Article:
Davies, M.J., Agarwal, S., Bodicoat, D.H. et al. (22 more authors) (2025) Increasing uptake of self-management education programmes for type 2 diabetes in primary care: the Embedding research programme including an RCT. Programme Grants for Applied Research, 13 (2). pp. 1-72. ISSN 2050-4322

https://doi.org/10.3310/kwyf5914

NIHR | National Institute for Health and Care Research

Journals Library

Check for updates

Programme Grants for Applied Research

Volume 13 • Issue 2 • February 2025

ISSN 2050-4330

Increasing uptake of self-management education programmes for type 2 diabetes in primary care: the Embedding research programme including an RCT

Melanie J Davies, Shona Agarwal, Danielle H Bodicoat, Alan Brennan, Simon Dixon, Helen Eborall, Agnieszka Glab, Laura J Gray, Michelle Hadjiconstantinou, Lisa Huddlestone, Nicky Hudson, Anju Keetharuth, Kamlesh Khunti, Caroline Kristunas, Graham Martin, Alison Northern, Mike Patterson, Daniel Pollard, Rebecca Pritchard, Sally Schreder, Jane Speight, Bernie Stribling, Jackie Sturt, Jess Turner and Christina Weis

DOI 10.3310/KWYF5914

NIHR | National Institute for Health and Care Research

Programme Grants for Applied Research

Check for updates

Extended Research Article

Increasing uptake of self-management education programmes for type 2 diabetes in primary care: the Embedding research programme including an RCT

Melanie J Davies,[1,2,3*] Shona Agarwal,[1,2] Danielle H Bodicoat,[4] Alan Brennan,[5] Simon Dixon,[5] Helen Eborall,[6] Agnieszka Glab,[1,2] Laura J Gray,[3,7] Michelle Hadjiconstantinou,[1,2,3] Lisa Huddlestone,[8] Nicky Hudson,[9] Anju Keetharuth,[5] Kamlesh Khunti,[1,2,3] Caroline Kristunas,[10] Graham Martin,[11] Alison Northern,[1] Mike Patterson,[12] Daniel Pollard,[5] Rebecca Pritchard,[1,2,3] Sally Schreder,[1,2,3] Jane Speight,[13,14] Bernie Stribling,[1,2,3] Jackie Sturt,[15] Jess Turner[9] and Christina Weis[9]

[1]Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, Leicester General Hospital, Leicester, UK
[2]Diabetes Research Centre, University of Leicester, Leicester, UK
[3]NIHR Leicester Biomedical Research Centre, Leicester General Hospital, Leicester, UK
[4]Independent researcher, Leicester, UK
[5]School of Health and Related Research, University of Sheffield, Regent Court (ScHARR), Sheffield, UK
[6]Usher Institute, The University of Edinburgh, Old Medical School, Edinburgh, UK
[7]Department of Health Sciences, University of Leicester, Leicester, UK
[8]Department of Health Sciences, University of York, Heslington, York, UK
[9]School of Applied Health Sciences, De Montfort University, The Gateway, Leicester, UK
[10]School of Dentistry, University of Birmingham, Edgbaston, Birmingham, UK
[11]THIS Institute, University of Cambridge, Cambridge, UK
[12]Public involvement representative, UK
[13]The Australian Centre for Behavioural Research in Diabetes, Melbourne, Australia
[14]School of Psychology, Deakin University, Geelong, Australia
[15]Nursing and Midwifery, King's College London, London, UK

*Corresponding author melanie.davies@uhl-tr.nhs.uk

Published February 2025
DOI: 10.3310/KWYF5914

This report should be referenced as follows:

Davies MJ, Agarwal S, Bodicoat DH, Brennan A, Dixon S, Eborall H, *et al.* Increasing uptake of self-management education programmes for type 2 diabetes in primary care: the Embedding research programme including an RCT. *Programme Grants Appl Res* 2025;**13**(2). https://doi.org/10.3310/KWYF5914

Programme Grants for Applied Research

ISSN 2050-4330 (Online)

A list of Journals Library editors can be found on the NIHR Journals Library website

Programme Grants for Applied Research (PGfAR) was launched in 2013 and is indexed by Europe PMC, NCBI Bookshelf, DOAJ, Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and Scopus® (Elsevier, Amsterdam, Netherlands).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE)(www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PGfAR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/pgfar.

