u> The intervention produced modest short-term improvements in body composition, but the economic incentive of a free 1-year gym membership provided to all participants was a more potent intervention than the education and social support intervention tested. However, longer-term fitness enhancement remains elusive and demands research and policy attention. These findings have policy implications in that employer-/insurer-subsidized gym memberships may require interventions targeting other levels of change (e.g., physical or social/environmental) to foster sustainable fitness improvements.

Dale KS, Mann JI, McAuley KA, Williams SM, Farmer VL. **Sustainability of lifestyle changes following an intensive lifestyle intervention in insulin resistant adults: Follow-up at 2-years.** Asia Pac J Clin Nutr 2009;18(1):114-20.

<u>Objective</u> The objective of this study was to determine whether overweight insulin resistant individuals who lost weight and improved cardiovascular risk factors during a 4-month lifestyle intervention could sustain these lifestyle changes in the long-term. <u>Methods</u> Seventy-nine insulin resistant adults were randomised to a control group or either a modest or intensive lifestyle intervention group for 4-

months. Thereafter the two intervention groups were combined and all participants were followed-up at 8, 12 and 24 months. Anthropometry, blood pressure, fasting glucose, lipids, insulin and aerobic fitness were measured and dietary intake was assessed. An interview was conducted to determine factors which participants perceived facilitated or hindered maintenance of healthy lifestyle habits. Results Seventy-two (91.1%), sixty-nine (87.3%) and sixty-two (78.5%) participants were retained at 8, 12 and 24-month respectively. At 4-months the adjusted difference in weight between the modest and control groups was -3.4 kg (95% CI -5.4, -1.3) p=0.002 and intensive and control groups was -4.7 kg (-6.9, -2.4) p=0.0001 respectively. At 2-years there were no significant differences for weight when the initial 3 groups were compared or when the combined intervention group was compared with the control group. At 2-years, 64% of participants reported that more frequent follow-up would have helped them to maintain healthy lifestyle habits. Conclusions Even intensive counselling for 4-months with 4-monthly and then yearly monitoring were not enough for maintaining lifestyle changes sufficient to sustain weight loss. More frequent monitoring for an indefinite period was perceived by two-thirds of participants as necessary for them to maintain their initial lifestyle changes.

McAuley KA, Williams S, Mann J, Goulding A, Chisholm A, Wilson N, et al. **Intensive lifestyle changes are necessary to improve insulin sensitivity.** Diabetes Care 2002;25:445-52.

Objective The extent to which lifestyle must be altered to improve insulin sensitivity has not been established. This study compares the effect on insulin sensitivity of current dietary and exercise recommendations with a more intensive intervention in normoglycemic insulin-resistant individuals. Research design and methods Seventynine normoglycemic insulin-resistant (determined by the euglycemic insulin clamp) men and women were randomized to either a control group or one of two combined dietary and exercise programs. One group (modest level) was based on current recommendations and the other on a more intensive dietary and exercise program. Insulin sensitivity was measured using a euglycemic insulin clamp, body composition was measured using dual-energy X-ray absorptiometry, and anthropometry and aerobic fitness were assessed before and after a 4-month intervention period. Four-day dietary intakes were recorded, and fasting glucose, insulin, and lipids were measured. Results Only the intensive group showed a significant improvement in insulin sensitivity (23% increase, P=0.006 vs. 9% in the modest group, P=0.23). This was associated with a significant improvement in aerobic fitness (11% increase in the intensive group, P=0.02 vs. 1% in the modest group, P=0.94) and a greater fiber intake, but no difference in reported total or saturated dietary fat. Conclusions Current clinical dietary and exercise recommendations, even when vigorously implemented, did not significantly improve insulin sensitivity; however, a more intensive program did. Improved

aerobic fitness appeared to be the major difference between the two intervention groups, although weight loss and diet composition may have also played an important role in determining insulin sensitivity.

Oldroyd J, Unwin N, White M, Imrie K, Mathers J, Alberti K. Randomised controlled trial evaluating the effectiveness of behavioural interventions to modify cardiovascular risk factors in men and women with impaired glucose tolerance: outcomes at six months. Diabetes Research and Clinical Practice 2001;52:29-43.

Aims To evaluate the efficacy of interventions to promote a healthy diet and physical activity in people with impaired glucose tolerance (IGT). Methods A randomised controlled trial in Newcastle upon Tyne, UK, 1995–98. Participants included 67 adults (38 men; 29 women) aged 24-75 years with IGT. The intervention consisted of regular diet and physical activity counselling based on the stages of change model. Main outcome measures were changes between baseline and 6 months in nutrient intake; physical activity; anthropometric and physiological measurements including serum lipids; glucose tolerance; insulin sensitivity. Results The difference in change in total fat consumption was significant between intervention and control groups (difference -21.8 (95% confidence interval (CI) -37.8 to-5.8) g/day, P = 0.008). A significantly larger proportion of intervention participants reported taking up vigorous activity than controls (difference 30.1, (95% CI 4.3-52.7)%, P = 0.021). The change in body mass index was significantly different between groups (difference -0.95 (95% CI -1.5 to -0.4) kg/m2, P = 0.001). There was no significant difference in change in mean 2-h plasma glucose between groups (difference -0.19 (95% CI -1.1 to 0.71) Mmol/l, NS) or in serum cholesterol (difference 0.02 (95% CI -0.26 to 0.31) mmol/l, NS). The difference in change in fasting serum insulin between groups was significant (difference -3.4 (95% CI -5.8 to -1.1) mU/l, P = 0.005). Conclusions After 6 months of intensive lifestyle intervention in participants with IGT, there were changes in diet and physical activity, some cardiovascular risk factors and insulin sensitivity, but not glucose tolerance.

Agurs-Collins T, Kumanyika S, Ten Have T, Adams-Campbell L. **A randomized** controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. Diabetes Care 1997;20(10):1503-11.

<u>Objective</u> To evaluate a weight loss and exercise program designed to improve diabetes management in older African-Americans. <u>Research design and methods</u> Overweight African-Americans (n = 64) ages 55-79 years with NIDDM were randomized to either an intervention (12 weekly group sessions, 1 individual session, and 6 biweekly group sessions) or usual care (1 individual session, and 6 biweekly

group sessions) or usual care (1 class and 2 informational mailings). Clinical and behavioral variables were assessed at 0, 3, and 6 months of treatment. Results Significant net differences in the intervention versus usual care were observed for weight (-2.0 kg, P = 0.006), physical activity, and dietary intake of fat, saturated fat, cholesterol, and nutrition knowledge at 3 months (all P < 0.05) and for weight at 6 months (-2.4 kg; P = 0.006) and mean HbA1c values at 3 and 6 months (respectively, -1.6 and -2.4%, both P < 0.01). After the adjustment for changes in weight and activity, the intervention participants were approximately twice as likely to have a one unit decrease in HbA1c value as those in usual care. Blood pressure increase sin usual care participants resulted in net differences (intervention minus control) at 3 and 6 months of -3.3 (P = 0.09) and -4.0 (P = 0.05) mmHg diastolic, respectively, and -8.4 (P = 0.06) and -5.9 (P > 0.10) mmHg systolic, respectively. Blood lipid profiles improved more in intervention than usual care participants, but not significantly. Conclusions The intervention program was effective in improving glycemic and blood pressure control. The decrease in HbA1c values was generally independent of the relatively modest changes in dietary intake, weight, and activity and may reflect indirect program effects on other aspects of self-care.

Clark M, Hampson SE, Avery L, Simpson R. **Effects of a brief tailored** intervention on the process and predictors of lifestyle behaviour change in patients with type 2 diabetes. Psychology, Health and Medicine 2004;9(4):440-9.

Objectives The aim of the present study was to develop, implement and evaluate a brief intervention to improve adherence to the recommended lifestyle changes for patients with Type 2 diabetes, in particular to help patients to reduce the total amount of fat consumed and to increase lifestyle physical activity levels. Design and method A brief, tailored lifestyle self-management intervention for patients with Type 2 diabetes was evaluated in a randomized controlled trial. One hundred participants (aged 40-70 yrs) completed assessments at three time points—baseline, three months and one year. Participants were allocated to either an intervention group who received the brief tailored intervention including follow-up telephone calls, or a usual care control group. Results indicate that the intervention was successful in helping patients to reduce fat intake and, to a lesser extent, increase lifestyle physical activity levels. These self-reported changes in behaviour were reflected in the objective data with weight maintenance in the intervention group compared to the control group, together with a significant reduction (2 cm) in waist circumference. Conclusions These results provide further evidence of the effectiveness of tailored interventions for lifestyle change.

Greaves CJ, Middlebrooke A, O'Loughlin L, Holland S, Piper J, Steele A, et al. **Motivational interviewing for modifying diabetes risk: a randomised controlled trial.** Br J Gen Pract 2008;58(553):535-40.

Background Around 10-15% of adults aged over 40 years have pre-diabetes, which carries a high risk of progression to type 2 diabetes. Intensive lifestyle intervention reduces progression by as much as 58%. However, the cost and personnel requirements of these interventions are major obstacles to delivery in NHS primary care. Aim To assess the effectiveness of a low-cost intervention, delivered in primary care by non-NHS staff, to reduce the risk of diabetes through weight loss and physical activity. Design of study Pragmatic single-blind randomised controlled trial with researchers and statistician blinded to group allocation. Setting UK primary care. Method One-hundred and forty-one participants with a body mass index of 28 kg/m2 or more, but without diabetes or heart disease, received either information leaflets or individual behavioural counselling using motivational interviewing techniques. The intervention was delivered by five counsellors recruited from the local community. The primary outcomes were the proportions of participants meeting predefined targets for weight loss (5%) and moderate physical activity (150 minutes/week) after 6 months. Results Using intention-to-treat analysis, more people in the intervention group achieved the weight-loss target (24% versus 7% for controls; odds ratio [OR] = 3.96; 95% confidence interval [CI] = 1.4 to 11.4; number needed to treat [NNT] = 6.1 (95% CI = 4 to 21). The proportion achieving the physical activity target did not increase significantly (38% versus 28% for controls; OR = 1.6; 95% CI = 0.7 to 3.8). Conclusion Short-term weight loss, at a level which, if sustained, is clinically meaningful for reducing diabetes risk, is achievable in primary care, without excessive use of NHS monetary or personnel resources.

Hardcastle S, Taylor A, Bailey M, Castle R. **A randomised controlled trial on the effectiveness of a primary health care based counselling intervention on physical activity, diet and CHD risk factors.** Patient Education and Counseling 2008;70:31-9.

<u>Objective</u> The aim of the study was to determine if multiple patient-centred lifestyle counselling sessions would be of interest to patients at risk of coronary heart disease (CHD), in a primary care setting, and if such sessions would result in changes in physical activity and diet, and health status. A randomised trial was conducted to compare the counselling intervention with usual care (health promotion leaflet), among 334 mostly obese patients. <u>Methods</u> Patients were randomised into an intervention group that received standard exercise and nutrition information plus up to five face-to-face counselling sessions with a Physical Activity Specialist (PAS) and Registered Dietitian (RD) over a 6-month period or to a control group that only received the standard information. <u>Results</u> Of those invited, patients randomised tended to be more obese, older and female. The mean (S.D.) sessions attended was

2.0 (1.6) with 50% attending at least 3. At 6 months, the counselling group were more active, particularly with respect to walking, and had reduced weight, blood pressure and cholesterol, but had not changed their diet, compared with the control group. Furthermore, those who did more sessions had greater increases in activity and reductions in weight, blood pressure and cholesterol. <u>Conclusion</u> Attending multiple sessions of client-centred counselling in primary care was of interest to patients, and generally reduced CHD risk factors. Practice implications: The primary care setting can be used effectively to promote particularly walking, using physical activity specialists and dietitians trained to use an adapted motivational interviewing (MI) counselling style.

Hayashi T, Farrell MA, Chaput LA, Rocha DA, Hernandez M. **Lifestyle** intervention, behavioral changes, and improvement in cardiovascular risk profiles in the California WISEWOMAN project. Journal of Women's Health (15409996) 2010;19(6):1129-38.

Background The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program in California (Heart of the Family) implements lifestyle interventions to improve health behaviors while reducing cardiovascular disease (CVD) risk factors among low income, uninsured, or underinsured Hispanic women aged 40-64 who participate in the Cancer Detection Programs: Every Woman Counts (CDP: EWC). This study reports the first-year results of the California WISEWOMAN program. Methods Heart of the Family is a within-site randomized controlled study with an enhanced intervention group (EIG) and a usual care group (UCG). The study was conducted between January 2006 and June 2007 at four community health centers in Los Angeles and San Diego counties. Lifestyle counseling focusing on health behaviors was provided by bilingual, bicultural (Spanish and English) community health workers. The study examines two outcome measures: changes in health behaviors; and changes in the CVD risk profile, as measured by the 10-year probability of having a coronary heart disease (CHD) event. Results Women in the EIG group (n = 433), compared to those in the UCG group (n = 433) = 436), experienced more improvements in health behaviors, both eating habits and physical activity. The improvement in the 10-year CHD risk was greater for EIG than UCG women. Multiple regression results indicate that this improvement was significantly greater when the women's CHD risk levels were in the upper quartile at baseline. Conclusions Compared with UCG women, women in the EIG were more likely to improve their health behaviors. The CVD risk profile, as measured by the 10-year CHD risk, improved in women with the highest baseline risk.

Sartorelli DS, Sciarra EC, Franco LJ, Cardoso MA. Beneficial effects of short-term nutritional counselling at the primary health-care level among Brazilian adults. Public Health Nutr 2005;8(7):820-5.

Objective To evaluate the impact of a low-cost nutritional intervention in changing the lifestyle of adults. Design Randomised clinical trial. Setting Primary health-care centre in Sao José do Rio Preto, Sao Paulo State, Brazil. Subjects We randomly assigned 104 adults (83 women and 21 men aged 30-65 years, body mass index 24-35 kg/m2, non-diabetic) into two groups: nutrition counseling and control. Each subject in the intervention group received three individualized nutritional counselling sessions during the first 6 months aimed at increasing intakes of fruits, vegetables and olive oil, reducing saturated fat and improving physical activity. Body composition, biochemical indicators and lifestyle were assessed at baseline and at 6 months and 1 year in both groups. Results After 6 months of follow-up, body weight, waist circumference, diastolic blood pressure, fasting blood glucose, total and lowdensity lipoprotein cholesterol, total and saturated fat, and dietary energy and cholesterol levels showed a more significant decrease among subjects in the intervention group than in the control group (P < 0.05). Moreover, the intervention group showed significantly greater improvement in each intervention goal, such as reduced intake of saturated fat and increased intakes of fruits, vegetables, fibre and olive oil (P < 0.05). After 12 months of follow-up, most of the outcomes were maintained. <u>Conclusions</u> The low-cost nutritional intervention programme improved serum lipids profile and weight control, and appeared to be feasible for use at a primary healthcare centre in a developing country.

Diabetes Prevention Program Research Group. **Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.** N Engl J Med 2002;346(6):393-403.

