

Effectiveness of shared medical appointments delivered in primary care for improving health outcomes in patients with long-term conditions: a systematic review of randomised controlled trials

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55 **ABSTRACT**

56 **Objectives**

57 Shared medical appointments (SMAs) have the potential to address interlinked challenges of
58 limited capacity in primary healthcare and rising prevalence of patients with multiple long-
59 term conditions (LTCs). This review aimed to examine the effectiveness of SMAs compared
60 to one-to-one appointments in primary care at improving health outcomes and reducing
61 demand on healthcare services.

62 **Methods**

63 We searched for randomised controlled trials (RCTs) of SMAs involving patients with LTCs
64 in primary care across six databases from 2013-2020 and added eligible papers identified
65 from previous relevant reviews. Data were extracted and outcomes narratively synthesised,
66 meta-analysis was undertaken where possible.

67 **Results**

68 Twenty-three unique trials were included. SMA models varied in terms of components, mode
69 of delivery and target population. Most trials recruited patients with a single LTC, most
70 commonly diabetes ($n=12$), although eight trials selected patients with multiple LTCs. There
71 was substantial heterogeneity in outcome measures which we categorised into health
72 outcomes (biomedical indicators, psychological and well-being measures), healthcare
73 utilisation, and cost and resource use. Meta-analysis showed that participants in SMA
74 groups had lower diastolic blood pressure than those in usual care ($d=-0.123$, $95\%CI = -$
75 0.22 , -0.03 , $n=8$). No statistically significant differences were found across other outcomes.
76 Compared with usual care, SMAs had no significant effect on healthcare service use.

77 **Conclusions**

78 SMAs were at least as effective as usual care in terms of health outcomes and did not lead
79 to increased healthcare service use in the short-term. To strengthen the evidence base,
80 future studies should target standardised behavioural and health outcomes and clearly
81 report SMA components so key behavioural ingredients can be identified. Similarly,
82 transparent approaches to measuring costs would improve comparability between studies.
83 To better understand SMA's potential to reduce demand on healthcare services, further
84 investigation is needed as to how SMAs can be best incorporated in the patient care
85 pathway.

86 **PROSPERO protocol registration:** *CRD42020173084*

87 299/300

STRENGTHS AND LIMITATIONS

- Focus on randomised controlled trials, highest quality evidence of the effectiveness of SMAs in primary care for long term conditions
- Robust search strategy, based on previous high-quality review; refined by information specialists to focus on primary care
- Rapidly evolving area of practice and publications and the most recent evidence may be missing.
- Small number of studies reported resource use and costs limiting conclusions regarding efficacy of SMAs in primary care.

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COMPETING INTERESTS

None to declare.

CHECKLIST

See supplementary material for PRISMA checklist.

INTRODUCTION

Shared Medical Appointments (SMAs), also known as group consultations, are a model of care with the potential to address the interlinked challenges of limited capacity in primary care and rising prevalence of patients with multiple long-term conditions (LTCs)[1,2]. SMAs are longer appointments (typically 60-120 minutes) whereby patients with the same LTCs meet with their physician together[3]. SMAs are typically co-led and/or facilitated by healthcare professionals, such as nurses, pharmacists, psychologists, and physiotherapists. The group typically consists of between 6-15 patients and may include family members and caregivers[4,5]. There are various models of SMA but generally they retain some features of a standard one-to-one appointment such as physical examinations and personalised review of medical charts[2]. In addition, SMAs provide participants an opportunity to ask questions of clinicians and other patient and receive formal education and counselling during the group session. SMAs have been used to deliver care for a range of health conditions including diabetes, hypertension, and chronic pain; though there is potential for wider application, including multimorbidity[6].

A recent synthesis of qualitative literature found that most patients and primary care practitioners regarded SMAs positively[6]. Key benefits included improved patient self-confidence and motivation for self-management; whilst practitioners felt that SMAs had the potential to provide a more efficient and effective way of delivering care[7]. Previous reviews of effectiveness were inconclusive but evidence, largely from the United States (US) and Australia, reported a promising effect of SMAs for some biomedical measures. For example, improvements in glycated haemoglobin A1C (HbA1C) and systolic blood pressure (SBP) were greater in patients attending SMAs compared to usual care for diabetes[8,9]. However, previous reviews include studies that evaluate the use of SMAs in secondary care settings as follow-up appointments to specialist treatment [4]. A mixed-methods review of SMAs in primary care settings for non-specialist treatment concluded that SMAs can yield improvements in patient satisfaction and some biophysical markers of disease [5]. However, this review conducted in 2015 included studies of SMAs for non-LTCs. It remains unclear whether SMAs are effective in supporting improved ongoing management of LTCs in primary care.

