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Systematic review

A mixed-methods systematic review of the effectiveness, acceptability and safety of self-acupuncture studies

Catrina Davy [a,b,*], Michael Loughlin [a], John Hughes [a,b]

[a] University of West London, St Mary's Road, Ealing, London, W5 5RF, United Kingdom
[b] Royal London Hospital for Integrated Medicine, 60 Great Ormond Street, London, WC1N 3HR, United Kingdom

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ABSTRACT

Introduction: Ongoing acupuncture is not recommended by the National Institute for Heath and Care Excellence for managing long-term conditions. Self-acupuncture (SA) may offer a solution. This mixed-methods systematic review aims to identify and appraise the quality of SA studies and evaluate the acceptability, effectiveness, and safety of SA.

Methods: CINAHL, Embase, Medline, and the Cochrane library databases were searched. We included studies evaluating SA for any condition, performed by a patient or their carer, written in any language and conducted at any time. We excluded studies where acupuncture needles were not inserted and where participants were not trained in SA. The methodological quality was appraised using the Mixed-Methods Assessment Tool. Data were extracted, categorised and synthesised.

Results: Twelve SA studies were identified, including 1 randomised, controlled trial; 1 mixed-methods feasibility study; 1 pilot of a randomised crossover study; 3 quantitative service reviews; 2 qualitative studies; 1 survey report; and 3 case reports, with a total of 378 participants. Four studies were of a high methodological quality. All studies assessing it found SA acceptable ($n = 9$) and effective ($n = 9$). Only one serious adverse effect was reported.

A strength of the review is that it is the first systematic review focused solely on SA. Limitations include the small number of studies and the lack of high-quality evidence.

Conclusions: There is a significant gap in high-quality SA research. Although SA appears acceptable and safe, more robust studies are needed to determine its effectiveness. If proven effective, SA could help patients manage long-term symptoms.

1. Introduction

Currently in the United Kingdom, the National Institute for Health and Care Excellence (NICE) guidelines recommend a course of up to ten acupuncture sessions for the management of headaches and migraines [1], and primary chronic pain conditions [2]. However, these guidelines do not recommend maintenance or ongoing acupuncture for the management of these conditions. Self-acupuncture (SA) may be an option for people to manage their symptoms when ongoing acupuncture is not recommended or possible.

SA involves people self-managing their symptoms by inserting acupuncture needles into specific locations on their body. A recent survey found that 19 % of UK acupuncturists teach SA [3]. SA has been taught at the Royal London Hospital for Integrated Medicine (RLHIM) since the 1970s [4]. It is taught there to help patients manage chronic pain, migraines and headaches. At RLHIM, patients are taught to insert sterilised, single-use acupuncture needles into traditional acupuncture points (acupoints) located on their limbs. Patients are only taught to needle acupoints on their limbs to reduce the risk of a serious adverse event (SAE). A SAE is classed as an event that 'results in death, requires

Abbreviations: BDI, Beck depression inventory; MA, Meta-analyses; MAE, Minor adverse event; MMAT, Mixed methods assessment tool; MMSR, Mixed-methods systematic review; NICE, National institute for health and care excellence; PDA, Practitioner-delivered acupuncture; PRISMA, Preferred Reporting Items for Systematic Review and Meta-Analysis; RCT, randomized controlled trial; RLHIM, Royal London Hospital for Integrated Medicine; SA, self-acupuncture; SAE, serious adverse event; SR, systematic review.

* Corresponding author.
E-mail address: Catrina.davy@nhs.net (C. Davy).

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hospital admission or prolongation of existing hospital stay, results in persistent or significant disability or incapacity, or is life threatening' [5]. SAEs in acupuncture, such as pneumothorax, central nervous system injury, heart injury, peripheral nerve injury, tissue injury and infection, are rare [6]. However, this has only been determined when acupuncture is delivered by a trained acupuncturist, not in SA.

To date, little research has been conducted on SA. Previous systematic reviews (SR), meta-analyses (MA) and literature reviews have evaluated SA studies alongside practitioner-delivered acupuncture (PDA) studies and/or other interventions [6–13]. All but two of those studies are reviews of acupuncture adverse events. A SR evaluating only SA studies, using any method of primary research, has not been conducted to date. The objectives of this SR are to identify SA studies, appraise their methodological quality, evaluate the evidence on the acceptability, effectiveness, and safety of SA (when it has been taught by a professional), and assess the certainty of the evidence.

2. Methods

The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Statement [14] was used to guide the reporting of this SR.

