REVIEW





A systematic review and meta-analysis of the effectiveness of self-management interventions in people with a stoma

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Abstract

Aims: Explore the evidence from randomized controlled trials for the effect of selfmanagement interventions on quality of life, self-management skills and self-efficacy, and to explore which intervention characteristics are associated with effectiveness.

Design: Systematic review.

Data sources: A search of the literature was conducted in these databases: MEDLINE (OVID), EMBASE (OVID) and PsychINFO (OVID) from January 2000 to February 2020. Review methods: Studies were included if participants had a bowel stoma, were over the age of 18 and the design was a randomized controlled trial of a self-management programme. The outcome measures for this review were quality of life, selfmanagement skills and self-efficacy. The Behaviour Change Technique Taxonomy was used to code interventions for underlying components and alongside other intervention characteristics, associations with improvements in outcomes were explored.

Results: The search identified 3141 articles, 16 of which were eligible. A meta-analysis of self-efficacy scores from five studies (N = 536) found an improvement in those that received the self-management intervention at follow-up with a 12-point mean difference compared with the usual care group. Effects on quality of life and selfmanagement skills were mixed, and meta-analyses of these data were not possible. Across 13 studies an average of 10 behaviour change techniques were used with, credible source (e.g. nurse, doctor, therapist) (n = 13), instruction on how to perform the behaviour (n = 13), demonstration of the behaviour (n = 12) used most often. The behaviour change technique of self-monitoring was associated with an improvement in quality of life. The involvement of a nurse was associated with higher self-efficacy and self-management skills.

Conclusion: This review suggests that self-management interventions can increase peoples' self-efficacy for managing their stoma.

Impact: A standardized approach to the reporting of interventions and the measures used is needed in future studies to better understand the effect on quality of life and self-management skills.

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KEYWORDS

meta-analysis, nurses, quality of life, self-efficacy, self-management, stoma, systematic review

1 | INTRODUCTION

There are no global estimates for the amount of people with an ostomy but around 1 million people in China, 1 million people in the United States and 700,000 people in Europe are thought to be living with a stoma (Claessens et al., 2015; Zhang, 2005). It is estimated that colorectal cancer is responsible for the formation of 50% of bowel stomas and Inflammatory Bowel Disease (IBD) is the biggest non-cancer cause (Carlsson et al., 2010; Claessens et al., 2015). The formation of a stoma can have a profound impact on a patient's life; for example, people with a stoma due to bowel cancer report lower quality of life (QoL) than those without a stoma (Wilson & Alexander, 2008). Although over 2 years QoL did improve in this group but remained below those that did not have a stoma. Further research has shown that QoL can improve over the course of a year in people with a stoma from other conditions as well as cancer (Ma et al., 2007; Marquis et al., 2003).

In several chronic conditions, self-management interventions have become an increasingly important tool for providing high-quality care to patients. Self-management interventions support an individual to manage their health condition on a day-to-day basis through providing education and passing on skills through training (Toomey et al., 2015). The aim of these interventions is to increase self-efficacy, a person's belief in their ability to carry out a certain action, to enhance their self-management skills, and improve their health status (Lorig & Holman, 2003). For people with a stoma, self-management interventions are often designed to educate and improve confidence in how to care for their stoma to reduce the chance of developing clinical complications and stoma appliance-related problems (Burch, 2004; Claessens et al., 2015; Lee, 2001; Shabbir & Britton, 2010; Weerakoon, 2001).

1.1 | Background

Systematic reviews of self-management interventions for people with a stoma suggest they can increase QoL and self-efficacy, but a positive effect on clinical outcomes (e.g. length of hospital stay and number of complications) has not been supported (Danielsen et al., 2013; Phatak et al., 2014). A recent systematic review synthesized results from education interventions for people with a stoma from colorectal cancer and identified 13 studies, five of which measured QoL (Faury et al., 2017). Of these, only three demonstrated an improvement in overall QoL, but, in the same review all six studies that measured self-management skills (measured by time to proficiency in managing their stoma and a survey scale), self-efficacy or psychosocial outcomes showed an improvement. The mixed findings presented in these reviews could be due to the inclusion of studies with

weaker study designs (pre-post). To better establish the efficacy of these interventions, a review of the evidence from randomized controlled trials (RCT) is necessary, with meta-analyses to formally test the effectiveness of these interventions across multiple studies.

In recent years there has been a move toward enhancing our understanding of the underlying characteristics of interventions, especially in the context of healthcare. To improve the reporting of interventions, guidelines and taxonomies have been developed. The template for intervention description and replication (TIDieR) checklist outlines areas to improve the reporting of interventions but also allows identification of factors that may be important (mode of delivery, provider, intervention duration) (Hoffman et al., 2014). Taxonomies have also been developed to classify pre-established behaviour change techniques (BCTs). The Behaviour Change Technique Taxonomy is one way in which the underlying components of interventions can be explored and has been used extensively in health research (Michie et al., 2013). Previous systematic reviews of chronic diseases have found that certain BCTs such as self-monitoring, instruction on how to perform the behaviour, feedback on behaviour and goal-setting are associated with improved outcomes (Dombrowski et al., 2012; van Vugt et al., 2013). Identifying these characteristics could help to inform future interventions for this population to improve QoL, self-management skills and self-efficacy. This is particularly important, given there have been calls for more feasible and effective interventions to improve patient outcomes for people with a stoma (Phatak et al., 2014).

2 | THE REVIEW

2.1 | Aims

The primary objective of this systematic review was to explore the effect of RCT self-management interventions on QoL, self-management skills and self-efficacy of people with a bowel stoma and conduct a meta-analysis. The secondary objectives of this review were to identify the characteristics of self-management interventions developed for people with a stoma and explore whether these were associated with improvements in QoL, self-management skills and self-efficacy.

2.2 | Design

This systematic review was registered with PROSPERO; CRD42020169762. This review was completed to the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses' checklist.

