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## **The impact of psychoeducational interventions on the outcomes of caregivers of patients with heart failure: A systematic review & Meta-analysis.**

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1 **Title**

2 The impact of psychoeducational interventions on the outcomes of caregivers of patients with heart  
3 failure: A systematic review and meta-analysis.

4

5 **Abstract**

6

7 **Background:** Heart failure is a global health care problem that causes a significant economic burden.  
8 Despite medical advancements, its prognosis remains poor as many patients with heart failure  
9 experience symptoms that negatively impact Quality of Life. Caregivers are often responsible for  
10 helping and supporting family members manage their heart failure symptoms at home. In addition to  
11 managing their own medical problems and maintaining social and personal lives, significant burden  
12 and stress can occur. At present, caregivers receive little guidance or information to support them in  
13 their caregiving role.

14

15 **Objectives:** This review aims to determine the impact of psychoeducational interventions on the  
16 outcomes of caregivers of heart failure patients.

17

18 **Design:** Systematic review and meta-analysis.

19

20 **Data source:** Five electronic databases: PsycINFO, Medline, CINAHL Plus, EMBASE and SCOPUS  
21 were searched from June 2007 to August 2019.

22

23 **Review methods:** The conduct and reporting of this review was based on the Cochrane Handbook  
24 for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews  
25 and Meta-Analyses. The Cochrane Risk of Bias Tool was used to assess the risk of bias among  
26 randomised controlled trials, and the Newcastle Ottawa Scale was used to assess risk of bias in one  
27 quasi-experimental study.

28

29 **Results:** Ten articles met the inclusion criteria, consisting of seven studies, with a total sample size of  
30 953 participants. The pooled result from two studies, conducted in America and China, reported that  
31 psychoeducational interventions significantly reduced depression at six months' follow-up (SMD -0.82;  
32 95% CI -1.17 to -0.47;  $p=0.73$ ,  $I^2=0\%$ ). The pooled result from two studies conducted in Sweden and  
33 Taiwan showed a significant improvement in heart failure knowledge at six months' follow-up (SMD  
34 0.97; 95% CI 0.70 to 1.25;  $p<0.00001$ ,  $I^2=0\%$ ). Finally, pooled results from three studies conducted  
35 in Sweden, China and Taiwan found a significant improvement in Quality of Life at 3 months' follow-  
36 up (SMD 0.25; 95% CI 0.25 to 0.48;  $p=0.03$ ). The three most common intervention components  
37 included: group based educational sessions, telemonitoring and telephone support, and written  
38 resources.

39

40 **Conclusions:** There was no specific type of psychoeducational intervention found to have a  
41 significant impact on caregiver outcomes, as interventions were heterogeneous consisting of multiple  
42 components. Further research is needed to determine the effectiveness of individual and combined  
43 components to identify the ideal intervention format and design for caregivers of patients with heart  
44 failure.

45

46 **Keywords:** Heart failure; Caregivers; Psychoeducational interventions; Systematic review; Meta-  
47 analysis.

48

## 49 **Contribution of the paper**

50

51 What is already known about this topic?

52

- 53 • Heart failure is a global health care issue causing a severe symptom burden on patients and  
54 consequential increased responsibility on caregivers.
- 55 • Published data confirms that caregivers of patients with heart failure experience unmet needs.  
56 However, there is limited evidence on interventions designed specifically to meet these needs.
- 57 • Psychoeducational intervention studies that have been conducted involved patient and caregiver  
58 dyads, with outcomes demonstrating patient benefit.

59

60 What this paper adds

61

- 62 • This review found that psychoeducational interventions had a significant impact on caregiver  
63 outcomes, with results showing improved depression at 6 months, heart failure knowledge at 6  
64 months, and quality of life at 3 months.
- 65 • The considerable heterogeneity across included study interventions highlights the need for a  
66 more standardised approach when designing future interventions for caregivers.
- 67 • Three main components were identified within the included interventions: group based  
68 educational sessions, telemonitoring and telephone support, and written resources.

69

70

## 71 **1. Introduction**

72 Heart failure (HF) has been described as a global health care problem, estimated to affect 26 million  
73 people worldwide, with over 5 million people in the United States of America (USA) and over half a  
74 million people in the United Kingdom (UK) (1,2). Despite recent medical advancements, the  
75 prognostic outlook for many patients remains poor (3), with most experiencing frequent hospital  
76 admissions – causing a significant economic burden on global health care systems. It is estimated  
77 that HF is responsible for around \$31 billion of the health care expenditure in the USA, and 1-2% of

78 the health care budget within Europe, with 60-70% of this cost incurred due to hospital admissions  
79 (4). HF has been referred to as the most malignant form of cardiovascular disease, as it causes a  
80 significant symptom burden for patients and survival rates are comparable with most cancers (5).  
81 Self-care behaviours and monitoring of symptoms are vital for improving patients' quality of life and  
82 clinical status, along with treatment plans involving complex medication regimens, frequent follow-up  
83 appointments and lifestyle changes (6,7). Patients find it difficult to manage and monitor those  
84 symptoms of heart failure which often impact their physical and mental wellbeing (8).

85 Self-care is the performance of specific activities that enable patients' to manage their illness and  
86 maintain their health, and has been referred to as the cornerstone of heart failure management (9,10).  
87 It is recommended as a key strategy within the European Society of Cardiology (ESC) 2016  
88 guidelines for managing and treating heart failure (7). Caregivers frequently help patients with daily  
89 activities that support self-care, taking on various responsibilities alongside managing their own  
90 personal, medical and social lives (11,12). Caregivers facilitate specific activities, such as: following  
91 diet restrictions, arranging hospital appointments, weighing the patient, navigating the healthcare  
92 system, providing information to clinicians at appointments and motivating the patient to improve self-  
93 care (13). These activities help monitor patient symptoms, while reducing the risk of hospital  
94 readmissions and improving patients' quality of life (6,14). However, evidence has found that  
95 caregivers of patients with HF can experience poor mental and physical health as a result of their  
96 caregiving responsibilities (15).

97 A recent study found that caregivers experienced high levels of burden, depression and anxiety that  
98 were linked to their caregiving role, as well as the health status of the patient. It was found that  
99 caregivers' level of burden was intensified when caring for a patient with depression and the level of  
100 burden was predicted by feelings of unpreparedness for their caregiving role (15). Caregivers often  
101 struggle with the uncertainty of HF, which can stem from the lack of information given from health  
102 care professionals concerning, for example, the patient's condition, signs and symptoms of HF, and  
103 what to expect now and in the future. Indeed, many caregivers have expressed the need for improved  
104 communication and information. The responsibility associated with the caregiving role can cause  
105 them to experience feelings of stress, anxiety, loneliness and depression (16). Qualitative research  
106 has found that caregivers often experience a lack of social support, and receive little guidance or  
107 support from health care professionals (11,17). Many caregivers are in need of better social and  
108 emotional support as a way to help maintain a sense of normality (15). Better emotional and  
109 informational support, along with improved service provision, have been recommended to help  
110 alleviate the burden (15,16).