Background Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors — elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle — are potentially reversible. We hypothesized that modifying these factors with a lifestyleintervention program or the administration of metformin would prevent or delay the development of diabetes. Methods We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups. Results The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the

lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin. Conclusions Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.

Goldberg RB, Temprosa M, Haffner S, Orchard TJ, Ratner RE, Fowler SE, et al. **Effect of progression from impaired glucose tolerance to diabetes on cardiovascular risk factors and its amelioration by lifestyle and metformin intervention: the Diabetes Prevention Program randomized trial by the Diabetes Prevention Program Research Group.** Diabetes Care 2009;32(4):726-32.

Objective Although subjects with diabetes have increased risk for cardiovascular disease (CVD), the evolution of this increased risk as pre-diabetic individuals progress to diabetes is not understood. This study examines the longitudinal relationship between selected CVD risk factors (blood pressure, triglycerides, HDL and LDL cholesterol, and LDL peak particle density [PPD]) and glycemia in the three treatment groups of the Diabetes Prevention Program. Research design and methods A total of 3,234 participants with impaired glucose tolerance (IGT) were followed for a mean of 3.2 years after randomization to intensive lifestyle intervention (ILS), metformin, or placebo. Using repeated-measures models, adjusted mean levels of risk factors were estimated for an annual change in glycemic status. Tests were also conducted to assess the risk factor trends with improvement or worsening of glycemic status. Results CVD risk factor values and changes from baseline became more unfavorable as glucose tolerance status deteriorated but improved with reversion to normal glucose tolerance (NGT), especially in the ILS intervention group (trend test P < 0.001 for all risk factors except for LDL PPD [P = 0.02] in ILS and HDL cholesterol [P = 0.02] in placebo). Although there were few significant differences in the transition from IGT to diabetes, there were strong relationships between risk factors and continuous measures of glycemia. Conclusions Progression from IGT to diabetes is associated with mild deterioration, whereas reversion to NGT is associated with improvement in risk factors. Early intervention with ILS, but less so with metformin, in participants at high risk for diabetes improves the cardiovascular risk and glucose tolerance profile simultaneously.

Molitch ME, Fujimoto W, Hamman RF, Knowler WC, Diabetes Prevention Program Research Group. **The diabetes prevention program and its global implications.** J Am Soc Nephrol 2003;14(7:Suppl:2):Suppl-7.

Background Type 2 diabetes affects over 150 million adults worldwide and this figure is expected to double over the next 25 yr. This increase will be accompanied by a marked increase in the number of patients with ESRD due to diabetes. We hypothesized that a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes. Methods We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7% weight loss and at least 150 min of physical activity per week. Results The mean age of the participants was 51 yr, and the mean body mass index was 34.0 kg/m2; 68% were women, and 45% were members of non-Caucasian racial/ethnic groups. The average follow-up was 2.8 yr. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence of diabetes by 58% (95% CI: 48 to 66%) and metformin by 31% (95% CI: 17 to 43%), compared with placebo; the lifestyle intervention was significantly more effective than metformin. Conclusion Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk and the lifestyle intervention was more effective than metformin. Because the lifestyle changes worked equally in all racial/ethnic groups in the Diabetes Prevention Program, they should be applicable to high-risk populations worldwide and may be able to reduce the projected progressive rise in the incidence of diabetes and the expected increase in ESRD.

Orchard TJ, Temprosa M, Goldberg R, Haffner S, Ratner R, Marcovina S, et al. **The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: The diabetes prevention program randomized trial.** Ann Intern Med 2005;142(8):611-9.

Background The metabolic syndrome is a high-risk state for diabetes and cardiovascular disease. Little is known about its prevalence and prevention in those with impaired glucose tolerance. Objective To determine the prevalence of the metabolic syndrome at baseline in the Diabetes Prevention Program and the effect of intensive lifestyle intervention and metformin therapy on the syndrome's incidence and resolution. Design Randomized, controlled clinical trial. Setting Research and community-based centers. Participants Participants had impaired glucose tolerance (World Health Organization criteria plus fasting plasma glucose level >5.3 mmol/L [>95 mg/dL]) and were followed for a mean of 3.2 years after random assignment to intensive lifestyle intervention, metformin therapy, or placebo. Interventions: Metformin, 850 mg twice daily, or intensive lifestyle intervention designed to achieve and maintain a 7% weight loss and 150 minutes of exercise per week. Measurements The metabolic syndrome was defined as having 3 or more characteristics (waist circumference; blood pressure; and levels of high-density lipoprotein cholesterol, triglycerides, and fasting plasma glucose) that met criteria

from the National Cholesterol Education Program Adult Treatment Panel III. Results Fifty-three percent of participants (n=1711) had the metabolic syndrome at baseline; incidence did not vary substantially by age. However, low levels of high-density lipoprotein cholesterol predominated in younger participants (age 25 to 44 years), and high blood pressure predominated in older participants (age 60 to 82 years). In life-table analyses (log-rank test), incidence of the metabolic syndrome was reduced by 41% in the lifestyle group (P < 0.001) and by 17% in the metformin group (P = 0.03) compared with placebo. Three-year cumulative incidences were 51%, 45%, and 34% in the placebo, metformin, and lifestyle groups, respectively. There was no significant heterogeneity by ethnic group. Limitations The study involved a volunteer group with impaired glucose tolerance, which limits generalizability. Conclusions The metabolic syndrome affected approximately half of the participants in the Diabetes Prevention Program at baseline. Both lifestyle intervention and metformin therapy reduced the development of the syndrome in the remaining participants.

Eriksson KM, Westborg CJ, Eliasson MC. A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors. SCAND J PUBLIC HEALTH 2006;34(5):453-61.

Aims To evaluate the effects of a lifestyle intervention programme in primary healthcare, targeted to patients with moderate to high risk of cardiovascular disease in terms of cardiovascular risk factors, physical activity, and quality of life. Method Randomized controlled trial with one-year follow-up, carried out in a primary healthcare centre in Northern Sweden. A total of 151 middle-aged men and women, with hypertension, dyslipidemia, type 2 diabetes, or obesity were enrolled. The subjects were randomized to either the intervention (n = 75) or the control group (n = 75)= 76). A total of 123 subjects completed the one-year follow-up. Interventions: Exercise: supervised endurance and circuit training in groups three times a week for three months. Diet: five group sessions of diet counselling with a dietitian. Followup meetings with a physiotherapist were conducted monthly thereafter. Primary outcomes were changes in anthropometry, maximal oxygen uptake, health-related quality of life, and self-reported physical activity. The secondary outcomes were changes in blood pressure and metabolic variables. Results After one year the intervention group significantly increased maximal oxygen uptake, physical activity, and quality of life and significantly decreased body weight, waist and hip circumference, body mass index, waist-hip ratio, systolic and diastolic blood pressure, triglycerides, and glycosylated haemoglobin. There were significant differences between groups, mean changes (and their 95% confidence intervals, CI) in waist circumference -1.9 cm (-2.80 to -0.90; p < 0.001), in waist—hip ratio -0.01 (-.02 to -0.004; p < 0.01) and in diastolic blood pressure -2.3 mmHg (-4.04 to -0.51; p < 0.05). Conclusion A prevention programme in primary healthcare with a focus on physical activity and diet counselling followed by structured follow-up meetings can

favourably influence several risk factors for cardiovascular diseases and quality of life in high-risk subjects for at least one year.

Eriksson MK, Franks PW, Eliasson M. A 3-year randomized trial of lifestyle intervention for cardiovascular risk reduction in the primary care setting: The Swedish Bjorknas study. PLoS ONE 2009;4(4)

Background Successfully transferring the findings of expensive and tightly controlled programmes of intensive lifestyle modification to the primary care setting is necessary if such knowledge is to be of clinical utility. The objective of this study was to test whether intensive lifestyle modification, shown previously in tightlycontrolled clinical trials to be efficacious for diabetes risk-reduction among high-risk individuals, can reduce cardiovascular risk factor levels in the primary care setting. Methodology / Principal Findings The Swedish Björknäs study was a randomized controlled trial conducted from 2003 to 2006 with follow-up on cardiovascular risk factors at 3, 12, 24 and 36 months. A total of 151 middle-aged men and women at moderate- to high-risk of cardiovascular disease from northern Sweden were randomly assigned to either an intensive lifestyle intervention (n = 75) or control (n = 75)= 76) group. The intervention was based broadly on the protocol of the Diabetes Prevention Program. The three-month intervention period was administered in the primary care setting and consisted of supervised exercise sessions and diet counselling, followed by regular group meetings during three years. The control group was given general advice about diet and exercise and received standard clinical care. Outcomes were changes in anthropometrics, aerobic fitness, selfreported physical activity, blood pressure, and metabolic traits. At 36 months post randomisation, intensive lifestyle modification reduced waist circumference (-2.2 cm: p = 0.001), waist-hip ratio (-0.02: p < 0.0001), systolic blood pressure (-4.9 mmHg: p = 0.036), and diastolic blood pressure (-1.6 mmHg: p = 0.005), and improved aerobic fitness (5%; p = 0.038). Changes in lipid or glucose values did not differ statistically between groups. At 36 months, self-reported time spent exercising and total physical activity had increased more in the intervention group than in the control group (p < 0.001). Conclusion / Significance A program of intensive lifestyle modification undertaken in the primary health care setting can favourably influence cardiovascular risk-factor profiles in high-risk individuals.

Eriksson MK, Malmgren-Olsson EB, Hagberg LA, Eliasson M. **Lifestyle** intervention, quality of life and cost-effectiveness, a randomized controlled trial. Eur J Cardiovasc Prev Rehabil 2010;S87.

<u>Background</u> Lifestyle interventions reduce cardiovascular risk and risk of diabetes mellitus, but reports on long-term effects on quality of life (QOL) and health care utilization are rare. We investigated the impact of a primary health care—based

lifestyle intervention program on QOL and cost-effectiveness over 3 years. Methods A total of 151 men and women, aged 18 to 65 years, at moderate to high risk for cardiovascular disease, were randomly assigned to either lifestyle intervention with standard care or standard care alone. Intervention consisted of supervised exercise sessions and diet counseling for 3 months, followed by regular group meetings over a 3-year period. Change in QOL was measured with EuroQol (5-dimensional EuroQol-5D [EQ-5D] and EuroQol-VAS [EQ-VAS]), the 36-Item Short-Form Health Survey (SF-36), and the 6-dimensional Short- Form 6D (SF-6D). The health economic evaluation was performed from a societal view and a treatment perspective. In a cost-utility analysis, the costs, gained qualityadjusted life-years (QALYs), and savings in health care were considered. Cost-effectiveness was also described using the net monetary benefit method. Results Significant differences between the groups over the 3-year period were shown in the EQ-VAS (P =.002), SF-6D (P =.01), and SF-36 (P =.04) physical component summary but not in the EQ-5D (P = .24) or SF-36 (P = .37) mental component summary. The net savings were \$47 per participant. Costs per gained QALY, savings not counted, were \$1668 to \$4813. Probabilities of cost-effectiveness were 89% to 100% when the amount of \$50 000 was used as stakeholder's threshold of willingness to pay for a gained QALY. Conclusion Lifestyle intervention in primary care improves QOL and is highly cost-effective in relation to standard care.

Kulzer B, Hermanns N, Gorges D, Schwarz P, Haak T. **Prevention of diabetes** self-management program (PREDIAS): effects on weight, metabolic risk factors and behavioral outcomes. Diabetes Care 2009;32:1143-6.

<u>Objective</u> To evaluate the efficacy of the group program PREDIAS for diabetes prevention. Research design and methods PREDIAS consists of 12 lessons and aims at lifestyle modification. The control group received written information about diabetes prevention. In this study, a total of 182 persons with an elevated diabetes risk participated (aged 56.3 ± 10.1 years, 43% female, and BMI 31.5 ± 5.3 kg/m2). Results After 12 months, weight loss was significantly higher (P = 0.001) in PREDIAS than in the control group (-3.8 \pm 5.2 vs. -1.4 \pm 4.09 kg). There were also significant effects (P = 0.001) on fasting glucose (control group 1.8 ± 13.1 mg/dl vs. PREDIAS -4.3 \pm 11.3 mg/dl), duration of physical activity per week (control group 17.9 ± 63.8 min vs. PREDIAS 46.6 \pm 95.5 min; P = 0.03), and eating behavior. Conclusions PREDIAS significantly modified lifestyle factors associated with an elevated diabetes risk.

Eiben G, Lissner L. Health Hunters - an intervention to prevent overweight and obesity in young high-risk women. Int J Obes 2006;30(4):691-6.

Aim The aim of the study was to develop and implement an obesity and weight gain prevention program targeted to a highrisk group. Method Women, 18–28 years old, with at least one severely obese parent, were randomized to the intervention or control group of the 'Health Hunters' program. During 1 year of follow-up, the intervention group received an individualized behavioral program focusing on food choice, physical activity and other lifestyle factors. Anthropometric measures, DXAbased body composition and fitness levels were measured at baseline and after 1 year. Self-reported changes in obesity-related behaviors were also assessed. Results Baseline examinations were conducted in 40 women, of whom 30 completed followup examinations 1 year later. Pregnancy was the most common reason for failure to complete the study. Compared to the control group (which gained weight), the intervention group displayed significant improvements in body weight, body mass index, waist circumference, waist-to-hip ratio and self-reported physical activity. Changes in body composition, although not significant, suggested that the intervention tended to be associated with improved body composition. Further analysis of changes in diet and fitness in relation to concurrent weight changes indicated that the strongest 'protective' associations were for energy percent protein, fiber density and fitness. Conclusion Pilot data from the Health Hunters obesity prevention program indicates that it is effective in high-risk young women with familial predisposition for obesity.

Parra-Medina D, Wilcox S, Wilson DK, Addy CL, Felton G, Poston MB. **Heart Healthy and Ethnically Relevant (HHER) Lifestyle trial for improving diet and physical activity in underserved African American women.** Contemp Clin Trials 2010;31(1):92-104.

Background African American women are at increased risk for CVD morbidity and mortality relative to white women. Physical inactivity and poor dietary habits are modifiable health behaviors shown to reduce CVD risk. Community health centers have the potential to reach large numbers of African Americans to modify their risk for CVD, yet few lifestyle counseling interventions have been conducted in this setting. Methods The HHER Lifestyle trial is a randomized controlled trial to compare the effects of a standard care intervention (provider counseling, nurse goal setting, and educational materials) to a comprehensive intervention (standard care intervention plus 12 months of telephone counseling and tailored print materials) on changes in physical activity and dietary fat consumption in financially disadvantaged African American women at 6 and 12 months. Secondary outcomes are body mass index, central adiposity, and total cholesterol. Potential mediators of outcome are self-efficacy for overcoming barriers, social support, and decisional balance. Results African American women (N=266; 130 standard care, 136 comprehensive intervention) 35 years and older from nine clinics within two community health centers were enrolled. Most participants were overweight or obese with existing chronic health conditions. Conclusion The HHER Lifestyle trial is unique in that it

targets financially disadvantaged African American women from community health centers, incorporates a standard care intervention into a routine clinical appointment, and includes a comprehensive process evaluation. The design will permit further research examining the added effect of regular telephone counseling and tailored print materials to a primary care provider and nurse intervention.

