# Report Supplementary Material 1 (Chapter 3)

## List of abbreviations

BCT: Behaviour change technique

CHEC: Consensus on Health Economic Criteria

CHEERS: Consolidated Health Economic Evaluation Reporting Standard

COPD: Chronic obstructive pulmonary disease

DFE: Dilated fundus examination

DRS: Diabetic retinopathy screening

GP: General Practitioner

HbA1c: Glycated haemoglobin

HMO: Health Maintenance Organisation

ICER: Incremental cost-effectiveness ratio

NR: Not reported

OPD: Outpatient department

OR: Odds ratio

PCPs: Primary Care Physicians

QALY: Quality-adjusted life year

QI: Quality improvement

RCT: Randomised controlled trial

## 1.1. Search strategies for phase 1 systematic review (reproduced from Lawrenson et al 2016[1]).

**The Cochrane Library**

#1 MeSH descriptor: [Diabetes Mellitus] explode all trees

#2 MeSH descriptor: [Diabetes Complications] explode all trees

#3 MeSH descriptor: [Diabetic Retinopathy] explode all trees

#4 (diabet* or proliferative or non-proliferative) near/4 retinopath*

#5 diabet* near/3 (eye* or vision or visual* or sight*)

#6 retinopath* near/3 (eye* or vision or visual* or sight*)

#7 DR near/3 (eye* or vision or visual* or sight*)

#8 #1 or #2 or #3 or #4 or #5 or #6 or #7

#9 MeSH descriptor: [Mass Screening] explode all trees

#10 MeSH descriptor: [Vision Tests] explode all trees

#11 MeSH descriptor: [Telemedicine] explode all trees

#12 MeSH descriptor: [Photography] explode all trees

#13 MeSH descriptor: [Ophthalmoscopes] explode all trees

#14 MeSH descriptor: [Ophthalmoscopy] explode all trees

#15 ophthalmoscop* or fundoscop* or funduscop*:ti

#16 (exam* or photo* or imag*) near/3 fundus

#17 photography or retinography

#18 (mydriatic or digital or retina* or fundus or steroscopic) near/3 camera*

#19 (mydriatic or digital or retina* or fundus or steroscopic) near/3 imag*

#20 screen$.tw.

#21 (eye* or retina* or ophthalm*) near/4 exam*

#22 (eye* or vision or retinopathy or ophthalmic) near/4 test*

#23 (eye* or retina* or ophthalm*) near/4 visit*

#24 MeSH descriptor: [Office Visits] this term only

#25 (telemedicine* or telemonitor* or telescreen* or telehealth or teleophthalmology)

#26 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25

#27 MeSH descriptor: [Quality of Health Care] explode all trees

#28 MeSH descriptor: [Quality of Health Care] this term only

#29 MeSH descriptor: [Quality Improvement] this term only

#30 MeSH descriptor: [Delivery of Health Care] this term only

#31 MeSH descriptor: [Delivery of Health Care, Integrated] this term only

#32 service delivery

#33 decision making

#34 consensus near/3 (process* or discuss)

#35 stakeholder*

#36 MeSH descriptor: [Quality Control] this term only

#37 MeSH descriptor: [Total Quality Management] this term only

#38 MeSH descriptor: [Quality Indicators, Health Care] this term only

#39 MeSH descriptor: [Quality Assurance, Health Care] this term only

#40 quality assurance

#41 quality near/2 improv*

#42 total quality

#43 continuous quality

#44 quality management

#45 (organisation* near/3 cultur*)

#46 MeSH descriptor: [Disease Management] this term only

#47 MeSH descriptor: [Program Evaluation] this term only

#48 (provider* or program*) near/3 (monitor* or evaluate* or modif* or practice)

#49 implement* near/3 (improve* or change* or effort* or issue* or impede* or glossary or tool* or innovation* or outcome* or driv* or examin* or reexamin* or scale* or strateg* or advis* or expert*)

#50 needs near/3 assess*

#51 (education* or learn*) near/5 (continu* or material* or meeting or collaborat*)

#52 MeSH descriptor: [Medical Audit] explode all trees

#53 audit or feedback or compliance or adherence or training or innovation:ti

#54 guideline* near/3 (clinical or practice or implement* or promot*)

#55 MeSH descriptor: [Health Services Accessibility] explode all trees

#56 outreach near/2 (service$ or visit*)

#57 intervention* near/3 (no or usual or routine or target* or tailor* or mediat*)

#58 usual care

#59 #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58

#60 MeSH descriptor: [Reminder Systems] explode all trees

#61 remind*

#62 improve* near/3 (attend* or visit* or intervention* or adhere*)

#63 increas* near/3 (attend* or visit* or intervention* or adhere*)

#64 appointment* near/3 (miss* or fail* or remind* or follow up)

#65 MeSH descriptor: [Telephone] this term only

#66 telephone*

#67 MeSH descriptor: [Cell Phones] this term only

#68 MeSH descriptor: [Mobile Applications] this term only

#69 MeSH descriptor: [Remote Consultation] this term only

#70 m-health or e-health or g-health or u-health

#71 phone* near/1 (smart or cell)

#72 smartphone* or cellphone*

#73 hand held device*

#74 mobile near/2 (health or healthcare or phone* or device* or monitor* or comput* or app or apps or application)

#75 MeSH descriptor: [Internet] this term only

#76 MeSH descriptor: [Social Networking] this term only

#77 email* or text* or message*

#78 letter or mail or mailed or print* or brochure* or newsletter*

#79 #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72 or #73 or #74 or #75 or #76 or #77 or #78

#80 MeSH descriptor: [Primary Health Care] this term only

#81 MeSH descriptor: [General Practitioners] this term only

#82 MeSH descriptor: [Physicians, Family] this term only

#83 MeSH descriptor: [Physicians, Primary Care] this term only

#84 MeSH descriptor: [Primary Prevention] this term only

#85 MeSH descriptor: [Preventive Health Services] this term only

#86 MeSH descriptor: [Community Health Services] this term only

#87 MeSH descriptor: [Nurses, Community Health] this term only

#88 MeSH descriptor: [Health Services, Indigenous] this term only

#89 MeSH descriptor: [Rural Health Services] explode all trees

#90 MeSH descriptor: [Mobile Health Units] this term only

#91 Ophthalmologist* or Optometrist* or Optician* or Orthopist* or Refractionists

#92 (Ophthalmic or eye) near/3 (surgeon* or nurse* or technician* or officer* or assistant* or staff*)

#93 MeSH descriptor: [Physician's Practice Patterns] this term only

#94 MeSH descriptor: [Professional Practice] this term only

#95 MeSH descriptor: [Education, Medical, Continuing] this term only

#96 MeSH descriptor: [Nurses] explode all trees

#97 MeSH descriptor: [Specialties, Nursing] this term only

#98 MeSH descriptor: [Nurse's Role] this term only

#99 MeSH descriptor: [Education, Nursing, Continuing] this term only

#100 nurse or nurses

#101 MeSH descriptor: [Pharmacists] this term only

#102 pharmacist*

#103 (role or roles) near/3 expan*

#104 task* near/3 shift*

#105 MeSH descriptor: [Medical Records Systems, Computerized] explode all trees

#106 MeSH descriptor: [Management Information Systems] this term only

#107 MeSH descriptor: [Database Management Systems] this term only

#108 MeSH descriptor: [Computer Systems] this term only

#109 MeSH descriptor: [Point-of-Care Systems] this term only

#110 MeSH descriptor: [Hospital Information Systems] this term only

#111 (health or healthcare) near/4 (record or management system*)

#112 (decision near/5 support) .ti.

#113 #80 or #81 or #82 or #83 or #84 or #85 or #86 or #87 or #88 or #89 or #90 or #91 or #92 or #93 or #94 or #95 or #96 or #97 or #98 or #99 or #100 or #101 or #102 or #103 or #104 or #105 or #106 or #107 or #108 or #109 or #110 or #111 or #112

#114 MeSH descriptor: [Economics] this term only

#115 MeSH descriptor: [Costs and Cost Analysis] this term only

#116 MeSH descriptor: [Cost Allocation] this term only

#117 MeSH descriptor: [Cost-Benefit Analysis] this term only

#118 MeSH descriptor: [Cost Control] this term only

#119 MeSH descriptor: [Cost Savings] this term only

#120 MeSH descriptor: [Cost of Illness] explode all trees

#121 MeSH descriptor: [Cost Sharing] this term only

#122 MeSH descriptor: [Deductibles and Coinsurance] this term only

#123 MeSH descriptor: [Medical Savings Accounts] this term only

#124 MeSH descriptor: [Health Care Costs] this term only

#125 MeSH descriptor: [Direct Service Costs] this term only

#126 MeSH descriptor: [Drug Costs] this term only

#127 MeSH descriptor: [Employer Health Costs] this term only

#128 MeSH descriptor: [Hospital Costs] this term only

#129 MeSH descriptor: [Health Expenditures] this term only

#130 MeSH descriptor: [Capital Expenditures] this term only

#131 MeSH descriptor: [Economics, Hospital] explode all trees

#132 MeSH descriptor: [Economics, Medical] explode all trees

#133 MeSH descriptor: [Economics, Nursing] this term only

#134 MeSH descriptor: [Economics, Pharmaceutical] this term only

#135 MeSH descriptor: [Fees and Charges] explode all trees

#136 MeSH descriptor: [Budgets] explode all trees

#137 low* near/2 cost*

#138 high* near/2 cost*

#139 (health care or healthcare) near/2 cost*

#140 fiscal or funding or financial or finance

#141 cost near/2 estimate*

#142 cost near/2 variable*

#143 unit near/2 cost*

#144 economic* or pharmacoeconomic* or price* or pricing

#145 MeSH descriptor: [Uncompensated Care] this term only

#146 MeSH descriptor: [Reimbursement Mechanisms] this term only

#147 MeSH descriptor: [Reimbursement, Incentive] this term only

#148 insurance near/3 (health or scheme*)

#149 financial or economic or pay or payment or copayment or paid or fee or fees or monetary or money or cash or incentiv* or disincentiv*

#150 #114 or #115 or #116 or #117 or #118 or #119 or #120 or #121 or #122 or #123 or #124 or #125 or #126 or #127 or #128 or #129 or #130 or #131 or #132 or #133 or #134 or #135 or #136 or #137 or #138 or #139 or #140 or #141 or #142 or #143 or #144 or #145 or #146 or #147 or #148 or #149

#151 #59 or #79 or #113 or #150

#152 MeSH descriptor: [Patient Acceptance of Health Care] explode all trees

#153 MeSH descriptor: [Attitude to Health] explode all trees

#154 MeSH descriptor: [Health Behavior] explode all trees

#155 barrier* or obstacle* or facilitat* or enable*

#156 uptake or takeup or attend* or accept* or adhere* or attitude* or participat* or facilitat* or utilisat* or utilizat*

#157 complie* or comply or compliance* or noncompliance* or non compliance*

#158 encourag* or discourage* or reluctan* or nonrespon* or non respon* or refuse* or refusal

#159 non-attend* or non attend* or dropout or drop out or apath*

#160 MeSH descriptor: [Health Education] this term only

#161 MeSH descriptor: [Patient Education as Topic] explode all trees

#162 MeSH descriptor: [Health Promotion] explode all trees

#163 health near/2 (promotion* or knowledge or belief*)

#164 educat* near/2 (intervention* or information or material or leaflet)

#165 MeSH descriptor: [Socioeconomic Factors] this term only

#166 MeSH descriptor: [Poverty] explode all trees

#167 MeSH descriptor: [Social Class] this term only

#168 MeSH descriptor: [Educational Status] this term only

#169 (school or education*) near/3 (status or level* or attain* or achieve*)

#170 MeSH descriptor: [Employment] this term only

#171 MeSH descriptor: [Healthcare Disparities] this term only

#172 MeSH descriptor: [Health Status Disparities] this term only

#173 MeSH descriptor: [Medically Underserved Area] explode all trees

#174 MeSH descriptor: [Rural Population] this term only

#175 MeSH descriptor: [Urban Population] this term only

#176 MeSH descriptor: [Ethnic Groups] explode all trees

#177 MeSH descriptor: [Minority Groups] this term only

#178 MeSH descriptor: [Vulnerable Populations] this term only

#179 (health* or social* or racial* or ethnic*) near/5 (inequalit* or inequit* or disparit* or equit* or disadvantage* or depriv*)

#180 disadvant* or marginali* or underserved or under served or impoverish* or minorit* or racial* or ethnic*

#181 #152 or #153 or #154 or #155 or #156 or #157 or #158 or #159 or #160 or #161 or #162 or #163 or #164 or #165 or #166 or #167 or #168 or #169 or #170 or #171 or #172 or #173 or #174 or #175 or #176 or #177 or #178 or #179 or #180

#182 #151 or #181

#183 #8 and #26 and #182

#184 (ranibizumab or bevacizumab or avastin or aflibercept):ti

#185 (cataract* or intraocular or glaucoma* or phaco* or photocoagulat* or photodynamic or laser* or vitrectom*):ti

#186 (macula* near/2 (degener* or oedema or edema)):ti

#187 nerve fiber layer:ti

#188 (coronary or cardiac or cardio* or heart or myocardia* or artery or aneurysm or atrial or echocardiography or hypertension or hypotension or stroke or pulmonary or COPD or lung* or organ* or smoking):ti

#189 (pregnan* or gestational or neonat* or perinatal or maternal or trimester or congenital or ovary or breast*):ti

#190 (kidney* or liver or cirrhosis or renal or hepatitis or dialysis or pancrea* or gastric or gastrectom* or surg* or duoden*):ti

#191 (blood glucose or blood pressure or ketoacidosis or hypoglycemi* or rosiglitazone):ti

#192 (lipid* or lipase* or statin* or hypercholesterolemia or albumin or platlet* or hemoglobin* or arterial):ti

#193 (cancer* or carcinoma* or neoplas* or adenoma* or metformin*):ti

#194 (urin* or incontinence or bladder or constipat* or bowel* or faecal or colorectal or colon*):ti

#195 (gene* or genotype* or genome or genomic or phenotyp* or biomarker* or polymorphism* or interleukin*):ti

#196 (cell* or molecular or assay):ti

#197 (cystic or fibrosis or CF or tuberculosis or TB or lupus):ti

#198 (neuropath* or nephropath* or prematurity):ti

#199 (*arthritis or steroid* or osteoporosis or atherosclerosis or sclerosis):ti

#200 (apnea or sleep or limb or oral* or celiac or coeliac or skin or MRSA or anesthesia or vitamin or HIV or testosterone or erectile or schizophren* or bipolar antipsychotic* or psychotic*):ti

#201 #184 or #185 or #186 or #187 or #188 or #189 or #190 or #191 or #192 or #193 or #194 or #195 or #196 or #197 or #198 or #199 or #200

#202 #183 not #201

**MEDLINE**

1. randomized controlled trial.pt.

2. random$.ab,ti.

3. placebo.ab,ti.

4. dt.fs.

5. trial.ab,ti.

6. (group or groups).ab,ti.

7. or/1-6

8. exp animals/

9. exp humans/

10. 8 not (8 and 9)

11. 7 not 10

12. exp Randomized Controlled Trials as Topic/

13. 11 or 12

14. exp Diabetes Mellitus/

15. exp Diabetes Complications/

16. exp Diabetic Retinopathy/

17. ((diabet$ or proliferative or non-proliferative) adj4 retinopath$).tw.

18. diabetic retinopathy.kw.

19. (diabet$ adj3 (eye$ or vision or visual$ or sight$)).tw.

20. (retinopath$ adj3 (eye$ or vision or visual$ or sight$)).tw.

21. (DR adj3 (eye$ or vision or visual$ or sight$)).tw.

22. or/14-21

23. exp Mass Screening/

24. exp Vision Tests/

25. exp Telemedicine/

26. exp Photography/

27. exp Ophthalmoscopes/

28. exp Ophthalmoscopy/

29. (ophthalmoscop$ or fundoscop$ or funduscop$).ti.

30. ((exam$ or photo$ or imag$) adj3 fundus).tw.

31. (photography or retinography).tw.

32. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 camera).tw.

33. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 imag$).tw.

34. screen$.tw.

35. ((eye$ or retina$ or ophthalm$) adj4 exam$).tw.

36. ((eye or vision or retinopathy or ophthalmic) adj4 test$).tw.

37. ((eye$ or retina$ or ophthalm$) adj4 visit$).tw.

38. Office Visits/

39. (telemedicine$ or telemonitor$ or telescreen$ or telehealth or teleophthalmology).tw.

40. or/23-39

41. "Quality of Health Care"/

42. Quality Improvement/

43. Delivery of Health Care/

44. Delivery of Health Care, Integrated/

45. service delivery.tw.

46. decision making.tw.

47. (consensus adj3 (process$ or discuss)).tw.

48. stakeholder$.tw.

49. Quality Control/

50. Total Quality Management/

51. Quality Indicators, Health Care/

52. Quality Assurance, Health Care/

53. quality assurance.tw.

54. (quality adj2 improv$).tw.

55. total quality.tw.

56. continuous quality.tw.

57. quality management.tw.

58. (organisation$ adj3 cultur$).tw.

59. Disease Management/

60. Program Evaluation/

61. ((provider$ or program$) adj3 (monitor$ or evaluate$ or modif$ or practice)).tw.

62. (implement$ adj3 (improve$ or change$ or effort$ or issue$ or impede$ or glossary or tool$ or innovation$ or outcome$ or driv$ or examin$ or reexamin$ or scale$ or strateg$ or advis$ or expert$)).tw.

63. (need$ adj3 assess$).tw.

64. ((education$ or learn$) adj5 (continu$ or material$ or meeting or collaborat$)).tw.

65. exp Medical audit/

66. (audit or feedback or compliance or adherence or training or innovation).ti.

67. (guideline$ adj3 (clinical or practice or implement$ or promot$)).tw.

68. exp Health Services Accessibility/

69. (outreach adj2 (service$ or visit$)).tw.

70. (intervention$ adj3 (no or usual or routine or target$ or tailor$ or mediat$)).tw.

71. usual care.tw.

72. exp Reminder Systems/

73. remind$.tw.

74. (improve$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw.

75. (increas$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw.

76. (appointment$ adj3 (miss$ or fail$ or remind$ or follow up)).tw.

77. Telephone/

78. telephone.tw.

79. Cell Phones/

80. Mobile Applications/

81. Remote Consultation/

82. (m-health or e-health or g-health or u-health).tw.

83. (phone$ adj1 (smart or cell)).tw.

84. (smartphone$ or cellphone$).tw.

85. (hand adj1 held device$).tw.

86. (mobile adj2 (health or healthcare or phone$ or device$ or monitor$ or comput$ or app or apps or application)).tw.

87. Internet/

88. Social Networking/

89. (email$ or text$ or message$).tw.

90. (letter or mail or mailed or print$ or brochure$ or newsletter$).tw.

91. Primary Health Care/

92. General Practitioners/ or Physicians, Family/ or Physicians, Primary Care/

93. Primary Prevention/

94. Preventive Health Services/

95. Community Health Services/

96. Community Health Nursing/

97. Health Services, Indigenous/

98. Rural Health Services/

99. Mobile Health Units/

100. (Ophthalmologist$ or Optometrist$ or Optician$ or Orthopist$ or Refractionists).tw.

101. ((Ophthalmic or eye) adj3 (surgeon$ or nurse$ or technician$ or officer$ or assistant$ or staff$)).tw.

102. Physician's Practice Patterns/

103. Professional Practice/

104. (professional adj3 (practice or develop$ or educat)).tw.

105. Education, Medical, Continuing/

106. exp nurses/

107. Specialties, Nursing/

108. Nurse's Role/

109. Education, Nursing, Continuing/

110. (nurse or nurses).tw.

111. Pharmacists/

112. pharmacist$.tw.

113. ((role or roles) adj3 expan$).tw.

114. (task$ adj3 shift$).tw.

115. exp Medical Records Systems, Computerized/

116. Management Information Systems/

117. Database Management Systems/

118. Computer Systems/

119. Point-of-Care Systems/

120. Hospital Information Systems/

121. ((health or healthcare) adj4 (record or management system$)).tw.

122. (decision adj5 support).ti.

123. Economics/

124. "costs and cost analysis"/

125. Cost allocation/

126. Cost-benefit analysis/

127. Cost control/

128. Cost savings/

129. Cost of illness/

130. Cost sharing/

131. "deductibles and coinsurance"/

132. Medical savings accounts/

133. Health care costs/

134. Direct service costs/

135. Drug costs/

136. Employer health costs/

137. Hospital costs/

138. Health expenditures/

139. Capital expenditures/

140. Value of life/

141. exp economics, hospital/

142. exp economics, medical/

143. Economics, nursing/

144. Economics, pharmaceutical/

145. exp "fees and charges"/

146. exp budgets/

147. (low adj cost).mp.

148. (high adj cost).mp.

149. (health?care adj cost$).mp.

150. (fiscal or funding or financial or finance).tw.

151. (cost adj estimate$).mp.

152. (cost adj variable).mp.

153. (unit adj cost$).mp.

154. (economic$ or pharmacoeconomic$ or price$ or pricing).tw.

155. Uncompensated Care/

156. Reimbursement Mechanisms/

157. Reimbursement, Incentive/

158. (insurance adj3 (health$ or scheme$)).tw.

159. (financial or economic or pay or payment or copayment or paid or fee or fees or monetary or money or cash or incentiv$ or disincentiv$).tw.

160. or/41-159

161. exp Patient Acceptance of health Care/

162. exp Attitude to Health/

163. exp Health Behavior/

164. (barrier$ or obstacle$ or facilitat$ or enable$).tw.

165. (uptake or takeup or attend$ or accept$ or adhere$ or attitude$ or participat$ or facilitat$ or utilisat$ or utilizat$).tw.

166. (complie$ or comply or compliance$ or noncompliance$ or non compliance$).tw.

167. (encourag$ or discourage$ or reluctan$ or nonrespon$ or non respon$ or refuse$).tw.

168. (non-attend$ or non attend$ or dropout or drop out or apath$).tw.

169. Health Education/

170. exp Patient Education as Topic/

171. exp Health Promotion/

172. exp Counseling/

173. "Attitude of Health Personnel"/

174. (health adj2 (promotion$ or knowledge or belief$)).tw.

175. (educat$ adj2 (intervention$ or information or material or leaflet)).tw.

176. Socioeconomic Factors/

177. exp Poverty/

178. Social Class/

179. Educational Status/

180. ((school or education$) adj3 (status or level$ or attain$ or achieve$)).tw.

181. Employment/

182. Healthcare Disparities/

183. Health Status Disparities/

184. exp Medically Underserved Area/

185. Rural Population/

186. Urban Population/

187. exp Ethnic Groups/

188. Minority Groups/

189. Vulnerable Populations/

190. ((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw.

191. (disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw.

192. or/161-191

193. 160 or 192

194. 13 and 22 and 40 and 193

195. (ranibizumab or bevacizumab or avastin or aflibercept).ti.

196. (cataract$ or intraocular or glaucoma$ or phaco$ or photocoagulat$ or photodynamic or laser$ or vitrectom$).ti.

197. (macula$ adj2 (degener$ or oedema or edema)).ti.

198. nerve fiber layer.ti.

199. (coronary or cardiac or cardio$ or heart or myocardia$ or artery or aneurysm or atrial or echocardiography or hypertension or hypotension or stroke or pulmonary or COPD or lung$ or organ$ or smoking).ti.

200. (pregnan$ or gestational or neonat$ or perinatal or maternal or trimester or congenital or ovary or breast$).ti.

201. (kidney or liver or cirrhosis or renal or hepatitis or dialysis or pancrea$ or gastric or gastrectom$ or surg$ or duoden$).ti.

202. (blood glucose or blood pressure or ketoacidosis or hypoglycemi$ or rosiglitazone).ti.

203. (lipid$ or lipase$ or statin$ or hypercholesterolemia or microalbumin$ or albumin$ or platlet$ or plasma$ or hemoglobin$ or haemochromat$ or arterial).ti.

204. (cancer$ or carcinoma$ or neoplas$ or adenoma$ or metformin$).ti.

205. (urin$ or incontinence or bladder or constipat$ or bowel$ or faecal or colorectal or colon$).ti.

206. (gene$ or genotype$ or genome$ or genomic or phenotyp$ or biomarker$ or polymorphism$ or interleukin$).ti.

207. (cell$ or molecular or assay).ti.

208. (cystic or fibrosis or CF or tuberculosis or TB or lupus).ti.

209. (neuropath$ or nephropath$ or prematurity).ti.

210. ($arthritis or steroid$ or osteoporosis or atherosclerosis or sclerosis).ti.

211. (apnea or sleep or limb or oral$ or celiac or coeliac or skin or MRSA or anesthesia or vitamin or HIV or testosterone or erectile or schizophren$ or bipolar or antipsychotic$ or psychotic$).ti.

212. prevalence.ti.

213. or/195-212

214. 194 not 213

**Embase**

1. exp randomized controlled trial/

2. exp randomization/

3. exp double blind procedure/

4. exp single blind procedure/

5. or/1-4

6. (animal or animal experiment).sh.

7. human.sh.

8. 6 and 7

9. 6 not 8

10. 5 not 9

11. exp clinical trial/

12. (clin$ adj3 trial$).tw.

13. random$.tw.

14. exp placebo/

15. placebo$.tw.

16. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.

17. exp experimental design/

18. exp crossover procedure/

19. exp control group/

20. exp latin square design/

21. or/11-20

22. 21 not 9

23. 22 not 10

24. exp comparative study/

25. exp evaluation/

26. exp prospective study/

27. (control$ or prospectiv$ or volunteer$).tw.

28. or/24-27

29. 28 not 9

30. 29 not (10 or 22)

31. 10 or 23 or 30

32. "randomized controlled trial (topic)"/

33. 31 or 32

34. exp diabetes mellitus/

35. exp diabetic retinopathy/

36. ((diabet$ or proliferative or non-proliferative) adj4 retinopath$).tw.

37. diabetic retinopathy.kw.

38. (diabet$ adj3 (eye$ or vision or visual$ or sight$)).tw.

39. (retinopath$ adj3 (eye$ or vision or visual$ or sight$)).tw.

40. (DR adj3 (eye$ or vision or visual$ or sight$)).tw.

41. or/34-40

42. exp Screening/

43. exp Vision Test/

44. Eye Examination/

45. Telemedicine/

46. Photography/

47. Eye Photography/

48. Ophthalmoscopy/

49. (ophthalmoscop$ or fundoscop$ or funduscop$).ti.

50. ((exam$ or photo$ or imag$) adj3 fundus).tw.

51. (photography or retinography).tw.

52. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 camera).tw.

53. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 imag$).tw.

54. screen$.tw.

55. ((eye$ or retina$ or ophthalm$) adj4 exam$).tw.

56. ((eye or vision or retinopathy or ophthalmic) adj4 test$).tw.

57. ((eye$ or retina$ or ophthalm$) adj4 visit$).tw.

58. (telemedicine$ or telemonitor$ or telescreen$ or telehealth or teleophthalmology).tw.

59. or/42-58

60. Health Care Quality/

61. Quality Improvement/

62. Health Care Delivery/

63. Integrated Health Care System/

64. service delivery.tw.

65. decision making.tw.

66. (consensus adj3 (process$ or discuss)).tw.

67. stakeholder$.tw.

68. Quality Control/

69. Total Quality Management/

70. quality assurance.tw.

71. (quality adj2 improv$).tw.

72. total quality.tw.

73. continuous quality.tw.

74. quality management.tw.

75. (organisation$ adj3 cultur$).tw.

76. disease management/

77. program evaluation/

78. ((provider$ or program$) adj3 (monitor$ or evaluate$ or modif$ or practice)).tw.

79. (implement$ adj3 (improve$ or change$ or effort$ or issue$ or impede$ or glossary or tool$ or innovation$ or outcome$ or driv$ or examin$ or reexamin$ or scale$ or strateg$ or advis$ or expert$)).tw.

80. (need$ adj3 assess$).tw.

81. ((education$ or learn$) adj5 (continu$ or material$ or meeting or collaborat$)).tw.

82. Medical audit/

83. (audit or feedback or compliance or adherence or training or innovation).ti.

84. (guideline$ adj3 (clinical or practice or implement$ or promot$)).tw.

85. (outreach adj2 (service$ or visit$)).tw.

86. (intervention$ adj3 (no or usual or routine or target$ or tailor$ or mediat$)).tw.

87. usual care.tw.

88. reminder system/

89. remind$.tw.

90. (improve$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw.

91. (increas$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw.

92. (appointment$ adj3 (miss$ or fail$ or remind$ or follow up)).tw.

93. telephone/

94. telephone.tw.

95. Mobile Phone/

96. Mobile Application/

97. Teleconsultation/

98. (m-health or e-health or g-health or u-health).tw.

99. (phone$ adj1 (smart or cell)).tw.

100. (smartphone$ or cellphone$).tw.

101. (hand adj1 held device$).tw.

102. (mobile adj2 (health or healthcare or phone$ or device$ or monitor$ or comput$ or app or apps or application)).tw.

103. Internet/

104. Social Network/

105. (email$ or text$ or message$).tw.

106. (letter or mail or mailed or print$ or brochure$ or newsletter$).tw.

107. Primary Health Care/

108. General Practitioner/

109. Primary Prevention/

110. Preventive Health Service/

111. Community Care/

112. Community Health Nursing/

113. exp Transcultural Care/

114. Rural Health Care/

115. Ophthalmologist/

116. (Ophthalmologist$ or Optometrist$ or Optician$ or Orthopist$ or Refractionists).tw.

117. ((Ophthalmic or eye) adj3 (surgeon$ or nurse$ or technician$ or officer$ or assistant$ or staff$)).tw.

118. Clinical Practice/

119. Professional Practice/

120. Continuing Education/

121. (professional adj3 (practice or develop$ or educat)).tw.

122. Nurse/

123. Nursing Discipline/

124. Nurse Attitude/

125. Nursing Education/

126. (nurse or nurses).tw.

127. pharmacist/

128. pharmacist$.tw.

129. ((role or roles) adj3 expan$).tw.

130. (task$ adj3 shift$).tw.

131. Electronic Medical Record/

132. Information System/

133. Data Base/

134. Computer System/

135. Hospital Information System/

136. ((health or healthcare) adj4 (record or management system$)).tw.

137. (decision adj5 support).ti.

138. cost benefit analysis/

139. cost effectiveness analysis/

140. cost of illness/

141. cost control/

142. economic aspect/

143. financial management/

144. health care cost/

145. health care financing/

146. health economics/

147. hospital cost/

148. (fiscal or financial or finance or funding).tw.

149. cost minimization analysis/

150. (cost adj estimate$).mp.

151. (cost adj variable$).mp.

152. (unit adj cost$).mp.

153. (economic$ or pharmacoeconomic$ or price$ or pricing).tw.

154. exp Reimbursement/

155. (financial or economic or pay or payment or copayment or paid or fee or fees or monetary or money or cash or incentiv$ or disincentiv$).tw.

156. (insurance adj3 (health$ or scheme$)).tw.

157. or/60-156

158. exp Patient Attitude/

159. exp Health Behaviour/

160. (barrier$ or obstacle$ or facilitat$ or enable$).tw.

161. (uptake or takeup or attend$ or accept$ or adhere$ or attitude$ or participat$ or facilitat$ or utilisat$ or utilizat$).tw.

162. (complie$ or comply or compliance$ or noncompliance$ or non compliance$).tw.

163. (encourag$ or discourage$ or reluctan$ or nonrespon$ or non respon$ or refuse$).tw.

164. (non-attend$ or non attend$ or dropout or drop out or apath$).tw.

165. Health Education/

166. exp Patient Education/

167. Diabetes Education/

168. Help Seeking Behavior/

169. Patient Participation/

170. Patient Decision Making/

171. exp Health Promotion/

172. (health adj2 (promotion$ or knowledge or belief$)).tw.

173. (educat$ adj2 (intervention$ or information or material or leaflet)).tw.

174. exp Socioeconomics/

175. Income/

176. Social Class/

177. Social Status/

178. Educational Status/

179. ((school or education$) adj3 (status or level$ or attain$ or achieve$)).tw.

180. Employment/

181. Health Care Disparity/

182. Health Disparity/

183. Rural Population/

184. Rural Area/

185. Urban Population/

186. Urban Area/

187. exp Ethnic Group/

188. Ethnicity/

189. Race Difference/

190. Minority Groups/

191. Vulnerable Populations/

192. ((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw.

193. (disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw.

194. or/158-193

195. 157 or 194

196. 33 and 41 and 59 and 195

197. (ranibizumab or bevacizumab or avastin or aflibercept).ti.

198. (cataract$ or intraocular or glaucoma$ or phaco$ or photocoagulat$ or photodynamic or laser$ or vitrectom$).ti

199. (macula$ adj2 (degener$ or oedema or edema)).ti.

200. nerve fiber layer.ti.

201. (coronary or cardiac or cardio$ or heart or myocardia$ or artery or aneurysm or atrial or echocardiography or hypertension or hypotension or stroke or pulmonary or COPD or lung$ or organ$ or smoking).ti.

202. (pregnan$ or gestational or neonat$ or perinatal or maternal or trimester or congenital or ovary or breast$).ti.

203. (kidney or liver or cirrhosis or renal or hepatitis or dialysis or pancrea$ or gastric or gastrectom$ or surg$ or duoden$).ti.

204. (blood glucose or blood pressure or ketoacidosis or hypoglycemi$ or rosiglitazone).ti.

205. (lipid$ or lipase$ or statin$ or hypercholesterolemia or microalbumin$ or albumin$ or platlet$ or plasma$ or hemoglobin$ or haemochromat$ or arterial).ti.

206. (cancer$ or carcinoma$ or neoplas$ or adenoma$ or metformin$).ti.

207. (urin$ or incontinence or bladder or constipat$ or bowel$ or faecal or colorectal or colon$).ti.

208. (gene$ or genotype$ or genome$ or genomic or phenotyp$ or biomarker$ or polymorphism$ or interleukin$).ti.

209. (cell$ or molecular or assay).ti.

210. (cystic or fibrosis or CF or tuberculosis or TB or lupus).ti.

211. (neuropath$ or nephropath$ or prematurity).ti.

212. ($arthritis or steroid$ or osteoporosis or atherosclerosis or sclerosis).ti.

213. (apnea or sleep or limb or oral$ or celiac or coeliac or skin or MRSA or anesthesia or vitamin or HIV or testosterone or erectile or schizophren$ or bipolar or antipsychotic$ or psychotic$).ti.

214. prevalence.ti.

215. or/197-214

216. 196 not 215

**PsychINFO**

1. exp Treatment Effectiveness Evaluation/

2. exp Clinical Trials/

3. exp Placebo/

4. placebo$.tw.

5. randomly.tw.

6. randomi#ed.tw.

7. trial$.tw.

8. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$ or dummy)).tw.

9. (factorial$ or allocat$ or assign$ or volunteer$).tw.

10. (crossover$ or cross over$).tw.

11. (quasi adj (experimental or random$)).tw.

12. (control$ adj3 (trial$ or study or studies or group$)).tw.

13. or/1-12

14. diabetes/

15. ((diabet$ or proliferative or non-proliferative) adj4 retinopath$).tw.

16. (diabet$ adj3 (eye$ or vision or visual$ or sight$)).tw.

17. (retinopath$ adj3 (eye$ or vision or visual$ or sight$)).tw.

18. (DR adj3 (eye$ or vision or visual$ or sight$)).tw.

19. or/14-18

20. exp Screening/

21. ophthalmologic examination/

22. telemedicine/

23. (ophthalmoscop$ or fundoscop$ or funduscop$).ti.

24. ((exam$ or photo$ or imag$) adj3 fundus).tw.

25. (photography or retinography).tw.

26. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 camera).tw.

27. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 imag$).tw.

28. screen$.tw.

29. ((eye$ or retina$ or ophthalm$) adj4 exam$).tw.

30. ((eye or vision or retinopathy or ophthalmic) adj4 test$).tw.

31. ((eye$ or retina$ or ophthalm$) adj4 visit$).tw.

32. (telemedicine$ or telemonitor$ or telescreen$ or telehealth or teleophthalmology).tw.

33. or/20-32

34. 13 and 19 and 33

## Web of Science Conference Proceedings Citation Index-Science and Emerging Sources Citation Index

#11 #10 AND #2 AND #1

#10 #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3

#9 TS = (photography OR retinography OR telemedicine* OR telemonitor* OR telescreen* OR telehealth OR teleophthalmology)

#8 TS = (fundus NEAR/3 exam* OR fundus NEAR/3 photo* OR fundus NEAR/3 imag*)

#7 TS = (imag* NEAR/3 mydriatic OR imag* NEAR/3 digital OR imag* NEAR/3 retina* OR imag* NEAR/3 fundus OR imag* NEAR/3 steroscopic OR camera NEAR/3 mydriatic OR camera NEAR/3 digital OR camera NEAR/3 retina* OR camera NEAR/3 fundus OR camera NEAR/3 steroscopic)

#6 TI = (ophthalmoscop* OR fundoscop* OR funduscop*)

#5 TS = (visit NEAR/4 eye* OR visit NEAR/4 retina* OR visit NEAR/4 ophthalmic)

#4 TS = (exam* NEAR/4 eye* OR exam* NEAR/4 retina* OR exam* NEAR/4 ophthalmic)

#3 TS = (screen* OR test* NEAR/4 eye OR test* NEAR/4 vision OR test* NEAR/4 retinopathy OR test* NEAR/4 ophthalmic)

#2 TS = (diabetic NEAR/3 retinopath* OR diabetic NEAR/3 eye* OR diabetic NEAR/3 vision OR diabetic NEAR/3 visual* OR diabetic NEAR/3 sight* OR diabetic NEAR/3 proliferative OR diabetic NEAR/3 "non proliferative")

#1 TS =(clinical trial* OR research design OR comparative stud* OR evaluation stud* OR controlled trial* OR follow-up stud* OR prospective stud* OR random* OR placebo* OR single blind* OR double blind*)

### Proquest

Ab (diabetic) AND ab (retinopathy OR eye OR vision OR visual OR sight) AND ab (screen OR screening OR test OR exam OR examination OR telemedicine) AND ab (random OR randomly OR randomised OR randomized).