111 Psychoeducational support has been recognised within ESC (2016) guidelines as a key component of  
112 heart failure management programmes to which caregivers should be involved (7).  
113 Psychoeducational interventions are gaining popularity and have shown positive effects on the  
114 wellbeing of caregivers of patients with psychosis, cancer and dementia (18,19,20). A  
115 psychoeducational intervention is defined as "a structured program that focuses on providing  
116 information about the care receiver's disease and about resources and services that can help

117 caregivers manage specific disease-related problems” (21). There is limited evidence on the  
118 effectiveness of such interventions for caregivers of patients with heart failure. Previous systematic  
119 reviews have identified the needs of caregivers of patients with HF and the problems they experience  
120 due to their caregiving role (22,23). An integrated review examined interventions focused on  
121 improving psychological outcomes in caregivers of patients with heart failure. The eight studies  
122 identified, published between 2005 and 2015, provided mixed results on a range of caregiver  
123 outcomes, with the most common interventions being: face-to-face, nurse led psychoeducational  
124 sessions; home visits and telephone calls (24). There was no attempt made to assess the  
125 effectiveness of these interventions, and it was concluded that due to the variation in outcome  
126 measures, format of interventions and length of follow-up, a meta-analysis was not possible. A  
127 systematic review that focused on intervention components, contexts and outcomes of dyadic HF self-  
128 care interventions produced a similar conclusion (25). This review included twelve intervention  
129 studies, published between 2000 and 2016, and concluded that the dyadic interventions were  
130 heterogeneous, and it was therefore not possible to identify what type of intervention was most  
131 effective. The review focused on dyads, and self-care interventions, with the outcome of studies being  
132 patient related and the specific effects of the interventions on caregiver reported outcomes was not  
133 assessed.

134 To date no systematic review has assessed the impact of psychoeducational interventions on  
135 caregiver reported outcomes or identified what elements are effective. This review will determine what  
136 elements of a psychoeducational intervention are the most effective at improving the wellbeing of  
137 carers to help guide the development of a novel intervention. Furthermore, given the increasing  
138 clinical need for caregiver support and education, an up-to-date systematic review was warranted to  
139 inform the design of a future clinical trial. Therefore, the aim of this review is to determine the impact  
140 of psychoeducational interventions involving caregivers and patients with heart failure on the  
141 outcomes of caregivers.

142

## 143 **2. Methods**

144

### 145 *2.1 Design*

146 We used the Cochrane Handbook for Systematic Reviews of Interventions to guide a systematic  
147 review examining the effects of psychoeducational interventions on caregivers of patients with heart  
148 failure (26). We also used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses  
149 to guide the conduct and reporting of this review (27).

150

### 151 *2.2 Eligibility criteria*

152 Eligible studies followed a strict inclusion and exclusion criteria:

153

154 *2.2.1 Participants*

155 Studies that included adult patients with heart failure and their caregivers, and studies that included  
156 caregivers solely were eligible. Caregivers were defined as someone who provided regular unpaid  
157 care for a family member, partner or friend who needs help because of their illness and cannot cope  
158 without their support (28). Studies that included paid or employed individuals (post-operative, hospice  
159 patients or caregivers) were excluded.

160

161 *2.2.2 Types of studies*

162 Randomised controlled trials (RCT) or quasi-experimental designs were included. Intervention studies  
163 were included as this meant that the effectiveness of the intervention was assessed. Non-  
164 interventional designs, including: qualitative, case-control as well as commentaries and conference  
165 abstracts were excluded.

166

167 *2.2.3 Types of interventions*

168 Studies that used psychoeducational interventions involving either dyads consisting of heart failure  
169 patients and their caregivers or caregivers were included. A psychoeducational intervention was  
170 defined as interventions that provided any form of information and support to caregivers about the  
171 patient's disease process, resources and services to help caregivers manage disease-related  
172 problems (21).

173

174 *2.2.4 Types of outcomes*

175 Studies were included that measured any of the following caregiver outcomes: caregiver burden,  
176 depression, heart failure knowledge or quality of life (QoL). Studies that reported patient outcomes  
177 only were excluded.

178

179 *2.3 Search methods*

180 A systematic search of articles published in English between June 2007 and August 2019 was applied  
181 across five electronic databases: PsycINFO, Medline, CINAHL Plus, EMBASE and SCOPUS. We  
182 used multi-purpose searches for text words and MESH terms including: caregiver, intervention study  
183 and heart failure. Key words under each concept were combined using 'OR' and then the three  
184 concepts were grouped with 'AND'. The search terms and key words used were: 1. Caregiver: ("carer"  
185 OR "informal caregiver" OR "informal carer" OR "family member" OR "dyad") AND 2. Intervention  
186 study: ("intervention program" OR "intervention" OR "randomised control trial") AND 3. Heart  
187 failure: ("advanced heart failure" OR "chronic heart failure" OR "end stage heart failure"). A MEDLINE  
188 search strategy was developed with assistance from a medical librarian and was translated into each

189 database using appropriate controlled vocabulary. An overview of the search strategy used is shown  
190 in Appendix 1.

191

#### 192 *2.4 Study selection*

193 Studies were screened by two reviewers (LC & JM) for relevance based on title and abstract. Full  
194 texts of potentially relevant articles were examined for eligibility based on the inclusion and exclusion  
195 criteria. We used our definition of psychoeducational interventions as part of our criteria for study  
196 inclusion. Any disagreements or discrepancies about inclusion of studies were resolved via discussion  
197 with a third (LH) and fourth reviewer (DF).

198

#### 199 *2.5 Data extraction*

200 Data was extracted using an adapted version of the Cochrane Effective Practice and Organisation of  
201 Care data extraction form (29). Key data was extracted in tabular form and reviewed by a second  
202 independent author (JM), with discrepancies resolved via discussion. Information was extracted from  
203 each study on: design, study location, intervention setting (in-hospital or remote), intervention delivery  
204 and components, comparison groups (control group or standard care), participant characteristics,  
205 outcome measures, time points and results. These details were reported narratively to allow for  
206 comparisons to be made across all interventions.

207

#### 208 *2.6 Risk of bias*

209 The Cochrane Risk of Bias Tool was used to critically appraise the quality of included randomised  
210 controlled trials by two independent authors (LC & JM) (29). This assessed the quality of studies  
211 across six domains: sequence generation, allocation concealment, blinding of participants/ personnel/  
212 outcomes, incomplete outcome data, selective outcome reporting and other sources of bias. The  
213 authors graded each risk of bias item as high, unclear or low risk of bias (Fig. 2). The Newcastle  
214 Ottawa Scale (NOS) was used to assess the quality of included non-randomized studies based on a  
215 star system that evaluates three domains: selection of study groups, comparability of groups and  
216 ascertainment of exposure. High quality choices were identified with a star, and a maximum of one  
217 star was allocated for each item within the 'Selection' and 'Exposure' categories and a maximum of  
218 two stars for 'Comparability'. A maximum of 9 stars can be awarded in total and a score of 7-8 was  
219 considered high quality, and studies with less than 5 stars were identified as high risk of bias (30,31).

220

#### 221 *2.7 Data synthesis*

222 Review Manager Software Version 5.3 was used to carry out a meta-analysis; forest plots were  
223 generated and pooled estimates were reported on the impact of psychoeducational interventions on  
224 caregiver reported outcomes (32). This was performed when studies reported on the same outcome,

225 with the same follow-up period and sufficient data, using the random effects model. When pooling of  
226 data was not possible the findings were reported narratively. The treatment effect was measured  
227 using standard mean difference (SMD) and 95% confidence intervals (CIs) were calculated for all  
228 data that were analysed. The  $I^2$  statistic was used to assess the statistical heterogeneity between  
229 selected studies, to detect consistency or inconsistency of findings.  $I^2$  values of 25%, 50% and 75%  
230 indicated low, moderate or high total variation across studies (33). The quality of the evidence of each  
231 outcome was assessed using the GRADE criteria by one independent author (LC). This rated risk of  
232 bias, consistency, imprecision, indirectness, and publication bias as high, moderate or low (34).  
233 Studies were downgraded based on the following: study design, inconsistency across studies, indirect  
234 evidence across studies, imprecise results and publication bias. The GRADEpro Guideline  
235 Development Tool was used to produce a 'Summary of Findings' table (See Appendix 2).