This review examined the effects of SMAs delivered in primary care on health outcomes and healthcare service use in patients with LTCs. We sought to answer two overarching research questions:

1. Are SMAs effective in improving health outcomes for patients with one or more long-term conditions?
2. Do SMAs reduce healthcare service use by patients with one or more long-term conditions?

METHOD

This systematic review follows Cochrane Handbook Guidance[10] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[11].

Protocol and registration

This study was registered on PROSPERO ([CRD42020173084](https://www.crd42020173084)). Regarding protocol changes, we proposed coding of Behaviour Change Techniques Taxonomy V1 (BCTTv1)[12] used in SMAs and associated with changes in outcomes. However, most included studies did not report the required detail and so instead we narratively described this information.

Inclusion/exclusion criteria

Studies were included if they met the criteria outlined in Table 1. The focus of this review was on models of SMAs that include one-to-one time for every patient in attendance as per the description of group consultations reported previously [1,2].

Table 1: Inclusion and exclusion criteria

PICOS Criterion	Description
Population	<p>Adult patients (≥ 18 years of age) with one or more long-term conditions who have attended at least one shared medical appointment (SMA) in a primary care setting were eligible for inclusion.</p> <p>Patients in primary care settings who were seen by a secondary care specialist during the SMA were excluded.</p>
Intervention (Model of care)	<p>All countries were eligible for inclusion.</p> <p>SMAs/group consultations/group visits conducted in primary care setting, delivered by a primary care healthcare professional (e.g. nurse, doctor, pharmacist), were eligible for inclusion.</p> <p>The present review considered SMAs to be clinical encounters in which groups of patients with the same/similar long-term condition meet with a healthcare professional for routine care.</p>
Comparison/control	<p>The SMA must have included one-to-one time for every patient in attendance. Therefore, peer support groups were excluded.</p> <p>No restrictions – usual care, active control (e.g., another SMA model).</p>
Outcomes	<p>Behavioural outcomes – e.g., healthcare utilisation, physical activity, medication adherence.</p> <p>Disease-specific measures – e.g., Haemoglobin A1C (HbA1C).</p> <p>Biophysical health indicators – e.g., cholesterol, weight, BMI.</p>

Study design	Cost/resource use. Other outcomes- e.g. psychological and wellbeing Only randomised controlled trials that were published in peer-reviewed journals were eligible for inclusion.
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Search strategy

A comprehensive search strategy was developed, based on the approach described in Booth et al.[13], to search for trials published after their search, namely the period 2013-2020. Key changes included the removal of the terms “group outpatient”, “GMV” or “GMA”, “group processes” and “Group care” to improve the sensitivity and specificity of the search (see S1). The search strategy was first used to search MEDLINE (via OVID) and then translated for the following databases: EMBASE (via OVID), Science citation index (via Web of Knowledge) Social Science Citation Index (via Web of Knowledge), Cumulative Index to Nursing and Allied Health Literature (via EBSCOhost), Cochrane Central Register of Controlled Trials (Wiley), DARE, NHS EED, and HTA (Centre for Reviews and Dissemination). Any relevant pre-2013 trials identified by forward and backward citation searches of the included trials, including those in relevant systematic reviews[4,6,14,15], were also included in the review.

Screening

Screening and data extraction was facilitated using the systematic review management tool, Covidence[16]. Two reviewers independently screened all titles and abstracts against the inclusion criteria, and a third reviewer adjudicated any disagreements. This process was also applied to the screening of full-text papers.

Data extraction

Information relating to the study design, population, and intervention were extracted based on a framework on form of delivery[17] (e.g. experience/training of the providers and facilitators), outcomes, and results were extracted from all relevant papers using a data extraction form (see S2). All information was double-extracted by two researchers, with disagreements resolved through discussion or third-party moderation.

Where data were reported for several time-points, the data-point closest to the end of the SMA intervention was used to calculate the effect size as this would be when the largest effects attributable to the SMA is expected. If available, intention-to-treat data were used to calculate effect sizes.

Quality assessment

Two researchers independently assessed the quality of all included studies using the Cochrane Risk of Bias Tool[18]. Percentages of judgements (high, low, or unclear) for each domain was calculated across the studies.