2.3 | Search methods

A systematic review of the literature was conducted in these databases: MEDLINE (OVID), EMBASE (OVID) and PsychINFO (OVID) from 1st January 2000 to 13th February 2020. These databases were selected based on their use in previous reviews of this subject area and they provided the greatest spread of research across medical and psychological-related fields. The search strategy for the MEDLINE database can be found in Appendix S1, but the search strategy for all databases combined synonyms for a stoma and selfmanagement interventions, with the outcomes and study design being assessed by the authors. The database search was supplemented by forward and backward searching of key articles to identify any potentially relevant papers missed by the search. The review was limited to studies published in the last 20 years to ensure their relevancy and was restricted to those published in English language publications. The studies were limited to the inclusion of at least one of three outcomes (QoL, self-management or self-efficacy). The search results were then screened for relevancy by reviewing their titles and abstracts against the inclusion and exclusion criteria independently by two authors. Full texts of the screened articles were then reviewed by the same authors to identify eligible studies. The search results and the screening process can be seen in Figure 1.

2.4 | Search outcomes

Studies were considered eligible if participants had a bowel stoma (either temporary or permanent) and were over the age of 18. Eligible studies were those that described and tested the effect of a self-management intervention. Studies were RCTs and could be pilot

or feasibility studies as long as there was a comparison or control group. For this review, self-management interventions were defined as those that actively involve people with a stoma in the form of education (imparting knowledge on consequences and management of their condition) or training (providing skills for daily life, goal-setting and problem solving) (Toomey et al., 2015), with the aim of the interventions being to improve the patient's ability to self-manage their condition, in relation to treatment, symptoms and lifestyle (Barlow et al., 2002). The key outcomes of the present review are QoL, self-management skills and/or self-efficacy. The original registration of this review specified the inclusion of pre-post study designs; however, this was later restricted to RCTs to ensure methodological rigour.

2.5 | Quality appraisal

The risk of bias for RCT studies was assessed using the Cochrane Risk of Bias assessment tool (Cochrane RoB) (Sterne et al., 2019). The results of each domain will be assessed from 'low' to 'high' risk of bias and an overall assessment made for each study, based on the study author's analysis.

2.6 Data abstraction

Data from the identified studies were extracted into a form adapted from the Cochrane Public Health Group's Data Extraction and Assessment Template including:

1. General: title, authors, country, year of publication.

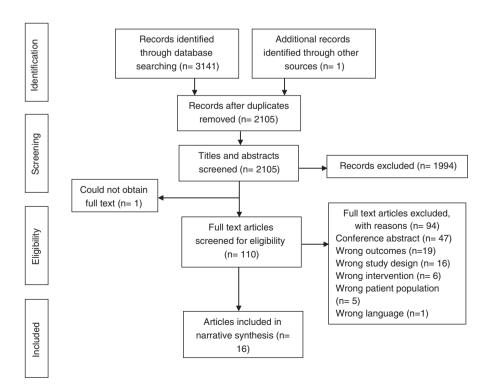


FIGURE 1 PRISMA flow. *Note*: 'Other sources' refers to forward and backward citation searching

- 2. Methods: duration of study, design.
- Participants: number, age, diagnostic criteria, baseline characteristics, setting.
- 4. Intervention characteristics: content, timing, duration, mode of delivery, provider and theoretical underpinning.
- 5. Outcomes: as specified above.
- 6. Results: for each outcome of interest.

2.7 | Synthesis

Meta-analyses were not able to be conducted due to the heterogeneity of variables for QoL and self-management, these results are discussed and compared narratively. A meta-analysis was able to be conducted to combine the results of comparable studies for self-efficacy. Means and standard deviations were extracted for the included studies. The meta-analysis was conducted in Review Manager v5.3 and was run as an inverse variance fixed effects meta-analysis. The level of significance for the Chi-squared test for heterogeneity was set at a more conservative p < .10, with a non-significant result indicating no heterogeneity. The l^2 values of percentage of variation across the studies that is, due to heterogeneity were judged as: 0%–40% low heterogeneity, 30%–60% moderate heterogeneity, 50%–90% substantial heterogeneity and 75%–100% considerable heterogeneity (Deeks et al., 2021).

The content of the interventions was used to identify the BCTs incorporated, this was done using the BCT Taxonomy (v1) to code the information (Michie et al., 2013). This taxonomy contains 93 distinct BCTs (e.g. action planning, monitoring of emotional consequences, social comparison) which are clustered into 16 groups (e.g. goals and planning, social support, reward and threat). A narrative synthesis was conducted which described the interventions characteristics (BCTs, timing, duration, mode of delivery, provider and theoretical underpinning).

Studies which showed an increase in either QoL, self-efficacy or self-management were grouped together and the BCTs used in each of those studies were quantified for each variable. This sought to highlight the most frequently used BCTs in the successful interventions. More formal analyses were not possible due to the heterogeneity of the interventions. Associations were also drawn between the wider intervention characteristics (mode of delivery, duration, theoretical underpinning, provider) and improvements in the outcome variables.

3 | RESULTS

3.1 | Study selection

Through searching databases 3141 records were obtained. This resulted in 16 eligible papers for inclusion in the systematic review (Chaudhri et al., 2005; Cheung et al., 2003; Crawford et al., 2012; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lim et al.,

2019; Lo et al., 2010, 2011; Pouresmail et al., 2019; Seo, 2019; Sier et al., 2017; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013). Figure 1 presents the PRISMA flow diagram of the study. Table 1 outlines the characteristics of the included studies and sample sizes for the studies ranged from 42(Chaudhri et al., 2005) to 218 (Sier et al., 2017). Table 2 outlines the characteristics of the interventions and key findings.

3.2 | Quality of life

Seven studies measured QoL (Cheung et al., 2003; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lim et al., 2019; Sier et al., 2017; Su et al., 2019; Xu et al., 2018). One study used a generic quality of life scale; the WHO Quality of Life Scale (Cheung et al., 2003). One study used an overall health-related quality of life scale; 15D (Forsmo et al., 2016). Six studies used disease/stoma-specific measures of quality of life; the Stoma-Quality of Life Questionnaire (Sier et al., 2017; Su et al., 2019), the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Cancer30 (Xu et al., 2018), the City of Hope-Quality of Life-Ostomy Questionnaire (Khalilzadeh Ganjalikhani et al., 2019), the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Colorectal29 (Lim et al., 2019) and the Quality of Life-Colostomy Scale (Cheung et al., 2003).