2.1. Eligibility criteria

Inclusion criteria:

- Studies on both children and adults evaluating any condition.
- Studies evaluating SA or acupuncture delivered by a carer (in this review both will be referred to as SA).
- Studies evaluating SA using any acupoint.
- Studies examining effectiveness, acceptability and/or safety of SA.
- Studies of any design (such as randomised controlled trials (RCT), qualitative studies, surveys, audits and case reports).
- Any primary, peer-reviewed study type (primary qualitative, quantitative or mixed-methods).
- Studies written in any language and published at any time.
- Full-texts or abstracts (when the full-text are not available)
- Grey literature (including conference abstracts if we could not retrieve the full texts, MSc and PhD theses).

Exclusion criteria:

- Studies based on acupuncture practice but where acupuncture needles were not inserted into the body. These included studies evaluating the use of semi-permanent studs and needles, ear seeds, and acupressure as it is likely that these interventions have different effects to acupuncture performed by inserting traditional acupuncture needles.
- Studies where people have not had SA training. These studies were excluded since the aim of this study it to determine the safety of self-acupuncture taught by a professional.
- MAs and SRs. Instead, the primary studies identified in these were evaluated.

2.2. Search strategy

Two researchers (CD, JGH) conducted the search for studies independently using the following databases: CINAHL, Embase, Medline and the Cochrane library. Although MAs, SRs, literature reviews were not eligible for inclusion, we examined their reference lists, as well as the reference lists of the identified studies, to find other eligible studies. We conducted the last search on 22 September 2024.

2.3. Search terms

Two researchers (CD, JGH) conducted the search independently. We used the following terms to search for studies: 'self-acupuncture,' 'self-needling,' 'self-administered acupuncture', 'home-acupuncture'. We applied no limits in the searches. The full search strategy is available in appendix A.

2.4. Study selection

Two researchers (CD, JGH) conducted the study selection independently. After we identified the studies, we removed duplications. Following this, we screened the titles and abstracts and excluded studies that did not fit the eligibility criteria. We examined the full texts (or abstracts if the full text was not available) of the remaining studies to determine if they met the eligibility criteria and excluded any studies that did not. The details of the eligible studies were entered into a standardised form.

2.5. Data extraction

Two researchers (CD, JGH) thoroughly reviewed the eligible studies by reading them multiple times. We then extracted relevant data and entered it into a standardised form. This included information on the author, year of publication, source, study design, objectives, intervention details, data collection and analysis methods, sample size, and the condition studied.

We defined categories to address the aims of the study and designed a second standardised form using these categories. The categories were: methodological quality, acceptability of the intervention to the participant, effectiveness of SA and safety of SA. We extracted and entered relevant data into the standardised form. This included the following data:

- Effectiveness of SA – including the statistical or clinically significant findings of the primary outcome measure, if available.
- Acceptability of SA to patients - including participants' views and reasons for dropping out (if they were related to acceptability of doing SA).
- Safety of SA – including incidences of minor adverse events (MAE) and SAEs.
- Methodological quality – using Mixed Methods Assessment Tool (MMAT) [15] or a non-validated tool [16] for the case reports.

We compared the two datasets and discussed and resolved any differences.

2.6. Data synthesis

Two researchers (CD, JGH) conducted a narrative synthesis of the extracted data. We included data from all studies and did not limit it to studies which had a high methodological quality. We had planned to conduct a MA of the quantitative data and meta-synthesis of the qualitative data but were unable to do this due to the lack and heterogeneity of the data (including heterogeneity in the study methods, conditions evaluated and outcome measured used).

2.7. Assessment of methodological quality

The methodological quality of the eligible studies was critically appraised by two researchers (CD, JGH) using the MMAT [15]. This appraisal tool was chosen because of its unique quality of assessing primary studies using any methodology: qualitative, quantitative, or mixed methods. Because the case reports did not pass the MMAT screening questions, an unvalidated tool [16] was used.

2.8. Certainty of evidence

The two researchers (CD, JGH) planned to use the GRADE system [17] to assess the certainty of evidence for each outcome. However, due to the heterogeneity of the data this could not be performed. In addition, due to the mixed methods study design, and the effect estimates of qualitative and quantitative data were not presented, it is inappropriate to evaluate with GRADE.

3. Results

3.1. Study characteristics

Initially, 115 records were identified through the database search and 10 records were identified through a search of reference lists. Forty records were excluded because they were duplications. The titles and abstracts of 85 records were screened. Sixty-three records were excluded at that point because they were irrelevant. We sought to retrieve 22 studies. Ten studies were excluded after the full texts were examined. Details of these studies including the reasons why they were excluded are documented in appendix B. Fig. 1 summarises the study screening process for the records identified.

In total, 12 SA studies met all the eligibility criteria. These were 1 RCT [18]; 1 mixed-methods feasibility study [19]; 1 pilot of a randomised crossover study [20]; 2 qualitative studies [21,22]; 3 quantitative service evaluations [23–25]; 1 survey report [3] and 3 case reports [26–28]. The total number of participants in the combined trials was 378. Tables 1 summarises the studies' characteristics.

