Example articles with extracted information highlighted

This section shows examples of key information extracted from articles. A variety of MCC information is shown. Examples of eligibility criteria, participant characteristics, and risk of bias assessment are included. For each article, there are excerpts from the article as well as the accompanying data form.

ELIGIBILITY CRITERIA

General Exclusion without Justification

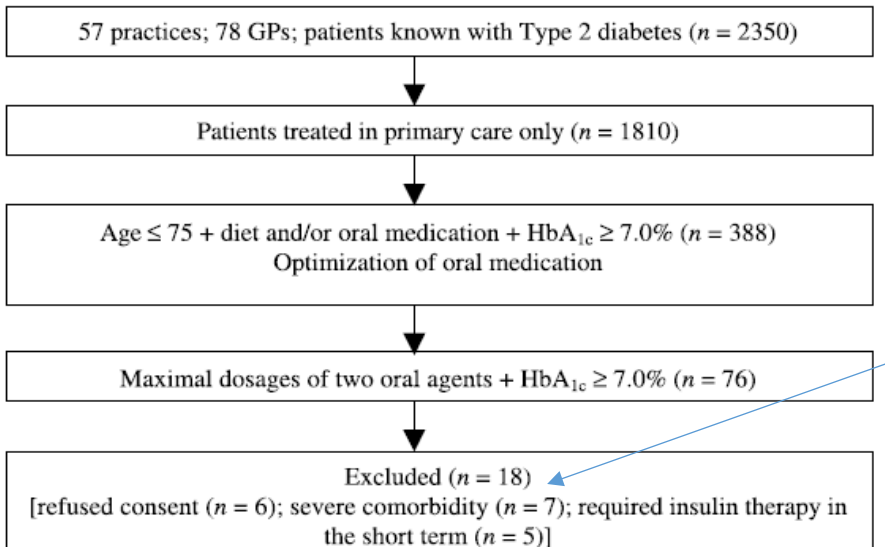
Goudswaard, A. N., et al. "Long-term effects of self-management education for patients with Type 2 diabetes taking maximal oral hypoglycaemic therapy: a randomized trial in primary care." *Diabetic Medicine* 21.5 (2004): 491-496.

- Is eligibility criteria reported? → Yes
- Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions? → Yes
- Is the number of individuals excluded for having comorbid chronic conditions reported? → Yes
- Is a justification for MCC exclusion provided? → No

Patients and practices

Patients were recruited from 57 general practices (78 GPs) in and around the city of Utrecht, the Netherlands. The CONSORT flow chart (Fig. 1) shows the recruitment process. An assessment of 1810 patients' medical records by two research assistants was followed by a completion of the database [7]. Subsequently, in patients under age 76 years and with HbA_{1c} ≥ 7.0%, oral medication was optimized [8]. After this optimization, 76 patients had HbA_{1c} ≥ 7.0% while taking the maximum feasible dosages of two different oral hypoglycaemic agents, mostly sulphonylurea and metformin. These patients were eligible for the present study. Exclusion criteria were: severe comorbidity (defined as having an illness that surpasses the impact of diabetes); insufficient understanding of spoken Dutch to follow instructions; or requirement for insulin therapy in the short term on account of severe hyperglycaemic symptoms. After 18 exclusions, and four withdrawals after randomization, the final study population included 54 patients.

Explicit exclusion of individuals with multiple chronic conditions, regardless of conditions



Number of individuals excluded for having comorbid chronic conditions

Eligibility

Record Number	106460_G

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Eligibility

Is eligibility criteria reported?	◯ No ⊗ Yes
Eligibility criteria	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Were any behavioral factors/conditions are used as inclusion or exclusion criteria?	⊗ No ◯ Yes
Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions?	◯ No ⊗ Yes
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Is the number of individuals excluded for having comorbid chronic conditions reported?	◯ No ⊗ Yes
Number of individuals excluded due to Multiple Chronic Conditions	7
Location	[*DATA REMOVED*]
Term(s) used to refer to individuals with multiple chronic conditions	☒ Comorbidity/Co-Morbid Condition(s) ☐ Multimorbidity ☐ Multiple Chronic Conditions ☐ Polypathology ☐ Pluripathology ☐ Other term (Check all that apply)
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Specific term(s) used	[*DATA REMOVED*]
Is a justification for MCC exclusion provided?	⊗ No ◯ Yes
Was the Charlson comorbidity index used in eligibility criteria?	⊗ No ◯ Yes