Pi-Sunyer X, Blackburn G, Brancati FL, Bray GA, Bright R, Clark JM, et al. **Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the look AHEAD trial.** Diabetes Care 2007;30(6):1374-83.

Objective The effectiveness of intentional weight loss in reducing cardiovascular disease (CVD) events in type 2 diabetes is unknown. This report describes 1-year changes in CVD risk factors in a trial designed to examine the long-term effects of an intensive lifestyle intervention on the incidence of major CVD events. Research design and methods This study consisted of a multicentered, randomized, controlled trial of 5,145 individuals with type 2 diabetes, aged 45-74 years, with BMI >25 kg/m2 (>27 kg/m2 if taking insulin). An intensive lifestyle intervention (ILI) involving group and individual meetings to achieve and maintain weight loss through decreased caloric intake and increased physical activity was compared with a diabetes support and education (DSE) condition. Results Participants assigned to ILI lost an average 8.6% of their initial weight vs. 0.7% in DSE group (P < 0.001). Mean fitness increased in ILI by 20.9 vs. 5.8% in DSE (P < 0.001). A greater proportion of ILI participants had reductions in diabetes, hypertension, and lipidlowering medicines. Mean A1C dropped from 7.3 to 6.6% in ILI (P < 0.001) vs. from 7.3 to 7.2% in DSE. Systolic and diastolic pressure, triglycerides, HDL cholesterol, and urine albumin-to-creatinine ratio improved significantly more in ILI than DSE participants (all P < 0.01). <u>Conclusions</u> At 1 year, ILI resulted in clinically significant weight loss in people with type 2 diabetes. This was associated with improved diabetes control and CVD risk factors and reduced medicine use in ILI versus DSE. Continued intervention and follow-up will determine whether these changes are maintained and will reduce CVD risk.

Racette S, Weiss E, Obert K, Kohrt W, Holloszy J. **Modest lifestyle intervention** and glucose tolerance in obese African Americans. Obesity Research 2001;9(6):348-55.

<u>Objective</u> Previous studies have demonstrated the benefit of short-term diets on glucose tolerance in obese individuals. The purpose of this study was to evaluate the effectiveness of modest lifestyle changes in maintaining improvements in glucose tolerance induced by short-term energy restriction in obese African Americans with impaired glucose tolerance or type 2 diabetes mellitus. <u>Research Methods and</u>

<u>Procedures</u> An intervention group (n = 45; 47 ± 1 year [mean \pm SE]), 105 ± 4 kg; body mass index: $39 \pm 1 \text{ kg/m2}$) received an energy-restricted diet ($943 \pm 26 \text{ kcal/d}$) for 1 week, followed by a lifestyle program of reduced dietary fat (-125 kcal/d) and increased physical activity (+125 kcal/d) for 1 year. Body weight and plasma concentrations of glucose, insulin, and C-peptide during an oral glucose tolerance test were measured at baseline, 1-week, and 4-month intervals. A control group (n = 24; 48 \pm 1 year; 110 \pm 5 kg; body mass index: 41 \pm 2 kg/m2) underwent these measurements at 4-month intervals. Results No changes in weight or glucose tolerance were observed in the control group. The intervention group had significant (p < 0.05) improvements in body weight and glucose tolerance in response to the 1week diet, which persisted for 4 months (p < 0.001 vs. control for change in weight). A total of 19 subjects (42%) continued the intervention program for 1 year, with sustained improvements (weight: $24.6 \pm 1.0 \text{ kg}$; p < 0.001 vs. control; oral glucose tolerance test glucose area: 2103 ± 44 mM * min; p < 0.05 vs. control). <u>Discussion</u> A modest lifestyle program facilitates weight loss and enables improvements in glucose tolerance to be maintained in obese individuals with abnormal glucose tolerance. However, attrition was high, despite the mild nature of the program.

Wadden TA, West DS, Neiberg RH, Wing RR, Ryan DH, Johnson KC, et al. **One-year weight losses in the Look AHEAD study: factors associated with success.** Obesity (Silver Spring) 2009;17(4):713-22.

Background This report provides a further analysis of the first year weight losses in the Look AHEAD (Action for Health in Diabetes) study and identifies factors associated with success. Methods Participants were a total of 5,145 men and women with type 2 diabetes who were recruited at 16 sites and randomly assigned to an intensive lifestyle intervention (ILI) or a control condition, Diabetes Support and Education (DSE). During year 1, participants in ILI received comprehensive diet and physical activity counseling in a total of 42 group and individual sessions, compared with three educational sessions for DSE participants. Results As reported previously, at the end of the year, ILI participants lost 8.6% of initial weight, compared to 0.7% for DSE (P < 0.001). Within the ILI group, all racial/ethnic groups achieved clinically significant weight losses (>5.5%), although there were significant differences among groups. For the year, ILI participants attended an average of 35.4 treatment sessions and reported exercising a mean of 136.6 min/week and consuming a total of 360.9 meal replacement products. Greater self-reported physical activity was the strongest correlate of weight loss, followed by treatment attendance and consumption of meal replacements. The use of orlistat, during the second half of the year, increased weight loss only marginally in those ILI participants who had lost <5% of initial weight during the first 6 months and chose to take the medication thereafter as a toolbox option. Conclusion The lifestyle intervention was clinically effective in all subsets of an ethnically and demographically diverse population.

Wing RR, Bahnson JL, Bray GA, Clark JM, Coday M, Egan C, et al. **Long-term** effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: Four-year results of the look AHEAD trial. Arch Intern Med 2010;170(17):1566-75.

Background Lifestyle interventions produce short term improvements in glycemia and cardiovascular disease (CVD) risk factors in individuals with type 2 diabetes mellitus, but no long-term data are available. We examined the effects of lifestyle intervention on changes in weight, fitness, and CVD risk factors during a 4-year study. Methods The Look AHEAD (Action for Health in Diabetes) trial is a multicenter randomized clinical trial comparing the effects of an intensive lifestyle intervention (ILI) and diabetes support and education (DSE; the control group) on the incidence of major CVD events in 5145 overweight or obese individuals (59.5% female; mean age, 58.7 years) with type 2 diabetes mellitus. More than 93% of participants provided outcomes data at each annual assessment. Results Averaged across 4 years, ILI participants had a greater percentage of weight loss than DSE participants (-6.15% vs -0.88%; P< .001) and greater improvements in treadmill fitness (12.74% vs 1.96%; P< .001), hemoglobin A1c level (-0.36% vs -0.09%; P< .001), systolic (-5.33 vs -2.97 mm Hg; P.001) and diastolic (-2.92 vs -2.48mmHg; P=.01) blood pressure, and levels of high-density lipoprotein cholesterol (3.67 vs 1.97 mg/dL; P<.001) and triglycerides (-25.56 vs -19.75 mg/dL; P<.001). Reductions in low-density lipoprotein cholesterol levels were greater in DSE than ILI participants (-11.27 vs -12.84 mg/dL; P=.009) owing to greater use of medications to lower lipid levels in the DSE group. At 4 years, ILI participants maintained greater improvements than DSE participants in weight, fitness, hemoglobin A1c levels, systolic blood pressure, and high density lipoprotein cholesterol levels. <u>Conclusions</u> Intensive lifestyle intervention can produce sustained weight loss and improvements in fitness, glycemic control, and CVD risk factors in individuals with type 2 diabetes. Whether these differences in risk factors translate to reduction in CVD events will ultimately be addressed by the Look AHEAD trial.

Lindstrom J, Eriksson JG, Valle TT, Aunola S, Cepaitis Z, Hakumaki M, et al. **Prevention of diabetes mellitus in subjects with impaired glucose tolerance in the Finnish Diabetes Prevention Study: results from a randomized clinical trial.** J Am Soc Nephrol 2003;14(7:Suppl:2):Suppl-13.

<u>Background</u> Type 2 diabetes mellitus is increasing worldwide largely as a result from increasing obesity and sedentary lifestyle. The Finnish Diabetes Prevention Study (DPS) is the first individually randomized controlled clinical trial to test the feasibility and efficacy of lifestyle modification in high-risk subjects. <u>Methods</u> We randomly assigned 522 (172 men, 350 women) middle-aged (mean age 55 yr),

overweight (mean body mass index 31 kg/m(2)) subjects with impaired glucose tolerance either to the lifestyle intervention or control group. Each subject in the intervention group received individualized counseling aimed at reducing weight and intake of total and saturated fat, and increasing intake of fiber and physical activity. An oral glucose tolerance test was performed annually to detect incident cases of diabetes and to measure changes in metabolic parameters. Results The mean (+/-SD) weight reduction from baseline to year 1 and to year 2, respectively, was 4.2 +/-5.1 kg and 3.5 +/-5.5 in the intervention group and 0.8 +/-3.7 kg and 0.8 +/-4.4 in the control group (P < 0.001 between the groups). At the time of first analysis of the outcome data the mean duration of follow-up was 3.2 yr. The risk of diabetes was reduced by 58% (P < 0.001) in the intervention group compared with the control group. The reduction in the incidence of diabetes was directly associated with number and magnitude of lifestyle changes made. Conclusion The DPS is the first controlled trial demonstrating that type 2 diabetes can be prevented by changes in lifestyle in high-risk subjects

Lindström J, Ilanne-Parikka P, Peltonen M, Aunola S, Eriksson JG, Hemiö K, et al. **Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study.** Lancet 2006;368(9548):1673-9.

<u>Background</u> Lifestyle interventions can prevent the deterioration of impaired glucose tolerance to manifest type 2 diabetes, at least as long as the intervention continues. In the extended follow-up of the Finnish Diabetes Prevention Study, we assessed the extent to which the originally-achieved lifestyle changes and risk reduction remain after discontinuation of active counselling. Methods Overweight, middle-aged men (n=172) and women (n=350) with impaired glucose tolerance were randomly assigned to intensive lifestyle intervention or control group. After a median of 4 years of active intervention period, participants who were still free of diabetes were further followed up for a median of 3 years, with median total followup of 7 years. Diabetes incidence, bodyweight, physical activity, and dietary intakes of fat, saturated fat, and fibre were measured. Findings During the total follow-up, the incidence of type 2 diabetes was 4.3 and 7.4 per 100 person-years in the intervention and control group, respectively (log-rank test p=0.0001), indicating 43% reduction in relative risk. The risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre, and increased physical activity. Beneficial lifestyle changes achieved by participants in the intervention group were maintained after the discontinuation of the intervention, and the corresponding incidence rates during the post-intervention follow-up were 4.6 and 7.2 (p=0.0401), indicating 36% reduction in relative risk. Interpretation Lifestyle intervention in people at high risk for type 2 diabetes resulted in sustained lifestyle changes and a reduction in diabetes incidence, which remained after the individual lifestyle counselling was stopped.

Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, et al. **Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance.** N Engl J Med 2001;344(18):1343-50.

Background Type 2 diabetes mellitus is increasingly common, primarily because of increases in the prevalence of a sedentary lifestyle and obesity. Whether type 2 diabetes can be prevented by interventions that affect the lifestyles of subjects at high risk for the disease is not known. Methods We randomly assigned 522 middleaged, overweight subjects (172 men and 350 women; mean age, 55 years; mean body-mass index, 31) with impaired glucose tolerance to either the intervention group or the control group. Each subject in the intervention group received individualized counseling aimed at reducing weight, total intake of fat, and intake of saturated fat and increasing intake of fiber and physical activity. An oral glucosetolerance test was performed annually; the diagnosis of diabetes was confirmed by a second test. The mean duration of follow-up was 3.2 years. Results The mean (±SD) amount of weight lost between base line and the end of year 1 was 4.2±5.1 kg in the intervention group and 0.8±3.7 kg in the control group; the net loss by the end of year 2 was 3.5±5.5 kg in the intervention group and 0.8±4.4 kg in the control group (P<0.001 for both comparisons between the groups). The cumulative incidence of diabetes after four years was 11 percent (95 percent confidence interval, 6 to 15 percent) in the intervention group and 23 percent (95 percent confidence interval, 17 to 29 percent) in the control group. During the trial, the risk of diabetes was reduced by 58 percent (P<0.001) in the intervention group. The reduction in the incidence of diabetes was directly associated with changes in lifestyle. Conclusions Type 2 diabetes can be prevented by changes in the lifestyles of high-risk subjects.

Uusitupa M, Louheranta A, Lindstrom J, Valle T, Sundvall J, Eriksson J, et al. **The Finnish Diabetes Prevention Study.** Br J Nutr 2000;83:Suppl-42.

<u>Aim</u> The aim of the Finnish Diabetes Prevention Study is to assess the efficacy of an intensive diet—exercise programme in preventing or delaying type 2 diabetes in individuals with impaired glucose tolerance (IGT) and to evaluate the effect of the programme on the risk factors of atherosclerotic vascular diseases and the incidence of cardiovascular events. <u>Methods</u> In this ongoing study, a total of 523 overweight subjects with IGT based on two oral glucose tolerance tests were randomized to either an intervention group or a control group. The main measure in the intervention group is individual dietary advice aimed at reducing weight and intake of saturated fat and increasing intake of dietary fibre. The intervention subjects are individually guided to increase their level of physical activity. The control group receives general information about the benefits of weight reduction, physical activity

and healthy diet in the prevention of diabetes. A pilot study began in 1993, and recruitment ended in 1998. Results By the end of April 1999 there were 65 new cases of diabetes, 34 drop-outs and one death. The weight reduction was greater (-4,6 kg) at 1 year in the intervention group (n = 152) than in the control group (n = 143, -0,9 kg, P<0,0001), and this difference was sustained in the second year of follow-up. At 1 year 43,4% and at 2 years 41,8% of the intervention subjects had achieved a weight reduction of at least 5 kg, while the corresponding figures for the control subjects were 14,0 and 12,0% (P<0,001 between the groups). At 1 year the intervention group showed significantly greater reductions in 2 h glucose, fasting and 2 h insulin, systolic and diastolic blood pressure, and serum triglycerides. Most of the beneficial changes in cardiovascular risk factors were sustained for 2 years. Conclusion These interim results of the ongoing Finnish Diabetes Prevention Study demonstrate the efficacy and feasibility of the lifestyle intervention programme.

Uusitupa M, Lindi V, Louheranta A, Salopuro T, Lindstrom J, Tuomilehto J, et al. Long-term improvement in insulin sensitivity by changing lifestyles of people with impaired glucose tolerance: 4-year results from the Finnish Diabetes Prevention Study. Diabetes 2003;52(10):2532-8.