236

### 237 **3. Results**

238

#### 239 *3.1 Search outcomes*

240 A total of 867 articles were identified and all were exported to a reference management programme  
241 which removed 326 duplicates, with 541 articles remaining that were screened for eligibility (Fig. 1).  
242 Abstracts and titles were screened in relation to inclusion/exclusion criteria, resulting in 504  
243 exclusions and leaving 37 articles. The remaining 37 articles were reviewed in full text by two  
244 reviewers (LC & JM) and any disagreement was resolved by a third (LH) and fourth reviewer (DF). A  
245 total of 27 articles were excluded, with main reasons being: unsuitable patient population (n = 6),  
246 unsuitable intervention (n = 11), and caregiver outcomes not explored (n = 10). In total, 10 articles  
247 (consisting of 7 studies) were included in this review.

248

249 **<Fig. 1. Insert>**

250

#### 251 *3.2 Quality of studies*

252 Fig. 2 provides a summary of the risk of bias across included randomised controlled trials. All studies  
253 reported an adequate method of "random sequence generation" and provided reasons for attrition  
254 rates. In individual trials there was unclear allocation concealment (35,36), and blinding of participants  
255 and personnel (35,37), with high risk of bias in one study (38). It was unclear in one study whether  
256 outcome assessment was blinded (35), and one study presented a high risk of bias as there was no  
257 outcome data reported for the control group (37). All articles provided reasons for exclusions and  
258 attrition rates, with 9 out of 10 providing a flowchart to illustrate this. One study assessed using the  
259 Newcastle Ottawa Scale (NOS) was rated as four stars, therefore representing high risk of bias (39).  
260 A high risk of bias was calculated due to the lack of randomisation used, and poor reporting methods.

261



262 *3.3 Study characteristics*

263 Seven studies reported in ten articles were included, six were randomized controlled trials and one  
264 was a quasi-experimental study (39). Three articles published a range of results from the same RCT  
265 (38,40,41), and two articles produced results based on another RCT (35,42). Studies were conducted  
266 across five countries, including: Sweden (n = 2) (35,38), USA (n = 2) (36,37), China (n = 1) (43),  
267 Taiwan (n = 1) (39), and Thailand (n = 1) (44). Sample sizes ranged from 20 (36) to 369 (37)  
268 participants, with a total sample size of 953 participants. Five trials (reported in seven articles)  
269 included dyads, consisting of patients with HF and their caregivers (36-41), one included caregivers  
270 who lived outside the patient's home (37). Two trials (reported in three articles) focused on family  
271 caregivers solely (35,42,43). The mean age of caregivers ranged from 41 to 70 years and the majority  
272 were female spouses or adult children. The mean age of patients ranged from 62 to 73 and the  
273 majority were male (see Table.1).

274

275 *3.4 Sociocultural aspects of carers*

276

277 There were country specific differences found between studies that may have affected the status of  
278 caregivers and their ability to participate in interventions. For example one study only accepted family  
279 caregivers who were able to pay for the Telehealth care intervention and the majority of these  
280 participants had a bachelor's degree, meaning that their participation was influenced by their  
281 economic and educational situation (39). Two studies included only caregivers who had access to an  
282 internet connection which may have had economic implications for inclusion (37,39). Three studies  
283 stated that the interventions tested were adapted to suit the cultural context of that specific country  
284 indicating that including participants from a low economic status could have been related to increased  
285 levels of burden (36,43, 44). A further study included African American caregivers only and adapted  
286 their intervention strategies to suit the customs and traditions of this specific population (36). One  
287 study included adult children caregivers who were significantly younger than those from Western  
288 countries, often shared caring responsibilities between family members and experienced less burden  
289 than full-time carers (44).

290

291 *3.5 Intervention details*

292 The duration of interventions from the included studies ranged from 1 month (39) to 12 months (37)  
293 and follow-up periods ranged from one month (39) to twenty- four months (41). Five studies were  
294 conducted in hospitals (35, 38, 39, 43, 44) and two in outpatient clinics (36,37) (See Table. 1).  
295 Interventions varied in terms of duration and intensity, as six studies used multi-component  
296 interventions (38, 39, 43, 36, 37, 44), including face-to-face educational sessions (38, 43, 44), written  
297 resources (38, 43, 36, 37, 44), telephone calls (36, 39, 37) and telemonitoring (39, 37). The remaining  
298 study used one component of face-to-face educational sessions (35).

299

300

301 *3.5.1 Educational sessions*

302 Four studies used face-to-face educational sessions in their interventions (35, 38, 43, 44). Two  
303 studies used group-based sessions (35,43) and two used single sessions with dyads (38,44). One  
304 study included eight participants in a group (35) and the other included ten (43). One study used  
305 sessions that were focused solely on heart failure self-care (44), whereas the remaining studies  
306 provided education on a range of topics including: medical aspects of HF, self-care, practical skills to  
307 help with managing heart failure, lifestyle modifications, nutrition and psychological aspects of the  
308 caregiver role. The intensity of the sessions ranged from one (44) to six sessions (35), with duration of  
309 each session between one (38, 43, 44) to two hours (35). Three studies provided participants with  
310 written resources to supplement the sessions (38,43,44), and one provided CD-ROMs (38). Two  
311 studies used nurses to deliver the educational sessions (38, 44) and two were delivered by  
312 multidisciplinary teams made up of a range of different healthcare professionals (35, 43).

313

314 **<Fig.2 Insert>**

315

316 *3.5.2 Telemonitoring and telephone support*

317 Two studies used telemonitoring in their interventions (37,39), which is known as using electronic  
318 means consisting of web-based or telephone-based systems to record and monitor patient  
319 physiological data at home (45). One study used an electronic device called the Telehealth device  
320 that allowed caregivers to measure patients' physical symptoms at home, which were uploaded,  
321 monitored and analysed by a HF specialist (39). Patients received 24-hour health education  
322 counselling and the opportunity to attend a medical referral service that was available 24-7 via  
323 telephone. A study used Interactive Voice Response (IVR) to administer self-management support  
324 calls to patients every week for 12 months, with caregivers receiving an email after each call  
325 describing the patient's symptoms and what they could do to help support self-management (37). It  
326 was not reported who administered the emails to caregivers. One study provided four weeks of post-  
327 hospital coaching delivered via telephone, focusing on skills to assist with managing HF at home (36).  
328 Each dyad took part in four weekly coaching sessions delivered by a nurse interventionist, helping  
329 caregivers set up routines to follow at home to help with the management of HF.

330

331 *3.5.3 Written resources*

332

333 Five studies used written resources within their interventions (36,37,38,43,44). These were described  
334 as: a guide, manual, brochure and printed guidelines all tailored towards the needs of caregivers. One  
335 study provided a brochure for caregivers that was developed by a multidisciplinary team with  
336 information on: medical aspects of HF, self-care, emotional distress and available coping resources  
337 (43). Another study provided caregivers with two guides designed by the American Heart Association,  
338 one that contained information on symptoms and the other focusing on staying healthy. They also

339 gave caregivers a list of local support organisations, a book on low-sodium recipes and a book called  
340 *Comfort At Home for Chronic Heart Failure: A Guide for Caregivers* (36). Patients and caregivers  
341 within one study were provided with a manual that explained key aspects of learning to live with HF,  
342 with skills training on: role-modelling, problem-solving and self-monitoring skills (44). They also  
343 received a DVD with matching content and were guided to watch this after reading each chapter.  
344 Caregivers were provided with printed guidelines in one study, containing information on how to  
345 communicate in a positive and motivating way to patients about self-care and HF related health (37).  
346 One study provided booklets to dyads as part of their intervention, however there were no details  
347 given about the content of these booklets (38).

