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Supplementary Table 1: Description of included studies: title, study question, research period, sponsorship

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author, Year** | **Title** | **Study question /aim** | **Research period** | **Sponsor** |
| Burch, 20211 | Increased Quality Of Life Among Newly Diagnosed Patients With Heart Failure With Reduced Ejection Fraction in the Months After Initiation of Guideline-Directed Medical Therapy and Wearable Cardioverter Defibrillator Prescription | How do patient-reported outcomes change in newly diagnosed patients with heart failure and reduced EF whom a WCD is prescribed? | March 1st, 2017 – June 15th, 2021 | ZOLL Medical Corporation |
| Garcia, 2021 | Wearable cardioverter-defibrillator in patients with a transient risk of sudden cardiac death: the WEARIT-France cohort study | Assessing the compliance and acceptability next to effectiveness and safety of WCD use | May 2014 – December 2016 and January 2017 – March 2018 | ZOLL and French National Institute of Health and Medical Research |
| Lackermaier, 2018 | Impairment of Quality of Life among Patients with Wearable Cardioverter Defibrillator Therapy (LifeVest®): A Preliminary Study | Assessing the impact of WCD-therapy on QoL | March 2012 – February 2016 | no information |
| VEST Trial, 20202 | The Impact of the Wearable Cardioverter-Defibrillators on Quality of Life: Insights from the VEST Trial | Does WCD affect patient-reported QoL, including depression, anxiety, physical activity, and various QoL measures? | July 2008 – April 2017 | National Institutes of Health, ZOLL Medical |
| Weiss, 2019 | Anxiety, depression and quality of life in acute high risk cardiac disease patients eligible for wearable cardioverter defibrillator: Results from the prospective multicenter CRED-registry | Assess the impact of WCD on acute high risk cardiac patients on psychological distress and QoL | May 1st, 2014 – December 31st, 2017 | University of Cologne, ZOLL Medical Corporation |

1 plus additional information from study registry (NCT03016754)

2 Olgin, 2018 “Wearable Cardioverter–Defibrillator after Myocardial Infarction”; Cheung, 2020 “The Impact of the Wearable Cardioverter-Defibrillators on Quality of Life: Insights from the VEST Trial”

EF – Ejection Fraction, QoL – Quality of Life, WCD – Wearable Cardioverter Defibrillator

Supplementary Table 2: Description of included studies: number of countries / centers, recruitment method, inclusion criteria, exclusion criteria

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author, Year** | **Number of countries / centers** | **Recruitment method** | **Inclusion criteria** | **Exclusion criteria** |
| Burch, 20211 | 67 centers in Austria, France, Germany and the US (15 centers in US or Germany were prospectively selected to collect patient-reported QoL) | not reported | - Patients (≥18 years) who were prescribed the WCD ≤ 10 days post-discharge after hospitalization for a primary reason of new onset HF (≤30 days since first HF hospitalization), with ischemic or nonischemic cardiomyopathy  - EF ≤ 35% during index hospitalization | - active unipolar pacemaker  - first hospitalization for HF that occurred more than 30 days before enrollment  - psychological or physical condition that would inhibit interaction with the wearable defibrillator |
| Garcia, 2021 | 88 centers in France | Patients who had completed the use of WCD and patients receiving a WCD during clinical appointment received an offering for participation | Patients receiving a WCD agreeing to participate in the study | no information |
| Lackermaier, 2018 | single center in Germany (in-patient and out-patient) | consecutive | Patients with high risk for SCD who were not eligible for ICD therapy at the time of diagnosis | no information |
| VEST Trial, 20202 | 107 (108) centers: 75 US (originally 76: 1 was dismissed and the participants were excluded), 24 Poland, 6 Germany, 2 Hungary | hospitalized patients | - Patients identified in the hospital with a diagnosis of an acute MI (STEMI or Non-STEMI) and enrollment within 7 days after discharge  - LVEF ≤35%, determined at the following time point:  a) if no PCI, ≥8 hours after MI  b) if acute PCI, ≥8 hours after PCI  c) if CABG is planned (before or within 7 days of discharge), most recent assessment at least 48 hours post CABG.  - Age >18 years | - Existing ICD or indication for an ICD - Existing unipolar pacemakers/leads - clinically significant valve disease - Chronic renal failure requiring hemodialysis after hospital discharge - Chest circumference too small/large for WCD - Participants discharged to a skilled nursing facility with anticipated stay >7 days - Pregnancy - Inability to consent  - Any condition/circumstance that makes the participant unsuitable for the study |
| Weiss, 2019 | 5 centers as part of the “Cologne registry of external defibrillation” (CRED) in Cologne, Germany | consecutive patients screening for eligibility in registry centers with consent | Increased risk of ventricular arrhythmias and SCD  - ICD explantation / ICD implantation is postponed due to ventricular thrombus  - first diagnosis of HF with reduced EF (EF<35%) just starting disease modifying therapy, or first diagnosis of left-ventricular dysfunction (EF<35%) due to disease with high likelihood of recovery such as myocarditis, peripartum cardiomyopathy or takotsubo cardiomyopathy  - ischemic cardiomyopathy with EF<35% in the setting of acute MI and/or revascularization with percutaneous coronary intervention or coronary artery bypass. | - age <18 Years  - missing consent  - severe language or intellectual deficits precluding an interview on medical history and psychological distress measures |