Background Lifestyle interventions reduce the incidence of type 2 diabetes among individuals with impaired glucose tolerance (IGT). However, it is unknown whether this is due to improved insulin sensitivity or insulin secretion. Methods We investigated at baseline insulin sensitivity and insulin secretion applying frequently sampled intravenous glucose tolerance test (FSIGT) in 87 of 101 obese middle-aged subjects with IGT randomized into an intervention or a control group in the Finnish Diabetes Prevention Study. FSIGT was repeated after 4 years in 52 people. Results There were no significant differences in any of the baseline anthropometric or metabolic characteristics between the groups. The 4-year weight and waist circumference decreases were greater in the intervention than in the control group (P = 0.043 and P = 0.025, respectively). At 4-year examination, insulin sensitivity (Si) tended to be higher in the intervention group (the difference between the mean values 36%; P = 0.067, and P = 0.136 after adjustment for age, sex, BMI, and baseline Si value). There was strong correlation between the 4-year changes in Si and weight (r = -0.628 and r = -0.710, for intervention and control groups; P < 0.001 for both). In the entire group, Si improved by 64% in the highest tertile of weight loss but deteriorated by 24% in those who gained weight (lowest tertile). Acute insulin response declined significantly in the control group. Conclusion Si markedly improved by weight reduction during the 4-year follow-up of individuals with IGT. Insulin secretion remained constant for years in individuals with IGT who were able to lose weight.

Uusitupa M, Peltonen M, Lindstrom J, Aunola S, Ilanne-Parikka P, Keinanen-Kiukaanniemi S, et al. **Ten-year mortality and cardiovascular morbidity in the Finnish Diabetes Prevention Study - Secondary analysis of the randomized trial.** PLoS ONE 2009;4(5).

Background The Finnish Diabetes Prevention Study (DPS) was a randomized controlled trial, which showed that it is possible to prevent type 2 diabetes by lifestyle changes. The aim of the present study was to examine whether the lifestyle intervention had an effect on the ten-year mortality and cardiovascular morbidity in the DPS participants originally randomized either into an intervention or control group. Furthermore, we compared these results with a population-based cohort comprising individuals of varying glucose tolerance states. Methods and Findings Middle-aged, overweight people with IGT (n = 522) were randomized into intensive intervention (including physical activity, weight reduction and dietary counseling), or control "mini-intervention" group. Median length of the intervention period was 4 years and the mean follow-up was 10.6 years. The population-based reference study cohort included 1881 individuals (1570 with normal glucose tolerance, 183 with IGT, 59 with screen-detected type 2 diabetes, 69 with previously known type 2 diabetes) with the mean follow-up of 13.8 years. Mortality and cardiovascular morbidity data were collected from the national Hospital Discharge Register and Causes of Death Register. Among the DPS participants who consented for register linkage (n = 505), total mortality (2.2 vs. 3.8 per 1000 person years, hazard ratio HR = 0.57, 95% CI 0.21–1.58) and cardiovascular morbidity (22.9 vs. 22.0 per 1000 person years, HR = 1.04, 95% CI 0.72-1.51) did not differ significantly between the intervention and control groups. Compared with the population-based cohort with impaired glucose tolerance, adjusted HRs were 0.21 (95% CI 0.09-0.52) and 0.39 (95% CI 0.20-0.79) for total mortality, and 0.89 (95% CI 0.62-1.27) and 0.87 (0.60–1.27) for cardiovascular morbidity in the intervention and control groups of the DPS, respectively. The risk of death in DPS combined cohort was markedly lower than in FINRISK IGT cohort (adjusted HR 0.30, 95% CI 0.17-0.54), but there was no significant difference in the risk of CVD (adjusted HR 0.88, 95% CI 0.64-1.21). Conclusions Lifestyle intervention among persons with IGT did not decrease cardiovascular morbidity during the first 10 years of follow-up. However, the statistical power may not be sufficient to detect small differences between the intervention and control groups. Low total mortality among participants of the DPS compared with individuals with IGT in the general population could be ascribed to a lower cardiovascular risk profile at baseline and regular follow-up.

Uusitupa M. Early lifestyle intervention in patients with non-insulindependent diabetes mellitus and impaired glucose tolerance. Annals of Medicine 1996;28(445):449. Background Non-insulin-dependent diabetes mellitus (NIDDM) is preceded by impaired glucose tolerance (IGT) lasting for years before manifesting as overt hyperglycaemia. Both genetic and environmental factors contribute to the development of IGT and NIDDM. Obesity, physical inactivity and high-fat diet have been found to predict IGT and NIDDM. Therefore, a diet and exercise intervention from diagnosis of NIDDM could improve the treatment outcome and prognosis of patients with NIDDM. Furthermore, because subjects with IGT are at increased risk for diabetes and atherosclerotic vascular diseases, it is reasonable to assume that in terms of reducing the incidence and longterm consequences of NIDDM an intervention at this phase is more effective than in overt diabetes. Although the nonpharmacological approach is generally accepted as the first-line treatment for NIDDM its efficacy has often been questioned. Therefore, it is important to carry out long-term controlled studies to find out to what extent lifestyle modification could improve the metabolic control and level of major cardiovascular risk factors known to be associated with poor outcome in NIDDM. This kind of study also gave relevant experience in planning studies aiming at primary prevention of NIDDM. Results One-year dietary and exercise intervention on newly diagnosed NIDDM patients in Kuopio, Finland resulted in a better metabolic control and a moderate reduction in cardiovascular risk factors as compared to the conventional treatment group. After the second year of follow-up only 12.5% in the intervention group were receiving oral antidiabetic drugs vs. 34.8% in the conventional treatment group. Weight reduction and a reduced use of saturated fats appeared to be the main determinants of successful treatment results. Good aerobic capacity was associated with an increase in HDL cholesterol. A multicentre primary prevention study on IGT patients is continuing in Finland applying the same principles of intervention as used in the study on newly diagnosed NIDDM patients. Conclusion Pilot results show that glucose tolerance can be improved by lifestyle changes.

Elmer PJ, Obarzanek E, Vollmer WM, Simons-Morton D, Stevens VJ, Young DR, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. Ann Intern Med 2006;144(7):485-95.

<u>Background</u> The main 6-month results from the PREMIER trial showed that comprehensive behavioral intervention programs improve lifestyle behaviors and lower blood pressure. <u>Objective</u> To compare the 18-month effects of 2 multi component behavioral interventions versus advice only on hypertension status, lifestyle changes, and blood pressure. <u>Design</u> Multicenter, 3-arm, randomized trial conducted from January 2000 through November 2002. <u>Setting</u> 4 clinical centers and a coordinating center. Patients: 810 adult volunteers with prehypertension or stage 1 hypertension (systolic blood pressure, 120 to 159 mm Hg; diastolic blood pressure, 80 to 95 mm Hg). <u>Interventions</u> A multi component behavioral intervention that implemented long-established recommendations ("established"); a

multi component behavioral intervention that implemented the established recommendations plus the Dietary Approaches to Stop Hypertension (DASH) diet ("established plus DASH"); and advice only. Measurements Lifestyle variables and blood pressure status. Follow- up for blood pressure measurement at 18 months was 94%. Results Compared with advice only, both behavioral interventions statistically significantly reduced weight, fat intake, and sodium intake. The established plus DASH intervention also statistically significantly increased fruit, vegetable, dairy, fiber, and mineral intakes. Relative to the advice only group, the odds ratios for hypertension at 18 months were 0.83 (95% CI, 0.67 to 1.04) for the established group and 0.77 (CI, 0.62 to 0.97) for the established plus DASH group. Although reductions in absolute blood pressure at 18 months were greater for participants in the established and the established plus DASH groups than for the advice only group, the differences were not statistically significant. <u>Limitations</u> The exclusion criteria and the volunteer nature of this cohort may limit generalizability. Although blood pressure is a wellaccepted risk factor for cardiovascular disease, the authors were not able to assess intervention effects on clinical cardiovascular events in this limited time and with this sample size. Conclusions Over 18 months, persons with prehypertension and stage 1 hypertension can sustain multiple lifestyle modifications that improve control of blood pressure and could reduce the risk for chronic disease.

Maruthur NM, Wang NY, Appel LJ. **Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial.** Circulation 2009;119(15):2026-31.

<u>Background</u> Although trials of lifestyle interventions generally focus on cardiovascular disease risk factors rather than hard clinical outcomes, 10-year coronary heart disease (CHD) risk can be estimated from the Framingham risk equations. Our objectives were to study the effect of 2 multicomponent lifestyle interventions on estimated CHD risk relative to advice alone and to evaluate whether differences can be observed in the effects of the lifestyle interventions among subgroups defined by baseline variables. Methods and Results A total of 810 healthy adults with untreated pre-hypertension or stage I hypertension were randomized to 1 of 3 intervention groups: An "advice-only" group, an "established" group that used established lifestyle recommendations for blood pressure control (sodium reduction, weight loss, and increased physical activity), or an "establishedplus-DASH" group that combined established lifestyle recommendations with the DASH (Dietary Approaches to Stop Hypertension) diet. The primary outcome was 10-year CHD risk, estimated from follow-up data collected at 6 months. A secondary outcome was 10-year CHD risk at 18 months. Of the 810 participants, 62% were women and 34% were black. Mean age was 50 years, mean systolic/diastolic blood pressure was 135/85 mm Hg, and median baseline Framingham risk was 1.9%. The relative risk ratio comparing 6-month to baseline Framingham risk was 0.86 (95%

confidence interval 0.81 to 0.91, P < 0.001) in the established group and 0.88 (95% confidence interval 0.83 to 0.94, P < 0.001) in the established-plus-DASH group relative to advice alone. Results were virtually identical in sensitivity analyses, in each major subgroup, and at 18 months. <u>Conclusions</u> The observed reductions of 12% to 14% in estimated CHD risk are substantial and, if achieved, should have important public health benefits.

Stolley M, Fitzgibbon M, Schiffer L, Sharp L, Singh V, Van Horn L, et al. **Obesity reduction black intervention trial (ORBIT): six-month results.** Obesity 2008;17:100-6.

Background The Obesity Reduction Black Intervention Trial (ORBIT) is a randomized controlled trial designed to assess the efficacy of a culturally proficient 6-month weight loss intervention followed by a 1-year maintenance intervention. This article describes the results of the 6-month weight loss intervention. Methods Two hundred thirteen obese black women aged 30-65 years were randomized to the intervention group or a general health control group. The intervention consisted of a 6-month culturally adapted weight loss program that targeted changes in diet and physical activity patterns. Weight, dietary intake, and physical activity were measured at baseline and 6 months. Results A total of 198 women (93%) completed both the baseline and post intervention assessments. Women in the intervention group lost significantly more weight than women in the control group (P < 0.001). However, weight change was variable within the intervention group, with a maximum weight loss of 19.4% of initial body weight and a maximum weight gain of 6.4% of initial body weight. Women in the intervention group also showed significant improvements in fruit intake (P < 0.01), Healthy Eating Index score (P < 0.001), and moderate (P = 0.05), and vigorous (P < 0.001) physical activity compared to women in the control group. Conclusions This study demonstrates that a culturally adapted program can successfully promote weight loss in obese black women. However, average weight loss was relatively modest, and weight change varied widely within the intervention group. Further research is needed in order to develop programs that will allow more black women to achieve their weight loss goals.

Ketola E, Makela M, Klockars M. **Individualised multifactorial lifestyle** intervention trial for high-risk cardiovascular patients in primary care. Br J Gen Pract 2001;51(465):291-4.

<u>Background</u> The multiprofessional teams in Finnish health centres are well placed to carry out interventions aimed at the prevention of cardiovascular diseases. <u>Aim</u> To evaluate the effectiveness of an individually tailored multifactorial lifestyle intervention in primary care for individuals at high risk for cardiovascular disease.

Design of study A randomised controlled trial was conducted over 24 months with interim assessments at six and 12 months. Setting A health centre in Finland with a patient population of 11 000. Method One hundred and fifty adults aged 18 to 65 years old with existing cardiovascular disease or multiple risk factors were randomised to active multiprofessional risk factor intervention or to standard care. The main outcome measure was a change in cardiovascular risk-factor score. Secondary outcomes were changes in blood pressure, weight, body-mass index, serum cholesterol, blood glucose, smoking cessation, and exercise habits. Results The cardiovascular risk score decreased by 28% in the intervention group (23% in the control group), body weight decreased by 3.7% (2%) and total cholesterol decreased by 10.8% (6.5%), while time engaged in exercise increased by 39% (43%). Differences were not significant. Conclusions Cardiovascular risk levels of high-risk individuals decreased in both intervention and control groups. Primary care prevention should be targeted to high-risk persons. Long-term follow-up studies are needed.

Roumen C, Corpeleijn E, Feskens EJ, Mensink M, Saris WH, Blaak EE. **Impact of 3-year lifestyle intervention on postprandial glucose metabolism: the SLIM study.** Diabet Med 2008;25(5):597-605.

Objective To determine the effect of a 3-year diet and exercise lifestyle intervention, based on general public health recommendations, on glucose tolerance, insulin resistance and metabolic cardiovascular risk factors in Dutch subjects with impaired glucose tolerance (IGT). Methods The study was a randomized controlled lifestyle intervention over 3 years. A total of 147 IGT subjects (75 male, 72 female) were randomized to the intervention (INT) group or control (CON) group; 106 subjects (52 INT, 54 CON) completed 3 years of intervention. Annually, glucose, insulin and free fatty acid (FFA) concentrations were determined fasting and after an oral glucose tolerance test. Measurements of body weight, serum lipids, blood pressure and maximal aerobic capacity were also performed. Results Analysis of those who completed the 3-year trial, showed that the lifestyle intervention improved body weight (INT-1.08±4.30 kg; CON +0.16±4.91 kg,P=0.01), homeostatis model assessment index for insulin resistance and 2-h FFA. Two-hour glucose concentrations improved in the INT group, the difference being most pronounced after1 year, with a return to baseline values after 3 years, from 8.59±1.55 to 8.55±0.34 mM; in contrast, 2-h glucose deteriorated in the CON group—from 8.46±1.84 to 9.35±2.50 mM(P=0.02). In the INT group, diabetes incidence was reduced by 58% (P=0.025). Conclusion Our lifestyle intervention showed a sustained beneficial effect on 2-h glucose concentrations, insulin resistanceand 2-h FFA, even after 3 years. Our lifestyle intervention is effective, but for implementation more information is needed about factors influencing adherence.

Sakane N, Sato J, Tsushita K, Tsujii S, Kotani K, Tzuaki K, et al. **Prevention of type 2 diabetes in a primary healthcare setting: three-year results of lifestyle intervention in Japanese subjects with impaired glucose tolerance.** BMC public health 2011;11:40.

Background A randomized control trial was performed to test whether a lifestyle intervention program, carried out in a primary healthcare setting using existing resources, can reduce the incidence of type 2 diabetes in Japanese with impaired glucose tolerance (IGT). The results of 3 years' intervention are summarized. Methods Through health checkups in communities and workplaces, 304 middleaged IGT subjects with a mean body mass index (BMI) of 24.5 kg/m2 were recruited and randomized to the intervention group or control group. The lifestyle intervention was carried out for 3 years by public health nurses using the curriculum and educational materials provided by the study group. Results After 1 year, the intervention had significantly improved body weight (-1.5 \pm 0.7 vs. -0.7 \pm 2.5 kg in the control; p = 0.023) and daily non-exercise leisure time energy expenditure (25 ± 113 vs. -3 ± 98 kcal; p = 0.045). Insulin sensitivity assessed by the Matsuda index was improved by the intervention during the 3 years. The 3-year cumulative incidence tended to be lower in the intervention group (14.8% vs.8.2%, log-rank test: p = 0.097). In a sub-analysis for the subjects with a BMI > 22.5 kg/m2, a significant reduction in the cumulative incidence was found (p = 0.027). Conclusions The present lifestyle intervention program using existing healthcare resources is beneficial in preventing diabetes in Japanese with IGT. This has important implications for primary healthcare-based diabetes prevention.