### OpenGrey

(screen OR test OR exam OR Ophthalmoscopy OR digital OR imaging OR fundus OR telemedicine OR telemonitor OR telescreen OR telehealth) AND diabetic retinopathy

### ISRCTN registry

(screen OR test OR exam OR ophthalmoscopy OR digital OR imaging OR fundus OR telemedicine OR telemonitor OR telescreen OR telehealth) within Condition: diabetic retinopathy

### ClinicalTrials.gov

(screen OR test OR exam OR Ophthalmoscopy OR digital OR imaging OR fundus OR telemedicine OR telemonitor OR telescreen OR telehealth) | Interventional Studies | diabetic retinopathy

### WHO International Clinical Trials Registry Platform

Condition = diabetic retinopathy AND Intervention = screen OR test OR exam OR Ophthalmoscopy OR digital OR imaging OR fundus OR telemedicine OR telemonitor OR telescreen OR telehealth

## 1.2. Characteristics of included, ongoing and excluded studies (phase 1 review).

**Studies targeting diabetic retinopathy screening**

| Anderson 2003[2] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness of personalized follow up compared to reminder letters, in increasing return rates at urban eye disease screening clinics for African Americans with diabetes and minimal or no retinopathy<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Nine free culture-specific (urban African American) community based eye screening clinics<br>**Total number of participants:** 132<br>**Percentage male:** 38%<br>**Diabetes type:** type 2 (98.5%)<br>**Average age (SD):** 55yrs (NR)<br>**Inclusion criteria:** African American adults with type 2 diabetes attending community eye clinic<br>**Exclusion criteria:** those who were not African American |
| **Interventions** | **Intervention (n=67):** single reminder letter including information on the day, time and location of the eye clinic appointment one month prior to the appointment. Follow up phone call 10 days after letter sent. Phone call also addressed barriers to attending and message that diabetes can lead to vision loss.<br>**Comparator (n=65):** single reminder letter including information on the day, time and location of the eye clinic appointment one month prior to the appointment<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** return rate for annual dilated fundus examination<br>**Secondary outcomes:** factors predicative of returning for a dilated fundus examination |
| **Notes** | **Date conducted:** 1995-1999<br>**Trial registration number:** NR<br>**Sources of funding**: National Institute of Health/National Institute of Diabetes and Digestive and Kidney Disease<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Low risk | Judgement comment: similar numbers of participants having ever had an eye examination by an ophthalmologist with similar numbers screened in last year. Table 1 p43. |
| **Similar baseline characteristics** | Low risk | Quote *'There were no statistically significant differences between the 2 groups on any of the variables in this table.'*<br>(Footnote Table 1 p43) |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: all outcome data reported. See Table 1 p42 |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the telephone reminder |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| Basch 1999[3] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of a multi-component health education intervention on the rate of ophthalmic examinations in African Americans with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** outpatient clinics at 5 sites in the New York metropolitan area with on-site ophthalmology services (secondary care)<br>**Total number of participants:** 280<br>**Percentage male:** 34.3%<br>**Diabetes type:** NR<br>**Average age (SD):** 54.8yrs (12.9)<br>**Inclusion criteria:** African Americans >18yrs with a diagnosis of diabetes with no record of receiving a dilated eye exam in the preceding 14 months<br>**Exclusion criteria:** blindness in both eyes, advanced eye disease, progressive medical illness, impaired cognitive ability |
| **Interventions** | **Intervention (n=137):** multicomponent educational intervention consisting of a booklet and motivational video describing the benefits of eye screening, semi-structured telephone outreach education and counselling<br>**Comparator (n=143):** mailed booklet produced by the American Medical Association on meal planning<br>**Duration:** 6 months (or until eye exam recorded) |
| **Outcomes** | **Primary outcome:** documented dilated retinal examination within 6 months of randomisation<br>**Secondary outcomes:** predictors of examination status |
| **Notes** | **Date conducted:** 1993-1995<br>**Trial registration number:** NR<br>**Sources of funding**: National Eye Institute, National Institute of Diabetes and Digestive and Kidney Disease<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement (Quote)** |
| **Adequate sequence generation** | Low risk | Quote *'After research staff confirmed subjects could be reached by telephone, they were enrolled and randomised within site and sex groups. We randomized subjects in pairs by using tables of random permutations.'*<br>p1879 |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Low risk | Quote: *'Eligibility criteria based on chart audits included a diagnosis of diabetes mellitus, being African American, being 18 years or older, having no documentation of a dilated retinal examination in the preceding 14 months, and having been seen at the clinic at least 1 other time in the past year.'*<br>p1879 |
| **Similar baseline characteristics** | Low | Quote *'There were no significant differences between groups on any of the available personal and demographic variables'*<br>(see Table 1 p1880). |
| **Incomplete outcome data addressed** | Unclear risk | Judgement comment: attrition not reported for comparator group (see Figure 1 p1880) |
| **Adequate blinding** | Low risk | Quote *'Research staff, unaware of subjects' group assignment, audited medical records.'*<br>p1879 |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the multi-component health education intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess. |

| | | |
|---|---|---|
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Bush 2014[4]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of 'Link Workers' on uptake of diabetic retinopathy screening in a hard-to-reach and high-risk population group<br>**Study design:** cluster RCT |
| **Participants** | **Country:** UK<br>**Setting:** General Practices in Coventry with a predominantly South Asian population<br>**Total number of clusters:** 10<br>**Number of providers:** NR<br>**Number of patients:** 2680<br>**Percentage male:** NR<br>**Diabetes type:** NR<br>**Average age (SD):** NR<br>**Inclusion criteria:** eligible for diabetic retinopathy screening service and failing to attend their first screening appointment<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=10 clusters, n=988 participants):** multi-lingual 'Link Worker' telephone calls to participants failing to attend their first appointment to remind them of the screening appointment and encourage attendance<br>**Comparator (n=10 clusters, n=1,692 participants):** usual care (participants who fail to attend their initial screen date were sent a further appointment date by post)<br>**Duration:** phone calls continued until an examination was reported or when 6 months had passed, whichever came first |
| **Outcomes** | **Primary outcome:** attendance for diabetic retinopathy screening within 6 months of randomisation<br>**Secondary outcomes:** none |
| **Notes** | **Date conducted:** 1st Jan to 31st Dec 2007<br>**Trial registration number:** ISRCTN79653731<br>**Sources of funding**: unfunded<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Low risk | Judgement comment: unit of allocation by GP practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low risk | Judgement comment: similar baseline retinopathy screening attendance (Table 1 p296) |
| **Similar baseline characteristics** | Unclear risk | Not reported |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: data reported for all participants |
| **Adequate blinding** | Low risk | Quote *'Data available for analyses comprised routinely collected and collated attendance data from the retinopathy screening unit.'* p295 |
| **Protected against contamination** | Low risk | Quote *'Following randomisation and throughout the study, there was no further contact with control practices.'* p295 |
| **Free of selective reporting** | Unclear risk | Judgement comment: trial retrospectively registered and so not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Conlin 2006[5]** |
|---|

| Conlin 2006[5] | |
|---|---|
| **Methods** | **Study aim:** to study whether non-mydriatic digital retinal imaging in an ambulatory care setting affected adherence to annual dilated ophthalmic examinations in patients with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Department of Veterans Affairs (VA) Boston Healthcare System<br>**Total number of participants:** 448<br>**Percentage male:** 98%<br>**Diabetes type:** NR<br>**Average age (SD):** 67yrs (21.2)<br>**Inclusion criteria:** adults with diabetes and a VA- based primary care provider<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=223):** teleretinal imaging by trained imager who demonstrated the basic anatomical structures of the ocular fundus using the retinal images. Acting as a care coordinator, the imager later acted on the image reader's report when necessary and communicated with the participant to establish an appropriate eye-exam schedule. The imager also educated the participant about the importance of optimal blood glucose and blood pressure control<br>**Comparator (n=225):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** documented dilated retinal examination within 12 months of randomisation<br>**Secondary outcomes:** diabetic retinopathy outcomes and characteristics of participants with ungradable images |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Department of the Army; VA Health Services Research and Development Service; National Institutes of Health<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: '*Randomization was accomplished with a random-variables generator and a series of sealed envelopes.'* p734 |
| **Allocation concealment** | Unclear risk | Quote: '*Randomization was accomplished with a random-variables generator and a series of sealed envelopes.'* p734<br>Judgment comment: not clear whether the envelope was assigned to the participant before opening |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Unclear risk | Not reported |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: data available for all participants (see Table 2) |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received teleretinal imaging |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| Davis 2003[6] | |
|---|---|
| **Methods** | **Study aim:** to determine if telemedicine improves eye examination rates in individuals with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** rural, federally funded primary care practice in South Carolina<br>**Total number of participants:** 59<br>**Percentage male:** NR<br>**Diabetes type:** NR<br>**Average age (SD):** NR<br>**Inclusion criteria:** >18 years with physician diagnosis of diabetes of any duration and on any form of treatment<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=30):** telemedicine retinal screening program. Ophthalmologist at a distant site evaluated retinal photographs and consulted with the participant using real time videoconferencing<br>**Comparator (n=29):** usual care (reminded to schedule appointments with their usual eye care provider)<br>**Duration:** NR |
| **Outcomes** | **Primary outcome:** retinal examination frequency<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Unclear risk | Not reported |
| **Incomplete outcome data addressed** | Unclear risk | Not reported |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Unclear risk | Judgement comment: not possible to assess |

| Ellish 2011[7] | |
|---|---|
| **Methods** | **Study aim:** to compare the effects of a tailored (individualized) and targeted (generic) print intervention in promoting dilated fundus examinations in older African Americans<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA |

| Ellish 2011[7] | |
|---|---|
| | **Setting:** primary care<br>**Total number of participants:** 72 (sub-population with diabetes of 379 study participants)<br>**Percentage male:** 25%<br>**Diabetes type:** NR<br>**Average age (SD):** 72.4yrs (6.3)<br>**Inclusion criteria:** African Americans aged ≥ 65yrs who had not had a dilated fundus examination in the last 2 years<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=39):** 'Tailored intervention'. Each participant received a four page newsletter including a testimonial designed to model eye examination behaviour and a barrier table to convey specific ideas to overcome barriers. The newsletter was specifically tailored by the addition of specific messages based on his/her responses to selected questions from a baseline questionnaire which identified barriers to screening and preventative health behaviours<br>**Comparator (n=33):** 'Targeted intervention'. Participants received a standard newsletter with the same sections as the intervention group but without the tailored messages<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** eye doctor confirmed dilated retinal examination at 6 months following randomisation<br>**Secondary outcomes:** predictors of retinal examination attendance |
| **Notes** | **Date conducted:** June 2007 and September 2008<br>**Trial registration number:** NCT00649766<br>**Sources of funding**: National Institutes of Health<br>**Declaration of interest:** none reported |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote *'As reported in Table 2, at baseline the intervention groups were comparable for demographic and other variables.'* p1594 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: low attrition. All participants accounted for (Figure 1 p1594) |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the tailored intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: trial retrospectively registered and so not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other sources of bias |

| Halbert 1999[8] | |
|---|---|
| Methods | **Study aim:** to determine whether multiple mailed patient reminders can produce an increase in attendance for diabetic retinal examinations over that seen with a single reminder<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA |

| Halbert 1999[8] | |
|---|---|
| | **Setting:** large network-based health maintenance organisation in California<br>**Total number of participants:** 23,740<br>**Percentage male:** 46.6%<br>**Diabetes type:** NR<br>**Average age (SD):** NR<br>**Inclusion criteria:** all members with diabetes ≥18 years with no claim for a dilated fundus examination who were enrolled in Health Net, a large network-based health maintenance organization (HMO) in California, during the study period<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=11,992):** at baseline, participating medical groups in the HMO network received a letter explaining the program, the current American Diabetes Association (ADA) guidelines for retinal examinations, a sample physician letter, and lists of their diabetic patients with their diabetic retinopathy screening exam status. Diabetic members who did not have a record of a diabetic retinopathy exam received educational materials and a report of their current retinopathy screening status and a reminder to obtain a dilated retinal examination. The intervention group received further reminders at 3 months, 6 months or 9 months after baseline if they had not had a dilated retinal examination according to the HMO claims database. Mailing of reminders was verified by postal receipt<br>**Comparator (n=11,748):** at baseline, the diabetic members and their medical groups received all the materials described above including a reminder to obtain a dilated retinal examination but received no further reminders.<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** claims from either an ophthalmologist or optometrist using procedural terminology codes<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** August 1996 to July 1997<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *'Table 1 describes the demographics of the eligible diabetic members by sex and by age-group. There were no differences in sex and age-group distribution between the single and multiple intervention groups (P values were 0.225 and 0.063, respectively) '*<br>p753 |
| **Incomplete outcome data addressed** | Unclear | Judgement comment: members who disenrolled from the HMO during the study period were excluded from the analysis. These were balanced across both arms of the study (18% single reminder, 17% multiple reminder group). Unclear if missing data would impact on outcome |
| **Adequate blinding** | Low risk | Judgement comment: outcome data obtained from procedural codes and therefore unlikely to be influenced by blinding |
| **Protected against contamination** | Low risk | Comparator group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |

| | | |
|---|---|---|
| **Free from other bias** | Low risk | Judgement comment: no evidence of other sources of bias |

| **Lian 2013[9]** | |
|---|---|
| **Methods** | **Study aim:** to assess whether a small co-payment would impact on uptake of diabetic retinopathy screening compared to free access<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** Hong Kong, China<br>**Setting:** two public family medicine clinics<br>**Total number of patients:** 4,644<br>**Percentage male:** 45.2%<br>**Diabetes type:** types 1 and 2<br>**Average age (SD):** 64.1yrs (11)<br>**Inclusion criteria:** adults with type 1 or type 2 diabetes<br>**Exclusion criteria:** those already under the regular care of an ophthalmologist |
| **Interventions** | **Intervention (n=2,319):** participants offered screening with small co-payment. A postal reminder of the appointment was sent to those who accepted screening. Participants not attending for screening were called to book a further appointment.<br>**Comparator (n=2,325):** participants offered screening with no charge. A postal reminder of the appointment was sent to those who accepted screening. Participants not attending for screening were called to book a further appointment.<br>**Duration:** NR |
| **Outcomes** | **Primary outcome:** uptake of screening and severity of diabetic retinopathy detected<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Health and Health Services Research Fund of the Hong Kong SAR Government and the Azalea Endowment Fund.<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'Randomization was based on the random allocation of digits 0 or 1 by computer..'*<br>*p1248* |
| **Allocation concealment** | Low risk | Quote: *' ..a research assistant generated the random sequence and assigned the participants…Two trained and experienced telephone interviewers were each allocated a random half of the subjects allocated to the free and pay groups.'*<br>*p1248* |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *'There were no differences between the characteristics of participants allocated to the free and pay groups (Table 1).'*<br>p1248 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: the majority of exclusions were due to participants already being under ophthalmologist care. Low attrition with reasons given and balanced across the two arms of the study |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Unclear risk | Quote : *'Two trained and experienced telephone interviewers were each allocated a random half of the subjects allocated to the free and pay groups.'*<br>p1248<br>Judgement comment: not clear how contamination was prevented |

| | | |
|---|---|---|
| **Free of selective reporting** | Unclear risk | Judgement comment: trial retrospectively registered and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other sources of bias |

| **Mansberger 2015[10]** | |
|---|---|
| **Methods** | **Study aim:** to determine the effectiveness of telemedicine for providing diabetic retinopathy screening examinations compared with traditional surveillance in community health clinics with a high proportion of ethnic minorities<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** two community health clinics<br>**Total number of participants:** 567<br>**Percentage male:** 48%<br>**Diabetes type:** NR<br>**Average age (SD):** 51.1yrs (11.8)<br>**Inclusion criteria:** adults with diabetes ≥18 years who were scheduled to visit their primary care provider<br>**Exclusion criteria:** cognitive impairment preventing informed consent; inability to transfer to a chair to perform non mydriatic imaging |
| **Interventions** | **Intervention (n=296):** participants in this group have digital images of their retina captured with a non-mydriatic camera and were encouraged to see an eye care provider annually for a diabetic eye exam<br>**Comparator (n=271):** participants in this group are encouraged to see an eye care provider annually for a diabetic eye exam<br>**Duration:** 48 months (intervention offered to comparator group after 18m) |
| **Outcomes** | **Primary outcome:** proportion of participants that receive an annual eye exam<br>**Secondary outcomes:** health belief factors associated with adherence |
| **Notes** | **Date conducted:** August 1, 2006 to September 31, 2009<br>**Trial registration number:** NCT01364129<br>**Sources of funding**: National Eye Institute; Centers for Disease Control and Prevention; Good Samaritan Foundation at Legacy Health<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'We used a random number generator to randomly assign participants to the telemedicine group or the traditional surveillance group.'*<br>p519 |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *There were no differences in demographic and medical characteristics at enrolment between the telemedicine (n = 296) and traditional surveillance (n = 271) groups.*<br>p521 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: no missing outcome data at 12 and 24m (see CONSORT flow diagram p519) |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the telemedicine intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: trial retrospectively registered and so not possible to assess |

| | | |
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| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Pizzi 2015[11]** | |
|---|---|
| **Methods** | **Study aim:** to investigate the outcomes and costs of an educational and telephone intervention on dilated fundus examination follow-up adherence in patients with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** tertiary eye care centre<br>**Total number of participants:** 356<br>**Percentage male:** 42%<br>**Diabetes type:** NR<br>**Average age (SD):** 60.7yrs (12.6)<br>**Inclusion criteria:** adults (≥18 years old) with diabetes who had been previously evaluated in the eye clinic, and had been recommended for a follow-up dilated fundus examination<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention arm 1 (mailed intervention) (n=117):** personalised letter encouraging scheduling a dilated fundus examination and a brochure about diabetic eye disease and reminder card and automatic reminder call the day before the scheduled appointment<br>**Intervention arm 2 (telephone intervention) (n=120):** standard reminder letter 1 month prior to exam due date followed by a personal telephone call offering assistance in scheduling an appointment and a reminder letter 3 weeks prior to appointment and automatic reminder call the day before the scheduled appointment<br>**Comparator (n=119):** usual care (standard reminder letter 1 month prior to exam due date and automatic reminder call the day before the scheduled appointment)<br>**Duration:** 3 months |
| **Outcomes** | **Primary outcome:** obtaining a dilated fundus examination within 90 days of the recommended follow up date<br>**Secondary outcomes:** costs of delivering the intervention |
| **Notes** | **Date conducted:** November 2012 to February 2013<br>**Trial registration number:** NR<br>**Sources of funding**: US Centers for Disease Control and Prevention<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'...randomized within age strata (<65 and>65years) using the method of random permuted block'*<br>p254 |
| **Allocation concealment** | Low risk | Quote: *'The study personnel in charge of randomization did not participate in the interventions.'*<br>p254 |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *'There were no statistically significant differences in demographics among the three study groups (Table 1)'*<br>p257 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: all outcome data reported (see Table 2 p258) |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the active interventions |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available |

| | | |
|---|---|---|
| | | and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Prela 2000[12]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the use of a single direct mailed reminder on rate of annual eye examinations in people with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Medicare beneficiaries<br>**Total number of participants:** 6,546<br>**Percentage male:** NR<br>**Diabetes type:** NR<br>**Average age (SD):** NR<br>**Inclusion criteria:** Medicare beneficiaries with diabetes (defined by International Classification of Diseases 9th revision. Clinical Modification ICD-9-CM codes of 250.XX)<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=4,092):** mailed intervention reinforcing the importance of annual eye examinations<br>**Comparator (n=2,454):** usual care (not specified)<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** claims for eye examinations; defined by Physicians Current Procedural Terminology, 4th Edition (CPT-4) codes 99201-99205<br>**Secondary outcomes:** none |
| **Notes** | **Date conducted:** 1994-1995<br>**Trial registration number:** NR<br>**Sources of funding**: US Centers for Disease Control and Prevention<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Low risk | Judgement comment: baseline retinal exams reported and balanced across study arms (see Table 2 p259) |
| **Similar baseline characteristics** | Low risk | Quote: *'The groups were comparable with regard to age, gender and use of preventative health services'*<br>p259 (see Table 2) |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: low attrition, outcome data reported on >90% (see Table 4 p260) |
| **Adequate blinding** | Low risk | Judgement comment: outcome data were obtained from Medicare claims databases |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the mailed intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Rosenkranz 1996[13]** | |
|---|---|
| **Methods** | **Study aim:** to study the impact of polaroid fundus photography during a clinical consultation on future screening behaviour for diabetic retinopathy<br>**Study design:** parallel group RCT |

| Rosenkranz 1996[13] | |
|---|---|
| **Participants** | **Country:** Germany<br>**Setting:** Diabetes Clinic within the University of Düsseldorf<br>**Total number of participants:** 103<br>**Percentage male:** 61.1%<br>**Diabetes type:** type 1 and type 2 (87% type 2)<br>**Average age (SD):** NR<br>**Inclusion criteria:** adults with diabetes living within a 100Km radius of the clinic<br>**Exclusion criteria:** diabetic retinopathy or treatment for diabetic retinopathy; individuals with glaucoma or cataract |
| **Interventions** | **Intervention arm 1 (n=35):** Group B. Polaroid photograph taken, shown and explained to the participant. The photograph was then given to the participant to take home. Results of all clinical investigations explained to participant and also included in a subsequent letter which also contained a recommendation for an eye exam performed by an ophthalmologist and the time frame for this exam.<br>**Intervention arm 2 (n=31):** Group C. Polaroid photograph taken, shown and explained to the participant The photograph was then retained in the participant file. Results of all clinical investigations explained to participant and also included in a subsequent letter which also contained a recommendation for an eye exam performed by an ophthalmologist and the time frame for this exam.<br>**Comparator (n=37):** Group A. Polaroid photograph of fundus taken but not shown to participant. Results of all clinical investigations explained to participant and also included in a subsequent letter which also contained a recommendation for an eye exam performed by an ophthalmologist and the time frame for this exam.<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** attendance for diabetic retinopathy screening<br>**Secondary outcomes:** factors affecting screening attendance |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Judgement comment: similar demographic characteristics across each arm of the study for age gender and socioeconomic status (see Table 1 p70) |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: all participant were followed up and reported (see Table 2 p71) |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | High risk | Judgement comment: given the nature of the intervention it is possible that the control group received the intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | High risk | Judgement comment: patients with existing diabetic retinopathy or previously treated for diabetic retinopathy were excluded |

| Walker 2008[14] | |
|---|---|
| **Methods** | **Study aim:** to study the impact of a tailored telephone intervention compared to a standard print intervention on screening for diabetic retinopathy in an urban minority population |

| Walker 2008[14] | |
|---|---|
| | **Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** three inner city health centres<br>**Total number of participants:** 635<br>**Percentage male:** 39.5%<br>**Diabetes type:** NR<br>**Average age (SD):** 56.6yrs (12.5)<br>**Inclusion criteria:** aged ≥18 years, diagnosed with diabetes, able to speak and read (or be read to in) English or Spanish, capable of providing informed consent, have access to a telephone, and report not having had a dilated fundus examination in the previous 12 months<br>**Exclusion criteria:** no access to a telephone; unable to speak English or Spanish; fundus examination in the previous 12 months |
| **Interventions** | **Intervention (n=326):** tailored telephone intervention to promote retinopathy screening (up to 7 calls over 6/12 period). Participants were interviewed to identify issues and barriers that might either motivate them or prevent them from going for a dilated fundus examination. Attempts were made to engage all participants with targeted self-management strategies and dilated fundus examination education, and they were encouraged to make a screening appointment if they indicated they were ready to change<br>**Comparator (n=309):** participants were sent a printed booklet on preventing diabetic eye problems<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** documentation of a dilated fundus examination within 6 months of randomization<br>**Secondary outcomes:** factors that contribute to receiving a dilated fundus examination within 6 months for participants in the tailored telephone intervention. HbA1c results, from a 1-year period encompassing the subjects' 6-month intervention period |
| **Notes** | **Date conducted:** 2001-2005<br>**Trial registration number:** NR<br>**Sources of funding**: National Institute of Health, Rockerfeller Foundation<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear risk | Not reported |
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *There were no significant differences between the two study groups on any characteristics.'*<br>p188 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: proportion of missing data low and balanced between intervention and control groups |
| **Adequate blinding** | Low risk | Quote: *'The trained chart auditor was masked to the subjects' group assignment.'*<br>p186 |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the tailored telephone intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| Weiss 2015[15] | |
|---|---|
| **Methods** | **Study aim:** to test the impact of a home-based behavioural activation program to improve rates of dilated fundus examinations in older African–Americans with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** two urban medical centres<br>**Total number of participants:** 206<br>**Percentage male:** 39.5%<br>**Diabetes type:** type 2<br>**Average age (SD):** 72.7yrs (6.2)<br>**Inclusion criteria:** aged ≥65 years, self-identification as an African American individual, diagnosis of type 2 diabetes mellitus, no self-report or medical documentation of a dilated fundus examination in the past 12 months, and access to a telephone<br>**Exclusion criteria:** cognitive impairment (based on an abbreviated version of the Mini-Mental State Examination), current significant psychiatric disorder, current medical disorder limiting life expectancy, need for dialysis, and hearing impairment that precluded research participation |
| **Interventions** | **Intervention (n=103):** behavioural intervention delivered by specially trained community health worker. Intervention consisted of education, identifying barriers to a dilated fundus examination and action-planning<br>**Comparator (n=103):** supportive therapy only without educational materials or behavioural strategies or goal-setting<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** medical documentation of a dilated fundus examination by the 6-month follow-up visit<br>**Secondary outcomes:** risk perceptions of diabetes, diabetes self-care behaviours, depressive symptoms |
| **Notes** | **Date conducted:** Oct 2010 to May 2013<br>**Trial registration number:** NCT01179555<br>**Sources of funding**: Pennsylvania Department of Health<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Authors' Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'..participants who completed the baseline assessment were randomized using random permuted blocks with a 1 to1 allocation ratio to BADRP or supportive therapy (ST).'* p1006 |
| **Allocation concealment** | Low risk | Quote: *'Randomization sheets were stored in sequentially numbered sealed envelopes that were opened by the project director after each participant completed baseline assessment.'* p1006 |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: '*The 2 arms were balanced with respect to age, education, sex, recruitment site, and marital status. Differences on the Risk Perceptions and Risk Knowledge Survey of Diabetes Mellitus, Diabetes Self-Care Inventory, Patient Health Questionnaire, Literacy Assessment for Diabetes, and the NEI-VFQ 25 composite scores that may have influenced the primary outcome were not identified. Participants in the BADRP group had lower HbA1c levels and chronic disease scores at baseline.'* p1008 |

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| **Incomplete outcome data addressed** | Low risk | Judgement comment: attrition (approx. 10%) balanced across groups and reasons for exclusion given (see CONSORT diagram p1008) |
| **Adequate blinding** | Low risk | Quote: *'Follow-up assessments were conducted in participants' homes at 6 months' follow-up by community health workers masked to treatment assignment.'* p1007 |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the behavioural intervention |
| **Free of selective reporting** | High risk | Judgement comment: per protocol analysis. Participants who had not received the intervention were excluded from the analysis |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Zangalli 2014[16]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness of a multifaceted intervention with personal communication to improve dilated fundus examination follow-up adherence among those who are less likely to adhere<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** tertiary eye clinic<br>**Total number of participants:** 522<br>**Percentage male:** 34%<br>**Diabetes type:** NR<br>**Average age (SD):** 61yrs (13.0)<br>**Inclusion criteria:** >18 years of age; had no, mild, or moderate DR; were recommended for a follow-up dilated fundus examination and had not previously scheduled a follow-up visit.<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=262):** intervention group received a personalized reminder letter with a one-page brochure about diabetic retinopathy 1 month prior to the recommended visit. Two weeks later, a research assistant called participants to offer personal assistance with scheduling an appointment. For participants who made an appointment, a reminder letter was mailed 3 weeks prior to the scheduled appointment. Participants also received automated reminder calls the day before the scheduled appointment<br>**Comparator (n=260):** usual care (consisting of participants receiving a reminder letter 1 month prior to the recommended follow-up date. Participants received no active assistance with scheduling appointments. Participants who made appointments received automated reminder calls the day before scheduled appointments)<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** the primary outcome measure was attendance at a follow-up appointment within 3 months of suggested return date<br>**Secondary outcomes:** barriers to care use |
| **Notes** | **Date conducted:** April to October 2012<br>**Trial registration number:** NR<br>**Sources of funding**: Centers for Disease Control and Prevention<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Risk of Bias Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'Participants were randomized to usual care or intervention within age strata (≥65 and <65 years) using the method of random permuted blocks with block sizes of 2, 4, and 6.'* p2 |

| | | |
|---|---|---|
| **Allocation concealment** | Unclear risk | Not reported |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *'Participants in the intervention and control groups had similar baseline characteristics with regard to sex, ethnicity, and age.'*<br>p3 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: low attrition and balanced across groups |
| **Adequate blinding** | Unclear risk | Not reported |
| **Protected against contamination** | Low risk | Judgement comment: it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear risk | Judgement comment: trial not registered and protocol not available and so not possible to assess |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

| **Zwarenstein 2014[17]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the printed educational messages aimed at family doctors on rates of retinal screening attendance amongst their patients with diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Canada<br>**Setting:** Primary care<br>**Total number of clusters:** 4,282<br>**Number of providers:** 5,048<br>**Total number of patients:** 179,833<br>**Percentage male:** 51.2%<br>**Diabetes type:** NR<br>**Average age (SD):** 61.7yrs (13.1)<br>**Inclusion criteria:** patients diagnosed with diabetes who were at least 30 years old and visited one of the target family practitioners within one year of the intervention mail-out<br>**Exclusion criteria:** patients who had already had an eye examination in the nine months immediately prior to the office visit |
| **Interventions** | Alternative printed educational messages (PEM) containing prompts to encourage diabetic retinopathy screening was mailed to each family physician in conjunction with a widely read professional newsletter ('Informed')<br>**Intervention arm 1 (n=1,066 clusters):** PEM consisting of a two-page insert, indistinguishable from the rest of 'Informed' in size and style (the 'insert'). The insert contained a concise summary of an evidence-based guideline and references).<br>**Intervention arm 2 (n=535 clusters):** (PEM) consisting of a short directive message on a postcard-sized card ('outsert') stapled to the front page of 'Informed'.<br>**Intervention arm 3 (n=536 clusters):** PEM 'outsert' and supplied with a pad of sticky take-home reminders (aimed at patients, to remind them to make an appointment for an eye exam), to be given to patients<br>**Intervention arm 4 (n=535 clusters):** PEM 'insert' and 'outsert'<br>**Intervention arm 5 (n=533 clusters):** PEM 'insert' and 'outsert' and take home reminders<br>**Comparator (n=1,077 clusters):** newsletter without the PEM<br>**Duration**: 3 months |
| **Outcomes** | **Primary outcome:** whether or not an eligible trial patient received an eye exam within 90 days of their first family practitioner visit.<br>**Secondary outcomes:** the impact of patient age on the uptake of eye exams |

| Zwarenstein 2014[17] | |
|---|---|
| **Notes** | **Date conducted:** 2005-2006<br>**Trial registration number:** NCT00210275<br>**Sources of funding**: Canadian Institutes for Health Research, Institute for Clinical Evaluation Sciences<br>**Declaration of interest:** none declared<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/18039361 |

| Risk of bias | | |
|---|---|---|
| **Risk of Bias Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low risk | Quote: *'Practices were randomly assigned to an intervention group by the study statistician, using computer generated random numbers.'*<br>p2 |
| **Allocation concealment** | Low risk | Judgement comment: unit of allocation by GP practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Unclear risk | Not reported |
| **Similar baseline characteristics** | Low risk | Quote: *'There were small, clinically unimportant, differences between the demographics of patients with diabetes who paid a visit to a study physician and those who did not, and between those who were and were not included in the analysis (Table 2).'*<br>p5 |
| **Incomplete outcome data addressed** | Low risk | Judgement comment: data from all clusters reported |
| **Adequate Blinding** | Low risk | Judgement comment: outcomes were obtained from routinely collected data |
| **Protected against contamination** | Low risk | Judgment comment: allocation by cluster and unlikely that the control group received the intervention |
| **Free of selective reporting** | Low risk | Judgement comment: reported outcomes consistent with trial registry NCT00210275 |
| **Free from other bias** | Low risk | Judgement comment: no evidence of other risks of bias |