3.2. Results of data synthesis

A summary of the data synthesis is available in Table 2.

3.2.1. Acceptability of SA to participants

Nine studies evaluated the acceptability of SA [18,19,21–25,27,28]. All studies concluded that SA was an acceptable intervention to the participants. Although it was deemed acceptable overall, there were some participants who did not find it acceptable. In one study [21], two out of eight participants did not find it acceptable. One participant commented that they found the experience strange: 'Very strange…Oh don't think I'd do this again'. The other participant struggled to do SA because they had memory problems. However, the majority did find it to be acceptable.

Two studies documented the reasons for participant dropouts/discontinuation of SA [23,24]. In the first of those studies, five out of 16 participants had stopped doing SA because it was not effective. In the latter, five of the 52 participants dropped out. The reasons for dropping out were lack of time ($n = 1$); lack of pain relief ($n = 1$); in too much pain to do SA ($n = 1$); and two participants gave no reason. In both studies, most participants found SA to be acceptable.

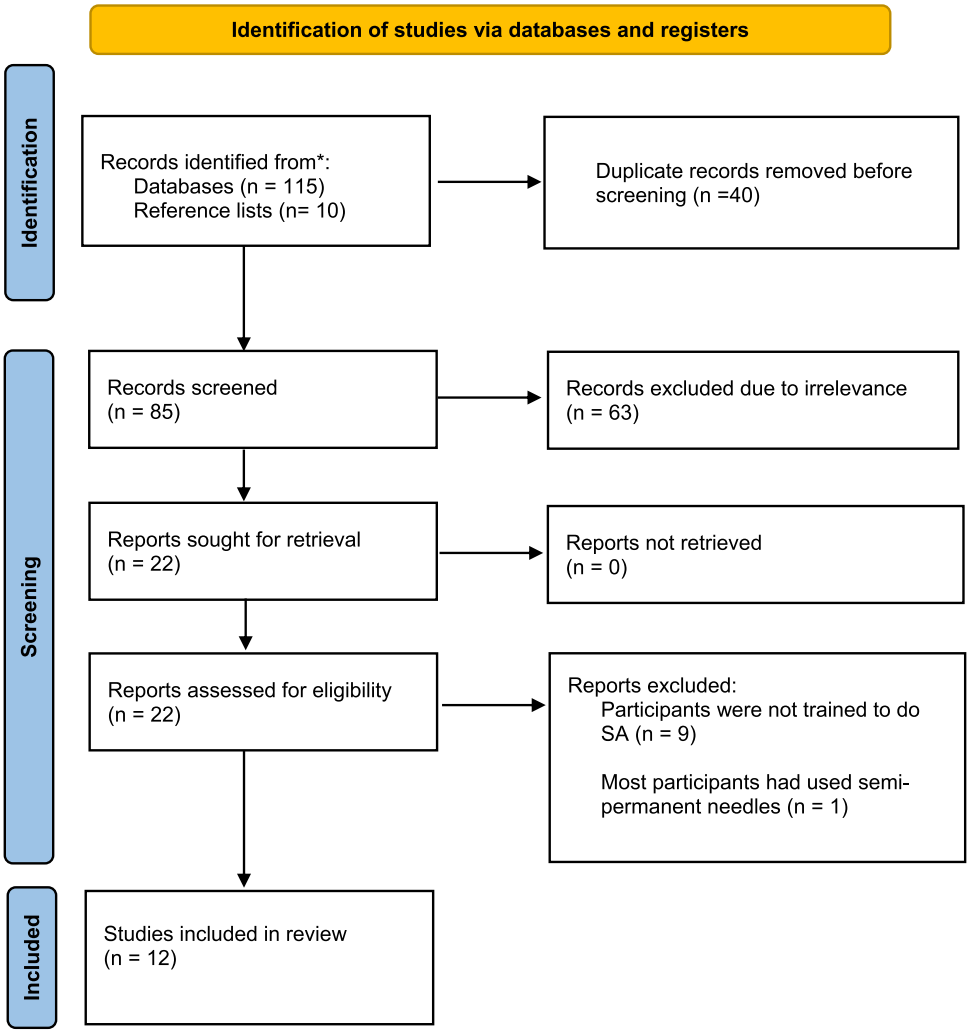

Fig. 1. Flow chart showing study screening process.

Table 1
Summary of studies' characteristics.