Are there any vague exclusions for medical or psychological conditions (not reported above)?
⊗ No
◯ Yes

Did trial exclude individuals with specific chronic conditions?
⊗ No
◯ Yes

Location
_____
(Page #, Paragraph #)

Were there any age restrictions for trial participants (aside from 18 years or older)?
◯ No
⊗ Yes

What type of age exclusion?
☐ Minimum Age
☒ Maximum Age

Excluded those above age:
75

Location
_____
(Page #, Paragraph #)

Is a justification for age exclusion(s) provided?
⊗ No
◯ Yes

List any eligibility criteria not captured in this form that may be relevant to this review
_____

General MCC Exclusion with Justification

Ravaud, P., et al. "Management of osteoarthritis (OA) with an unsupervised home based exercise programme and/or patient administered assessment tools. A cluster randomised controlled trial with a 2× 2 factorial design." *Annals of the rheumatic diseases* 63.6 (2004): 703-708.

- Is eligibility criteria reported? → Yes
- Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions? → Yes
- Is the number of individuals excluded for having comorbid chronic conditions reported? → No
- Is a justification for MCC exclusion provided? → Yes

PATIENTS AND METHODS

Trial design

The study was an open cluster RCT with a 2×2 factorial design and planned duration of 6 months. Rheumatologists, not patients, were randomised. Randomisation was performed centrally using a table of random numbers, by a statistician blinded to the identity of the rheumatologists.

Recruitment of rheumatologists

A total of 1189 rheumatologists representing approximately 80% of French rheumatologists were invited by letter to join the study. Those agreeing to participate were assigned to one of the four intervention groups: (*a*) patient administered assessment tools (standardised tools; ST), (*b*) home based exercise programme (EX), (*c*) tools + exercises (ST+EX), or (*d*) usual care (UC).

Patients

Each rheumatologist was to enrol four patients with OA (three with knee OA, one with hip) who met clinical and radiographic American College of Rheumatology criteria for OA. Additional inclusion criteria were ⩾6 months' history of pain, pain scored by the patient at ⩾30 mm on a 100 mm visual analogue scale (VAS), and pain for at least 14 days during the month preceding the study.

Patients were excluded if they (*a*) had secondary arthritis as defined by Osteoarthritis Research Society International; (*b*) had comorbidities that precluded their safe involvement in the exercise programme (such as recent myocardial infarction); (*c*) had surgery scheduled within the 12 months following the start of the study or had serious concomitant illness (neoplasia, infectious disease, unstable metabolic or cardiovascular disease, systemic disease); (*d*) had received any intra-articular injection (hyaluronic acid, corticosteroid, or joint lavage) during the 3 months preceding the study or had used slow acting anti-osteoarthritic drugs during the 2 months preceding the study; or (*e*) were participating in another research study.

Explicit exclusion of individuals with multiple chronic conditions, regardless of conditions

Justification for MCC exclusion

Eligibility

Record Number	106813_B

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Eligibility

Is eligibility criteria reported?	◯ No ⊗ Yes
Eligibility criteria	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Were any behavioral factors/conditions are used as inclusion or exclusion criteria?	⊗ No ◯ Yes
Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions?	◯ No ⊗ Yes
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Is the number of individuals excluded for having comorbid chronic conditions reported?	⊗ No ◯ Yes
Term(s) used to refer to individuals with multiple chronic conditions	☒ Comorbidity/Co-Morbid Condition(s) ☐ Multimorbidity ☐ Multiple Chronic Conditions ☐ Polypathology ☐ Pluripathology ☐ Other term (Check all that apply)
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Specific term(s) used	[*DATA REMOVED*]
Is a justification for MCC exclusion provided?	◯ No ⊗ Yes
Is this justification based on ability to participate in the study?	◯ No ⊗ Yes
MCC exclusion justification	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)

