Appendix D. Risk of Bias Assessments for Included Studies

Table D1. Risk of bias evaluations and rationale

| **Author, Year**  **Trial Namea** | **Randomi-zation Method Adequate?** | **Allo-cation Conceal-ment Ad-equate?** | **Are Groups Similar at Base-line?** | **Outcome Asse-ssors Blinded?** | **Overall Attrition**  **Differential Attrition** | **Does High Attrition Rate Raise Concern for Bias?** | **Inter-vention Fidelity Ad-equate?** | **ITT Ana-lysis?**  **Appro-priate Method for Handling Missing Data?** | **Utiliz-ation Out-comes: Valid, Reliable, Con-sistent?** | **Health and Social Out-comes: Valid, Reliable, Cons-istent?** | **Risk of Bias**  **Rationale for Any High or Unclear Risk of Bias Ratings** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Albert et al., 20071 | Yes | Yes | No | NR/CND | 19% lost to follow-up; 29% died or were lost to follow-up  1.1% loss to follow-up; 6% differential attrition when counting those who either died or were lost to follow-up | Yes | Yes | Yes  No | NR/CND | NR/CND | High  Baseline characteristics not similar (more women in the usual care group, more smokers in the intervention group). Inadequate method of handling missing data (completer’s analysis). The authors did not describe how mortality and health utilization measures were ascertained. |
| Aldamiz-Echevarría Iraúrgui et al,, 20072 | Yes | Yes | Yes | NR/CND | 0%  0% | No | NR/CND | Yes  NA | Yes | Yes | Medium |

| Table D1. Risk of bias evaluations and rationale (continued) | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, Year**  **Trial Namea** | **Randomi-zation Method Adequate?** | **Allo-cation Conceal-ment Ad-equate?** | **Are Groups Similar at Base-line?** | **Outcome Asse-ssors Blinded?** | **Overall Attrition**  **Differential Attrition** | **Does High Attrition Rate Raise Concern for Bias?** | **Inter-vention Fidelity Ad-equate?** | **ITT Ana-lysis?**  **Appro-priate Method for Handling Missing Data?** | **Utiliz-ation Out-comes: Valid, Reliable, Con-sistent?** | **Health and Social Out-comes: Valid, Reliable, Cons-istent?** | **Risk of Bias**  **Rationale for Any High or Unclear Risk of Bias Ratings** |
| Angermann et al., 20123 | Yes | NR/CND | Yes | Yes | 0% for mortality and utilization outcomes; no QoL available for those who died or did not complete a follow-up phone call (58%)  NA for mortality/ utilization; unclear for QoL | No | NR/CND | Yes  Yes | Yes | Yes | Medium |
| Barth et al., 20014 | NR/CND | NR/CND | Yes | NR/CND | 0%  NA | No | NR/CND | Unclear or NR  NA | Unclear | Yes | High  High risk of selection bias; unclear how the 34 participants were recruited from the overall population. Methods used to measure utilization outcomes were not described. |
| Benatar et al., 20035 | NR/CND | NR/CND | Yes, for age, sex, race, NYHA, EF; higher propor-tions with DM, ACEI use, BB use in NTM group | NR/CND | 0% (3 ms)  0% (3 ms) | No | NR/CND | Unclear or NR  NA for 3 ms; NR beyond that | NR/CND | Yes | Unclear (utilization outcomes); Medium (QoL)  Rated unclear for utilization outcomes; ascertainment NR. Measures for QoL, psychological distress, and self-efficacy more clearly described and used validated measures. Masking of outcome assessors NR. Methods or randomization and allocation concealment NR. Although study reports that all randomized patients completed at least 3 months, no flow chart or data included to report attrition over the course of the study. Whether ITT analysis used NR. Unclear how missing data handled (and how much there was) beyond 3 months. Potential COI with senior author as developer of the hardware and software. |
| Cabezas et al., 20066 | NR/CND | NR/  CND | Yes | NR/CND | 0%; no QoL outcomes for 13% who died at 6 months  0%; 10% when including deaths at 6 months | No | NR/CND | Unclear or NR  NA | Yes | Yes | Medium |
| Dar et al., 20097 | Yes | Yes | Yes | NR/CND | 0%  0% | No | Yes | Yes  Yes | Yes | Yes | Medium |
| Davis et al., 20128 | NR/CND | NR/CND | Yes | Yes | 13%  0% | No | NR/CND | Yes  Yes | Yes | Yes | Medium |