Data analysis/synthesis

We mapped all reported outcomes into the following categories agreed by the wider research team to best reflect SMA effectiveness and efficiency: health outcomes (biomedical indicators, psychological and well-being measures), healthcare utilisation and cost and resource use.

Meta-analyses were performed in StataC 15. Given the heterogeneity between studies, a random-effects model was used[19]. Meta-analyses were conducted where there were at least two studies reporting a specific outcome[20]. Outcome effect sizes were calculated as Cohen's d (standardised mean difference). Heterogeneity was assessed using Higgins I-Square (I^2), whereby 50-90% was considered as representing substantial heterogeneity[21]. Authors were contacted for additional information if data needed to calculate effect sizes were not sufficiently reported in the published paper(s). Where this information could not be obtained from authors, p -values and confidence intervals were used to calculate effect sizes[10]. Only studies in which the comparator was usual care were pooled into the meta-analysis.

Using meta-regression, sensitivity analyses were conducted to explore whether results differed according to sources of bias identified from the risk of bias assessment.

Studies that were too heterogeneous to perform meta-analysis, and where the comparator was not usual care, were synthesised narratively. Extracted data was tabulated by outcome measure to enable comparisons and relationships across studies to be more easily examined [22]. For each outcome measure, evidence of an effect was determined by the p -values reported in the papers. To assess the certainty of the evidence, number of study participants, confidence intervals and the consistency of effects across studies, the risk of bias of the studies, how directly the included studies address the planned question (directness) were taken into consideration.

Patient and Public Involvement

The PRU BehSci Public Patient Involvement group provided their patient perspective about outcome measures of interests.

RESULTS

<Figure 1 – PRISMA diagram of study selection process here>

Characteristics of the included studies

Twenty-three unique trials (reported in thirty-four papers) were identified, for PRISMA details see Figure 1 and Table 2. See S3 for list of included papers.

277 Table 2: Characteristics of included studies grouped by health condition(s)

Study	Condition(s)	Country	Setting	Sample size (N)	Model	Comparator
Scott (2004) [23] Coleman (2001)[24]	^Chronic conditions	USA	Large health maintenance organisation	295	CHCC model-'group visits'	Usual care
Gardiner (2017) [25] Gardiner (2019)[26]	Chronic pain and depression	USA	Community Health Centres serving low-income, racially and ethnically diverse populations	159	Integrated medical group visit	Usual care
Berry (2016)[27]	Diabetes (Type 2)	USA	Community-based health center serving low-income population who are working	80	Group visits	Usual care
Clancy 2003a [28] Clancy 2003b[29]	Diabetes (Type 2)	USA	University Primary Care Center serving uninsured or inadequately insured patients	120	CHCC model-'group visits'	Usual care
Clancy (2007a) [30] Clancy (2007b)[31] Clancy 2008[32]	Diabetes (Type 2)	USA	University Primary Care Center serving mainly minority, inadequately insured patients	186	CHCC model-'group visits'	Usual care
Cole (2013)[33]	Diabetes (Prediabetes)	USA	Military health system	65	SMA	Individual counselling
Drake (2018)[34]	Diabetes (Type 2)	USA	Family medicine centre	33	SMA + personalised health planning	SMA
Ee (2020)[35]	Diabetes (Type 2)	Australia	University primary care center	18	SMA	Usual care
Liu (2012)[36]	Diabetes (Type 2)	China	General practices	208	CHCC model-'group visits'	Usual care
Naik (2011)[37]	Diabetes (Type 2)	USA	Veterans Affairs Medical Centres	87	Group clinic	**Enhanced usual care
Schillinger (2008) [38] Schillinger (2009)[39] Wallace (2013)[40]	Diabetes (Type 2)	USA	University affiliated-Safety net settings- community health network	339	Group medical visit	Automated telephone self-management
Vaughan (2017)[41]	Diabetes (Prediabetes/ Type 2)	USA	Community health clinic serving low-income Hispanic adults	62	Group visit	Usual care After 6 months, the control group received the intervention
Vaughan (2020)[42]	Diabetes (Type 2)	USA	Community health clinic serving low-income Hispanic adults	89	Group visits	Usual care