Due to the use of different scales to measure QoL a meta-analysis was not considered appropriate. The study that measured generic QoL reported significantly greater improvements in QoL in the intervention group when compared with the usual care group (Cheung et al., 2003), whereas the study that measured overall health-related QoL did not report significant differences between the two groups in regards to QoL (Forsmo et al., 2016). Of the six studies that used stoma and disease-specific QoL questionnaires, four reported greater improvements in scores in the intervention group when compared with the usual care group (Khalilzadeh Ganjalikhani et al., 2019; Sier et al., 2017; Su et al., 2019; Xu et al., 2018). The other two studies found no difference in between the intervention and control group (Cheung et al., 2003; Lim et al., 2019).

3.3 | Self-management skills

Six studies reported on self-management skills (Chaudhri et al., 2005; Crawford et al., 2012; Lim et al., 2019; Lo et al., 2010, 2011; Seo, 2019). Two studies measured self-management through the time to stoma proficiency (Chaudhri et al., 2005; Lim et al., 2019), two studies used scales of self-care attitudes and behaviours (Lo et al., 2010, 2011), and two studies used nurse observation of participants in their ability to manage their stoma with grading on scales for completion of self-management behaviours (Crawford et al., 2012; Seo, 2019).

Two studies measured time to stoma proficiency, with one finding that the intervention significantly decreased time to stoma

TABLE 1 Characteristics of included studies

Author, year	Country	Sample size	Retention rate at follow-up	Male N	Age in years, mean (SD)	Stoma type (n)	Reason for stoma formation
Chaudhri et al. (2005)	ž	CG = 21	N.	CG = 13	CG = Median 62 (range 43-82)	CG = Ileostomy (15), colostomy (6)	Colorectal cancer
		IG = 21		IG = 11	IG = Median 69 (range 36-79)	IG = Ileostomy (16), colostomy (5)	Liveli
Cheung et al. (2003)ª	China	63	CG = 30	CG = 20	CG = 56.4 (13.5)	CG = Colostomy (16), ileostomy (14)	Colorectal cancer
			IG = 29	IG = 20	IG = 60.1 (10.9)	IG = colostomy (10), ileostomy (19)	Keseirch
Crawford et al. (2012)ª	USA	88	CG = 34	CG = 16	CG = 54.7 (13.1)	CG = Ileostomy (26), colostomy (8)	N.
			IG = 34	IG = 18	IG = 59.8 (15.1)	IG = ileostomy (19), colostomy (15)	
Forsmo et al. (2016)	Norway	CG = 61	Z.	CG = 41	CG = Median 66 (range 19-89)	CG = Colostomy (30), ileostomy (31)	Colorectal cancer
		IG = 61		IG = 34	IG = Median 64 (range 23-88)	IG = colostomy (35), ileostomy (26)	
Khalilzadeh Ganjalikhani et al. (2019)	Iran	CG = 30	ZZ Z	CG = 19	N N	CG = Colostomy (24), ileostomy (6)	CG = Cancer = 26, Other = 4
		IG = 30		IG = 14		IG = colostomy (22), ileostomy (8)	IG = Cancer = 26, Other = 4
Lim et al. (2019)	Singapore	CG = 31	CG = 24	CG = 17	CG = 62.3 (13.4)	CG = Colostomy (15), ileostomy (9)	Cancer
		IG = 32	IG = 27	IG = 16	IG = 63.5 (13.3)	IG = colostomy (11), ileostomy (16)	
Lo et al. (2010)	Taiwan	CG = 27	Z Z	CG = 14	CG = 63 (17.6)	NR	Colon cancer
		IG = 27		IG = 17	IG = 57.9 (17.5)		
Lo et al. (2011)	Taiwan	CG = 57	CG = 56	CG = 32	CG = 62 (15.8)	Z Z	Colon cancer
Pouresmail et al. (2019)	Iran	CG = 27	CG = 23	6 = 90 CB = 6	CG = 53.8 (9.2)	CG = Colostomy (16), ileostomy (7)	CG = Cancer = 21, Fistula = 0,
		IG = 26	IG = 23	IG = 12	IG = 45.9 (10.4)	IG = colostomy (18), ileostomy (5)	IG = Cancer = 20, Fistula = 1, Polyp = 1, Other = 1

(Continues)

TABLE 1 (Continued)

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Author, year	Country	Sample size	Retention rate at follow-up	Male N	Age in years, mean (SD)	Stoma type (n)	Reason for stoma formation
Seo (2019)	South Korea	CG = 20	Z.	CG = 15	CG = 61 (9.2)	CG = Ileostomy (18), colostomy (2)	Z Z
		IG1 = 20		IG1 = 17	IG1 = 58 (14.0)	IG1 = ileostomy (18), colostomy (5)	
		IG2 = 20		IG2 = 15	IG2 = 56 (8.7)	IG2 = ileostomy (15), colostomy (2)	
Sier et al. (2017)	Netherlands	CG = 113	¥	CG = 70	CG = 60.8 (13.4)	CG = Colostomy (61), ileostomy (50)	CG = Malignancy = 82, Ulcerative Colitis = 8, Crohn's Disease = 4, Diverticulitis = 2, Anal diseases = 1, Other = 15
		IG = 105		IG = 71	IG = 63.7 (10.5)	IG = colostomy (66), ileostomy (37)	IG = Malignancy = 90, Ulcerative Colitis = 3, Crohn's Disease = 3, Diverticulitis = 2, Anal diseases = 1, Other = 6
Su et al. (2019)	China	CG = 64	CG = 57	CG = 32	CG = 59.1 (12.9)	CG = lleostomy (40), colostomy (17)	Rectal cancer
		IG = 60	IG = 50	IG = 35	IG = 57 (14.7)	IG = ileostomy (41), colostomy (9)	
Wang et al. (2018)	China	CG = 106	CG = 103	CG = 67	CG = 59.2 (14.1)	CG = Colostomy (82), ileostomy (17), other (4)	CG = Rectal cancer = 67 , colon cancer = 18 , bladder cancer = 2 , other = 16
		IG = 106	IG = 100	IG = 62	IG = 57 (14.9)	IG = colostomy (74), ileostomy (18), other (8)	$IG = Rectal \ cancer = 65,$ $colon \ cancer = 11,$ $bladder \ cancer = 6,$ $other = 18$
Wen et al. (2019)	China	CG = 45 IG = 47	ZZ Z	CG = 25 IG = 30	52.8 (11.1)	NR.	Colorectal cancer
Xu et al. (2018)	China	CG = 28	N.	CG = 19	CG = 61.1 (13.6)	Colostomy	Cancer
Zhang et al. (2013)	China	CG = 60 $IG = 61$	CG = 51 IG = 52	CG = 36	CG = 55.3 (13.7) IG = 52.9 (13.3)	Colostomy	Rectal cancer

Abbreviations: CG, control group; IG, intervention group; NR, not reported; RCT, randomized controlled trial.