| Dendale et al., 20129 | NR/CND | Yes | Yes | Yes | 0%  0% | No | NR/CND | Yes  NA | NR | Yes | Unclear  Unclear fidelity- study reports that 76% of the GPs logged into the website at least once during the study. Unclear if the GPs could receive patient alerts outside of the website. It is unclear how utilization outcomes were measured; no specific information is given. |
| Domingues et al., 201110 | NR/CND | NR/CND | Yes | NR/CND | 4%  3% | No | Yes | Yes  No | Yes | NA | Medium |
| Ducharme et al., 200511 | Yes | Yes | Yes | Yes for QoL, No for utilization outcomes. | 0%  0% | NA | Yes | Yes  NA | Yes | Yes | Low |
| Duffy et al., 201012 | No | No | NR/CND | NR/CND | NR/CND  NR/CND | Unclear or NR | NR/CND | Unclear or NR  NA | unclear | Yes | High  Sample characteristics not given for separate arms; in the text, noted that there were no differences. Unclear if the database used to capture healthcare utilization is comprehensive or based on only nurse input of known utilization. Control arm poorly described and received nearly as many home visits as the intervention group. |
| Dunagan et al., 200513 | Yes | NR/CND | Yes | Yes | 0% for utilization outcomes; see Risk of bias/Rationale for rating column for QoL  0% for utilization outcomes; see Risk of bias/Rationale for rating column for QoL | No | NR/CND | Yes  NA for utilization outcomes; no for QoL outcomes | Yes | Yes | Medium |
| Ekman et al., 199814 | Yes | Yes | For most characteristics, however more patients in usual care group had AF | NR/CND | 0%  NA | No | NR/CND | Yes  NA | Yes | Yes | Medium |
| Goldberg et al., 200315 | NR/CND | NR/CND | Yes | Yes | 11.4%  CND, but article reports that there was no difference between groups in % of patients who failed to complete 6 months | No | Yes | Yes  NR/CND for utilization (likely censored); completers analysis for health and social outcomes | Yes | Yes | Medium |
| Holland et al., 200716 | Yes | NR/CND | No | NR/CND | 1%  0% | No | Yes | Yes  NA | Yes | Yes | Medium |
| Jaarsma et al., 199917 | NR/CND | NR/CND | Yes | No | 5% "non-response" rate; 17% of sample died  0% for loss to follow-up | No | NR/CND | Yes  Unclear | Yes | Yes | Medium |
| Jerant et al., 200118  Jerant et al., 200319 | Yes | Yes | Yes | No | 0%  0% | No | No | Yes  NA | Yes | Yes | High  Small study (37 participants) that suffers from concerns regarding intervention fidelity. Authors note that at least one technical problem affected 76% of all telemonitoring encounters. |
| Kasper et al., 200220 | Yes | NR/CND | Yes | Yes | 0%  0% | No | Yes | Yes  NA | Yes | Yes | Low |
| Kimmelstiel et al., 200421 | NR/CND | NR/CND | Yes | Yes | 4.5% due to death at 12 weeks  NR | No | Yes | Yes  NA | Yes | Yes | Medium |
| Koelling et al., 200522 | Yes | Yes | Yes | Yes | 0.0%  0.0% | No | Yes | Yes  NA | Yes | Yes | Low |
| Kwok et al., 200723 | Yes | NR/CND | No | Yes for functional status; unclear for utilization rates | 2.8%  1.5% | No | NR/CND | Yes  NR/CND | Yes | Yes | Medium |
| Laramee et al., 200324  RCT | Yes | NR/CND | Yes, for most, but some differences for PVD, class I and II NYHA, prior CHF admis-sions, and read-mission risk factors | No | 8.7%  8.8% | No | NR/CND | Yes  No | Yes | Yes | Medium  . |
| Linne et al., 200625 | Yes | Yes | Yes, for most characteris-tics | Yes | 2.6%  1.4% | No | NR/CND | Yes  NR/CND | NR/CND | NR/CND | Unclear  Unclear risk of bias, mainly due to inadequate reporting of information to allow complete assessment of risk of measurement bias. Groups similar at baseline Unclear how missing data handled, but very few subjects had missing outcome data (2/108 and 4/122 refused to participate further in the control and intervention groups, respectively), so likely minimal potential impact. They were likely censored in the survival analysis. Unclear risk of measurement bias: authors only report that they used "an administrative system, PAS, ... to verify all-cause readmissions and deaths within 6 months from discharge." Study conducted in Sweden, and no additional information about validity and reliability of that system’s readmission and death information. |