Wagner (2001)[43]	Diabetes (Type 1 & 2)	USA	Primary care practices in health maintenance organisation	708	Chronic care clinic	Usual care
Cohen (2011)[44]	Diabetes (Type 2) and cardiovascular risk	USA	Veterans Association Medical Center	99	SMA programme (2 phases)	Usual care
Taveira (2014)[45]	Diabetes and cardiovascular risk	USA	Veterans Association Medical Center	200	Group medical visit	CRRC Individual clinic Usual care
Wu (2018)[46]	Diabetes (Type 2) and cardiovascular risk	USA	Veterans Health Administration Hospital primary care services	250	Group medical visit	Usual care
Taveira (2011)[47]	Diabetes (Type 2) and depression	USA	Veterans Affairs Medical Centres	88	SMA/ Group medical appointment	Usual care
Yancy (2020)[48] Crowley (2017)[49]	Diabetes (Type 2) and overweight	USA	Veterans Association Medical Center	263	Group medical visit with IWM	Group medical visit
Edelman (2010)[50] Crowley (2013)[51] Crowley (2014)[52] Eisenberg (2019)[53]	Diabetes (Type 2) and hypertension	USA	Veterans Association Medical Center	239	Group clinic	Usual care
Gao (2015)[54]	Hypertension	China	Community Health Care Centre	1346	CHCC model+ 'group visits'	Usual care
Simon (2015)[55]	Hypertension	Germany	Physician practices	48	CHCC model 'group medical visit'	Usual care
Baqir (2020)[56]	Osteoporosis	UK	General practices	158	Group consultation	Usual care

Multiple papers for the same trial were found therefore we bolded the one used as the index paper throughout the rest of the paper. ^Chronic conditions (including asthma, COPD, heart failure, diabetes, arthritis, deafness, blindness). **Enhanced usual care- patients required to attend 2 diabetes group education sessions. CRRC- Cardiovascular Risk Reduction Clinic, IWM- intensive weight management, SM- Self-management, SMA- Shared medical appointment, UC- usual care.

Fifteen trials (70%) were for a single LTC, of these: 12 were for diabetes[27,29,30,33–38,41–43], two for hypertension[54,55]; and one was for osteoporosis[56]. Eight trials considered multiple LTCs: three were diabetes and hypertension/cardiovascular risk[44–46,50]; one was diabetes and depression[47], one was for overweight patients with diabetes [48]; one was chronic pain and depression[26]; and one included multiple LTCs including: arthritis, hypertension, cancer, deafness and diabetes[23]. Overall, 20/23 (87%) of trials focused on patients with diabetes.

Eighteen trials (83%) were conducted in the US[23,26,27,29,30,33,34,37,38,41–48,50], two in China[36,54] and one each in Australia[35], Germany[55] and the UK[56]. Eleven trials were measured the effectiveness, impact or efficacy of SMAs compared to usual care[23,26,27,30,33,36,37,42,43,46,50], Eight trials examined feasibility parameters[28,34,35,38,41,42,47,54], and two trials were non-inferiority/superiority trials[48,49,56].

In eight trials (35%) participants were veterans or military personnel[33,37,44–48,50]. Participants were from low-income communities in four trials[26,27,41,42], and uninsured communities in three US trials[29,30,38]. Two trials were tailored for non-English speaking participants, where written materials were available in Spanish[38,42]. The majority of participants were over 50 years old, the mean age of participants ranged between 50.5[25,26] to 74 years old[56]. Two trials were specifically for older patients over 55 or 60 years respectively[23,55], and two trials excluded patients over 75[48] and 80 years[36]. Twelve trials (52%) had a majority of female participants[23,27,28,36,41,42,54,56]. Ten trials had majority of male participants[33–35,37,44–48,50]. One trial did not report the gender balance of participants[55]. Five studies had a majority White population[26,33,43,46,47], six trials had a majority Black population[27,29,30,34,48,50], two trials had a majority Hispanic population[41,42], two trials had a majority Asian population[35,36], and one trial had a majority White-Latino population [38]. Five studies did not report the ethnicity of participants[23,44,54–56].

Most trials ($n=17$, 78%) had a two-arm design that compared SMAs with usual care, typically a one-to-one (1:1) appointment with primary care physician[23,26,27,29,30,35,36,41–47,50,54,56]. In three other two-arm trials, the comparator was a 1:1 appointment plus two diabetes group education sessions[37], an SMA without an integrated weight management programme[48] or an SMA with a personal health planning component (PHP)[34]. Two trials had a delayed six-month waitlist control design[41,42]. Two trials had a three-arm design: one examined the effectiveness of a cardiovascular risk reduction clinic compared with

group medical visits and usual care[45]; and a second compared an automated telephone self-management service with SMAs and usual care[38]. Where descriptions of usual care were available, usual care was delivered by a primary care provider, typically a physician/GP or nurse practitioner [57–62]and, in some cases, a pharmacist [62,63]or dietician [64]. A review of medication and chronic disease monitoring (e.g., measures of blood pressure and HbA1c) commonly took place in these sessions [58,59,63,65,66]. In some of the SMAs for diabetes, the usual care sessions included some form of individualised diabetes self-management education[58,62,64] or referrals were made available to see a diabetes educator dietician [59,67].