1 plus additional information from study registry (NCT03016754)

2 Olgin, 2018 “Wearable Cardioverter–Defibrillator after Myocardial Infarction”; Cheung, 2020 “The Impact of the Wearable Cardioverter-Defibrillators on Quality of Life: Insights from the VEST Trial”

CABG – Coronary Artery Bypass Graft, EF – Ejection Fraction, HF – Heart Failure, ICD – implantable Cardioverter Defibrillator, LVEF – Left Ventricular Ejection Fraction, MI – Myocardial Infarction, PCI – Percutaneous Coronary Intervention, QoL – Quality of Life, SCD – Sudden Cardiac Ceath, STEMI – Segment Elevation Myocardial Infarction, US – United States, WCD – Wearable Cardioverter Defibrillator

Supplementary Table 3: Inclusion and exclusion criteria

|  |  |
| --- | --- |
| **Inclusion criteria** | **Exclusion criteria** |
| Patients ≥ 18 years and prescribed with a WCD | Patients <18 years |
|  | Unsuitable publication type |
|  | Study questioning did not contain a WCD therapy or study did not report PRO outcome |

PRO: patient reported outcomes, WCD – wearable cardioverter defibrillator

Supplementary Table 4: Publication excluded in full text selection step

|  |  |
| --- | --- |
| **Publication** | **Reason for exclusion** |
| Barsheshet A, Kutyifa V, Vamvouris T, Moss A, Biton Y, Chen L et al. Study of the wearable cardioverter defibrillator in advanced heart-failure patients (SWIFT). J Cardiovasc Electrophysiol. 2017;28:778–784. | No PRO endpoints reported |
| Cheung CC, Olgin JE, Lee BK. Wearable cardioverter-defibrillators: A review of evidence and indications. Trends Cardiovasc Med. 2021;31(3):196-201. | No reference for further relevant primary studies |
| Delle Donna P, Petrovic L, Nasir U, Ahmed A, Suero-Abreu GA. Phantom Shocks Associated With a Wearable Cardioverter Defibrillator. J Med Cases. 2021;12(2):49-53. | Study question inappropriate |
| Ettinger S, Stanak M, Szymański P, Wild C, Tandara Haček R, Erčević D, et al. Wearable cardioverter defibrillators for the prevention of sudden cardiac arrest: a health technology assessment and patient focus group study. Med Devices (Auckl). 2017;10:257-71. | Method for PRO assessment inadequate |
| Healy CA, Carrillo RG. Wearable cardioverter-defibrillator for prevention of sudden cardiac death after infected implantable cardioverter-defibrillator removal: A cost-effectiveness evaluation. Heart Rhythm. 2015;12(7):1565-73. | Cost-effectiveness study, no reference for further relevant primary studies |
| Jiang X, Ming WK, You JHS. Potential cost-effectiveness of wearable cardioverter-defibrillator for patients with implantable cardioverter-defibrillator explant in a high-income city of China. J Cardiovasc Electrophysiol. 2019;30(11):2387-96. | Cost-effectiveness study, no reference for further relevant primary studies |

Supplementary Table 5: Search history of the systematic literature search in PubMed