Penn L, White M, Oldroyd J, Walker M, Alberti KGMM, Mathers JC. **Prevention of type 2 diabetes in adults with impaired glucose tolerance: The European Diabetes Prevention RCT in Newcastle upon Tyne, UK.** BMC public health 2009;9, 2009. Article Number: 342.

Background Diabetes prevalence is increasing. The Finnish Diabetes Prevention Study (DPS) showed a 58% reduction in Type 2 Diabetes (T2D) incidence in adults with impaired glucose tolerance (IGT). The European Diabetes Prevention Study (EDIPS) extends the DPS to different European populations, using the same study design. In the Newcastle arm of this study (EDIPSNewcastle), we tested the hypothesis that T2D can be prevented by lifestyle intervention and explored secondary outcomes in relation to diabetes incidence. Methods We recruited 102 participants (42 men and 60 women, mean age 57 years, mean BMI 34 kgm-2) with IGT to EDIPS-Newcastle and randomised to Intervention and usual care Control groups. The intervention included individual motivational interviewing aimed at: weight reduction, increase in physical activity, fibre and carbohydrate intake and reduction of fat intake (secondary outcomes). The primary outcome was diagnosis of T2D. Results Mean duration of follow-up was 3.1 years. T2D was diagnosed in 16

participants (I = 5, C= 11). Absolute incidence of T2D was 32.7 per 1000 person-years in the Intervention-group and 67.1 per 1000 person-years in the Control-group. The overall incidence of diabetes was reduced by 55% in the Intervention-group, compared with the Control-group: RR 0.45 (95%CI 0.2 to 1.2). Explanatory survival analysis of secondary outcomes showed that those who sustained beneficial changes for two or more years reduced their risk of developing T2D. Conclusion Our results are consistent with other diabetes prevention trials. This study was designed as part of a larger study and although the sample size limits statistical significance, the results contribute to the evidence that T2D can be prevented by lifestyle changes in adults with IGT. In explanatory analysis small sustained beneficial changes in weight, physical activity or dietary factors were associated with reduction in T2D incidence.

Pan X, Li G, Hu Y, Wang J, Yang W, Hu Z, et al. **Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study.** Diabetes Care 1997;20(4):537-44.

Objective Individuals with impaired glucose tolerance (IGT) have a high risk of developing NIDDM. The purpose of this study was to determine whether diet and exercise interventions in those with IGT may delay the development of NIDDM, i.e., reduce the incidence of NIDDM, and thereby reduce the overall incidence of diabetic complications, such as cardiovascular, renal, and retinal disease, and the excess mortality attributable to these complications. Research design and methods In 1986, 110,660 men and women from 33 health care clinics in the city of Da Qing, China, were screened for IGT and NIDDM. Of these individuals, 577 were classified (using World Health Organization criteria) as having IGT. Subjects were randomized by clinic into a clinical trial, either to a control group or to one of three active treatment groups: diet only, exercise only, or diet plus exercise. Follow-up evaluation examinations were conducted at 2-year intervals over a 6-year period to identify subjects who developed NIDDM. Cox's proportional hazard analysis was used to determine if the incidence of NIDDM varied by treatment assignment. Results The cumulative incidence of diabetes at 6 years was 67.7% (95% CI, 59.8-75.2) in the control group compared with 43.8% (95% CI, 35.5-52.3) in the diet group, 41.1% (95% CI, 33.4-49.4) in the exercise group, and 46.0% (95% CI, 37.3-54.7) in the dietplus-exercise group (P < 0.05). When analyzed by clinic, each of the active intervention groups differed significantly from the control clinics (P < 0.05). The relative decrease in rate of development of diabetes in the active treatment groups was similar when subjects were stratified as lean or overweight (BMI < or > or = 25 kg/m2). In a proportional hazards analysis adjusted for differences in baseline BMI and fasting glucose, the diet, exercise, and diet-plus-exercise interventions were associated with 31% (P < 0.03), 46% (P < 0.0005), and 42% (P < 0.005) reductions in risk of developing diabetes, respectively. Conclusions Diet and/or exercise

interventions led to a significant decrease in the incidence of diabetes over a 6-year period among those with IGT.

Fysisk aktivitet, kosthold og tobakk

Vi fant 3 primærstudier om tiltak for å fremme økt fysisk aktivitet, sunnere kosthold og røykeslutt. Tabell 4 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 4. Kort beskrivelse av primærstudier om tiltak for å fremme økt fysisk aktivitet, sunnere kosthold og røykeslutt. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|--------------|---|--|------------|
| Ferrer 2009 | Pasienter i primærhelsetjeneste uten helseforsikring (USA) | Fysisk aktivitet, kosthold, røykeslutt | 2 måneder |
| Steptoe 1999 | Voksne i primærhelsetjeneste med risiko for hjerte- og karsykdom | Fysisk aktivitet, energiinntak, antall sigaretter/dag, BMI, blodtrykk, kolesterol | 4 måneder |
| Wister 2007 | Voksne med risiko for eller etablert hjerte- og karsykdom | Fysisk aktivitet, kosthold, risiko for hjerte- og karsykdom | 12 måneder |

Ferrer RL, Mody-Bailey P, Jaen CR, Gott S, Araujo S. **A medical assistant-based program to promote healthy behaviors in primary care.** ANN FAM MED 2009;7(6):504-12.

<u>Purpose</u> Most primary care patients have at least 1 major behavioral risk: smoking, risky drinking, low physical activity, or unhealthy diet. We studied the effectiveness of a medical assistant-based program to identify and refer patients with risk behaviors to appropriate interventions. Methods We undertook a randomized control trial in a practice-based research network. The trial included 864 adult patients from 6 primary care practices. Medical assistants screened patients for 4 risk behaviors and applied behavior specific algorithms to link patients with interventions. Primary outcomes were improved risk behaviors on standardized assessments. Secondary outcomes included participation in a behavioral intervention and the program's effect on the medical assistants' workfl ow and job satisfaction. Results Follow-up data were available for 55% of participants at a mean of 12 months. The medical assistant referral arm referred a greater proportion of patients than did usual care (67.4 vs 21.8%; P <.001) but did not achieve a higher success rate for improved behavioral outcomes (21.7 vs 16.9%; P = 0.19). Qualitative interviews found both individual medical assistant and organizational effects on program adoption. Conclusion Engaging more primary care team members to address risk behaviors improved referral rates. More extensive medical assistant

training, changes in practice culture, and sustained behavioral interventions will be necessary to improve risk behavior outcomes.

Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S. **Behavioural** counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. BMJ 1999;319:943-8.

Objective To measure the effect of behaviourally oriented counselling in general practice on healthy behaviour and biological risk factors in patients at increased risk of coronary heart disease. Design Cluster randomised controlled trial. Participants 883 men and women selected for the presence of one or more modifiable risk factors: regular cigarette smoking, high serum cholesterol concentration (6.5-9.0 mmol/l), and high body mass index (25-35) combined with low physical activity. Intervention Brief behavioural counselling, on the basis of the stage of change model, carried out by practice nurses to reduce smoking and dietary fat intake and to increase regular physical activity. Main outcome measures Questionnaire measures of diet, exercise, and smoking habits, and blood pressure, serum total cholesterol concentration, weight, body mass index, and smoking cessation (with biochemical validation) at 4 and 12 months. Results Favourable differences were recorded in the intervention group for dietary fat intake, regular exercise, and cigarettes smoked per day at 4 and 12 months. Systolic blood pressure was reduced to a greater extent in the intervention group at 4 but not at 12 months. No differences were found between groups in changes in total serum cholesterol concentration, weight, body mass index, diastolic pressure, or smoking cessation. <u>Conclusions</u> Brief behavioural counselling by practice nurses led to improvements in healthy behaviour. More extended counselling to help patients sustain and build on behaviour changes may be required before differences in biological risk factors emerge.

Wister A, Loewen N, Kennedy-Symonds H, McGowan B, McCoy B, Singer J. **One-year follow-up of a therapeutic lifestyle intervention targeting cardiovascular disease risk.** CMAJ Canadian Medical Association Journal 2007;177(8):859-65.

<u>Background</u> In this study, we tested the efficacy of a low intensity lifestyle intervention aimed at reducing the risk of cardiovascular disease among mid-life individuals. <u>Methods</u> We conducted a randomized controlled trial in which participants were randomly assigned either to receive a health report card with counselling (from a Telehealth nurse) on smoking, exercise, nutrition and stress or to receive usual care. The patients were divided into 2 groups on the basis of risk: the primary prevention group, with a Framingham risk score of 10% or higher

(intervention, n = 157; control, n = 158), and the secondary prevention group, who had a diagnosis of coronary artery disease (intervention, n = 153; control, n = 143). The primary outcome was a change in the Framingham global risk score between baseline and 1-year follow-up. Data were analyzed separately for the 2 prevention groups using an intention-to-treat analysis controlling for covariates. Results Within the primary prevention group, there were statistically significant changes for the treatment group relative to the controls, from baseline to year 1, in Framingham score (intervention, -3.10 [95% confidence interval (CI) -3.98 to -2.22]; control, -1.30 [95% CI - 2.18 to - 0.42]; p < 0.01) and scores for total cholesterol (intervention, -0.41 [95% CI -0.59 to -0.23]; control, -0.14 [95% CI -0.32 to 0.04]; p < 0.05), systolic blood pressure (intervention, -7.49 [95% CI -9.97 to -5.01]; control, -3.58 [95% CI -6.08 to -1.08]; p < 0.05), nutrition level (intervention, 0.30 [95% CI 0.13 to 0.47]; control, -0.05 [95% CI -0.22 to 0.12]; p < 0.01), and health confidence (intervention, 0.20 [95% CI 0.09 to 0.31]; control, 0.04 [95% CI -0.07 to 0.15]; p < 0.05), with adjustment for covariates. No significant changes in outcome variables were found for the secondary prevention group. <u>Interpretation</u> We found evidence for the efficacy of an intervention addressing multiple risk factors for primary prevention at 1 year using Framingham risk score report cards and telephone counselling.

Fysisk aktivitet, kosthold, tobakk og alkohol

Vi fant 2 primærstudier (6 publikasjoner) om tiltak for å fremme økt fysisk aktivitet, sunnere kosthold, røykeslutt og redusert bruk av alkohol. Tabell 5 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 5. Kort beskrivelse av primærstudier om tiltak for å fremme økt fysisk aktivitet, sunnere kosthold, røykeslutt og redusert bruk av alkohol. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|----------------------------|---|--|-----------|
| Koelewijn 2010 | Voksne i primærhelsetjeneste | Røyking, alkohol, fysisk aktivitet, kosthold | 4 uker |
| Aadal 2011 ^a | Voksne i befolkningen med høy risiko for hjerte- og karsykdom | Fysisk aktivitet | 6 måneder |
| Pisinger 2009 ^a | Voksne i befolkningen med høy risiko for hjerte- og karsykdom | Livskvalitet | 6 måneder |
| Toft 2008 ^a | Voksne i befolkningen med høy risiko for hjerte- og karsykdom | Energiinntak | 6 måneder |
| Toft 2009 ^a | Voksne i befolkningen med høy risiko for hjerte- og karsykdom | Alkoholkonsum | 6 måneder |
| von Huth 2008 ^a | Voksne i befolkningen med høy risiko for hjerte- og karsykdom | Fysisk aktivitet | 6 måneder |

Kolewijn-van Loon M, van der Weijden T, Ronda G, van Steenkiste B, Winkens B, Elwyn G, et al. **Improving lifestyle and risk perception through patient involvement in nurse-led cardiovascular risk management: a cluster-randomized controlled trial in primary care.** Preventive Medicine 2010;50:35-44.

Objective To determine if lifestyle improved at a short term through an intervention to involve patients in cardiovascular risk management by the practice nurse. Methods The IMPALA study (2006, the Netherlands) was a cluster-randomised controlled trial involving 25 general practices and 615 patients who were eligible for cardiovascular risk management. The intervention consisted of (1) individual 10year cardiovascular risk assessment, (2) risk communication, (3) use of a decision aid and (4) adapted motivational interviewing, applied by practice nurses in two consultations. Outcomes were smoking, alcohol, diet, physical activity and the secondary outcomes risk perception, anxiety, confidence about the decision and satisfaction with the communication, measured at baseline and after 12 weeks. Results Patients of both groups improved their lifestyle, but no relevant significant differences between the groups were found. Intervention group patients improved in terms of the appropriateness of risk perception, although not significantly. Intervention group patients improved significantly in terms of appropriateness of anxiety and were more satisfied with the communication compared to control group patients. Conclusion The intervention seems to have improved the patients' risk perception, anxiety and satisfaction with the communication, which are important conditions for shared decision making. However, we found no additional effect of the intervention on lifestyle.

Aadahl M, L, Toft U, Pisinger C, Jorgensen T. **Does a population-based** multifactorial lifestyle intervention increase social inequality in physical activity? The Inter99 study. Br J Sports Med 2011;45(3):209-15.

<u>Aim</u> To examine the effect of a multifactorial lifestyle intervention on 5-year change in physical activity (PA) and to explore whether length of education had an impact on the effect of the intervention. <u>Methods</u> Two random samples (high intervention group A, n=11 708; low intervention group B, n=1308) were invited for a health examination, assessment of absolute risk of ischemic heart disease and individual lifestyle counselling. The participation rate was 52.5%. High-risk individuals in group A were also offered group-based counselling on diet and PA and/or smoking cessation. High-risk individuals in group B were referred to usual care. All high-risk individuals were reinvited for examination and counselling after 1 and 3 years, and all participants were reexamined after 5 years. The control group (group C, n=5264,

response rate 61.1%) answered a mailed questionnaire. Change in self reported PA from baseline to 5-year follow-up was the main outcome. Level of education was classified as no vocational training, .4 years and >4 years. Data were analysed using longitudinal linear regression models with random intercepts. Results In men, the high-intensity intervention had a benefi cial effect on PA level after 5 years. The ageor time-related decrease in PA was approximately 30 min/week less compared to men in the control group (p<0.0001). Level of education had no significant impact on the effect of the intervention neither in men (p=0.39) nor in women (p=0.32). Conclusion A population-based multifactorial lifestyle intervention did not influence social inequality in PA.

Pisinger C, Ladelund S, Glumer C, Toft U, Aadahl M, Jorgensen T. **Five years of lifestyle intervention improved self-reported mental and physical health in a general population: the Inter99 study.** Prev Med 2009;49(5):424-8.