SMA components and mode of delivery

There was much variation in the SMAs models reported by studies (see S9 for detailed description). Key features of SMA models were: facilitated group discussion or group question and answer session (15 trials)[19,22,25,26,29,30,32–34,37–39,40,43,46,50], ‘group education’ (14 trials)[19,23,25,31–33,37,38,42,43,44,46,50], and the opportunity to socialise (11 trials)[19,22,25,26,29,32,34,37,38,46,50].

SMAs were delivered face-to-face in all trials, although three SMA models included digital technologies, namely website and telephone support[26] and phone calls or text message support and/or reminders[41,42]. In three trials[37,45,56] SMAs were delivered by a single healthcare professional though mostly they were delivered by multidisciplinary teams. Professionals most commonly involved were family physicians[23,27,28,34–38,43,48,50,54,55], nurse practitioners[27,30–33,36,48,49] or nurses[23,24,43,44,46,50–54]. It was not always possible to tell what role each member of staff had in the delivery of the SMA. Provider characteristics other than profession or role were rarely reported, though two trials involving a majority Hispanic/Latino participants reported that the community health worker and or physician were bilingual[38,42]. Four trials reported that the same interventionists attended all visits for a particular group[44,48,50,55]. One trial of diabetes SMAs reported that group assignments were maintained for all SMAs to facilitate peer interactions and relationships within groups[37]. The consistency in group composition in terms of patient and interventionists attending each session was not reported by most studies.

Trial outcome measures varied across trials though most included biomedical indicators, psychological and well-being measures, healthcare service use and cost and resource use. Full details of all outcome measures reported by the studies are presented in S4.

Risk of bias

Risk of bias item across the studies was generally low across the items, except for 'Blinding of participants and personnel' (83% of trials high, 17% unclear) (See S5).

Sensitivity analyses

There were no differences for any of the outcomes according to the risk of bias assessment criteria relating to random sequence generation, allocation concealment, blinding, incomplete outcome data, and selected reporting (see S5).

Effectiveness of SMAs

Biomedical indicators

Glycated haemoglobin A1C (HbA1c) (%)

Of the 14 trials measuring HbA1c (%) which compared SMA to usual care, nine trials[27,30,35,38,42,45–47] were included in a meta-analysis. No statistically significant difference between SMAs and usual care was found for HbA1c (%) at follow-up ($d=-0.098$, $95\%CI = -0.34, 0.14$, $n=9$) ($p=0.420$) (see Figure 2a). Substantial heterogeneity was observed ($I^2 = 70.9\%$). Of four other SMA trials reporting HbA1c (%) but not in the meta-analysis[29,43,44,50], only one reported significant between group differences, whereby the SMA group had significantly higher odds of attaining HbA1c goals ($< 7\%$) compared to usual care[27]. However, this was a high risk of bias study, scoring 'unclear' across the six domains.

Diastolic blood pressure

Of 11 studies which reported diastolic blood pressure (DBP)[27,30,33–36,38,41,42,45,50,54], eight were included in meta-analysis[27,33,35,38,41,42,45,54]. A very small statistically significant pooled effect was found at follow-up ($d=-0.123$, $95\%CI = -0.22, -0.03$, $n=8$) ($p=0.008$), whereby participants in the SMA group had lower DBP than those in usual care (see Figure 2b).

Of the three studies not included in the meta-analysis[30,36,50], one trial of SMAs for diabetes and hypertension reported that mean DBP was lower in the SMA group (78.3 mmHg) than in the usual care group (82.1 mmHg) at 12 months[50].

Systolic blood pressure

Of 13 trials reporting SBP[27,30,33,35,36,38,41,42,44–46,50,54], nine could be meta-analysed[27,33,35,38,41,42,45,46,54]. No statistically significant difference between SMAs and usual care was found for SBP at follow-up ($d=-0.018$, $95\%CI = -0.11, 0.08$, $n=9$) ($p=0.709$), with low level of heterogeneity observed ($I^2 = 3.8\%$) (see Figure 2c). Of the four trials not in the meta-analysis[30,36,44,50], two moderately robust studies reported statistically significant between group differences in SBP at follow-up[36,50], whereby the SMA group showed greater decreases in SBP compared to usual care.