These studies did not provide a breakdown of the complete sample size into IG and CG but only those that completed follow-up.

TABLE 2 Intervention details and outcome measures

Author, year	Intervention summary (Content/Duration/ Mode of delivery/Provider/Timing)	Key outcome findings
Lo et al. (2010)	Content: Multimedia learning education programme focussed on reasons for stoma formation, the anatomy, stoma care and irrigation. Duration: 1 session lasting 30–45 min. Mode of delivery: film and pictures, face-to-face. Provider: instructor. Timing: Postop.	Self-management (Attitude of self-care scale and Behaviour of self-care scale): Significant difference in change scores from baseline to follow-up for IG and CG for attitude (27.04 (SD = 7.14) vs. 14.56 (SD = 5.96), t = 6.97, p < .001) and behaviour (27.04 (SD = 4.02) vs. 19.41 (SD = 7.18), t = 4.82, p < .001) scores.
Lo et al. (2011)	Content: Multimedia education programme had two sections, the first focussed on information about the formation and reasoning behind the formation of a stoma. The second section focussed on stoma care. Duration: 1 session lasting 30–45 min. Mode of delivery: 2D anime (style of hand-drawn computer animation), film and pictures to reinforce the information. Provider: researcher. Timing: Postop	Self-management (Attitude of self-care scale and Behaviour of self-care scale): IG scores were significantly higher on attitudes ($F = 8.91, p < .001$) and behaviours ($F = 9.48, p < .001$) than CG.
Crawford et al. (2012)	Content: taught hands-on skills through verbal instruction and printed materials. Session 2 for the intervention group was delivered via a DVD teaching a step-by-step approach to stoma appliance care. Complications, diet and practical advice for living with a stoma. Duration: 3, 1-h long sessions both IG and CG. Mode of delivery: intervention DVD for 1 session and face-to-face. Provider: nurse. Timing: Postop	Self-efficacy (visual analogue scale from 0 to 100): IG 79.09 (SD = 18.74); CG 78.18 (SD = 19.87); $t = -0.20$, $p = .84$. Self-management (nurse observation scored pass fail on 4 self-care skills): IG median score 4 (range 2–4); CG median score 4 (range 1–4); $t = -0.19$, $p = .85$.
Khalilzadeh Ganjalikhani et al. (2019)	Content: Education on how to care for the stoma and change the appliance (shown through modelling and practice). Information was also provided on complications, how to live with a stoma and stoma appliances. Duration: 1, 2-h long session. Mode of delivery: face-to-face and a training booklet. Provider: stoma nurse. Timing: Postop	Quality of life (COH-QOL): Baseline IG 144.8 (SD = 34.07); CG 185.7 (SD = 84.9); $t = -2.40$, $p = .10$. Follow-up IG 229.9 (SD = 83.3); CG 202.7 (SD = 38.3); $t = 1.65$, $p = .009$.
Forsmo et al. (2016)	Content: Education pre-op included importance of their role in training and information on the surgery, training in stoma care, impact of stoma on relationships and everyday life. Post-op were taught how to change stoma appliance, where to buy equipment and told about national stoma association. They also received equipment to take home. Duration: Pre-op education was 1 or 2 sessions at 45–60 min and daily education postop. Mode of delivery: face-to-face. Provider: enhanced recovery after surgery nurse and stoma nurse specialist. Timing: Preop and postop.	Quality of life (15D): no statistically significant difference between IG and CG scores from baseline (IG 0.871 ; CG 0.870) to follow-up (IG 0.812 ; CG 0.811 , $p = ns$). Test score not reported.

TABLE 2 (Continued)

	Intervention summary (Content/Duration/	
Author, year	Mode of delivery/Provider/Timing)	Key outcome findings
Chaudhri et al. (2005)	Content: education on how to manage a stoma appliance and patient assessed for competence. Immediately prior to surgery they were assessed on competency again. Duration: two home visits (45 min each). Mode of delivery: conducted prior to surgery face-to-face. Provider: colorectal nurse. Timing: Preop.	Self-management (Time to stoma proficiency (days from surgery to reach proficiency on set criteria)): IG 5.5 days (range 2–10); CG 9 days (range 4–10); p = .0005. Test score not reported.
Zhang et al. (2013)	Content: Reinforcing self-care skills, encouragement to attend an ostomy club to hear other experiences, verbal encouragement to increase confidence, providing social support and reducing negative emotions. Duration: There were two telephone sessions delivered and a third was offered if self-efficacy was still low. Mode of delivery: follow-up telephone calls after discharge. Provider: enterostomal nurse. Timing: Postop	Self-efficacy (SSES): Both IG and CG improved over time ($F = 44.81, p < .001$), there was no statistical between group difference ($F = 1.29, p = .259$) and there was an interaction between group and time ($F = 10.11, p = .002$). With higher scores for the IG.
Cheung et al. (2003)	Content: progressive muscle relaxation therapy was taught to participants in order to lower the risk of peristomal hernia. Participants were also given an audio-recording to guide them through the therapy at home and a manual with visual illustrations. Duration: Two teaching sessions. They were instructed to carry out the relaxation exercise 2–3 times per week and record the frequency in a log sheet. They were also phoned every 2 weeks. Mode of delivery: postop face-to-face, via telephone, audio recording and manual. Provider: nurse or therapist. Timing: Postop	Quality of life (QOL-Colostomy & WHOQOL-BREF-HK): QOL-Colostomy there was a significant increase in scores in both IG and CG over time ($F=35.96, p<.001$), but there was no between group difference ($F=2.63, p=.01$). WHOQOL-BREF-HK there was a significant increase in scores over time in both IG and CG ($F=97.63, p<.001$) and a significant group difference between IG and CG ($F=26.52, p<.001$) with IG scores higher.
Seo (2019)	Content: Ostomy management reinforcement education allows practice in changing a stoma appliance and receive reinforcement and feedback afterwards. Additional education was provided on self-care, everyday life with an ostomy and how to deal with complications. This knowledge was assessed, and feedback provided with explanations. Duration: Control group received one session and intervention groups 1 and 2 received 2 and 3 sessions respectively, 30 mins each. Mode of delivery: face-to-face. Provider: research team and nurse. Timing: Postop	Self-efficacy (self-efficacy scale score from 10 to 100 points for 17 items): Higher scores for IG1 and IG2 than the CG ($F = 8.62$, $p = .001$). But no significant difference between IG1 and IG2. Self-management (nurse observation scored from 1 to 4 on 10 self-care items): Higher scores for IG1 and IG2 than the CG ($F = 49.54$, $p < .001$). But no significant difference between IG1 and IG2.