**Studies targeting general quality improvement for diabetes care**

| Adair 2013[18] | |
|---|---|
| **Methods** | **Study aim:** to test whether patients with chronic disease working with lay "care guides" would achieve more evidence-based goals than those receiving usual care<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Six primary care clinics in Minnesota<br>**Total number of participants:** 2135 participants with hypertension, diabetes or congestive heart failure (1366 with diabetes)<br>**Percentage male:** 51%<br>**Diabetes type:** type 1 and 2<br>**Average age (SD):** 60.5yrs (11.5)<br>**Inclusion criteria:** aged 18-79 and a primary care office visit during the 6 month enrolment period<br>**Exclusion criteria:** pregnancy |
| **Interventions** | **Intervention (n=930 with diabetes):** provided with disease-specific care goals and culturally matched laypersons acting as 'care guides' helped patients to achieve goals. Care guides met with patients in person and/or were contacted by telephone<br>**Comparator (n=436 with diabetes):** provided with care goals followed by usual clinical care<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** change in the % of disease-specific care goals met 12 months after enrolment compared to baseline<br>**Secondary outcomes:**<br>• percentage of goals met by and the achievement of each individual goal determined from electronic patient records (included 'retinal examination within 2yrs')<br>• to determine whether the benefit of working with the care guide could be predicted by patient demographics |
| **Notes** | **Date conducted:** July 2010 to April 2012<br>**Trial registration number:** NCT01156974<br>**Sources of funding**: Robina Foundation<br>**Declaration of interest:** none declared (Quote 'Disclosures can be viewed at https://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M12-3106')<br><br>*Trial investigators confirmed all retinal examinations reported in Table 4 were performed on patients with diabetes* |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote *'Research supervisors prepared sealed opaque envelopes containing either a purple card (assignment to a care guide) or gold card (assignment to usual care). One hundred eighty envelopes (120 with purple cards and 60 with gold cards) were given to the small clinic, 360 (240 purple and 120 gold cards) were given to the medium-sized clinics, and 540 (360 purple and 180 gold cards) were given to the large clinic. Each clinic's envelopes were shuffled before delivery and daily thereafter.'*<br>p177 |
| **Allocation concealment** | Low | Quote *'Research supervisors prepared sealed opaque envelopes…'*<br>Quote *'Patients who consented to enroll received identical written information about the benefits of meeting disease-specific goals. They then selected and opened an envelope to determine treatment assignment.'*<br>p177 |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar outcome characteristics. Table 3<br>p179 |

| | | |
|---|---|---|
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline characteristics. Table 2 p179 |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and missing data balanced across both arms of the trial |
| **Adequate Blinding** | High | Quote *'Patients, providers, and persons performing outcome assessments were not blinded to treatment assignment.'* p176<br><br>Judgement comment: retinopathy screening data extracted from electronic patient record and knowledge of allocation could have influenced outcome |
| **Protected against contamination** | Low | Quote:*' Care guides and the research team did not interact with the usual care patients after enrollment and randomization.'* p178 |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT01156974 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Barcelo 2010[19]** | |
|---|---|
| **Methods** | **Study aim:** to assess the impact of integrated care, comprising specialist support, collaborative learning and case management, on the quality of diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Mexico<br>**Setting:** ten urban public health centres<br>**Number of clusters:** 10<br>**Number of providers:** 43 primary care teams<br>**Total number of patients:** 307<br>**Percentage male:** NR<br>**Diabetes type:** type 1 and 2 (97.4% type 2)<br>**Average age (SD):** NR<br>**Inclusion criteria:** patients were selected based on 'their capacity to communicate, their advanced knowledge of diabetes, and their willingness to collaborate'<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=5 clusters, n=196 patients ):** diabetes education program, in service training of primary care personnel. specialist support to primary care, case management of patients not achieving care goals<br>**Comparator (n=5 clusters, n=111 patients):** usual care (not specified)<br>**Duration:** 3 learning sessions within 18 months |
| **Outcomes** | **Primary outcome:** change in the proportion of patients achieving quality improvement targets (metabolic control, cholesterol, blood pressure, eye and foot examinations)<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** November 2002 to May 2004<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by community health centre and allocation performed prior to the start of the study |
| **Similar baseline outcome** | Unclear | Not reported |

| | | |
|---|---|---|
| **measurements** | | |
| **Similar baseline characteristics** | Unclear | Not reported |
| **Incomplete outcome data addressed** | Unclear | Judgement comment: cannot tell whether an ITT or per-protocol analysis was conducted. No flow diagram provided with losses to follow up, do not know whether losses to follow up were similar between both arms. |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | High | Quote: *'... avoiding the "contamination" of centers that acted as controls (those centers providing usual diabetes care) was not possible, because of the visibility and publicity of the intervention at the local level.'*<br>p151 |
| **Free of selective reporting** | Unclear | Comment: no protocol or trial registry entry available and therefore not possible to assess. |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Choe 2005[20]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect of case management by a clinical pharmacist on glycaemic control and preventive measures in patients with type 2 diabetes mellitus<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** university affiliated primary care internal medicine clinic<br>**Total number of participants:** 80<br>**Percentage male:** 47.5%<br>**Diabetes type:** type 2<br>**Average age (SD):** 51.6yrs (10.1)<br>**Inclusion criteria:** high-risk individuals whose most recent HbA1c levels ≥8.0%<br>**Exclusion criteria:** type 1 diabetes mellitus (based on diagnosis before age 30 years), if they were older than 70 years, or if they were diagnosed as having cancer, renal failure, severe cirrhosis, malignant hypertension, or a severe concurrent illness that would substantially limit life expectancy or require extensive systemic treatment |
| **Interventions** | **Intervention (n=41):** on-site clinical pharmacist acting as a case manager, providing evaluation and modification of pharmacotherapy, self-management diabetes education (including an emphasis on the importance of self-care, medications, and screening processes). Generally, the clinical pharmacist contacted the participants by telephone on a monthly basis, unless more frequent assessment or recommendations were needed, and saw the participants in conjunction with routine primary care visits<br>**Comparator (n=39):** usual care (unspecified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** HbA1c level at 12 months<br>**Secondary outcomes:** diabetes process measures, including low-density lipoprotein measurement, dilated retinal examination, urine microalbumin screening (or use of angiotensin-converting enzyme inhibitors), and monofilament testing for diabetic neuropathy within the 2-year time frame of the study |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: funding for the clinical pharmacist was provided by the University of Michigan College of Pharmacy<br>**Declaration of interest:** NR |
| **Risk of bias** | |
| **Domain** | **Judgement:** | **Support for judgement** |

| | | |
|---|---|---|
| **Adequate sequence generation** | Low | Quote: *'Randomization within each stratum was simple: because the study was small, randomization was done by hand, drawing numbers from a container that included "0" for the control group or "1" for the intervention group.'*<br>p255 |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Judgement comment: baseline characteristics of participants were similar in each arm (see Table 1 p256) |
| **Incomplete outcome data addressed** | High | Judgement comment: attrition not balanced across arms (12% loss to follow up in intervention group and 26% in control group). See CONSORT flow diagram p255 |
| **Adequate Blinding** | Unclear | Judgement comment: data on eye screening obtained by chart review but not clear if outcome assessor was masked |
| **Protected against contamination** | Unclear | Judgement comment: control group not described and not clear if contamination was prevented |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Clancy 2007[21]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect of group visits on clinical outcomes concordant with 10 American Diabetes Association (ADA) guideline processes of care<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** adult primary care centre, Medical University of South Carolina<br>**Total number of participants:** 186<br>**Percentage male:** 28%<br>**Diabetes type:** type 2<br>**Average age (SD):** 56yrs (NR)<br>**Inclusion criteria:** aged >18 years with poorly controlled diabetes mellitus (HbA1c>8.0%)<br>**Exclusion criteria:** primary diagnosis of substance abuse or dependence; current pregnancy; dementia; inability to hear, speak English; obtain transportation to the clinic |
| **Interventions** | **Intervention (n=96):** monthly group visits (14-17 per group), co-led by an internal medicine physician and a registered nurse. One-on-one visits were available for care as needed between scheduled group visits or for specific medical needs not amenable to group visits. Group visit content consisted of educational topics such as nutrition, exercise, foot care, medications, complications of diabetes, and the emotional aspects of diabetes<br>**Comparator (n=90):** control participants received usual care in the clinic, seeing faculty or resident physicians, physician assistants, nurse practitioners, or medical or physician assistant students with access to a dietician and diabetes educator<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** 10 ADA process-of-care indicators [>2 yearly HgA1c, at least yearly cholesterol levels, treatment for LDL cholesterol levels >100 mg/dl, yearly ophthalmologic referrals, influenza vaccinations, foot exams, and checks for microalbuminuria, ACE-inhibitor or angiotensin receptor blocker use, daily aspirin unless contraindicated, and at least 1 pneumococcal vaccine]<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** Sept 2002-Feb 2003<br>**Trial registration number:** NR<br>**Sources of funding**: Agency for Healthcare Research and Quality; Robert Wood Johnson Foundation; National Institutes of Health |

| Clancy 2007[21] | |
|---|---|
| | **Declaration of interest:** two authors reported receiving grants from Pfizer and Elli Lilly |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Subjects meeting criteria for inclusion into the study were randomized after informed consent and baseline data collection using randlst software (http://odin.mdacc.tmc.edu/anonftp/) allowing for stratification and blocking. Subjects were stratified by race and gender using a block size of 4.'*<br>p621 |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'Demographic variables were well balanced between patients randomized to group visits or usual care at baseline (Table 1).'*<br>p622<br><br>Quote: *'Clinical variables were also well balanced at baseline (Table 1) 'with a mean HgbA1c level at baseline of 9.3% for group patients and 8.9% for control patients. The mean total cholesterol level for group patients was 193.4 and 196.1 mg/dl for control patients. Blood pressures, triglycerides, LDL, and HDL levels showed no significant baseline differences between the 2 groups.'*<br>p622 |
| **Incomplete outcome data addressed** | Low | Judgement comment: missing data balanced across two arms of study (17% in the intervention arm and 16% in the comparator arm). Reasons given for missing data provided |
| **Adequate Blinding** | Low | Quote: *'Upon study completion, medical records were blindly abstracted for the 10 ADA process-of-care indicators.'*<br>p621 |
| **Protected against contamination** | High | Quote: *'These providers also had patients in the usual care arm as part of the general pool of clinic patients; thus, it is possible through contamination that providers may have adopted some of the group visit strategies (e.g., group visit educational content) for control patients.'*<br>p623 |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Davis 2010[22] | |
|---|---|
| **Methods** | **Study aim:** to evaluate a remote comprehensive diabetes self-management education intervention to improve adherence to American Diabetes Association (ADA) guidelines<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** underserved population in three community health centres in South Carolina<br>**Total number of participants:** 165<br>**Percentage male:** 25.4%<br>**Diabetes type:** NR |

| Davis 2010[22] | |
|---|---|
| | **Average age (SD):** 59.6yrs (9.3)<br>**Inclusion criteria:** HbA1c >7%, aged ≥35 yrs, seen in the last year in the community health centre, diagnosis of diabetes and willingness to participate<br>**Exclusion criteria:** BMI <25, pregnancy, acute and chronic illness preventing participation |
| **Interventions** | **Intervention (telehealth) (n=85):** remote diabetes self-management educational intervention consisting of 13 sessions (3 individual and 10 group). Participants were offered optional retinal imaging in the primary care setting when they were due for their annual eye exam<br>**Comparator (n=80):** usual care (consisting of one 20 minute diabetes education session using ADA materials). Access to existing services at the community health centre (including care managers and a nurse practitioner)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** HbA1c measured at baseline, 6 months, and 12 months<br>**Secondary outcomes:** LDL cholesterol, blood pressure, albumin to creatinine ratio, BMI (measured at 6 and 12 months) and uptake of annual eye examinations |
| **Notes** | **Date conducted:** April 2005 to October 2006<br>**Trial registration number:** NCT00288132<br>**Sources of funding**: National Institutes of Health<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of self-reported annual eye examinations. Table 2 p1714 |
| **Similar baseline characteristics** | Low | Judgement comment: no significant differences in baseline characteristics. Table 2 p1714 |
| **Incomplete outcome data addressed** | low | Quote: *'Retention rates at 6 and 12 months were 90.9 and 82.4%, respectively.'* p1716 |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00288132 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Dickinson 2014[23] | |
|---|---|
| **Methods** | **Study aim:** to compare the effectiveness of a program to improve diabetes care by a). increasing the practice's organizational capacity to manage change (Reflective Adaptive Process (RAP)), and b). implementing and sustaining the Chronic Care Model to support the clinicians efforts to improve care for diabetes (Continuous Quality Improvement (CQI))<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA |

| Dickinson 2014[23] | |
|---|---|
| | **Setting:** Small to midsized community health centers and independent mixed payer primary care practices in Colorado<br>**Number of clusters:** 40<br>**Number of providers:** NR<br>**Total number of patients:** 822<br>**Percentage male:** 48.7%<br>**Diabetes type:** NR<br>**Average age (SD):** 60.6yrs (12.7)<br>**Inclusion criteria:** diagnosis of diabetes and at least one visit to the practice in 18 months before practice enrolment and at least one visit in the 18 months after enrolment<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (RAP) (n=15 clusterss, 312 patient charts reviewed):** practice facilitation using the RAP model (consisting of changing organizational functioning to improve diabetes care). Practices received training in change management strategies and provided with audit and feedback<br>**Intervention (CQI) (n=10 clusters, 189 patients charts reviewed):** practice facilitation using the 'Model for Improvement' (consisting of forming and facilitating practice improvement teams and provision of audit and feedback)<br>**Comparator (n=15 clusters, 312 patients charts reviewed):** practices received limited feedback on baseline work culture and level of implementation of the Chronic Care Model (CCM). Practices were given access to a website regarding quality improvements and received audit and feedback as in the other groups.<br>**Duration:** practice facilitation of 6 months (RAP) or 18 months (CQI) |
| **Outcomes** | **Primary outcome:** HbA1c, blood pressure, lipids, process of care measured at baseline, 9 and 18 months (including diabetes-related visits to ophthalmologist)<br>**Secondary outcomes:** patient report (by survey) of their primary care experience |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NCT00414986<br>**Sources of funding**: National Institute of Diabetes and Kidney Diseases and the National Institute of Mental Health<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by community health centre and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: rates of dilated eye examinations were not statistically different between study arms. Table 2 p13 |
| **Similar baseline characteristics** | Unclear | Quote: *'…baseline HbA1c level, systolic blood pressure, and total cholesterol level differed significantly across groups (all P <.05), with slightly better baseline control of each in RAP practices.'* p11<br>Judgement comment: unclear whether differences in baseline characteristics would have influenced outcome |
| **Incomplete outcome data addressed** | Unclear | Judgement comment: random sample of patients taken from each cluster. Missing data from some practices for chart audit |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective** | Low | Judgement comment: reported outcomes consistent with trial |

| | | |
|---|---|---|
| **reporting** | | registry NCT00414986 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Dijkstra 2005[24]** | |
|---|---|
| Methods | **Study aim**: to investigate whether a comprehensive strategy involving both patients and professionals, with the introduction of a diabetes passport as a key component, improves diabetes care.<br>**Study design:** cluster RCT |
| Participants | **Country**: Netherlands<br>**Setting**: nine general hospitals throughout the Netherlands<br>**Number of clusters**: 9<br>**Number of providers**: 42<br>**Total number of patients**: 1350<br>**Percentage male**: 48%<br>**Diabetes type**: types 1 and 2<br>**Average age (SD)**: 58yrs (15.5)<br>**Inclusion criteria:** all patients under the care of an internist for diabetic monitoring<br>**Exclusion criteria**: pregnancy; patients with low life expectancy |
| Interventions | **Intervention (n=4 clusters, n=600 patients):** feedback on aggregated patient baseline data was given to the healthcare professionals. During an educational meeting with a national diabetes opinion leader, guidelines were issued on the prevention and treatment of diabetes complications as well as guidance on the use and dissemination of diabetes passports. The 'diabetes passport' is a patient-held booklet with important personal information that can be used to track results, record treatment targets and give information. The passport also records the medications used, results of laboratory and physical examinations and patient education. For patients additional educational meeting were organised.<br>**Comparator (n=5 clusters, n=750 patients):** usual care (national diabetes guidelines issued to all hospitals during the intervention period)<br>**Duration:** 12 months |
| Outcomes | **Primary outcome:** measures consisted of process and outcome indicators taken from evidence-based Dutch guidelines on the treatment of diabetes and prevention of complications (including yearly examination of HbA1c, creatinine, total cholesterol or total cholesterol/HDL ratio, urine for microalbuminuria, weight, BMI and blood pressure, as well as advice with regard to smoking and physical exercise). The guidelines advise an eye examination every 1–2 years (yearly in the case of those at higher risk of retinopathy)<br>**Secondary outcomes**: NR |
| Notes | **Date conducted:** November 1999-March 2000<br>**Trial registration number:** NR<br>**Sources of funding**: Netherlands organisation for health research and development<br>**Declaration of interest**: NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Quote: *'Random allocation was done by a person outside the research group and concealed from the investigators until the start of the intervention.'*<br>p128 |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar baseline eye examinations <12 months or <24 months (see Table 2 p131) |
| **Similar baseline characteristics** | Low | Judgement comment: baseline characteristics similar across the two arms of the study (see Tables 1 and 2 p131) |
| **Incomplete** | High | Judgement comment: high attrition (58.5% and 55.7% of those |

| | | |
|---|---|---|
| **outcome data addressed** | | randomised to intervention and control respectively were analysed) |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation was by hospital and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Dijkstra 2008[25]** | | |
|---|---|---|
| **Methods** | **Study aim:** to investigate whether the introduction of a diabetes passport improves diabetes care<br>**Study design:** cluster RCT | |
| **Participants** | **Country:** Netherlands<br>**Setting:** primary care practices in the middle and south regions of The Netherlands<br>**Number of clusters:** 40<br>**Number of providers:** 61<br>**Total number of patients:** 2059<br>**Percentage male:** 49.8%<br>**Diabetes type:** types 2<br>**Average age (SD):** 63.4yrs (9.6)<br>**Inclusion criteria:** individuals with type 2 diabetes <80 years under the care of a general practitioner<br>**Exclusion criteria:** those with a life expectancy <1 year; patients who received their diabetes treatment in secondary care | |
| **Interventions** | **Intervention (n=20 clusters, n=1,004 patients):** dissemination of diabetes passports. The 'diabetes passport' is a patient-held booklet with important personal information that can be used to track results, record treatment targets and give information. The passport also records the medications used, results of laboratory and physical examinations and patient education. Additional patient education meetings were organised.<br>**Comparator (n=20 clusters, n=1,055 patients):** usual care (not specified)<br>**Duration:** 15 months | |
| **Outcomes** | **Primary outcome:** self-reported use of the passport by patients<br>**Secondary outcomes:** process and outcome diabetes care indicators (including eye examination within the previous 24 months) | |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Netherlands Organisation for Health Research and Development<br>**Declaration of interest:** NR | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by community health centre and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar baseline % of eye examinations within 24 months (see Table 3 p75) |
| **Similar baseline characteristics** | Unclear | Quote: *'Comparison of the baseline data from the intervention and control groups showed that there were some differences. The patients in the intervention group were more often women and fewer monitored glucose themselves than in the control group (Table 1).'* |

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| | | Judgement comment: baseline characteristic differences could have influenced outcome |
| **Incomplete outcome data addressed** | Low | Judgement comment: eye screening data available for all participants |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation was by hospital and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Unclear | Quote: *'Table 2 shows that, in addition to the research intervention activities, several control and intervention practices had initiated organizational interventions and revision of professional roles during the intervention period.'* p75<br><br>Judgement comment: not clear how these changes impacted on the outcome |

| **Eccles 2007[26]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness and efficiency of a computerised diabetes register and management system on the quality of diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** UK<br>**Setting:** 3 Primary Care Trusts in the northeast of England<br>**Number of clusters:** 58<br>**Number of providers:** 58<br>**Total number of patients:** 3608<br>**Percentage male:** 53%<br>**Diabetes type:** type 2<br>**Average age (SD):** 66yrs (11.5)<br>**Inclusion criteria:** people with type 2 diabetes appearing on the registers, aged over 35 years and receiving diabetes care exclusively from study general practices or shared between study general practices (GPs) and hospital<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=30 clusters, n=1674 patients):** computerised diabetes register incorporating a full structured recall and management system, including individualised patient management prompts to primary care clinicians based on locally-adapted, evidence-based guidelines<br>**Comparator (n=28 clusters, n=1934 patients):** usual care (not specified)<br>**Duration:** 15 months |
| **Outcomes** | **Primary outcomes:** clinical process and outcome variables held on the diabetes registers; patient reported outcomes (SF36 health status profile, the Newcastle Diabetes Symptoms Questionnaire and the Diabetes Clinic Satisfaction Questionnaire); service and patient costs.<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** 1st April 2002 to 30th June 2003<br>**Trial registration number:** ISRCTN32042030<br>**Sources of funding**: Diabetes UK, and Northern and Yorkshire Regional NHS R&D Office.<br>**Declaration of interest:** one of the author's was a partner in a software company that maintained the software used in the study. The remaining authors declared no competing interests<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/11914161 |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |

| | | |
|---|---|---|
| **Adequate sequence generation** | Low | Quote: *'Randomisation was performed using electronically-generated random numbers by the study statistician and was stratified by PCT and practice size.'*<br>p3 |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar % of recorded fundoscopy at baseline |
| **Similar baseline characteristics** | Low | Quote: *'Table 1 shows the baseline characteristics of control and intervention practices and patients. None of the differences in these variables between the intervention and control group are statistically significant.'*<br>p5 |
| **Incomplete outcome data addressed** | Low | Judgement comment: although there was a high attrition for patient reported outcomes, the register derived outcomes were available for all patients |
| **Adequate Blinding** | Low | Judgement comment: data on fundoscopy obtained directly from the registry |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry ISRCTN32042030 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Franco 2006[27]** | |
|---|---|
| **Methods** | **Study aim:** to study the impact of an outreach visit by a diabetes specialist on general practitioners management of type 2 diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Réunion (French overseas territory)<br>**Setting:** General practices on the island of Réunion<br>**Total number of clusters:** 120 randomised 82 participated<br>**Number of providers:** 82<br>**Number of patients:** 1581<br>**Percentage male:** 25%<br>**Diabetes type:** type 2<br>**Average age (SD):** 59.9 (NR)<br>**Inclusion criteria:** GPs were selected if they had been working for 2 years or more and were likely to be employed for the duration of the study.<br>**Exclusion criteria:** see above |
| **Interventions** | **Intervention (n=42 clusters, 792 patients):** 2 outreach visits by visiting GP with diabetes expertise. First visit consisted of a presentation on guideline recommendations, provision of teaching materials and clinical tools for diabetes assessment e.g. esthesiometer. Second visit reinforced guideline recommendations and provided feedback on a questionnaire relating to 3 consecutive patients with diabetes seen following the first visit.<br>**Comparator (n=40 clusters, 789 patients):** usual care (not specified)<br>**Duration:** 2 outreach visits and outcomes measured within 6 months of the last visit |
| **Outcomes** | **Primary outcome:** compliance with processes of care recommendations for the management of type 2 diabetes including HbA1c, foot and fundus examination, creatinine clearance and assessment for proteinuria/microalbuminuria which were measured within 6 months following delivery of intervention<br>**Secondary outcomes:** none |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement (Quote)** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by GP practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of retinopathy screening attendance at baseline (see Table 2 p2) |
| **Similar baseline characteristics** | Low | Quote: *'Le nombre, l'âge, le sex-ratio et le statut vis-à-vis de l'emploi des patients étaient semblables dans les deux groupes (tableau I).* [The number , age, sex ratio and employment status of patients were similar in both groups (Table I)]*'* p2 |
| **Incomplete outcome data addressed** | High | Judgement comment: high attrition (approx. 30% in both arms) |
| **Adequate Blinding** | High | Judgement comment: GPs in the intervention group provided the the data on retinopathy screening |
| **Protected against contamination** | Low | Quote *'Dans le groupe témoin,contacté seulement à la fin de l'étude…* [In the control group, contacted only at the end of the stud]'. p2 Judgement comment: allocation by cluster and unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| Frei 2014[28] | |
|---|---|
| **Methods** | **Study aim:** to test whether the implementation of elements of the 'Chronic Care Model (CCM)' via a specially trained practice nurse leads to an improved cardiovascular risk profile among type 2 diabetes patients.<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Switzerland<br>**Setting:** Primary Care Practices<br>**Total number of clusters:** 30<br>**Number of providers:**30<br>**Number of patients:** 326<br>**Percentage male:** 57%<br>**Diabetes type:** type 2<br>**Average age (SD):** 67 yrs (10.6)<br>**Inclusion criteria:** adults (>18 years) with type 2 diabetes<br>**Exclusion criteria:** unable to read and understand the patient information form due to dementia, illiteracy or language skills. Patients with oncological diseases and/or an estimated life expectancy of less than six months due to severe diseases |
| **Interventions** | **Intervention (n=15 clusters, n=164 patients):** implementation of team care using elements of the Chronic Care Model (CCM) via a specially trained practice nurse and utilising a computerised monitoring tool and decision support<br>**Comparator (n=15 clusters, n=162 patients):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** HbA1c level<br>**Secondary outcomes:** guideline adherence (recommended treatment goals) including receiving at least one eye examination per year. Quality of life |

| Frei 2014[28] | |
|---|---|
| **Notes** | **Date conducted:** 2010-2013<br>**Trial registration number:** ISRCTN05947538<br>**Sources of funding**: Swiss Academy for Medical Sciences; A. Menari AG, Switzerland<br>**Declaration of interest:** none declared<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/20550650 |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote *'The PCPs who agreed to participate in the study were alphabetically ordered by their family names in a list with numbers from 1 to 30. An independent research assistant, who was not involved in the study and was blind to the identity of the PCPs, randomly allocated by statistical computer software SPSS (version 18.0) 15 letters A and 15 letters B to numbers 1–30 and to the corresponding PCPs, respectively. The assignment of the letters A and B to either the intervention or control group was randomly conducted by a second research assistant who drew blinded a ticket with the letters A or B and a ticket with the group allocation intervention or control group from an envelope.'* p1041 |
| **Allocation concealment** | Low | Quote *'We informed all PCPs about the group allocation after the inclusion of patients and baseline assessments to minimize selection bias.'* p1041 |
| **Similar baseline outcome measurements** | High | Judgement comment: different rates of retinopathy screening attendance at baseline (control 64%, intervention 73.5%) (see supplementary Table 2) |
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline characteristics (Table 1 p1009, Table 2 p1044) |
| **Incomplete outcome data addressed** | Low | Judgement comment: data available for all providers and low rate of attrition in outcome data (see CONSORT diagram p1042) |
| **Adequate Blinding** | Unclear | Quote *'….due to the study design, it was not possible to blind PCPs and practice nurses to group allocation, which might have influenced the results or might have led to a more pronounced effect of the intervention.'* p1045 |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with study protocol and trial registry ISRCTN05947538 |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| Frijling 2002[29] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness of a multifaceted intervention to improve clinical decision making of general practitioners (GPs) for patients with diabetes.<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Netherlands |

| Frijling 2002[29] | |
|---|---|
| | **Setting:** primary care practices in the southern part of the Netherlands<br>**Number of clusters:** 124<br>**Number of providers:** 185<br>**Total number of patients:** 1410<br>**Percentage male:** 44.6%<br>**Diabetes type:** type 2<br>**Average age (SD):** 65yrs (11.5)<br>**Inclusion criteria:** people with type 2 diabetes<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=62 clusters, n=703 patients):** GPs given feedback reports about his or her current clinical decision making with regard to the diabetes guidelines issued by the Dutch College of General Practitioners and received outreach visits from facilitators. As part of the visits, the facilitator specifically addressed the clinical decision making for patients with type 2 diabetes. The facilitator provided guidance, support, and educational materials to facilitate improvement<br>**Comparator (n=62 clusters, n=707 patients):** usual care (not specified)<br>**Duration:** 21 months |
| **Outcomes** | **Primary outcome:** compliance rates for evidence-based indicators for management of patients with type 2 diabetes (including eye examination in the past 24 months)<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** 1996 to 1999<br>**Trial registration number:** NR<br>**Sources of funding**: Netherlands Heart Foundation.<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'A random-number generator was used to select permuted blocks with a block size of four'*<br>p837 |
| **Allocation concealment** | Low | Quote: *'The practices were numbered and the person responsible for the randomization process was blind to the practice identities.'*<br>p837 |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar % of eye examinations at baseline |
| **Similar baseline characteristics** | Low | Quote*: ' The ages of the patients, the proportions of males and the proportions of patients with uncontrolled blood glucose were found to be equally distributed across the intervention and control groups at baseline and post-intervention measurement (Table 1)'*<br>p838<br><br>Judgement comment: similar baseline clinical characteristics (see Table 2 p840) |
| **Incomplete outcome data addressed** | Low | Judgement comment: low cluster attrition. High compliance with completion of encounter forms |
| **Adequate Blinding** | Low | Judgement comment: although GPs completing the encounter forms following each consultation were unmasked, the data were entered into a computer by personnel blind to group allocation. |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Gabbay 2006[30] | |
|---|---|
| **Methods** | **Study aim:** to measure the impact of a patient-oriented structured approach to care coordination and patient education and counselling on improvements in BP, glycaemic control, lipids, complication screening and diabetes-related distress<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** two primary care clinics of Penn State Hershey Medical Centre<br>**Total number of participants:** 332<br>**Percentage male:** 54.5%<br>**Diabetes type:** type 2<br>**Average age (SD):** 64.5yrs (16.4)<br>**Inclusion criteria:** persons with diabetes, ≥18 years, identified by ICD 9 codes; two or more visits for diabetes within the last year<br>**Exclusion criteria:** unable to speak English; residents of nursing homes |
| **Interventions** | **Intervention (n=150):** nurse case manager implementing diabetes management using algorithms under the supervision of the patient's primary care physician (PCP) (a family physician or an internist). Goals were based on the ADA recommendations. The nurse case manager used behavioural goal-setting, established individualized care plan, provided self-management education and surveillance of participants, including phone calls to participants, organised referrals to a certified diabetes nurse educator or a dietitian where appropriate, ordered protocol-driven laboratory tests, tracked the outcomes using the computerized data registry and made therapeutic recommendations based on ADA diabetes guidelines with approval of the PCP<br>**Comparator (n=182):** usual care by their PCP, and had no interaction with the nurse case manager<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** changes in BP, HbA1c, lipids and complication screening process measures (including annual retinal screening)<br>**Secondary outcomes:** diabetes-related distress, as measured by the PAID questionnaire at 6 and 12 months. The PAID scale is a 20-item measure of emotional adjustment to life with diabetes with lower scores indicating better adjustment and coping with diabetes |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NCT00308386<br>**Sources of funding**: NR<br>**Declaration of interest:** NR<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/19328244 |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | High | Quote: *'A total of 332 patients were randomized (by method of odd and even numbers) to either NCM intervention (intervention group), or a usual routine care (control group).'*<br>p30<br><br>Judgement comment: inappropriate method of sequence generation |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'The intervention group (n =150) and the control/ usual care group (n =182) were statistically equivalent on baseline demographic and clinical characteristics.'*<br>p31 |

| | | |
|---|---|---|
| **Incomplete outcome data addressed** | Unclear | Judgement comment: attrition not reported |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Unclear | Judgement: although baseline characteristics were balanced across study arms, only 60% of participants randomised to the intervention group agreed to participate |

| **Gabbay 2013[31]** | |
|---|---|
| **Methods** | **Study aim:** to determine whether the addition of nurse case managers trained in motivational interviewing would result in improved outcomes in type 2 diabetes patients at high risk of cardiovascular complications<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** 12 primary care clinics within two health systems in Central Pennsylvania<br>**Total number of participants:** 545<br>**Percentage male:** 37.8%<br>**Diabetes type:** type 2<br>**Average age (SD):** 58yrs (11)<br>**Inclusion criteria:** people 18–75 years with type 2 diabetes were eligible if they had one or more of the following: (i) HbA1c >8.5%; (ii) blood pressure >140/90 mmHg; and/or (iii) Low-density lipoprotein (LDL) >130 mg/dL<br>**Exclusion criteria:** excluded if the person with diabetes could not communicate in either English or Spanish, or if they were residents of nursing homes |
| **Interventions** | **Intervention (n=232 ):** bilingual nurse case manager (NCM) met individually with participants at baseline, 2 and 6 weeks, at 3, 6 and 12 months and at least 6 monthly thereafter to review clinical laboratory test results, medication adherence and health-related lifestyle behaviour relating to managing their diabetes. The NCM also checked whether the participant was due for complications screening and reminded them of specialist visits<br>**Comparator (n=313):** usual care (not specified)<br>**Duration:** 24 months |
| **Outcomes** | **Primary outcome:** % of participants reaching the following outcomes 2 years after enrolment [1]. HbA1C (<7), [2]. BP goal (<130/80), [3]. LDL at goal (<100)<br>**Secondary outcomes:** % of participants with yearly ophthalmologic exam ,% with yearly foot exam ,% with assessment for nephropathy |
| **Notes** | **Date conducted:** August 2006 to March 2008<br>**Trial registration number:** NCT00308386<br>**Sources of funding**: National Institute of Diabetes and Kidney Diseases<br>**Declaration of interest:** none declared<br><br>Study protocol has been published:https://www.ncbi.nlm.nih.gov/pubmed/19328244 |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |

| | | |
|---|---|---|
| **Similar baseline characteristics** | Low | Quote: *'Baseline characteristics of the study population are given in Table 1. There were no significant differences in study measures between the two groups.'* Table 1 p353 |
| **Incomplete outcome data addressed** | High | Judgement comment: high attrition and missing data unbalanced across two arms of study (intervention 19%, comparator 26%) |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the telephone reminder |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00308386 |
| **Free from other bias** | High | Judgement comment: per protocol analysis. N=42 participants originally randomized to the intervention arm were moved to the control group since they did not receive the nurse MI. Analysis and baseline data presented following the switch |

| **Glasgow 2005[32]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness of a computer-assisted patient-centred intervention to improve the quality of diabetes care in primary care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** family physicians and general internists insured by Sopic Insurance Co in Colorado<br>**Number of clusters:** 52<br>**Number of providers:** 52<br>**Total number of patients:** 886<br>**Percentage male:** 48%<br>**Diabetes type:** type 2<br>**Average age (SD):** 62.9yrs (12.7)<br>**Inclusion criteria:** adult s ≥25 years with type 2 diabetes and able to read English<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=24 clusters, n=469):** interactive computer program recording when patient last received 11 items on the National Committee on Quality Assurance/American Diabetes Association Provider Recognition Program (PRP) measures, followed by a printout of a self-management action plan. This was overseen by a designated 'care manager' who met with the patient and reinforced self-management strategies by telephone<br>**Comparator (n=28 clusters, n=417 patients):** interactive computer program recording when last received 11 items on the National Committee on Quality Assurance/American Diabetes Association Provider Recognition Program (PRP) measures, followed by a printout of a self-management action plan. Control patients did not meet or receive calls from the care manager<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** patient reports of provision of receiving the 11 items in the PRP measures (included dilated eye examination)<br>**Secondary outcomes:** Quality of Life assessed using the revised 'Problem Areas in Diabetes Scale (PAID-2) and the Patient Health Questionnaire (PHQ); HbA1c and ratio of total cholesterol to HDL cholesterol levels |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Agency for Health Research and Quality<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |

| | | |
|---|---|---|
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar compliance with dilated eye examination attendance at baseline (see Table 2 p36) |
| **Similar baseline characteristics** | Low | Quote *'Initial analysis failed to show baseline differences between conditions in any socioeconomic or baseline measures.'* p36 |
| **Incomplete outcome data addressed** | Unclear | Judgement comment: high attrition (19% intervention, 13% control). Reasons for missing data not given. Unclear if missing data would impact on outcome |
| **Adequate Blinding** | Unclear | Judgement comment: eye screening outcome data based on self-reports and not clear if outcome assessor was unmasked |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Guldberg 2011[33]** | | |
|---|---|---|
| **Methods** | **Study aim:** to evaluate the effect of an electronically delivered feedback system on the quality of care for people with type 2 diabetes<br>**Study design:** cluster RCT | |
| **Participants** | **Country:** Denmark<br>**Setting:** eighty six general practices in Vejle country Denmark<br>**Number of clusters:** 86<br>**Number of providers:** 160<br>**Total number of patients:** 2716<br>**Percentage male:** 46.1%<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** patients aged 40-70 diagnosed with type 2 diabetes prior to the intervention<br>**Exclusion criteria:** death during intervention, moved out of geographic area during intervention, GP retired during intervention | |
| **Interventions** | **Intervention (n=40 clusters, n=1453 patients):** electronic feedback system presenting register data on patients with type 2 diabetes<br>**Comparator (n=36 clusters, n=1263 patients):** usual care (not specified)<br>**Duration:** 15 months | |
| **Outcomes** | **Primary outcome:** ophthalmologist-conducted eye examination, redeemed prescriptions, results of blood tests (HbA1c, serum cholesterol)<br>**Secondary outcomes:** qualitative study of how the intervention was used and received by the GPs | |
| **Notes** | **Date conducted:** March 2007 to May 2008<br>**Trial registration number:** NCT01009528<br>**Sources of funding**: Vejle County Quality Committee; Central Region Denmark Quality Committee; Danish Council for Independent Research; Tryg Foundation; Vissings Foundation; Danielsens Foundation; A. P.Moellers Foundation Promoting Medical Science<br>**Declaration of interest:** none declared | |
| **Risk of bias** | | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Randomization was unrestricted and was done using Stata software..'* p326 |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by GP practice and allocation performed prior to the start of the study |

| | | |
|---|---|---|
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *' There were no statistically significantly differences concerning the quality of treatment between the people with Type 2 diabetes in the control and the intervention groups at baseline'* Table 2 p328 |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and missing data balanced across two arms of study |
| **Adequate Blinding** | Low | Quote: *'In this study, most tasks were performed by one researcher. Therefore, and because a very visible tool like the electronic feedback system was tested, both blinding and allocation concealment were impossible in the study design.'* p328<br><br>Judgement comment: data on annual eye examinations obtained from national registry and therefore unlikely to be influenced by knowledge of allocation |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: trial retrospectively registered and therefore not possible to assess |
| **Free from other bias** | High | Judgement comment: selection bias of providers as only 59% of GPs accepted invitation, and these may have been more willing to change according to guidelines, or already have a high quality of care |

| **Gutierrez 2011[34]** | |
|---|---|
| **Methods** | **Study aim:** to assess the impact of shared medical appointments on the quality of care for Hispanic patients with type 2 diabetes attending a family medicine residency clinic<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** single family medicine residency clinic<br>**Total number of patients:** 103<br>**Percentage male:** NR<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** Hispanic race/ethnicity, aged 18 years and older, diagnosis of type 2 diabetes with HbA1c ≥7%<br>**Exclusion criteria:** dementia, current pregnancy or mothers who were breast-feeding |
| **Interventions** | **Intervention (n=50):** shared medical appointments with a mean of nine patients per group. Clinical team consisted of a resident or fellow researcher, faculty member, pharmacist, lead nurse, medical assistant, registration clerk, and social worker.<br>**Comparator (n=53):** usual care (not specified)<br>**Duration:** 17 months |
| **Outcomes** | **Primary outcome:** HbA1c, immunisations, aspirin use, eye and foot examinations<br>**Secondary outcomes:** quality of life (Diabetes Quality of Life Brief Clinical Inventory) and diabetes knowledge (Diabetes Knowledge Questionnaire) |
| **Notes** | **Date conducted:** September 2006 to August 2007<br>**Trial registration number:** NR<br>**Sources of funding**: Department of Family and Community Medicine, University of Texas; Community Action Research Experience project funded by grant D58HP08301 from the Department of Health and Human Services Health Resources and Services Administration; foundation grant from the Texas Academy of Family Physicians.<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *' We assigned participants to an SMA group or a control group using a table of random numbers.'*<br>p212 |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'The SMA and control patients did not differ significantly by demographic, clinical, or other characteristics'*<br>p213 |
| **Incomplete outcome data addressed** | Unclear | Not reported |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Unclear | Quote: *'…the possibility of a "halo effect" exists, where providers participating in the SMAs could have gained new knowledge and insight that allowed them to better treat patients in the control group. For example, a patient in the control group could have been advised by the pharmacist to ask his or her physician about switching to a different medication because a patient with similar clinical status in the SMA group was recently switched to that medication.'*<br>p214<br>Judgement comment: unclear if potential for contamination would have influenced retinopathy screening attendance |
| **Free of selective reporting** | Unclear | Comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Harris 2005[35]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effects of a continuing medical education intervention using teleconferencing on glycaemic control (HbA1c) and family physician adherence to national diabetes guidelines<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Canada<br>**Setting:** family physician clinics from 8 geographic regions in Canada<br>**Number of clusters:** 90<br>**Number of providers:** 90<br>**Total number of patients:** 660<br>**Percentage male:** 56%<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** type 2 diabetes of at least 2 years' duration; aged ≥ 18 years; a physician visit within the past year and competent to consent<br>**Exclusion criteria:** participating in the REACT2 study; pregnancy in previous 2 years |
| **Interventions** | **Intervention (n=47 clusters, n=347 patients):** eight one-hour small-group educational sessions, each covering a module related to the management of type 2 diabetes based on national guidelines. Participants received an educational manual with defined learning objectives for each module, guideline recommendations, detailed clinical cases, and pertinent research articles. Flow sheets listing the recommended screening tests and clinical targets, designed to serve as reminders in patients' medical records, were also provided. |

| Harris 2005[35] | |
|---|---|
| | **Comparator (n=43 clusters, n=313 patients):** usual care (unspecified)<br>**Duration:** 3 months |
| **Outcomes** | **Primary outcome:** glycaemic control as measured by glycated haemoglobin (Hb A1c)<br>**Secondary outcomes:** medication management and physician adherence to clinical practice guideline complication screening recommendations (including eye examinations) |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: GlaxoSmithKline<br>**Declaration of interest:** two authors had been consultants and received honoraria for CME-related speaking engagements and research support from Glaxo Smith Kline |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Judgement comment: gender balance, similar mean age at diagnosis and disease duration at baseline |
| **Incomplete outcome data addressed** | High | Quote: *'Of the 90 physicians randomly assigned, 29 (32%) withdrew or were unable to identify patients for audit.'*<br>p90<br><br>Quote: *'Patient consent per physician ranged from 17% to 100%'*<br>p90 |
| **Adequate Blinding** | Low | Quote: *'Medical record auditors were blind to physician randomization.'*<br>p89 |
| **Protected against contamination** | Low | Judgement comment: allocation was by practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Hayashino 2016[36] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect of a multifaceted intervention using the 'Achievable Benchmark of Care (ABC)' method for improving the technical quality of diabetes care in primary care settings<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Japan<br>**Setting:** primary care physicians within District Medical Associations<br>**Total number of clusters:** 22<br>**Number of providers:** 192<br>**Number of patients:** 2,199<br>**Percentage male:** 63%<br>**Diabetes type:** type 2<br>**Average age (SD):** 56.5 yrs (5.9)<br>**Inclusion criteria:** type 2 diagnosis of diabetes prior to registration, aged 40–64 years and care provided by a single medical doctor in charge of the patient's diabetes treatment<br>**Exclusion criteria:** history of haemodialysis, hospitalization, bed confinement, resident in a nursing home, blindness, history of lower limb amputation, history of diagnosis with a |