Was the Charlson comorbidity index used in eligibility criteria?
⊗ No
◯ Yes

Are there any vague exclusions for medical or psychological conditions (not reported above)?
⊗ No
◯ Yes

Did trial exclude individuals with specific chronic conditions?
⊗ No
◯ Yes

Location
_____
(Page #, Paragraph #)

Were there any age restrictions for trial participants (aside from 18 years or older)?
⊗ No
◯ Yes

List any eligibility criteria not captured in this form that may be relevant to this review
_____

Specific Chronic Condition Exclusion + Behavior, Age, and Vague

Rachmani, R., et al. "Teaching patients to monitor their risk factors retards the progression of vascular complications in high-risk patients with Type 2 diabetes mellitus—a randomized prospective study." *Diabetic Medicine* 19.5 (2002): 385-392.

- Is eligibility criteria reported? → Yes
- Were any behavioral factors/conditions used as inclusion or exclusion criteria? → Yes
- Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions? → No
- Are there any vague exclusions for medical or psychological conditions? → Yes
- Did trial exclude individuals with specific chronic conditions? → Yes
- Is a justification for MCC exclusion provided? → No
- Were there any age restrictions for trial participants (aside form 18 years or older)? → Yes

Patients and methods

Patients

Patients were recruited among those referred for evaluation to the diabetes out-patient clinic of Meir Hospital from affiliated primary care clinics during 1995–1996. One hundred and sixty-five patients, with diabetes mellitus Type 2, hypertension and hyperlipidaemia were eligible. Diabetes mellitus Type 2 was defined as hyperglycaemia first diagnosed after age 40 and maintained on diet alone or oral medications for at least 1 year [17]. Hypertension was defined as sitting blood pressure values > 140 mmHg systolic or 90 mmHg diastolic on three consecutive determinations over a 2-week observation period or known hypertension on drug treatment. Hyperlipidaemia was defined as LDL-C values > 120 mg/dl, on two consecutive determinations.

The exclusion criteria were age under 45 or over 70, current smoking, duration of diabetes of > 10 years, body mass index (BMI) > 35 kg/m^2, serum creatinine > 2 mg/dl (176 µmol/l), albumin/creatinine ratio ≥ 200 mg/g, a history of a cerebrovascular event, acute myocardial infarction or unstable angina, a history of vascular surgery of any kind, malignancy, liver disease, an autoimmune disease or any life-threatening condition with a life expectancy < 5 years. Patients were recruited from an area of generally middle class income. All but five had high school education. Forty-two patients had a university degree.

Exclusion based on age

Exclusion based on behavioral factors/ conditions (smoking & weight)

Excluded specific chronic conditions (Chronic Kidney Disease, Coronary Artery Disease, and Cancer)

Vague exclusion criteria

Eligibility

Record Number	113103_G

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Eligibility

Is eligibility criteria reported?	◯ No ⊗ Yes
Eligibility criteria	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Were any behavioral factors/conditions are used as inclusion or exclusion criteria?	◯ No ⊗ Yes
Which of the following behavioral factors/conditions were reported as eligibility criteria?	☐ Alcohol use ☒ Smoking or tobacco use ☐ Other substance use ☐ Physical activity ☐ Diet ☒ Weight
Specific eligibility criteria for Smoking or tobacco use	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Specific eligibility criteria for Weight	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions?	⊗ No ◯ Yes
Location	_____ (Page #, Paragraph #)
Was the Charlson comorbidity index used in eligibility criteria?	⊗ No ◯ Yes
Are there any vague exclusions for medical or psychological conditions (not reported above)?	◯ No ⊗ Yes
Is this exclusion based on ability to participate in the study?	⊗ No ◯ Yes

Vague medical/psychological condition exclusions

[*DATA REMOVED*]

Location

[*DATA REMOVED*]
(Page #, Paragraph #)

Did trial exclude individuals with specific chronic conditions?

◯ No
⊗ Yes

Location

[*DATA REMOVED*]
(Page #, Paragraph #)

Is this exclusion based on ability to participate in the study?

