## Citation

Lee CS, Westland H, Faulkner KM, Iovino P, Thompson JH, Sexton J, Farry E, Jaarsma T, Riegel B. The effectiveness of self-care interventions in chronic illness: A meta-analysis of randomized controlled trials. Int J Nurs Stud. 2022 Oct;134:104322. doi: 10.1016/j.ijnurstu.2022.104322. Epub 2022 Jul 5. PMID: 35907275.

## Permissions

International Journal of Nursing Studies 134 (2022) 104322

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ns

# The effectiveness of self-care interventions in chronic illness: A meta-analysis of randomized controlled trials

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ARTICLE INFO

*Article history:*
Received 18 January 2022
Received in revised form 21 June 2022
Accepted 28 June 2022
Available online xxxx

*Keywords:*
Self-care
Chronic disease
Heart failure
Hypertension
Asthma, Chronic obstructive pulmonary disorder
Diabetes mellitus, Type 2
Meta-analysis

ABSTRACT

*Objective:* To characterize and explain variation in the comparative effectiveness of self-care interventions on relevant outcomes of chronic illness compared with controls.
*Design:* Meta-analysis and meta-regression.
*Methods:* Data extraction was framed within the context of a previously-published scoping review of randomized trials designed to enhance self-care in type 2 diabetes mellitus, heart failure, hypertension, asthma, coronary artery disease, and chronic obstructive pulmonary disease (published between 2008 and 2019). Data were pooled using random-effects meta-analyses. Meta-regression was used to test the effect of potential moderators on trial effectiveness.
*Results:* 145 trials involving 36,853 participants were included. Overall, the effect size of self-care interventions on improving outcomes was small (Hedges' $g = 0.29$ (95% CI = 0.25–0.33), $p < 0.001$) with statistically significant heterogeneity across trials ($Q = 514.85$, $p < 0.001$, $I^2 = 72.0\%$). A majority of trials (n = 83, 57.2%) were rated as having a high risk of bias. There was no statistically significant difference in trial effectiveness based on the use of theory, specific components of self-care addressed, the number of modes of delivery, the number of behavioral change techniques, specific modes of delivery, specific behavioral change techniques, intervention duration, total number of hours of intervention, or either participant age or gender.
*Conclusions:* Self-care interventions are modestly effective in improving outcomes. Poor trial quality limits the strength of conclusions in this area of science. There is much to be done to enhance the design, conduct and reporting of self-care trials in order to gain more insight into the effectiveness of self-care interventions.



## What is already known

- Self-care is viewed as being essential to the management of chronic illness.
- Evidence supporting the effectiveness of self-care in improving patient outcomes is weak.

## What this paper adds

- Across 145 trials in six chronic conditions, the effect size of self-care interventions on improving outcomes is small.
- Common design features are not helpful in explaining variability in trial outcomes across conditions.
- There were at least two areas of high or uncertain risk of bias in a majority of trials pointing towards numerous requisite improvements in future self-care trial design.

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https://doi.org/10.1016/j.ijnurstu.2022.104322

## 1. Introduction

The World Health Organization defines self-care as the ability to promote health, prevent disease, maintain health, and cope with illness and disability among individuals, families and communities with or without the support of a healthcare provider (World Health Organization, 2021). In the context of chronic illness, self-care is theoretically defined as a process involving three types of behavior (Riegel et al., 2012). First, self-care maintenance behaviors involve maintaining stability in the chronic condition by adhering to prescribed therapies and engaging in preventative health measures. Second, self-care monitoring behaviors involve surveillance for signs and symptoms that may indicate a change in the underlying chronic condition. Third, self-care management behaviors involve recognizing and responding to symptoms of the chronic condition (Riegel et al., 2012). These three types of self-care behavior are believed to contribute to the prognosis and wellness of those living with chronic illness via minimizing disease progression, early detection of underlying changes, and swift action in response to changes when they occur (Riegel et al., 2019).

Self-care is widely acknowledged as essential for anyone with chronic illness (World Health Organization, 2021; Riegel et al., 2019). Yet, data supporting the effectiveness of self-care in improving patient outcomes within specific chronic conditions are surprisingly weak (Jaarsma et al., 2020a). For example, in a meta-analysis of self-care interventions in chronic obstructive pulmonary disease, the overall risk of all-cause hospitalization was only reduced by 2% (Jonkman et al., 2016a). Additionally, in a meta-analysis of self-care interventions in heart failure, there was only a small effect in improving heart failure related quality of life (Jonkman et al., 2016b). Only a few prior investigators have demonstrated that self-care can decrease the need for emergency care and hospitalization, lower mortality rates, or improve quality of life in specific chronic conditions (Jovicic et al., 2006; Zwerink et al., 2014).

Self-care research has grown considerably over the past two decades; but, the quality of research has not necessarily improved with the growth in publications (Riegel et al., 2019). That is, research involving self-care interventions remains hampered by imprecise language, uncertain theoretical basis, inadequate reporting on intervention characteristics and fidelity, and nonstandard reporting of sample characteristics (Jonkman et al., 2017). Our recent scoping review of self-care interventions revealed a predominant focus on changing single health behaviors like medication or diet adherence, a lack of attention to psychological consequences of chronic illness, limited use of technology, and insufficient reporting on interventionalist training and treatment fidelity (Riegel et al., 2020). Another limitation of existing self-care intervention research is insufficient attention paid to behavioral change techniques and their underlying mechanism of action (Jonkman et al., 2017; Riegel et al., 2020). Many self-care interventions use specific behavioral change techniques like providing information on health consequences that have a clear mechanism of action in improving behavior (Carey et al., 2019). Other self-care interventions use behavioral change techniques like action planning that have no clear mechanism of action in improving behavior (Connell et al., 2019) but are used frequently and are included in common taxonomies of behavioral change (Michie et al., 2013). Although much is known about effective behavioral change techniques, few investigators apply this knowledge to self-care intervention in chronic illness.

In general, self-care behaviors are consistent across different chronic illnesses (Riegel et al., 2012). That is, anyone prescribed a medication for a chronic illness needs to take the medicine routinely if they are to benefit from it. Yet, we also know that different chronic illnesses require different specific self-care behaviors and the outcomes differ among conditions (e.g., HbA1c for diabetes, blood pressure for hypertension). Because of the challenges involved in dealing with this heterogeneity, self-care studies of various chronic illness are almost never pooled together (Jonkman et al., 2016c). As such, the effectiveness of self-care interventions across chronic conditions is unknown. The objectives of this meta-analysis of randomized control trials were to: 1) quantify the comparative effectiveness of self-care interventions compared with controls on relevant outcomes of chronic illness, 2) quantify and explain variation in effect sizes within and across chronic conditions, and 3) qualify risk of bias across trials to provide guidance for future design, conduct and reporting.