| Hayashino 2016[36] | |
|---|---|
| | malignant tumour within the last 5 years, pregnancy or potential pregnancy |
| **Interventions** | **Intervention (n=11 clusters, n=954 patients):** physicians assigned to the intervention group were able to use a disease management system of monitoring and provided feedback on the quality of diabetes care, which was evaluated in terms of adherence to the eight clinical indicators. Other intervention components included lifestyle advisors that provide reminders for regular visits and advice on lifestyle modifications by telephone or face to face<br>**Comparator (n=11, n=1245 patients):** usual medical care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** quality of diabetes care score calculated on the outcomes of eight quality indicators (including fundoscopy at least every 12 months)<br>**Secondary outcomes:** the effect of intervention on patient outcomes comprising HbA1c, systolic and diastolic blood pressure, and BMI |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** umin.ac.jp/ctr UMIN000002186<br>**Sources of funding**: Japan Agency for Medical Research and Development; Ministry of Health Labour and Welfare<br>**Declaration of interest:** none declared<br>Study protocol has been published: (Izumi, K., Hayashino, Y., Yamazaki, K. et al. Diabetol Int (2010) 1: 83. doi:10.1007/s13340-010-0015-6) |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | *Quote ''The statistician, blind to the identities of the clusters, randomly allocated 0 (control) or 1 (intervention) codes generated by statistical software, to 22 clusters stratified by each DMA.'*<br>p2 |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by cluster and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of retinopathy screening attendance at baseline (Table 3 p7) |
| **Similar baseline characteristics** | Low | Quote: *'There was no statistical difference in baseline characteristics other than the type of diabetes therapy between the IG and the CG; patients in the IG were more likely to receive diabetes medication (P = 0.049).'*<br>p5 |
| **Incomplete outcome data addressed** | Low | Judgement comment: data available for 100% providers and low rate of attrition in outcome data (see CONSORT diagram p5) |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation by cluster and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with protocol (Izumi 2010) |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| Hermans 2013[37] | |
|---|---|
| **Methods** | **Study aim:** to assess the effect of 'benchmarking' on quality of primary care for patients with type 2 diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Belgium, Greece, Luxembourg, Portugal, Spain and the UK |

| Hermans 2013[37] | |
|---|---|
| | **Setting:** general practitioner or hospital-based outpatient clinics to represent country-specific diabetes management practices<br>**Number of clusters:** 477<br>**Number of providers:** 477<br>**Total number of patients:** 4027<br>**Percentage male:** 55%<br>**Diabetes type:** type 2<br>**Average age (SD):** 65.6yrs (10.8)<br>**Inclusion criteria:** outpatients previously diagnosed with type 2 diabetes and ≥18 years of age<br>**Exclusion criteria:** persons with gestational diabetes, patients with type 1 diabetes, those who were hospitalized as a result of their diabetes, participants in other clinical trials, and members of the Belgian Diabetes Convention (a quality assurance program with benchmarked feedback) |
| **Interventions** | **Intervention (n= 293 clusters, n=2509 patients):** usual care consisting of routine monitoring, treatment and counselling of patients with type 2 diabetes with feedback benchmarked against other centres in each country<br>**Comparator (n=184 clusters, n=1518 patients):** usual care (as intervention but without feedback)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** HbA1c, LDL cholesterol, and systolic BP [SBP]) at 12m<br>**Secondary outcomes:** % of patients achieving targets in comparison with baseline of preventive screening, such as retinopathy, neuropathy; dietary counselling, microalbuminuria; smoking habits; BMI and physical activity |
| **Notes** | **Date conducted:** 2010<br>**Trial registration number:** NCT00681850<br>**Sources of funding**: editorial assistance and assistance with manuscript preparation and coordination was funded by AstraZeneca Belgium<br>**Declaration of interest:** H.V. is a full-time employee of AstraZeneca, all other authors declared that they had sat on advisory boards or received honoraria from pharmaceutical companies<br><br>Study protocol has been published: https://www.ncbi.nlm.nih.gov/pubmed/219395 |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Quote: *' Investigators were randomized by a centralized randomization procedure (What Health, Brussels, Belgium) to either a benchmarking group or a control group'*<br>p3389 |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar baseline retinopathy screening attendance (<10% difference in baseline rates of annual ophthalmic examinations between arms. Table 2 p3393) |
| **Similar baseline characteristics** | Low | Quote: *' Baseline demographic and disease characteristics were similar between groups'*<br>p3390 |
| **Incomplete outcome data addressed** | High | Judgement comment: 23% of clusters enrolled did not contribute to the final analysis |
| **Adequate Blinding** | Low | Quote: *'The sequence was concealed until the intervention was assigned, and investigators were blinded to group assignment. Because randomization was at the investigator level, blinding of patients was not applicable. '*<br>p3389 |

| | | |
|---|---|---|
| **Protected against contamination** | Low | Judgement comment: allocation was by centre and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00681850 |
| **Free from other bias** | High | Judgement comment: all authors had links to pharmaceutical companies |

| **Herrin 2006[38]** | |
|---|---|
| **Methods** | **Study aim:** to assess the effectiveness of diabetes resource nurse case management and physician profiling in improving diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** Family Medicine and Internal Medicine practices within the Texas Health Provider Network (HTPN) - physician component of the Baylor Health Care System- Dallas-Fort Worth, Texas. HTPN- fee for service setting<br>**Number of clusters:** 22<br>**Number of providers:** 92<br>**Total number of patients:** 2155<br>**Percentage male:** 49.8%<br>**Diabetes type:** NR<br>**Average age (SD):** 72.9yrs (NR)<br>**Inclusion criteria:** people aged ≥65 years on January 1, 2000, with a physician visit related to diabetes in 2000 and Medicare insurance coverage<br>**Exclusion criteria:** people who did not fulfil National Diabetes Quality Improvement Alliance criteria for diagnosis of diabetes mellitus; patients whose charts were not available for abstraction |
| **Interventions** | **Intervention (claims plus MR group) : (n= 7 clusters, n=849 patients)** Medicare claims feedback plus feedback on clinical measures from medical record (MR) abstraction<br>**Intervention (claims plus MR plus DRS group): (n= 8 clusters, n=654 patients):** both types of feedback plus diabetes resource nurse (DRS)<br>**Comparator (claims only group):(n=7 clusters, n=652 patients):** Medicare claims feedback only<br>**Duration:** 24 months |
| **Outcomes** | **Primary outcome:** HbA1c level; LDL level; diastolic and systolic blood pressures as dichotomous outcomes based on based on the ADA and National Diabetes Quality Improvement Alliance guidelines<br>**Secondary outcomes:** HbA1c, LDL, and diastolic and systolic blood pressures as continuous measures; processes of care measures including annual HbA1c assessment, annual lipid assessment, annual blood pressure measurement, annual eye exam, annual foot exam, and annual renal assessment |
| **Notes** | **Date conducted:** 2001<br>**Trial registration number:** NR<br>**Sources of funding**: American Diabetes Association; Pfizer, Inc; and the Baylor Health Care System.<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Quote*: 'practices were stratified … to ensure even distribution across arms…. Within each stratum practices were sampled and randomized triplets to ensure even distribution'*<br>*p97*<br><br>Judgement comment: not clear if method for sequence generation was appropriate |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by cluster and allocation performed prior to the start of the study |

| | | |
|---|---|---|
| **Similar baseline outcome measurements** | Low | Judgement comment: similar attendance for annual eye examination based on Medicare claims Table 3 p99 |
| **Similar baseline characteristics** | Low | Quote: *'There were no differences in baseline clinical measures or in the data missing across study arms. There were no missing values for process measures, as patients were assumed to have failed the criteria if no record was found in the medical record or Medicare data.'* p99 |
| **Incomplete outcome data addressed** | Low | Quote: *'There were no missing values for process measures, as patients were assumed to have failed the criteria if no record was found in the medical record or Medicare data.'* p98 |
| **Adequate Blinding** | Low | Quote: *' Both medical record and Medicare claims data were, however, collected by individuals blinded to patients' study arm assignments.'* p101 |
| **Protected against contamination** | Low | Judgement comment: allocation was by cluster and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: part-funded by pharmaceutical company, however states that the company had no involvement in study design, data collection, data analysis, or interpretation of data or asked to approve the final version of the manuscript. |

| **Hurwitz 1993[39]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness and acceptability of centrally organised prompting for coordinating community care of non-insulin dependent diabetic patients<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** UK<br>**Setting:** two hospital outpatient clinics, 38 general practices, and 11 optometrists in the catchment area of a district general hospital in Islington, UK<br>**Total number of participants:** 181<br>**Percentage male:** 58%<br>**Diabetes type:** type 2<br>**Average age (SD):** 62.6yrs (10)<br>**Inclusion criteria:** mobile people with type 2 diabetes under the age of 80 who had attended the district general hospital diabetic clinics in the previous two years<br>**Exclusion criteria:** women of childbearing age; those with one or more of three established significant diabetic complications, namely, nephropathy with creatinine concentration >150 μmol/l; ischaemia severe enough to have resulted in gangrene or amputation, and retinopathy worse than background in one eye |
| **Interventions** | **Intervention (n=89):** prompting system using a database which sends requests to patients to provide blood and urine samples for testing at 6 monthly intervals. Results were incorporated within personalised medical records which were sent to participants with a request to take them to their general practitioner within 10 days. General practitioner clinical assessments paralleled those of the hospital clinic. Participants not already under the care of a hospital eye clinic also received an annual eye test prompt and a map identifying local optometrists who performed dilated fundoscopy. Copies of optometry feedback are sent to the participant's general practitioner, who is thereby kept informed of eye assessments<br>**Comparator (n=92):** usual care (hospital diabetes clinic review)<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** number of diabetic reviews; glycaemic control; recording of processes of care (including random plasma glucose, HbA1c, eye screening)<br>**Secondary outcomes:** views of participating persons with diabetes, GPs and optometrists |

| Hurwitz 1993[39] | |
|---|---|
| **Notes** | **Date conducted:** April 1988 to October 1990<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |
| **Risk of bias** | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'..were randomised (by using Cambridge tables of random numbers).'*<br>*p624* |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *' Comparisons of control and prompted patient groups at the start of the study are shown in table II. The groups were well matched for demographic variables and also for most important diabetic attributes, although mean systolic blood pressure was recorded as 9 mm Hg greater in the control group (95% confidence interval 2.1 to 16.0 mm Hg; p=0.011) and 14 patients in the prompted group were documented as having signs of leg ischaemia compared with only four controls $\chi 2=5.7$, df=1; p=0.017).'*<br>p624<br><br>Judgement comment: differences in baseline characteristics unlikely to influence outcome |
| **Incomplete outcome data addressed** | Low | Quote: *'At the end of October 1990, 94% (170/181) of the general practitioner notes for the study patients were traced.'*<br>p624 |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: control participants unlikely to receive the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Ilag 2003[40] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of a systematic patient evaluation and patient and provider feedback on the processes and outcomes of diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** university primary care internal medicine practices affiliated with a managed care organization<br>**Number of clusters:** 9<br>**Number of providers:** 44<br>**Total number of patients:** 284<br>**Percentage male:** 47%<br>**Diabetes type:** type 1 and 2<br>**Average age (SD):** 59yrs (13.1)<br>**Inclusion criteria:** members of the managed care organisation with diabetes aged ≥18 years<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=5 clusters, n=173 patients):** Annual Diabetes Assessment Program (ADAP) |

| Ilag 2003[40] | |
|---|---|
| | program visits in years 1 and 2. This consisted of a 1 hr focused encounter with non-physician providers within the primary care centre assessing key diabetes and cardiovascular health parameters measured (including fundus photography) and discussed with the patient by a certified diabetes educator. A tailored report with guideline driven recommendations for care was sent to the patient's primary care provider and incorporated into the electronic patient record)<br>**Comparator (n=4 clusters, n=111 patients):** usual care in year 1, ADAP program visits delivered in year 2<br>**Duration:** 24 months |
| **Outcomes** | **Primary outcome:** diabetes processes of care measures including: frequency of dilated retinal examinations, urine microalbumin measurements, foot examination, measurement of blood pressure HbA1c and LDL cholesterol<br>**Secondary outcomes:** patient and provider views of the ADAP program |
| **Notes** | **Date conducted:** Oct 1999-Sept 2001<br>**Trial registration number:** NR<br>**Sources of funding**: National Institutes of Health<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Method for cluster randomisation not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Judgement comment: baseline characteristics balanced across the two arms of the study (see Table 1 p2724) |
| **Incomplete outcome data addressed** | High | Judgement comment: high attrition (results reported for 47% of intervention subjects and 64% of comparison subjects) |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Quote: *'We believe it was necessary to randomize by site to avoid within site contamination.'* |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Jacobs 2012[41] | |
|---|---|
| **Methods** | **Study aim:** to assess whether pharmacists working with physicians and other healthcare providers in an ambulatory care setting can improve quality of care for patients with type 2 diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA |

| Jacobs 2012[41] | |
|---|---|
| | **Setting:** single ambulatory general internal medicine setting<br>**Total number of participants:** 396<br>**Percentage male:** NR<br>**Diabetes type:** type 2<br>**Average age (SD):** 62.9yrs (11)<br>**Inclusion criteria:** > 18 years with a documented HbA1c value > 8% obtained more than 6 months before the data acquisition date<br>**Exclusion criteria:** received primary care outside of the Lahey Clinic Burlington campus, were diagnosed with type 1 diabetes, had an HbAl c <8% within 6 months of randomization, were enrolled in any other pharmacist-run or diabetes management study, were receiving diabetes management by an outside endocrinologist, or were unable to adhere to scheduled follow up |
| **Interventions** | **Intervention (n=195):** pharmacist-patient clinic visits included obtaining a comprehensive medication review; performing targeted physical assessment; ordering laboratory tests; reviewing, modifying, and monitoring participants medication therapy and providing detailed counselling on all therapies; facilitating self-monitoring of blood glucose; and providing reinforcement of dietary guidelines and exercise<br>**Comparator (n=201):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** achieving targets for HbAlc (<7%), LDL cholesterol (<100 mg/dL) and blood pressure (<130/80 mm Hg)<br>**Secondary outcomes:** compliance with microvascular screening parameters including retinopathy, neuropathy and nephropathy |
| **Notes** | **Date conducted:** 2003<br>**Trial registration number:** NCT00541606<br>**Sources of funding**: unrestricted medical grant from Pfizer<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: ' *Eligible patients were randomized to either an intervention or control group using a computer randomized sequence of ones and zeros'*<br>p615 |
| **Allocation concealment** | Unclear | Not report |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'Baseline characteristics were similar between the two groups and reflect an obese white population of patients with diabetes, with a large percentage having comorbid medical conditions and existing microvascular complications (Table 1).'*<br>p617<br><br>Judgement comment: differences in baseline characteristics unlikely to affect outcome |
| **Incomplete outcome data addressed** | High | Judgement comment: per protocol analysis (patients discontinuing intervention were not included in the analysis). High attrition, unbalanced across study arms |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation was by cluster and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: trial retrospectively registered and therefore not possible to assess |

| | | |
|---|---|---|
| **Free from other bias** | High | Judgement comment: risk of selection bias<br><br>Quote: *'Patients who agreed to participate in the study were likely more motivated to adhere to a diabetes treatment program. Although the control patients had to have obtained a minimum number of laboratory tests to be included, some patients in this group may not have participated in the study and may have been a less motivated group than the intervention group.'*<br>p619 |

| **Jansink 2013[42]** | |
|---|---|
| **Methods** | **Study aim:** to assess the effectiveness of a comprehensive diabetes programme in general practice that integrates patient-centred lifestyle counselling into structured diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Netherlands<br>**Setting:** general practices in the South-eastern part of the Netherlands<br>**Number of clusters:** 58<br>**Number of providers:** 58<br>**Total number of patients:** 940<br>**Percentage male:** 54.9%<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** people aged <85 years with a HbA1c >7% and a BMI >25 Kg/$m^2$<br>**Exclusion criteria:** complex co-morbidity and treatment in hospital |
| **Interventions** | **Intervention (n= 29 clusters, n=422 patients):** nurses in the intervention group received a programme consisting of (a) training in lifestyle counselling based on motivational interviewing; (b) tools for structuring diabetes care, such as training in agenda setting, a local diabetes protocol based on the national guidelines and a social map for lifestyle support; (c) instruction on record keeping to integrate lifestyle counselling into general practice; and (d) introduction of tools to sustain improvements including an instruction chart (reminder) , regular telephone follow-ups with the target patients, a help desk that also enquired proactively about the progress of diabetes management, and a follow-up meeting for the nurses<br>**Comparator (n=29 clusters, n= 518 patients):** nurses in the comparator group were advised to administer care consistent with current diabetes guidelines<br>**Duration:** 14 months |
| **Outcomes** | **Primary outcome:** HbA1c and reported changes in lifestyle related to diet and physical activity<br>**Secondary outcomes:** other diabetes processes of care recommendations ( including eye examination); quality of life (using EQ-5D) |
| **Notes** | **Date conducted:** 2008<br>**Trial registration number:** ISRCTN68707773<br>**Sources of funding**: ZonMW-the Netherlands Organization for Health Research and Development<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by general practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline characteristics<br>Table 1 p123 |
| **Incomplete** | High | Quote: *'A limitation of the study is the loss to follow-up in the* |

| | | |
|---|---|---|
| **outcome data addressed** | | *lifestyle measures from the patient questionnaire'*<br>p125<br>Judgement comment: large losses to follow up, reasons not provided. Reported on 47.8% of eligible patients |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation was by cluster and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry ISRCTN68707773 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Kirwin 2010[43]** | |
|---|---|
| **Methods** | **Study aim:** to assess whether pharmacists working with primary care physicians can improve the quality diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** single hospital-based primary care practice<br>**Number of clusters:** 8<br>**Number of providers:** 72<br>**Total number of patients:** 346<br>**Percentage male:** 34.2%<br>**Diabetes type:** types 1 and 2<br>**Average age (SD):** 63yrs (NR)<br>**Inclusion criteria:** ≥18 years or older; diagnosis of diabetes; with a primary care physician practicing within the study clinic; seen in the practice at least once during the 2 years prior to the start of the study.<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=4 clusters, n=171 patients):** primary care physicians received a personalised letter from a pharmacist for patients with upcoming clinic visits. The letter contained information extracted from the electronic patient record on overdue testing and drug therapy to achieve diabetes-related treatment targets<br>**Comparator (n= 4 clusters, n=175 patients):** usual care (not specified)<br>**Duration:** recommendation letter sent and outcome determined 30 days following the visit to the primary care physician |
| **Outcomes** | **Primary outcome:** process measure of annual HbA1c testing<br>**Secondary outcomes:** 4 processes of care measures (including annual eye examination) and 3 biomarker measures (HbA1c <7%, LDL <100mg/dL, BP <130/80) |
| **Notes** | **Date conducted:** 2004<br>**Trial registration number:** NCT00122421<br>**Sources of funding**: none<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: ' *In July 2003, we identified 1,349 patients meeting these criteria and used a random number generator to randomly select 560 being cared for by 72 PCPs for inclusion in the study (Figure 1).'*<br>*p106*<br>Quote: *'We randomized the intervention at the level of clinical suites within the study practice immediately after patients were identified in July 2003.'*<br>*p106* |
| **Allocation concealment** | Low | Judgement comment: unit of allocation at the level of the cluster and allocation performed prior to the start of the study |

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| **Similar baseline outcome measurements** | Low | Judgement comment: similar baseline annual eye examination in intervention and control (38% vs 37.1%) |
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline characteristics. Baseline imbalance in annual lipid profile assessment but unlikely to influence outcome. |
| **Incomplete outcome data addressed** | High | Judgement comment: per protocol analysis, baseline based on those analysed. Reasons for missing data not provided. |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation by cluster and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00122421 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Krein 2004[44]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effects of a collaborative case management intervention for patients with poorly controlled type 2 diabetes on glycaemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Department of Veterans Affairs (VA) Medical Centres<br>**Total number of participants:** 246<br>**Percentage male:** 96.5%<br>**Diabetes type:** type 2<br>**Average age (SD):** 61yrs (10.5)<br>**Inclusion criteria:** people with at least one prescription for an oral hypoglycemic agent, insulin, or blood glucose monitoring supplies filled in the previous 12 months; most recent glycated haemoglobin (HbA1c) ≥8.5% (within the last year); general medicine clinic visit scheduled between May 1999 and January 2000<br>**Exclusion criteria:** <18 years; type 1 diabetes or were diagnosed before the age of 30 years, had no telephone; did not speak English, were not competent for interview, reported primary source of diabetes care outside the VA, were being treated for cancer (other than non-melanoma skin cancer), had kidney failure, symptomatic heart failure, liver disease, or blindness; spent winter at another residence; or planned to move |
| **Interventions** | **Intervention (n=123):** two nurse practitioner acting as case managers working with participants and their primary care providers, monitoring and coordinating care through the use of telephone contacts, collaborative goal setting, and treatment algorithms<br>**Comparator (n=123):** provision of educational materials and usual care by their primary care physician<br>**Duration:** 18 months |
| **Outcomes** | **Primary outcome:** glycaemic control, as measured by HbA1c level; control of low-density lipoprotein (LDL) cholesterol; and blood pressure<br>**Secondary outcomes:** health status and patient satisfaction were assessed using a self-administered written survey, which included the Short Form Health Survey for Veterans and the Patient Satisfaction Questionnaire—Form II (general satisfaction subscale); demographic characteristics, receipt of eye screening, aspirin use, and health care services received outside the VA |

| Krein 2004[44] | |
|---|---|
| **Notes** | **Date conducted:** 2000<br>**Trial registration number:** NR<br>**Sources of funding**: Office of Research and Development, Health Services Research and Development Service, Department of Veterans Affairs; Michigan Diabetes Research and Training Center Grant; National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'One member of a matched pair, within one of four possible blocks/cells (site by baseline HbA1C level), was then assigned randomly to the case management group and the other to the control group by the project manager who had no knowledge about the patients other than site and baseline HbA1c level.'* p733 |
| **Allocation concealment** | Low | Quote: *'One member of a matched pair, within one of four possible blocks/cells (site by baseline HbA1C level), was then assigned randomly to the case management group and the other to the control group by the project manager who had no knowledge about the patients other than site and baseline HbA1c level.' p733* |
| **Similar baseline outcome measurements** | Low | Judgment comment: similar baseline attendance for diabetic retinopathy screening (9% baseline difference, see Table 1 p735) |
| **Similar baseline characteristics** | Low | Quote: *'The baseline attributes of the intervention and control groups were similar (Table 1). Except for having a higher percentage of non-white participants, study enrollees were demographically representative of VA ambulatory patients.'* p734 |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition, balanced across the arms of the study and missing data accounted for |
| **Adequate Blinding** | Low | Judgement comment: eye screening data obtained from VA medical information system and therefore unlikely to be influenced by lack of masking |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Lafata 2002[45] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effectiveness of a mailed intervention for improving diabetes management<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** multi-specialty primary care group practice<br>**Total number of participants:** 3,309<br>**Percentage male:** 47.8%<br>**Diabetes type:** NR<br>**Average age (SD):** 59.8yrs (NR)<br>**Inclusion criteria:** aged ≥18 yrs with a diabetes aligned to a primary care physician within a multi-speciality practice<br>**Exclusion criteria:** none |

| Lafata 2002[45] | |
|---|---|
| **Interventions** | **Intervention (n=1,641):** mailed reminder intervention consisting of a letter from the primary care physician, self-care handbook, preventive care checklist and specific recommendations regarding receipt of routine monitoring and screening<br>**Comparator (n=1,668):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** documented receipt of fasting lipid profile, HbA1c measurement, dilated retinal exam during the period 6-12 months following randomisation<br>**Secondary outcomes:** HbA1c and cholesterol levels 1 yr after randomisation |
| **Notes** | **Date conducted:** 1999<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement (Quote)** |
| **Adequate sequence generation** | Low | Quote: *'Using the random number generator In SAS (Version 8.2: SAS Institute, Inc.,Cary, NC) each month, each eligible patient with a birthday on the month was assigned to receive either the mailed reminder packet or usual care.'*<br><br>p522 |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Low | Judgement comment: baseline retinal exams reported and balanced across study arms (Table 2 p527) |
| **Similar baseline characteristics** | Low | Quote: *'Almost 60% of the study population received an HbA1c in the 6 months preceding the mailed reminder program, and approximately half received a lipid profile and a retinal exam in the 12 months preceding the mailed reminder program, We found no statistically significant differences in these and other characteristics listed in Table 2 between patients randomized to receive the mailed reminder program or usual care.'*<br><br>p526 |
| **Incomplete outcome data addressed** | Low | Judgement comment: no missing outcome data (see Table 3 p528) |
| **Adequate Blinding** | Low | Judgement comment: outcomes were obtained from automated clinical administrative databases |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the mailed intervention |
| **Free of selective reporting** | Unclear | Judgement comment: trial retrospectively registered and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| Litaker 2003[46] | |
|---|---|
| **Methods** | **Study aim:** to compare a traditional physician-only model of care with a more collaborative, team-based approach to chronic disease management<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA |

| Litaker 2003[46] | |
|---|---|
| | **Setting:** Department of General Internal Medicine at the Cleveland Clinic Foundation, Ohio<br>**Total number of participants:** 157<br>**Percentage male:** 41%<br>**Diabetes type:** type 2<br>**Average age (SD):** 60.5yrs (9)<br>**Inclusion criteria:** people with established diagnoses of mild or moderate hypertension and non-insulin dependent diabetes mellitus without known end-organ complications<br>**Exclusion criteria:** medically complex individuals (Charlson index greater than five) or those requiring three or more medications for blood pressure control |
| **Interventions** | **Intervention (n=79):** clinical practice algorithms, patient education on disease self-management strategies, and regular monitoring and feedback delivered primarily by a nurse practitioner. The nurse practitioner acted as the first-line contact for care, in treatment decisions and to standardize treatment and for assessing treatment adherence and individual barriers to adherence<br>**Comparator (n=78):** physician-only or 'usual' care defined as any form of treatment offered by an individual's primary care physician that reflected the practice style prevalent at the study site prior to the current investigation<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** measures to reflect the process and quality of care; documented evidence of annual ophthalmologic and foot examinations; HbA1c assessment at least once during the study year (other than study measures at 0 and 12 months); documentation of influenza and pneumococcal vaccination status and administration when appropriate<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** Oct 1996-Jan 1998<br>**Trial registration number:** NR<br>**Sources of funding**: Arison Foundation and the I.H. Page Center for Health Outcomes Research at the Cleveland Clinic Foundation<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'Members of the two patient groups did not differ significantly at study entry with respect to age, gender or racial composition, years of education completed, number of comorbid conditions, or baseline HbA1c and blood pressure control, total cholesterol or HDL-c values.'*<br>p229 |
| **Incomplete outcome data addressed** | Low | Judgement comment: outcome on all participants randomised were reported |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Quote: *' Routine use of reminder systems, forms to facilitate documentation of care, monitored use of clinical guidelines or active collaboration with a nurse practitioner were not aspects of usual care for physicians in this practice during the study period.'*<br>p226 |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |

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| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Maljanian 2005[47]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate an intensive telephone follow-up as an additional component of a diabetes disease management program already shown to be effective in improving glycemic control, adherence with American Diabetes Association (ADA) standards of care, and health-related quality of life (HRQOL)<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** acute care teaching hospital<br>**Total number of participants:** 336<br>**Percentage male:** 46.7%<br>**Diabetes type:** type 1 and 2<br>**Average age (SD):** 58yrs (12.7)<br>**Inclusion criteria:** adults with type 1 or type 2 diabetes mellitus who were referred to the hospital-based disease management program<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=176):** both the intervention and control groups received the standard of care provided in the diabetes disease management program as follows: (1) three 4-h educational classes covering topics such as living with diabetes, introduction to diabetes and the metabolic syndrome, nutrition and exercise, the importance of adherence to the ADA standards of care (e.g. annual eye exams, foot exams, blood glucose monitoring) and strategies to enhance self-management skills; (2) individual visits with a Registered Nurse and a nutritionist; (3) collaborative care management with written evaluations and recommendations provided to the participants primary care provider, and scheduled follow-up visits. The intervention group also received a series of 12 weekly phone calls to reinforce education and self-management skills. The first call was 15–20 min in length; subsequent calls were 5–7 min each<br>**Comparator (n=160):** usual care consisting of the diabetes disease management programme as defined above, without the intensive telephone intervention<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** glycaemic control; general and disease-specific health-related quality of life; symptoms of depression; adherence to self-management guidelines, and patient satisfaction<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** March 2000-August 2001<br>**Trial registration number:** NR<br>**Sources of funding**: Aetna Quality of Care Research Foundation through the Academic Medicine and Managed Care Forum<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | High | Quote: *'A comparison of demographic and baseline measures indicated that the two groups differed on age, BMI, when diagnosed, language used in the DLC class attended, ethnicity (Caucasian, non-Caucasian dichotomy), HbA1c, PCS, MCS, and symptoms of depression (CES-D).'*<br>*p18* |

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| | | Judgement comment: the reported baseline imbalance could have influenced retinopathy screening attendance |
| **Incomplete outcome data addressed** | High | Quote: *'The 171 participants who did not return for their two follow-up visits represent a significant attrition rate (34%).'* p18<br>Quote: *'The fact that individuals with better glycemic control were more likely to return may explain some of the floor effect on glycemic control in the total study population. Further, that those patients with worse glycemic control and larger BMI at enrollment were the ones more likely to miss later appointments is concerning because those are the patients who most need their diabetes education reinforced and self-management encouraged.'* p23 |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: unlikely that control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **McCall 2011[48]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of commercial programs for disease management that use nurse-based call centres on the quality of clinical care, acute care utilisation, and Medicare expenditures for Medicare fee-for-service beneficiaries.<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** Primary Care practices<br>**Total number of participants:** 188,169 people with diabetes<br>**Percentage male:** NR<br>**Diabetes type:** NR<br>**Average age (SD):** NR<br>**Inclusion criteria:** Medicare beneficiaries in each of eight geographic areas who met the selection criteria for heart failure or diabetes and had a Hierarchical Condition Category (HCC) risk score of 1.35<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (n=126,557 patients):** Medicare Health Support Pilot Program consisting of eight commercial programs for disease management that used nurse-based call centres to assess the needs of individual beneficiaries and used health coaches to target those beneficiaries at immediate high risk for adverse events. The goals of the intervention were to improve beneficiaries' understanding of their disease or diseases, their ability to manage self-care, and their ability to communicate with providers. Various educational resources including literature, videos, and Internet resources were provided. A small portion of the intervention population received intensive case management services.<br>**Comparator (n=61,612 patients):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** changes from baseline compared between the intervention and control groups with regard to the quality of clinical care provided, the utilization of acute care, and Medicare expenditures.<br>**Secondary outcomes:** none |
| **Notes** | **Date conducted:** 2004-2007<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** none declared |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar baseline screening attendance (see Table 1. Online supplement) |
| **Similar baseline characteristics** | Low | Quote: *'The characteristics of the beneficiaries were well balanced between the intervention and control groups at baseline (Table 1).'* p1707 |
| **Incomplete outcome data addressed** | Unclear | Not reported |
| **Adequate Blinding** | Low | Judgement comment: data on retinopathy screening obtained from routinely collected data |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the Medicare Health Support Program |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| Mc Clellan 2003[49] | |
|---|---|
| **Methods** | **Study aim:** to determine if an intervention that includes claims-based feedback about patterns of HbA1c measurement results in more frequent monitoring of HbA1c in diabetic Medicare beneficiaries<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** primary care physicians in a Southern State treating Medicare beneficiaries<br>**Number of clusters:** 123<br>**Number of providers:** 477<br>**Total number of patients:** 22,971<br>**Percentage male:** 43%<br>**Diabetes type:** type 1 and type 2<br>**Average age (SD):** 74yrs (NR)<br>**Inclusion criteria:** diabetes diagnosis based on two outpatient claims 30 days apart or one inpatient claim for the care of diabetes mellitus (250.xx, 357.2x, 362.0x, 366.41). Patients had to be age at least 65 years old, enrolled in Medicare for a minimum of 11 months in 1996 or 1998<br>**Exclusion criteria:** any Health Maintenance Organization (HMO) coverage or a skilled nursing facility stay longer than 60 days |
| **Interventions** | **Intervention (n=247 clusters, n=11,904 patients):** mailing to physicians at baseline, 2 months, 4 months, and 6 months containing clinical practice guidelines, general information about patterns of diabetes care in the state, an educational tape, and practice aids to implement guideline recommendations (chart stickers, pocket guides, wall posters, etc.). Intervention physicians were provided with fliers to remind patients to have regular check-ups of their urine, eyes, feet, and blood; an American Diabetes Association catalogue containing diabetes related publications and patient education presentations and a "Diabetic Passport" that allowed a patient to record their diabetic test results. The passport displayed the ADA recommendations for HbA1c, eye, urine, and lipid monitoring<br>**Comparator (n=230 clusters, n=11,067 patients):** newsletter sent to intervention and comparator groups containing an article devoted to early detection of microvascular complication and the importance of glycaemic control which opened up to create a poster |

| Mc Clellan 2003[49] | |
|---|---|
| | showing the tests/screenings that patients with diabetes mellitus require on a regular basis<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** changes in frequency of measurement of HbA1c, quantitative urine protein and dilated eye examinations<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** 1996-1998<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'After assigning patients to physicians and physicians to counties, the counties were ordered alphabetically and a random number table was used to assign a county to either the intervention or comparison group.'*<br>p1212 |
| **Allocation concealment** | Low | Quote: '*None of the staff involved with the design and implementation of the intervention were involved with the randomization of counties or selection of physicians within counties.'*<br>p1212 |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar proportion of baseline eye exams (see Table 2 p1214) |
| **Similar baseline characteristics** | Low | Quote: *'The two groups were comparable with respect to race, gender, and the mean age of the diabetic.'*<br>p1213 (see also Table 1 p1214)<br>Judgement comment: Similar quality indicators at baseline (see Table 2 p1214) |
| **Incomplete outcome data addressed** | Low | Quote: *'…the dropout rate among practices in the comparison and intervention groups was small, 3.6 and 3.0%, respectively, and thus was unlikely to bias our results.'*<br>p1215 |
| **Adequate Blinding** | Low | Judgement comment: eye screening outcomes obtained from routinely collected claims data |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Mc Dermott 2001[50] | |
|---|---|
| **Methods** | **Study aim:** to evaluate a paper-based recall and reminder system and basic diabetes education of healthcare workers in improving the quality of diabetes care in a remote indigenous community<br>**Study design:** cluster RCT |

| Mc Dermott 2001[50] | |
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| **Participants** | **Country:** Australia<br>**Setting:** 21 primary health care centres in Torres Strait and Northern Peninsula Area in Queensland Australia<br>**Number of clusters:** 21<br>**Number of providers:** 3<br>**Total number of patients:** 555<br>**Percentage male:** 38%<br>**Diabetes type:** NR<br>**Average age (SD):** 52.3yrs (13.5)<br>**Inclusion criteria:** patients with diabetes<br>**Exclusion criteria:** patients aged <15 years diagnosed <1 year before the audit |
| **Interventions** | **Intervention (n= 8 clusters, n=250 patients)):** intervention and comparator sites received audit and feedback on patients with diabetes benchmarked against guidelines. Evidence-based guidelines were issued and a new diabetes outreach service was established (comprising a diabetologist, nutritionist, podiatrist, and diabetes healthcare worker). Intervention and comparator sites were visited by the outreach team who saw individual patients on a referral basis. A recall system was established in intervention sites and healthcare workers in these sites received clinical training on the basics of diabetes care<br>**Comparator (n= 13 clusters, n=305 patients):** see above<br>**Duration**: 12 months |
| **Outcomes** | **Primary outcome:** proportion of patients fulfilling diabetes care indicators (including 'eye check' and 'ophthalmologist check' in the last 12 months<br>**Secondary outcomes:** diabetes related hospital admissions and hospitalisations |
| **Notes** | **Date conducted:** March 1999 to February 2000<br>**Trial registration number:** NR<br>**Sources of funding**: National Health and Medical Research Council<br>**Declaration of interest:** NR |

| Risk of bias | | |
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| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | High | Quote: *'..eight intervention sites were chosen randomly by being picked from a hat containing the names of all 21 clinics'* p498<br><br>Judgement comment: inappropriate method of sequence generation |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of eye checks and ophthalmology visits at baseline |
| **Similar baseline characteristics** | Low | Quote: *'There were no significant differences in age, sex ratio and duration of diabetes at baseline…'* p498<br><br>Judgement comment; baseline differences between arms in diabetes processes of care (Table 2 p499) but unlikely to influence outcome |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and balanced across arms |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective** | Unclear | Judgement comment: no protocol or trial registry entry available |