<u>Introduction</u> Self-reported health has been shown to predict mortality. We lack knowledge on whether a lifestyle intervention can improve self-reported mental and physical health in a general population. Methods Inter99, Denmark (1999–2006) is a randomised population-based intervention study. We screened for ischemic heart disease and repeatedly offered advice and assistance to obtain a healthier lifestyle. Health related quality of life was measured by Short Form 12 (SF-12); completed by 9322 atbaseline and 7719 at five-year follow-up. In linear mixed models we investigated the effect of the intervention on self-reported health over time. Results At baseline men had higher physical health-component scores (PCS) than women. Living with a partner, being employed, and being healthy was associated with high PCS. The mental health-component scores (MCS) showed the same sociodemographic differences, except that MCS increased with age. Significantly fewer participants in the intervention groups had decreased their PCS and MCS compared with the control group. Adjusted multilevel analyses confirmed that the intervention significantly improved physical- (p=0.008) and mental health (p<0.001) over time compared with the control group. Conclusion Screening for ischemic heart disease and offering lifestyle intervention had a significantly beneficial effect on mental and physical self-reported health in the long term in a general population.

Toft U, Kristoffersen L, Ladelund S, Ovesen L, Lau C, Borch-Johnsen K, et al. **The** impact of a population-based multi-factorial lifestyle intervention on changes in long-term dietary habits: the Inter99 study. Prev Med 2008;47(4):378-83.

<u>Objective</u> To evaluate the effectiveness of a population-based multi-factorial lifestyle intervention on long-term changes in dietary habits compared to a non-intervention control group. <u>Methods</u> The study was a randomized controlled lifestyle intervention

study, Inter99 (1999–2006), Copenhagen, Denmark, using a high-risk strategy. Participants in the intervention group (n=6 091) had at baseline a medical healthexamination and a face-to-face lifestyle counselling. Individuals at high risk of ischemic heart disease were repeatedly offered both individual and group-based counselling. The control group (n=3 324) was followed by questionnaires. Dietary habits were measured by a validated 48-item food frequency questionnaire and changes were analyzed by multilevel analyses. Results At the 5-year follow-up the intervention group compared to the control group had significantly increased their intake of vegetables (men: net-change: 23 g/week; p=0.04; women: net-change: 27 g/week; p=0.005) and decreased the intake of highly saturated fats used on bread and for cooking (men: OR=0.59 (0.41-0.86); women: OR=0.42 (0.30-0.59)). Significant effects on fruit and fish intake were found at the 3- year follow-up but the effect attenuated at the 5-year follow-up. Conclusion A population-based multifactorial lifestyle intervention promoted significant greater beneficial long-term dietary changes compared to the control group, especially the intake of vegetables and saturated fat was improved.

Toft U, Pisinger C, Aadahl M, Lau C, Linneberg A, Ladelund S, et al. **The impact of a population-based multi-factorial lifestyle intervention on alcohol intake: the Inter99 study.** Prev Med 2009;49(2-3):115-21.

<u>Purpose</u> To investigate the effect of screening and five years of multi-factorial lifestyle intervention on changes in alcohol intake in a general population. Methods The study was a pre-randomized intervention study on lifestyle, Inter99 (1999– 2006), Copenhagen, Denmark. Participants in the intervention group (n=6 091) had at baseline a medical health examination and a face-to-face lifestyle counselling. Individuals at high risk of ischemic heart disease were repeatedly offered both individual and group-based counselling. The control group (n=3 324)was followed by questionnaires. Alcohol intake was measured by questionnaires. Changes were analysed by multilevel analyses. Results Binge drinking decreased both in men and women at three and five-year follow-ups (men: five year: net-change: -0.13; p=0.03; women: five-year: net-change: -0.08; p=0.04). Furthermore, in women the ratio between wine and total alcohol was increased compared with the control group at five-year follow-up (net-change: 0.04; p = 0.01). In men with a high intake of alcohol (> 21 drinks per week) the effect on total alcohol intake was maintained at five-year follow-up (net-change: -3.7; p=0.01). No significant effects were found in women on total alcohol intake. Conclusion Multi-factorial lifestyle intervention, including low intensity alcohol intervention, improved long-term alcohol habits in a general population.

von Huth SL, Ladelund S, Borch-Johnsen K, Jorgensen T. **A randomized** multifactorial intervention study for prevention of ischaemic heart

disease (Inter99): the long-term effect on physical activity. SCAND J PUBLIC HEALTH 2008;36(4):380-8.

Aim To examine the effect of a randomized multiple risk factor intervention study for prevention of ischaemic heart disease (IHD) on the development in physical activity over a 36-month period. Methods Two random samples (high intensity intervention, group A, n=11,708; low intensity intervention, group B, n=1,308) were invited for a health examination, an assessment of absolute risk of developing IHD, and an individualized lifestyle intervention. The participation rate was 52.5%. Highrisk persons in group A were also offered diet/physical activity and/or smoking cessation group counselling. High-risk persons in group B were referred to their GP. High-risk persons were re-counselled after 12 and 36 months. The control group (group C, =55,264, response rate=61.3%) answered a mailed questionnaire. Data were analysed using longitudinal linear regression models with random effects. Main outcome Change in physical activity from baseline to 12- and 36-month followup. Results: In men, the high-intensity (group A) intervention had a beneficial effect at 12-month follow-up, whereas after 36 months both the high-intensity and the low-intensity (group B) intervention had a beneficial effect on the development in physical activity when compared with group C. This was regardless of baseline physical activity level. At 36-month follow-up there was no significant difference between groups A and B. There was no intervention effect among women. Conclusions Only men seemed to benefit from the intervention.

Kosthold

Vi fant 5 primærstudier (6 publikasjoner) om tiltak for å fremme sunnere kosthold. Tabell 6 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 6. Kort beskrivelse av primærstudier om tiltak for å fremme sunnere kosthold. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|-----------------------------|-------------------------------------|--|--------------|
| Ammermann 2003 | Voksne med høyt kolesterol | Kosthold | 6 måneder |
| Hall 2003 | Kvinner i/etter overgangsalderen | Kosthold, BMI, blodtrykk, kolesterolverdier, glukoseverdier, insulinverdier | 12 måneder |
| Swinburn 2001 | Voksne med nedsatt glukosetoleranse | Energiinntak, vekt, BMI, glukoseverdier, insulinverdier | 12 måneder |
| Howard 2006 | Kvinner i/etter overgangsalderen | Energiinntak, dødelighet og sykelighet i hjerte- og karsykdom | > 12 måneder |
| Ellingsen 2006a | Friske menn med høyt kolesterol | Energiinntak | 5 år |
| Ellingsen 2003 ^a | Friske men med høyt kolesterol | Dødelighet i iskemisk hjertesykdom | 5 år |

Ammerman AS, Keyserling TC, Atwood JR, Hosking JD, Zayed H, Krasny C. **A** randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol. Prev Med 2003;36(3):340-51.

Background Many rural residents do not have access to high-quality nutrition counseling for high blood cholesterol. The objective of this study was to assess the effectiveness of an intervention program designed to facilitate dietary counseling for hypercholesterolemia by rural public health nurses. Methods Eight health departments (216 participants) were randomized to give the special intervention (SI) and nine (252 participants) to give the minimal intervention (MI). The SI consisted of three individual diet counseling sessions given by a public health nurse, using a structured dietary intervention (Food for Heart Program), referral to a nutritionist if lipid goals were not achieved at 3-month follow-up, and a reinforcement phone call and newsletters. Diet was assessed by the Dietary Risk Assessment (DRA), a validated food frequency questionnaire, at baseline, 3-, and 12-month follow-up; blood lipids and weight were assessed at baseline, 3-, 6-, and 12-month follow-up. Results Participants were largely female (71%), older (mean age 55), and white (80%). At 3-month follow-up, the average reduction (indicating dietary improvement) in total Dietary Risk Assessment score was 3.7 units greater in the SI group (95% confidence interval [CI] 1.9 to 5.5, P = 0.0006), while both groups experienced a similar reduction in blood cholesterol, 14.1 mg/dL (0.37 mmol/L) for SI and 14.5 mg/dL (0.38 mmol/L) for minimal intervention group (difference -0.4 mg/dL [-0.010 mmol/L], 95% CI -12.5 to 11.7 [-0.32 to 0.30], P = 0.9). At 12-month follow-up, the reduction in total Dietary Risk Assessment score was 2.1 units greater in the SI group (95% CI 0.8 to 3.5, P = 0.005), while the reduction in blood cholesterol was similar in both groups, 18.4 mg/dL (0.48 mmol/L) for SI and 15.6 mg/dL (0.40 mmol/L) for minimal intervention group (difference 2.8 mg/dL [0.07 mmol/L, 95% CI -7.5 to 13.1 [-0.19 to 0.34], P = 0.6). During follow-up, weight loss was greater in the SI group; the difference between groups was statistically significant at 3 (1.9 lb [0.86 kg], 95% CI 0.3 to 3.4 [0.14 to 1.55], P = 0.022) and 6 months (2.1 lb [0.95 kg], 95% CI 0.1 to 4.1 [0.04 to 1.86], P = 0.04). At 12 months, the difference was not significant (1.6 lb [0.73 kg], 95% CI -0.05 to 3.7 [-0.02 to 1.68], P = 0.13). <u>Conclusions</u> Improvement in self-reported dietary intake was significantly greater in the SI group, while reduction in blood cholesterol was similar in both groups.

Hall D, Feng Z, George V, Lewis C, Oberman A, Huber M, et al. **Low-fat diet: effect on anthropmetrics, blood pressure, glucose, and insulin in older women.** Ethnicity & Disease 2003;13:337-43.

Objective The Women's Health Trial: Feasibility Study in Minority Populations (WHT: FSMP) documented that a low-fat diet was associated with a reduced fat intake in older women of diverse ethnic backgrounds. The purpose of the current study was to examine the effect of the low-fat diet on anthropometric and biochemical variables. Design Randomized clinical trial in 2,208 postmenopausal women, 50 to 79 years of age. Results The decrease in fat intake correlated directly with a decrease in body weight (r=.22, P<.001). After 6 months, the intervention group had an average weight loss of 1.8 kg. Body mass index decreased 0.7 kg/m2. Waist circumference decreased 1.8 cm. All of these changes were statistically significant, compared to changes in the control group (P<.01). Changes in systolic (-3.1 mm Hg) and diastolic (-1.1 mm Hg) blood pressures (BP) occurred in the intervention group. The decrease in systolic BP reached statistical significance (P=.02), relative to the control group. Decreases in plasma glucose were small (-0.2 mmol/L) in the intervention group, although there was a trend for difference from the control group (P=.11). Decreases in serum insulin levels were small (-0.5 microIU/mL) in the intervention group, although there was, again, a trend for difference from the control group. Conclusions In older White, Black, and Hispanic women, a long-term low-fat dietary intervention was accompanied by modest, but statistically significant, decreases in body weight and anthropometric indices, without any particular attempt being made to reduce calories. Changes in glucose and insulin were small. The long-term biological significance of the glucose and insulin changes is unknown.

Swinburn B, Metcalf P, Ley S. Long-term (5-year) effects of a reduced-fat diet intervention in individuals with glucose intolerance. Diabetes Care 2001;24:619-24.

Objective To determine whether reducing dietary fat would reduce body weight and improve long-term glycemia in people with glucose intolerance. Research design and methods A 5-year Follow-up of a 1-year randomized controlled trial of a reduced-fat ad libitum diet versus a usual diet. Participants with glucose intolerance (2-h blood glucose 7.0-11.0 mmol/l) were recruited from a Workforce Diabetes Survey. The group that was randomized to a reduced-fat diet participated in monthly small-group education sessions on reduced-fat eating for 1 year. Body weight and glucose tolerance were measured in 136 participants at baseline 6 months, and 1 year (end of intervention), with follow-up at 2 years (n = lo4), 3 years (n = 99), and 5 years (n = 103). Results Compared with the control group, weight decreased in the reduced-fat-diet group (P < 0.0001); the greatest difference was noted at 1 year (-3.3 kg), diminished at subsequent follow-up (-3.2 kg at 2 years and -1.6 kg at 3 years), and was no longer present by 5 years (1.1 kg). Glucose tolerance also improved in patients on the reduced-fat diet; a lower proportion had type 2 diabetes or impaired glucose tolerance at 1 year (47 vs. 67%, P < 0.05), but in subsequent years, there

were no differences between groups. However, the more compliant 50% of the intervention group maintained lower fasting and 2-h glucose at 5 years (P = 0.041 and P = 0.026 respectively) compared with control subjects. <u>Conclusions</u> The natural history for people at high risk of developing type 2 diabetes is weight gain and deterioration in glucose tolerance. This process may be ameliorated through adherence to a reduced fat intake

Howard BV, Van HL, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, et al. **Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial.**JAMA 2006;295(6):655-66.

Context Multiple epidemiologic studies and some trials have linked diet with cardiovascular disease (CVD) prevention, but long-term intervention data are needed. Objective To test the hypothesis that a dietary intervention, intended to be low in fat and high in vegetables, fruits, and grains to reduce cancer, would reduce CVD risk. Design, Setting, and Participants Randomized controlled trial of 48 835 postmenopausal women aged 50 to 79 years, of diverse backgrounds and ethnicities, who participated in the Women's Health Initiative Dietary Modification Trial. Women were randomly assigned to an intervention (19 541 [40%]) or comparison group (29 294 [60%]) in a free-living setting. Study enrollment occurred between 1993 and 1998 in 40 US clinical centers; mean follow-up in this analysis was 8.1 years. <u>Intervention</u> Intensive behavior modification in group and individual sessions designed to reduce total fat intake to 20% of calories and increase intakes of vegetables/ fruits to 5 servings/d and grains to at least 6 servings/d. The comparison group received diet-related education materials. Main Outcome Measures Fatal and nonfatal coronary heart disease (CHD), fatal and nonfatal stroke, and CVD (composite of CHD and stroke). Results By year 6, mean fat intake decreased by 8.2% of energy intake in the intervention vs the comparison group, with small decreases in saturated (2.9%), monounsaturated (3.3%), and polyunsaturated (1.5%) fat; increases occurred in intakes of vegetables/ fruits (1.1 servings/d) and grains (0.5 serving/d). Low-density lipoprotein cholesterol levels, diastolic blood pressure, and factor VIIc levels were significantly reduced by 3.55 mg/dL, 0.31 mm Hg, and 4.29%, respectively; levels of high-density lipoprotein cholesterol, triglycerides, glucose, and insulin did not significantly differ in the intervention vs comparison groups. The numbers who developed CHD, stroke, and CVD (annualized incidence rates) were 1000 (0.63%), 434 (0.28%), and 1357 (0.86%) in the intervention and 1549 (0.65%), 642 (0.27%), and 2088 (0.88%) in the comparison group. The diet had no significant effects on incidence of CHD (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.90-1.06), stroke (HR, 1.02; 95% CI, 0.90-1.15), or CVD (HR, 0.98; 95% CI, 0.92-1.05). Excluding participants with baseline CVD (3.4%), the HRs (95% CIs) for CHD and stroke were 0.94 (0.86-1.02) and 1.02 (0.90-1.17), respectively. Trends toward greater reductions in CHD risk were observed in those

with lower intakes of saturated fat or trans fat or higher intakes of vegetables/fruits. <u>Conclusions</u> Over a mean of 8.1 years, a dietary intervention that reduced total fat intake and increased intakes of vegetables, fruits, and grains did not significantly reduce the risk of CHD, stroke, or CVD in postmenopausal women and achieved only modest effects on CVD risk factors, suggesting that more focused diet and lifestyle interventions may be needed to improve risk factors and reduce CVD risk.