No statistically significant effect of SMAs compared to usual care was found for other biomedical health outcomes including: total cholesterol, high density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, weight, and BMI (see S6).

Trials with non-usual care comparators

Three trials had enhanced SMAs as their comparator[34,37,48], all of which found greater reductions in the enhanced SMA group compared to the standard SMA group [64,68,69]. Drake et al. (2018) reported that there significantly greater improvements in HbA1c (%) were observed in the PHP SMA group compared to the standard SMA group at follow-up[68]. Naik et al. (2011) found that HbA1c (%) was significantly lower in the SMA group than the traditional diabetes group education group immediately following the active interventions at three months, and the between group differences remained clinically and statistically significant at one year follow-up[64]. Yancy et al. (2020) found that the mean reduction in HbA1c (%) was significantly greater in the enhanced SMA group compared to the standard GMV group at 16 and 32 weeks. However, at 48 weeks, no between group differences in HbA1c (%) were observed[69].

Further, Drake et al., (2018) reported that participants in the PHP SMA group had lower DBP ($M=86$ mmHg) at 8 months follow-up compared to participants in the standard SMA group ($M=79.8$ mmHg)[34]. Yancy et al. (2020) reported patient weight loss in the SMAs with intensive weight management was comparable to weight loss amongst patients attending SMAs but statistical significance was unclear[48]. It is possible that other studies could not detect statistically significant differences between arms due to small sample sizes.

<Insert Figure 2 a,b,c, here>

Psychological and well-being measures

Quality of life

Six trials reported quality of life (QoL) outcomes[23,26,35,38,44,46] of which two trials reported significant between group differences[23,38]. One trial of SMAs for chronically ill patients with multiple LTCs found that participants in the SMA group ($M=7.2$, $SD=1.8$) reported significantly better QoL than the usual care group ($M=6.3$, $SD=2.0$) ($p=.002$) at 24 months[23]. Schillinger et al., (2008) measured QoL using the short form (SF)-12 instrument which comprised of mental health and physical health subscales. Improvements in SF-12 mental health was observed for SMA group compared to SMA (effect size=0.31, $p=0.03$) and usual care (effect size=0.18, $p=0.2$)[38]. However, this was considered as a high risk of bias study, with high/unclear judgements across four out of six domains.

Patient satisfaction

Four trials measured patient satisfaction[23,34,43,56]. Scott et al. (2004) reported significant differences at follow-up, with SMA patients reporting higher satisfaction with practitioner discussions compared to controls[23]. The other three studies found no between group differences.

Patient self-efficacy

Self-efficacy was measured in nine trials[23,27,36,38,44,47,50,54], of which five studies were included in meta-analysis[23,26,27,38,54]. No statistically significant effect was found ($d=0.167$, $95\%CI = -0.08, 0.41$, $n=5$) ($p=0.182$) (See S7). High levels of heterogeneity were observed ($I^2=78.9\%$). Of the four other studies not included in meta-analysis[36,44,47,50], two reported that SMA patients had significant improvements in self-efficacy to manage diabetes compared to usual care[36,50].

No statistically significant effect of SMAs compared to usual care was found for other depression, the only other psychological and well-being measure identified (see S7).

Trials with non-usual care comparator

Drake et al. (2018) reported significant improvements in self-efficacy, as measured using the Diabetes Empowerment Scale, for the PHP SMA group compared to the standard SMA group[30]. Naik et al. (2011) did not find any differences in diabetes self-efficacy scores between the SMA group and the traditional diabetes group education group[37].

Healthcare service utilisation

Hospital admissions

Seven trials reported hospital admissions within six to 24 months[23,27,29,43,45,47,50] and three were included in a meta-analysis[23,27,45]. There was no difference between SMAs and usual care in terms of hospital admissions at follow-up ($d=-0.016$, $95\%CI = -0.38, 0.35$, $n=3$; $p=0.931$) (see Figure 3a). Substantial heterogeneity was observed ($I^2 = 71.1\%$).

None of the other four trials[29,43,47,50] reported significant between group differences for hospital admissions at follow-up.

Emergency department use

Of eight relevant trials[23,26,27,29,43,45,47,50], four were included in a meta-analysis[23,27,43,45]. No difference between SMAs and usual care was found for admissions to emergency departments at follow-up ($d=-0.083$, $95\%CI = -0.30, 0.13$, $n=4$, $p=0.453$ (Figure 3b). Considerable heterogeneity was observed ($I^2 = 61.7\%$).