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| **reporting** | | and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Meigs 2003[51]** | |
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| **Methods** | **Study aim:** to evaluate effects of a web-based decision support tool, the diabetes 'Disease Management Application (DMA)' to improve evidence-based management of type 2 diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** Adult Medicine Clinic (AMC) in Harvard Medical School in Boston Massachusetts USA<br>**Number of clusters:** 26<br>**Number of providers:** 26<br>**Total number of patients:** 598<br>**Percentage male:** 48.1%<br>**Diabetes type:** type 2<br>**Average age (SD):** 67.5yrs (12)<br>**Inclusion criteria:** people with at least one visit to the AMC during the pre-intervention year (May 1997 to April 1998) were identified by billing claims, and people with type 2 diabetes were identified by ICD-9 codes 250.00 –250.90<br>**Exclusion criteria:** type 1 diabetes |
| **Interventions** | **Intervention (n= 12 clusters, n=307 patients):** web-based information management/clinical decision support tool providing a single-screen view of patient-specific information, enabling decision support at the time of patient contact. The decision support tool generated patient-specific recommendations based on evidence-based guidelines<br>**Comparator (n= 14 clusters, n=291 patients):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** change in rates of annual HbA1c, LDL cholesterol, blood pressure, and eye and foot screening and change in the absolute values of HbA1c, LDL cholesterol, and blood pressure<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** May 1998 to April 1999<br>**Trial registration number:** NR<br>**Sources of funding**: National Pharmaceutical Council; MGH Primary Care Operations Improvement and Clinical Research Programs<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'A coin was tossed to select an intervention group and a control group.'*<br>p751 |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | High | Quote: *'..rates of eye and foot screening were lower in the intervention group.'*<br>p793<br><br>Judgement comment: baseline imbalance in diabetic retinopathy screening |
| **Similar baseline characteristics** | Low | Quote: '*Baseline staff provider and patient characteristics were similar comparing the intervention group with the control group (Table 1).'*<br>*p*793 |
| **Incomplete outcome data addressed** | Low | Judgement comment: data from all patients reported |

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| **Adequate Blinding** | Low | Quote: *'Clinical data from paper and electronic charts were abstracted by three nurses blinded to group status of providers and patients.'*<br>p752 |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **O'Connor 2005[52]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of a quality improvement (QI) intervention on the quality of diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** primary care medical practices in Minnesota<br>**Number of clusters:** 12<br>**Number of providers:** 329<br>**Total number of patients:** 754<br>**Percentage male:** 54.3%<br>**Diabetes type:** NR<br>**Average age (SD):** 57.8yrs (NR)<br>**Inclusion criteria:** aged > 19 years who had two or more ICD-9 diagnostic codes for diabetes in a defined 12 month period<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (12 clusters, n=428 patients):** IDEAL (Improving Care for Diabetes Through Empowerment Active Collaboration and Leadership) model consisting of facilitation of leadership actions in support of change, training for the leader and facilitator of an intra-clinic multidisciplinary continuous quality improvement (CQI) team, and consultative and networking support of the change process<br>**Comparator (10 clusters, n=326 patients):** usual care (not specified)<br>**Duration:** 18 months |
| **Outcomes** | **Primary outcome:** % of patients with annual tests of HbA1c, LDL and blood pressure; % of patients with annual screening for foot eye or kidney complications<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Centres for Disease Control and Prevention; HealthPartners Research Foundation<br>**Declaration of interest:** one author reported being a member of advisory boards and receiving honoraria from LifeScan, NovoNordisk and AmerisourceBergen |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar attendance for annual eye exams at baseline |
| **Similar baseline characteristics** | Low | Quote: *'Table 1 shows that the clinics and patients in the intervention and control group were similar in size and in patient mix…'*<br>p1892 |

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| **Incomplete outcome data addressed** | High | Judgement comment: reported data was based on those 754 subjects who completed the pre and post intervention surveys and consented to have their medical record reviewed. Response rates to the survey averaged 55-65% across study sites |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Perria 2007[53]** | |
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| **Methods** | **Study aim**: to assess the effectiveness of different strategies for the implementation of an evidence-based guideline for the management of non-complicated type 2 diabetes mellitus<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Italy<br>**Setting:** primary care setting of Italian National Health Service in Lazio region of Central Italy<br>**Number of clusters:** 252<br>**Number of providers:** 252<br>**Total number of patients:** 6,290<br>**Percentage male:** 52%<br>**Diabetes type:** type 2<br>**Average age (SD):** 65yrs (10)<br>**Inclusion criteria:** people with uncomplicated type 2 diabetes<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (active implementation)(n=84 clusters, n=1,952 patients):** two-day training module and consequent administration of a diabetes guideline<br>**Intervention (passive implementation) (n=85 clusters, n=2,106 patients):** GPs received the guideline without any training but with a written request to implement the guideline<br>**Comparator (n=83 clusters, n=2232 patients):** usual care (not specified)<br>**Duration:** 1 month |
| **Outcomes** | **Primary outcome**: GPs' adherence to guideline recommendations for diabetes management (including proportion of patients who were prescribed all microvascular complications assessment tests: eye examination or fundus and blood creatinine or creatinine clearance and microalbuminuria) per year<br>**Secondary outcomes:** GPs' drug prescribing behaviour |
| **Notes** | **Date conducted:** Dec 2003-Dec 2004<br>**Trial registration number:** ISRCTN80116232<br>**Sources of funding**: Italian Ministry of Health<br>**Declaration of interest:** None declared<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/15196307 |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Our randomisation sequences was computer-generated. GPs who accepted to take part in the study, were assigned by simple random allocation by the REXSCO software…'*<br>p4 |
| **Allocation concealment** | Low | Quote: *'Randomisation was performed by a researcher not involved in the study and who was blind to the identity of the practices.'*<br>p4 |

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| **Similar baseline outcome measurements** | Low | Judgment comment: similar retinal screening attendance at baseline (see Table 3 p6) |
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline demographic and clinical characteristics |
| **Incomplete outcome data addressed** | High | Judgement comment: high attrition and missing data not balanced across study arms |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Quote: *'Our randomisation sequences was computer-generated. GPs who accepted to take part in the study, were assigned by simple random allocation by the REXSCO software, which assigns to same-practice partners a nil probability of being randomised, thus minimising the chances of participant contamination.'* p4 |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry ISRCTN80116232 |
| **Free from other bias** | High | Judgement comment: only 25% of eligible GPs agreed to take part |

| **Peterson 2008[54]** | |
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| **Methods** | **Study aim:** to determine whether implementation of a multicomponent organizational intervention can produce significant change in diabetes care and outcomes in community primary care practices<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** 24 community care practices in Minnesota<br>**Number of clusters:** 24<br>**Number of providers:** 238<br>**Total number of patients:** 8,405<br>**Percentage male:** 50.3%<br>**Diabetes type:** type 2<br>**Average age (SD):** 62.8yrs (0.9)<br>**Inclusion criteria:** people with type 2 diabetes aged 18–89 years<br>**Exclusion criteria:** documented as not receiving diabetes care at the practice (referred care); deceased; no longer in the practice (documented transfer or no contact or 24 months); permanently residing in a long-term care facility |
| **Interventions** | **Intervention (n=12 clusters, n=4,588 patients):** multicomponent intervention (TRANSLATE) consisting of implementation of an electronic diabetes registry, visit reminders, and patient-specific physician alerts. A site coordinator facilitated pre-visit planning and a monthly review of performance with a local physician champion<br>**Comparator n=12 clusters, (n=3,819 patients):** usual care (practices were provided with a report of their process and outcome measures at baseline and were encouraged to continue usual quality improvement)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** percentage of patients achieving target values for the composite of systolic blood pressure (SBP) <130 mmHg, LDL cholesterol <100 mg/dl, and HbA1c <7.0% at baseline and 12 months<br>**Secondary outcomes:** six diabetes care process measures (including annual eye examination) |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NCT00108927<br>**Sources of funding**: National Institute of Diabetes, Digestive, and Kidney Disorders, National Institutes of Health<br>**Declaration of interest:** NR |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |

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| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Quote: *'Practices were randomized in blocks of four using six sets of opaque envelopes to ensure that equal numbers of control and intervention clinics were abstracted simultaneously. Envelopes were prepared by the statistician, assigned in order of postmark, and opened under observation.'*<br>p2239 |
| **Similar baseline outcome measurements** | High | Judgement comment: higher attendance for eye examination in intervention clinics at baseline (35.5% versus 24.8%, Table 3 p2241) and baseline imbalance in diabetic retinopathy (Table 2 p2240) |
| **Similar baseline characteristics** | Low | Quote: *'No statistically significant differences existed between intervention and control practices in patient demographics, total number of diabetes complications, or relevant clinical measures.'*<br>p2240<br><br>Judgement comment: with the exception diabetic retinopathy, all other baseline clinical characteristics were similar (Table 2 p2240) |
| **Incomplete outcome data addressed** | Low | Judgement comment: data from all patients included in the analysis |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00108927 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Piette 2001[55]** | |
|---|---|
| **Methods** | **Study aim:** to evaluated automated telephone disease management (ATDM) with telephone nurse follow-up as a strategy for improving diabetes treatment processes and outcomes in Department of Veterans Affairs (VA) clinics<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** 4 university-affiliated Veterans Affairs clinics in northern California<br>**Total number of participants:** 292<br>**Percentage male:** 97%<br>**Diabetes type:** NR<br>**Average age (SD):** 60.5yrs (10)<br>**Inclusion criteria:** adults with a diagnosis of diabetes and an active prescription for a hypoglycaemic agent<br>**Exclusion criteria:** >75 years of age; mentally ill; a life expectancy of <12 months; were newly diagnosed; planned to discontinue receiving services from the clinic within the 12-month follow up period; did not have a touch-tone telephone |
| **Interventions** | **Intervention (n=146):** biweekly automated telephone disease management (ATDM) health assessment and self-care education calls, and a nurse educator follow up with patients based on their ATDM assessment reports<br>**Comparator (n=146):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** impact on processes of care (including use of ophthalmology services); glycaemic control<br>**Secondary outcomes:** participants self-care activities and satisfaction with care |

| Piette 2001[55] | |
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| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Health Services Research and Development Service, Mental Health Strategic Health Care Group, Quality Enhancement Research Initiative, Department of Veterans Affairs; American Diabetes Association<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Patients were randomized using sealed envelopes containing group assignments and a sequence generated using a table of random numbers.'*<br>p203 |
| **Allocation concealment** | Low | Quote: *'Patients, their clinicians, and research staff were not aware of patients' group assignment until after they consented to participate and the envelope was opened.'*<br>p203 |
| **Similar baseline outcome measurements** | High | Judgement comment: large baseline imbalance in the use of ophthalmology services (intervention 69%, comparator 41%). See Table 2 p205 |
| **Similar baseline characteristics** | Low | Quote: *'Intervention and control groups had similar characteristics at baseline.'*<br>p204 |
| **Incomplete outcome data addressed** | Low | Judgement comment: approx. 90% follow up and missing data balanced across study arms |
| **Adequate Blinding** | Low | Quote: *'Data on patients' use of specialty outpatient services were obtained from electronic utilization databases and survey self-reports.'*<br>p204<br><br>Judgement comment: although blinding of outcome assessor not reported, unlikely to influence outcome |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Prezio 2014[56] | |
|---|---|
| **Methods** | **Study aim:** to determine the impact of a culturally tailored diabetes education program led by a community health worker (CHW) on the HbA1c, blood pressure, body mass index (BMI) and lipid status of uninsured Mexican Americans with diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** primary care (faith-based urban health services clinic serving exclusively uninsured patients of largely Mexican American origin)<br>**Total number of participants:** 180<br>**Percentage male:** 39.5%<br>**Diabetes type:** type 2<br>**Average age (SD):** 46.8 yrs (10.9)<br>**Inclusion criteria:** people with diabetes who were uninsured, had no previous exposure to the Community Diabetes Education (CoDE) program , were 18 to 75 years of age, had type 2 diabetes either treated with anti-diabetic medications or diet controlled<br>**Exclusion criteria:** , advanced complications from diabetes, pregnancy |

| Prezio 2014[56] | |
|---|---|
| **Interventions** | **Intervention (n=90):** community diabetes educational programme delivered by community health workers (CHW). Three educational modules were delivered during individual 1 hour sessions over the first 8 weeks. These sessions covered areas recommended by the American Diabetes Association. The CHW facilitated immediate physician contact to address acute problems, assisted with pharmacy refills, and arranged specialty visits such as dental care and dilated retinal exams. Participants were provided with a blood glucose monitor and testing strips free of charge and instructed in correct use of the device by medical assistants.<br>**Comparator (n=90):** usual medical care at the discretion of the clinic physicians. Participants in this group were provided with a blood glucose monitor and testing strips free of charge and instructed in correct use of the device by medical assistants. Culturally tailored printed diabetes education materials were provided by physicians and clinic staff.<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** impact of the intervention on HbA1c, lipid status, blood pressure and BMI<br>**Secondary outcomes:** participants attitudes and knowledge about diabetes self-management, American Diabetes Association standards of care (including annual dilated fundus examination) |
| **Notes** | **Date conducted:** 2006<br>**Trial registration number:** NCT00151190<br>**Sources of funding**: University of Texas School of Public Health, Institute for Faith-Health Research, Dallas<br>**Declaration of interest:** none declared<br><br>Study protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/17431443 |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement (Quote)** |
| **Adequate sequence generation** | Low | Quote: *'All patients were given informed consent in the preferred language of the study subject followed by (1:1) assignment to either the intervention or control groups using a computer generated randomization schedule.'*<br>*p20 Prezio 2013* |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Low | Judgement comment: baseline retinal exams reported and similar across study arms (see Table 3 p129) |
| **Similar baseline characteristics** | Low | *Quote: 'No significant differences in baseline clinical, demographic, and behavioral characteristics were found between the intervention and control groups, with the exception that significantly more control group participants were employed at study entry (P = .02; Table 2).'*<br>*Table 2 p127*<br>Judgement comment: employment status may have influenced attendance for retinopathy screening |
| **Incomplete outcome data addressed** | Low | Judgement comment: intention to treat analysis. All subjects accounted for.<br>See ' Study participant flow diagram' Fig 1 p21 Prezio 2013 |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | High | Judgement comment: all participants were from the same faith-based community services clinic and no evidence that the study was protected from contamination |

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|---|---|---|
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry NCT00151190 |
| **Free from other bias** | Low | Judgment comment: no evidence of other risks of bias |

| **Schnipper 2010[57]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate whether a new document-based clinical decision support system is effective in improving the quality of care in coronary artery disease and diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** Primary care practices at Brigham and Women's Hospital and Massachusetts General Hospital<br>**Number of clusters:** 10<br>**Number of providers:** 239<br>**Total number of patients:** 7,009 (71.5% with diabetes)<br>**Percentage male:** NR<br>**Diabetes type:** type 1 and 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** participants with type 1 or type 2 diabetes<br>**Exclusion criteria:** participants already under the regular care of an ophthalmologist |
| **Interventions** | **Intervention (n=5 clusters, n=3,431 patients):** 'smart form' with reminders. Document-based clinical support system built into an electronic heath record. The system highlights missing and 'requests' missing data<br>**Comparator (n=5 clusters, n=3,578 patients):** usual care (not specified)<br>**Duration:** 9 months |
| **Outcomes** | **Primary outcome:** mean % of deficiencies in disease management within 1 month of a clinic visit (including eye examination documentation-diabetes patients only)<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** 2008<br>**Trial registration number:** NR<br>**Sources of funding**: Agency for Healthcare and Quality<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Primary care physicians were assigned to receive the Smart Form or usual care on the basis of random number generation in Microsoft Excel (Redmond, WA).'*<br>*pSP73* |
| **Allocation concealment** | Low | Judgement comment: unit of allocation at the level of the primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | High | Judgement comment: a number of baseline differences in characteristics including: female (<0.001), number of problems on problem list ( <0.001), race (<0.001), primary insurance (0.002), median household income (0.01), |
| **Incomplete outcome data addressed** | Unclear | Not reported |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation by primary care practice and it is unlikely that the control group received the intervention |

| | | |
|---|---|---|
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Simpson 2011[58]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect of adding pharmacists to the primary care team on the management of people with type 2 diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** Canada<br>**Setting:** two public family medicine clinics (primary care)<br>**Total number of patients:** 260<br>**Percentage male:** 42.7%<br>**Diabetes type:** type 2<br>**Average age (SD):** 59.1yrs (11.6)<br>**Inclusion criteria:** people were eligible if they had type 2 diabetes, were regularly seen by the primary care team, and did not qualify for urgent specialist referral and assessment<br>**Exclusion criteria:** people who were followed in specialty clinics for diabetes, hypertension, or dyslipidemia; who were cognitively impaired; who were not responsible for their own medication administration; or who were unable to communicate in English. |
| **Interventions** | **Intervention (n=131):** pharmacists performed medication assessments and limited history and physical examinations and provided guideline-concordant recommendations to optimise medication management.<br>**Comparator (n=129):** usual care (not specified)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** achievement of a clinically important reduction in blood pressure, defined as a 10% decrease in systolic blood pressure at 1 year<br>**Secondary outcomes:** absolute change in systolic blood pressure from baseline to 1 year, achievement of recommended blood pressure targets (<130/80 mmHg), and antihypertensive medication changes. Healthcare-related contacts during the study period (including visits to an ophthalmologist or optometrist) |
| **Notes** | **Date conducted:** 2009<br>**Trial registration number:** ISRCTN97121854<br>**Sources of funding**: Canadian Diabetes Association, the Institute of Health Economics, and the Alberta Heritage Foundation for Medical Research<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: '*A central randomization service (www.epicore.ualberta.ca) provided computer generated random sequences stratified by the primary care clinic for treatment allocation.'*<br>*p21* |
| **Allocation concealment** | Low | Quote: '*Pharmacists, analysts, and investigators were unaware of the block size and allocation sequence to preserve allocation concealment.'*<br>*p21* |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'Baseline characteristics were well balanced between the groups (Table 1).'*<br>p23 |
| **Incomplete outcome data addressed** | Low | Quote: *'There were no differences in age, sex, diabetes duration, or baseline blood pressure between the patients who did or did not complete the study.'*<br>p22 |

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|---|---|---|
| | | Judgement comment: intention to treat analysis analysis and reasons for losses to follow up provided and balanced across study arms |
| **Adequate Blinding** | Unclear | Judgement comment: not clear whether eye screening outcome assessors were masked |
| **Protected against contamination** | High | Quote : *'.. there was the possibility of "contamination" or "cointervention" because both intervention and control patients were drawn from the same primary care team.'* p25 |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry ISRCTN97121854 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Sonnichsen 2010[59]** | | |
|---|---|---|
| **Methods** | **Study aim:** to evaluate whether a disease management programme consisting of physician and patient education, standardised documentation and therapeutic goals improves metabolic control (HbA1c) and quality of care for adults with type 2 diabetes managed in primary care<br>**Study design:** cluster RCT | |
| **Participants** | **Country:** Austria<br>**Setting:** primary care practices with a contract with the public health insurance in Austria (province of Salzburg)<br>**Number of clusters:** 6<br>**Number of providers:** 92<br>**Total number of patients:** 1,494<br>**Percentage male:** 52.2%<br>**Diabetes type:** type 2<br>**Average age (SD):** 65.5yrs (10.4)<br>**Inclusion criteria:** all people with type 2 diabetes willing to participate in the study<br>**Exclusion criteria:** dementia/psychiatric illness with inability to participate or to give informed consent | |
| **Interventions** | **Intervention (n=3 clusters, n=654 patients):** Disease Management Programme (DMP) containing the following modules:<br>• standardised documentation of physical examination, laboratory findings, and diabetes complications in a DMP-form once a year.<br>• structured interdisciplinary care according to the guidelines of the Austrian Diabetes Association<br>• agreement on therapeutic goals in a shared patient-physician decision-making process at three-monthly intervals.<br>**Comparator (n=3 clusters, n=840 patients):** usual care (not specified)<br>**Duration:** 12 months | |
| **Outcomes** | **Primary outcome:** change in HbA1c from baseline to 12 months<br>**Secondary outcomes:** improvement in systolic or diastolic blood pressure, lipids, and body mass index; measures of process quality including the frequency of HbA1c measurements, eye and foot examinations; participation in patient education | |
| **Notes** | **Date conducted:** 2008<br>**Trial registration number:** ISCTN27414162<br>**Sources of funding**: Paracelsus Medical University, Public Health Insurance of Salzburg, Salzburg Savings Bank, Roche Diagnostics.<br>**Declaration of interest:** none declared | |
| **Risk of bias** | | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: '…cluster-randomisation at the level of the districts was performed with computerised sequence generation.' p4 |

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| **Allocation concealment** | Low | Quote: *' To assure concealment of allocation at the physician level, GPs and internists were not told whether they would be in the intervention or the control group until after obtaining their consent to participate.'* p4 |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: *'Baseline data are shown in table 2. There were no significant differences between the intervention and the control group except for BMI and cholesterol, with intervention patients being slightly heavier and having higher cholesterol levels than controls.'* p4<br><br>Judgement comment: baseline differences unlikely to influence outcome |
| **Incomplete outcome data addressed** | High | Judgement comment: intention to treat (ITT) and per protocol analysis. For ITT, after randomization, n=6 GP practices withdrew before recruiting patients, and n=5 in intervention group were excluded since they withdrew consent and did not provide baseline values. The trialists excluded these values and considered it an ITT |
| **Adequate Blinding** | High | Quote: *' As typical for pragmatic trials, blinding was not possible and the knowledge of being in the intervention or control group may have influenced the result. '* p8 |
| **Protected against contamination** | Low | Judgement comment: allocation by primary care practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Low | Judgement comment: reported outcomes consistent with trial registry ISCTN27414162 |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Steyn 2013[60]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect introducing a structured clinical record (with embedded national guideline recommendations) and training of healthcare providers in its use, on the quality of care for diabetes and hypertension.<br>**Study design:** cluster RCT |
| **Participants** | **Country:** South Africa<br>**Setting:** public sector primary healthcare Clinics (Community Health Centres) in working class residential area in Cape Town<br>**Number of clusters:** 18<br>**Number of providers:** NR<br>**Total number of patients:** 446<br>**Percentage male:** 26.1%<br>**Diabetes type:** types 1 and 2 (91% type 2)<br>**Average age (SD):** 58.3yrs (10.9)<br>**Inclusion criteria:** ≥15 years; a documented attendance at the particular community health clinic with at least four visits during the previous year for hypertension or diabetes; and having received treatment for these conditions at each visit<br>**Exclusion criteria:** unable to provide answers to a questionnaire |
| **Interventions** | **Intervention (n=9 clusters, n=229 patients):** multi-component intervention consisting of:: structured record, which incorporated the National Guidelines for the management of patients with diabetes or hypertension; physician educational package consisted of an outreach visit by a recognised local diabetes and hypertension expert<br>**Comparator (n=9 clusters, n=217 patients):** usual care (guidelines passively disseminated by |

| Steyn 2013[60] | |
|---|---|
| | the National Department of Health.)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** mean level of HbA1c<br>**Secondary outcomes:** proportion of patients with diabetes BP<130/85 mmHg); proportion with uncontrolled glycaemia (percentage with HbA1c >7%) ; proportions of patients with recorded examinations for complications (retinopathy, nephropathy, foot problems) |
| **Notes** | **Date conducted:** 2000<br>**Trial registration number:** Pan African Clinical Trial Registry (www.pactr.org) PACTR201303000493351<br>**Sources of funding**: South African Medical Research Council; unrestricted grant from Hoechst, Marion, Roussel.<br>**Declaration of interest:** one author NL received honoraria from Novartis and travel support from Novo Nordisk, Eli Lilly Laboratories and Sanofi Aventis; all other authors reported no conflict of interest |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Study clinics were randomly allocated, by stratum, to intervention or control using a computer-generated list of random numbers.'*<br>p3 |
| **Allocation concealment** | Low | Judgement comment: unit of allocation at the level of the primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of eye examinations between arms at baseline (intervention 18%, control 9%) |
| **Similar baseline characteristics** | Low | Judgement comment: similar baseline characteristics (Table 1 p5) |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and reasons for missing data provided. |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: allocation by primary care practice and it is unlikely that the control group received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: trial retrospectively registered and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Taylor 2003[61] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the efficacy of a nurse-care management system designed to improve outcomes in people with complicated diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** a medical centre in Santa Clara, California<br>**Total number of participants:** 169<br>**Percentage male:** 53%<br>**Diabetes type:** type 1 and type 2<br>**Average age (SD):** 55.1yrs (10.2)<br>**Inclusion criteria:** people with an HbA1c >10.0% and an ICD-9–based diagnosis of diabetes and hypertension, dyslipidaemia, or CVD<br>**Exclusion criteria:** did not speak English; not willing or able to participate in the group sessions once a week for 4 weeks; had congestive heart failure as their primary diagnosis; were <18 years of age; were pregnant; were enrolled in a diabetes management clinic; or fell into the |

| Taylor 2003[61] | |
|---|---|
| | "other" category (e.g., living too far away/moving, deceased, or no-show to baseline appointment) |
| **Interventions** | **Intervention (n=84):** participants met with a nurse-care manager to establish individual outcome goals, attended group sessions once a week for up to 4 weeks, and received telephone calls to manage medications and self-care activities<br>**Comparator (n=85):** usual care (under the treatment of their primary care physician. Each participant received a folder containing diabetes pamphlets and sheet of instructions encouraging them to maintain contact with their personal physician and to attend general diabetes education classes at their medical centre)<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** % of participants meeting process outcome goals at 12 months (including self-reported dilated eye exam); number of physician visits during the study period<br>**Secondary outcomes:** participant and physician views regarding the intervention |
| **Notes** | **Date conducted:** 2000-2001<br>**Trial registration number:** NR<br>**Sources of funding**: Robert Wood Johnson Foundation<br>**Declaration of interest:** NR |

| Risk of bias | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Unclear | Note reported |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar % of reported dilated eye exams across arms |
| **Similar baseline characteristics** | Low | Quote: *'The demographics of the 169 patients enrolled in the study can be seen in Table 1.There were no differences between usual care and intervention subjects for any of these variables.'* p1060 |
| **Incomplete outcome data addressed** | Unclear | Judgement comment: missing data approx. 20% in intervention group and 17% for comparator group (due to dropping out or being lost to follow up). Unclear if missing data would influence outcome |
| **Adequate Blinding** | Low | Quote: *'All eligible patients met with a research assistant blinded to the subject's random assignment for baseline and follow-up assessments at 1 year.'* p1059 |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Varney 2014[62] | |
|---|---|
| **Methods** | **Study aim:** to measure the effect of a 6-month telephone coaching intervention on glycaemic control, risk factor status and adherence to diabetes management practices<br>**Study design:** parallel group RCT |

| Varney 2014[62] | | |
|---|---|---|
| **Participants** | **Country:** Australia<br>**Setting:** hospital diabetes clinic<br>**Total number of participants:** 94<br>**Percentage male:** 68%<br>**Diabetes type:** type 2<br>**Average age (SD):** 61.5yrs (NR)<br>**Inclusion criteria:** adults with type 2 diabetes with HbA1c >7%<br>**Exclusion criteria:** those who were unable to provide informed consent; non-English speaking; cognitively impaired; receiving palliative care; severely hearing impaired or without telephone access | |
| **Interventions** | **Intervention (n=47):** usual care plus intensive telephone coaching 6 months duration by a dietician experienced in type 2 diabetes management. Subjects received an average of 6 sessions<br>**Comparator (n=47):** usual care (consisting of attendance at the diabetes clinic 3-6 monthly with GP visits as required)<br>**Duration:** 6 months | |
| **Outcomes** | **Primary outcome:** HbA1c at 6 months, adjusted for baseline value<br>**Secondary outcomes: adjusted** mean HbA1c at 12 months, as well as 6- and 12-month adjusted mean fasting glucose, lipids, blood pressure (BP), weight, waist circumference, body mass index, physical activity and Kessler Psychological Distress Scale score. Participants were asked researcher-generated questions to determine adherence to guidelines recommending annual foot examinations, biennial eye examinations, annual influenza vaccinations, pneumococcal vaccination every 5 or 10 years and smoking cessation | |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** ACTRN12609000075280; http://www.anzctr.org.au<br>**Sources of funding**: St Vincent's Hospital Research Endowment Fund<br>**Declaration of interest:** none declared | |
| **Risk of bias** | | |
| **Domain** | **Judgement:** | **Support for judgement (Quote)** |
| **Adequate sequence generation** | Low | Quote: *'A researcher, not involved in recruitment, randomised participants into intervention and control groups. Computer-generated block randomisation was undertaken to obtain a one-to-one balanced design.'*<br>p891 |
| **Allocation concealment** | Low | Quote: *'Allocation blinding was maintained until randomisation, after which participants and the principal researcher were informed of randomisation outcome.'*<br>P891 |
| **Similar baseline outcome measurements** | Low | Judgement comment : no differences in baseline eye examinations (see Table 1 p893) |
| **Similar baseline characteristics** | Low | Quote: *'Study participants differed from the population attending the diabetes clinic in the recruitment period, being younger 61.4 (59.2–63.5) versus 64.1 years (63.2–65.0, P = 0.02), and being less likely to require an interpreter, 0% versus 29%, P < 0.001, reflecting the study's inclusion criteria.'*<br>*P892*<br>(see Table 1 )<br>Judgement comment : baseline difference unlikely to influence |

| | | |
|---|---|---|
| | | outcome |
| **Incomplete outcome data addressed** | High | Judgement comment: approximately 25% attrition at 12m which may have biased the results |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: it is unlikely that the control group received the telephone coaching intervention |
| **Free of selective reporting** | Unclear | Judgement comment: trial retrospectively registered and so not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other risks of bias |

| **Vidal-Pardo 2013[63]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the effect of an educational intervention among primary care physicians on several indicators of good clinical practice in diabetes care<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Spain<br>**Setting:** primary care physicians in Galicia (north-west Spain)<br>**Number of clusters:** 108<br>**Number of providers:** 108<br>**Total number of patients:** 2,938<br>**Percentage male:** 52.4%<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** individuals aged ≥40 years with more than 1 year of diagnosis of type 2 diabetes.<br>**Exclusion criteria:** women with gestational diabetes |
| **Interventions** | **Intervention (n=58 clusters, n=1,437 patients):** educational intervention comprising (a) distribution of educational materials; (b) physicians' specific bench-marking information (audit and feedback); (c) an on-line course and three on-site educational workshops on diabetes.<br>**Comparator (n=50 clusters, n=1,501 patients):** usual care (not specified)<br>**Duration:** 6 months |
| **Outcomes** | **Primary outcome:** measurement of risk factors (HbA1c ; blood pressure; LDL cholesterol); processes of care including annual eye examination<br>**Secondary outcomes:** NR |
| **Notes** | **Date conducted:** 2009<br>**Trial registration number:** NR<br>**Sources of funding**: unrestricted grant from Merck Sharp & Dohme (MSD) and the Fundacion Escola Galega de Administracion Sanitaria (FEGAS).<br>**Declaration of interest:** none declared |

| **Risk of bias** | | |
|---|---|---|
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation at the level of the primary care physician and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar rates of eye examinations between arms at baseline |

| | | |
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| **Similar baseline characteristics** | Low | Quote: *'Table 2 compares the groups of patients. Differences between the intervention and control groups are slight and not statistically significant, except for some variables at baseline such as family history of ischaemic heart disease, personal history of prior coronary revascularisation, presence of neuropathy and insulin use.'*<br>*p753*<br><br>Judgement comment: small baseline differences unlikely to influence outcome |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and balanced across study arms |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | High | Judgement comment: possibility of contamination as control and intervention physicians worked in the same healthcare system. |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Wagner 2001[64]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of primary care group visits (chronic care clinics) on the process and outcome of care for people with diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** USA<br>**Setting:** primary care clinics in the Group Health Cooperative in western Washington<br>**Number of clusters:** 35<br>**Number of providers:** NR<br>**Total number of patients:** 707<br>**Percentage male:** 53.4%<br>**Diabetes type:** NR<br>**Average age (SD):** 60.7yrs (NR)<br>**Inclusion criteria:** people with diabetes ≥ 30 years of age<br>**Exclusion criteria:** people who were terminally ill, demented or psychotic, or otherwise not able to participate in the study |
| **Interventions** | **Intervention (n=14 clusters, n=278 patients):** patients invited to attend a half day chronic care clinic at their primary care clinic in groups of approx. 8 diabetic patients at intervals of 3–6 months. Each chronic care clinic group visit consisted of: an assessment, individual visits with the primary care physician, nurse, and clinical pharmacist, and a group educational/ peer support session. Self-management support was also provided through one-on-one counselling with the practice nurse<br>**Comparator (n=21 clusters, n=429 patients):** usual care (not specified)<br>**Duration:** 24 months |
| **Outcomes** | **Primary outcome:** processes of diabetes care and satisfaction of intervention and control patients at baseline and at 24 months<br>**Secondary outcomes:** health related quality of life using the SF36 |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Robert Wood Johnson Foundation<br>**Declaration of interest:** NR |
| **Risk of bias** | |
| **Domain** | **Judgement:** | **Support for judgement** |

| | | |
|---|---|---|
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by primary care practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | Low | Judgement comment: similar % of baseline retinal exams across arms |
| **Similar baseline characteristics** | Low | Quote: *'Table 1 shows that there were no significant demographic, treatment, or health status differences between groups.'*<br>p697 |
| **Incomplete outcome data addressed** | High | Quote: *'Completed follow-up responses were obtained from 87% of surviving intervention patients and 79% of surviving control patients.'*<br>p697<br><br>Judgement comment: imbalance in missing data could have influenced outcome |
| **Adequate Blinding** | Unclear | Not reported |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| **Ward 1996[65]** | |
|---|---|
| **Methods** | **Study aim:** to evaluate the impact of audit and feedback to general practitioners on the quality of their management of type 2 diabetes<br>**Study design:** cluster RCT |
| **Participants** | **Country:** Australia<br>**Setting:** Western Australia metropolitan general practices<br>**Number of clusters:** 139<br>**Number of providers:** 139<br>**Total number of patients:** 386<br>**Percentage male:** NR<br>**Diabetes type:** type 2<br>**Average age (SD):** NR<br>**Inclusion criteria:** NR<br>**Exclusion criteria:** NR |
| **Interventions** | **Intervention (doctor interview) (n=130 patients):** each doctor was sent data by post on their management of patients compared to those of all doctors on the project along with a recommended standard. This was followed by an interview with an academic general practitioner to discuss their results using an interview proforma<br>**Intervention (nurse interview) (clusters NR, n=121 patients):** in addition to receiving their postal data, the doctor as interviewed by a state registered nurse to discuss their results using the same interview proforma<br>**Comparator (no interview)(clusters NR, n=135 patients):** each doctor was sent their data by post only<br>**Duration:** 12 months |
| **Outcomes** | **Primary outcome:** 21 process outcomes on the Diabetic Healthcare Checklist (DHC), including eye examination (or referral to an ophthalmologist)<br>**Secondary outcomes:** NR |

| Ward 1996[65] | | |
|---|---|---|
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: NR<br>**Declaration of interest:** NR | |
| **Risk of bias** | | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Unclear | Not reported |
| **Allocation concealment** | Low | Judgement comment: unit of allocation by general practice and allocation performed prior to the start of the study |
| **Similar baseline outcome measurements** | High | Judgement comment: baseline differences in annual eye exams (29.6% comparator group, 23.1% doctor interview group, 19.8%, nurse interview group). See Table 1 p145 |
| **Similar baseline characteristics** | Unclear | Judgement comment: unclear if baseline differences in process of care influence outcome |
| **Incomplete outcome data addressed** | Low | Judgement comment: data from all participants available for analysis |
| **Adequate Blinding** | High | Judgement comment: one of the outcome assessors was the research nurse who conducted the nurse interviews in one arm of the trial and was therefore unmasked |
| **Protected against contamination** | Low | Judgement comment: control group unlikely to have received the intervention |
| **Free of selective reporting** | Unclear | Judgement comment: no protocol or trial registry entry available and therefore not possible to assess |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

| Welch 2011[66] | |
|---|---|
| **Methods** | **Study aim:** to evaluate the clinical usefulness of a nurse-led diabetes care program for poorly controlled Hispanic people with type 2 diabetes<br>**Study design:** parallel group RCT |
| **Participants** | **Country:** USA<br>**Setting:** a single urban community healthcare centre in Springfield, Massachusetts.<br>**Total number of patients:** 46<br>**Percentage male:** 33%<br>**Diabetes type:** type 2<br>**Average age (SD):** 55.8yrs (10)<br>**Inclusion criteria:** duration of type 2 diabetes of at least 1 year based on medical record review and treatment history; age 30–85 years; HbA1c >7.5% within the past 3 months but not >14%; Hispanic ethnicity; independently living and ambulatory<br>**Exclusion criteria:** severe diabetes complications, severe psychiatric illness, or severe visual restrictions, or would not be available for the study period (e.g. leaving the area, pregnant or planning to become pregnant) |
| **Interventions** | **Intervention (n=25):** seven 1-hour diabetes care visits over a 12-month period conducted by a bicultural/bilingual diabetes nurse and dietician team (both certified diabetes educators). Use of CDMP diabetes care management software that provides tools for continuous care and contact between patients and their providers. Patients in the intervention group also received diabetes eye screening using the Diabetes Eye Care and Treatment (DECAT) program using the clinically validated Joslin Vision Network (JVN) protocol<br>**Comparator ('attention control')(n=21):** diabetes education intervention consisting of seven 1-hour visits over a 12-month period conducted by bicultural/bilingual clinic support staff who also encouraged patients to formulate diabetes related questions for discussion with their primary care provider at the next scheduled primary care visit. |

| Welch 2011[66] | | |
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| | **Duration:** 12 months | |
| **Outcomes** | **Primary outcome:** adherence to national clinical practice guidelines (blood glucose, blood pressure, foot exam, eye exam), and levels of diabetes distress, depression, and treatment satisfaction<br>**Secondary outcomes:** NR | |
| **Notes** | **Date conducted:** NR<br>**Trial registration number:** NR<br>**Sources of funding**: Baystate Medical Center Academic Affairs Internal Research Grant<br>**Declaration of interest:** NR | |
| **Risk of bias** | | |
| **Domain** | **Judgement:** | **Support for judgement** |
| **Adequate sequence generation** | Low | Quote: *'Participants were randomly assigned to the CDMP intervention group (IC) or the attention control group (AC) by a fair coin toss.'*<br>*p682* |
| **Allocation concealment** | Unclear | Not reported |
| **Similar baseline outcome measurements** | Unclear | Not reported |
| **Similar baseline characteristics** | Low | Quote: '*There were no differences between groups at baseline Except for marital status (P = .04) (Table 1).'*<br>p684 |
| **Incomplete outcome data addressed** | Low | Judgement comment: low attrition and balanced between study arms |
| **Adequate Blinding** | Unclear | Judgement comment: not clear whether eye screening outcome assessors were masked |
| **Protected against contamination** | High | Quote : '*the diabetes educators in the intervention condition trained and supervised the attention control clinical staff.'*<br>*p687* |
| **Free of selective reporting** | Unclear | Judgement comment: not possible to judge from the primary report. |
| **Free from other bias** | Low | Judgement comment: no evidence of other sources of bias |