## 2. Methods

This meta-analysis was framed within the context of a parent scoping review of interventions designed to enhance self-care in patients with a chronic conditions (Riegel et al., 2020). In brief, randomized control trials for adults with a chronic condition (asthma, coronary artery disease, chronic obstructive pulmonary disease, type 2 diabetes mellitus, heart failure or hypertension) were included in the scoping review if the trial investigators compared a behavioral self-care intervention to a control condition.

### 2.1. Design

The current analysis represents the formal quantitative synthesis of the effectiveness of self-care interventions on outcomes of chronic illness that were included in a scoping review published previously in this journal (Riegel et al., 2020). The current meta-analysis was conducted in accordance with the Cochrane Handbook (Higgins et al., 2022a), as well as the U.S. Agency for Healthcare Research and Quality Methods Guide for Effectiveness and Comparative Effectiveness Reviews (Morton et al., 2008).

### 2.2. Study criteria and search strategy

Inclusion criteria for studies were that they: a) involved self-care behaviors, b) included self-care monitoring (i.e. surveillance for signs and symptoms) (Riegel et al., 2012), c) included active patient engagement, d) focused on symptomatic chronic conditions that are associated with high morbidity and mortality (Goodman et al., 2013), e) reported on randomized controlled trials involving a behavioral intervention compared with another intervention or usual care, f) focused on adults, g) reported in the English language, and h) had full-text versions available.

The expertise of two medical librarians was solicited to develop an exhaustive search strategy using the search engines PubMed, Embase, PsychINFO, and Cumulative Index to Nursing and Allied Health Literature. The timeframe between 2008 and 2019 was selected because of theoretical advancements that occurred during that time and the presumed integration of such advancements into self-care interventions, the emergence of new measures to measures self-care, and the integration of technology into self-care interventions. The exact search strategy including Medical Subject Headings has been published previously (Riegel et al., 2020). As an example on the identification of Type 2 Diabetes Mellitus trials, we used combinations of terms related to diabetes (e.g. “diabetes mellitus”[MeSH] OR “diabetes mellitus”[Title/Abstract] OR “diabetes mellitus, type 2”[MeSH] OR “diabetes mellitus type 2” [Title/Abstract] OR “insulin resistance”[MeSH] OR “insulin resistance” [Title/Abstract]), terms related to self-care (e.g. AND (“self-management” [MeSH Terms] OR self manag[Title/Abstract] OR “self care”[MeSH Terms] OR self care[Title/Abstract]), and key terms for trials (e.g. AND (“randomized controlled trial” [Publication Type] OR “randomized controlled trial”[Title/Abstract] OR “randomized controlled trial”[Title/Abstract] OR “controlled clinical trial” [Publication Type] OR “clinical trial*” [Title/Abstract] OR “random allocation” [MeSH] OR “random allocation”[Title/Abstract] OR “randomly allocated” [Title/Abstract]) in addition to filters by year, language and adults.

### 2.3. Study selection for meta-analysis

The parent scoping review included 233 randomized control trials in total (Riegel et al., 2020). For the purposes of this meta-analysis, we focused on chronic conditions where there was a) a sufficient number of trials to perform meta-analyses (10 or more as a convention) (Morton et al., 2008) and b) sufficient information on outcomes that could be compared across trials.

### 2.4. Outcome selection

Four members of the authorship team completed an exhaustive review of clinical and patient-oriented outcomes that were reported by chronic condition. The average duration of intervention across studies was 6 months. Thus, outcomes were chosen to capture the measurement period closest to 6 months after randomization.

#### 2.4.1. Type 2 diabetes mellitus

Glucose control (as measured by change in HbA1c) was reported in a majority of trials in type 2 diabetes mellitus. As such, improvement in HbA1c was selected as the type 2 diabetes trial outcome for meta-analysis.

#### 2.4.2. Heart failure

Patient-reported data on health-related quality of life (as measured by standard heart failure-specific measures like the Minnesota Living with Heart Failure Questionnaire, or standard general health-related measures like the RAND SF-36) was reported in a majority of heart failure trials – there was no other outcome in common across trials. Hence, improvement in health-related quality of life was selected as the heart failure trial outcome for meta-analysis.

#### 2.4.3. Hypertension

Blood pressure (as measured by change in systolic blood pressure) was reported in a majority of hypertension trials. Accordingly, improvement in systolic blood pressure was selected as the hypertension trial outcome for meta-analysis.

#### 2.4.4. Asthma

Lung function (as measured by change in forced expiratory volume or forced expiratory volume over one second) was reported in a majority of trials in asthma. Other common measures across asthma trials were patient reported data on asthma control (as measured standardized clinical asthma control questionnaires) and physical activity (as measured by the Paffenbarger Physical Activity Questionnaire). Improvement in forced expiratory volume, asthma control and physical activity were selected as the asthma trial outcomes for meta-analysis.

#### 2.4.5. Coronary artery disease

Patient-reported outcomes (measured by change in standard measures of quality of life or depression), physical activity (as measured by change in pedometry, walking times or energy expenditure) and cholesterol (as measured by change in low density lipoproteins) were common outcomes across coronary artery disease trials. Accordingly, improvement in quality of life and depression, physical activity, and cholesterol were selected as coronary artery disease trial outcomes for meta-analysis.

#### 2.4.6. Chronic obstructive pulmonary disease

Aerobic capacity (as measured by change in 6-min walk or shuttle tests), lung function (as measured by change forced expiratory flow), and patient-reported outcomes (as measured by change in standard measures of quality of life, depression or dyspnea distress) were common outcomes across trials in chronic obstructive pulmonary disease. As such, improvement in aerobic capacity, lung function, and quality of life and depression were selected as chronic obstructive pulmonary disease trial outcomes for meta-analysis.

### 2.5. Data extraction

Most studies included sufficient data on central tendency and dispersion in both trial arms both pre- and post-intervention, or they reported sufficient information on change in outcome within each trial arm. The dominant method of reporting was pre- and post-intervention means and standard deviations in each trial arm – these data were extracted and verified in duplicate. Change statistics along with metrics of dispersion also were extracted and verified with the original source publications by two researchers. When necessary standard errors or CIs were changed to standard deviations using standard Cochrane manual conversions (Higgins et al., 2022a) in StataMP 16 (College Station, Texas, USA). Calculated effect sizes also were extracted and verified in duplicate. Finally, theory use (no explicit use, randomized control trial was informed by theory, or randomized control trial was guided by theory), specific components of self-care (monitoring and management, maintenance monitoring and management, or maintenance and monitoring), modes of delivery (group face to face, individual face to face, skills training, telephone, self-monitoring, audio/visual online, web-based or printed materials), and common behavioral change techniques (goal setting, problem solving, action planning, review of goals, feedback on behavior, health consequences, social support and reminders) (Michie et al., 2013) were chosen a priori as potential moderators of intervention effectiveness and extracted from each study. Additionally, we tested duration of the intervention (in months), total number of hours of the intervention (in hours) mean participant age (at the study level), and percentage of participants who were female (at the study level) as potential moderators once substantive heterogeneity was detected and unexplained by other moderators. The original publication was used as the source document to resolve any differences between multiple data extractors.