| Liu et al., 201226 | Yes | NR/CND | Yes | Yes | 0.00%  0% | No | NR/CND | Yes  NA | Yes | Yes | Low |
| McDonald et al., 200127  McDonald et al., 200228  Ledwidge et al., 200329 | NR/CND | NR/CND | Yes | NR/CND | 0%  0% | No | NR/CND | Yes  NA | Unclear | Unclear for mortality; Yes for social outcomes | Unclear  Unclear measurement bias. Method of outcome assessment (measurement of mortality and utilization) not described and unclear. |
| Naylor et al., 200430 | Yes | Yes | Yes | Yes | 20.5%  1.4% | No | NR/CND | Yes  Yes | Yes | Yes | Low |
| Nucifora et al., 200631 | NR/CND | NR/CND | No | NR/CND | 0% lost to follow-up; 11% died  0% NA for missing data; 6% for deaths | No | NR/CND | Yes  Yes | Yes | Yes | Medium  . |
| Oddone et al., 199932 | NR/CND | NR/CND | Yes | Yes | NR/CND  NR | Unclear or NR | Yes | Unclear or NR  Unclear or NR | Yes | Yes | Medium |
| Pekmezaris et al., 201233 | Yes | NR/CND | Yes | NR/CND | 0%  0% | No | Yes | Yes  Yes | Yes | NA | Medium |
| Pugh et al., 200134 | NR/CND | NR/CND | Yes | NR/CND | 10% due to withdrew; 29% died or withdrew  1% | No | NR/CND | Unclear or NR  No | Unclear | Yes | High  Patients who withdrew or who died appear to be excluded from the readmission/ utilization analysis. Unclear if 11 patients who died had also experienced a readmission or ER visit during study. NR whether those who withdrew were contacted and asked about health care utilization. Randomization and allocation concealment not described. |
| Rainville et al., 199935 | Yes | NR/CND | No | NR/CND | 14% died; no loss to follow-up reported after randomization  0% for loss to follow-up; 17% for death | Yes | NR/CND | Unclear or NR  No | Yes | Yes | Medium |
| Rich et al., 199336 | NR/CND | NR/CND | Yes | NR/CND | 0%  0% | No | NR/CND | Unclear or NR  NA | Yes | NA | Medium |
| Rich et al., 199537 | Yes | Yes | No | NR/CND | 0%  0% | No | NR/CND | Yes  NA | Unclear | Yes | Medium |
| Riegel et al., 200238 | No | NR/CND | No | NR/CND | 0% for outcomes of interest (acute care resources)  NA | No | Yes | Unclear or NR  NA | Yes | NA | Medium |
| Riegel et al., 200439 | Yes | NR/CND | No | NR/CND | 31.8%  1.5% | Yes | Yes | Yes for utilization outcome; no for self-care/social outcomes (those were completer's analysis)  No | NR/CND | NR/CND for mortality; Yes for self-care measures | High  High risk of selection bias, measurement bias, and confounding. Over 30% of sample dropped out, high attrition; methods of handling missing data NR for utilization outcomes. Unclear how utilization outcomes were ascertained, and unclear how complete data was for utilization outcomes (focus of study on self-care and social support outcomes). Masking of outcome assessors NR. Several baseline differences between groups: fewer married in intervention group, fewer retired, fewer with stage 3/4 NYHA when collapsing those groups (57% vs. 69%), fewer with COPD and history of MI. |
| Riegel et al., 200640 | NR/CND | Yes | Yes | Yes | 0.0%  0.0% | No | Yes | Yes  NA | Yes | Yes | Medium |
| Schwarz et al., 200841 | NR/CND | NR/CND | No | NR/CND | 21% including death, nursing home and withdrawal from study; appears that mortality and utilization outcomes were available for full sample.  8% | No | Yes | Yes  Yes | Yes | Yes | Medium |
| Sethares et al., 200442 | NR/CND | NR/CND | Yes | Mixed (yes for readmis-sion, no for QoL for the inter-vention group) | 20.5%  CND | Yes | NR/CND | No  No | Yes | Yes | High  High risk of selection bias and confounding. Completers analysis, 18/88 post-randomization exclusions due to death (10) or missing data (8); analysis only included 70 subjects who did not die and not lost to follow-up. Unclear why more detailed assessments of the 10 deaths not included in analysis. No reporting of which groups the 18 post-randomization exclusions were in to allow determination of differential attrition. The |