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Database | | Medline | | |
| Interface | | Pubmed (https://pubmed.ncbi.nlm.nih.gov/advanced/) | | |
| Date of search | | 22nd of February 2022 | | |
| Time span | | no limits | | |
| Filters | | none | | |
| # | Search term | | Search details | Results |
| 1 | wcd OR wearable defibrillator OR wearable cardiac defibrillator OR wearable cardioverter defibrillator OR Lifevest OR Life Vest OR external defibrillator jacket OR defibrillator vest OR portable cardioverter OR portable defibrillator OR mobile cardioverter OR mobile defibrillator | | "wcd"[All Fields] OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("cardiacs"[All Fields] OR "heart"[MeSH Terms] OR "heart"[All Fields] OR "cardiac"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR "Lifevest"[All Fields] OR (("life"[MeSH Terms] OR "life"[All Fields]) AND "Vest"[All Fields]) OR (("defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR ("external"[All Fields] AND "defibrillator"[All Fields]) OR "external defibrillator"[All Fields]) AND ("jacket"[All Fields] OR "jacketed"[All Fields] OR "jacketing"[All Fields] OR "jackets"[All Fields])) OR (("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields]) AND "Vest"[All Fields]) OR (("portability"[All Fields] OR "portable"[All Fields] OR "portables"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields])) OR (("portability"[All Fields] OR "portable"[All Fields] OR "portables"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("mobile"[All Fields] OR "mobiles"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields])) OR (("mobile"[All Fields] OR "mobiles"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) | 1,153 |
| 2 | patient-related outcome OR PRO OR patient-reported outcome OR Quality of life OR QoL OR patient related outcome OR patient reported outcome | | ("patient-related"[All Fields] AND ("outcome"[All Fields] OR "outcomes"[All Fields])) OR ("pract radiat oncol"[Journal] OR "pro"[All Fields]) OR ("patient reported outcome measures"[MeSH Terms] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields] AND "measures"[All Fields]) OR "patient reported outcome measures"[All Fields] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields]) OR "patient reported outcome"[All Fields]) OR ("quality of life"[MeSH Terms] OR ("quality"[All Fields] AND "life"[All Fields]) OR "quality of life"[All Fields]) OR "QoL"[All Fields] OR (("patient s"[All Fields] OR "patients"[MeSH Terms] OR "patients"[All Fields] OR "patient"[All Fields] OR "patients s"[All Fields]) AND ("family"[MeSH Terms] OR "family"[All Fields] OR "relation"[All Fields] OR "relatability"[All Fields] OR "relatable"[All Fields] OR "related"[All Fields] OR "relates"[All Fields] OR "relating"[All Fields] OR "relational"[All Fields] OR "relations"[All Fields]) AND ("outcome"[All Fields] OR "outcomes"[All Fields])) OR ("patient reported outcome measures"[MeSH Terms] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields] AND "measures"[All Fields]) OR "patient reported outcome measures"[All Fields] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields]) OR "patient reported outcome"[All Fields]) | 1,139,199 |
| 3 | #1 AND #2 | | ("wcd"[All Fields] OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("cardiacs"[All Fields] OR "heart"[MeSH Terms] OR "heart"[All Fields] OR "cardiac"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("wearability"[All Fields] OR "wearable"[All Fields] OR "wearables"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR "Lifevest"[All Fields] OR (("life"[MeSH Terms] OR "life"[All Fields]) AND "Vest"[All Fields]) OR (("defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR ("external"[All Fields] AND "defibrillator"[All Fields]) OR "external defibrillator"[All Fields]) AND ("jacket"[All Fields] OR "jacketed"[All Fields] OR "jacketing"[All Fields] OR "jackets"[All Fields])) OR (("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields]) AND "Vest"[All Fields]) OR (("portability"[All Fields] OR "portable"[All Fields] OR "portables"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields])) OR (("portability"[All Fields] OR "portable"[All Fields] OR "portables"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields])) OR (("mobile"[All Fields] OR "mobiles"[All Fields]) AND ("cardiovert"[All Fields] OR "cardioverted"[All Fields] OR "cardioverters"[All Fields] OR "cardioverting"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "cardioverter"[All Fields])) OR (("mobile"[All Fields] OR "mobiles"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields]))) AND (("patient-related"[All Fields] AND ("outcome"[All Fields] OR "outcomes"[All Fields])) OR ("pract radiat oncol"[Journal] OR "pro"[All Fields]) OR ("patient reported outcome measures"[MeSH Terms] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields] AND "measures"[All Fields]) OR "patient reported outcome measures"[All Fields] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields]) OR "patient reported outcome"[All Fields]) OR ("quality of life"[MeSH Terms] OR ("quality"[All Fields] AND "life"[All Fields]) OR "quality of life"[All Fields]) OR "QoL"[All Fields] OR (("patient s"[All Fields] OR "patients"[MeSH Terms] OR "patients"[All Fields] OR "patient"[All Fields] OR "patients s"[All Fields]) AND ("family"[MeSH Terms] OR "family"[All Fields] OR "relation"[All Fields] OR "relatability"[All Fields] OR "relatable"[All Fields] OR "related"[All Fields] OR "relates"[All Fields] OR "relating"[All Fields] OR "relational"[All Fields] OR "relations"[All Fields]) AND ("outcome"[All Fields] OR "outcomes"[All Fields])) OR ("patient reported outcome measures"[MeSH Terms] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields] AND "measures"[All Fields]) OR "patient reported outcome measures"[All Fields] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields]) OR "patient reported outcome"[All Fields])) | 203 |