### 2.6. Appraisal of risk of bias

The Cochrane Collaboration's tool for assessing risk of bias in randomized trials was completed for each study included in this meta-analysis (Higgins et al., 2011). Specific domains evaluated were random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and researchers (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other non-specific bias (Higgins et al., 2011). Trials were further categorize as low risk of bias (low risk in all specific domains), unclear risk of bias (low or unclear risk of bias in all domains), or high risk of bias (high risk of bias in one or more key domain). Across trials, information on risk of bias can be used to ascertain if a) most data from trials presents a low risk of bias in interpretation, b) most data from trials has low or uncertain influence on interpretation, or c) the risk of bias should be considered when interpreting results (Higgins et al., 2011).

### 2.7. Statistical analysis

Hedges' *g*, standardized mean difference that is adjusted for sample size, were calculated from extracted means and standard deviations (Lakens, 2013). Hedges' *g* of 0.2, 0.5 and ≥0.8 was considered small, medium and large effect sizes, respectively (Cohen, 1992). Due to variation in the direction of outcomes included, all Hedges' *g* were calculated to show improvement, meaning that a positive number favored the intervention arm and negative number favored the control condition.

Random effects meta-analysis was performed due to potential sources of variation in effect sizes across studies including sampling error (Cheung and Vijayakumar, 2016). Weights were applied to each trial using the inverse variance method described by DerSimonian and

Laird (1986). Precision of summary estimates is represented by 95% confidence intervals (CI), *Z*-scores and *p*-values that reflect the significance against the null hypothesis that interventions were not effective. Between-study variability attributed to heterogeneity is presented using Q (chi-square with *k*-1 degrees of freedom (*df*) distribution) and the associated *p*-value, as well as $I^2$ that can range from 0% (heterogeneity is spurious) to 100% (considerable heterogeneity).

Predictive intervals were estimated to project the expected range of effect sizes that may be observed in similar trials (IntHout et al., 2016). Duval and Tweedie nonparametric trim and fill method was performed along with funnel plots for visual inspection of publication bias (Duval and Tweedie, 2000). Cumulative meta-analysis was conducted to iteratively quantify pooled estimates and 95% confidence intervals with the addition of each study (Lau et al., 1992). Orwin's N was calculated under different assumptions to estimate the stability of random effects estimates with the addition of additional studies (Orwin, 1986).

Meta-regressive techniques were used to test the influence of the four a priori chosen moderators; a) theory use, b) self-care components, c) modes of delivery, and d) behavioral change techniques. Four additional post-hoc moderators were tested once substantive heterogeneity was detected: a) duration of the intervention, b) total number of hours of the intervention, c) mean participant age, and d) percentage of participants who were female. Results were reported as sub-group comparisons, with between-group tests of heterogeneity (*Q*) and p-values, or meta-regression models with restricted maximum likelihood estimation (Viechtbauer, 2005) and Knapp-Hartung modification (Knapp and Hartung, 2003) reported as slope coefficients and standard errors. All analyses were performed using Comprehensive Meta-Analysis 3.3 (Englewood, New Jersey, USA) or StataMP 17 (College Station, Texas, USA).

## 3. Results

A total of 145 randomized control trials were included in this meta-analysis, including 36,853 patients with chronic illness who were randomized to self-care interventions or control conditions (Supplemental Table 1). Trials were conducted in North America (n = 65, 44.8%), Asia (n = 41, 28.3%), Europe (n = 30, 20.7%), Australia and New Zealand (n = 5, 3.5%), and South America (n = 4, 2.8%). Compared with the parent scoping review, 68.2% (n = 58) of diabetes trials, 59.3% (n = 16) of heart failure trials, 81.3% (n = 26) of hypertension trials, 93.3% (n = 14) of asthma trials, 80.0% (n = 12) of coronary artery disease trials, and 100% (n = 19) of chronic obstructive pulmonary disease trials were eligible for inclusion in this meta-analysis (*see parent review flowchart (*Riegel et al., *2020)* and Supplemental Fig. 1). Risk of bias information across the 145 trials is presented in Supplemental Fig. 2. The two greatest areas of risk were performance bias (blinding of researchers and participants), and detection bias (blinding of outcome assessment), and a majority of trials (n = 83, 57.2%) were rated as having a high risk of bias.

### 3.1. Within individual chronic illnesses

Fifty-eight self-care trials in type 2 diabetes mellitus involving 13,344 patients were included (Eakin et al., 2013; Cheong et al., 2009; Kempf et al., 2018; Wayne et al., 2015; Salinero-Fort et al., 2011; Guo et al., 2014; Chew et al., 2018; Jaipakdee et al., 2015; Katalenich et al., 2015; Kim et al., 2015a; Booth et al., 2016; Bosi et al., 2013; Tang et al., 2013; Piette et al., 2011; Pibernik-Okanovic et al., 2009; French et al., 2008; Lee et al., 2017; Kirk et al., 2009; Rosal et al., 2011; Hermanns et al., 2012; Lorig et al., 2010; Lutes et al., 2017; Chamany et al., 2015; Sevick et al., 2012; D'Eramo Melkus et al., 2010; Kempf et al., 2013; Lee et al., 2011; Agarwal et al., 2019; Jahangard-Rafsanjani et al., 2015; De Greef et al., 2010; Ludman et al., 2013; Polonsky et al., 2011; Moriyama et al., 2009; Hermanns et al., 2017; Ismail et al., 2013; Greenwood et al., 2015; Kan et al., 2017; Anderson et al., 2010; Aguiar et al., 2018; Hemmati Maslakpak et al., 2017; Hansen et al., 2017; Lu et al., 2011; Lim et al., 2016; Mohamed et al., 2013; Nesari et al., 2010; Rothschild et al., 2014; Taveira et al., 2010; Wichit et al., 2017; Kempf et al., 2017; Shahid et al., 2015; Kim et al., 2015b; Anzaldo-Campos et al., 2016; Jayasuriya et al., 2015; Sun et al., 2008; Al Mazroui et al., 2009; Garcia de la Torre et al., 2013; Song and Kim, 2009; Farsaei et al., 2011). Overall, self-care interventions improved HbA1c compared with control conditions (Supplemental Fig. 3); the overall summary effect size was small-to-moderate ($g = 0.34$ (95%CI = 0.27–0.42), $z = 15.92$, $p < 0.001$).