(Continues)

TABLE 2 (Continued)

Author, year	Intervention summary (Content/Duration/ Mode of delivery/Provider/Timing)	Key outcome findings
Sier et al. (2017)	Content: Education around the surgery and its consequences; stoma care and practice with appliance and provided a stoma diary. Also evaluated stoma care, discussed experiences and tackled any problems or complications. Duration: 1 home visit before surgery and 2 after, 2 h long each. Mode of delivery: face-to-face. Provider: Stoma therapist. Timing: preop and postop.	Quality of life (Stoma-QoL): IG scores were higher than CG at 1 month (63.4 (SD = 10.5) vs. 56.6 (SD = 10.9), $p < .001$) and at 3 months (65.3 (SD = 10.2) vs. 60.5 (SD = 10.8, $p = .002$). Test score not reported.
Lim et al. (2019)	Content: Psychoeducational session preop, encouraging communication and a positive attitude; identifying resources in the community; how to cope with new situations to continue normal life; identifying and reducing fears and uncertainty; assessing needs and empowering self-care. An educational booklet on stoma care was also provided. Duration: one session preop, five telephone calls were also arranged, 1 preop and 4 postop 15 mins each to explore any issues that arise from the educational session and postop and discharge. Mode of delivery: face-to-face, telephone and an educational booklet. Provider: researcher who is a nurse. Timing: preop and postop.	Quality of life (EORTC QLQ-CR29): No difference in IG and CG over time ($F = .32$, $p = .58$), there was no statistical between group difference ($F = 3.41$, $p = .07$) and no statistical interaction between group and time ($F = .23$, $p = .64$). Self-efficacy (SSES): No statistical difference in IG and CG over time ($F = .18$, $p = .68$), there was no statistical between group difference ($F = 3.28$, $p = .08$) and no statistical interaction between group and time ($F = 1.74$, $p = .20$). Self-management (Time to stoma proficiency (days from surgery to reach proficiency on set criteria)): No statistically significant difference between IG and CG ($Z = -1.24$, $p = .22$)
Su et al. (2019)	Content: information on what a stoma is, self-care of the stoma, how to manage daily, recording of self-management schemes and information to contact the clinical team. Advice on any problems and complications, emotional support and individuals were directed to the self-management scheme section of the manual. Duration: Four phone calls lasting 10–20 min, and 1 outpatient appointment lasting up to 20 min. Mode of delivery: Stoma self-management manual, telephone and face-to-face. Provider: enterostomal therapist and a wound ostomy continence nurse. Timing: postop	Quality of life (Stoma-QoL): Both IG and CG improved over time $(F=16.90, p<.001)$, there was a between group difference $(F=17.99, p<.001)$ and an interaction between group and time $(F=3.89, p=.022)$. With higher scores for the IG. Self-efficacy (SSES): Both IG and CG improved over time $(F=11.32, p<.001)$, there was a between group difference $(F=11.88, p=.001)$ and an interaction between group and time $(F=7.30, p=.001)$. With higher scores for the IG.
Pouresmail et al. (2019)	Content: Control and intervention group both taught stoma care, how to change the appliance and how to recognise and prevent complications. The intervention group in two sessions were able to practice skin care and changing the appliance on a physical simulator and could identify any problems before practicing on their stoma. Duration: four sessions, 30–45 min. Mode of delivery: face-to-face. Provider: enterostomal therapy nurse. Timing: postop	Self-efficacy (SSES): IG scores were significantly higher than the CG from baseline to follow-up ($F=13.56, p=.001$).

TABLE 2 (Continued)