Supplementary Table 6: Search history of the systematic literature search in Cochrane

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Database | | Cochrane Library | | |
| Interface | | https://www.cochranelibrary.com/ | | |
| Date of search | | 22nd of February 2022 | | |
| Time span | | no limits | | |
| Filters | | none | | |
| # | Search term | | Filters | Results |
| 1 | (wcd OR wearable defibrillator OR wearable cardiac defibrillator OR wearable cardioverter defibrillator OR Lifevest OR Life Vest OR external defibrillator jacket OR defibrillator vest OR portable cardioverter OR portable defibrillator OR mobile cardioverter OR mobile | | Limits | 184 |
| 2 | Patient-related outcome OR PRO OR patient-reported outcome OR Quality of life OR QoL OR patient related outcome OR patient reported outcome | | Limits | 306.771 |
| 3 | #1 AND #2 | | Limits | 99 |

Supplementary Table 7: Quality assessment of the randomized controlled trial of Olgin et al., 20181

|  |  |  |  |
| --- | --- | --- | --- |
| **Kriterien zur Beurteilung von RCTs** | **Ja** | **Nein** | **Unklar** |
| **Selektion** | | | |
| Wurde eine adäquate Methode der Randomisierung  verwendet, um die Studienteilnehmer/innen  unterschiedlichen Behandlungsgruppen zuzuteilen? | x/x |  |  |
| War die Geheimhaltung der Randomisierungssequenz  gewährleistet? (allocation concealment) |  |  | x/x |
| **Vergleichbarkeit** | | | |
| Waren die Behandlungsgruppen nach der Randomisierung  ähnlich in Bezug auf wesentliche prognostische  Merkmale oder Confounder? | x/x |  |  |
| Waren die Studienteilnehmer/innen verblindet? |  | x/x |  |
| Waren jene Personen, die die Intervention verabreichten,  verblindet? |  | x/x |  |
| Waren jene Personen, die die Endpunkte erhoben,  verblindet? |  | x/x |  |
| Erhielten alle Studiengruppen außer der zu untersuchenden  Intervention identische Behandlungen? | x/x |  |  |
| **Endpunkte** | | | |
| Wurden die Endpunkte in allen Behandlungsgruppen  zum selben Zeitpunkt erhoben? | x/x |  |  |
| War die allgemeine Drop-out-Rate geringer als 20 %? | x/x |  |  |
| War die differenzielle Drop-out-Rate zwischen den  Studiengruppen geringer als 15 Prozentpunkte? | x/x |  |  |
| Wurde eine Intention-to-treat-(ITT-)Analyse  durchgeführt und war diese korrekt? | x/x |  |  |
| Kann angenommen werden, dass alle erhobenen  Endpunkte auch berichtet wurden? | x/x |  |  |
| **Beurteilung des Bias-Risikos** | **Gering** | **Unklar** | **Hoch** |
| x/x |  |  |