348

349 <Table. 1. Insert>

350

351 *3.6 Impact of intervention*

352

353 *3.6.1 Caregiver burden*

354 Caregiver burden was measured in five studies (36,38,39,41,43), two of which used the 22-item  
355 Caregiver Burden Scale (CBS) (38,41,46). One study used the Chinese version of the 22-item ZBI  
356 scale (43,47), one used the Chinese version of the 28-item Caregiver Burden Inventory CBI scale  
357 (39,48,49) and one used a modified 17-item scale (36,50). All studies provided baseline data, one  
358 study provided 1 month follow-up data (39), two studies provided 3 month follow-up data (38,43), two  
359 studies provided 6 month follow-up data (36,43), one study provided 12 month follow-up data (38) and  
360 one provided 24 month follow-up data (41). A higher score across all scales meant a greater level of  
361 burden.

362 A meta-analysis (Fig. 3) of two studies measuring the impact of psychoeducational interventions on  
363 caregiver burden at 3 months (38,43) found no significant improvement (SMD -0.22; 95% CI -1.04 to  
364 0.61;  $p= 0.0007$ ), and a high level of heterogeneity between studies ( $I^2 = 91\%$ ). A non-significant  
365 improvement in caregiver burden was also found between two studies measuring the impact of  
366 psychoeducational interventions on caregiver burden at 6 months (36,43) (SMD -0.29; 95% CI -0.87  
367 to 0.29,  $p= 0.32$ ), with a moderate level of heterogeneity between studies ( $I^2 = 43\%$ ) (Fig. 3)

368

369 <Fig. 3. Insert>

370

371 Using GRADE summary of evidence, the quality of evidence was very low, and outcomes were  
372 downgraded due to high risk of bias, inconsistency, indirectness and imprecision. Two studies were  
373 excluded from the meta-analysis as follow-up periods and outcome measures were different. One  
374 study tested the impact of a psychoeducational intervention on caregiver burden at 24 month follow-  
375 up (41), and found no significant difference between the intervention group and control group ( $p=$

376 0.803). Another tested the impact of a telehealth intervention on caregiver burden at 1 month follow-  
377 up (39), and found a significant reduction in caregiver burden within the intervention group compared  
378 to the control group ( $p < 0.001$ ).

379

### 380 3.6.2 Depression

381 Six studies measured depression (36,37,38,40,42,43). Three studies used different versions of the  
382 Center for Epidemiologic Studies Depression Scale (CES-D) (36,37,43). Two studies used the 10-  
383 item version (36,37,51,52,53), and one study used the 20-item Chinese version (43,54). Two studies  
384 (38,40) used the 21-item Beck Depression Inventory (BDI-II) (55), and one (42) used the Hospital  
385 Anxiety and Depression Scale (HADS) (56). All studies provided baseline data, two provided 3 month  
386 follow-up data (38,43), three provided 6 month follow-up data (36,37,43), two provided 12 month  
387 follow-up data (37,38) and one provided 24 month follow-up data (40). A higher score across all  
388 scales indicated a higher level of depression.

389 A meta-analysis was conducted on two studies that measured the impact of psychoeducational  
390 interventions on depression at 3 month follow-up (38,43). Fig. 4. shows a non-significant difference in  
391 depression found between intervention group and control group (SMD -0.40; 95% CI -0.92 to 0.13;  $p =$   
392 0.14) and a high level of heterogeneity between studies ( $I^2 = 79\%$ ). Two studies measured the impact  
393 of psychoeducational interventions on depression at 6 months and a significant reduction was  
394 identified (36,43) (SMD -0.82; 95% CI -1.17 to -0.47;  $p = < 0.00001$ ) with no heterogeneity between  
395 studies ( $I^2 = 0\%$ ) (Fig. 4).

396

### 397 <Fig.4. Insert>

398

399 Using GRADE, the quality of evidence was very low, and outcomes were downgraded for high risk of  
400 bias, inconsistency, and indirectness. Three studies were excluded due to lack of sufficient data and  
401 different follow-up periods. One study found no significant difference in depression between the  
402 intervention and control group at 6 months' following a psychoeducational intervention (42). One  
403 study found a significant reduction in depression at 6 months' ( $p = < 0.001$ ), but a non-significant  
404 reduction at 12 months' ( $p = 0.031$ ) (37). Another study found no significant reduction in depression at  
405 24 month follow-up (40).

406

### 407 3.6.3 Heart failure knowledge

408 Two studies measured heart failure knowledge (35,44), with the 15-item Dutch Heart Failure  
409 Knowledge Scale DHFKS used in one study (44,57). A modified questionnaire was used in one study  
410 containing 13 questions that were based on a questionnaire that was originally developed for patients  
411 with chronic heart failure (35,58). Both studies included baseline and 6 month follow-up data. Higher  
412 scores indicated higher levels of heart failure knowledge across both scales.

413

414 **<Fig. 5. Insert>**

415

416 A statistically significant improvement in heart failure knowledge was found in the intervention group  
417 compared to the control group (SMD 0.97; 95% CI 0.70 to 1.25;  $p < 0.00001$ ), with no heterogeneity  
418 between studies ( $I^2 = 0\%$ ) (Fig. 5). Using GRADE, the quality of evidence was very low, downgraded  
419 for unclear risk of bias, inconsistency and indirectness.

420

#### 421 *3.6.4 Quality of life*

422 Five studies measured quality of life (38,40,42,43,44). Three studies used the Short Form (SF) 36  
423 item scale (38,40,43) that provided a summary of physical (PCS) and mental health (MCS) (59-61).  
424 One study used the Short-Form (SF) 12-item scale that also provided a summary of physical and  
425 mental health (44,62). One study used the Cantril Ladder of Life, which measured overall quality of  
426 life on a scale of 1-10 (42,63). Baseline and post-intervention data was provided for all studies, three  
427 provided 3 month follow-up data (38,43,44), three studies provided 6 month follow-up data (42,43,44),  
428 one provided 12 month follow-up data (38), and one provided 24 month follow-up data (40). All scales  
429 stated that a higher score indicated a better level of quality of life.

430 A meta-analysis was conducted on three studies that measured the impact of psychoeducational  
431 interventions on QoL (MCS) at 3 months (38,43,44). An improvement was found in QoL (MCS) (SMD  
432 0.25; 95% CI 0.25 to 0.48;  $p = 0.03$ ), with low level of heterogeneity between studies ( $I^2 = 20\%$ ). Two  
433 studies measured the impact of psychoeducational interventions on QoL (MCS) at 6 months follow-up  
434 (43,44). Fig.6 demonstrates a non-significant difference between the intervention and control groups  
435 (SMD 0.35; 95% CI -0.23 to 0.94;  $p = 0.24$ ) and a high level of heterogeneity ( $I^2 = 79\%$ ).