Author, year	Intervention summary (Content/Duration/ Mode of delivery/Provider/Timing)	Key outcome findings
Wen et al. (2019)	Content: Group education in self-care skills, how to cope with complications and strategies to implement when at home. Group discussion of problems faced and problem solving, encouraged to explore their current stage of behavioural change, reflect on failures and to share experiences. A stoma self-management manual and links to websites and other services were provided. Duration: There were four sessions, 1 h each within the hospital. At baseline, a couple of days before discharge and then at follow-up visits at 1 and 3 months after discharge. Mode of delivery: group education and discussion and stoma self-management manual. Provider: researcher and an enterostomal therapy nurse. Timing: Postop	Self-efficacy (self-efficacy scale consisting of eight items scored from 1 to 5): Both IG and CG improved over time ($F = 57.63$, $p < .001$), there was a between group difference ($F = 188.98$, $p < .001$) and an interaction between group and time ($F = 41.37$, $p < .001$). With higher scores for the IG.
Wang et al. (2018)	Content: Taught in hospital how to use a mobile application. This application could be used at home to book appointments with the nurse, upload photos to receive a diagnosis on their stoma and consultations could be provided over the app to receive support. Educational sessions were also conducted over the app teaching stoma care skills, sharing experiences of other people with a stoma, promoting confidence in patient's role in self-care, and tackling negative emotions and fears. Duration: weekly smartphone sessions in the first month followed by biweekly sessions over the next 2 months. Mode of delivery: face-to-face app training, primarily mobile application. Provider: enterostomal therapy nurses. Timing: postop	Self-efficacy (SSES): Both IG and CG improved over time ($F = 682.21, p < .001$), there was a between group difference ($F = 23.16, p < .001$) and an interaction between group and time ($F = 49.58, p < .001$). With higher scores for the IG.
Xu et al. (2018)	Content: Intervention to improve self- efficacy included direct and alternative experience, verbal persuasion and social and psychological support. Duration: There were four sessions within the first month, two within the second month and 1 within the last month. Mode of delivery: face-to-face or over the phone. Provider: nurse. Timing: postop	Quality of life (EORTC QLQ-C30): Cognitive function IG 61.67 (SD = 23.63); CG 36.31 (SD = 29.41); $t = 3.19$, $p = .003$. Emotional function IG 67.50 (SD = 21.44); CG 47.32 (SD = 26.84); $t = 2.79$, $p = .008$. Physical function IG 73.33 (SD = 19.10); CG 52.62 (SD = 28.88); $t = 2.80$, $p = .008$. Role function IG 57.50 (SD = 36.06); CG 36.90 (SD = 28.82); $t = 2.20$, $p = .033$. Social function IG 70.83 (SD = 24.70); CG 55.39 (SD = 23.59); $t = 2.20$, $p = .033$. Self-efficacy (SSES): IG scores were higher than CG at 1 month (80.25 (SD = 10.74) vs. 75.25 (SD = 6.16), $t = 2.04$, $p = .047$) and at 3 months (91.15 (SD = 10.71) vs. 62.43 (SD = 12.63 , $t = 8.26$, $p < .001$).

Abbreviations: CG, Control Group; COH-QOL-O, The City of Hope Quality of Life Ostomy Questionnaire; DDQ-15, Digestive Disorders Questionnaire; EORTC QLQ, The European Organization for Research and Treatment of Cancer Quality of life Questionnaire; ESCA, Exercise of Self-Care Agency; F, F-test repeated ANOVA; FACT-C, Functional Assessment of Cancer Therapy—Colorectal; IG, Intervention Group; ns, non-significant; SD, Standard Deviation; SF-36, 36-Item Short Form Survey; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; SSES, Stoma Self-Efficacy Scale; Stoma-QoL, Stoma Quality of Life Scale; t, independent sample t-test; WHOQOL-BREF-HK, Hong Kong Chinese version of the World Health Organisation Quality of Life Measure-Abbreviated Version; Z, Mann-Whitney U test.

proficiency compared with the usual care group (Chaudhri et al., 2005) whereas the other study found no significant difference between the control and intervention group (Lim et al., 2019). Two studies used self-report measures of self-management, they both found that the interventions group reported significant improvements over the usual care group (Lo et al., 2010, 2011). Two studies had direct nurse observation of participants, one study found significant higher scores in stoma management ability in participants in the intervention group compared with the control (Seo, 2019) but the other study found no significant differences between the two groups (Crawford et al., 2012).

3.4 | Self-efficacy

Nine studies measured self-efficacy (Crawford et al., 2012; Lim et al., 2019; Pouresmail et al., 2019; Seo, 2019; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013). Six studies used the Stoma Self-Efficacy Scale (Lim et al., 2019; Pouresmail et al., 2019; Su et al., 2019; Wang et al., 2018; Xu et al., 2018; Zhang et al., 2013), and three studies developed their own self-efficacy scales (Crawford et al., 2012; Seo, 2019; Wen et al., 2019).

Five studies all used the same measure of self-efficacy (stoma self-efficacy scale), had similar lengths of follow-up periods (45-90 days) and broadly similar content and providers for the interventions making them appropriate for a meta-analysis to be conducted (Lim et al., 2019; Pouresmail et al., 2019; Su et al., 2019; Wang et al., 2018; Zhang et al., 2013), one study which used the same measure had a different follow-up period and therefore was not included (Xu et al., 2018). The results of the meta-analysis can be seen in Figure 2. Participants who received a self-management intervention reported higher self-efficacy compared with participants who received usual routine care (MD = 11.57; 95%CI 9.13, 14.00) at follow-up and there were low levels of heterogeneity ($I^2 = 29\%$). Of those five studies there were 536 participants between them. The four studies that could not be included in the meta-analysis, three reported significantly higher self-efficacy scores compared with the control group (Seo, 2019; Wen et al., 2019; Xu et al., 2018) and one did not report any significant differences compared with the control group (Crawford et al., 2012).

3.5 | Intervention characteristics

Only 13 interventions provided sufficient detail to be able to be coded for BCTs (Chaudhri et al., 2005; Cheung et al., 2003; Crawford et al., 2012; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lim et al., 2019; Pouresmail et al., 2019; Seo, 2019; Sier et al., 2017; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Zhang et al., 2013). The studies used an average of 10 BCTs (range 6–22). Credible source (n = 13), instruction on how to perform the behaviour (n = 13), demonstration of the behaviour (n = 12), behavioural practice/rehearsal (n = 12), information about health consequences (n = 11) and monitoring of behaviour by others without feedback (n = 9) were the most described BCTs in the interventions. The other BCTs described are covered in Appendix S2.

Twelve of the interventions were conducted post-operatively (Cheung et al., 2003; Crawford et al., 2012; Khalilzadeh Ganjalikhani et al., 2019; Lo et al., 2010, 2011; Pouresmail et al., 2019; Seo, 2019; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013), two of the interventions were conducted pre-operatively (Chaudhri et al., 2005) and two of them covered both the pre-op and post-op period (Forsmo et al., 2016; Lim et al., 2019; Sier et al., 2017). Thirteen of the interventions involved a healthcare professional in the delivery (Chaudhri et al., 2005; Cheung et al., 2003; Crawford et al., 2012; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lim et al., 2019; Pouresmail et al., 2019; Sier et al., 2017; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013), with the other three delivered by the research team or an instructor (Lo et al., 2010, 2011; Seo, 2019). Five of the interventions were delivered face-to-face (Chaudhri et al., 2005: Forsmo et al., 2016; Pouresmail et al., 2019; Seo, 2019; Sier et al., 2017) and one each were delivered via telephone and a mobile application (Wang et al., 2018; Zhang et al., 2013). The other nine interventions used various combinations of face-to-face, telephone, manuals and other multimedia to deliver the interventions (Cheung et al., 2003; Crawford et al., 2012; Khalilzadeh Ganjalikhani et al., 2019; Lim et al., 2019; Lo et al., 2010, 2011; Su et al., 2019; Wen et al., 2019; Xu et al., 2018). The duration of the interventions varied from only one session (Crawford et al., 2012; Khalilzadeh Ganjalikhani et al., 2019; Lo et al., 2010, 2011), to 2-3 sessions (Chaudhri et al., 2005;