Sixteen self-care trials involving 6950 patients with heart failure were included in this meta-analysis (Deek et al., 2017; Bekelman et al., 2015; Peters-Klimm et al., 2010; Woodend et al., 2008; Flynn et al., 2009; Dracup et al., 2014; Copeland et al., 2010; Hagglund et al., 2015; Kalter-Leibovici et al., 2017; Cajanding, 2016; Baker et al., 2011; Dalal et al., 2019; Wang et al., 2016; Gary et al., 2010; Otsu and Moriyama, 2011; Sezgin et al., 2017). Self-care interventions improved quality of life in heart failure compared with control conditions (Supplemental Fig. 4); but the overall effect size was small ($g = 0.20$ (95%CI = 0.11–0.28), $z = 6.53$, $p < 0.001$).

Twenty-six self-care trials in hypertension involving 8753 patients were included (Blom et al., 2014; Bennett et al., 2018; Kuhmmer et al., 2016; Bennett et al., 2010; Augustovski et al., 2018; Dusek et al., 2008; Green et al., 2008; McManus et al., 2018; Bennett et al., 2012; Bove et al., 2013; Takada et al., 2018; Piette et al., 2012; Daniali et al., 2017; Nolan et al., 2018; Bosworth et al., 2009; Margolius et al., 2012; Feldman et al., 2016; Brennan et al., 2010; Kim et al., 2014; Okada et al., 2018; McManus et al., 2010; Chan et al., 2018; McManus et al., 2014; Xue et al., 2008; Hinderliter et al., 2014; Perl et al., 2016). Overall, self-care interventions improved systolic blood pressure compared with control conditions (Supplemental Fig. 5); the overall effect size was small-to-moderate ($g = 0.34$ (95%CI = 0.24–0.44), $z = 14.23$, $p < 0.001$).

Fourteen self-care randomized control trials in asthma involving 2244 patients were included (Shelledy et al., 2009; Mancuso et al., 2012; Ma et al., 2015; Janson et al., 2009; Baptist et al., 2013; Huang et al., 2009; Nokela et al., 2010; Foster et al., 2014; Patel et al., 2017; van der Meer et al., 2009; Farag et al., 2018; Lv et al., 2012; Grammatopoulou et al., 2017; Lim et al., 2014). Overall, self-care interventions improved asthma outcomes compared with control conditions (Supplemental Fig. 6), but the overall summary effect was small ($g = 0.21$ (95%CI = 0.11–0.31), $z = 4.76$, $p < 0.001$).

Twelve self-care randomized control trials involving 1427 patients with coronary artery disease were included (Johnson et al., 2009; O'Neil et al., 2014; Reid et al., 2012; Lear et al., 2015; Mok et al., 2013; Widmer et al., 2017; Devi et al., 2014; Vernooij et al., 2012; Pfaeffli Dale et al., 2015; Vibulchai et al., 2016; Wolkanin-Bartnik et al., 2011; Houle et al., 2011). Overall, self-care interventions improved coronary artery disease outcomes compared with control conditions (Supplemental Fig. 7); the overall summary effect was small-to-medium ($g = 0.34$ (95%CI = 0.24–0.44), $z = 6.78$, $p < 0.001$).

Nineteen self-care randomized control trials involving 4135 patients with chronic obstructive pulmonary disease were included in this meta-analysis (Berry et al., 2010; Cruz et al., 2016; Farmer et al., 2017; Blackstock et al., 2014; Wan et al., 2017; Trappenburg et al., 2011; Maltais et al., 2008; Jolly et al., 2018; Cameron-Tucker et al., 2016; Pinnock et al., 2013; Moy et al., 2015; Lamers et al., 2010; Effing et al., 2011; Rixon et al., 2017; Bucknall et al., 2012; Donesky et al., 2014; Kuo et al., 2013; Varas et al., 2018; Hospes et al., 2009). Overall, self-care interventions improved outcomes in chronic obstructive pulmonary disease compared with control conditions (Supplemental Fig. 8), but the overall summary effect was small ($g = 0.13$ (95%CI = 0.05–0.20), $z = 6.78$, $p < 0.001$).

Heterogeneity across trials within each chronic condition is presented in the Supplemental Figs. 3–8. Risk of bias information within each chronic condition is presented in Supplemental Fig. 9.

### 3.2. Across all chronic illnesses

Across all trials and chronic conditions, the overall effect size of self-care interventions on improving outcomes was small ($g = 0.29$ (95%CI = 0.25–0.33), $z = 14.03$, $p < 0.001$) (Fig. 1). There was statistically significant and substantive heterogeneity in effects across trials ($Q = 514.85$, $df = 144$, $p < 0.001$, $I^2 = 72.0\%$) meaning that self-care interventions varied considerably in improving outcomes. The predictive internal ranged from −0.09 to 0.67 indicating that future trials of similar quality may expect to find effect sizes that range from small effects favoring control conditions to medium effects that favor self-care interventions. Effects sizes also varied significantly across conditions (between-study $Q = 24.39$, $df = 5$, $p < 0.001$) indicating that self-care interventions are not equally effective across these chronic conditions.

There was no evidence of publication bias (Supplemental Fig. 10). In cumulative meta-analysis, the pooled estimate approximated the final pooled estimate after inclusion of the first 50 studies – adding subsequent studies further narrowed the confidence interval (Supplemental Table 2). Based on Orwin's N, the only scenarios where a small number of additional missing studies would change the summary estimate to the outer bounds of the confidence interval required the mean effect size of those studies to be much higher or lower than what was observed in this meta-analysis (Supplemental Table 3).