436

437 **<Fig.6.Insert>**

438

439 Using GRADE, the quality of evidence for outcomes was very low, downgraded for high risk of bias,  
440 inconsistency, indirectness and imprecision. One study was excluded from meta-analysis as sufficient  
441 data was unavailable, with patient and caregiver data presented as one unit (40). However, the study  
442 showed no significant differences in QoL (MCS) at 24 month follow-up for dyads ( $p = 0.601$ ) following  
443 a psychoeducational intervention.

444

445

#### 446 **4. Discussion**

447 This paper used a rigorous systematic process and high-quality methodology to identify and examine  
448 the impact of psychoeducational interventions on a number of caregiver related outcomes. Our review

449 found a significant reduction in depression at 6 months, improved heart failure knowledge at 6 months  
450 and improved QoL (MCS) at 3 months. It is uncertain whether psychoeducational interventions  
451 improve caregiver outcomes as a result of considerable heterogeneity and low quality of evidence  
452 found across studies. The lack of statistical significance presented across outcomes could be  
453 accounted for by the differences between interventions, including variations in intensity, duration,  
454 format, and outcome measures. These findings are consistent with other reviews that have attempted  
455 to assess the impact of psychoeducational interventions for caregivers and patients with HF but have  
456 failed due to the high level of heterogeneity found between interventions (9,10). Despite this, some  
457 similarities were identified across the seven trials.

458 Caregivers often lack confidence in their caregiving role due to a lack of information and education on  
459 HF and self-care (15,22). All the interventions included education and information on self-care,  
460 although different resources and delivery strategies were used to deliver this information. They all  
461 aimed to guide and teach activities caregivers could do at home to help the patient's self-care through  
462 the provision of information and training of key skills. These included: weighing the patient, managing  
463 medications, following dietary recommendations and limiting fluid intake. Written resources were a  
464 key component used to provide caregivers with tailored information, and were used within five studies  
465 (36,37,38,43,44). The most common topics covered in these resources included: medical aspects of  
466 HF, symptom management, skills to help with self-care and communication. Educating caregivers on  
467 self-care and other aspects of HF is vital, as this can help them to support and confidently care for the  
468 patient at home (64). Lack of preparedness for caregiving is an issue that has been commonly  
469 mentioned within literature, and can contribute to poor quality of life for caregivers (15,22,65,66).

470 A number of studies incorporated nurses, illustrating their key position in organising the overall care  
471 for patients with HF, especially following hospitalisation and during follow-up appointments that are  
472 usually held in nurse-led HF clinics (67). Specialist heart failure nurses provide information and advice  
473 during consultations and can help identify those caregivers in need of advice and support (67).  
474 Hospital discharge has been suggested as the most appropriate time to engage with caregivers,  
475 provide information to promote self-care and to equip them with essential skills to care for the patient  
476 at home (68). As hospital resources become scarcer, there is an increasing shift towards community  
477 or informal care for patients at home across many Western societies; therefore more caregivers are  
478 looking after chronically ill patients (69). It is important that caregivers are included in the planning of  
479 care and actively involved at hospital appointments and post-discharge (70). Providing caregivers with  
480 support and guidance can also help benefit patients, as an American study found after four weeks of  
481 post-discharge telephone coaching provided to patients and caregivers, patients experienced  
482 significantly less HF-related rehospitalisation's compared to those that received standard care (36).  
483 This result highlights that caregivers should be considered an integral part of the health care team  
484 (68).

485 Multidisciplinary involvement has been recognised as a key part of non-pharmaceutical interventions  
486 to support patients with HF and their family caregivers (7). Two studies used multidisciplinary teams to  
487 deliver group-based educational sessions, made up of a range of different health care professionals,

488 including: a dietician, cardiologist, social worker, and cardiac nurse (35,43). Interestingly, the study  
489 that produced the most significant results overall - with improvements in caregiver burden, depression  
490 and QoL - used a multidisciplinary approach (43). Another study also showed a significant  
491 improvement in HF related knowledge using the same approach (35). Three studies used nurse-led  
492 educational sessions, and showed no significant improvements in any caregiver outcomes (38,44). In  
493 summary, a multidisciplinary approach ensures that a broad range of needs are met using expert  
494 advice, and is therefore recommended due to caregivers having multiple needs requiring expertise  
495 from a number of different disciplines (43,69).

496 Research on family caregiving is advancing (68); however, as this review indicates there are very few  
497 intervention studies that have been designed to improve outcomes for caregivers only. Most  
498 interventions involving caregivers have focused on improving patient outcomes (68), most commonly  
499 in terms of health care utilisation. Many studies testing family partnership interventions in heart failure  
500 have shown improvements in patient outcomes, including improved medication adherence, low-  
501 sodium diet adherence, perceived confidence and hospital admissions (70-74).

502

#### 503 *4.1 Limitations*

504 We recognise that there are important limitations in this systematic review. The search strategy was  
505 restricted to English language and did not include grey literature which may have introduced  
506 publication bias (75). In addition, there was considerable heterogeneity across included studies in  
507 terms of design, resources used, delivery of the interventions, populations and outcomes measured,  
508 therefore making the presentation of meaningful data challenging (76). There were large variations  
509 between the patient and caregiver characteristics within the majority of studies, as well as cultural  
510 differences that may have affected the approach, content and delivery of some interventions. These  
511 limitations and the low quality of evidence, limits the robustness of the findings. This highlights the  
512 importance of future research to identify and agree standardised patient outcome measures or core  
513 outcome sets to represent the minimum which should be reported in randomised trials (77).

514 It was not possible to identify a specific component of the intervention that was most successful at  
515 improving outcomes for caregivers of patients with HF, as the interventions implemented consisted of  
516 multiple components. We were unable to explore individual components of multi-component  
517 interventions, as included studies did not test the specific impact of each intervention component.  
518 Further research to understand what combined intervention components work and why is required  
519 (78). The results presented within the meta-analyses should be interpreted with caution as there were  
520 a small number of heterogeneous studies included which provided hierarchical data. The small  
521 numbers of included studies meant it was not possible to undertake a hierarchical modelling approach  
522 as recommended by Cochrane (29). This limits the robustness of the findings and it is recommended  
523 that a hierarchical approach is used when more studies become available to allow for a more robust  
524 meta-analysis to be performed.

525

526 *4.2 Implications for practice*

527 There is a need for improved communication and support within clinical settings, which could be aided  
528 through improved nurse engagement with family caregivers and patients during clinic visits. Nurses  
529 have a high degree of patient contact and are therefore vital in achieving optimal patient care.  
530 Incorporating more support for caregivers into their role could help involve caregivers in the  
531 coordination of care and improve their outcomes. In addition to this direct contact, caregivers are in  
532 need of readily available resources that could be distributed within the clinical setting.

533

534 **5. Conclusion**

535 A number of international studies have shown significant improvements in, caregiver burden,  
536 depression, heart failure knowledge and quality of life. Unfortunately, it remains difficult to state which  
537 psychoeducational intervention and or component was the most successful at improving caregiver  
538 outcomes. Overall, the quality of evidence was very low and there was notable heterogeneity across  
539 studies; however, interventions had similar components, such as: educational sessions delivered by  
540 multidisciplinary teams, telemonitoring and telephone support, and written resources. As a result,  
541 future trials should include an element of group-based education, with involvement from  
542 multidisciplinary teams and provision of information tailored specifically to carers. In addition, further  
543 research is warranted into psychoeducational interventions that are adequately powered and are  
544 targeted towards improving caregiver outcomes, with detailed process evaluation.