Authors	Year	Country	Study methodology	Study aims	Intervention (including acupoints, frequency of SA, duration of intervention, needle retention time	Data collection methods	Analysis methods	Population and number of participants in study	Condition/ indication
Fagan N and Staten P [23]	2003	UK	Quantitative service evaluation	To assess the efficacy of teaching patients SA	**Acupoints:** LI11, LI4, TE3, LR3, SP10, GB31, BL60. All participants needled 1–4 acupoints per session **Frequency:** every 2 days to once every 6 weeks (most did SA twice a week) **Duration:** not documented **Needle retention time:** 1 to 20 min (most did 10 min)	Participants were asked questions about doing SA at a routine follow-up appointment, including how effective they found the treatment (either no effect, slight, moderate, good or excellent on a verbal scale).	Data was analysed using descriptive statistics	16 adults – a mixture of NHS patients, private patients and staff at a GP practice	Chronic pain
Teig S et al. [24]	2006	UK	Quantitative service evaluation	To investigate the effectiveness and safety of teaching SA in a pain clinic	**Acupoints:** L14, ST44 and LR3 **Frequency:** mean of 2.6 times a week (SD 1.40) **Duration:** a mean of 10.67 months (SD 10.4) **Needle retention time:** mean duration was 23 min (SD 10.16)	A questionnaire requesting details on the use of acupuncture, effectiveness and details of adverse events was sent to participants.	Descriptive statistics were used to identify compliance, pain relief, quality of life, adverse effects of treatment and reasons for non–compliance.	52 adult patients	Chronic pain
Cheville AM and Bassford JR [25]	2007	USA	Quantitative service evaluation	To assess the efficacy of carer-delivered acupuncture	**Acupoints:** Shen men, point zero, salivary gland II, LI 4, mid-lateral nail bed of LI channel **Frequency:** not documented **Duration:** not documented **Needle retention time:** not documented	Not documented	Not documented	57 adult carers	Xerostomia in head and neck cancer patients
Adler Z and Hansen P [20]	2012	USA	Pilot of randomized crossover trial	To evaluate if patients can be taught safe SA	**Acupoints:** P6 **Frequency:** 1 to 3 times a day **Duration:** 1st week of chemotherapy **Needle retention time:** not documented	Participants completed daily logs of nausea on a scale of 1–10, emesis, medications used and time acupuncture was done.	Not documented	20 adult patients	Chemotherapy-induced nausea
Molassiotis A et al. [18]	2013	UK	Phase III unblinded, pragmatic randomised trial using a three-group design	To assess the effectiveness of SA	**Acupoints:** Sp6 and St36 **Frequency:** once a week **Duration:** 4 weeks **Needle retention time:** not documented	Participants completed MFI, HADS, FACT-G at baseline, week 10 and week 18	Data was summarised using descriptive statistics. A simple one-way ANOVA was applied to fatigue change scores (week 10/ end of 4-week maintenance treatment − week 6/re-randomization week). The primary analysis was of covariance of the week 10 GF scores	65 = PDA, 67 = SA and 65 = no maintenance	Cancer-related fatigue

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Table 1 (*continued*)

Authors	Year	Country	Study methodology	Study aims	Intervention (including acupoints, frequency of SA, duration of intervention, needle retention time	Data collection methods	Analysis methods	Population and number of participants in study	Condition/ indication
							with the week 6 GF score as a covariate and trial arm as grouping factor. Similar analyses were carried out for a number of secondary outcomes, i.e. subscales from the MFI, HADS and FACT-B		
Davy C and Hughes J [3]	2022	UK	Survey report	To find out practitioner' SA teaching practices. To develop SA guidelines	**Recommended acupoints:** LI4, St36, Sp6, P6, Liv3, TE5 **Recommended frequency:** not documented **Recommended duration:** not documented **Recommended needle retention time:** not documented	A weblink for the survey was published in the three largest UK professional acupuncture associations. The survey asked participants to provide demographic information, to indicate if they had taught SA and, if applicable, to disclose information about their SA practices, including incidences of SAEs.	Data was summarised using descriptive statistics	n/a	Top 6 out of 20 symptoms practitioner taught people SA to help: pain (n = 10, 56 %), nausea (n = 7, 39 %), anxiety (n = 6, 33 %), hot flushes (n = 6, 33 %), headaches/ migraines (n = 4, 22 %) and breathlessness (n = 4, 22 %)
Bardy J et al. [21]	2015	UK	Qualitative research study	To explore the practitioners' experiences of teaching SA and the patients' experiences of performing SA	See details of trial by Molassiotis et al. [18]	Data was collected through focus groups and interviews of patients and practitioners, nested within the Molassiotis et al. [18] study	The interviews/ focus groups were transcribed verbatim and analysed thematically by the process of content analysis	8 adult patients and 15 practitioners	Cancer-related fatigue
Hughes J and Davy C [22]	2020	UK	Qualitative service evaluation	To explore the experiences of patients taught SA	**Acupoints:** LI4, LR3, SP6 and ST36 **Frequency:** 1 to 2 times a week **Duration:** not documented **Needle retention time:** 20 to 25 min	Semi-structured interviews were conducted with the participants.	Data were analysed inductively using thematic analysis	15 patients	Chronic pain
Davies S et al. [19]	2011	UK	Mixed-methods feasibility study	To evaluate the acceptability, practicality, and safety of teaching people SA to manage the frequency of self-harm	**Acupoints:** self-selected by participants **Frequency:** week 1: mean of 5.6 days per week; week 6: average 4.8 days per week **Duration:** 6 weeks **Needle retention time:** not documented	Participants logged their thoughts and feeling s on SA and self-harm in a daily diary. Data was also collected though participant interviews. Participants also completed BDI at baseline and follow-up	Framework analysis was conducted on interviews and diary entries. Changes in coping behaviours and acupuncture use was measured using diary entries. Mean pre and post BDI scores were compared using paired t-tests. Reduction in self-harm was explored through measuring frequency of entries	10 adult patients	Patients at risk of self-harm