⊗ No
◯ Yes

Which chronic conditions were subject to exclusions?

☐ Arthritis
☐ Asthma
☐ Autism Spectrum Disorder
☒ Cancer
☐ Cardiac Arrhythmias
☒ Chronic Kidney Disease
☐ Chronic Obstructive Pulmonary Disease
☐ Congestive Heart Failure
☒ Coronary Artery Disease
☐ Dementia
☐ Depression
☐ Diabetes
☐ Hepatitis
☐ Human Immunodeficiency Virus (HIV)
☐ Hyperlipidemia
☐ Hypertension
☐ Osteoporosis
☐ Schizophrenia
☒ Stroke
☐ Substance Abuse Disorders
(Check all that apply)

Location

[*DATA REMOVED*]
(Page #, Paragraph #)

Is the number of individuals excluded for having Cancer reported?

⊗ No
◯ Yes

Is exclusion of individuals with Cancer narrowed?

☒ No
☐ Yes- narrowed by type
☐ Yes- narrowed by severity
☐ Yes- narrowed by onset
☐ Yes- narrowed by other specification

Is a justification for Cancer exclusion provided?

⊗ No
◯ Yes

Is the number of individuals excluded for having Chronic Kidney Disease reported?

⊗ No
◯ Yes

Is the exclusion for Chronic Kidney Disease based on the named condition or diagnostic criteria?

◯ Condition name
⊗ Diagnostic criteria

Location

_____
(Page #, Paragraph #)

Specific diagnostic criterion for Chronic Kidney Disease

[*DATA REMOVED*]

Location
_____
(Page #, Paragraph #)

Is exclusion of individuals with Chronic Kidney Disease narrowed?
☒ No
☐ Yes- narrowed by type
☐ Yes- narrowed by severity
☐ Yes- narrowed by onset
☐ Yes- narrowed by other specification

Is a justification for Chronic Kidney Disease exclusion provided?
⊗ No
◯ Yes

Is the number of individuals excluded for having Coronary Artery Disease reported?
⊗ No
◯ Yes

Is exclusion of individuals with Coronary Artery Disease narrowed?
☐ No
☒ Yes- narrowed by type
☐ Yes- narrowed by severity
☐ Yes- narrowed by onset
☐ Yes- narrowed by other specification

Specific exclusion criteria for Coronary Artery Disease narrowed by type
[*DATA REMOVED*]

Location
_____
(Page #, Paragraph #)

Is a justification for Coronary Artery Disease exclusion provided?
⊗ No
◯ Yes

Is the number of individuals excluded for having Stroke reported?
⊗ No
◯ Yes

Is exclusion of individuals with Stroke narrowed?
☒ No
☐ Yes- narrowed by type
☐ Yes- narrowed by severity
☐ Yes- narrowed by onset
☐ Yes- narrowed by other specification

Is a justification for Stroke exclusion provided?
⊗ No
◯ Yes

Were there any age restrictions for trial participants (aside from 18 years or older)?
◯ No
⊗ Yes

What type of age exclusion?
☒ Minimum Age
☒ Maximum Age

Excluded those below age:
45

Location
[*DATA REMOVED*]
(Page #, Paragraph #)

Excluded those above age:
70

Location
[*DATA REMOVED*]
(Page #, Paragraph #)

Is a justification for age exclusion(s) provided?
⊗ No
◯ Yes

List any eligibility criteria not captured in this form that may be relevant to this review
_____

PARTICIPANT CHARACTERISTICS

MCC in Participant Characteristics and General + Flow Diagram

Østerås, N., et al. "Limited effects of exercises in people with hand osteoarthritis: results from a randomized controlled trial." *Osteoarthritis and Cartilage* 22.9 (2014): 1224-1233.