1A translation of the checklist can be found in Supplementary Table 12

x/x: Answer Reviewer 1 / Answer Reviewer 2

Source Checklist: Ludwig Boltzman-Institut. Methodenhandbuch für Health Technology Assessment Version 1.2012. Wien: Gesundheit Österreich GmbH; 2012. Available from: <https://hta.lbg.ac.at/uploads/tableTool/UllCmsPage/gallery/Methodenhandbuch.pdf.>

Supplementary Table 8: Quality assessment of the comparative prospective study of Weiss et al., 20191

|  |  |  |  |
| --- | --- | --- | --- |
| **Kriterien zur Beurteilung von Kohortenstudien** | **Ja** | **Nein** | **Unklar** |
| **Selektion** | | | |
| Wurden die Studiengruppen aus derselben Population  und während derselben Zeitperiode rekrutiert? |  |  | x/x |
| Wurde durch die Autoren ausgeschlossen, dass  ein definierter Endpunkt bereits zu Studienbeginn  vorhanden war? | x/x |  |  |
| Wurden Interventionen in allen Gruppen  auf gleiche Art und Weise beurteilt? | x/x |  |  |
| **Vergleichbarkeit** | | | |
| Ist die Verteilung der prognostischen Faktoren  zwischen den Gruppen ausreichend beschrieben? | x/x |  |  |
| Ist die Verteilung der prognostischen Faktoren zwischen den Gruppen ähnlich? |  | x/x (higher rate of anxiety in WCD group) |  |
| **Endpunkte** | | | |
| Wurden Endpunkte auf dieselbe Art und verblindet beurteilt? |  | x/x no blinding in study; assessment comparable |  |
| Wurden potenzielle Confounder in der statistischen Auswertung berücksichtigt? |  |  | x/x |
| War die Studienlaufzeit adäquat und für alle Gruppen identisch? | x/x |  |  |
| War die allgemeine Drop-out-Rate geringer als 20%? |  | x/x |  |
| War die differenzielle Drop-out-Rate zwischen den  Studiengruppen geringer als 15 Prozentpunkte? |  | x/x |  |
| **Beurteilung des Blas-Risikos** | **Gering** | **Unklar** | **Hoch** |
|  |  | x/x |

1A translation of the checklist can be found in Supplementary Table 13

x/x: Answer Reviewer 1 / Answer Reviewer 2

Source Checklist: Ludwig Boltzman-Institut. Methodenhandbuch für Health Technology Assessment Version 1.2012. Wien: Gesundheit Österreich GmbH; 2012. Available from: <https://hta.lbg.ac.at/uploads/tableTool/UllCmsPage/gallery/Methodenhandbuch.pdf.>

Supplementary Table 9: Quality assessment of the non-comparative retrospective study of Burch et al., 2021

|  |  |
| --- | --- |
| **Question** | **Reviewer 1 / Reviewer 2** |
| 1. Is the hypothesis/aim/objective of the study stated clearly in the abstract, introduction, or methods section? | Yes / Yes |
| 2. Are the characteristics of the participants included in the study described? | Yes / Yes |
| 3. Were the cases collected in more than one centre? | Yes / Yes |
| 4. Are the eligibility criteria (inclusion and exclusion criteria) for entry into the study explicit and appropriate? | Yes / Yes |
| 5. Where the participants recruited consecutively? | uncertain / uncertain |
| 6. Did participants enter the study at a similar point in the disease? | Yes / Yes |
| 7. Was the intervention clearly described in the study? | No / No |
| 8. Were additional interventions (co-interventions) clearly reported in the study? | Yes / Yes |
| 9. Are the outcome measures clearly defined in the introduction or methods section? | Yes / Yes |
| 10. Were relevant outcomes appropriately measured with objective and/or subjective methods? | Yes / Yes |
| 11. Were outcomes measured before and after intervention? | Yes / Yes |
| 12. Were the statistical tests used to assess the relevant outcome appropriate? | Yes / Yes |
| 13. Was the length of follow-up reported? | Yes / Yes |
| 14. Was the loss to follow-up reported? | Yes / Yes |
| 15. Does the study provide estimates of the random variability in the data analysis of relevant outcomes? | Yes / Yes  (Mainly graphically) |
| 16. Are adverse events reported? | No / No |
| 17. Are the conclusion of the study supported by results? | Yes / Yes |
| 18. Are both competing interests and sources of support for the study reported? | Yes / Yes |