Of four trials not in the meta-analysis [26,29,47,50], only Edelman et al. (2010) reported significant between group differences in emergency department use favouring SMAs with 0.4 ($95\%CI = 0.20, 0.70$) fewer emergency care visits than the usual care group over the 12-month study period [50].

Primary care visits

Four trials reported the number of primary care visits participants made during the study period[23,43,47,50]. Three were pooled in a meta-analysis[23,43,47] showing no statistically significant difference ($d=0.034$, $95\%CI = -0.09, 0.16$, $n=3$, $p=0.575$) (see Figure 3c).

Edelman et al. (2010), which could not be included into the meta-analysis, reported that SMA participants had significantly fewer primary care visits than controls (5.3 vs. 6.2 per patient-year) at 12 months[50].

No statistically significant effect of SMAs compared to usual care were found for other behavioural outcomes including medication adherence and physical activity (see S8)

<Insert Figure 3a,b,c here>

Cost and resource use

Few studies reported the costs involved in the delivery of the SMA and those that did were unclear about cost parameters (i.e whether scheduling and preparation time was included or not) or how the costs were attributed. One trial of diabetes SMAs reported that overall costs

per patient were higher in SMAs than those in usual care group for the study period of six months[29]. However, another trial found no significant difference between SMA and usual care in terms of total costs incurred during the 24 months study period, but showed a positive effect of the SMA at 13 months post-study where cost decreased by 6% for the SMA but increased by 13% for usual care $p<0.01$ [43]. The SMA trial for osteoporosis reported that the costs incurred during the study period were lower for the SMA group compared to control groups[56]. A trial of chronic condition SMAs (reported that total costs incurred by the SMA group were lower than the usual care group[23].

DISCUSSION

Our systematic review identified 23 unique RCTs comparing SMAs for one or more LTCs to usual care or an enhanced SMA. We found that SMAs significantly improved diastolic blood pressure for diabetes patients. In line with the findings of previous reviews[15], no harm was observed for the use of SMAs across these outcomes and there was not enough evidence of an effect on healthcare service use compared to usual care. This indicates that whilst SMAs may not be superior to usual care in terms of most health outcomes or reducing demand on services, they do not appear to increase demand at least in the short-term. Evidence reporting costs is too heterogeneous to draw firm conclusions.

Comparison with previous literature

Like previous reviews of SMAs for LTCs[4,15,70], more than half of the included RCTs included patients with diabetes, and as such the most commonly reported outcome measure was HbA1C. However, unlike previous reviews[71,72], we did not observe any significant improvements in HbA1c. This may be because previous reviews included trials in secondary care. Our meta-analysis showed that SMA participants had lower DBP compared to patients who received usual care. [54]

Previous systematic reviews have been inconclusive with regards to the impact of SMAs on healthcare utilisation. Edelman et al.'s (2012) review[72] of SMAs for patients with chronic medical conditions in older adults found a lower pattern of healthcare utilisation, whilst Booth et al. (2015)[4] reported a mixed pattern of changes. Our meta-analyses show that SMAs do not differ from usual care in terms of healthcare utilisation. There is no evidence in the present data to suggest that patients compensate for a lack of privacy by returning to primary care or that they risk hospitalisation because issues are not adequately addressed during the SMA session(s). However, it should be noted that the key source of bias across the included studies was the lack of blinding of participants and personnel. Therefore,

possible selection bias may result in recruitment of SMA participants with less concern about sharing their personal/medical information.

In comparison to biomedical outcomes and psychological outcomes, healthcare service use and costs and resource use and other behavioural outcomes were less frequently reported by studies. This echoes the findings of Edelman et al. (2015)[46] which found there to be limited data on key patient-centred outcomes such as patient satisfaction. Behavioural outcomes such as medication adherence are important across many LTCs and are key to understanding how patients are self-managing their conditions. In line with Kelly et al.'s (2017)[12] recommendation, future studies should report outcome effectiveness measures that are common or comparable across different LTCs such as physical activity, self-efficacy, medication adherence, and quality of life. It would be advantageous to agree a Core Outcome Set (COS), consisting of a standardised group of outcomes, to be reported by all SMA trials. This can help with future evaluations of SMAs through reducing heterogeneity and facilitating meta-analysis and ensuring that outcome measures are relevant to key stakeholders[73].