Ellingsen I, Hjermann I, Abdelnoor M, Hjerkinn EM, Tonstad S. **Dietary and antismoking advice and ischemic heart disease mortality in men with normal or high fasting triacylglycerol concentrations: a 23-y follow-up study.** Am J Clin Nutr 2003;78(5):935-40.

Background In the Oslo Diet and Antismoking Trial, 1232 highrisk men aged 40-49 y were randomly assigned to either a lifestyle intervention group or a control group for 5 y. The study showed a significant reduction in ischemic heart disease (IHD) events in the intervention group. Objective Our objective was to examine this cohort 23 y after the start of the trial. <u>Design</u> We examined the effect of group assignment on IHD mortality in subjects with a normal (below the median; range: 0.69-2.00 mmol/L; n = 615) or a high (at or above the median; range: 2.01–13.80 mmol/L; n = 617) fasting triacylglycerol concentration in 1972–1973 (at inclusion into the study). We recorded vital status on 31 December 1996 and ascertained causes of death by linkage to Statistics Norway. Results In the men with a high triacylglycerol concentration, IHD death occurred in 25 (8.13%) subjects in the intervention group and in 44 (14.2%) subjects in the control group (relative risk: 0.57; 95% CI: 0.36, 0.91; P = 0.02). An adjusted Cox proportional hazards model yielded a hazard ratio of 0.56 (95% CI: 0.34, 0.93; P = 0.027). In the men with a normal triacylglycerol concentration, the intervention had no detectable effect on IHD mortality (adjusted hazard ratio: 1.10; 95% CI: 0.66, 1.83; P = 0.7). Conclusions These data suggest that advice to change diet and smoking habits reduced the relative risk of IHD mortality after 23 y in men with high triacylglycerol concentrations. Men with normal triacylglycerol concentrations did not appear to achieve this long-term benefit of lifestyle intervention.

Ellingsen I, Hjerkinn EM, Arnesen H, Seljeflot I, Hjermann I, Tonstad S. **Follow-up of diet and cardiovascular risk factors 20 years after cessation of intervention in the Oslo Diet and Antismoking Study.** Eur J Clin Nutr 2006;60(3):378-85.

<u>Objective</u> The Oslo Diet and Antismoking study was a 5-year randomised trial initiated in 1972–1973, which studied the effect of dietary change and smoking cessation for the prevention of coronary heart disease among high-risk middle-aged men. To test the long-term maintenance of lifestyle change, we examined diet and

cardiovascular risk factors in subjects initially randomized to the control and intervention groups 20 years after cessation of the intervention. Subjects and design Of the original cohort that included 1232 participants, 910 survivors were identified in 1997 and cardiovascular risk factors were measured in 563 (62%) in 1997-1999. Of these, 558 (99%) also completed questionnaires about their food intake and attitudes to health and diet. Results Cigarette smoking was nearly halved between baseline and 20-year follow-up in each of the intervention and control groups (P<0.001 within groups), but did not differ between the intervention group (39%) versus the control group (34%); P = 0.07. Body mass index increased by 1.4±2.6 and 1.6±2.6 kg/m2 between baseline and 20-year follow-up in the intervention and control groups, respectively (P<0.001 within groups; NS between groups). Serum total cholesterol and triglyceride concentrations decreased substantially in subjects treated or untreated with statins (P<0.001 within the intervention and control groups) but did not differ between the groups (total cholesterol change of -1.4±1.3 and -1.3±1.2 mmol/l, respectively, and triglyceride change of -0.5±1.0 mmol/l in both groups). Men in the intervention group reported a less atherogenic fat quality score and lower intakes of fat, saturated fat and cholesterol, higher intakes of long chain polyunsaturated fatty acids, protein and beta-carotene and greater attention to lifestyle and change of diet than the control group (all P<0.05). The fatty acid concentrations did not differ, however, between the intervention and control groups (P>0.05). Conclusions No long-term differences in smoking rates or lipid concentrations between the intervention and control groups were observed in the surviving attendees two decades after the end of the trial. Lifestyle intervention still influenced the dietary intake, though modestly.

Røykeslutt

Systematiske oversikter

Vi fant 3 systematiske oversikter om effekter av tiltak for å fremme røykeslutt. Tabell 7 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 7. Kort beskrivelse av systematiske oversikter om effekter av tiltak for å fremme røykeslutt.

| Forfatter | Populasjon | Tema | Utfall | Varighet |
|------------|--|--|-------------------------|--------------------------|
| Hajek 2009 | Voksne røykere som: Hadde sluttet/ Var påtvunget avholdenhet/ Deltok i røykesluttprogrammer | Tobakk: forebygging av tilbakefall | Avholdenhet fra røyking | 1 sesjon – 12 måneder |
| Lai 2010 | Voksne røykere | Tobakk | Røykeslutt | 1 – 4 samtaler |
| Rice 2008 | Voksne røykere | Tobakk | Røykeslutt | 1 – 12 sesjoner |

Hajek P, Stead LF, West R, Jarvis M, Lancaster T. **Relapse prevention** interventions for smoking cessation. Cochrane Database of Systematic Reviews 2009;(1)

Background A number of treatments can help smokers make a successful quit attempt, but many initially successful quitters relapse over time. Several interventions were proposed to help prevent relapse. Objectives To assess whether specific interventions for relapse prevention reduce the proportion of recent quitters who return to smoking. Search strategy We searched the Cochrane Tobacco Addiction Group trials register in August 2008 for studies mentioning relapse prevention or maintenance in title, abstracts or keywords. Selection criteria Randomized or quasi-randomized controlled trials of relapse prevention interventions with a minimum follow up of six months. We included smokers who quit on their own, or were undergoing enforced abstinence, or who were participating in treatment programmes. We included trials that compared relapse prevention interventions to a no intervention control, or that compared a cessation programme with additional relapse prevention components to a cessation programme alone. Data collection and analysis Studies were screened and data extracted by one author and checked by a second. Disagreements were resolved by discussion or referral to a third author. Main results Fifty-four studies met inclusion criteria, but were heterogeneous in terms of populations and interventions. We considered 36 studies that randomized abstainers separately from studies that randomized participants prior to their quit date. Looking at studies of behavioural interventions which randomised abstainers, we detected no benefit of brief and 'skills-based' relapse prevention methods for women who had quit smoking due to pregnancy, or for smokers undergoing a period of enforced abstinence during hospitalisation or military training. We also failed to detect significant effects of behavioural interventions in trials in unselected groups of smokers who had quit on their own or with a formal programme. Amongst trials randomising smokers prior to their guit date and evaluating the effect of additional relapse prevention components we also found no evidence of benefit of behavioural interventions in any subgroup. Overall, providing training in skills thought to be needed for relapse avoidance did not reduce relapse, but most studies did not use experimental designs best suited to the task, and had limited power to detect expected small differences between interventions. For pharmacological interventions, extended treatment with varenicline significantly reduced relapse in one trial (risk ratio 1.18, 95% confidence interval 1.03 to 1.36). Pooling of five studies of extended treatment with bupropion failed to detect a significant effect (risk ratio 1.17; 95% confidence interval 0.99 to 1.39). Two small trials of oral nicotine replacement treatment (NRT) failed to detect an effect but treatment compliance was low and in two other trials of oral NRT randomizing short-term abstainers there was a significant effect of intervention. Authors' conclusions At the moment there is insufficient evidence to support the use of any specific behavioural intervention for helping smokers who have successfully quit for a short time to avoid relapse. The verdict is strongest for interventions

focusing on identifying and resolving tempting situations, as most studies were concerned with these. There is little research available regarding other behavioural approaches. Extended treatment with varenicline may prevent relapse. Extended treatment with bupropion is unlikely to have a clinically important effect. Studies of extended treatment with nicotine replacement are needed.

Lai Douglas TC, Cahill K, Qin Y, Tang J. **Motivational interviewing for smoking cessation.** Cochrane Database of Systematic Reviews: Reviews 2010 Issue 1 John Wiley & Sons, Ltd Chichester, UK DOI: 10.1002/14651858.CD006936.pub2. In: Chichester (UK): John Wiley & Sons, Ltd; 2010.

Background Motivational Interviewing (MI) is a directive patient-centred style of counselling, designed to help people to explore and resolve ambivalence about behaviour change. It was developed as a treatment for alcohol abuse, but may help smokers to a make a successful attempt to quit. Objectives To determine the effects of motivational interviewing in promoting smoking cessation. Search strategy We searched the Cochrane Tobacco Addiction Group Specialized Register for studies with terms (motivational OR motivation OR motivating OR motivate OR behavi* OR motivat*) and (interview* OR session* OR counsel* OR practi*) in the title or abstract, or as keywords. Date of the most recent search: April 2009. Selection criteria Randomized controlled trials in which motivational interviewing or its variants were offered to smokers to assist smoking cessation. Data collection and analysis We extracted data in duplicate. The main outcome measure was abstinence from smoking after at least six months follow up. We used the most rigorous definition of abstinence in each trial, and biochemically validated rates where available. Subjects lost to follow up were treated as continuing smokers. We performed meta-analysis using a fixed-effect Mantel-Haenszel model. Main results We identified 14 studies published between 1997 and 2008, involving over 10,000 smokers. Trials were conducted in one to four sessions, with the duration of each session ranging from 15 to 45 minutes. All but two of the trials used supportive telephone contacts, and supplemented the counselling with self-help materials. MI was generally compared with brief advice or usual care in the trials. Interventions were delivered by primary care physicians, hospital clinicians, nurses or counsellors. Our meta-analysis of MI versus brief advice or usual care yielded a modest but significant increase in quitting (RR 1.27; 95% CI 1.14 to 1.42). Subgroup analyses suggested that MI was effective when delivered by primary care physicians (RR 3.49; 95% CI 1.53 to 7.94) and by counsellors (RR 1.27; 95% CI 1.12 to 1.43), and when it was conducted in longer sessions (more than 20 minutes per session) (RR 1.31; 95% CI 1.16 to 1.49). Multiple session treatments may be slightly more effective than single sessions, but both regimens produced positive outcomes. Evidence is unclear at present on the optimal number of follow-up calls. There was variation across the trials in treatment fidelity. All trials used some variant of motivational interviewing.

Critical details in how it was modified for the particular study population, the training of therapists and the content of the counselling were sometimes lacking from trial reports. <u>Authors' conclusions</u> Motivational interviewing may assist smokers to quit. However, the results should be interpreted with caution due to variations in study quality, treatment fidelity and the possibility of publication or selective reporting bias.

Rice VH, Stead LF. **Nursing interventions for smoking cessation.** Cochrane Database of Systematic Reviews: Reviews. Cochrane Database of Systematic Reviews 2008 Issue 1.Chichester (UK): John Wiley & Sons, Ltd; 2008.

Background Healthcare professionals, including nurses, frequently advise patients to improve their health by stopping smoking. Such advice may be brief, or part of more intensive interventions. Objectives To determine the effectiveness of nursingdelivered smoking cessation interventions. Search strategy We searched the Cochrane Tobacco Addiction Group specialized register and CINAHL in July 2007. Selection criteria Randomized trials of smoking cessation interventions delivered by nurses or health visitors with follow up of at least six months. Data collection and analysis Two authors extracted data independently. The main outcome measure was abstinence from smoking after at least six months of follow up. We used the most rigorous definition of abstinence for each trial, and biochemically validated rates if available. Where statistically and clinically appropriate, we pooled studies using a Mantel-Haenszel fixed effect model and reported the outcome as a risk ratio (RR) with 95% confidence interval (CI). Main results Forty-two studies met the inclusion criteria. Thirty-one studies comparing a nursing intervention to a control or to usual care found the intervention to significantly increase the likelihood of quitting (RR 1.28, 95% CI 1.18 to 1.38). There was heterogeneity among the study results, but pooling using a random effects model did not alter the estimate of a statistically significant effect. In a subgroup analysis there was weaker evidence that lower intensity interventions were effective (RR 1.27, 95% CI 0.99 to 1.62). There was limited indirect evidence that interventions were more effective for hospital inpatients with cardiovascular disease than for inpatients with other conditions. Interventions in non-hospitalized patients also showed evidence of benefit. Nine studies comparing different nurse delivered interventions failed to detect significant benefit from using additional components. Five studies of nurse counselling on smoking cessation during a screening health check, or as part of multifactorial secondary prevention in general practice (not included in the main meta-analysis) found nursing intervention to have less effect under these conditions. Authors' conclusions The results indicate the potential benefits of smoking cessation advice and/or counselling given by nurses to patients, with reasonable evidence that intervention is effective. The evidence of an effect is weaker when interventions are brief and are provided by nurses whose main role is not health promotion or smoking cessation. The challenge will be to incorporate smoking behaviour

monitoring and smoking cessation interventions as part of standard practice, so that all patients are given an opportunity to be asked about their tobacco use and to be given advice and/or counselling to quit along with reinforcement and follow up.

Primærstudier

Vi fant 5 primærstudier om tiltak for å fremme økt fysisk aktivitet. Tabell 8 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 8. Kort beskrivelse av primærstudier om tiltak for å fremme røykeslutt. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet |
|----------------|---|------------|---|
| Young 2008 | Voksne røykere i primærhelsetjeneste | Røykeslutt | 4 uker |
| Lancaster 1999 | Voksne røykere i primærhelsetjeneste | Røykeslutt | 6 uker |
| Hollis 1993 | Voksne røykere i primærhelsetjeneste | Røykeslutt | 8 uker |
| Wadland 2001 | Voksne røykere | Røykeslutt | 8 uker |
| Pisinger 2010 | Voksne røykere i primærhelsetjeneste | Røykeslutt | Gruppe: 5 x 2 timer Internett: 13 sesjoner, 6 måneder |

Young JM, Girgis S, Bruce TA, Hobbs M, Ward JE. **Acceptability and effectiveness of opportunistic referral of smokers to telephone cessation advice from a nurse: A randomised trial in Australian general practice.** BMC Fam Pract 2008;9, 2008. Article Number: 16.