Source Checklist: Moga C, Guo B, Schopflocher D, Harstall C Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique. Edmonton AB: Institute of Health Economics 2012

Supplementary Table 10: Quality assessment of the non-comparative pro- and retrospective study of Garcia et al., 2021

|  |  |
| --- | --- |
| **Question** | **Reviewer 1 / Reviewer 2** |
| 1. Is the hypothesis/aim/objective of the study stated clearly in the abstract, introduction, or methods section? | No / No (not clearly stated for acceptability) |
| 2. Are the characteristics of the participants included in the study described? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 3. Were the cases collected in more than one centre? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 4. Are the eligibility criteria (inclusion and exclusion criteria) for entry into the study explicit and appropriate? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 5. Where the participants recruited consecutively? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 6. Did participants enter the study at a similar point in the disease? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 7. Was the intervention clearly described in the study? | Yes / Yes |
| 8. Were additional interventions (co-interventions) clearly reported in the study? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 9. Are the outcome measures clearly defined in the introduction or methods section? | No / No |
| 10. Were relevant outcomes appropriately measured with objective and/or subjective methods? | Yes / Yes |
| 11. Were outcomes measured before and after intervention? | No / No |
| 12. Were the statistical tests used to assess the relevant outcome appropriate? | Yes / Yes |
| 13. Was the length of follow-up reported? | No / No |
| 14. Was the loss to follow-up reported? | No / No (not stated for subsample that answered questionnaire) |
| 15. Does the study provide estimates of the random variability in the data analysis of relevant outcomes? | No / No (not stated for subsample that answered questionnaire) |
| 16. Are adverse events reported? | Yes / Yes  (for total study) |
| 17. Are the conclusion of the study supported by results? | uncertain / uncertain (not clearly stated for subsample that answered questionnaire) |
| 18. Are both competing interests and sources of support for the study reported? | Yes / Yes |

Source Checklist: Moga C, Guo B, Schopflocher D, Harstall C Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique. Edmonton AB: Institute of Health Economics 2012

Supplementary Table 11: Quality assessment of the non-comparative retrospective study of Lackermair et al., 2021

|  |  |  |
| --- | --- | --- |
| **Question** | **Reviewer 1 / Reviewer 2** | |
| 1. Is the hypothesis/aim/objective of the study stated clearly in the abstract, introduction, or methods section? | | No / No |
| 2. Are the characteristics of the participants included in the study described? | | Yes / Yes |
| 3. Were the cases collected in more than one centre? | | No / No |
| 4. Are the eligibility criteria (inclusion and exclusion criteria) for entry into the study explicit and appropriate? | | No / No |
| 5. Where the participants recruited consecutively? | | Yes / Yes |
| 6. Did participants enter the study at a similar point in the disease? | | n. r. / n. r. |
| 7. Was the intervention clearly described in the study? | | No / No |
| 8. Were additional interventions (co-interventions) clearly reported in the study? | | Yes / Yes |
| 9. Are the outcome measures clearly defined in the introduction or methods section? | | No / No |
| 10. Were relevant outcomes appropriately measured with objective and/or subjective methods? | | No / No |
| 11. Were outcomes measured before and after intervention? | | No / No |
| 12. Were the statistical tests used to assess the relevant outcome appropriate? | | Yes / Yes |
| 13. Was the length of follow-up reported? | | No / No |
| 14. Was the loss to follow-up reported? | | No / No |
| 15. Does the study provide estimates of the random variability in the data analysis of relevant outcomes? | | No / No |
| 16. Are adverse events reported? | | No / No |
| 17. Are the conclusion of the study supported by results? | | Yes / Yes |
| 18. Are both competing interests and sources of support for the study reported? | | No / No |