545

546 **Conflict of interest**

547 The authors have no conflicts of interest to disclose.

548

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558



559 **Ethical review**

560 This review was not subject to ethical review.

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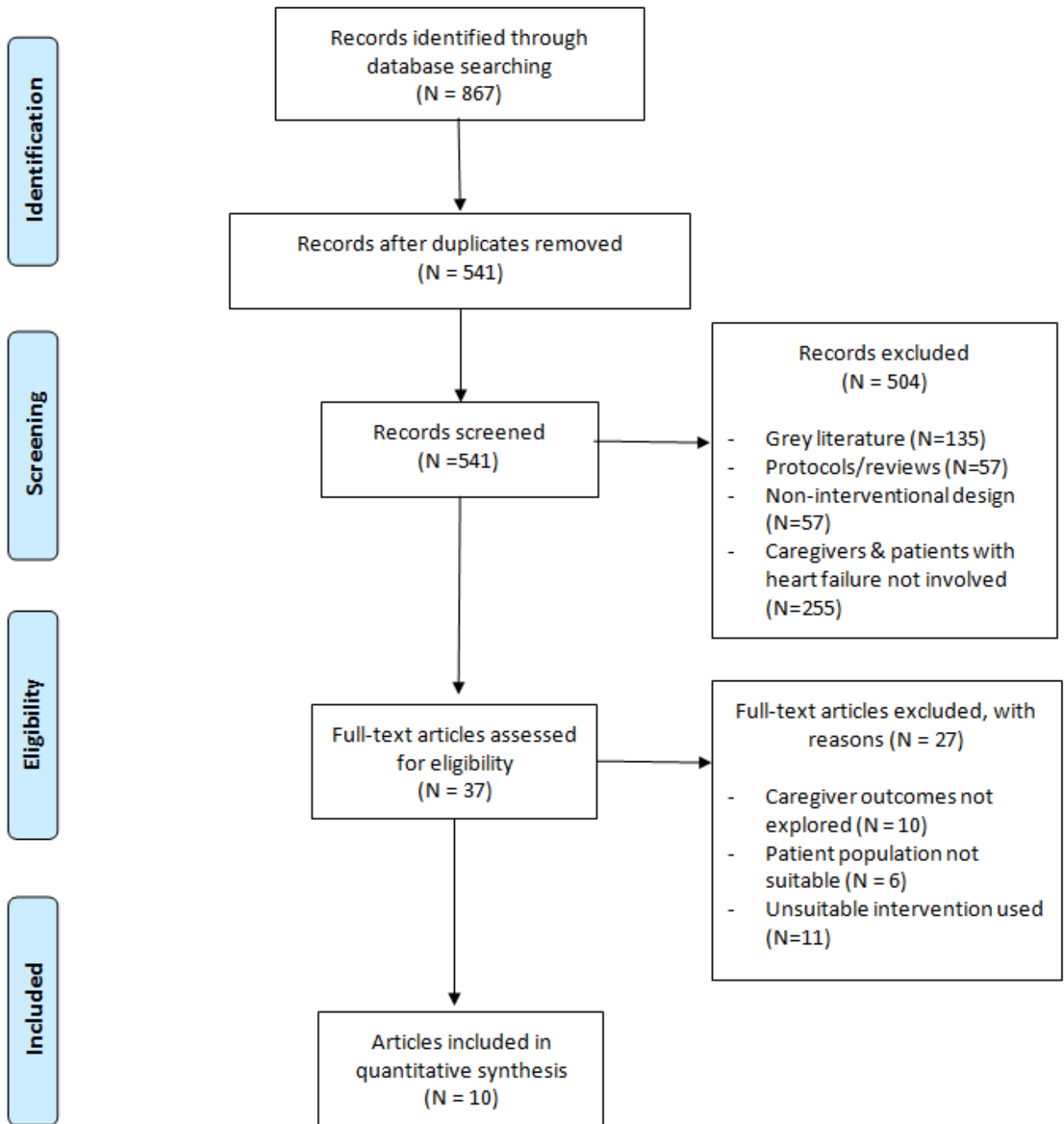
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Fig. 1: PRISMA Flow diagram of study screening and selection (27)

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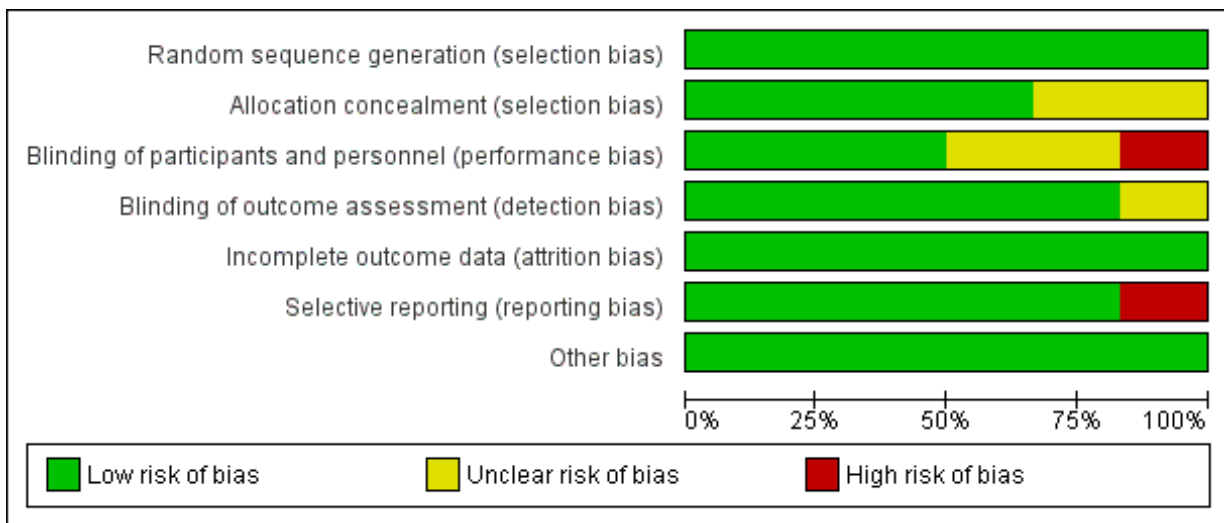