- Is a participant flow diagram presented? → Yes
- Are multiple chronic conditions included in the participant characteristics? → Yes
- Is this description general or condition specific? → General

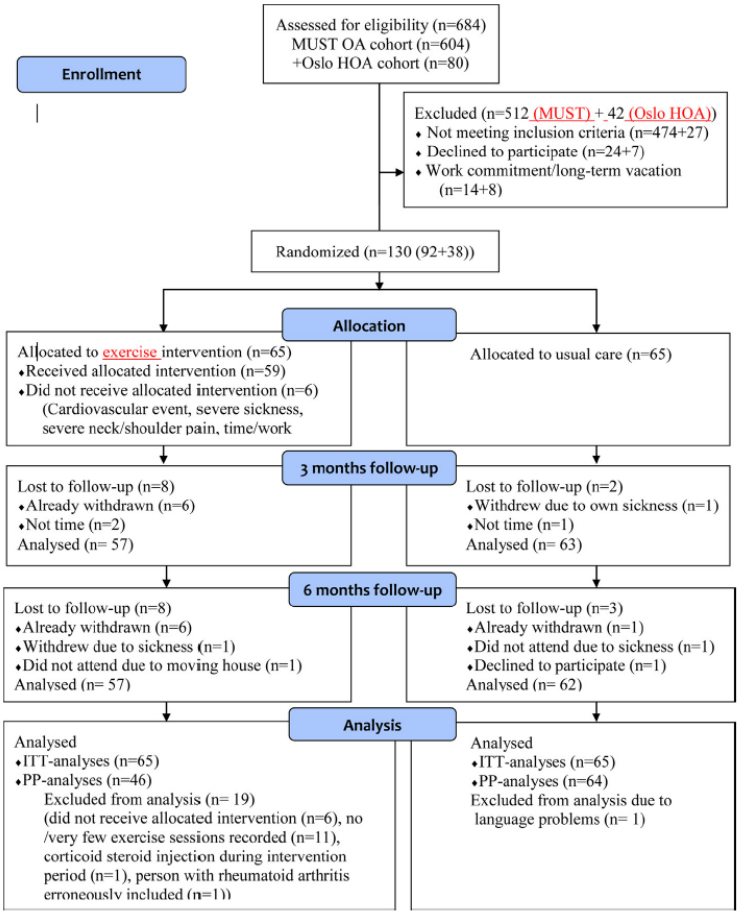


Fig. 1. Flow diagram.

Table II
Baseline characteristics of participants stratified by study group

	Intervention group ($n = 65$)	Control group ($n = 65$)
MUST cohort/Oslo HOA cohort, *n*	46/19	46/19
Females, *n* (%)	58 (89)	59 (91)
Age, mean (SD)	67 (8)	65 (9)
BMI*, mean (SD)	28 (5)	27 (4)
Marital status, *n* (%)		
Married	37 (57)	46 (71)
Divorced/separated	9 (14)	14 (22)
Widowed	15 (23)	4 (6)
Single	3 (5)	0 (0)
Occupational status, *n* (%)		
Working full-time or part-time	9 (14)	18 (28)
Sick-listed	1 (2)	1 (2)
Disability pensioner	16 (25)	10 (15)
Age retired	39 (60)	36 (55)
Education, *n* (%)		
Lower secondary school	15 (23)	9 (14)
Upper secondary school	28 (44)	36 (56)
University 1–4 years	16 (25)	16 (25)
University >4 years	5 (8)	3 (5)
Self-reported hip or knee OA, *n* (%)		
Hip	25 (39)	30 (46)
Knee	26 (40)	33 (51)
Fulfilment of ACR criteria for hand OA, *n* (%)	59 (91)	59 (91)
Years with OA diagnosis, mean years (SD)	11 (9)	12 (7)
Comorbidities, *n* (%)		
Other rheumatic disease†	8 (13)	10 (15)
Other chronic non-rheumatic disease	23 (35)	21 (33)
No other rheumatic or chronic disease	36 (56)	37 (58)
Severe mental distress‡, *n* (%)	11 (17)	25 (39)

* BMI: Body Mass Index (kg/m^2).
† Other rheumatic diseases include: psoriasis, Sjogren's syndrome and fibromyalgia.
‡ GHQ20: General Health Questionnaire 20 items (bimodal scoring 0-0-1-1, range 0–20, ≥4 = severe distress).