Background GPs often lack time to provide intensive cessation advice for patients who smoke. This study aimed to determine the effectiveness of opportunistic referral of smokers by their GP for telephone cessation counselling by a trained nurse. Methods Adult smokers (n = 318) attending 30 GPs in South Western Sydney, Australia were randomly allocated to usual care or referral to a telephone-based program comprising assessment and stage-based behavioural advice, written information and follow-up delivered by a nurse. Selfreported point prevalence abstinence at six and 12 months was compared between groups. Characteristics of patients who accepted and completed the intervention were investigated. Results Of 169 smokers randomised to the intervention, 76 (45%) consented to referral. Compared with smokers in 'pre-contemplation', those further along the stage-ofchange continuum were significantly more likely to consent (p = 0.003). Those further along the continuum also were significantly more likely to complete all four calls of the intervention (OR 2.6, 95% CI:0.8-8.1 and OR 8.6, 95% CI: 1.7-44.4 for 'contemplation' and 'preparation' respectively). At six months, there was no significant difference between groups in point prevalence abstinence (intention to treat) (9% versus 8%, p = 0.7). There was no evidence of differential intervention

effectiveness by baseline stage-of-change (p = 0.6) or patient sex (p = 0.5). At 12 months, point prevalence abstinence in the intervention and control groups was 8% and 6% respectively (p = 0.6). Conclusion Acceptance of opportunistic referral for nurse delivered telephone cessation advice was low. This trial did not demonstrate improved quit rates following the intervention. Future research efforts might better focus support for those patients who are motivated to quit.

Lancaster T, Dobbie W, Vos K, Yudkin P, Murphy M, Fowler G. **Randomized trial of nurse-assisted strategies for smoking cessation in primary care.**British Journal of General Practice 1999;49:191-4.

Background Brief advice to stop smoking from general practitioners (GPs) has been repeatedly shown to increase smoking cessation by a small, but measurable amount. Some studies have suggested that adding more intensive interventions to brief advice may increase its effectiveness, but it is unclear whether this is true in general practice. Aims To determine whether brief advice from a doctor together with counselling and follow-up from a trained practice nurse is more effective than brief advice alone in helping people to stop smoking. Methods The design was a randomized controlled trial. Four hundred and ninety-seven general practice patients aged older than 18 years and smoking at least one cigarette per day in six general practices in Oxfordshire, Berkshire, and Buckinghamshire were randomized to one of two interventions: brief verbal or written advice from a GP plus extended counselling and follow-up from a trained practice nurse; brief advice from a GP alone. The primary outcome was sustained abstinence from smoking at three and 12 months. A secondary outcome was forward movement in the stages of change cycle. Results The proportion showing sustained abstinence was 3.6% in the extended counselling group, and 4.4% in the brief advice group (difference = -0.8%; 95% confidence interval = -4.3% to 2.6%). Seventy-four (30%) of those randomized to extended counselling actually took up this offer. No significant progression in stages of change was detected between the two groups. <u>Conclusions</u> In unselected general practice patients who smoke, brief advice from a GP combined with intensive intervention and follow-up by a practice nurse is no more effective than brief advice alone.

Hollis J, Lichtenstein E, Vogt T, Stevens V, Biglan A. **Nurse-assisted counseling for smokers in primary care.** Annals of Internal Medicine 1993;118:521-5.

<u>Objective</u> Physician-delivered advice to stop smoking is effective, but time demands often reduce the number of smokers who receive assistance. We evaluated three nurse-assisted interventions designed to minimize physician burden and increase counseling in primary care settings. <u>Design</u> Randomized controlled trial with a 12-month follow-up. <u>Setting</u> Internal medicine and family practice offices in a health

maintenance organization. Participants Smokers (n = 3161) who were patients of participating physicians or other medical care providers (n = 60). <u>Intervention</u> Medical care providers delivered a 30-second stop-smoking prompt to 2707 smokers and referred them to an on-site nurse smoking counselor. The nurse randomly provided a two-page pamphlet (advice control) or one of three nurse-assisted interventions: 1) self-quit training; 2) referral to a group cessation program; or 3) a combination of self-quit training and referral. Each nurse-delivered intervention included a 10-minute video, written materials, and a follow-up phone call. Results Physicians delivered brief advice to 86% of identified smokers during the 1-year program. The proportion of participants reporting abstinence after both 3 and 12 months of follow-up nearly doubled (P = 0.01) for the nurse-assisted self-quit (7.1%), group-referral (7.6%), and combination (6.9%) interventions, compared to brief physician advice alone (3.9%) (P < 0.05). Saliva cotinine tests confirmed these effects (P < 0.004), although quit rates were lower (3.4%, 4.7%, 4.3%, and 2.3%, respectively) because roughly one half of quitters chose not to provide a saliva sample and were counted as smokers. Conclusion Involving nurses in counseling smokers reduces physician burden, makes counseling more likely, and significantly increases cessation rates compared with brief physician advice alone.

Wadland WC, Soffelmayr B, Ives K. **Enhancing smoking cessation of low-income smokers in managed care.** J Fam Pract 2001;FAM.(2):138-44.

<u>Background</u> Although office-based and telephone support, services enhance the rate ofsmoking cessation in managed care systems, it is not clear whether such services are effective for very low-income smokers. We evaluated the comparative effectiveness of usual care (physician- delivered advice and follow-up) and usual care enhanced by 6 computer-assisted telephonic counseling sessions by office nurses and telephone counselors for smoking cessation in very low-income smokers in Medicaid managed care. Methods Randomized clinical trial comparing the 2 approaches was conducted in 3 Michigan community health centers. All clinicians and center staff received standard training in usual care. Selected nurses and telephone counselors received special training in a cornputer-assisted counseling program focusing on relapse prevention. Results The majority of the study population (233 adult srnokers with telephones) were white (64%) women (70%) with annual incomes of less than S10,000 (79%)) and with prescriptions of nicotine replacement therapy (>90%). At 3 months, quit rates (smoke-free status verified by carbon monoxide monitors) were 8,1% in the usual-care group and 21 % in the telephonic-counseling group (p = 0.009) by intention-to-treat analysis. Special tracking methods were successful in maintaining participants in treatment. Conclusions Smoking cessation rates are enhanced in a population of very lowincome smokers if individualized telephonic counseling is provided- State and Medicaid managed care plans should consider investing in both office-based nurse and centralized telephonic-counseling services for low-income smokers.

Pisinger C, Jorgensen MM, Moller NE, Dossing M, Jorgensen T. A cluster randomized trial in general practice with referral to a group-based or an Internet-based smoking cessation programme. J PUBLIC HEALTH 2010;32(1):62-70.

Background Reviews state that there is a room for improvements of smoking cessation (SC) intervention in general practice. Methods In 2005, all 61 general practitioners (GPs) in four municipalities in Copenhagen, Denmark, were invited to participate. Twenty-four GPs accepted and were cluster randomized to one of three groups: Group A, referral to group-based SC counselling (national model), n = 10; Group B, referral to internet-based SC programme (newly developed), n = 8; or Group C, no referral ('do as usual'), n 1/4 6. A total of 1518/1914 smokers were included, and 760 returned a questionnaire at 1-year follow-up. Results The participating GPs reported significantly more SC counselling than GPs who refused participation (P = 0.04). Self-reported point abstinence was 6.7% (40/600), 5.9% (28/476) and 5.7% (25/442) in Groups A, B and C, respectively. Only 40 smokers attended group-based SC counselling, and 75 logged in at the internet-based SC programme. In cluster analyses, we found no significant additional effect of referral to group-based (OR: 1.05; 95% CI: 0.6–1.8) or internet-based SC programmes (OR: 0.91; 95% CI: 0.6–1.4). Conclusions We found no additional effect on cessation rates of GPs' referring to group-based SC counselling or internet-based SC programme. This finding might, to some degree, be explained by the short time used by the GPs on SC counselling and the selection of the participating doctors.

Alkohol

Vi fant 5 primærstudier om tiltak for å redusere bruk av alkohol. Tabell 9 beskriver kort populasjon, utfall og varighet på tiltakene.

Tabell 9. Kort beskrivelse av primærstudier om tiltak for å redusere bruk av alkohol. Studiene er presentert i stigende rekkefølge basert på tiltakets varighet.

| Forfatter | Populasjon | Utfall | Varighet | |
|--------------|---------------------------------------|---------------|----------|--|
| Ball 2007 | Voksne med høyt alkoholkonsum | Alkoholkonsum | 3 uker | |
| Gordon 2003 | Eldre med risikofylt alkoholkonsum | Alkoholkonsum | 6 uker | |
| Kelly 2000 | Voksne kvinner | Alkoholkonsum | 6 uker | |
| Maisto 2001 | Eldre med risikofylt alkoholkonsum | Alkoholkonsum | 6 uker | |
| Sellman 2001 | Voksne med alkoholavhengighet | Alkoholkonsum | 6 uker | |

Ball S, Todd M, Tennen H, Armeli S, Mohr C, Affleck G, et al. **Brief motivational enhancing and coping skills interventions for heavy drinking.** Addictive Behaviors 2007;32:1105-18.

Background Two brief (3-session) interventions were evaluated in a community sample of 98 non-dependent heavy drinking adults. Methods Three weeks of intensive daily monitoring of drinking using a hand-held computer were completed before and after a 3-week intervention phase in which participants were randomly assigned to a brief coping skills, brief motivational enhancement, or waiting list condition. Results Waiting list participants drank more before, during, and after the brief intervention than brief intervention subjects, but all participants demonstrated reductions in drinking amount and frequency. No differences in drinking were found between the two brief interventions. Conclusion The potential value of intensive daily monitoring as a tool for non-alcohol dependent individuals interested in reducing their drinking was considered.

Gordon A, Conigliaro J, Maisto S, McNeil M, Kraemer K, Kelley M. **Comparison of consumtion effects of brief interventions for hazardous drinking elderly.** Substance Use & Misuse 2003;38(8):1017-35.

Objective We sought to determine if Brief Interventions [BIs, Motivational Enhancement (ME), and Brief Advice (BA)] reduced alcohol consumption among hazardous alcohol drinking elderly (65 years or older) and whether the elderly responded similarly to younger populations. Methods In 12 primary care offices from October 1995 to December 1997, we screened 13,438 patients of whom 2702 were elderly (180 were hazardous drinkers). Forty-five elderly enrollees were randomized to receive ME (n = 18), BA (n = 12), and Standard Care (SC, n = 12). Results At baseline, the elderly drank more alcohol and abstained fewer days than the younger cohort (p<0.05). During the year, the elderly in ME, BA, and SC intervention arms increased the number of days abstained, decreased the number of drinks per day, and reduced the number of total days per month drinking. There were trends toward decreases in the alcohol consumption measures in the ME and BA treatment arms compared to SC. The elderly's response to all interventions was similar to that of the younger cohort. Conclusion This study suggests that hazardous alcohol consumption in the elderly is common and that BIs reduce alcohol consumption in the elderly similar to younger populations.

Kelly A, Halford K, Young R. Maritally distressed women with alcohol problems: the impact of a short term alcohol-focused intervention on drinking behaviour and marital satisfaction. Addiction 2000;95(10):1537-49.

Aim To evaluate the efficacy of a short-term alcohol-focused intervention for maritally distressed women, and to explore changes in relationship functioning. Design Participants were assigned randomly to an alcohol-focused treatment or to a waiting-list control group. The waiting-list control group began the intervention at 1month follow-up. Setting The intervention took place at a research and training centre offering outpatient psychology services to the community. Participants A sample of 32 women with alcohol and marital problems were recruited through the media. Participants reported protracted alcohol problems, moderate to severe impact of alcohol on social and occupational functioning, and moderate to severe marital distress. Measurements Measures of average alcohol consumption, marital distress, relational efficacy and depression were administered at pre- and posttherapy, and at 1, 6 and 12-month follow-up. Intervention The intervention involved six 1-hour sessions, consisting of clinical assessment, motivational interviewing, cognitive-behavioural strategies and relapse prevention. Results At 1-month followup, the intervention was associated with statistically significant improvements in alcohol consumption, marital satisfaction, relational efficacy and depression, and these effects were sustained at 12-month follow-up. Conclusions At 1-month followup the intervention was associated with decreased alcohol consumption and depression, and increased marital satisfaction and relational efficacy, with evidence of maintained effects at 12-month follow-up. However, it is unlikely that reduced problem drinking and improved confidence in resolving problems were the only factors producing low marital quality in these couples. Further research is needed to identify those individuals who might benefit from marital interventions.

Maisto S, Conigliaro J, McNeil M, Kraemer K, Conigliaro R, Kelley M. **Effects of two types of brief intervention and readiness to change on alcohol use in hazardous drinkers.** Journal of Studies on Alcohol 2001;62(5):605-14.

Objective Brief interventions for hazardous and low-dependent drinkers in the primary care setting have considerable empirical support. The purpose of this study was to (1) evaluate the effects of brief advice (BA) and motivational enhancement (ME) interventions on alcohol consumption. In addition, a hindsight matching design was used to (2) study the moderator effects of patient readiness to change (alcohol use) on alcohol consumption. Method The subjects (N = 301, 70% men) were patients 21 years of age or older who presented for treatment at one of 12 primary care clinics. After screening for eligibility and providing consent to participate in the study, the patients completed a baseline assessment and were randomly assigned to the BA, ME or standard care (SC) interventions condition. Follow-up assessments were completed at 1-, 3-, 6-, 9- and 12-months postbaseline assessment. Results Evaluation of the first hypothesis (n = 232 for these analyses) showed that all participants tended to reduce their alcohol use considerably between the baseline and 12-month assessments. In addition, evaluation of the second hypothesis showed a moderator effect of readiness to change in predicting the

number of drinks at 12 months, such that the BA intervention seemed more effective for patients relatively low in readiness to change compared to those higher in readiness. Readiness to change did not seem to be related to changes in drinking of participants in the SC or ME conditions. <u>Conclusions</u> The results confirm that, among primary care patients, substantial changes in alcohol consumption are possible. They further suggest that matching studies of patient readiness to change their alcohol use, as well as other variables, are warranted.

Sellman D, Sullivan P, Dore G, Adamson S, McEwan I. A randomized controlled trial of Motivational Enhancement Therapy (MET) for mild to moderate alcohol dependence. Journal of Studies on Alcohol 2001;62:389-96.

Objective This study was designed to conduct a randomized controlled trial of motivational enhancement therapy (MET) with two control conditions: nondirective reflective listening (NDRL) and no further counseling (NFC); and to conduct this study in a sample of patients with a primary diagnosis of mild to moderate alcohol dependence, in a "real-life" clinical setting. Method Patients with mild to moderate alcohol dependence were recruited, assessed and treated at the Community Alcohol and Drug Service of Christchurch, New Zealand. All patients received a feedback/education session before randomization to either four sessions of MET, four sessions of NDRL, or NFC. Outcome data on 122 subjects (57.4% men) were obtained 6 months following the end of treatment, by an interviewer who was blind to the treatment condition. The primary drinking outcome was unequivocal heavy drinking, defined as drinking 10 or more standard drinks six or more times in the follow-up period. Global assessment scale (GAS) measured general personal/social functioning. Results Of patients treated with MET, 42.9% showed unequivocal heavy drinking compared with 62.5% of the NDRL and 65.0% of the NFC groups (p = .04). No significant differences were found for GAS score according to treatment condition. Conclusions In patients with mild to moderate alcohol dependence, MET is more effective for reducing unequivocal heavy drinking than either a feedback/education session alone or four sessions of NDRL. MET can be considered an effective "value added" counseling intervention in a real-life clinical setting. In patients with mild to moderate alcohol dependence, nondirective reflective listening provides no additional advantage over a feedback/education session alone.