### 3.3. Moderators of self-care trial effectiveness

Potential moderators by chronic condition are reported in Supplemental Table 4. In brief, a majority of trials (66.9%) were not explicitly informed by theory, a majority of trials (65.5%) targeted all three components of self-care (i.e. maintenance, monitoring and management), telephone was the most common mode of delivery (used in 51.0% of trials), the average number of modes of delivery used by trials was 3.2 ± 0.9, and the two most common behavioral change techniques were goal setting (used in 41.4% of trials) and problem solving (used in 33.8% of trials. Additionally, the average during of interventions was 6.9 ± 4.4 months, the average number of hours of intervention was 12.8 ± 13.7, the mean age of participants was 59.0 ± 8.6 years, and the average percent of participants who were female was 49.4% ± 22.0%. The only statistically significant differences in moderators across chronic conditions were a) group face-to-face delivery that was more common in type 2 diabetes mellitus but not used in coronary artery disease and heart failure, b) skills training that was most common in chronic obstructive pulmonary disease but not used in asthma, c) mean age of participant with the youngest average age in asthma trials, and d) the percentage of participants who were female with the highest percentage in hypertension trials. There was no statistically significant difference in trial effectiveness across conditions regarding a) use of theory (Fig. 2), b) components of self-care (Fig. 3), c) number of modes of delivery (Fig. 4), d) number of behavioral change techniques (Fig. 5), e) specific modes of delivery, f) specific behavioral change techniques (Supplemental Table 5), g) duration of interventions (Supplemental Fig. 11), h) total number of hours of intervention (Supplemental Fig. 12), i) mean age of participants (Supplemental Fig. 13), and j) percentage of participants who were female (Supplemental Fig. 14).

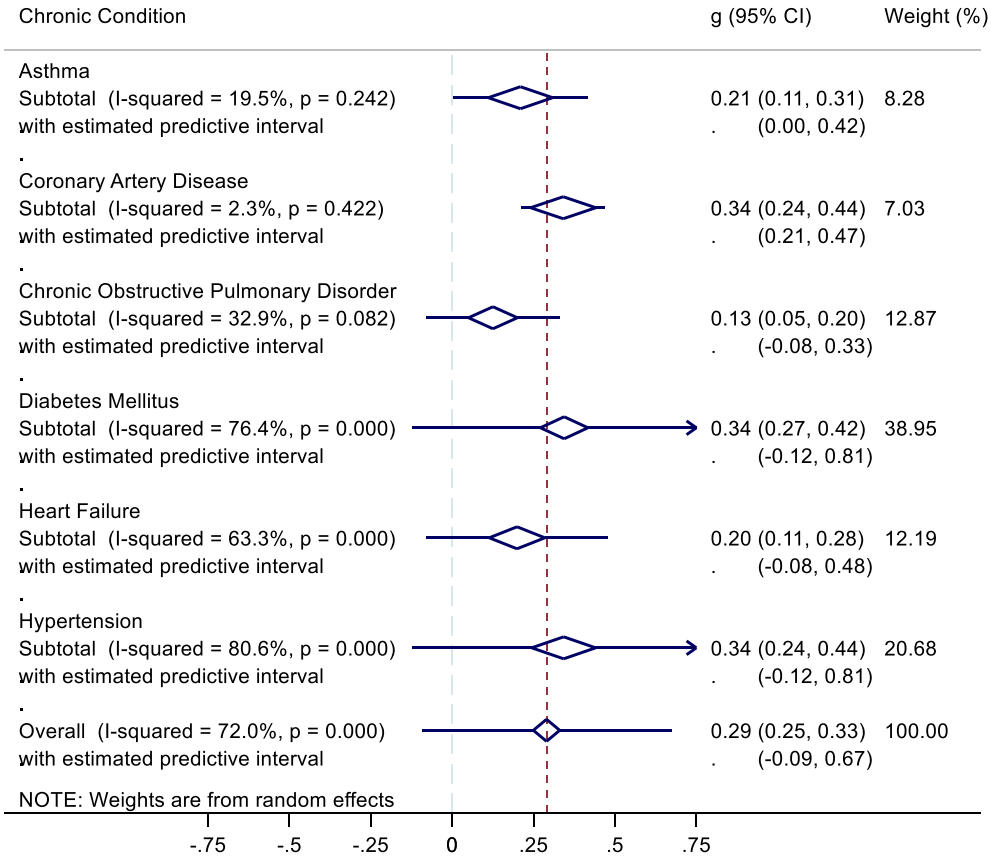


**Fig. 1.** Effectiveness of self-care interventions across chronic conditions. This forest plot shows condition-specific and overall summary effects in the metric of Hedges' *g* (standardized mean difference adjusted for sample size). Positive numbers favor intervention over control conditions. The vertical red dashed line indicates the summary average effect, the horizontal dark blue diamonds span the width of the confidence interval for trials within each condition, and the horizontal lines extending from the horizontal diamonds represent the predictive interval (what might be expected in practice or in similar future studies). CI = confidence interval; g = Hedges' g. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

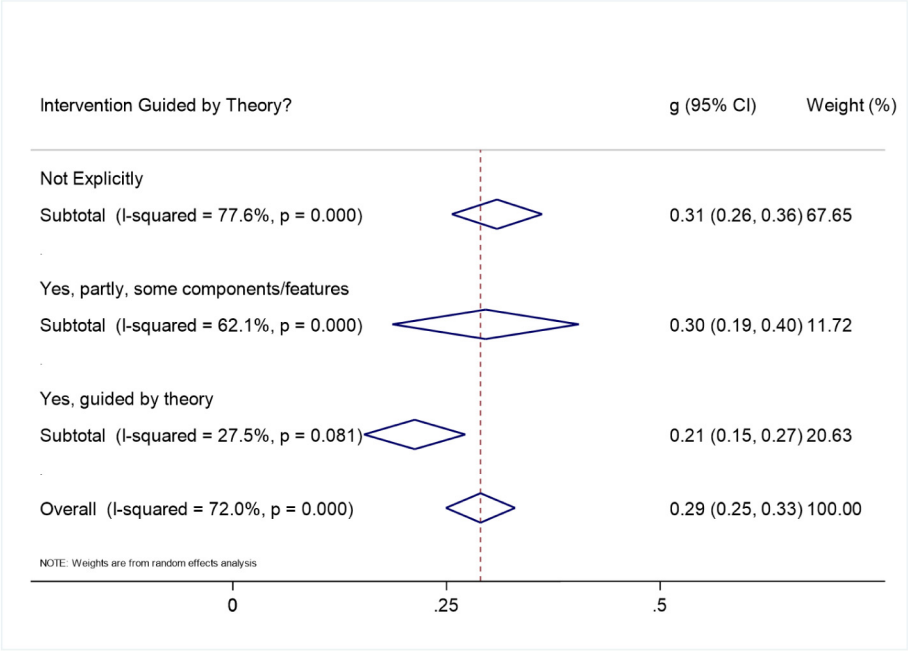


**Fig. 2.** Subgroup meta-regression by use of theory. This forest plot shows overall summary effects in the metric of Hedges' g (i.e. standardized mean difference adjusted for sample size) comparing trials that did not use theory explicitly, trials wherein some components were guided by theory, and trails that were guided by theory. Positive numbers favor intervention over control conditions. Overall, the use of theory did not moderate trial effectiveness (between-study $Q = 1.826$, $df = 2$, $p = 0.401$). CI = confidence interval; g = Hedges' g.