| Sethares et al., 200442 (continued) |  |  |  |  |  |  |  |  |  |  | 10 deaths, if adequately assessed for readmission and attributed to appropriate study groups, could significantly change results, since only 6 people readmitted in intervention group and 12 in control group. Inadequate handling of missing data; methods of randomization and allocation concealment NR |
| Stewart et al., 199843 | No | NR/CND | Yes | NR/CND | NR/CND; appears to be mortality and utilization outcomes on all participants  NA | Unclear or NR | Yes | Yes  NA | Yes | Yes | Medium |
| Stewart et al., 199944 | Yes | Yes | Yes | Yes | NR/CND; 10% of the intervention group withdrew and unclear how missing data handled  10% of intervention group withdrew; attrition NR for usual care group | No | NR/CND | Yes  Unclear | Yes | Yes | Medium |
| Stromberg et al., 200345 | Yes | Yes | Yes, for most (but more with HTN in intervene-tion group and fewer with DM) | Yes | 0% lost to follow-up; 15% died before 3 months  0% lost to follow-up; 18% for deaths by 3 months | No | Yes | Yes  Yes | Yes | Yes | Low  Patients who died were censored in analysis. |
| Thompson et al., 200546 | NR/CND | NR/CND | No | Yes | 0% for utilization outcomes; 57% for QoL  0% for utilization outcomes; NR/CND for QoL | Yes (QoL only) | Yes | Yes  No (no for QoL only) | Yes | Yes | High  Study used cluster randomization according to treating GP, resulting in important baseline differences between groups; analysis done at patient level. Higher proportion of diabetes (27% vs. 14%) and lower proportion of medication use for ACEIs, BBs, Aspirin, and warfarin at time of hospital discharge for control group than intervention group. Thus, control group at higher risk of readmissions and death than intervention group. QoL outcome data have high risk of bias due to very high attrition, with fewer than half of subjects returning questionnaire. |
| Triller et al., 200847 | Yes | Yes | Yes | NR/CND | 0%  NA | No | No | Yes  NA | Unclear | No | Unclear  No information provided on method used to measure readmission and other utilization outcomes. Neither type of QoL measured nor QoL scale used are described, making validity of those data unclear. Only 53% of sample received full 3 visits from a pharmacist. Unclear fidelity. |
| Tsuyuki et al., 200448 | Yes | NR/CND | Yes | No | 2.5%  0.8% | No | NR/CND | Yes  NR/CND | Yes | Yes | Medium |
| Wakefield et al., 200849  Wakefield et al., 200950 | NR/CND | NR/CND | Yes | NR/CND | 0% for readmission and mortality | No | Unclear | Yes  NA | Yes | Yes | Medium |
| Woodend et al., 200851 | NR/CND | NR/CND | No | NR/CND | NR/CND at eligible time points  NR/CND | Unclear or NR | NR/CND | Yes  NR/CND | No | unclear | High  Fewer patients in telemonitoring group had angina compared with usual care. Loss to follow-up and death reported for 12 months, unclear if these were included in data analysis for earlier time points or excluded. At 12 months, 22% of the intervention group also received home visits. Utilization outcomes assessed by self-report only. Not clear if attempt made to account for utilization among those lost to follow-up or who were later found to have died. |

a Three studies involved crossover designs or contamination: Duffy et al., 2010,12 Pekmezaris et al., 201233 and Woodend et al., 2008.51

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; BB = beta-blocker; CND = cannot determine; COI = conflict of interest; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; ER = emergency room; GP = general practitioner; CHF = congestive heart failure; HTN = hypertension; ITT = intent-to-treat; MI = myocardial infarction; Ms = months; NA = not applicable; NR = not reported; NTM = no telemonitoring; NYHA = New York Heart Association functional classification; PVD = peripheral vascular disease; QoL = quality of life; RoB = risk of bias; vs. = versus

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