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Table 1 (*continued*)

Authors	Year	Country	Study methodology	Study aims	Intervention (including acupoints, frequency of SA, duration of intervention, needle retention time	Data collection methods	Analysis methods	Population and number of participants in study	Condition/ indication
							of episodes of self-harm recorded in diaries. Use of SA was plotted as time series.		
Hasegawa J et al. [26]	1991	Japan	Single case report	To report a SAE	**Acupoints:** not documented **Frequency:** not documented **Duration:** not documented **Needle retention time:** not documented	Observation	Descriptive statistics	1 adult patient	Not documented
Dyer L et al. [27]	2013	UK	Single case report	To report on the efficacy of SA	**Acupoints:** non-traditional acupoints on the participants masseter muscles and back **Frequency:** every 3 to 4 days **Duration:** participant had received 320 acupuncture sessions for her facial pain and 120 for her back pain delivered by her partner **Needle retention time:** 10 to 30 min	Observation	Descriptive statistics	1 adult patient	Myofascial pain
Walter WA and Curtis HC [28]	2013	UK	Single case report	To report on the efficacy of SA	**Acu points:** LR3, GB34 and ST25 **Frequency**: weekly to every 2 weeks **Duration:** 14 months **Needle retention time:**30 min	Observation	Descriptive statistics	1 adult patient	Abdominal pain

BDI= Beck Depression Inventory; FACT-*B*= Functional Assessment of Cancer Therapy-Breast Cancer scale; GF= General Fatigue; HADS= Hospital Anxiety and Depression Scale, MFI= Multidimensional Fatigue Inventory; PDA= practitioner-delivered acupuncture; RCT= randomized controlled trial; SA= self-acupuncture; SAE= serious adverse effect; UK= United Kingdom.

3.2.2. *Effectiveness of SA*

Nine studies evaluated the effectiveness of SA [18–20,22–25,27,28]. The study by Adler and Hansen [20] had a statistically significant finding for reduction in nausea but the p value was not reported. They reported that there was no statistically significant finding for reduction in emesis. The study by Davies et al. [19] had a clinically significant finding - a reduction in mean score on the Beck Depression Inventory from 44.4 (SD 8.8) at baseline to 34.4 (SD 12.2) at 6-week follow-up. The study by Molassiotis et al. [18] had no statistically significant finding ($p = 0.11$). However, the similar mean differences scores in the PDA (0.57) and SA (0.54) groups suggest that SA is as good as PDA for maintaining the effects of the initial course of PDA. And therefore, the authors of this study concluded that SA was effective. Six studies [22–25] assessed effectiveness of SA but did not calculate the clinical or statistical significance of their findings. In the study by Fagan and Staten [23], 10 out of 16 patients rated their response as good or excellent. Teig et al. [24] found pain relief was 5.7 (SD 2.6) measured on a visual analogue scale. In the study by Cheville and Bassford [25], 49 (86 %) participants rated their xerostomia symptoms as good or better (>3 on a 5-point ordinal scale). The qualitative study by Hughes and Davy [22] found that all patients perceived that SA reduced the frequency and severity of their chronic pain. Two of the case reports [27,28] found SA effective.

3.2.3. *Safety of SA*

The incidence of SAEs was reported in ten studies. Nine studies reported no incidence of SAEs (total number of participants $n = 377$) [3, 18–20,22–24,27–28]. One study, a case report [26], documented the incidence of a SAE – delayed cardiac tamponade and haemothorax. So, there has only been one report of SAE caused by someone trained to do SA.

Nine studies reported the incidence of MAEs [18–20,22–24,27,28]. The MAEs reported were bleeding, bruising, tiredness, drowsiness, headache and pain. The study by Davies et al. [19] reported that one participant had an allergic reaction to the needles so was given hypo-allergenic needles to use instead.