## 4. Discussion

In this meta-analysis of 145 randomized control trials involving 36,853 adults with chronic illness, we observed that interventions designed to support self-care had varying degrees of effectiveness in type 2 diabetes mellitus (HbA1c), heart failure (health-related quality of life), hypertension (systolic blood pressure), asthma (lung function, asthma control or physical activity), coronary artery disease (quality of life and depression, physical activity or cholesterol), and chronic obstructive pulmonary disease (aerobic capacity, lung function, quality of life or depression). Summary effect sizes were statistically significant but small-to-moderate at best. There was statistically significant variation in effect sizes across studies in type 2 diabetes mellitus, heart failure and hypertension, and more than half of all trials were rated as having a high risk of bias. Moreover, differences between studies in the explicit use of theory, specific self-care behaviors targeted, modes of delivery, behavioral change techniques used, intervention duration in months and intensity in hours, and both participant age and gender did not

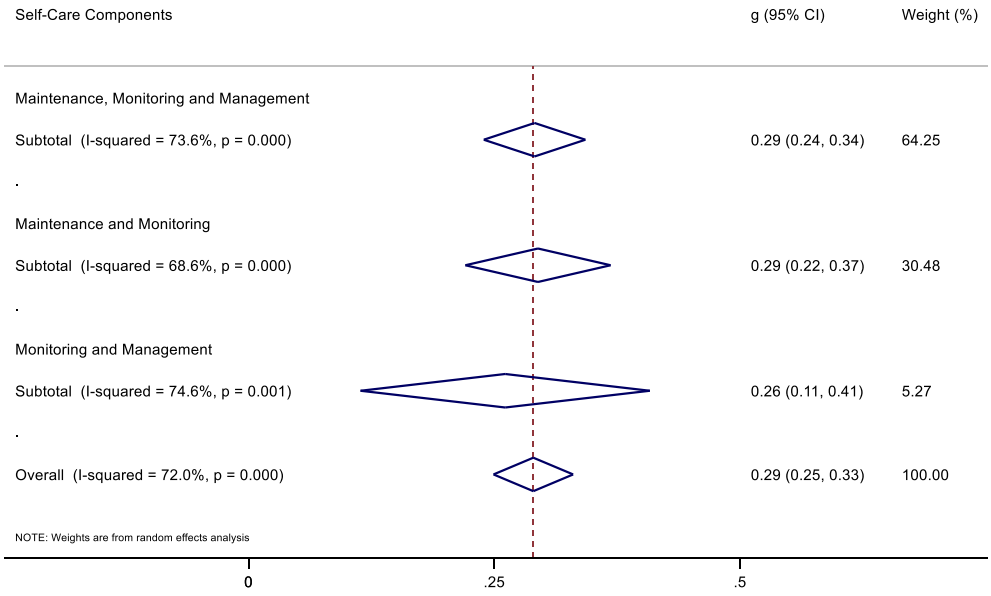


**Fig. 3.** Subgroup meta-regression by components of self-care. This forest plot shows overall summary effects in the metric of Hedges' g (i.e. standardized mean difference adjusted for sample size) comparing trials that focused on self-care maintenance, monitoring and management, trials that focused on maintenance and monitoring, and trails that focused on monitoring and management. Positive numbers favor intervention over control conditions. Overall, the focus on different components of self-care did not moderate trial effectiveness (between-study $Q = 3.111$, $df = 2$, $p = 0.211$). CI = confidence interval; g = Hedges' g.

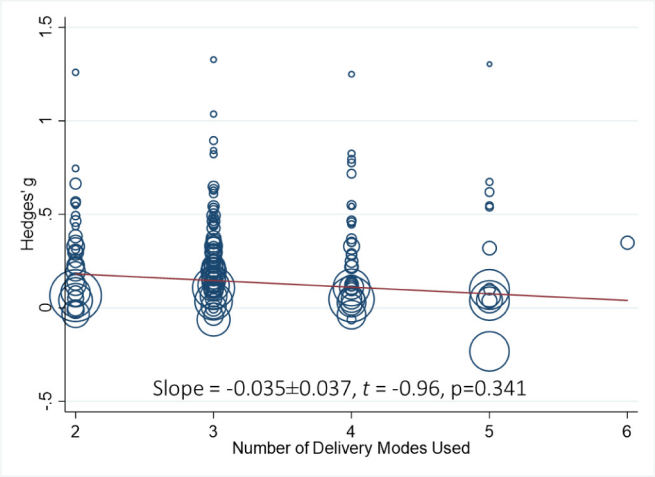


**Fig. 4.** Meta-regression by number of delivery modes. This forest plot shows overall summary effects in the metric of Hedges' g (i.e. standardized mean difference adjusted for sample size) based on the number of delivery modes used. Positive numbers favor intervention over control conditions. Overall, the number of modes used did not influence trial effectiveness.

translate into statistically significant differences in intervention effectiveness. Hence, despite a clear statistical synthesis in support of interventions over controls in improving outcomes, there is work required in this field to enhance the design, conduct and reporting of self-care trials. Confidence in conclusions regarding the effectiveness of self-care in improving outcomes cannot be made until the quality of research improves.

To the best of our knowledge, this is the first study to aggregate outcomes of self-care trials across six chronic conditions. But, our findings are consistent with the small-to-moderate effects observed in prior meta-analysis of trials within specific chronic conditions. In an analysis of 14 trials in chronic obstructive pulmonary disorder, self-care interventions had a small effect on improving quality of life, and a moderate effect on reducing hospitalization (Jonkman et al., 2016d). In an analysis of 20 trial in heart failure, self-care interventions had a small effect on improving quality of life, and a moderate effect on the risk of hospitalization or death (Jonkman et al., 2016b). In a network meta-analysis of

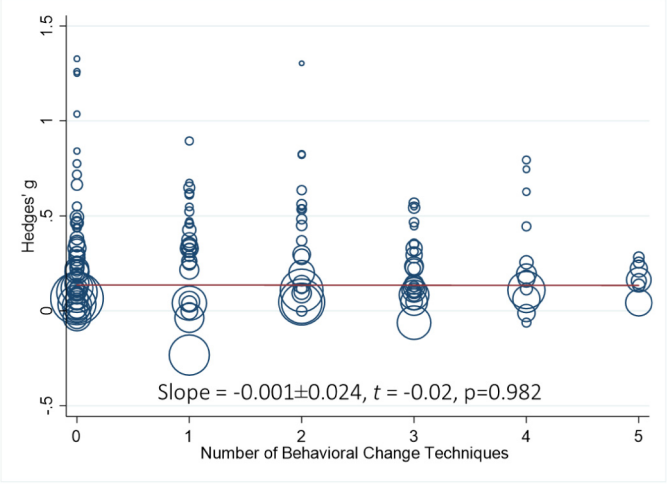


**Fig. 5.** Meta-regression by number of behavioral change techniques. This forest plot shows overall summary effects in the metric of Hedges' g (i.e. standardized mean difference adjusted for sample size) based on the number of behavioral changes techniques used in RCTs. Positive numbers favor intervention over control conditions. Overall, the number of behavioral change techniques used did not influence trial effectiveness.