Strengths and limitations

Although previous reviews have explored the effectiveness of SMAs in improving health outcomes, this review provides a focus on primary care which is key to managing LTCs. We found ten additional trials with 1160 participants since the comprehensive work by Booth et al. (2015)[4] indicating a rapidly growing field. We used robust methods whereby our search strategy was developed with input from Information Specialists through an iterative process and key stages of the review (including screening, data extraction, and quality appraisal) were undertaken independently by two reviewers. We included studies regardless of type of LTC so that we were able to summarise all the available evidence on effectiveness of SMAs for LTCs in primary care in one analysis. However, evidence of an effect was determined by $p < 0.05$ in the papers. This assumes that studies were adequately powered, which may not be the case, particularly for some of the secondary outcomes of the included studies.

Limitations of evidence base and implications for future research

Despite using a form of delivery framework to extract relevant study information[17], some important contextual factors, such characteristics of the healthcare professionals delivering the SMA, may not have been captured as this information was missing from the authors' descriptions of the SMAs. Similar components may be described differently by different authors or, conversely, similar descriptions are used to describe different components. Using standardised taxonomies for describing form of delivery and intervention content when designing the intervention/SMA content could help to identify important behavioural

components and key implementation processes that contribute to intervention effectiveness, allowing for replication. However, for this to be possible, it is also important that interventionists clearly specify which target behaviours (e.g. to increase physical activity) the SMAs aim to change. None of the included studies included measures of fidelity which is also important for determining whether the session(s) are delivered as intended to achieve optimum effects[74]. Further, theoretical underpinnings were lacking in the included SMA interventions, making it difficult to identify ‘mechanisms of action’ through which interventions bring about change[75]. Future SMAs interventions should be theory-based and be explicit in reporting its theoretical underpinnings.

Where multiple healthcare professionals are involved in the SMA, their key role and purpose in the SMA were rarely clearly defined. There was also limited reporting on the composition of the SMA groups across some of the included studies (i.e. how patients were selected for recruitment and size). Therefore, it is unclear which groups of patients might benefit from attending the same SMAs together and what implications SMAs may have for intervention-generated health inequalities. One third of the included studies were conducted on US veterans and one third of studies have involved participants from low-income/uninsured population groups. Generalisability of these groups to other healthcare settings in other countries is unclear. There needs to be further examination into how SMAs have been implemented into typical NHS practice. It was envisaged that “they are not an addition to one-to-one appointments – they replace them.” (p.65, Clay & Stern, 2015). However, there is anecdotal evidence that SMAs are being used in addition to usual care models of chronic disease management rather than as replacements. Further investigations into SMAs for patients with one or more LTCs is required, including a wider variety of LTCs (such as asthma and chronic obstructive pulmonary disease) and with more diverse population groups. For example, including low-income and disadvantaged groups in other countries, including the UK.

Conclusions

This review is the first to examine the effects of SMAs delivered in primary care on health outcomes and healthcare service use in patients with one or more LTCs. Our review suggests that SMAs are unlikely to result in less favourable outcomes to patients with LTCs compared to usual care. To identify key intervention components that contribute to effectiveness, future studies will benefit from using standardised taxonomies to report intervention content. The use of an evaluation framework, with a core outcome set, is recommended to improve evidence in this field.

AUTHOR CONTRIBUTIONS

EK and FS designed the study. MYT, FG, CR, and FB developed the search strategy and undertook the searches. FG and MYT carried out the screening, data extraction, and analysis. All authors contributed to the interpretation. MYT and FG wrote the manuscript that all authors contributed to and approved.

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ETHICS STATEMENT

Ethical approval was not required due to the present study being a systematic review.

AVAILABILITY OF DATA

As this study is a systematic review, all data reported has been previously published and is in the public domain.

SUPPLEMENTARY MATERIAL

PROSPERO PROTOCOL

PRISMA checklist

Supplementary File 1- Search strategy for Ovid MEDLINE

Supplementary File 2- Data Extraction Form

Supplementary File 3- List of included peer-reviewed papers

Supplementary File 4- Outcomes reported by studies

Supplementary File 5- Quality assessment of included studies with sensitivity analyses

Supplementary File 6- Additional biomedical measures examined with forest plots

Supplementary File 7- Additional psychological and well-being measures examined with forest plots

Supplementary File 8- Additional behavioural outcomes examined with forest plots

Supplementary File 9- SMA delivery, dose and components

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FIGURE LEGENDS

Figure 1: PRISMA diagram of study selection process

Figure 2: Forest plot for a) HbA1C(%), b) diastolic blood pressure, c) systolic blood pressure

Figure 3: Forest plot for a) hospital admissions, b) emergency department use, c) primary care visits