Table 2
Summary of the studies' findings.

Authors	Acceptability to patients	Effectiveness	Safety
Fagan N and Staten P [23]	5 out of 16 participants stopped due to lack of effectiveness.	10 out of 16 patients rated their response as good or excellent.	No SAEs or MAEs reported
Teig S et al. [24]	5 out of 52 participants dropped out. They gave the following reasons: lack of time ($n = 1$); lack of pain relief ($n = 1$); too much pain to be able to do SA ($n = 1$); and no reason ($n = 2$).	Reported pain relief was 5.7 (SD 2.6) measured on a visual analogue scale.	No SAEs reported. 7 patients reported MAEs: Bleeding ($n = 1$), bruising ($n = 1$), tiredness/fatigue ($n = 5$), headache ($n = 1$), increased pain ($n = 1$), drowsiness ($n = 2$)
Cheville AM and Bassford JR [25]	All caregivers reported comfort with needle insertion but acknowledged that additional training would be helpful	49 (86 %) participants rated their xerostomia symptoms as good or better (>3 on a 5 point ordinal scale).	Safety issues not documented
Adler Z and Hansen P [20]	Not reported	There was a small statistically significant reduction in nausea severity. P value not documented. There was no statistically significant reduction in emesis	No SAEs or MAEs reported
Molassiotis A et al. [18]	The authors reported that participants carried out the treatment as planned. They concluded that SA was acceptable	The primary outcome was MFI general fatigue score at 10 weeks. The finding was not statistically significant ($P = 0.11$). Trial arm effects were not statistically significant ($p = 0.18$). There were similar mean differences scores in the PDA (0.57) and SA (0.54) groups. Secondary outcome analysis at 10 weeks (PDA and SA vs no maintenance) $p = 0.07$	No SAEs reported. Some MAEs were reported. These were spot bleeding and minor pain/ discomfort. They did not report on how many participants had MAEs.
Davy C and Hughes J [3]	n/a	n/a	No SAEs reported MAEs not documented
Bardy J et al. [21]	6 out of 8 participants said that they would do SA again. Two participants reported that they would not self-needle again. In one case this was owing to memory problems	n/a – findings reported in study by Molassiotis et al. [18]	n/a – findings reported in study by Molassiotis et al. [18]
Hughes J and Davy C [22]	Participants found self-acupuncture practical to administer. 'All patients felt they had received sufficient instructions to be able to safely apply self-acupuncture. Patients typically found the process of inserting the needles themselves as 'easy', as you 'just tap them in''	All patients perceived that SA reduced the frequency and severity of their chronic pain.	No SAEs reported. Most participants reported MAEs (the number of participants were not reported. MAEs reported were mild bleeding, bruising, minor discomfort and or/soreness.
Davies S et al. [19]	'Most participants persevered with SA in the hope that its effects would provide them with a viable alternative to self-harm.'	There was a clinically significant reduction in BDI score between baseline and at the 6-week follow-up. 44.4 (SD 8.8) and at 6-week follow-up was 34.4 (SD 12.2). There was no statistically significant reduction in BDI ($p = 0.055$)	No SAEs reported. 1 participant had an allergic reaction to the needles.
Hasegawa J et al. [26]	Not reported	n/a	Delayed cardiac tamponade and haemothorax.
Dyer L et al. [27]	'I was confident with the lessons I had been taught and felt quite relaxed about performing acupuncture at home…….. After a couple of tries at performing the treatment at home, I was very pleased with the results. It was obvious that increasing the amount of sessions per week was really helping.'	SA proved equally as effective as practitioner delivered acupuncture.	No SAEs reported. MAE= minor bleeding
Walter WA and Curtis HC [28]	'….It feels really different knowing that I have another solution too, one that means the pain will go, I won't have a drug trip while trying to go back to sleep and I'll be fine in the morning. I don't have complete faith that it will always work that well, but I am very hopeful both of reducing the attacks and dealing with them when they occur.'	SA provided effective pain relief and reduced the frequency and severity of pain attacks.	No SAEs reported. MAE= bruising and minimal bleeding

BDI= Beck Depression Inventory; MAE= minor adverse effect; MFI= Multidimensional Fatigue Inventory; n/*a*= not applicable; PDA= practitioner delivered acupuncture; SA= self-acupuncture' SAE= serious adverse effect; SD= standard deviation.

3.2.4. *Methodological quality*

There was a significant variation in the methodological quality of the nine studies appraised using MMAT. Five studies were deemed low methodological quality [3,20,23–25]; and four studies were deemed

high methodological quality [18,19,21,22]. Neither the RCT [18] nor mixed-methods feasibility study [19] had published protocols, so we were unable to check if there was bias due to missing results, which affected the methodological quality. However, the methodological quality of these studies was still deemed high.