105 trials in asthma, regularly supported self-care (defined as > two hours of support at regular intervals by health professionals) had a small effect on reducing healthcare use, and a moderate effect on improving quality of life (Hodkinson et al., 2020). In a meta-analysis of 12 trials in hypertension, self-care interventions had a small effect on lowering blood pressure (Van Truong et al., 2021). Finally, in a meta-analysis of 47 trials in type 2 diabetes, self-care interventions were effective in reducing HbA1c significantly but not at a clinically-relevant degree of change (Odgers-Jewell et al., 2017).

There are two major reasons for the nominal improvements in outcomes related to self-care interventions observed in this study and ostensibly the work of others. First, it is possible that self-care interventions by themselves are not very effective at improving outcomes. Self-care is a critical component in the management of type 2 diabetes mellitus (Powers et al., 2015), heart failure (Heidenreich et al., 2022), hypertension (Unger et al., 2020), asthma (Bateman et al., 2008), coronary artery disease (Knuuti et al., 2020), and chronic obstructive pulmonary disease ((GOLD) GIfCOLD, 2021) according to guidelines developed by professional societies. But, there may need to be more equipoise about how effective self-care interventions are at improving outcomes. Moreover, small-to-moderate effects may be all that can be expected given other elements of disease management, including but not limited to the influence of healthcare providers and even family (World Health Organization, 2021). Although some self-care interventions are driven by theory, they may lack an essential component that would enhance the effectiveness of the intervention. Motivating factors and other outside influences may drive the quality of self-care interventions and their effectiveness on outcomes, but more research is needed to evaluate these effects. Additionally, not all trials included in this meta-analysis were designed specifically to improve clinical outcomes – some primarily were aimed at improving individual behaviors - and not all of these investigators would categorize their trials as being related to self-care. Such variation in trial design has made us rethink our operational definition of self-care interventions in the context of chronic illness (Riegel et al., 2022). Second, there is limited harmonization of trial design features within chronic conditions including but not limited to the choice, timing, and reporting of primary outcomes. Moreover, there is little evidence that trials are conducted in a way that builds on lessons learned from prior trials, or that they are informed appropriately by theory (Jaarsma et al., 2020b) The lack of harmonization of design and outcomes and underreporting of intervention details as well as the lack of consideration for prior research in a given area will continue to hamper our ability to draw stronger conclusion about the effectiveness of self-care interventions unless there is a major course correction in this area of science. Third, it may be inattention to the mechanism of action involving the behavioral change techniques used in self-care trials that result in modest effectiveness. In a review of self-care interventions in heart failure and chronic obstructive pulmonary disorder, Jonkman and colleagues argued that in order to have higher quality information on effectiveness greater attention must be paid to mechanisms in trial design (Jonkman et al., 2017). Goal setting and problem solving were the two most commonly used behavioral change techniques in these trails. But, there may be other techniques that have a clear mechanism of action, such as providing feedback on behavior, health consequences, and social support (Carey et al., 2019), that may be more helpful in improving self-care behaviors (Abraham and Michie, 2008) and the downstream outcomes reported in this analysis. Thinking about self-care in the broader context of disease management as well as using robust trial designs and evidence-based behavioral change techniques may improve the quality of science in this area.

The rigor and reproducibility of trials included in this meta-analysis are questionable due to risk of bias. Similarly, poor quality in trial design and reporting has been identified previously within specific chronic conditions. For example, in a review of 34 self-care interventions in cardiovascular disease, the lack of treatment fidelity and consistent outcome measurement were identified as common methodological flaws

(Dickson et al., 2013). In a systematic review of 27 self-care behavioral interventions in type 2 diabetes mellitus, the risk of bias was high in most studies included and most often was related to blinding of outcomes (Batalha et al., 2021). Finally, in a meta-analysis of 25 trials of self-care interventions in heart failure, blinding of participants and personnel, incomplete outcome data, and selective reporting were identified as common elements of risk of bias – all but two studies had a high risk of bias (Jiang et al., 2018). Unfortunately, risk of bias from poor trial design and/or reporting is common in chronic illness self-care trials.

A majority of all trials included in this meta-analysis suffered from biases that could have influenced the findings. Most of the trials suffered from selection bias, particularly with regard to random allocation of participants to study groups. Many trials also suffered from lack of blinding of participants and researchers (performance bias), lack of concealment of the outcome metric (detection bias) and selective reporting of outcomes. In many instances, information on these criteria were not reported, which limits our ability to evaluate scientific rigor with any certainty. These biases could have inflated the findings, suggesting that effects could in fact be smaller or non-existent in real world practice. Although it may be a common assumption that blinding is impossible in behavioral interventions (Juul et al., 2021), there are several ways in which blinding of participants and key study personnel can be optimized. For example, participants can be blinded to hypotheses, details of the intervention and control arms, and randomization in many instances, those involved with outcome collection can be blinded to all elements except the outcome measures, investigators can be blinded to randomization and outcome measures in many instances, and statisticians can be blinded to most study elements including details of the study arms and even randomization in many instances (Friedberg et al., 2010). These and other steps outlined by Friedberg et al. (2010) may help reduce the risk of performance and detection bias. Many of the included trials also failed to discuss how intervention fidelity was maintained during the course of the trial, which could deflate the findings by dampening the effectiveness of self-care interventions that are otherwise well designed. A lack of sufficient reporting on intervention fidelity makes it difficult to determine if the interventions were carried out as intended in these trials and thus, establish if this aspect influenced the findings of these trials (Bellg et al., 2004). Future studies should be designed, reported and evaluated carefully to enhance scientific rigor, and reporting guidelines, such as those recommended by the Cochrane Collaborative and the Medical Research Council (Craig et al., 2008), should be followed consistently.