Fig 2: Risk of bias summary

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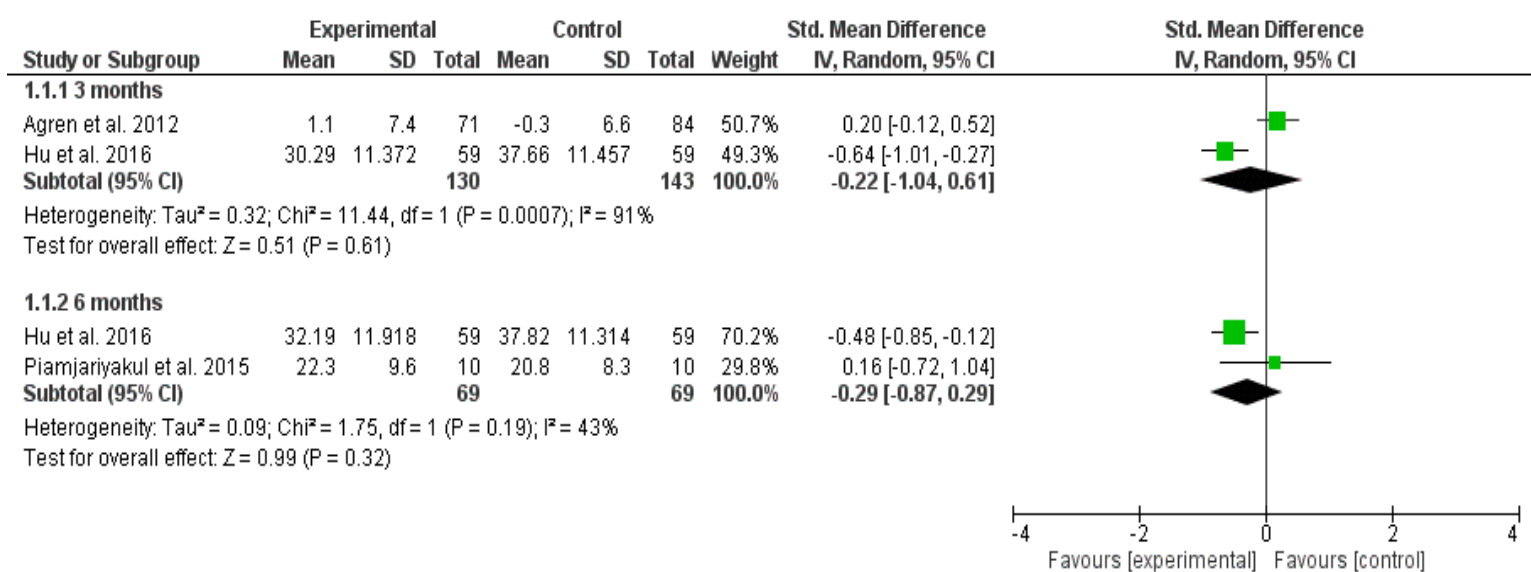
818 Table 1: Summary of included studies

Authors	Country	Design	Setting	Sample	Intervention	Outcomes and time points	Results
Agren et al. (2012) (38)	Sweden	RCT	Hospital	155 dyads	<b>Intervention (n= 71):</b> 12-week intervention with education and psychosocial support delivered in 3 nurse-led face-to-face sessions in dyads homes or HF clinic, a computer-based CD-ROM program, and other written teaching materials. <b>Control group (n= 84):</b> received care as usual.	<b>Patient and caregiver outcomes:</b> QoL (SF-36), depression (Beck Depression Inventory (BDI-II)), perceived control (Control Attitude Scale (CAS)). <b>Patient only:</b> Self-care (European Heart Failure Self-Care Behaviour Scale (EHFscBS)) <b>Caregiver only:</b> Caregiver burden (Caregiver Burden Scale (CBS)) <i>Baseline, 3 &amp; 12 month follow-up.</i>	No significant improvements in any carer outcomes. Significant improvement in patient perceived control at 3-month follow-up, but not at 12-month follow-up.
Liljeroos et al. (2015) (40)						<b>Dyad outcomes:</b> QoL (SF-36), Depression (Beck Depression Inventory (BDI-II)), Perceived control (The Control Attitude Scale (CAS)). Patient readmissions. <i>Baseline and 24-month follow-up.</i>	No significant effects on any patient-partner dyads after 24 months.
Liljeroos et al. (2017) (41)						<b>Caregiver outcomes:</b> Caregiver burden (Caregiver Burden Scale (CBS)). <i>Baseline and 24-month follow-up.</i>	No significant improvements in caregiver burden at 24-month follow-up.
Chiang et al. (2012) (39)	Taiwan	Quasi-experimental	Hospital	63 dyads	<b>Intervention (n=30 families):</b> discharge plan and telehealth device that caregivers were trained how to use along with 24-hour specialist education telephone counselling. <b>Comparison group (n=30 families):</b> discharge planning from hospital.	Caregiver burden (Chinese version of the Caregiver Burden Inventory) <i>Before patient discharge &amp; 1-month follow-up</i>	Caregiver burden significantly improved in intervention group.
Hu et al. (2016) (43)	China	RCT	Hospital	118 caregivers	<b>Intervention (n=59):</b> 3-month multidisciplinary program: brochure, 3x 60-minute support group sessions, 3x 30-	Caregiver burden (ZBI 22-item scale), Health related QoL (SF-36), Depression (CES-D 20-item scale)	Significant improvements in depression, caregiver burden & mental QoL in

					minute peer group support sessions & regular telephone follow-up. <b>Control group (n=59):</b> usual care only.	<i>Baseline, 3 &amp; 6 months</i>	intervention group.
Löfvenmark et al. (2011) (35)	Sweden	RCT	Hospital	128 family members	<b>Intervention (n=65):</b> 6 support group sessions with a multidisciplinary team over 6-month period. <b>Control (n=63):</b> received information during hospitalisation according to routine hospital practice.	Heart failure knowledge (modified questionnaire) <i>Baseline, 2 weeks after intervention &amp; 6 months after.</i>	Significant improvement in heart failure knowledge score in intervention group.
Löfvenmark et al. (2013) (42)						QoL (Cantril Ladder of Life), Depression and anxiety (Hospital Anxiety and Depression Scale (HADS)), Health related QoL (SWED-QUAL). <i>Baseline, 2 weeks after intervention &amp; 6 months after.</i>	No significant improvements in anxiety and depression or QoL among the intervention group.
Piamjariyakul et al. (2015) (36)	America	RCT	Outpatient clinic	20 dyads	<b>Intervention (n=10):</b> 4 weeks of telephone coaching with nurse and two caregiving guides, list of support organisations, low-sodium booklet, pill organiser & book for caregivers. <b>Standard care group (n=10):</b> education and materials routinely given in hospital to patients	Caregiver burden (Caregiving burden of HF home care management 17-item) Depression (CES-D 10-item scale) <i>Baseline &amp; 6 months</i>	Significantly lower depression & improvements in caregiver burden-medium effect size in total caregiving burden score.
Piette et al. (2015) (37)	America	RCT	Outpatient clinic	369 dyads	<b>Intervention group (mHealth+ CP) (n=189):</b> patients received weekly self-support calls for 12 months with notifications sent to clinicians and booklet for caregivers, plus emails sent to care-partners.  <b>Comparison group (Standard mHealth) (n=180):</b> patients received weekly self-support calls for 12 months & caregivers received a booklet.	Caregiver strain (Caregiver strain index) Depressive symptoms (CES-D 10-item version) <i>Baseline, 6 &amp; 12 months</i>	Significantly less caregiver strain & depressive symptoms in intervention group.