Patient Selection

Record Number	309573_G

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Overall

Is the number of individuals assessed for eligibility reported?	◯ No ⊗ Yes
What is the number of individuals assessed for eligibility?	684
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Is a participant flow diagram presented?	◯ No ⊗ Yes
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Are multiple chronic conditions included in the participant characteristics?	◯ No ⊗ Yes
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Could the inclusion of individuals with multiple chronic conditions be inferred?	◯ No ◯ Yes ⊗ Extracted before 8/7/15 (DON'T SELECT)
Is this description general or condition specific?	☒ General ☐ Condition Specific
How many additional specific chronic conditions were reported or inferred?	[*DATA REMOVED*]
Condition Specific N Reported	_____
Are any of the following statistics regarding participants with MCC reported?	☒ Number ☐ Percentage ☐ Mean ☐ Charlson comorbidity index ☐ Not reported
Number of participants with MCC	44
Location	[*DATA REMOVED*] (Page #, Paragraph #)
MCC or Specific Condition Reported N or Percent	44

Are supplementary tables referenced for information relevant to this review?	⊗ No ◯ Yes
Are any other patient characteristics reported that may be relevant to this review?	◯ No ⊗ Yes
Other relevant patient characteristics	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
How was information about potential participants' target chronic condition(s) obtained?	☐ Baseline Assessment, ☐ Medical Record ☐ Patient Reported ☒ Other Method ☐ Method Not Reported
Location	[*DATA REMOVED*] (Page #, Paragraph #)
How was information about participants' or potential participants' other chronic condition(s) obtained?	☐ Baseline Assessment, ☐ Medical Record ☐ Patient Reported ☒ Other Method ☐ Method Not Reported ☐ Not clear if information was obtained
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Did the authors comment on inclusion of patients with MCC?	⊗ No ◯ Yes

QUALITY ASSESSMENT

All Low Risk of Bias (Selection, Performance, Detection, Attrition, and Reporting)

Stone, Roslyn A., et al. "Active care management supported by home telemonitoring in veterans with type 2 diabetes the diatel randomized controlled trial." *Diabetes care* 33.3 (2010): 478-484.

Low Risk Performance Bias

Low Risk Detection Bias

Low Risk Attrition Bias

Low Risk Selection Bias

Low Risk Reporting Bias

levels ≥8% after ≥1 year receiving pharmacological therapy under conditions of usual care.

RESEARCH DESIGN AND METHODS — The DiaTel Study was a RCT of veterans with type 2 diabetes receiving their primary care at the VA Pittsburgh Healthcare System (VAPHS) at one of the three main Pittsburgh campuses or five outlying community-based clinics. The study was approved by the VAPHS Institutional Review Board and conducted according to the principles of the Declaration of Helsinki. All participants provided signed informed consent.

Under a separate VAPHS-approved protocol, a sampling frame of potentially eligible veterans was developed from VAPHS electronic medical and pharmacy records using the following criteria: had at least one outpatient visit in a primary care clinic between 1 June 2004 and 31 December 2005, were aged <80 years, received pharmacological treatment for diabetes for ≥12 months, had no referrals to the VAPHS Diabetes Clinic in the preceding 18 months, and had a most recent A1C ≥8.0%. Approximately 20% of veterans with diabetes in our sampling frame met that A1C criterion.

After review and approval by their primary care providers (PCPs), potentially eligible veterans were invited by letter to participate. Nonresponders were contacted by primary [illegible] solicit their participat[illegible] described to interested veterans by research staff who obtained signed consent. Eligibility was further verified by a point-of-care capillary A1C ≥7.5% at enrollment using a DCA 2000 analyzer (Bayer Healthcare). Veterans were excluded if they had a life expectancy of <6 months, were participating in another study, resided in an institutional setting, or did not have a land-based, analog home telephone line as required for the home telemonitoring device used.

Participants were randomly assigned to the ACM+HT or CC group. Randomization was stratified by quartile of capillary A1C within each site and blocked on time. The project statistician generated the random sequences, the study nurses enrolled the participants, and the study coordinator informed the nurses of the intervention assignment after each participant was enrolled. After an initial education session, participants were informed of their intervention assignments. Because of the nature of the intervention, neither participants nor study nurses could be blinded. However, primary outcomes were ascertained by personnel unconnected to this study who were unaware of intervention assignments. Recruitment started 1 October 2005; the final 6-month follow-up was 11 January 2007.