Key: DFE= NR=not reported

**Characteristics of studies including economic evaluations**

| Study | Adair 2013[18] |
|---|---|
| **Funding source for study** | Robina Foundation |
| **Type of economic evaluation** | Cost-outcome description |
| **Study objective** | To test whether patients with chronic disease working with lay "care guides" would achieve more evidence-based goals than those receiving usual care. |
| **Interventions** | Patients provided with disease-specific care goals and culturally matched laypersons acting as 'care guides' helped patients to achieve goals. Care guides met with patients in person and/or were contacted by telephone<br>Reminders about unmet goals |
| **Comparator(s)** | Patients were provided with care goals followed by usual clinical care |
| **Effectiveness data** | Parallel-group randomized trial, stratified by clinics ( 6 clinics) |
| **Outcome measure** | Primary outcome: change in the % of disease-specific care goals met 12 months after enrolment compared to baseline<br>Secondary outcomes: percentage of goals met by patients with each diagnosis and the achievement of each individual goal determined from electronic patient records (included 'retinal examination within 2yrs'); to determine whether the benefit of working with the care guide could be predicted by patient demographics |
| **Duration of study** | 12 months |
| **Location** | Minnesota, USA |
| **Setting** | Six primary care clinics in urban, sub-urban and rural area |
| **Study population** | 2135 patients with hypertension, diabetes or congestive heart failure (1366 with diabetes). Intervention=930, usual care=436. Aged 18-79years |
| **Cost data** | Data on charges were extracted from Allina Health billing data 4 months after the 1-y anniversary of the last patient enrolment and were modified by mean collection rates.<br>"Previous year" was defined as the 365 days before each patient's enrolment; "intervention year" was defined as the following 365 days.<br>Compensation for care guides and supervisors, the cost of training, and the cost of creating 12 workstations estimated based on time spent |
| **Analytical perspective** | Healthcare |
| **Resources** | 12 care guides with 2 weeks training<br>2 experienced nurses<br>Average of 5 visits<br>4 provider contacts and 7 patient contacts (2 face-to-face, 7 telephone)<br>Modular furniture and equipment for 12 work station<br>At baseline: Hospitalization rate:-<br>Usual care=0.29, intervention=0.37<br>After study: usual care=0.35, intervention=0.35<br>At baseline:<br>Emergency dept. visit:-usual care=0.45, intervention=0.50<br>After study: usual care=0.57, intervention=0.57<br>Intervention time spent on:<br>Social support= 0.138<br>Help= 0.202<br>Individualized care= 0.099<br>Reinforcement= 0.169<br>Understanding= 0.178 |
| **Results** | Both arms increased the % of goals met in 1 year compared to baseline with intervention achieving 10% increase and usual care 3.9%. Intervention reduced unmet goal by 30.1% compared to usual care with 12.6%<br>Decrease in mean hospitalizations per patient for intervention from 0.37 to 0.35 while usual care increased from 0.29 to 0.35 |

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| **Direct cost** | Compensation for 12 care guides=$511,176 at $16/hr plus benefits estimation by care guide under normal condition for 190 patients=$286 per patient/year<br>2 nurse supervisors=$116,736<br>Modular furniture and equipment for 12 work station=$108,000<br>Training costs=$3031<br>Average Hospital charges: p=0.157<br>Before study:-intervention=$30,041, usual care=$25,815<br>Post study:-intervention=$32,791,usual care=$32,734<br>Average professional charges: p=0.77<br>Before study:-intervention=$3746, usual care=$3759<br>Post study:-intervention=$3812, usual care=$3851 |
| **direct total cost** | Estimated total cost per patient =$286/year |
| **Indirect cost** | Not stated |
| **Incremental cost** | Not stated |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | Not applicable |
| **Discounting** | No discounting reported |
| **Cost inflation** | None. Same year for the study |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | Laypersons with relevant skills and training who are located in clinic waiting rooms, where they can meet patients and providers face to-face, can help patients with chronic disease and their providers improve the quality of care. |

| **Study** | **Clancy 2007[21]** |
|---|---|
| **Funding source for study** | Agency for Healthcare Research and Quality; Robert Wood Johnson Foundation; National Institutes of Health |
| **Type of economic evaluation** | Comparative resource utilization-outcome analysis |
| **Study objective** | To evaluate the effect of group visits on clinical outcomes concordant with 10 American Diabetes Association (ADA) guideline processes of care |
| **Interventions** | Monthly group visits (14-17 per group), co-led by an internal medicine physician and a registered nurse. One-on-one visits were available for care as needed between scheduled group visits or for specific medical needs not amenable to group visits. Group visit content consisted of educational topics such as nutrition, exercise, foot care, medications, complications of diabetes, and the emotional aspects of diabetes, vaccinations, foot exams, medication adjustments, laboratory orders, and referrals for retinal examinations could be done in the group visits |
| **Comparator(s)** | Usual care in the clinic , seeing faculty or resident physicians, physician assistants, nurse practitioners, or medical or physician assistant students with access to a dietician and diabetes educator every quarter |
| **Effectiveness data** | Not applicable |
| **Outcome measure** | 10 ADA process-of-care indicators [>2 yearly HgA1c, at least yearly cholesterol levels, treatment for LDL cholesterol levels >100 mg/dl, yearly ophthalmologic referrals, influenza vaccinations, foot exams, and checks for microalbuminuria, ACE-inhibitor or angiotensin receptor blocker use, daily aspirin unless contraindicated, and at least 1 pneumococcal vaccine] |
| **Duration of study** | 12 months |
| **Location** | South Carolina, USA |

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| **Setting** | Adult primary care centre, Medical University of South Carolina |
| **Study population** | 186 type 2 diabetes patients, intervention=96, comparator=90<br>Parallel RCT group<br>Average age (SD): 56yrs<br>Inclusion criteria: aged >18 years with poorly controlled diabetes mellitus (HbA1c>8.0%)<br>Exclusion criteria: primary diagnosis of substance abuse or dependence; current pregnancy; dementia; inability to hear, speak English; obtain transportation to the clinic |
| **Cost data** | Not stated |
| **Analytical perspective** | Healthcare perspective |
| **Resources** | Not reported |
| **Results** | Patients in group care more likely to have had each of the ADA processes of care indicators with use their drugs , vaccine shot, foot and eye examination compared to usual care<br>HbA1c percentage reduction<br>Usual care=62%, group care=79%. p=0.1193<br>Foot examination<br>Usual care=28%, group care=65%. p=<0.0001<br>Eye examination<br>Usual care=53%, group care=75% p=0.00171 |
| **Direct cost** | Deposit fee for group visit=$15/visit, for 12visits=$180<br>Deposit for control patients=$45/visit, for 4 visits= $180 |
| **Direct total cost** | Not stated |
| **Indirect cost** | Not stated |
| **Incremental cost** | Not stated |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | Not applicable |
| **Discounting** | No discounting reported |
| **Cost inflation** | Not stated |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | Group visits in disadvantaged patients with type 2 diabetes reveals significant improvements in process-of-care indicators for diabetes and sex/age appropriate cancer screening without differences in medical outcomes |

| **Study** | **Davis 2011[67]** |
|---|---|
| **Funding source for study** | NIH/NIDDK |
| **Type of economic evaluation** | Cost-Effectiveness Analysis |
| **Study objective** | Evaluation of the cost effectiveness of a 12-month remote diabetes self-management education program that increased the availability of a certified diabetes educator |
| **Interventions** | Diabetes Telecare (12-month diabetes self-management education) administered by dietician and nurse diabetic educator which included 13 sessions , 3 individuals and 10 group<br>Two sessions for each individual was held at first month<br>3 group session were in-person and others video conference + On site availability of eye examination for those due for it |

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| **Comparator(s)** | Usual care= one 20 minutes education session with materials by CDE for 15 mins followed by approximately 4 hours of education by a health educator<br>Usual availability of existing services which included diabetic collaboration with care manager and nurse to help patients with highest blood sugar level |
| **Effectiveness data** | RCT data evaluating a remote diabetes self-management education for diabetes patients with blood glucose level >7% and ≥35years in a community health centre |
| **Outcome measure** | Reduction in blood glucose level (HbA1c), cholesterol level, blood pressure, BMI, self-report of eye examination, health utilities, costs |
| **Duration of study** | 12 months |
| **Location** | South Carolina, USA |
| **Setting** | Primary care |
| **Study population** | Three community health centres. African American adults ≥35years with type 2 diabetes and blood sugar >7%. randomized n=165, 85 intervention, 80 usual care |
| **Cost data** | Not stated |
| **Analytical perspective** | Hospital care |
| **Resources** | Staff time and fringe benefit (dietician, nurse and certified diabetic educator)<br>Transportation<br>Telemedicine equipment<br>Equipment & supplies<br>Teaching aids<br>Mailing &shipping materials |
| **Results** | Significant reduction in blood glucose level (HbA1c ) by 0.6%, 11mg/dl reduction in cholesterol level and 81.2% received an eye examination in intervention group compared to usual care=38.8% with baseline percentage examination at 51% and 46.3% respectively BMI and weight did not improve |
| **Direct cost** | Staff time and fringe benefit:<br>*Usual care= $12*<br>*DTC intervention=$802*<br>*Screening eye exam=$20*<br>Transportation:<br>*Usual care=$19*<br>*Intervention=$217*<br>*Screening EE=0*<br>Supplies& incentives:<br>*Usual care=$1*<br>*DTC intervention=$99*<br>*Screening EE=0*<br>Telemedicine equipment :<br>*DTC intervention=$225*<br>Equipment & supplies<br>*Screening EE=$266*<br>Teaching aids<br>*DTC intervention=$45*<br>Mailing &shipping<br>*DTC Intervention=$25* |
| **Direct total cost** | Usual care=$32/person<br>Intervention=$1413/person<br>Screening eye exam=$286 |
| **Indirect cost** | Not stated |
| **Incremental cost** | $1380/year compared with usual care |
| **ICER** | $17,000/year |
| **Modelling and statistical extrapolation** | Not stated |
| **Monetary benefit and utility valuations** | Not stated |
| **Measure of benefit** | QALY |

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| **time horizon of costs and effects** | 1 year |
| **Discounting** | No discounting reported |
| **Cost inflation** | None |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Non reported |
| **Conclusions** | Diabetes self-management education is cost effective |

| **Study** | **Eccles 2007[26]** |
|---|---|
| **Funding source for study** | Diabetes UK, and Northern and Yorkshire Regional NHS R&D Office. |
| **Type of economic evaluation** | Cost-consequence analysis |
| **Study objective** | To evaluate the effectiveness and efficiency of an area-wide, 'extended' computerised diabetes register incorporating a full-structured recall and management system, actively involving patients, and including individualised patient-management prompts to primary care clinicians based on locally-adapted, evidence-based guidelines. |
| **Interventions** | Computerised diabetes register incorporating a full structured recall and management system, including individualised patient management prompts to primary care clinicians based on locally-adapted, evidence-based guidelines |
| **Comparator(s)** | Usual care |
| **Effectiveness data** | Two-arm cluster randomised controlled trial with the general practice |
| **Outcome measure** | Clinical process and outcome variables held on the diabetes registers; patient reported outcomes (SF36 health status profile, the Newcastle Diabetes Symptoms Questionnaire and the Diabetes Clinic Satisfaction Questionnaire); service and patient costs |
| **Duration of study** | 15 months (1st April 2002-30th June 2003) |
| **Location** | North east England |
| **Setting** | Primary care |
| **Study population** | 58 practices randomized (3608 patients; mean = 62.2 patients per cluster), 30 practices (1674 patients)=intervention, 28 practices (1934 patients)=control with type 2 diabetes patients appearing on the registers, aged over 35 years and receiving diabetes care exclusively from the general practices or shared between study general practices (GPs) and hospital. |
| **Cost data** | Questions on the costs incurred by patients were developed by the study health economist and were included in a questionnaire. These questions included the self-reported use of medication.<br>2002 NHS reference costs and the 2002 unit costs of health and social care were used to assign costs to healthcare resources, supplemented when necessary with unit cost data from Report by the Comptroller and Auditor General: NHS Direct in England and local surveys. Drug costs were taken from the British National Formulary.<br>Patients reported on the use of NHS (National Health Service) services, medications, travel costs, costs for the purchase of special items, private treatments/consultations and time off work, sick leave and related pay loss, as well as time off work and related pay loss to their companions over a twelve-month period |
| **Analytical perspective** | Health service and patient |
| **Resources** | Cost of guideline and software development<br>Staff time and consumables<br>Mean number of follow up appointments: intervention=2.02, control=1.34 |
| **Results** | No significant difference in patient-reported<br>Outcomes between intervention and control groups<br>Modest and statistically significant lowering of serum cholesterol of 0.15 mmol/l in the intervention group compared to the control group<br>Impact of the intervention on medication, including lipid lowering therapy, was unclear from the register-derived data and negative from the patient-reported data.<br>Recording of care in chronic disease management is important<br>**Fundoscopy recorded**: |

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| | Intervention- 43.1% at baseline and 60.6% follow up,<br>Control 49.5% at baseline and 50.5% follow up<br>**Feet examination recorded:**<br>Intervention-48.0% at baseline and 67.3% follow up,<br>Control-46.1% at baseline and 48.8% follow up<br>**Dietary advice recorded:**<br>Intervention-25.3% at baseline and 46.3% follow up,<br>Control-19.9% at baseline and 29.2% follow up<br>**BP recorded:**<br>Intervention-55.3% at baseline and 71.4% follow up, control-59.3% at baseline and 48.3% follow up<br>**HbA1c recorded:**<br>Intervention-60.9% at baseline and 79% follow up, control-64% at baseline and 66% follow up<br>**Diabetic medication:**<br>Biaguanide, sulphonylurea or thiazol-<br>Intervention-646 at baseline and 923 follow up<br>Control-944 at baseline and 1128 follow up<br>**Any medication:**<br>Intervention-1283 at baseline and 1549 follow up, control-1674 at baseline and 1838 follow up<br>Diabetes symptom score<br>Control- 2.18, intervention- 2.20<br>**SF-36**<br>Physical function:-intervention-48.8 , control- 48.9<br>Role physical:-intervention 39.2, control-39.1<br>Bodily pain:-intervention- 52.9,control- 52.8<br>General health;-intervention- 45.2, control- 45.2<br>Vitality;-intervention- 44.0, control- 42.9<br>Social Function;-intervention- 66.4, control- 64.0<br>Role emotional;-intervention- 54.1, control- 52.9<br>Mental health:-intervention- 68.0, control- 67.8 |
| **Direct cost** | **Health service costs (mean cost/patient in £)**<br>Primary care visits/consultations (n = 965) = control-135.61, intervention-136.67 (40.40) p=0.96, mean (95%Cl) =0.5 (-21.5; 22.5)<br>Secondary care visits/consultations (n = 1091) = control-189.03, Intervention- 186.45. p=0.62, mean (95%Cl) =-7.41 (-37.58; 22.77)<br>All tests/investigations (n = 1046) =control 65.71, intervention 72.06 p=0.68, mean (95%Cl) =2.75 (-10.77; 16.28)<br>NHS pre-booked transport service (n = 1259) =control- 19.34, intervention- 17. p=0.49, mean (95%Cl) =-7.24 (-28.34; 13.85)<br>All drugs except insulin (n = 1330) =control- 22.07, intervention-20.81 p=0.72, mean (95%Cl) =-0.55(-3.6; 2.49)<br>Insulin (n = 1388) =control- 6.13 intervention- 6.18. p=0.83, mean (95%Cl) =0.20(-1.65; 2.06)<br>Cardiovascular drugs (all categories) (n = 1341)=control- 18.3 intervention-17.05. p=0.69, mean (95%Cl)=-0.66(-3.15;1.84)<br>***Intervention costs***<br>£11,443 = guideline development<br>£14,034 = software development,<br>£2408 = educational activities.<br>Sum total =£27,885<br>£11,170=Additional cost of running the system |
| **Direct total cost** | Annual cost per patient including staff time and consumables=£76.46 |
| **Indirect cost** | **Mean cost/patient in £**<br>All private special items/equipment (n = 1285) = control-20.80 intervention-26.98 p=0.10, mean (95%Cl) =4.89(-0.97; 10.75)<br>All private consultations (n = 1348) control-3.21, intervention- 2.45. p=0.49, mean (95%Cl) |

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| | =-0.60 (-2.32; 1.12)<br>Patient-Pay loss because of time off (n = 1295) =control- 1.10, intervention- 3.73. p=0.06, mean (95%Cl) =3.01 (-0.15; 6.16)<br>Patient-Pay loss because of sick leave (n = 1195) =control- 4.12 intervention-36.76. p=0.06, mean (95%Cl) =27.67 (-7.28; 62.63)<br>Patient-Hours off other activities (n = 1120) =control- 1.67, intervention-0.86. p=0.12, mean (95%Cl) =-0.77(-1.6; 0.07)<br>Patient-Days off other activities (n = 1034) =control- 0.18, intervention-0.20. p=0.07, mean (95%Cl)=0.5 (-21.5;22.5)<br>Companion-Pay loss (n = 1233)=control- 1.66, intervention-2.89 p=0.65, mean (95%Cl)=0.85 (-2.98; 4.67)<br>Companion-Days off (n = 734) =control-0.62, intervention- 0.82 p=0.66, mean (95%Cl)=0.10(-0.37; 0.58)<br>Companion – Hours off (n = 858) =control-2.50, intervention- 2.11 .p=0.74, mean (95%Cl)=-0.23(-1.65;1.19) |
| **Incremental cost** | Not stated |
| **ICER** | Not stated |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | SF-36, the Newcastle Diabetes Symptoms Questionnaire the Diabetes Clinic Satisfaction Questionnaire |
| **Measure of benefit** | Not stated |
| **Time horizon of costs and effects** | All costs were expressed in 2002/2003 values. |
| **Discounting** | No discounting all costs incurred in a 12 month period |
| **Cost inflation** | None |
| **Currency** | UK pounds |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | There are benefits from an area-wide, computerised diabetes register incorporating a full structured recall and individualised patient management system achieved at a cost. However, rise in performance will result in difficulty in demonstrating smaller incremental improvements |

| **Study** | **Frei 2014[28]** |
|---|---|
| **Funding source for study** | Swiss Academy for Medical Sciences,<br>Margrit und Ruth Stellmacher foundation,<br>A. Menari AG, Switzerland |
| **Type of economic evaluation** | Comparative resource utilization |
| **Study objective** | To test whether the implementation of elements of the 'Chronic Care Model (CCM)' via a specially trained practice nurse leads to an improved cardiovascular risk profile among type 2 diabetes patients |
| **Interventions** | Implementation of team care using elements of the Chronic Care Model (CCM) via a specially trained practice nurse and utilising a computerised monitoring tool and decision support involvement of specially trained nurses in diabetes care and consultation |
| **Comparator(s)** | Usual care |
| **Effectiveness data** | Not applicable |
| **Outcome measure** | Primary outcome: HbA1c level<br>Secondary outcomes: Guideline adherence (recommended treatment goals) including receiving at least one eye examination per year. Quality of life<br>Resource utilisation was not stated as an outcome but was recorded |
| **Duration of study** | 12 months |
| **Location** | Switzerland |
| **Setting** | Primary Care Practices |
| **Study population** | 30 primary care practices with 326 patients with type 2 diabetes, >18years |

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| | Intervention= 15 practices,164 patients<br>Comparator= 15 practices ,162 patients<br>Patients unable to read and understand the patient information form due to dementia, illiteracy or language skills. Patients with oncological diseases and/or an estimated life expectancy of less than six months due to severe diseases were excluded |
| **Cost data** | Not applicable |
| **Analytical perspective** | Hospital care |
| **Resources** | 6-day training on diabetes treatment for nurses<br>Two 4-hour interactive workshops for physician and nurses<br>Number of hospitalization/year due to :<br>Hypoglycaemic episodes, intervention=1, usual care=1<br>Hyperglycaemic Episodes: intervention=0, usual care=3<br>Cardiovascular episodes, intervention=8, usual care=6<br>Other reasons, intervention=7, usual care=12<br>Number GP visits/year<br>At baseline, intervention=8, usual care=7.9<br>Study period, intervention=9.6, usual care=8.4<br>Antihypertensive and antidiabetic treatments |
| **Results** | No significant statistical difference between two arms in HbA1c level but there was improvement in both arms, -0.27% for intervention and -0.22% for usual care. P=<0.708<br>Statistical differences in the secondary outcomes between two groups.<br>Foot pathological status/complication reduced in intervention arm from 30 to 26, while usual care increased from 22 to 28 patients<br>Number of non-adherence to annual eye examination decreased in Intervention arm from 43 to 19 and that of usual care from 58 to 56<br>Number of diabetic therapy usage decreased from 155 to 143 for intervention and from157 to 146 for usual care<br>Number of antihypertensive reduced in intervention from 117 to 113 while usual care was constant at 129<br>Annual eye examination:<br>Intervention; at baseline=162, follow up=144<br>Control; at baseline=161, follow up=155<br>Antiplatelet and antidepressants increased for both arms |
| **Direct cost** | Not applicable |
| **Direct total cost** | Not applicable |
| **Indirect cost** | Not applicable |
| **Incremental cost** | Not applicable |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not reported but SF-36 used to measure Health Related Quality of Life (HRQoL) |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | Not applicable |
| **Discounting** | Not applicable |
| **Cost inflation** | Not applicable |
| **Currency** | Not applicable |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | Incorporating multifaceted interventions can help facilitate better chronic care management and improve quality of diabetes care.<br>A chronic care management (CCM) involving practice nurses in diabetes care improved cardiovascular risk profile, and experienced by patient as a better form of care<br>CCM can be implemented even in small primary care practices |

| Study | Frijling 2002[29] |
|---|---|
| **Funding source for study** | Netherlands Heart Foundation |
| **Type of economic evaluation** | Cost-outcome description |
| **Study objective** | To evaluate the effectiveness of a multifaceted intervention to improve clinical decision making of general practitioners (GPs) in the process of diabetes care |
| **Interventions** | GPs given feedback reports about his or her current clinical decision making with regard to the diabetes guidelines issued by the Dutch College of General Practitioners and received outreach visits from facilitators. Facilitators address and discuss specifically clinical decision making for T2DM at high cardiovascular risk based on feedback reports from performance data of GP.<br>First 8 visits= practise organization; 7 visits=clinical decision making |
| **Comparator(s)** | Usual care=No special attention or feedback support |
| **Effectiveness data** | Cluster RCT in general practice from 1996 to 1999 |
| **Outcome measure** | Compliance rates for evidence based indicators for the actual management of patients with T2DM. Indicators which allowed detection of 15% difference in compliance rates between intervention and comparator (including eye examination in the past 24 months) |
| **Duration of study** | 21 months |
| **Location** | Netherlands |
| **Setting** | Primary care |
| **Study population** | Cluster randomized controlled trial with 124 practices and 185 GPs in urban and non-urban locations<br>Intervention=62 clusters,703 patients<br>Comparator=62 clusters,707 patients<br>Inclusion criteria were the presence of a clinical computer system, employment of practice assistant(s) and no major changes in personnel or premises planned during the course of the trial.<br>Management of patients with high cardiovascular risk.<br>Patient on insulin were excluded |
| **Cost data** | Costs of the 21-month intervention were calculated with data provided by the facilitators and salary scales. The calculations included the time which the facilitators spent to prepare and make the visits, their travel costs, and also the time spent by the GPs to attend the visits. Amount of time the GPs spent to read the feedback reports and carry out the change plans was asked by the facilitators and included in the calculations.<br>Time spent for costs of clinical decision making for diabetes was estimated at 10% of the costs of the entire 21-month intervention.<br>Calculations did not include the costs for generating the feedback reports and training the facilitators |
| **Analytical perspective** | Hospital care |
| **Resources** | 80 hours training for facilitators.<br>1 GP researcher supervisor per facilitator throughout for the intervention.<br>15 outreach visits per practice, average of 1hour.<br>3 hour per GP for implementation of intervention.<br>1410 consultations at baseline<br>1449 consultations after the intervention period |
| **Results** | Compliance rates for indicators pertaining to foot and eye examination improved by 19% and 9% respectively in comparison with the comparator with 9% and -2% compliance rates for foot and eye examination.<br>No significant effect/change on other indicators relating to medication use, blood pressure measurement and scheduling follow-up appointments.<br>Increase in foot examinations can also be achieved within a complex programme aimed at all aspects of cardiovascular and diabetes care |
| **Direct cost** | Not stated |
| **Direct total cost** | £240 per practice for clinical decision making |
| **Indirect cost** | Not reported |

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| **Incremental cost** | Not reported |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable: the study is a cost analysis. |
| **Monetary benefit and utility valuations** | Not applicable: the study is a cost analysis. |
| **Measure of benefit** | Not applicable: the study is a cost analysis. |
| **time horizon of costs and effects** | Not applicable |
| **Discounting** | Not reported |
| **Cost inflation** | None |
| **Currency** | UK Pounds |
| **Analysis of uncertainty** | No sensitivity analysis reported |
| **Conclusions** | There was improvement in GP's clinical decision making for some of the aspects of diabetes care (foot and eye examination) with the feedback reports and support from facilitators who were not trained as physicians<br>The effectiveness of support from non-physicians is important in terms of the salary costs when compared with support from physicians |

| **Study** | **Krein 2004[44]** |
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| **Funding source for study** | Office of Research and Development, Health Services Research and Development Service, Department of Veterans Affairs<br>Michigan Diabetes Research and Training Centre Grant |
| **Type of economic evaluation** | Comparative resource utilization |
| **Study objective** | To evaluate the effects of a collaborative case management intervention for patients with poorly controlled type 2 diabetes on glycaemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization. |
| **Interventions** | Patients assigned to a case manager. Patient contact with case manager occurred primarily by telephone, although face-to-face visits could be arranged case managers were directed to encourage patient self-management, including diet and exercise; provide reminders for recommended screenings/tests; help with appointment scheduling; monitor home glucose and blood pressure levels; and identify and initiate medication and dose changes as needed. case manager allowed to schedule follow up based on individuals need |
| **Comparator(s)** | Provision of educational materials and usual care by their primary care physician |
| **Effectiveness data** | Randomized trial to evaluating the effectiveness of a collaborative case management intervention for patients with type 2 diabetes, focusing on glycaemic control but with attention also to blood pressure and lipid control. |
| **Outcome measure** | Physical examinations and patient surveys at baseline and exit, HbA1c level<br>Secondary outcome-low-density lipoprotein (LDL) cholesterol and blood pressure |
| **Duration of study** | 18 months |
| **Location** | Michigan, USA |
| **Setting** | Primary care ( Medical centre in suburban area) |
| **Study population** | 246 patient with baseline levels 7.5% were enrolled in the study and assigned randomly to the intervention=123 or control group=123. subjects were those with at least one prescription for an oral hypoglycaemic agent, insulin, or blood glucose monitoring supplies filled in the previous 12 months and had a general medicine clinic visit scheduled between May 1999 and January 2000<br>Exclusion criteria: <18 years; type 1 diabetes or were diagnosed before the age of 30 years; had no telephone; did not speak English; were not competent for interview; reported primary source of diabetes care outside the VA; were being treated for cancer (other than non-melanoma skin cancer); had kidney failure, symptomatic heart failure, liver disease, or blindness; spent winter at another residence; or planned to move |
| **Cost data** | Not stated |
| **Analytical** | Healthcare system |

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| **perspective** | |
| **Resources** | Two days training for case managers (nurse practitioner) case manager at each site working 20 hours a week, provided care for about 60 patients (2 nurses for the intervention group) quarterly patient profiles, as well as training updates and reinforcement at 2 months and then at approximately 6-month intervals thereafter average of 0.5 hospitalizations and 6 primary care outpatient visits during study period for both groups |
| **Results** | Baseline characteristics were similar.<br>No significant difference in HbA1c for both arms after studies.<br>LDL cholesterol level and diastolic blood pressure decreased for both groups<br>Patients in intervention group were more satisfied. Hence, extra attention and assistance provided by case managers did not improve glycaemic control, lipid and blood pressure<br>Little difference in resource utilization between groups<br>87% of Intervention group and 79% usual care undergone a dilated eye examination in the past 12 months and also been taken daily aspirin (71% vs. 62%) but no statistical significance.<br>No evidence that the intensity of medication treatment was greater in the intervention group based on medication costs.<br>At a site over 70% of attempted telephone contact including scheduling visits were unsuccessful |
| **Direct cost** | Not stated.<br>Resources utilized by patients<br>Cost of medication, intervention=$1003, control=951, p value=0.70 |
| **Direct total cost** | Not stated |
| **Indirect cost** | Not stated |
| **Incremental cost** | Not stated |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | Not stated |
| **Discounting** | No discounting reported |
| **Cost inflation** | Not stated |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | Study demonstrates that case management may not be a sufficient strategy for achieving long-term improvements in outcomes for some high-risk patients or in certain practice settings.<br>Collaborative case management did not improve key physiologic outcomes for high-risk patients with type 2 diabetes. |

| **Study** | **Litaker 2003[46]** |
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| **Funding source for study** | Arison Foundation and the I.H. Page Centre for Health Outcomes Research at the Cleveland Clinic Foundation. |
| **Type of economic evaluation** | Cost-outcome description |
| **Study objective** | To examine the potential value of interdisciplinary, complementary approaches from the patient's perspective by comparing a traditional physician-only model of care with a more collaborative, team-based management within the context of hypertension and diabetes management |
| **Interventions** | Chronic disease management and use of clinical practice algorithms, patient education on disease self-management strategies, regular monitoring and feedback delivered by the nurse practitioner (NP).Discussions between the physician and NP to evaluate management |

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| | strategies<br>Routine use of reminder systems, forms to facilitate documentation of care, monitored use of clinical guidelines or active collaboration with a nurse practitioner |
| **Comparator(s)** | Usual care taken as any form of treatment offered by an individual's primary care physician that reflected the practice style prevalent at the study site prior to the current investigation. physician determined the frequency and content of their own office visits according to their preference or judgment |
| **Effectiveness data** | Randomization of 157 patients with established diagnoses of mild or moderate hypertension and non-insulin dependent diabetes mellitus without known end-organ complication in the department of General Internal Medicine in a tertiary care teaching hospital |
| **Outcome measure** | **Clinical outcomes**<br>*Glycosylated haemoglobin (HbA1c)*<br>*Systolic and diastolic blood pressure*<br>*High density lipoprotein cholesterol*<br>**Patient-derived Outcomes**<br>*Satisfaction with care*<br>*Health-related quality of life (Short Form 12)*<br>*Diabetes quality of life instrument*<br>**Economic outcomes**<br>*Personnel costs associated with patient management*<br>**Quality measures**<br>I*nfluenza vaccination*<br>*Pneumovax, if previously unvaccinated*<br>*Foot exam*<br>*Referral for eye examination by ophthalmologist*<br>**Patient education topics**<br>*Smoking cessation*<br>*Routine exercise*<br>*Dietary sodium reduction*<br>*Moderation in alcohol consumption*<br>*Medication side effects*<br>*Weight control or reduction*<br>*Medication adherence* |
| **Duration of study** | 12 months |
| **Location** | Cleveland, Ohio, USA |
| **Setting** | Department of General Internal Medicine in a tertiary care teaching hospital |
| **Study population** | 157 patients with established diagnoses of mild or moderate hypertension and non-insulin dependent diabetes mellitus without known end-organ complications identified by physician referral or advertisement who were then randomly assigned to their primary care physician and a nurse practitioner (intervention) =79 or their primary care physician alone (comparator)=78<br>Medically complex individuals (Charlson index greater than five) or those requiring three or more medications for blood pressure control were excluded |
| **Cost data** | Physician salary estimate was generated by averaging salaries for all physicians in the practice during the study period. Average provider time spent with patients was determined for each of five levels of outpatient service in a time study preceding the trial.<br>Personnel costs associated with each encounter was estimated by multiplying service level and provider (MD vs. NP)-specific time with the provider salary reduced to per minute value for each level of office visit.<br>Data on billing levels for each outpatient visit, retrospectively assigned by a professional coder unaware of group assignment or study hypotheses, was used to provide additional confirmation for estimated personnel costs associated with each level of outpatient service for both patient management strategies |
| **Analytical perspective** | Hospital care perspective |
| **Resources** | Nurse training<br>Average contact time of patients throughout 1 year follow up, intervention= 180, usual care= 85 min |

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| **Results** | Two groups did not differ significantly at study entry with respect to patient demographic, clinical characteristics, HRQoL and patient satisfaction.<br>After study completion, no difference in blood pressure and cholesterol level between two groups. There was small but significant reduction in HbA1c level in the intervention group. Effect of intervention on diabetic control (HbA1c) disappeared within 12months after study<br>Foot exam: intervention=79%, usual care=28%. p=<0.001<br>Eye exam by ophthalmologist: intervention=62%, usual care=53%. p=0.10<br>Weight control or reduction: intervention=79%, usual care=59%. p=<0.001<br>Medication adherence; intervention=79%, usual care=74%. p=0.06<br>HbA1c, mean change from baseline: intervention=-0.63, usual care= -0.15. p=0.02<br>SF-12 Health survey, change from baseline<br>Physical component score, mean: intervention= 0.50, usual care= -1.27. p=0.19<br>Mean mental component score: intervention=3.27, usual care=1.13. p=0.17<br>Mean diabetes satisfaction: intervention= 9.18, usual care=3.76. p=0.04<br>Total additional personnel costs associated with this program were nearly 50% higher than for the usual approach to providing care. p=<0.001 |
| **Direct cost** | Mean personnel costs for 12-month patient management:<br>Intervention= $134.68, usual care= $93.70 |
| **Direct total cost** | Total personnel costs, intervention =$10,639.70, usual care= $7,308.53 |
| **Indirect cost** | Not stated |
| **Incremental cost** | $3331.17 for personnel costs |
| **ICER** | Not reported |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **time horizon of costs and effects** | 12 months |
| **Discounting** | No discounting reported |
| **Cost inflation** | None |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Not reported |
| **Conclusions** | There is potential added value associated with the use of non-physician professionals in collaborative chronic disease management at modest incremental costs |

| **Study** | **McCall 2011[48]** |
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| **Funding source for study** | None |
| **Type of economic evaluation** | Cost analysis |
| **Study objective** | To examine whether commercial disease-management companies that use nurse-based call centres were able to achieve meaningful savings for the Medicare program while improving the quality of care for beneficiaries and reducing acute care utilization. |
| **Interventions** | Medicare Health Support Pilot Program consisting of eight commercial programs for disease management that used nurse-based call centres to assess the needs of individual beneficiaries and used health coaches to target those beneficiaries at immediate high risk for adverse events. The goals of the intervention was to improve beneficiaries' understanding of their disease or diseases, their ability to manage self-care, and their ability to communicate with providers. Various educational resources including literature, videos, and Internet resources were provided. A small portion of the intervention population received intensive case management services |
| **Comparator(s)** | Usual care |
| **Effectiveness data** | Claims filed under Medicare were collated for 12 months to establish baseline, thereafter collected over the subsequent 36 months or less |

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| **Outcome measure** | Change from baseline between two arms in process of care for diabetes: glycated haemoglobin testing, urinary protein screening, retinal eye exam and low density lipoprotein cholesterol testing<br>Rate of hospitalization and emergency room<br>Rate of utilization of ambulatory care services<br>Medicare costs |
| **Duration of study** | 30 months |
| **Location** | USA |
| **Setting** | Primary Care practices |
| **Study population** | Eight commercial companies with programs involving remote nurse-based call centres to assess the need of patients and health coaches to target beneficiary with high risk of adverse events.<br>Study included 242,417 patients who were randomly assigned to receive disease-management services (intervention) = 163,107 or usual care =79,310 patients with heart failure or diabetes and had a Hierarchical Condition Category (HCC) risk score of 1.35, indicating that their fee for- service cost was at least 35% greater than the average.<br>Average of 57% of the beneficiaries with diabetes alone and 20% with diabetes and heart failure.<br>Average of more than 1 hospitalization annually in 2004 and average of $15,000 in Medicare expenditures |
| **Cost data** | Analysis of costs were assembled from claimed files for 12 months before start date up till 36months or less if the company terminated participation early.<br>Average costs per beneficiary per month were constructed at the beneficiary level in the baseline and intervention periods by dividing total Medicare payments by the number of months that the beneficiary was eligible.<br>Calculations of gross savings were based on mean differences in the changes from baseline in the cost for individual beneficiaries<br>Net program savings were defined as average monthly gross savings minus fees paid to the company |
| **Analytical perspective** | Health insurance |
| **Resources** | Companies contacted participants every 2.7 months on average, with 80 days between contacts.<br>Average 1 contact per month<br>Of the 40 evidence-based, process-of-care measures, 14 differed significantly between the Intervention(I) and Control(C) groups<br>**Aetna- Intervention (N = 20,259), Control(N = 10,118)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) = I-104, C-101<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-51,C-50<br>**Healthways- Intervention (N = 20,031) Control (N = 10,016)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-86, C-85<br>Prior emergency room visit for any reason (rate/100 beneficiaries) = I-59, C-59<br>**CIGNA Health Support- Intervention (N = 20,361), Control(N = 10,146)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-79, C-75<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-97, C-84<br>**Health Dialog- Intervention (N = 20,039) Control (N = 8,018)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-98, C-95<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-69, C-65<br>**Green Ribbon Health- Intervention (N = 22,605) Control (N = 11,316)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-73, C-72<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-55, C-55<br>**LifeMasters- Intervention (N = 20,120) Control (N = 10,078)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-91, C-90<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =1-78, C-76<br>**McKesson- Intervention(N = 20,120),Control (N = 10,107)**<br>Prior hospitalization for any reason (rate/100 beneficiaries) =I-90, C-88<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-103, C-101<br>**XLHealth- Intervention(N = 19,518),Control (N = 9,511)** |