The methodological quality of two studies [3,23] were downgraded due to the small sample size, making it hard to compare them to a larger population. Two studies [24,25] were downgraded because there was not enough information to determine if any attempts were made to ensure the participants represented the target population. Those studies [3,23–25] were also downgraded because we could not determine the risk of nonresponse bias; three studies [23–25] were service evaluations and did not make it clear if other people had been taught SA who did not take part in the evaluation and one study [3] was a survey report which had a low response rate of 19 % and so the risk or nonresponse bias is likely to be high. The methodological quality of three of those studies [23–25] were also downgraded because the clinical or statistical significance of the effectiveness of SA was not reported. The methodological quality of one study [20] was downgraded in all categories because there was insufficient information published about the trial. A summary of the MMAT appraisal of the studies is provided in table 3.

The three case reports did not meet the criteria set by the MMAT screening questions. Instead, the methodological quality of these studies was assessed using an unvalidated tool designed by Murad et al. [16]. The methodological qualities of the case reports [26–28] were deemed adequate. All studies were downgraded because it was unclear if the cases represented patients with a similar presentation. In two case reports [27,28] it was not clear if other causes of the observation were ruled out. A summary of the assessment is available in Table 4.

4. Discussion

This mixed-methods systematic review (MMSR) has identified a significant gap in SA research with only four studies having a high methodological quality and just one RCT found. The MMSR highlights the need for future high-quality RCTs on this subject.

Nine studies assessed the effectiveness of SA; however, only three [18–20] reported statistical or clinical significance. Of these, two studies [19,20] showed positive findings - one clinically significant and the other statistically significant- though the findings were not detailed. Both studies had small sample sizes raising concerns about the reliability of the findings. Conversely, the study by Molassiotis et al. [18], with a high methodological quality and detailed results, is likely to be the only study with reliable findings on the effectiveness of SA. However, it's four-week duration limits conclusions about SA's long-term efficacy.

Five studies [22–24,27,28] examined the effectiveness of SA in managing pain, while three studies [18,20,25] explored its role in alleviating cancer treatment side effects: xerostomia, fatigue and nausea. However, variations in study designs and data collection methods among the pain studies complicate direct comparisons, impacting the reliability and validity of the findings. Similarly, the cancer treatment side effects studied were different across these studies, preventing direct comparison of their results. These limitations affect the overall reliability of the MMSR, making it difficult to draw definitive conclusions about SA's effectiveness.

Despite methodological limitations, the consistency of findings across the nine studies on the acceptability and 10 studies on the safety of SA is notable. While some studies were of a lower quality, this suggests that SA is generally acceptable to patients and safe.

The main strength of this study is that it is the first SR focused exclusively on SA studies. A key strength of the methodology is its broad inclusion criteria, which increases the likelihood of identifying a greater number of SA studies. By including studies of any design, this MMSR ensured that evidence from various study types was identified to achieve its objectives. Among the study designs identified, the mixed-methods studies proved to be the most suitable for evaluating the acceptability, effectiveness, and safety of SA, such as the studies by Davies et al. [19] and the qualitative study by Bardy et al. [21], nested within the study by Molassiotis et al. [18].

However, this MMSR is limited by the small number of studies identified, particularly the lack of controlled trials and the small sample sizes in all but three studies, which affect the reliability of the findings. Many studies were retrospective, such as case reports and service evaluations, making them prone to reporting or recall bias, potentially compromising their findings. Significant heterogeneity among the studies further complicated the analysis. Due to this heterogeneity, a MA could not be performed, preventing the pooling of results—a process that improves precision and provides a more accurate estimate of the true effect [29]. Additionally, the certainty of the evidence could not be assessed due to the data heterogeneity. Only four studies were rated as having high methodological quality, meaning the findings from lower-quality studies may be unreliable. As this is the first SR of SA studies, its findings cannot be compared to previous SRs, which also impacts validity. Although studies in any language were eligible, only English-language databases were searched. This likely resulted in missing studies, particularly from East Asia, where acupuncture originated and is widely practiced. Another limitation is that the MMSR was not registered prior to its conduct, which may introduce reporting bias.

This review highlights the need for further high-quality research on SA. There is now sufficient evidence supporting acupuncture as an effective treatment for conditions such as headaches and migraines [1], and primary chronic pain conditions [2]. This robust evidence provides a rationale for exploring the use of SA as a long-term management strategy for these conditions.

The findings from this MMSR highlight the necessity of conducting randomised, controlled, mixed-methods studies to evaluate the effectiveness, acceptability, and safety of SA. It is crucial to assess all these aspects to determine whether SA is a viable intervention for implementation within healthcare systems. To date, the cost-effectiveness of SA has not been evaluated, which is a key factor in considering new interventions.