RESULTS — Of the 1,055 veterans in the initial sampling frame deemed appropriate for the study, 658 (62.4%) responded to letters of invitation to participate and 381 (57%) agreed to be contacted. Of these, 211 presented to VAPHS for signed informed consent, additional screening, and baseline measurements. The 150 consenting veterans who had a capillary A1C ≥7.5% at the baseline were randomly assigned to the ACM+HT ($n = 73$) or CC ($n = 77$) groups. Of these, 3 ACM+HT and 2 CC participants were excluded because they were subsequently found to meet baseline exclusion criteria; 2 CC participants withdrew before the initial education session and 6 ACM+HT participants withdrew afterward. This analysis includes the remaining 64 ACM+HT and 73 CC participants (supplementary Table 4A, available in an online appendix at http://care.diabetesjournals.org/cgi/content/full/dc09-1012/DC1).

All participants completed the baseline assessment; 6 ACM+HT and 4 CC participants missed the 3-month assessment and 8 ACM+HT and 7 CC participants missed the 6-month assessment. A total of 8 A1C values in the ACM+HT group and 9 A1C values in the CC group were missing, and 10 A1C values were truncated.

Baseline patient characteristics

There were no significant differences by treatment group for age, sex, race, or any of the other baseline characteristics as shown in supplementary Table A1. Approximately one-third of the participants in both groups were aged ≥65 years; the vast majority were male and non-Hispanic white. The predominant comorbidities were coronary artery disease and congestive heart failure.

Medication management

Most participants in each group were tak[illegible]gents (predomi[illegible]metformin) and antihypertensive and lipid-lowering medications at baseline, 3 months, and 6

[illegible] participants, $P = 0.29$) of oral hypoglycemic agents (1.8 for ACM+HT vs. 1.8 for CC participants, $P = 0.91$).

At baseline, 39 ACM+HT and 40 CC participants were using insulin. By 6 months, 1 ACM+HT and 1 CC participant had discontinued insulin, whereas 5 ACM+HT and 3 CC participants had begun insulin. Although the average daily insulin dose was similar in both groups at baseline, the average daily dose for ACM+HT participants was ~18 IU higher than that for CC participants at 3 and 6 months ($P = 0.02$ and $P = 0.048$, respectively). The average number of adjustments in insulin dose was also higher in ACM+HT (6.6) than in CC (2.8) participants ($P < 0.001$). However, no significant correlation was found between the frequency of insulin adjustment and A1C a[illegible] 0.12; [illegible] participants.

Primary outcomes

Dotplots of individual values for A1C, weight, blood pressure, and lipids are shown by treatment group for each time point in Fig. 1. Baseline values were similar for both groups ($P > 0.45$ for each) (Table 1). A1C was significantly lower for ACM+HT than for CC participants at both 3 and 6 months (0.7% lower at each time point, $P < 0.001$ for each). Significantly greater decreases in A1C were observed in the ACM+HT group relative to the CC group at 3 months (1.7 vs. 0.7%) and 6 months (1.7 vs. 0.8%), corresponding to differential decreases of ~0.9% ($P < 0.001$ for each) (supplementary Table A3). There was no significant interaction between baseline insulin usage and treatment response at any time point ($P > 0.39$ for each) (supplementary Fig. 1).

None of the other primary outcomes differed significantly by treatment group at either 3 or 6 months (Table 1). However, except for weight and HDL cholesterol levels, the direction of the differences favored the ACM+HT group. Within both treatment groups, A1C,

Quality Assessment

Record Number	300491_A

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Bias Assessment

Random sequence generation (selection bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Allocation concealment (selection bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Blinding of participants and personnel (performance bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Blinding of outcome assessment (detection bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Incomplete outcome data (attrition bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)

Selective outcome reporting (reporting bias)	⊗ Low Risk ◯ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)
Quality Score	-6

Majority Unclear Risk And High Risk for Attrition Bias

Groessl, Erik J., and Terry A. Cronan. "A cost analysis of self-management programs for people with chronic illness." *American Journal of Community Psychology* 28.4 (2000): 455-480.