Source Checklist: Moga C, Guo B, Schopflocher D, Harstall C Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique. Edmonton AB: Institute of Health Economics 2012

n.r.: not reported

Supplementary Table 12: Translation of terms of checklist for randomized controlled trials

|  |  |
| --- | --- |
| **German** | **English** |
| Kriterien zur Beurteilung von RCTs | Criteria for the quality assessment of RCTs |
| ja | yes |
| nein | no |
| unklar | unclear |
| Selektion | selection |
| Wurde eine adäquate Methode der Randomisierung  verwendet, um die Studienteilnehmer/innen  unterschiedlichen Behandlungsgruppen zuzuteilen? | Was the method of randomization for the allocation of participants into different study groups adequate? |
| War die Geheimhaltung der Randomisierungssequenz  gewährleistet? (allocation concealment) | Was the allocation concealment ensured? |
| Vergleichbarkeit | Comparability |
| Waren die Behandlungsgruppen nach der Randomisierung  ähnlich in Bezug auf wesentliche prognostische  Merkmale oder Confounder? | Were the study groups similar in terms of prognostic factors or confounders after randomization? |
| Waren die Studienteilnehmer/innen verblindet? | Were the participants blinded? |
| Waren jene Personen, die die Intervention verabreichten,  verblindet? | Were those individuals, who administered the intervention, blinded? |
| Waren jene Personen, die die Endpunkte erhoben,  verblindet? | Were those individuals, who collected data on outcomes, blinded? |
| Erhielten alle Studiengruppen außer der zu untersuchenden  Intervention identische Behandlungen? | Did all study groups receive identical treatment apart from the intervention under investigation? |
| Endpunkte | Outcomes |
| Wurden die Endpunkte in allen Behandlungsgruppen  zum selben Zeitpunkt erhoben? | Was outcome data collected at the same time in all study groups? |
| War die allgemeine Drop-out-Rate geringer als 20 %? | Was the general drop-out rate below 20%? |
| War die differenzielle Drop-out-Rate zwischen den  Studiengruppen geringer als 15 Prozentpunkte? | Was the differential drop-out rate between study arms lower than 15 percentage points? |
| Wurde eine Intention-to-treat-(ITT-)Analyse  durchgeführt und war diese korrekt? | Was an intention-to-treat (ITT-) analysis performed correctly? |
| Kann angenommen werden, dass alle erhobenen  Endpunkte auch berichtet wurden? | Can it be assumed that all outcome data collected is also reported? |
| Beurteilung des Bias-Risikos | Assessment of risk of bias |
| Gering | low |
| Hoch | high |

Supplementary Table 13: Translation of terms of checklist for comparative cohort study

|  |  |
| --- | --- |
| **German** | **English** |
| Kriterien zur Beurteilung von Kohortenstudien | Criteria for the quality assessment of cohort studies |
| ja | yes |
| nein | no |
| unklar | unclear |
| Selektion | selection |
| Wurden die Studiengruppen aus derselben Population  und während derselben Zeitperiode rekrutiert? | Were the study arms recruited from the same population and during the same period? |
| Wurde durch die Autoren ausgeschlossen, dass  ein definierter Endpunkt bereits zu Studienbeginn  vorhanden war? | Did the authors eliminate the possibility of having defined outcomes at the commencement of the study? |
| Wurden Interventionen in allen Gruppen  auf gleiche Art und Weise beurteilt? | Were interventions assessed equally among all study arms? |
| Vergleichbarkeit | Comparability |
| Ist die Verteilung der prognostischen Faktoren  zwischen den Gruppen ausreichend beschrieben? | Is the distribution of prognostic factors between groups adequately described? |
| Ist die Verteilung der prognostischen Faktoren zwischen den Gruppen ähnlich? | Is the distribution of prognostic factors similar between groups? |
| Endpunkte | Outcomes |
| Wurden Endpunkte auf dieselbe Art und verblindet beurteilt? | Were outcomes assessed equally and was the assessment blinded? |
| Wurden potenzielle Confounder in der statistischen Auswertung berücksichtigt? | Were potential confounders considered in the statistical analysis? |
| War die Studienlaufzeit adäquat und für alle Gruppen identisch? | Was the study period adequately chosen and identical for all study arms? |
| War die allgemeine Drop-out-Rate geringer als 20%? | Was the general drop-out rate below 20%? |
| War die differenzielle Drop-out-Rate zwischen den  Studiengruppen geringer als 15 Prozentpunkte? | Was the differential drop-out rate between study arms lower than 15 percentage points? |
| Beurteilung des Bias-Risikos | Assessment of risk of bias |
| Gering | low |
| Hoch | high |