If SA is found to be acceptable to patients, as well as safe and effective, it could offer a valuable option for patients to learn how to self-manage chronic symptoms.

5. Conclusion

This MMSR highlights a major gap in the current research. Insufficient studies have been conducted on SA to confirm its effectiveness. The available evidence indicates that SA is both safe and well-accepted by patients. However, further high-quality research is needed to confirm this. If proven to be an effective, acceptable and safe intervention, SA could potentially be taught to patients to aid in the long-term self-management of their symptoms or condition.

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CRediT authorship contribution statement

Catrina Davy: Methodology, Validation, Formal analysis, Investigation, Writing – original draft, Visualization, Project administration. **Michael Loughlin:** Writing – review & editing, Supervision. **John Hughes:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Table 3
MMAT appraisal of the studies.

Category study designs	Methodological quality criteria	Fagan N and Staten P [23]	Teig S et al. [24]	Cheville AM and Bassford [25]	Adler Z and Hansen P [20]	Molassiotis A et al. [18]	Davy C and Hughes J [3]	Bardy J et al. [21]	Hughes J and Davy C [22]	Davies S et al. [19]
Screening questions	S1. Are there clear research questions?	Y	Y	Y	Y	Y	Y	Y	Y	Y
	S2. Do the collected data allow to address the research questions?	Y	Y	Y	Y	Y	Y	Y	Y	Y
1. Qualitative	1.1. Is the qualitative approach appropriate to answer the research question?							Y	Y	
	1.2. Are the qualitative data collection methods adequate to address the research question?							Y	Y	
	1.3. Are the findings adequately derived from the data?							Y	Y	
	1.4. Is the interpretation of results sufficiently substantiated by data?							Y	Y	
	1.5. Is there coherence between qualitative data sources, collection, analysis and interpretation?							Y	Y	
2. Quantitative randomized controlled trials	2.1. Is randomization appropriately performed?				CT	Y				
	2.2. Are the groups comparable at baseline?				CT	Y				
	2.3. Are there complete outcome data?				N	Y				
	2.4. Are outcome assessors blinded to the intervention provided?				CT	N				
	2.5 Did the participants adhere to the assigned intervention?				CT	Y				
3. Quantitative nonrandomized	3.1. Are the participants representative of the target population?									
	3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?									
	3.3. Are there complete outcome data?									
	3.4. Are the confounders accounted for in the design and analysis?									
	3.5. During the study period, is the intervention administered (or exposure occurred) as intended?									
4. Quantitative descriptive	4.1. Is the sampling strategy relevant to address the research question?	Y	Y	Y			Y			
	4.2. Is the sample representative of the target population?	CT	CT	CT			CT			
	4.3. Are the measurements appropriate?	Y	Y	Y			Y			
	4.4. Is the risk of nonresponse bias low?	CT	CT	CT			CT			
	4.5. Is the statistical analysis appropriate to answer the research question?	N	N	N			N			
5. Mixed methods	5.1. Is there an adequate rationale for using a mixed methods design to address the research question?									Y
	5.2. Are the different components of the study effectively integrated to answer the research question?									Y

(*continued on next page*)

Table 3 (*continued*)

Category study designs	Methodological quality criteria	Fagan N and Staten P [23]	Teig S et al. [24]	Cheville AM and Bassford [25]	Adler Z and Hansen P [20]	Molassiotis A et al. [18]	Davy C and Hughes J [3]	Bardy J et al. [21]	Hughes J and Davy C [22]	Davies S et al. [19]
	5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?									Y
	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?									Y
	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?									Y

CT= can't tell, *N*= No, *Y*= yes,.

Table 4
Assessment of methodological quality of case reports using tool designed by Murad MH, Sultan S, Haffar S, et al.

Domains	Leading explanatory questions	Hasegawa et al. [26]	Dyer et al. [27]	Walter and Curtis [28]
Selection	1. Does the patient(s) represent(s) the whole experience of the investigator (centre) or is the selection method unclear to the extent that other patients with similar presentation may not have been reported?	No	No	No
Ascertainment	2. Was the exposure adequately ascertained?	Yes	Yes	Yes
	3. Was the outcome adequately ascertained?	Yes	Yes	Yes
Causality	4. Were other alternative causes that may explain the observation ruled out?	Yes	No	No
	5. Was there a challenge/ rechallenge phenomenon?	No	No	No
	6. Was there a dose–response effect?	N/a	Yes	Yes
	7. Was follow-up long enough for outcomes to occur?	N/a	Yes	Yes
Reporting	8. Is the case(s) described with sufficient details to allow other investigators to replicate the research or to allow practitioners make inferences related to their own practice?	No	Yes	Yes

N/*a*= not applicable.

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Data availability

Data will be made available on request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.eujim.2025.102433.

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