Bias Assessment	
Random sequence generation (selection bias)	Unclear Risk
Justification for grade	Randomization method not reported
Location	Page #, Paragraph #
Allocation concealment (selection bias)	Unclear Risk
Justification for grade	Concealment method not reported
Location	Page #, Paragraph #
Blinding of participants and personnel (performance bias)	Unclear Risk
Justification for grade	Blinding of participants and personnel not reported
Location	Page #, Paragraph #
Blinding of outcome assessment (detection bias)	Unclear Risk
Justification for grade	Blinding of outcome assessment not reported
Location	Page #, Paragraph #
Incomplete outcome data (attrition bias)	High Risk
Justification for grade	Reasons for attrition not provided
Location	465, 2 Page #, Paragraph #
Selective outcome reporting (reporting bias)	Unclear Risk
Justification for grade	Study does not indicate a primary outcome
Location	Page #, Paragraph #

Procedures

Letters explaining the study and inviting people
sent to 3000 recipients randomly selected from a large
list of 50,450 people age 60 or older. Based on prev
49% (AARP, 1995), we estimated that approximatel
would have osteoarthritis. To be eligible to particip
to have osteoarthritis, be at least 60 years old, and l
to attend 10 weekly meetings and 10 monthly me
were informed that the purpose of the study was to
three types of interventions (social support, educatior
of the two) on living with osteoarthritis. Three hun
the 3000 contacted by mail volunteered; this indicate
of approximately 25% for those who had osteoarthrit
to participate were asked to attend an interview that
1.5 hr. After the nature of the study was explained,
to participate completed each of the study measures.
and QWB measures were recorded from verbal int
university students. Participants then completed all oth
sisted) in a pen-and-paper format. Participants wer
items that they felt uncomfortable answering, resulting in variability in
sample sizes between measures.

After the interview, participants were randomly assigned to one of three health intervention groups or to a control group. Participation in the three experimental conditions (education, social support, or combination) involved attendance at 10 weekly 2-hr meetings followed by 10 monthly 2-hr meetings.

RESULTS

Analyses were conducted to determine whether there were preexisting differences among the participants assigned to the four groups (education, social support, combination, and control). No statistically significant differences were found. Analyses also examined whether the participants of the study differed from HMO members who did not volunteer to participate, on health care costs. No significant differences were found.

Attrition from the study was measured by failure to complete either the 1-year, the 2-year, or the 3-year assessment. Attrition from the study after the intervention period was more likely to occur in the social support group (27.6%, 36.8%) than in the education group (11.3%, 17.5%) at the 1-year ($\chi^2 = 9.22$, $p = .027$) and 2-year ($\chi^2 = 7.98$, $p = .046$) assessment periods, respectively. Differential attrition was not significant by the 3-year assessment period. Assessment data were available for 245 participants at all four assessment interviews; however, the data on specific measures were not always complete resulting in some variation in sample sizes. The availability of health care cost data was not reduced by attrition because health care utilization was assessed via the p

High Risk Attrition Bias

Unclear Selection Bias

Quality Assessment

Record Number	107468_E

Form History

Date Form Completed	[*DATA REMOVED*]
Staff Initials	[*DATA REMOVED*]

Bias Assessment

Random sequence generation (selection bias)	◯ Low Risk ◯ High Risk ⊗ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)
Allocation concealment (selection bias)	◯ Low Risk ◯ High Risk ⊗ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)
Blinding of participants and personnel (performance bias)	◯ Low Risk ◯ High Risk ⊗ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)
Blinding of outcome assessment (detection bias)	◯ Low Risk ◯ High Risk ⊗ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)
Incomplete outcome data (attrition bias)	◯ Low Risk ⊗ High Risk ◯ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	[*DATA REMOVED*] (Page #, Paragraph #)

Selective outcome reporting (reporting bias)	◯ Low Risk ◯ High Risk ⊗ Unclear Risk
Justification for grade	[*DATA REMOVED*]
Location	_____ (Page #, Paragraph #)
Quality Score	1