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| | Prior hospitalization for any reason (rate/100 beneficiaries) =I-76, C-75<br>Prior emergency room visit for any reason (rate/100 beneficiaries) =I-84, C-87 |
| **Results** | Only one company was successful in slowing the rate of growth in hospitalizations for any condition with 44 reductions per 1000 beneficiaries. Another slowed the rate of growth in hospitalizations for ambulatory care–sensitive conditions by minus 5 per 1000 beneficiaries Observed gross savings were 1.24% of the control group's cost per beneficiary per month for one company, which was not significantly different from zero.<br><br>**Aetna- Intervention (N = 20,259), Control(N = 10,118)**<br>Overall Participation Rate (%) =84<br>Mean No. of Contacts per active month =0.5<br>Difference in growth rate per 100 beneficiaries for HbA1c-1.6<br>Difference in growth rate per 100 beneficiaries for urinary protein=0.1<br>Difference in growth rate per 100 beneficiaries for retinal eye examination=1.3<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol=1.0<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=-44, emergency room visits=13<br>% change in gross saving per beneficiary per month cost=-1.24<br><br>**Healthways- Intervention (N = 20,031) Control (N = 10,016)**<br>Overall Participation Rate (%) =90<br>Mean No. of Contacts per active month =0.8<br>Difference in growth rate per 100 beneficiaries for HbA1c =2.4<br>Difference in growth rate per 100 beneficiaries for urinary protein =-0.3<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =0.9<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol=2.1<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=-29, emergency room visits=13<br>% change in gross saving per beneficiary per month cost=0.4<br><br>**CIGNA Health Support- Intervention (N = 20,361), Control(N = 10,146)**<br>Overall Participation Rate (%) =89<br>Mean No. of Contacts per active month =1.0<br>Difference in growth rate per 100 beneficiaries for HbA1c = 1.12<br>Difference in growth rate per 100 beneficiaries for urinary protein =1.18<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =0.1<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol = 1.2<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=27, emergency room visits=12<br>% change in gross saving per beneficiary per month cost=0.23<br><br>**Health Dialog- Intervention (N = 20,039) Control (N = 8,018)**<br>Overall Participation Rate (%) =96<br>Mean No. of Contacts per active month =0.8<br>Difference in growth rate per 100 beneficiaries for HbA1c =-0.1<br>Difference in growth rate per 100 beneficiaries for urinary protein =0.1<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =0.3<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol =0.5<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=-6, emergency room visits=-4<br>% change in gross saving per beneficiary per month cost=0.3<br><br>**Green Ribbon Health- Intervention (N = 22,605) Control (N = 11,316)**<br>Overall Participation Rate (%) =86 |

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| | Mean No. of Contacts per active month =0.7<br>Difference in growth rate per 100 beneficiaries for HbA1c =1.5<br>Difference in growth rate per 100 beneficiaries for urinary protein =1.3<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =0.3<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol =-0.3<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=12, emergency room visits=15<br>% change in gross saving per beneficiary per month cost= -1.07<br><br>**LifeMasters- Intervention (N = 20,120) Control (N = 10,078)**<br>Overall Participation Rate (%) =76<br>Mean No. of Contacts per active month =0.9<br>Difference in growth rate per 100 beneficiaries for HbA1c =0.9<br>Difference in growth rate per 100 beneficiaries for urinary protein =1.7<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =2.1<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol =2.4<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=21, emergency room visits=62<br>% change in gross saving per beneficiary per month cost= 2.67<br><br>**McKesson- Intervention(N = 20,120),Control (N = 10,107)**<br>Overall Participation Rate (%) =82<br>Mean No. of Contacts per active month =0.4<br>Difference in growth rate per 100 beneficiaries for HbA1c =1.3<br>Difference in growth rate per 100 beneficiaries for urinary protein =0.0<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =0.8<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol =2.9<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=18, emergency room visits=43<br>% change in gross saving per beneficiary per month cost= 0.65<br><br>**XLHealth- Intervention(N = 19,518),Control (N = 9,511)**<br>Overall Participation Rate (%) =75<br>Mean No. of Contacts per active month =0.5<br>Difference in growth rate per 100 beneficiaries for HbA1c =0.6<br>Difference in growth rate per 100 beneficiaries for urinary protein =1.7<br>Difference in growth rate per 100 beneficiaries for retinal eye examination =2.7<br>Difference in growth rate per 100 beneficiaries for LDL cholesterol =0.5<br>Differences in Rates of Growth between intervention and control for Acute Care Utilization per 1000 Beneficiaries between the Last 12 Months of the Medicare Health Support Pilot Program and a 1-Year Baseline Period- Hospitalization=20, emergency room visits=22<br>% change in gross saving per beneficiary per month cost= -0.14 |
| **Direct cost** | **Prior total Medicare payments per beneficiary per month ($)**<br>Aetna =I-1,534, C-1503<br>Healthways =I-1397, C-1413<br>CIGNA Health Support=I-1198, C-1127<br>Health Dialog=I-1330, C-1290<br>Green Ribbon Health = I-1231, C-1214<br>LifeMasters=I-1292, C -1296<br>McKesson= I-1241, C-1216<br>XLHealth=I-1153, C-1138<br>Average prior total Medicare payments per beneficiary per month:<br>Intervention=$1297<br>Control=$1275 |
| **Direct total cost** | Not stated |

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| **Indirect cost** | Not stated |
| **Incremental cost** | Not stated |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | 12months |
| **Discounting** | Not applicable |
| **Cost inflation** | None. Study year=2003/2004 |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Not applicable |
| **Conclusions** | Modest improvements in quality of care measures was achieved and It is unlikely that simple care management of elderly patients through telephone contact or an occasional visit will achieve good level of the level of savings. For such services to be effective, they require intensive, costly, personal clinical attention |

| **Study** | **Piette 2001[68]** |
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| **Funding source for study** | Health Services Research and Development Service, Mental Health Strategic Health Care Group, and Quality Enhancement Research Initiative, Department of Veterans Affairs, and by the American Diabetes Association. |
| **Type of economic evaluation** | Comparative resource utilization |
| **Study objective** | To Evaluate automated telephone disease management (ATDM) with telephone nurse follow-up as a strategy for improving diabetes treatment processes and outcomes in Department of Veterans Affairs (VA) clinics |
| **Interventions** | Biweekly automated telephone calls assessment lasting 5-8mins which consisted of hierarchically structured messages with statements and queries recorded in a human voice. During each ATDM assessment, patients used their touch-tone keypad to report information about their self-monitored blood glucose (SMBG) readings, other self-care activities, perceived glycaemic control, symptoms, and use of guideline-recommended medical care and option of listening to health promotion messages.<br>Nurse educator followed up with patients based on their ATDM assessment reports. Nurse could also schedule clinic appointments Telephone surveys were used to measure patients' self-care, symptoms, and satisfaction with care. Outpatient service use was evaluated using electronic databases and self-reports, and glycaemic control was measured |
| **Comparator(s)** | Usual care |
| **Effectiveness data** | Not applicable |
| **Outcome measure** | Primary outcome-impact on processes of care (including use of ophthalmology services), glycaemic control<br>Secondary outcome;-self-care behaviour, symptoms and perceptions towards telephone care |
| **Duration of study** | 12 months |
| **Location** | USA |
| **Setting** | 4 university-affiliated Veterans Affairs clinics in northern California |
| **Study population** | 292 adults (146=intervention, 146=control) with a diagnosis of diabetes with an active prescription for a hypoglycaemic agent treated in Department of Veterans Affairs (VA) outpatient clinics were randomized.<br>Participants were recruited from three general medicine clinics and one diabetes specialty clinic within a university-affiliated VA health care system.<br>>75 years of age, mentally ill, life expectancy of <12 months, newly diagnosed, plan to discontinue receiving services from the clinic within the 12-month follow-up period, or did not have a touch-tone telephone were excluded |

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| **Cost data** | Not stated |
| **Analytical perspective** | Hospital |
| **Resources** | 5-8 mins assessment calls each for intervention group<br>Average of 1.1 times per month follow up calls by study nurse = 13 contacts with each patients for 3.8hours<br>Nurse communication with pry care providers<br>15 automated contacts per patient |
| **Results** | 51% reported very satisfied and 31% moderately satisfied. 97% reported easy understanding of the message.<br>66% of follow up call time discussed adherence problems and side effect of medication.<br>Glucose self-monitoring-60%<br>Non-diabetic medication,32%<br>Non-diabetic symptoms, 37%<br>Psychological problems such as depression and anxiety,24%.<br>23% of follow up calls resulted in follow up contact with primary care provider<br>Intervention group reported more frequent self-monitored blood glucose and foot inspection. Intervention group had;<br>62% podiatry visits vs 42% for usual care p=0.003<br>40% ophthalmology visit vs 38% for usual care. p=0.8<br>61% diabetic clinic visit vs 25% usual care. p=0.03<br>Significant difference in blood glucose level from 9.5 to 8.7 for intervention and 9.2 unchanged for usual care with baseline ≥ 8%. For baseline ≥ 9%, HbA1c changed from 10.3 to 9.1 for intervention and unchanged for control. p=0.04 |
| **Direct cost** | Approx. $15-$25 per patient annually for automated calls |
| **Direct total cost** | Not stated |
| **Indirect cost** | Not stated |
| **Incremental cost** | Not stated |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **Time horizon of costs and effects** | Not applicable |
| **Discounting** | No discounting reported |
| **Cost inflation** | Not stated |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Mon reported |
| **Conclusions** | Automated telephone diabetic management with nurse follow-up improved the process and outcomes of VA diabetes care. |

| **Study** | **Pizzi 2015[11]** |
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| **Funding source for study** | US Centre for Disease Control and Prevention |
| **Type of economic evaluation** | Cost-effectiveness analysis |
| **Study objective** | To examine the costs and outcomes of two distinct intervention (mail vs telephone) to improve Diabetic Fundus Examination follow-up adherence among patients with diabetes in and urban eye clinic compared to usual care |
| **Interventions** | **Intervention 1=Mail** = Personalized letter encouraging scheduling a follow up &educational brochure sent 1 month prior to recommended date. Reminder card for those who made appointment. Automated call a day before scheduled appointment<br>**Intervention 2=Telephone**= usual care+ call from a Research assistant (RA) offering personal |

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| | scheduling assistance two week after reminder letter. 3attempts made to contact unreachable patients, reminder message and contact phone left on available answering machine/voice mail. Reminder letter 3weeks to scheduled appointment sent and automated reminder call a day to appointment |
| **Comparator(s)** | Usual care= standard generic, 1 page reminder letter on institutional letter head sent 1 month prior recommended follow up date<br>Automated reminder call a day to appointment for those who made the appointment |
| **Effectiveness data** | Prospective RCT of an educational and telephone follow up intervention involving 356 diabetes patients due for dilated fundus examination at an urban eye clinic in Philadelphia |
| **Outcome measure** | Percentage of appointments kept defined as completion rate in an intervention minus completion rate in the usual care<br>Primary outcome=completion of a follow-up appointment within 3 months of recommended return date<br>Secondary outcome=scheduling an appointment and intervention costs |
| **Duration of study** | 3 months |
| **Location** | Philadelphia, Pennsylvania USA |
| **Setting** | Primary care (urban, academic, tertiary eye clinic) |
| **Study population** | >18 years diabetes patients identified and previously evaluated in the eye clinic and recommended for a follow up dilated fundus examination. 356 patients<br>Mail intervention=117,<br>Telephone intervention=120,<br>Usual care=119<br>58% female, mean age=61 years, 70% African American |
| **Cost data** | Cost-effectiveness defined as cost per appointment completed<br>Personal cost associated with each intervention were calculated by multiplying time spent performing the task by an employee's wage per hour inclusive of fringe benefit costs. Wage rate obtained from US Bureau of Labour Statistics National Employment and Wages<br>Cost of all materials used calculated by multiplying costs of each material by number of patients in the intervention<br>Cost of telephone calculated by multiplying cost of phone per minute by length of call using local telephone rate<br>Institutional overhead added to the subtotal of costs at a rate of 8.7% |
| **Analytical perspective** | Healthcare system |
| **Resources** | 1 hour supervision of medical assistant for every 20hour intervention work<br>Medical assistant time spent on mailing, calling, preparation and documentation personnel time and materials, research staff time<br>Time spent on planning and implementation (two meetings lasting one hour) by medical assistant, health services manager and ophthalmologist<br>Stationery such as papers, printing and postage<br>80 telephone calls on 1st attempt<br>50 telephone calls on 2nd attempt<br>35 telephone calls on 3rd attempt |
| **Results** | On first attempt 81% made appointment of the 79 people<br>13% made appointment after 2nd call and 6% after 3rd call. Diminishing effectiveness from each successful calls<br>Scheduled follow up appointments: p=<0.0001<br>Usual care=42%<br>Mailed intervention=38%<br>Telephone intervention=65%<br>Completed follow-up of the eye examination in timely manner: p=<0.024<br>Usual care=35%<br>Mailed intervention=32%<br>Telephone intervention=50%<br>14% higher diabetes fundus examination rate in telephone intervention |
| **Direct cost** | Medical assistant time:<br>For mail= $61.61 for each intervention (telephone, mailed and usual care)<br>For calling=$94.08 for telephone intervention |

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| | For preparation and documentation=$317.76 for telephone<br>Planning and implementation meeting=$15.41 for each intervention<br>Supervisor time=usual care-$13.37, telephone-$53.89, mailed-$13.37<br>Supervisor time for planning and implementation meeting=$36.47 for each intervention<br>Ophthalmologist time for planning and implementation meeting=$78.53<br>Wage per hour:<br>*Health care manager=$40.52/hr*<br>*Medical assistant=$23.11/hr*<br>*Physician=$117.80/hr*<br>For each intervention mail reminder per patient includes:<br>Stationery=$0.57<br>Cost of educational brochure=$1.32<br>Cost of reminder letter=$143.38<br>Cost of telephone=80 calls (first attempt)=$223.32, 50 calls (second attempt)=$139.50, 35 calls (third attempt)=$97.65<br>Staff time for delivering the program<br>Postage ($0.29/envelope) = usual care-$34.51 telephone-$34.80 mailed-$33.93<br>Stationary and printing ($0.28/letter) =usual care-$33.32, telephone- $33.60 mailed-$32.76<br>Telephone call fees*($0.034/min)= $8.24<br>Brochure ($1.32/ brochure)=mailed intervention-$154.44<br>8.7% Overhead= usual care-$23.77 telephone-$63.89 mailed-$37.11<br>Total cost/appointment made =usual care-$5.82 telephone-$10.10 mailed-$10.30<br>Total cost/appointment kept =usual care-$6.91, telephone-$13.09 mailed-$12.20 |
| **Direct total cost** | Telephone intervention=$798.28 or $6.65/patient<br>Mailed intervention=$463.63 or $3.96/patient<br>Usual care=$296.99 or $2.50/patient |
| **Indirect cost** | Not calculated |
| **Incremental cost** | Telephone intervention=$25.94/additional patient |
| **ICER** | $25.94 per additional patient attending a Diabetes Fundus Examination |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | None reported |
| **Measure of benefit** | Completion of DFE appointment |
| **Time horizon of costs and effects** | Three months |
| **Discounting** | Not required, time horizon less than 12 months |
| **Cost inflation** | 2013 |
| **Currency** | US dollars |
| **Analysis of uncertainty** | One-way sensitivity analysis model to estimate the impact of changing costs of each phone call and limiting the number of phone call attempts |
| **Conclusions** | Personal phone assistance in scheduling dilated fundus examination is more effective but also most costly. Effect of educational materials sent cannot be confirmed |

| **Study** | **Prezio 2014[56]** |
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| **Funding source for study** | No funding source stated |
| **Type of economic evaluation** | Cost-effectiveness analysis |
| **Study objective** | To determine the impact of a culturally tailored diabetes education program led by a community health worker (CHW) on the HbA1c, blood pressure, body mass index (BMI) and lipid status of uninsured Mexican Americans with diabetes |
| **Interventions** | Community diabetes educational programme delivered by community health workers (CHW) plus usual care. Three educational modules were delivered during individual 1 hour sessions over the first 8 weeks. These sessions covered areas recommended by the American Diabetes |

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| | Association. The CHW facilitated immediate physician contact to address acute problems, assisted with pharmacy refills, and arranged specialty visits such as dental care and dilated retinal exams. Subjects were provided with a blood glucose monitor and testing strips free of charge and instructed in correct use of the device by medical assistants. |
| **Comparator(s)** | Usual care at the discretion of the clinic physicians.<br>Subjects in this group were provided with a blood glucose monitor and testing strips free of charge and instructed in correct use of the device by medical assistants. Culturally tailored printed diabetes education materials were provided by physicians and clinic staff |
| **Effectiveness data** | RCT performed in an urban clinic serving uninsured Mexican American with T2DM, intervention=90,usual care=90 |
| **Outcome measure** | Diabetic retinopathy, nephropathy and neuropathy, ICER<br>Secondary outcomes: patients' attitudes and knowledge about diabetes self-management using American Diabetes Association standards of care (including annual dilated fundus examination) |
| **Duration of study** | 12 months |
| **Location** | USA |
| **Setting** | Faith based urban clinic (primary care) |
| **Study population** | Simulation of n=10,000 for both intervention and comparator using RCT of 180 uninsured Mexican American with T2DM, intervention=90,usual care=90<br>20-75years with T2DM being treated with no advanced complication with HbA1c $\geq$ 7% |
| **Cost data** | Derived by multiplying cost-generating events by the cost of events based on 2006 Medicare data |
| **Analytical perspective** | Health care system |
| **Resources** | 7 Community Diabetic Education (CODE)<br>3 hours clinic based culturally tailored DE and 4hours quarterly case management provided by specially trained bilingual community health worker: reinforcement of knowledge and skills, patient follow-up reminders, referrals for retinal examination<br>1 hour physician time for supervision of community health workers |
| **Results** | CHW led CODE was reported by the study authors as cost effective over a 20-year time horizon as compared to usual care ($50,000 per QALY gained)<br>Statistical significance in fewer foot ulcers at 5years and fewer leg amputation at 20years for intervention arm while no statistical significance with reduction in diabetic retinopathy, bilateral blindness and myocardial infarction<br>Raising program costs by 50% increased the ICER to $30,267 per QALY gained, whereas lowering program costs by 50% resulted in the program becoming cost saving. |
| **Direct cost** | Salary + fringe benefits for physician=$66.31/hour<br>CODE CHWs=$17.55/hr<br>Annual cost of diabetes supply for each participants=$51.07<br>Opportunity cost of each CODE/year=$435 |
| **Direct total cost** | Cost for each program over 20 years=$4958 |
| **Indirect cost** | Time spent by participants=$15.65/hr<br>Opportunity cost per participant/year=$435 |
| **Incremental cost** | Not stated |
| **ICER** | For entire population:<br>$355 over 20 years<br>$38,726 for 10 years<br>$100,195 for 5years<br>Individual:<br>$37,221 for 5years aged 55-75years patient<br>At 6% discounting=$4471/QALY<br>The intervention was cost-effective ($33,703 per QALY gained) when program effectiveness was reduced by 25% (relative change in HbA1c, 17.5%). When program effectiveness was reduced by 30%, the ICER increased to $55,061 per QALY gained |
| **Modelling and statistical extrapolation** | Archimedes simulation model of human physiology, disease progression and healthcare utilization. Each simulated individual has unique physiology which changes over time and may affect health outcomes. Model tracks utilization of services, health outcomes, QoL and costs |
| **Monetary benefit** | Quality of life was calculated by multiplying the time patient spent in a particular symptom or |

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| **and utility valuations** | health outcome by the associated decrease in QoL. Tool used to estimate utilities was not reported |
| **Measure of benefit** | Presence or absence of diabetes-related complications and other cardio metabolic conditions |
| **Time horizon of costs and effects** | 20 years |
| **Discounting** | 3-6% |
| **cost inflation** | Inflated to 2012 |
| **Currency** | US dollars |
| **Analysis of uncertainty** | One way sensitivity analysis-evaluation of changes in results over 5,10 and 20 years' time horizons<br>Variation in discounting rate to 3%,0% and 6% to influence changes in medical costs and QALY<br>Change in program adherence<br>*Reference scenario*<br>Discount rate: 3%<br>Program effectiveness: 100%<br>Program cost: $0.68/day<br>Discount rate for cost and quality of life;<br>At 0% 5years time horizon= $96,058, 10 years=$ 35,338, 20 years=Cost saving<br>At 6% , 5 years=$104,401, 10 years=$42,415 , 20 years=$4,471<br>Program effectiveness<br>At 80% for 10 years=$94,813 for 20 years=$21,386<br>At 75% for 20 years=$ 33,703<br>At 70% for 20years=$55,061<br>Program cost<br>50% increase for 10 years= $103,389 for 20 years=$30,267<br>50% decrease =Cost saving for 5,10 and 20years |
| **Conclusions** | CHWs may be able to deliver successful, cost-effective DSME interventions for uninsured Mexican Americans with diabetes when carefully designed. Although non-adherence to behavioural interventions has often been reported, the one-to-one encounters between the CoDE CHW and the diabetes patient promotes both patient and provider accountability. |

| **Study** | **Schechter 2008[69]** |
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| **Funding source for study** | National Institutes of Health grant |
| **Type of economic evaluation** | Cost-Effectiveness Analysis |
| **Study objective** | To outline the costs and estimate the cost-effectiveness of telephone intervention to promote dilated fundus examination in adults with diabetes mellitus |
| **Interventions** | Tailored telephone intervention to promote retinopathy screening (up to 7 calls over 6/12 period). Patients were interviewed to identify issues and barriers that might either motivate them or prevent them from going for a dilated fundus examination (DFE). Attempts were made to engage all participants with targeted self-management strategies and dilated fundus examination education, and were encouraged to make a screening appointment if they indicated they were ready to change. |
| **Comparator(s)** | Standard mailed pamphlet with information about retinal disease in diabetes and its prevention through DFE (print information) |
| **Effectiveness data** | Randomized controlled trial of a telephone-based intervention to increase adherence with DFE screening recommendations in a population of predominantly low income minority adults with diabetes in Bronx, NY |
| **Outcome measure** | Primary outcome: documentation of a dilated fundus examination within 6 months of randomization.<br>Secondary outcomes: factors that contribute to receiving a DFE within 6 months for participants in the tailored telephone intervention. HbA1c results |
| **Duration of study** | 2001 to 2005 |
| **Location** | USA |
| **Setting** | Three inner city health centres |

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| **Study population** | 603 patients, 305=telephone intervention, 298=print intervention aged >18 years (mean age of 56.6years), diagnosed with diabetes, able to speak and read (or be read to in) English or Spanish, capable of providing informed consent, have access to a telephone, and report not having had a dilated fundus examination in the previous 12 months |
| **Cost data** | Number of calls to each patient, their durations, and the number of attempted calls that were not completed were tallied and then associated several types of costs with each call costs of labour for the health educators during the phone calls was accounted based on US median earnings for the job category identified from a commercial compensation database (Pay Scale, Inc. 2008) attributed an annual salary of US$70,000 to the supervisor, a slight increment above the median US$59,140 reported for a registered nurse credentialed as a certified diabetes educator<br>Average salary health educator= $36,500 per year labour costs incurred an additional 28% charge for benefits.<br>Telephony charges accounted at US$0.05 for each call (completed or attempted), plus an additional US$0.10 for each minute's duration of a completed call. |
| **Analytical perspective** | Provider of health care to a population of patients with diabetes (healthcare) |
| **Resources** | 20 hours of training for health educators about diabetes, retinopathy, counselling for behaviour change health educators received 1 hour of supervision for every 20 hours of intervention work from a nurse certified diabetes educator<br>Estimation of 5 minutes of preparation time (e.g., to locate and review the records).<br>Subjects received, on average, 3.2 phone calls and spoke with a health educator for 28.1 minutes over the 6-month<br>For completed calls, an additional 5 minutes for making notes and re-filing the chart.<br>4,147 attempted calls plus 930 calls resulting in contact with the patients, having a total duration of 8,212 minutes. |
| **Results** | Of the 305 telephone group participants 103 (33.8%) ultimately underwent DFE within 6 months of randomization, compared with 57 (19.5%) of 293 controls intervention thus resulted in a gain of 43.7 DFEs, which were associated with an additional 3 incident diagnoses of macular oedema and 16.4 incident diagnoses of diabetic retinopathy hence, the telephone group's participation in DFE screening exceeded that of the print group by 74%.<br>Labour costs dominated the expenses |
| **Direct cost** | Health educator payment for calls=$14,890.83<br>Cost of training and supervision=$3,535.63<br>Telephone charges=$871.80"<br>Print intervention cost US$2.04 per participant for the brochure, envelope, postage, and mailing labour= 2.04x293=$597.72 |
| **Direct total cost** | Telephone intervention=$19,298.26 |
| **Indirect cost** | Not reported |
| **Incremental cost** | $18,676.06 |
| **ICER** | US$427.37 per DFE gained |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | None reported |
| **Measure of benefit** | Number of DFEs generated/gained by the intervention |
| **time horizon of costs and effects** | 6 months |
| **Discounting** | No discounting because the time-frame of the intervention and its sequelae was only 6 months |
| **Cost inflation** | None. study year=2008 |
| **Currency** | US dollars |
| **Analysis of uncertainty** | Probabilistic sensitivity analysis was performed holding the salaries, fringe levels, and telephony charges constant at their base case levels and generating 1,000 bootstrap samples from the clinical trial data set of individual patient records, thus capturing the uncertainty in the effectiveness of the intervention and in number and duration of calls |
| **Conclusions** | Telephone calls by bilingual health educators can improve diabetic retinopathy screening by |

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| | 74%, thereby reducing the risk of eye complications in a poor urban population. |

| **Study** | **Wagner 2001[64]** |
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| **Funding source for study** | Robert Wood Johnson Foundation |
| **Type of economic evaluation** | Cost-outcome description |
| **Study objective** | To evaluate the impact of primary care group visits (chronic care clinics) on the process and outcome of care for diabetic patients. |
| **Interventions** | Chronic care (mini clinic) patients divided into a group of 6-10 to attend half a day clinics together at intervals of 3–6 months, consisting of individual visits with the primary care physician, nurse, and clinical pharmacist; and a group educational/ peer support session. Self-management provided through one-on-one counselling with the practice nurse and a group session. The 1-h group sessions by the practice nurse or relevant health professional covered various self-management issues and group involvement encouragement |
| **Comparator(s)** | Usual care |
| **Effectiveness data** | Primary care practices randomized to intervention and control groups in a large-staff model health maintenance organization (HMO). Patients included diabetic patients 30 years of age in each participating primary care practice, selected at random from an automated diabetes registry. |
| **outcome measure** | Processes of diabetes care and satisfaction of intervention and control patients at baseline and at 24 months (General health, Physical function, Physical role limitation, Bed disability days, restricted activity days, depression scale<br>Hb1Ac, cholesterol level)<br>Costs and resource use ( primary care visit, ER visit, speciality visit, % hospital admission, total costs) |
| **Duration of study** | 24months |
| **Location** | Seattle, USA |
| **Setting** | Primary care |
| **Study population** | From a diabetic registry, 35 clusters of 707 diabetic patients ≥30 years of age in primary care practice were randomly selected with preference for those receiving insulin or oral hypoglycaemic therapy<br>Intervention=14 clusters, 278 patients, usual care=21 clusters,429 patients.<br>Patients who were terminally ill, demented or psychotic, or otherwise not able to participate in the study were excluded |
| **Cost data** | Not stated |
| **Analytical perspective** | Healthcare |
| **Resources** | Intervention at baseline<br>Primary care visit per year-5.6<br>Emergency room visit per year-0.15<br>Specialty visit per year-4.1<br>% hospital admission -32.7<br>Usual care at baseline<br>Primary care visit per year-5.7<br>Emergency room visit per year-0.1<br>Specialty visit per year-4.1<br>% hospital admission -32.9<br>Intervention at 24 months<br>primary care visit per year-6.4<br>Emergency room visit per year-0.1<br>Specialty visit per year-2.8<br>% hospital admission -16.9<br>Usual care at 24 months<br>primary care visit per year-5.5<br>Emergency room visit per year-0.2<br>Specialty visit per year-3.7 |

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| | % hospital admission -21% |
| **Results** | Medical care satisfaction (mean % excellent)= 27.0 at base line and 45.3 after 3-6 visits<br>Diabetes care satisfaction (mean % very satisfied)= 54.4 at baseline and 69.7 after 3-6 visits<br>General health= 47.2 at baseline and 46.7 after 3-6 visits<br>Bed disability days (% )=36.7 at baseline and 26.3 after 3-6 visits<br>Restricted activity days (% )= 44.1 and 39.3 after 3-6 visits<br>HbA1c (mean %)= 8.1 at baseline and 7.7 after 3-6 visits<br>Cholesterol (mean mg/dl)= 206.8 at baseline and 195.5 after 3-6 visits<br>Primary care visits per year= 6.3 at baseline and 6.9 after.<br>Statistical significant difference in most outcome measures.<br>Somewhat higher rates of foot exam, retinal exams and medication review, reduction in specialty and emergency room visits but no statistical significant difference for all outcomes. Total health care costs did not differ between the groups.<br>Study nurses played an important role that must be considered when estimating the full cost of the intervention. impact of monoclinic on clinical and health outcomes would have been much greater if practice nurses had sufficient time and training to provide clinical case management |
| **Direct cost** | Healthcare cost.<br>Baseline =$2540, p=0.60<br>24 months= $2122, p=0.79<br>Usual care<br>Baseline=$2670<br>24 months=$2208 |
| **Direct total cost** | Healthcare cost<br>Baseline =$2540<br>24 months= $2122<br>Usual care<br>Baseline=$2670<br>24 months=$2208 |
| **Indirect cost** | Not reported |
| **Incremental cost** | Not reported |
| **ICER** | Not applicable |
| **Modelling and statistical extrapolation** | Not applicable |
| **Monetary benefit and utility valuations** | Not applicable |
| **Measure of benefit** | Not applicable |
| **time horizon of costs and effects** | Not applicable |
| **Discounting** | No discounting reported |
| **Cost inflation** | not stated |
| **Currency** | US dollars |
| **Analysis of uncertainty** | None reported |
| **Conclusions** | Bringing groups of chronically ill patients into special primary care sessions designed to meet their clinical, educational, and psychosocial needs appears to be a feasible and effective way of improving their care. |

**Characteristics of ongoing studies**

| ISRCTN31439939 | |
|---|---|
| **Study name** | The Kilimanjaro Diabetic Programme: the development of a sustainable regional eye health screening program to prevent blindness among diabetic patients due to diabetic retinopathy |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria**: all known adult diabetic patients resident in Kilimanjaro region and attending a diabetic clinic at Kilimanjaro Christian Medical Centre (KCMC) or at one of the district diabetic clinics in the 6 rural districts of Kilimanjaro region |
| **Interventions** | Phase I:<br>**Intervention group**: a digital diabetic retinopathy screening camera will be placed in the diabetic clinic at KCMC<br>**Control group**: patients will be advised to go to the eye clinic at KCMC for a dilated screening examination by an ophthalmologist<br><br>All patients will receive 3 information leaflets on diabetic retinopathy and be counselled by the health workers in the diabetic clinic that they should have screening for diabetic retinopathy. Visual acuity measurement will be performed and dilating drops installed by the screening team<br><br>Phase II: the retinopathy screening camera will go to all district diabetic clinics twice in the 6 month intervention period. Patients registered at these clinics will all be advised by clinic staff to attend for retinopathy screening. The intervention group will receive a text message by mobile phone advising them of the date of the screening and inviting them to come |
| **Outcomes** | From ISRCTN Registry<br>**Primary outcome**: uptake of screening for diabetic retinopathy<br>**Secondary outcomes**: prevalence of diabetic retinopathy in urban and rural diabetic patients in Kilimanjaro region; prevalence of cataract in urban and rural diabetic patients in Kilimanjaro region |
| **Starting date** | 10/12/2010 to 31/07/2011 |
| **Contact Information** | Christoffel Blinden, Mission (CBM) e.V., Nibelungenstrasse 124,Bensheim D-64625, Germany |
| **Notes** | |

| ISDR (ISRCTN87561257) | |
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| **Study name** | Individual risk-based screening for diabetic retinopathy (ISDR) |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria:** patients aged 12 or above who attend the community clinic for retinal screening |
| **Interventions** | **Intervention:** personalised risk-based screening intervals<br>**Comparator:** annual screening intervals (usual care) |
| **Outcomes** | From ISRCTN Registry<br>**Primary outcome**: comparison of attendance rates for follow-up screening in the two arms of the study [non-attendance will be defined as failure to attend two appointments for screening (usually within 6 weeks of each other)]<br>**Secondary outcomes**: number of cases of STDR detected; retinopathy level at screening (Liverpool and NDESP grading); maculopathy level at screening (Liverpool and NDESP grading); number of false positive screening episodes; number of screening appointments; number of dedicated diabetes assessment clinic appointments; number of other eye appointments for diabetic eye disease; visual acuity (logMAR); new visual impairment (≥ +0.50 logMAR); new visual impairment due to diabetic retinopathy (≥ +0.50 logMAR); number of missed appointments to screening; patient acceptability measures (using a |

| ISDR (ISRCTN87561257) | |
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| | questionnaire designed for the trial); quality-adjusted life years (QALYs) estimated using EQ-5D-5L and Health Utilities Index Mark 3 (HUI3); cost per QALY gained |
| **Starting date** | November 2014 to January 2018 |
| **Contact Information** | ISDR Project Manager, Department of Eye and Vision Science, 3rd Floor University Clinical Department, Royal Liverpool University Hospital, Prescot Street, Liverpool, L7 8XP, United Kingdom |
| **Notes** | |

| CARRS (NCT01212328) | |
|---|---|
| **Study name** | Improving diabetes care: multi-component cardiovascular disease risk reduction strategies for people with diabetes in South Asia - The CARRS Multi-center Translation Trial |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria:** aged 35 years and older with a confirmed diagnosis of diabetes and poor glycemic control (as evidenced by HbA1c >=8.0%) and one or both of: dyslipidemia [Low density Lipoprotein (LDL) >=130 mg/dl] or systolic hypertension [Systolic Blood Pressure (SBP) >=140 mmHg], irrespective of lipid- or BP-lowering medication use, respectively |
| **Interventions** | **Intervention**: the patients will receive integrated diabetes care management consisting of current diabetes management guidelines and non-physician care coordinator assistance and electronic health records- decision support software (EHR-DSS) (The software will generate diabetes management prompts for the treating physician and reminders for clinic visits for the intervention arm patients)<br>**Comparator**: patients will continue with the usual diabetes care with no care coordinator assistance and no decision support software - management prompt |
| **Outcomes** | From ClinicalTrials.gov<br>**Primary outcome:** multiple CVD risk factor control targets (blood glucose and either blood pressure or cholesterol, or all three)<br>**Secondary outcomes**: single risk factor control of at least one target either HbA1c or blood pressure or LDL-Cholesterol ; process and patient centered measures; cost effectiveness analysis of the intervention compared to the usual care; prescriber and patient acceptability of the Digital Support software and care coordinator with management guidelines |
| **Starting date** | October 2010 to June 2014 |
| **Contact Information** | Kavita Singh, MSc Tel: +91-11-26850118 ext 39 email;kavita@ccdcindia.org |
| **Notes** | Trial protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/23084280 |

| NCT01351857 | |
|---|---|
| **Study name** | Diabetes care management compared to standard diabetes care in adolescents and young adults with type 1 diabetes (TransClin) |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria**: patients between the ages of 17 and 20 years with an established type 1 diabetes diagnosis for a minimum of one year |
| **Interventions** | From ClinicalTrials.gov<br>**Intervention**: a certified diabetes educator will act as a 'Transition Coordinator' to provide transition support and the link between paediatric and adult diabetes care. The Transition Coordinator is central to the intervention and will provide ongoing contact with the medical system as well as education and clinical support where appropriate.<br>**Comparator**: current standard of care (subjects in the control group will transition to adult care equal to the intervention group and will differ only by exclusion of Transition Coordinator) |

| NCT01351857 | |
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| **Outcomes** | **Primary outcome**: proportion of subjects who fail to attend at least one outpatient adult endocrinology visit during the second year after transition to adult diabetes care<br>**Secondary Outcomes:** frequency of HbA1C measurement (in the 2 year transfer to adult care); frequency of retinal exam, microalbumin to creatinine ratio, fasting lipid profile and foot exam testing **;** rate of hospitalization/ER visits for acute complications of diabetes |
| **Starting date** | April 2012 to April 2017 |
| **Contact Information** | Cheril Clarson, MD, London Health Sciences Centre Children's Hospital |
| **Notes** | Trial protocol has been published:<br>https://www.ncbi.nlm.nih.gov/pubmed/24106787 |