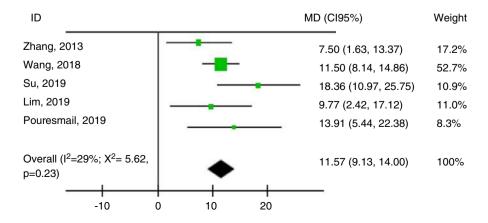


FIGURE 2 Meta-analysis of self-management interventions on self-efficacy. *Note*: MD, Mean Difference; X^2 , Chi-squared test; I^2 , percentage of variation across the studies that is due to heterogeneity; the meta-analysis was run as an inverse variance fixed effects meta-analysis

Cheung et al., 2003; Forsmo et al., 2016; Seo, 2019; Sier et al., 2017; Zhang et al., 2013), to 4 or more sessions (Lim et al., 2019; Pouresmail et al., 2019; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018).

Across the studies only five reported some level of theoretical underpinning (Lim et al., 2019; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Zhang et al., 2013), four cited Bandura's Social Learning Theory (Lim et al., 2019; Su et al., 2019; Wang et al., 2018; Zhang et al., 2013), with the other using the Transtheoretical Model (Wen et al., 2019). Across the studies the description of how the theory was used was fairly consistent. All five studies reported how the theory was used to select/develop the interventions but only one study mentioned how the theory was used to tailor the intervention to participants (Wen et al., 2019). All five studies measured theory relevant constructs pre- and post-intervention. An average of 15 BCTs (range 9-22) were identified in these five studies, compared with an average of 7 (range 6-9) for those studies with no theoretical underpinning.

3.6 | Associations with intervention characteristics

The BCTs of credible source, instruction on how to perform the behaviour, demonstration of the behaviour, behavioural practice/ rehearsal, information about health consequences and monitoring of behaviour by others without feedback were all associated with improvements in QoL, self-efficacy and self-management. For all the number of studies which showed an improvement in one of the key outcomes and the BCTs used in those interventions see Appendix S3. There was no association between the number of BCTs used in a study and improvement in any of the outcome variables.

Those studies that measured QoL and found an improvement (Cheung et al., 2003; Khalilzadeh Ganjalikhani et al., 2019; Sier et al., 2017; Su et al., 2019; Xu et al., 2018) were more likely to have face-to-face interactions post-op than those that found no improvement (Forsmo et al., 2016; Lim et al., 2019). Furthermore, the studies that found an improvement in at least one QoL scale measured reported encouraging the BCT of self-monitoring of behaviour more than compared with those that did not find any difference in QoL (Cheung et al., 2003; Khalilzadeh Ganjalikhani et al., 2019; Sier et al., 2017; Su et al., 2019).

Those studies that measured self-efficacy and were not included in the meta-analysis and reported significantly improved self-efficacy in the intervention group included in-person training with a nurse or a longer period of time (24 h) with a digital intervention (Seo, 2019; Wen et al., 2019; Xu et al., 2018). Whereas, the study by Crawford et al. (2012) that did not report any significant difference between the intervention and control group provided a light-touch intervention with a 1-h session of in-person nurse training replaced with a DVD.

Of the four studies that measured stoma self-management more objectively with time to proficiency and through nurse-rated management scores, there were differences in the intervention content.

The two studies that found decreased time to stoma proficiency or higher nurse-rated management scores tested interventions that focussed more on how to manage the stoma, with direct involvement of the nurse, providing feedback and encouragement (Chaudhri et al., 2005; Seo, 2019). The two studies where there was no difference in time to stoma proficiency or nurse-rated management scores tested interventions that did not have the direct involvement of the nurse in teaching stoma self-management, with this either provided through a booklet (Lim et al., 2019) or a DVD (Crawford et al., 2012).

There was no association that could be drawn between the studies that had a theoretical underpinning (Lim et al., 2019; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Zhang et al., 2013) and those that did not on any of the outcome variables (Chaudhri et al., 2005; Cheung et al., 2003; Crawford et al., 2012; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lo et al., 2010, 2011; Pouresmail et al., 2019; Seo, 2019; Sier et al., 2017; Xu et al., 2018). There was also no association based on the level of expertise of the nurse (enterostomal nurse vs. a nurse with no specialization).

3.7 Risk of bias in included studies

Figure 3 outlines the risk of bias in the included RCTs. The quality of the included studies was low with only one RCT being deemed to be at low risk of bias (Lim et al., 2019). The rest of the RCTs was deemed to be at high risk of bias (Chaudhri et al., 2005; Cheung et al., 2003; Crawford et al., 2012; Forsmo et al., 2016; Khalilzadeh Ganjalikhani et al., 2019; Lo et al., 2010, 2011; Pouresmail et al., 2019; Seo, 2019; Sier et al., 2017; Su et al., 2019; Wang et al., 2018; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013), due to 'Deviations from the intended interventions'.