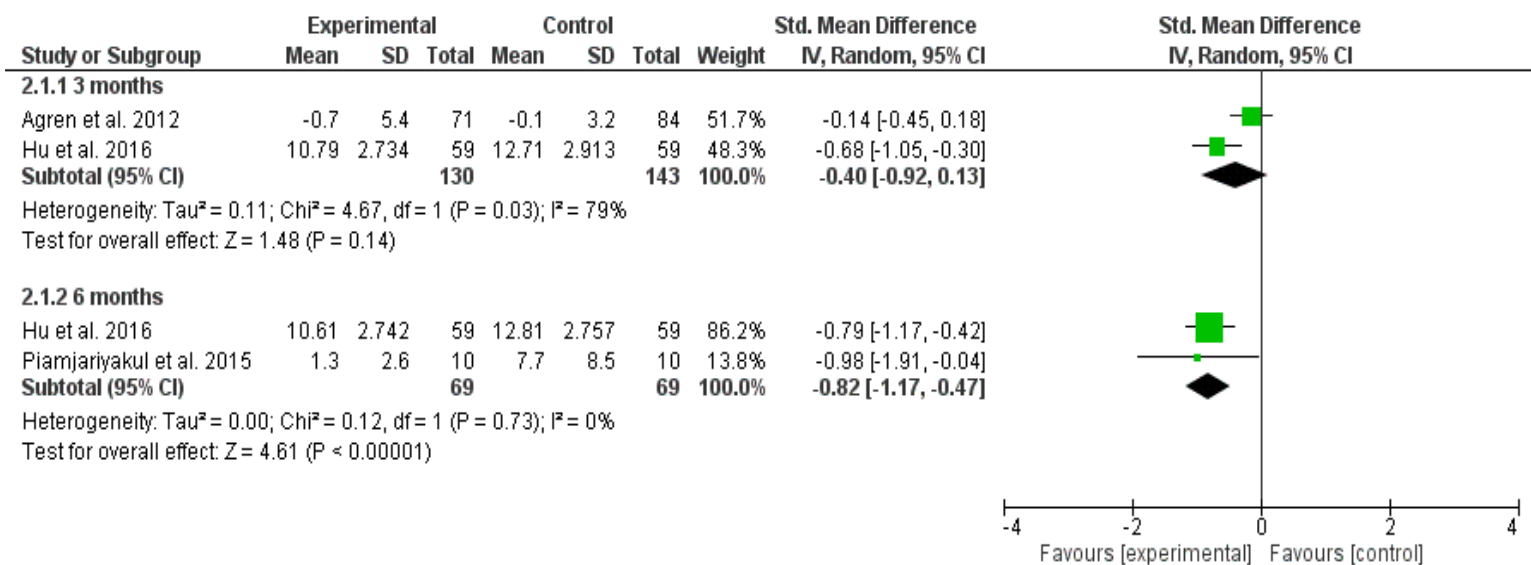
Srisuk et al. (2016) (44)	Thailand	RCT	Hospital	100 dyads	<b>Intervention group (n=50):</b> 6 month programme: 1 face-to-face education session, manual, DVD & telephone follow-up. <b>Usual care group (n=50):</b> standard medical & nursing care from hospital.	Heart failure knowledge (Dutch Knowledge Scale: DHFKS) General QoL (caregivers) (SF-12 Short-Form 12 health survey) <i>Baseline, 3 &amp; 6 months</i>	Significantly higher heart failure knowledge scores in intervention group.
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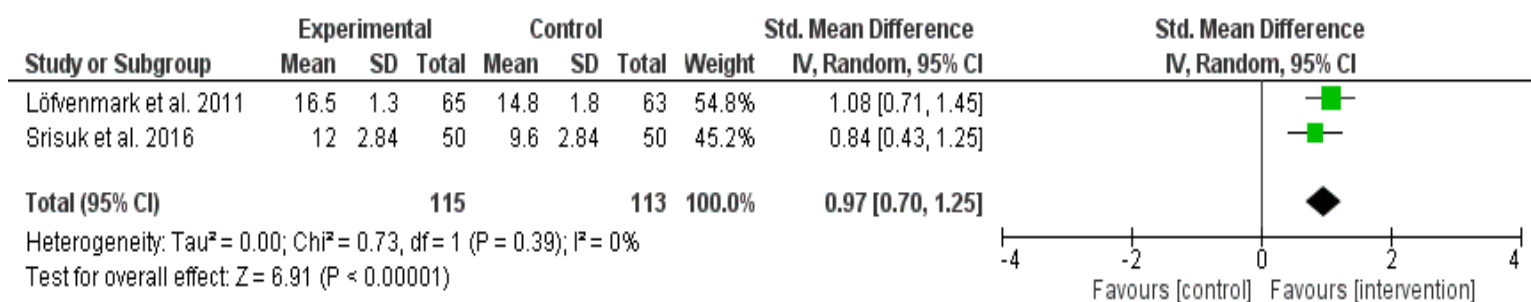
**Fig. 3: Forest plot of the effect of psychoeducational interventions on caregiver burden at 3 & 6 months follow-up**

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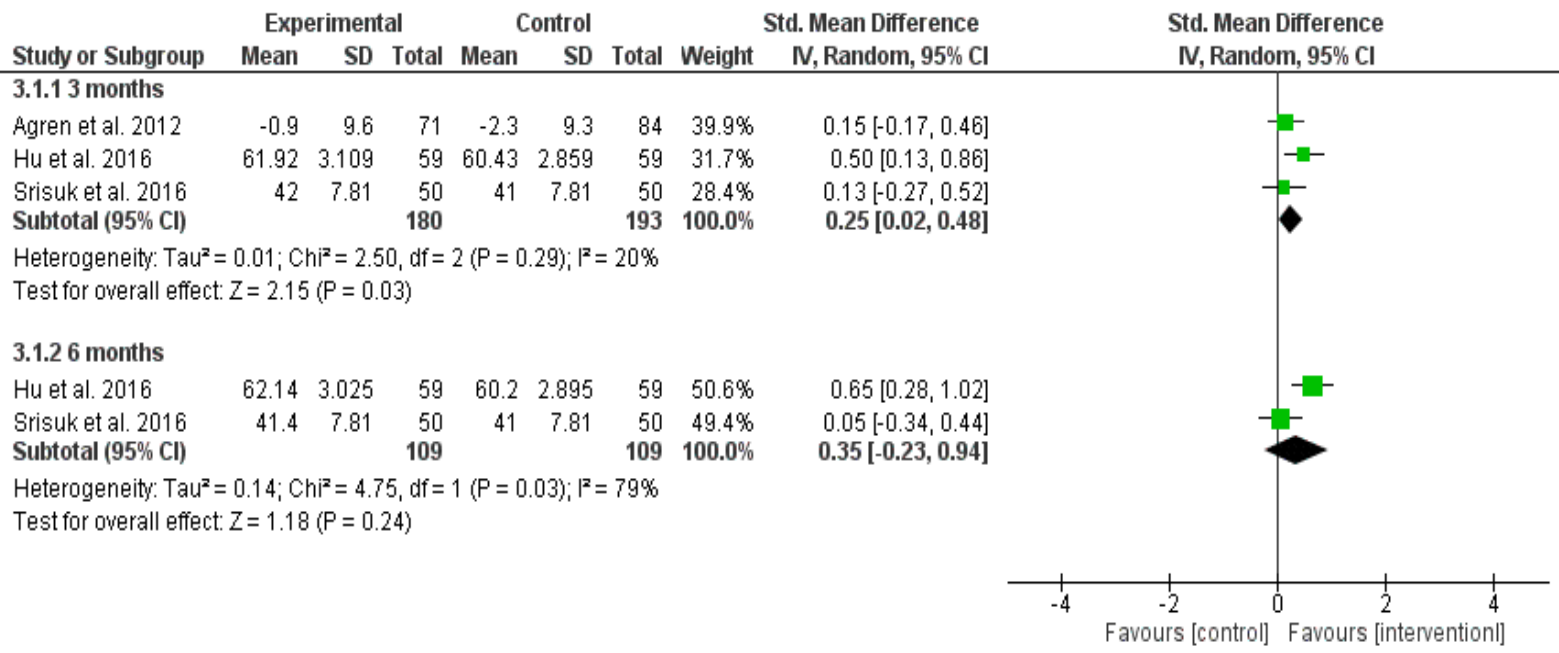
**Fig. 4: Forest plot of the effect of psychoeducational interventions on depression at 3 & 6 months follow-up**

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**Fig. 5: Forest plot of the effect of psychoeducational interventions on heart failure knowledge at 6 month follow-up**

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**Fig. 6: Forest plot of the effect of psychoeducational interventions on QoL (MCS) at 3 & 6 months follow-up**

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