| NCT01837121 | |
|---|---|
| **Study name** | A trial of using SMS reminder among diabetic retinopathy patients in rural China (SMS) |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria**: patients with diabetes with access to a cell phone |
| **Interventions** | **Intervention**: patient will receive a SMS reminder message about the revisit time and venue 1 week and 1 day before the appointment<br>**Comparator:** usual care |
| **Outcomes** | From ClinicalTrials.gov<br>**Primary outcome:** non-attendance rate<br>**Secondary outcomes:** knowledge about diabetic retinopathy **;** presenting vision in the better-seeing and worse-seeing eyes **;** vision Loss of two or more lines of presenting vision in better-seeing eye thought due to diabetic retinopathy**;** satisfaction with care; number of treatments received for diabetic retinopathy |
| **Starting date** | April 2013 to June 2015 |
| **Contact Information** | Nathan G Congdon MD MPH. Blindness Prevention and Treatment Department, Zhongshan Ophthalmic Center |
| **Notes** | |

| IDEAS (NCT02339909) | |
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| **Study name** | Incentives in diabetic eye assessment by screening (IDEAS) |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria:** diabetic patients (>16 years) who were invited to screening in the last 24 months on a yearly basis and failed to attend or contact the screening service to rearrange an appointment |
| **Interventions** | **Intervention ('Fixed Incentive'):** Standard invitation letter from the screening service, with additional text offering a fixed financial incentive (£10) if they attend screening<br>**Intervention 'Probabilistic incentive'**: invitation letter from the screening service, with additional text offering a probabilistic financial incentive (entry into a lottery offering at least a 1 in 100 chance to win £1000) if they attend screening.<br>**Comparator**: standard intervention from the screening service |
| **Outcomes** | From ClinicalTrials.gov<br>**Primary outcome**: attendance at screening appointment at designated appointment date (between three months and one year)<br>**Secondary outcome:** outcome from diabetic retinopathy screening |
| **Starting date** | March 2015 to January 2016 |
| **Contact Information** | Colin Bicknell, Clinical Senior Lecturer and Consultant Vascular Surgeon, Imperial College London |

| IDEAS (NCT02339909) | |
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| **Notes** | Trial protocol has been published<br>http://bmcophthalmol.biomedcentral.com/articles/10.1186/s12886-016-0206-4 |

| NCT02866734 | |
|---|---|
| **Study name** | Diabetic Retinopathy Screening in Private Practice |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria:** patients diagnosed to have diabetic mellitus. Able to give informed consent<br>**Exclusion Criteria:** pregnancy |
| **Interventions** | **Intervention:** pay screening group ($150) Subjects in this group receiving diabetic retinopathy screening will be charged HK$150.<br>**Intervention:** pay screening group ($300). Subjects in this group receiving diabetic retinopathy screening will be charged HK$300.<br>**Comparator**: free screening group. Subjects in this group receive free diabetic retinopathy screening. |
| **Outcomes** | From ClinicalTrials.gov<br>**Primary outcome**: the overall, & at different fee level, uptake (as a percentage of participants) of screening from those at-risk patients who attend private GP's [ Time Frame: one year ]<br>**Secondary outcome:** percentage of participants with diabetes who are only under the care of a private GP, or also attend specialist service, and have had access to DRS [ Time Frame: one year ]<br>Prevalence of DR (overall, and for sight-threatening diabetic retinopathy) among diabetic patients in private primary care [ Time Frame: one year |
| **Starting date** | August 2016 to April 2017 |
| **Contact Information** | Jonathan Cheuk Hung Chan, MBBS The University of Hong Kong |
| **Notes** | |

| NCT02579837 | |
|---|---|
| **Study name** | CLEAR SIGHT: A trial of non-mydriatic ultra-widefield retinal imaging to screen for diabetic eye disease |
| **Methods** | Parallel group RCT |
| **Participants** | **Inclusion criteria**: patients with a known diagnosis of Type 1 diabetes for >/= 5 years or Type 2 diabetes. of any duration with at least a 12 months interval since the last screening for diabetic eye disease by an eye care professional |
| **Interventions** | **Intervention**: on-site screening. Participants randomized to the on-site screening group will be advised by their Endocrinologist during their diabetes clinic visit to arrange an eye examination with their usual eye care professional (as per current standard of care).<br>In addition they will also undergo:<br>-non-mydriatic ultra-widefield (UWF) retinal imaging on the same day as their diabetes clinic visit<br>-half of this group will by random allocation undergo optical coherence tomography (OCT) using the Zeiss Cirrus OCT, which may or may not be done on the same day (for practical reasons regarding availability of OCT at the hospital)<br>**Comparator:** usual screening. Participants randomized to the usual screening group will be advised by their Endocrinologist during their diabetes clinic visit to arrange an eye examination with their usual eye care professional (as per current standard of care) |
| **Outcomes** | From ClinicalTrials.gov<br>**Primary outcome**: proportion of participants with Actionable Eye Disease (AED)<br>**Secondary outcomes**: screening adherence (determined by (i) the proportions of participants who have screening completed within 12 months of randomization by the primary screening method, viz., non-mydriatic UWF images (On-site Screening group) or an eye examination by an eye care professional (Usual Screening group); (ii) for participants in the onsite screening |

| NCT02579837 | |
|---|---|
| | group, the proportion who have also had a screening eye examination by an eye care professional within 1 year of randomization); proportion of participants with Diabetic Maculopathy (DME) |
| **Starting date** | February 2016 to January 2019 |
| **Contact Information** | Nour Abu-Romeh, St. Joseph's Hospital, London, Ontario, Canada, N6A 4V2<br>Tel: 519-646-6100 ext 65593 |
| **Notes** | |

| ACTRN12614001110673 | |
|---|---|
| **Study name** | The diabetes and eye health project: increasing eye examinations for adults newly diagnosed with type 2 diabetes. |
| **Methods** | Parallel group RCT (Solomon four group design) |
| **Participants** | **Inclusion criteria**: diagnosed with type 2 diabetes in the past three years; Australian residents; able to read English; registered with the National Diabetes Services Scheme (NDSS); one of either: young adult (aged 18-39 years), or live in rural/regional locations of Victoria, Australia |
| **Interventions** | **Intervention**: printed materials (leaflet) containing persuasive behaviour change messages designed to raise awareness of the importance of maintaining optimal blood glucose and blood pressure levels to minimise the risk of diabetic retinopathy, increase intentions to engage in regular eye examinations and increase self-reported eye examinations. The leaflet will be mailed on a single occasion to study participants.<br>**Comparator:** participants randomized to the usual screening group will be advised by their Endocrinologist during their diabetes clinic visit to arrange an eye examination with their usual eye care professional (as per current standard of care). |
| **Outcomes** | From anzctr.org.au<br>**Primary outcome:** self-reported eye health examinations assessed via response to a single questionnaire item ("Since you were diagnosed with diabetes, have you had your eye health checked?"). In order to minimise social desirability bias and any potential confounding influence of question-behaviour effect, the question will be embedded within a suite of standard self-management questions based on information already provided to all new National Diabetes Service Scheme registrants<br>**Secondary outcomes:** intention to seek eye health examinations assessed via summed response to three intention items designed specifically for this purpose |
| **Starting date** | September 2014 |
| **Contact Information** | Prof Jane Speight, The Australian Centre for Behavioural Research in Diabetes, 206 Queensberry Street, Melbourne, VIC 3000, Australia. +61 (0)3 8648 1844, jspeight@acbrd.org.au |
| **Notes** | |

## 3. Table of excluded studies

| Study | Reason for Exclusion |
|---|---|
| Abraira 2003[70] | No data on retinopathy screening attendance |
| Aleo 2015[71] | No data on retinopathy screening attendance |
| Alfadda 2011[72] | Not RCT |
| Anderson 2003[73] | Not RCT |
| Anderson 2010[74] | No data on retinopathy screening attendance |
| Arora 2014[75] | No data on retinopathy screening attendance |
| Bellazzi 2004[76] | No data on retinopathy screening attendance |
| Denig 2014[77] | No data on retinopathy screening attendance |
| Gangwar 2014[78] | No data available on control group (contacted author) |
| Gary 2004[79] | No data on retinopathy screening attendance |
| Harris 2013[80] | Not RCT |
| Hazavehei 2010[81] | Evaluated intentions to attend for retinopathy screening rather than attendance |
| Hollander 2005[82] | Not RCT |
| Jones 2006[83] | Not RCT |
| Kuvaja-Kollner 2013[84] | Not RCT |
| Lewis 2007[85] | Qualitative study. No data on retinopathy screening attendance |
| Maberley 2003[86] | Health economic paper. No data on retinopathy screening attendance |
| Mangione 2006[87] | Not RCT |
| Mazzuca 1988[88] | No data on retinopathy screening attendance |
| McCulloch 1998[89] | Not RCT |
| Montori 2002[90] | Not RCT |
| Montori 2004[91] | Not RCT |
| Peters 1998[92] | Not RCT |
| Polak 2003[93] | Health economic paper. No data on retinopathy screening attendance |
| Rees 2013[94] | No data on retinopathy screening attendance |
| Samoutis 2010[95] | Not RCT |
| Schectman 2004[96] | Not RCT |
| Shah 2014[97] | No data on retinopathy screening attendance |
| Shea 2006[98] | No data on retinopathy screening attendance |
| Solorio 2015[99] | Not RCT |
| Thoolen 2008[100] | No data on retinopathy screening attendance |
| Wagner 2008[101] | Knowledge of diabetic retinopathy rather than attendance |
| Weston 2008[102] | Used vignettes rather than real patients |
| Young 2014[103] | No data on retinopathy screening attendance |

## 1.3. Further details of the review of economic evidence (phase 1 review).

***1. Summary of reasons for exclusion of potentially eligible economic studies***

Protocols of five studies[17, 16, 42, 53, 54] (Zwarenstein 2014; Zangalli 2014; Jansink 2013; Peterson 2008; Perria 2007) indicated that economic evaluations would be carried out and further searches were conducted to identify possible reports for these economic evaluations. Two of the studies[17, 53](Perria 2007 and Zwarenstein 2014) were excluded as the reports for the economic evaluation could not be identified. The clinical effectiveness reports of these studies revealed that the intervention strategy did not demonstrate a statistically significant improvement in outcomes, which may have been the reason for the missing economic evaluation. Of the remaining studies, Peterson 2008[54] was excluded since the study result showed no significant change in the HbA1c (Peterson 2008). Jansink 2013[42] was excluded because there was no economic evaluation report in the published paper (Jansink 2013), while Zangalli 2014[16] aimed to carry out an economic evaluation in the future (which couldn't be identified by the search) (Zangalli 2014). After excluding these studies 17 potentially eligible studies were included for full text screening. Three studies were further excluded after the full text screening. The reasons for exclusion of these studies are described in the section on excluded studies.

***2: Detailed summary of the methodological quality of identified economic studies***

Five studies[26, 28, 48, 64, 68] (Frei 2014, McCall 2011, Eccles 2007, Piette 2001 and Wagner 2001 did not attempt to define what the competing alternatives (usual care) were. In terms of analytical perspective, Clancy 2007[21], although not a full economic evaluation, reported the costs covered partially from the patient perspective. The study did not report the cost of the intervention to the hospital care. The societal perspective for consideration of costs and benefit is the widest perspective adopted in an economic evaluation and only Eccles 2007[26] claimed to adopt this approach although as noted above the narrower perspective of health service and patient was in fact adopted. All other studies considered a hospital/healthcare perspective. Eccles 2007[26] did not however report the incremental analysis of costs and outcomes. The authors argued that this was because the time horizon reported was reported as not sufficient to estimate the incremental costs and outcomes. The chosen time horizon (the time period over which costs and effects are considered) for all of the partial economic were also limited, with an average of 12 months. A longer time horizon is often necessary in economic evaluations to capture appropriate relevant differences in costs and outcomes. Discounting in economic evaluation is considered necessary to adjust future costs and outcomes of an intervention to its present value. Discounting was reported only by Prezio 2014[56] at 3-6% (Prezio 2014) but would have been appropriate in all other included studies given that their stated follow-up was longer than 12 months.

Since nine studies were partial economic evaluations, important and relevant costs for each alternative were not reported. An exception to these was Adair 2013[18] which included important costs for the interventions. When estimating costs it is important to consider the resources used and the cost of each resource (their unit cost) separately[18] (Adair 2013). Few studies however reported the total costs, unit costs and level of resources utilized for the interventions. Wagner 2001[64] did not report the resource utilization and costs of staff time but did report the total costs of the intervention. McCall 2011[48] did not report the cost of the intervention and resources utilized. This is also the same for Clancy 2007[21], which reported resource utilization but not the associated costs. This study however

reported the costs paid by patients for the intervention. Frei 2014[28] only reported the level of resources used to provide the intervention but did not report the costs of the intervention. Frei 2014[28], Schechter 2008[69], Piette 2001[55], Wagner 2001[64], and Krein 2004[44] did not report the sources of the costs valuation.

With respect to conflict of interests, a potential conflict of interest was reported by all except McCall 2011[48] (McCall 2011). In summary, the full economic evaluations methodological quality was relatively good compared with the partial economic evaluations.

***3: Detailed description of the resources required to provide the intervention***

Prezio 2014[56] intervention required the use of a specially trained community health worker. The worker had seven sessions with patients with one hour of physician time for supervising the health workers. Time spent on training the workers was not reported in this study, as training was provided at no cost by local experienced sources (endocrinologist, certified diabetes educator and registered dieticians). Schechter 2008[69] reported 20 hours of training for the health educators on diabetes retinopathy and behavioural change. For every 20 hours of intervention delivered, the health workers received one hour supervision from a certified diabetes nurse educator. The health educators spent an average of five minutes to prepare for the telephone call which lasted about 20 minutes. The subjects involved received an average of 3.2 calls over the 6-month period. An additional five minutes was spent after call completion for writing notes and chart filling. Other resources were telephone charges and printing and postage of reminder letters and educational materials. The resources used in Schechter 2008[69] were similar to that of Pizzi 2015[11], except that the staff used for the telephone calls were medical assistants and there was additional two one-hour meetings with the medical assistant, health service manager and ophthalmologist. Because the personnel used in delivering the intervention in the two studies were different, it was significant in the training hours. The health educators in Schechter 2008[69] had 20 hours of training and 1 hour supervision for every 20 hour intervention delivered whereas the medical assistant had just 1 hour supervision for every 20 hour intervention and two one-hour meeting with health services managers and ophthalmologists.

In Davis 2011[104], staff, which included a dietician and nurse diabetic educator had 13 sessions (15 minutes with the nurse and four hours with health educator) broken down into three individual sessions and 10 group sessions. Only three of the group sessions were face to face with the remaining seven being video conference. Training time for staff wasn't reported, however it was noted that the nurses were trained on how to conduct the eye screening examination for patients because of the availability of the retinal camera site.

In Frijling 2002[29], where the intervention was feedback support delivered by a facilitator, 80 hours training was received by the facilitators for the programme. The facilitator conducted fifteen one-hour outreach visits to each practice, which included one GP researcher per facilitator as supervisor for the visit. The GP spent an average of 3 hours to implement the intervention/feedback support received.

In Adair 2013[18], 12 care guides, trained for two weeks were used to deliver the intervention. Two experienced nurses acted as supervisors for the care guides. The care guides visited the clinics five times on average. Four contacts were made to the clinic providers and about seven patients' contacts through the phone and two face-to-face contacts. Other resources used were furniture and equipment for the intervention.

For Frei 2014[28] the intervention resources included a 6-day training programme on diabetes treatment for the nurses. There were also two 4-hour interactive workshops for physicians and nurses.

In Krein 2004[44], the intervention resources included two days training for case managers (nurse). Twenty hours per week were spent with the patients. There was quarterly patient profiling and training was updated at two months and subsequently at six-month intervals.

In Piette 2001[68], the intervention had 13 nurses contacting patients for follow-up after an automated call assessing patient health (a total of 15 automated call for each patient). The follow-up calls lasted an average of 3.8 hours per month. No form of training was reported in this study.

Litaker 2003[46] reported training of the nurses but the duration and length of training was not reported. The nurses had an average contact time of 180 mins per patient over the 12 month follow-up period. This excluded time spent to manage problems over the telephone.

Eccles 2007[26], which had a completely different intervention to any of the other studies, reported the main resources utilized to be the costs associated with guidelines and software development. Time spent by staff for follow-up was not stated but an average of two follow-ups per patient was reported.

Overall, the bulk of the resources utilized were on staff training to deliver the intervention. For all the interventions requiring training of staff before delivery, non-health workers required more training time compared to health workers such as nurses. This was evident in Adair 2013[18] where the care guides received two weeks training and also in Frei 2014[28] where the facilitators were trained for 80 hours.

In studies that focused on diabetic retinopathy screening[11, 69] (Pizzi 2015; Schechter 2008), the main resource drivers were the staff time spent on telephone calls and costs of telephone calls. For studies that considered the process of diabetes care, resource intensity was based on the approach of delivering the interventions [18,21,22,26,28,29,44,46,48,55,56 64] (Adair 2013, Clancy 2007, Davis 2010, Eccles 2007, Frei 2014, Frijling 2002, Krein 2004, Litaker 2003, McCall 20l1, Piette 2000, Prezio 2014, Wagner 2001). In cases where patient education was used, the cost of training and supervising the personnel when not delivered by a physician was one of the major resources. The other resource was the time spent by the personnel, either by a physician or a trained health worker to educate patients. These same resources were involved when a case management approach was used. This approach involved time spent by both the physician and non-physician with patients and time spent by both the physician and non-physician together to review records and provide feedback for alignment of data.

***3: Summary of costs reported in the identified studies***

In Prezio 2014[56], the intervention costs of the physician was £48.76/hour while that of the community health worker was £12.91/hr (Prezio 2014)[56]. The opportunity costs in terms of time spent by participants was £11.51/hr and estimated as £319.90 per year. The training of the health workers was locally sourced and done at no additional cost. The direct total costs of the programme over 20 years was estimated to be £3646.10 per patient.

Pizzi 2015[11] included two different interventions. The cost of staff time for 120 patients was estimated at £501.13 for the telephone intervention while that of the mailed intervention for 117 patients was £173.17 over one month period (Pizzi 2015)[11]. The wage rate for the staff were £85.24/hr for the physician, £29.32/hr for a health services manager and £16.72/hr for a medical assistant. The cost of materials was £30.25 for the telephone intervention, while the mailed intervention was £135.46. The total cost for providing the telephone intervention to 120 patients (staff and stationeries inclusive) was £577.64 for the telephone intervention while that of the mailed intervention for 117 patients was £335.48. Thus, the total cost per patient was estimated as £4.81 and £2.87 for the telephone and mailed intervention respectively. When an appointment is made and kept, total cost per patient for telephone intervention was £7.31 and £9.47 respectively while that of the mailed intervention for appointment made and kept per patient was £7.45 and £8.83 respectively.

Schechter 2008[69] estimated the costs of health educators for telephone calls to be £14890.83, the cost of training and supervision was £2756.44 for the 305 patients (Schechter 2008)[69]. The number of staff associated with the cost was not stated. Other costs were telephone charges, which were £679.67 for 305 patients and costs of printing and mailing estimated at £465.99. There was a significant difference in the telephone cost for Schechter 2008[69] compared with the costs estimated by Pizzi 2015 (Pizzi 2015)[11]. This was because Schechter 2008[69] made up to seven attempts to contact the patient, while Pizzi[11] stopped at the third telephone attempt. Both studies reported that subsequent telephone calls after three or more attempts did not yield significant better outcomes but rather increased the costs and resources associated with the intervention.

For Adair 2013[18], the estimated cost for the compensation of 12 care guides was £375,917 over a year at the rate of £11.77/hour (Adair 2013)[18]. One guide served approximately 120 patients with a total of 1423 patients. The training of the care guides cost £2228.99. The cost of two supervisory nurses was estimated to £85,847.24, while the duration of supervision was not reported by this study. The cost of modular furniture and equipment for the twelve stations used was £79,422.81. The total direct costs of the Intervention were estimated to be £463,993.22. Therefore the total cost per patient for the intervention was £326. It was assumed that the total cost per patient would reduce to £210 assuming a care guide serves about 190 patients excluding research duties.

The original currency year of Davis 2011[67] was not reported but was assumed to be 2008/2009 based on the study period (Davis 2011)[67]. The staff cost per person was estimated to £625.25 while the costs of the other resources used was estimated at £476.35 over 12 months. The direct cost was estimated at £1101 per person. The screening examination cost was also reported as £222.97 per person.

Litaker 2003[46] original currency year was also not reported but assumed based on study year to be 1998/1999 (Litaker 2003). The estimated mean personnel costs for the intervention per month was £130.15 while the total additional personnel costs were estimated at £10281.97. However, this study did not report the costs associated with time spent on the telephone with patients while estimating personnel costs and the costs of the telephone calls itself. This reduced the observed differences in the costs per patient between the intervention (£130.15) and usual care (£90.55).

Frijling 2002[29] estimated the cost of £341.51 per practice for clinical decision making (Frijling 2002). [29]

In Eccles 2007[26] the intervention costs included the cost of developing the guidelines at £10,208, the cost of software development at £12519.36, and the cost of educational activities at £2148.11 plus the additional cost of running the system at £9964.46 (Eccles 2007).[26] In addition to these was the annual cost per patient which included staff time and consumables estimated at £68.21. The average indirect costs per patient included privately purchased items averaging £18.56, including an average cost of private consultation at £2.13, an average loss of pay because of time-off work at £3.33, an average loss of pay because of sick leave at £32.71, and an average loss in the pay of companions at £2.58. The total indirect costs per patient was £83.66.

The cost of the intervention (group visit) was bore by the patients in Clancy 2007.[21] It was reported that deposit fee of £13.40 /visit amounting to £160.60 for 12 group visits was paid by the patients (original currency year estimated to be 2003/2004) (Clancy 2007).[21]

There was insufficient details in the cost estimate for Piette 2001[68] but original currency was year was assumed to be 1999/2000 (Piette 2001).[68] A price range of but a price range of £14-£24 was reported as the estimated cost of annual automated calls.

The cost expression for each study varies, hence it is difficult to compare directly across the studies. Nevertheless, the estimated training cost differs between the few studies that reported this information. In Prezio 2014[56], training was provided at no cost (Prezio 2014)[56] while training of 12 care guides in Adair 2013[18] costed £2228.99 (Adair 2013). Supervision rate and time was not stated by Adair 2013.[18] Schechter 2008[69] gave an estimate of £2756.44 but this cost also included training and does not specify the number of health educators (Schechter 2008).[69]

Personnel costs is based on the level/status of the staff employed. This can be observed in hourly rate of the staff costs used for delivering the same intervention in Pizzi 2015 and Schechter 2008 (Pizzi 2015 and Schechter 2008)[11, 69]. Pizzi 2015[11] used medical assistants to deliver the telephone intervention while Schechter 2008[69] used health educators. This higher cost was also observed in Davis 2011 (Davis 2011).[67] This cost were incurred in Clancy 2007, Frei 2014, Krein 2004 and Litaker 2003 but the costs associated with the staff used were not reported as well (Clancy, Frei 2014, Krein 2004 and Litaker 2003).[21, 28, 44,46]

Costs of treatment and care of diabetes was reported by Prezio 2014, McCall 2011, Eccles 2007, Krein 2004 and Wagner 2001 (Prezio 2014, McCall 2011, Eccles 2007, Krein 2004 and Wagner 2001).[26, 44, 48, 56, 64] There was no obvious difference in the healthcare costs between the interventions and comparators in these studies. This was also the same when the costs at baseline and post intervention period were compared in most of all studies. Diabetes complication costs are usually future costs, hence it is difficult to identify any differences in these costs given the short-follow-up in most studies. Healthcare cost over 12 months was similar across studies reporting it. Wagner reported the cost of £1025/year (original price year assumed to be 1998/1999) (Wagner 2001)[64] while McCall[48] reported the cost of £1004.52/year (McCall 2011).[48] In some studies (Adair 2013)[18], the treatment costs increased in the intervention group when compared with the costs before the intervention period. Mean hospital charges for Adair 2013[18] were £24,114.38 for the intervention group and £24,073 for the usual care group over a 12 month follow-up period. After adjusting for baseline imbalances the study identified no evidence of any difference between groups (p=0.157). A similar finding was provided by Wagner 2001(Wagner 2001)[64], which reported total treatment costs

(median) for intervention group was £2050.65 compared with usual care group, which was £2134 over 24 months but the difference in cost was not statistically significant (p=0.79). No study except Eccles 2007[26] defined what was included in the treatment costs, making it difficult to judge how comparable data were between studies. Eccles 2007[26] estimated the annual costs of treatment to the NHS per patient for the intervention group at £181.76 for primary care visit , the cost of secondary care consultations at £247.96, cost of test/investigation at £95.83, cost of NHS pre-booked transportation at £22.61, cost of all drugs excluding insulin at £27.68, cost of insulin at £8.22. Total estimate of treatment cost per patient for intervention was £606.73 while usual care was £455.58.

McCall 2011[48] gave an estimate of £1004.52 for health insurance coverage of the patients and also no significant gross savings for the Medicare fees (McCall 2011).[48] For one of the eight health insurers, the percentage of gross saving per beneficiary per month was -1.24% (Aetna insurance, while other had between 0.40 to 0.65% monthly gross saving. Only one of the insurance company, Lifemasters had 2.67% per beneficiary, per month monthly gross savings which was not statistically tested. Prezio 2014[56] estimated the annual costs of diabetes supply for each patient to be £37.56. The price difference after intervention was not reported.

***4: Detailed summary of cost-effectiveness data***

Davis 2011[104] reported an incremental cost per QALY of £13,154 over one year for a diabetes telecare intervention compared to no intervention. However, it is unclear what tool was used to estimate QALYs. Prezio 2014[56] used an established whole disease model, the Archimedes Model simulator, to estimate the incremental cost per QALY. The Archimedes Model simulator uses an approach similar to that used in probabilistic sensitivity analysis but did not use these data to explore imprecision around the point estimates of cost-effectiveness presented. Using a discount rate of 3% and program effectiveness at 100%, the incremental cost per QALY was £73,683 over five years and £261 over 20 years for the intervention (culturally tailored diabetes education program delivered by community health worker) compared with the usual care (Prezio 2014).[56] However, the tool used to derive health state utilities use to estimate QALYs was unclear from the study report. The intervention was cost saving when discounted to 0% and the incremental cost was £3288 per QALY gained for a 20 year time horizon when a 6% discount rate was used. The sensitivity analysis carried out showed that the incremental cost per QALY results are sensitive to the program cost and effectiveness. Thus the incremental cost per QALY when the programme was only 70% and 80% programme effectiveness over 20 years was £40,492 and £15,727 respectively. When programme cost decreased by 50%, the intervention was on average both cost saving and more effective. The incremental cost per QALY was also sensitive to the age of the patient. The cost per QALY over 10 years for aged 20-34 years, 35-54 years and 55-75 years was £39,501, £38,069 and £5885 respectively.

Schechter 2008[69] also reported an incremental cost-effectiveness ratio. In this study, the unit of effectiveness was the number of Diabetes Fundus Examination (DFE) gained, which was associated with number of cases of diabetic retinopathy diagnosed (Schechter 2008).[69] The incremental cost per DFE gained for telephone intervention compared to the mailed/printed intervention was £333.19. Sensitivity analysis showed that if the telephone calls were stopped after five calls, money would have been saved and the incremental cost per DFE gained would be £274.93 (90% CI= £237-£540).

Pizzi 2015[11] reported a cost-effectiveness analysis (although described as a cost-outcome analysis in the paper) and reported an Incremental cost-effectiveness ratio for the telephone intervention was £18.77per additional patient attending a DFE compared with usual care (Pizzi 2015).[11] The ratio was not calculated for the mailed intervention because it was dominated by usual care.

## 1.4. Completed checklists for methodological quality assessment of economic evaluations (phase 1 review).

**CHEC criteria checklists**

Commented [PA1]: I thought we compressed it as a single table

| | **Adair 2013[18]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | Y |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Clancy 2007[21]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | N |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | N |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | N |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) | Y |

| | | |
|---|---|---|
| | and funder(s)? | |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Davis 2011[67]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | Y |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | unclear |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | unclear |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | Y |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Eccles 2007[26]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | N |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | Y |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | Y |
| 16 | Do the conclusions follow from the data reported? | N |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Frei 2014[28]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | N |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | N |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | N |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Frijling 2002[29]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Krein 2004[44]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | N |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | N |
| 11 | Are all outcomes measured appropriately? | N |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Litaker 2003[46]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | Y |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | Y |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | N |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **McCall 2011[48]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |

| | | |
|---|---|---|
| 2 | Are competing alternatives clearly described? | N |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | N |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | N |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | N |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | N |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Piette 2001[68]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | N |
| 3 | Is a well-defined research question posed in answerable form? | N |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | N |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | N |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Pizzi 2015[11]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |

| | | |
|---|---|---|
| 4 | Is the economic study design appropriate to the stated objective? | Y |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | Y |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | Y |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | Y |
| 14 | Are all future costs and outcomes discounted appropriately? | Y |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | Y |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Prezio 2014[56]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | Y |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | Y |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | Y |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | Y |
| 14 | Are all future costs and outcomes discounted appropriately? | Y |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | Y |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Schechter 2008[69]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | Y |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | Y |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | Y |

| | | |
|---|---|---|
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | Y |
| 8 | Are all costs measured appropriately in physical units? | Y |
| 9 | Are costs valued appropriately? | Y |
| 10 | Are all important and relevant outcomes for each alternative identified? | Y |
| 11 | Are all outcomes measured appropriately? | Y |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | Y |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | Y |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

| | **Wagner 2001[64]** | |
|---|---|---|
| 1 | Is the study population clearly described? | Y |
| 2 | Are competing alternatives clearly described? | N |
| 3 | Is a well-defined research question posed in answerable form? | Y |
| 4 | Is the economic study design appropriate to the stated objective? | N |
| 5 | Is the chosen time horizon appropriate to include relevant costs and consequences? | N |
| 6 | Is the actual perspective chosen appropriate? | Y |
| 7 | Are all important and relevant costs for each alternative identified? | N |
| 8 | Are all costs measured appropriately in physical units? | N |
| 9 | Are costs valued appropriately? | N |
| 10 | Are all important and relevant outcomes for each alternative identified? | N |
| 11 | Are all outcomes measured appropriately? | N |
| 12 | Are outcomes valued appropriately? | N |
| 13 | Is an incremental analysis of costs and outcomes of alternatives performed? | N |
| 14 | Are all future costs and outcomes discounted appropriately? | N |
| 15 | Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis? | N |
| 16 | Do the conclusions follow from the data reported? | Y |
| 17 | Does the study discuss the generalizability of the results to other settings patient/client groups? | Y |
| 18 | Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)? | Y |
| 19 | Are ethical and distributional issues discussed appropriately? | Y |

Key: Y=Yes N=No

**CHEERS checklists**

| **Adair 2013[18]** | | |
|---|---|---|
| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 176 |
| | Present the study question and its relevance for health policy or practice decisions. | 176 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 177 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 177 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | 178-179 |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | - |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | - |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | - |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | 179 |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | 179 |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; | - |

| | | |
|---|---|---|
| | extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | w65 |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | w65 |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | - |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 183 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 183 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 183 |

| **Clancy 2007[21]** | | |
|---|---|---|
| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | - |
| | Present the study question and its relevance for health policy or practice decisions. | 620 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 621 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | - |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they | 620-621 |

| | | |
|---|---|---|
| | were chosen. | |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | - |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | 620 |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | - |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | 622 |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | - |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | - |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | - |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | - |

| **Other** | | |
|---|---|---|
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 624 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 624 |

| **Davis 2011[67]** | | |
|---|---|---|
| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | Abstract, A325 |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | Abstract , A325 |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | Abstract , A325 |
| | Present the study question and its relevance for health policy or practice decisions. | 1712 of main report |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 1714 of main report |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | A325 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | A325 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | A325 |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | 1713 of main report |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | A325 |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | N/A |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported | - |

| | | |
|---|---|---|
| | costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | N/A |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | N/A |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | N/A |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | - |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | A325 |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | N/A |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | - |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | - |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 1716 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 1716 |

| **Eccles 2007[26]** | | |
|---|---|---|
| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 2 |
| | Present the study question and its relevance for health policy or practice decisions. | 2 |

| | | |
|---|---|---|
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 2 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 2 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | 4 |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 4 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | 4 |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | 3 |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | 3 |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | 3 |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | 4 |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | - |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | 8-12 |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising | If applicable, report differences in costs, outcomes, or cost-effectiveness that | - |

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| heterogeneity | can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 6, 10 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 11 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 11 |

| **Frei 2014[28]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 1040 |
| | Present the study question and its relevance for health policy or practice decisions. | 1040 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 1043 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 1040 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 1040 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | - |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | - |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | N/A |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. | - |

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| | Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | - |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
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| **Discussion** | | |
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| **Other** | | |
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| **Frijling 2002[29]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and | - |

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| | uncertainty analyses), and conclusions. | |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 837 |
| | Present the study question and its relevance for health policy or practice decisions. | 837 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 838 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 838 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 837 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
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| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
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| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 841 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 841 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | - |

| **Krein 2004[44]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 732 |
| | Present the study question and its relevance for health policy or practice decisions. | 732 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 733 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 733 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
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| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |

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| based outcomes | | |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
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| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
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| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 738 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 732 |
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| **Litaker 2003[46]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared. | Front page |

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| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 224 |
| | Present the study question and its relevance for health policy or practice decisions. | 224 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 225 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 225 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 226 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
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| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | 226 |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
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| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | - |
| Characterising | *Single study-based economic evaluation:* Describe the effects of sampling | - |

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| uncertainty | uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | 232 |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 234 |
| **Other** | | |
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| **Pizzi 2015[11]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | Front page |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | Front page |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 254 |
| | Present the study question and its relevance for health policy or practice decisions. | 254 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 254 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 254 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | 255 |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 254 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | 256 |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | 256 |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | 255 |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | 254-255 |
| | *Synthesis-based estimates:* Describe fully the methods used for | - |

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| | identification of included studies and synthesis of clinical effectiveness data. | |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | 256 |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | 256 |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | 256 |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | 256-257 |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | 256 |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | 258-259 |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | 260 |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | 258-260 |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | 258-260 |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 261-262 |
| **Other** | | |
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| **Krein 2004[44]** | | |
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| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | - |

| **McCall 2011[48]** | | |
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| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
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| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 1705 |
| | Present the study question and its relevance for health policy or practice decisions. | 1705 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 1708 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 1705 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | - |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |

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|---|---|---|
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | - |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | - |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | - |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | - |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | - |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | - |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 1712 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | - |

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| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | - |

| **Piette 2001[68]** | | |
|---|---|---|
| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 202-203 |
| | Present the study question and its relevance for health policy or practice decisions. | - |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 204 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 203 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 177 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | - |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | - |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | - |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | - |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | - |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |

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| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | - |
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| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | - |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 207 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 207 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | - |

| **Prezio 2014[56]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | 771 |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | 771 |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 772 |
| | Present the study question and its relevance for health policy or practice decisions. | 772 |
| **Methods** | | |
| Target population and | Describe characteristics of the base case population and subgroups | 772 |

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| subgroups | analysed, including why they were chosen. | |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 772 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | 772 |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 772 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | 772 |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | 772 |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | 774 |
| Measurement of effectiveness | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | 772 |
| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | - |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | - |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | 772 |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | 772 |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | 772 |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | 772-774 |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | 774 |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | 774-776 |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | 777 |
| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | 776-777 |
| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | - |

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| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | 777 |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 775 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 778 |
| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 778 |

| **Schechter 2008[69]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | 763 |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | 763 |
| **Introduction** | | |
| Background and objectives | Provide an explicit statement of the broader context for the study. | 763-764 |
| | Present the study question and its relevance for health policy or practice decisions. | 764 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 764 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 764 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | 764 |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | 764 |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | 764 |
| Discount rate | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | 765 |
| Choice of health outcomes | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | 764 |
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| | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | N/A |
| Measurement and valuation of preference based outcomes | If applicable, describe the population and methods used to elicit preferences for outcomes. | 765 |
| Estimating resources and costs | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to | 764 |

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| | opportunity costs. | |
| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | 764 |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | N/A |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | N/A |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | 765 |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | 766 |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | 765 |
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| | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | N/A |
| Characterising heterogeneity | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | 765 |
| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 767 |
| **Other** | | |
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| Conflicts of interest | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | 768 |

| **Wagner 2001[64]** | | |
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| **Section of paper** | **Component** | **Where in paper** |
| | Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared. | - |
| Abstract | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | - |
| **Introduction** | | |

| | | |
|---|---|---|
| Background and objectives | Provide an explicit statement of the broader context for the study. | 695 |
| | Present the study question and its relevance for health policy or practice decisions. | 695 |
| **Methods** | | |
| Target population and subgroups | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | 697 |
| Setting and location | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | 695-696 |
| Study perspective | Describe the perspective of the study and relate this to the costs being evaluated. | - |
| Comparators | Describe the interventions or strategies being compared and state why they were chosen. | - |
| Time horizon | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | - |
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| Currency, price date, and conversion | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | - |
| Choice of model | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | - |
| Assumptions | Describe all structural or other assumptions underpinning the decision-analytical model. | - |
| Analytical methods | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | - |
| **Results** | | |
| Study parameters | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | 697-698 |
| Incremental costs and outcomes | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | - |

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| Characterising uncertainty | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | - |
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| **Discussion** | | |
| Study findings, limitations, generalisability, and current knowledge | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | 698-699 |
| **Other** | | |
| Source of funding | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 699 |

## 1.5. References.


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