Interestingly, heterogeneity was smaller among the chronic conditions that had inconsistent outcome metrics. For example, coronary artery disease trials used several outcome metrics (physical activity, low density lipoprotein levels, quality of life, etc.), yet heterogeneity in effect sizes was low and not statistically significant. This can be contrasted with hypertension trials, all of which used systolic blood pressure as an outcome metric yet there was statistically significant heterogeneity. But, the effectiveness of self-care trials in hypertension and coronary artery disease trials was identical both in average effect and in the 95% CI. The reasons behind these findings are not clear but there are several possibilities. Although outcome may have been similar in hypertension trials, the self-care interventions used in these trials were not consistent. There also may have been large variation in clinical characteristics among these studies (e.g. age, disease severity, comorbidity, cultural background, educational level, etc.), and control conditions may have differed more considerably among hypertension trials compared with trials in coronary artery disease. Finally, it could be that there was more variation in outcomes in hypertension because they were objectively-measured and biological, as opposed to the composite of patient-reported and objectively-measured data in coronary artery disease. Surely, future comparisons between trials in hypertension and coronary artery disease would be of interest, especially because of the link between these two chronic conditions (Fuchs and Whelton, 2020).

The marked and unexplained heterogeneity in trial effectiveness across conditions is another interesting finding. Considerable heterogeneity across self-care trials within specific chronic conditions has been identified by others. For example, in a meta-analysis of 25 trials of self-care interventions in heart failure, depression was improved at three-to-six months but with significant heterogeneity across trials ($I^2 = 68\%$) (Jiang et al., 2018). In a meta-analysis of 12 trials in hypertension, self-care interventions reduced systolic blood pressure but with significant heterogeneity across studies ($I^2 = 70.2\%$) (Van Truong et al., 2021). Finally, in a meta-analysis of 47 trials of self-care interventions in type 2 diabetes, HbA1c was reduced but with significant heterogeneity across trials ($I^2 = 70.2\%$) (Odgers-Jewell et al., 2017). Hence, heterogeneity also is common in the study of self-care interventions in specific chronic illness.

Based on our findings, self-care trials are not equally effective across chronic conditions. Further, none of our tested moderators of effectiveness were statistically significant in our meta-regression modeling. There are a few lessons learned from our findings related to potential moderators of trial effectiveness. First, more modes of delivery and more behavioral change techniques may not translate into greater effectiveness across chronic conditions. Hence, self-care investigators should choose and implement a mode of delivery and a behavioral change technique in a well-reasoned fashion (Michie et al., 2013), but not try more modes as the only means of enhancing effectiveness. Moreover, no individual mode of delivery or behavioral change technique was statistically significant as a moderator of trial effectiveness. Based on effect sizes, however, interventions based on skills training tended to have lower effectiveness, and those incorporating health consequences as a behavioral change technique tended to have higher effectiveness. Second, a majority of trials had no explicit theoretical underpinning, and the way in which theory is used appears to make no difference on randomized control trial effectiveness. It may be that theory is not being used well (Dalgetty et al., 2019), that tangential theories are being used, or that theories used in randomized control trials are not that informative or even misleading in the design and conduct of trials. Third, the specific components of self-care targeted in randomized control trials made no difference in effectiveness across conditions. The self-care components are not described universally in randomized control trials as maintenance, monitoring and management; hence, differences in the effectiveness of self-care components may emerge with increased harmonization and uptake of this nomenclature. It may also be that all of these behaviors are important in improving outcomes and as such targeting any combination of these behaviors has clinical outcome benefit. Fourth, the quality of randomized control trials included in this meta-analysis was generally poor. Thus, little can be gleaned from meta-regressive methods involving moderators of trial effectiveness until the quality of self-care trials improves considerably.

### 4.1. Strengths and limitations

There are strengths of this meta-analysis that should be considered when interpreting our results. First, we were able to focus exclusively on randomized control trials to address our aims as opposed to quasi-experimental or observational data. Both the number of trials and cumulative number of participants was high. Second, we used a number of robust methods including the use of prediction intervals to project the range of future finding in this area of science, the use of meta-regression for testing moderating effect of several trial design features, and our qualification of risk of bias to be transparent about areas of uncertainty due to poor trial design and/or reporting. Third, we did not perform any sensitivity analysis beyond the presentation of meta-analyses across and within chronic conditions, and our a priori determined subgroup analysis because doing so in this case would have been arbitrary and non-additive (Higgins et al., 2022b).

There also are several limitations that must be considered when interpreting our results. First, only randomized control trials written in

English were included in this meta-analysis; therefore, additional studies that may have contributed information to this meta-analysis may not have been reviewed. Second, the risk of publication bias is always a concern with meta-analyses. Even though our formal tests of publication bias failed to provide evidence of the need to conduct trim-and-fill methods to adjust effects estimates for possible missing studies, publication bias may increase our effectiveness estimates compared with what might be seen in clinical practice. Third, this meta-analysis was conducted within the framework of a scoping review designed to identify the components of self-care interventions across chronic conditions, so studies were not selected with specific interventions or outcomes in mind. Fourth, although some chronic conditions in the scoping review were well-represented, others, such as stroke and chronic renal disease, were not and therefore excluded this meta-analysis. Finally, this meta-analysis covers trials published from 2008 to 2019; hence, studies published before or since were not taken into consideration.

## 5. Conclusion

Self-care interventions improve outcomes of chronic illness modestly compared with control conditions. Importantly, the quality of randomized control trials in this area of science is generally poor with major weakness in study design, conduct and/or reporting. In addition, it appears that there is limited added value in using theory, focusing on specific components of self-care, having multiple modes of delivery, or having more than one behavioral change technique based on these poor-quality trial data. Significant advancement in trial design, implementation and reporting are necessary to move the science of self-care in chronic illness forward. Otherwise, there will be a need for greater equipoise about including self-care as part of chronic illness guidelines.

## Funding

This work was supported in part by a grant from Australian Catholic University that established the International Center for Self-Care Research. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of Australian Catholic University.

## Data Sharing Statement

Extracted data are available upon request to the corresponding author.

## CRediT authorship contribution statement

Christopher S. Lee: Conceptualization, Methodology, Software, Visualization, Writing – Original draft preparation – Reviewing and Editing Heleen Westland: Methodology, Data Curation, Writing – Reviewing and Editing Kenneth M. Faulkner: Methodology, Data Curation, Visualization, Writing – Reviewing and Editing Paolo Iovino: Data Curation, Writing – Reviewing and Editing Jessica Harman Thompson: Data Curation, Writing – Reviewing and Editing Jessica Sexton: Data Curation, Visualization, Writing – Reviewing and Editing: Elizabeth Farry: Data Curation, Writing – Reviewing and Editing Tiny Jaarsma: Methodology, Data Curation, Writing – Reviewing and Editing Barbara Riegel: Methodology, Data Curation, Writing – Reviewing and Editing.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2022.104322.

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