4 | DISCUSSION

This is the first systematic review to synthesize the international evidence from RCTS of self-management interventions for people with a stoma, and meta-analyse the effects on self-efficacy. The meta-analysis demonstrated a mean difference in self-efficacy scores of 12 (95%CI 9.13, 14.00) post-intervention (45-90 days), between the intervention and control groups with higher scores in the intervention group. There was also some evidence to suggest self-management interventions have a broadly positive effect on self-reported self-management skills. However, the findings were more mixed for QoL and objective measures of self-management skills, such as time to stoma proficiency and observation of stoma ability. This review is also the first to identify the intervention characteristics, including BCTs, used in self-management interventions of people with a stoma and look at the associations with positive outcomes. Across the interventions an average of 10 BCTs were used, however, the number of BCTs used was not associated with an improvement in any of the outcomes. Furthermore, the direct involvement of a nurse in teaching stoma care management was

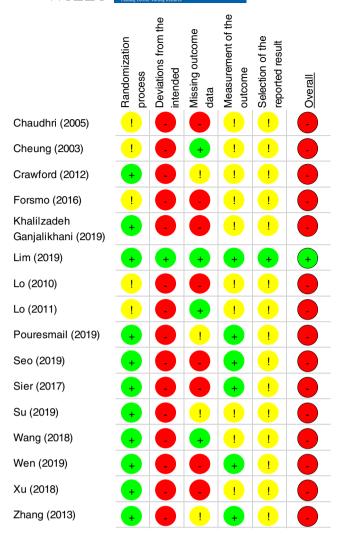


FIGURE 3 Risk of bias classification for included studies. Note: Green circles indicate low bias, yellow circles indicate some concerns and red circles indicate high bias

associated with improved self-efficacy and self-management skills and contact post-operatively and self-monitoring were associated with higher QoL.

The results from the present review in regards to QoL, self-efficacy and self-report self-management are in line with those of Faury et al. (2017) and Danielsen et al. (2013). In both previous reviews a majority of the studies that measured the same outcomes showed an increase in scores. However, there is a difference between the self-report and objective measures of self-management. In this present review the findings from the objective measures were mixed which is different from the previous reviews. This could suggest that the self-management interventions may not be imparting effective self-management practices. Furthermore, although this review was able to conduct a meta-analysis showing there was 12-point mean difference between the intervention and control groups at follow-up, favouring the intervention, there is no research currently to suggest that this is a clinically meaningful difference for individuals.

Across interventions that saw improved outcomes compared with those that did not, the number of BCTs used was broadly similar to reviews of other conditions (Eisele et al., 2018; van Rhoon et al., 2020). However, we are unable to determine which of the BCTs that are used are influencing the outcomes. Several the most coded BCTs are likely to occur due to the nature of the information and support that needs to be provided to the patient to manage their stoma and the fact that, at least in the UK, this is routinely delivered by a stoma care nurse in hospital post-surgery (Royal College of Nursing, 2009). Previous cross-sectional research has suggested that social support can be beneficial in helping people with a stoma to adjust, whether this is from medical staff (Nam et al., 2019) or through family and community support (de Gouveia Santos et al., 2006, 2016; Simmons et al., 2007). However, the BCT social support was only identified in four studies in this review with three of the studies showing an improvement in outcomes, which suggests that it may be under-used as a tool to support people with a stoma in the identified interventions. This may highlight that the nature of these interventions is medicalized and focussed on ensuring the participant can manage their stoma while potentially ignoring the social consequences of the stoma. The majority of studies reported an overall score of QoL, exploring constituent subscales of these measures might provide a more nuanced view of the impact of these interventions on the QoL of the participants.

Furthermore, this review suggests that the involvement of a nurse in delivering the intervention appears to be related to improvements in self-efficacy and self-management skills. The importance of nurses has been highlighted in a previous review in relation to effectiveness in care and chronic disease management and health promotion (Keleher et al., 2009). However, what is not known in the present review is whether there is continuity of care for individuals during the intervention. Borwell (2013) has emphasized the importance of continuity of care for people with a stoma, therefore, future research should seek to provide greater clarity on this aspect by ensuring that the interventions are described in detail

This review identified that the majority of studies did not have a theoretical underpinning. Previous reviews of other diseases have found that interventions with a theoretical underpinning result in better health and psychological outcomes for patients (Ayling et al., 2015; Naz et al., 2018). Nevertheless, in this review there was no association between better outcomes and a theory-based intervention. However, this should be treated with caution as it could be that the appropriate theory was not being used for this population. For example, the integration of nursing theories into self-management intervention development, especially when these interventions are majority delivered by nurses, might be of benefit to future research. Furthermore, theory-based interventions could have had a meaningful impact on the outcomes but none of the used measures had any research suggesting what a clinically meaningful difference would be.

4.1 | Limitations

This review has some limitations. First, as has been highlighted in previous reviews, coding of the BCTs is dependent on the accuracy and quantity of the detail that authors go into when describing the intervention (Cradock et al., 2017; van Rhoon et al., 2020), which restricts the ability to adequately code every intervention for BCTs. The heterogeneity also meant that meta-analyses could not be conducted for QoL and self-management measures. Furthermore, due to the complexity of self-management interventions, it is difficult to identify which components are contributing to the success of the interventions. Only associations can be drawn between components and improved outcomes, with additional research needed to unpick this. Also, this review limited included papers to those in English language publications, therefore, research conducted in other languages could have been missed. The search strategy for the present review did not include two large academic databases, CINAHL and PubMed, however, a thorough forward and backward citation search of key papers did not elicit any additional papers that would be included in the final review. Finally, this review did not assess the reliability of the measures used as it was beyond the scope of the objectives, however, future reviews should consider this to aid in the interpretability of the results.

5 | CONCLUSIONS

Although this is the first review to identify the BCTs and other characteristics used in self-management interventions for this population we are unable to assess the effectiveness of these components. Future research is required to determine which components are the most effective in increasing QoL, self-efficacy and self-management skills. One possible approach to testing multiple combinations of the intervention characteristics to ascertain their efficacy is the multiphase optimization strategy (MOST) methodology (Collins et al., 2011). Furthermore, we do not know whether there needs to be different BCTs used when delivering the intervention in different environments (e.g. hospital or home), different countries with varying healthcare systems or with different populations of people with a stoma (e.g. temporary vs. permanent, IBD or cancer, bowel stomas or urostomies).

In conclusion, evidence from RCTs suggests self-management interventions for people with a stoma appear to be an effective way to improve outcomes for this group, particularly self-efficacy. This review also provides an important first step in determining the effective components of self-management interventions for people with a stoma. Future self-management interventions for this patient group should consider the direct involvement of a nurse in the delivery of the intervention and consider incorporating social support. Further research, utilizing the MOST methodology, is needed to determine effective intervention characteristics to ensure successful patient self-management.

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None

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors met each of the following four criteria to qualify for authorship:

- 1. Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
- Been involved in drafting the manuscript or revising it critically for important intellectual content.
- 3. Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- 4. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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