Criteria for inclusion in the *Programme Grants for Applied Research* journal

Manuscripts are published in *Programme Grants for Applied Research* (PGfAR) if (1) they have resulted from work for the PGfAR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Programme Grants for Applied Research programme

The Programme Grants for Applied Research (PGfAR) programme, part of the National Institute for Health and Care Research (NIHR), was established in 2006 to fund collaborative, multidisciplinary programmes of applied research to solve health and social care challenges. Findings are expected to provide evidence that lead to clear and identifiable patient benefits, in the relatively near future.

PGfAR is researcher led and does not specify topics for research; however, the research must be in an area of priority or need for the NHS and the social care sector of the Department of Health and Social Care, with particular emphasis on health and social care areas that cause significant burden, where other research funders may not be focused, or where insufficient funding is available.

The programme is managed by the NIHR Central Commissioning Facility (CCF) with strategic input from the Programme Director. For more information about the PGfAR programme please visit the website: https://www.nihr.ac.uk/explore-nihr/funding-programmes/programme-grants-for-applied-research.htm

This article

The research reported in this issue of the journal was funded by PGfAR as award number RP-PG-1212-20004. The contractual start date was in February 2016. The draft manuscript began editorial review in June 2022 and was accepted for publication in March 2024. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, PGfAR or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the PGfAR programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).

Abstract

Background: Self-management education and support programmes help people with type 2 diabetes to manage their diabetes better. However, most people do not attend these programmes.

Objective: Increase type 2 diabetes self-management programme attendance.

Design: Workstream 1: develop intervention (mixed methods). Workstream 2: refine intervention and trial design (feasibility study). Workstream 3: evaluate effectiveness (18-month wait-list cluster randomised controlled trial with ethnography component; baseline: months −3 to 0; step one: months 1–9; step two: months 10–18; minimum clinically significant difference in glycated haemoglobin: 1.1 mmol/mol; target sample size: 66 practices). Workstream 4: health economics analysis; 12-month observational follow-up of trial population; qualitative substudy.

Setting: Primary care practices and providers of self-management programmes (East Midlands, Thames Valley and South Midlands, Yorkshire and Humber).

Participants: Workstream 1: 103 stakeholders. Workstream 2: 6 practices. Workstreams 3–4: 64 practices (92,977 people with type 2 diabetes). Qualitative substudy: 30 participants.

Intervention: Embedding Package (marketing strategy for self-management programmes; user-friendly referral pathway; new/amended professional roles; resources toolkit) delivered through an online portal for practices and providers ('toolkit'; 88 live accounts; average of 19 page views/week); people working with practices and providers to embed self-management programmes into routine practice ('embedders'). Additionally, a patient digital support programme (MyDESMOND) was developed. The comparator was usual care.

Main outcome measures: Patient-level glycated haemoglobin (primary outcome, continuous, mmol/mol) and referrals to, and attendance at, self-management programmes (main secondary outcomes; binary yes/no variables) compared between control (wait-list: baseline and step one; immediate: baseline) and intervention (wait-list: step two; immediate: steps one and two) conditions.

Data sources: Existing interviews, published literature, workshops, patient-level practice data, patient self-completed questionnaire, patient-level provider data, ethnographic data and one-to-one interviews.

Results: Workstreams 1 and 2: intervention and trial successfully developed then refined.

Workstream 3: glycated haemoglobin was not significantly different ($p = 0.503$) between intervention and control conditions (adjusted mean difference −0.10 mmol/mol, 95% confidence interval −0.38 to 0.18; −0.01%, 95% confidence interval −0.03% to 0.02%). Both patient-level referral to, and attendance at, structured self-management education programmes were lower or similar during the intervention than control conditions. There was no significant difference in most other secondary outcomes. Prespecified analyses indicated that glycated haemoglobin was statistically significantly lower ($p = 0.004$) among ethnic minority individuals during intervention than control conditions (−0.64 mmol/mol, 95% confidence interval −1.08 to −0.20; −0.06%, 95% confidence interval −0.10 to −0.02). This difference was not clinically significant and self-management programme attendance did not improve. Ethnography analyses found that the intervention's attractiveness and usefulness were not self-evident to practices and providers, much of the activity was led by the embedders, and embedders covering multiple localities were not best placed to adapt the intervention to local contexts.

Workstream 4: the intervention cost £0.52 per patient. There was no evidence of a difference in costs (−£33, 95% confidence interval −£2195 to +£2171) or quality-adjusted life-years (+0.002, 95% confidence interval −0.100 to +0.098) in the base-case analysis. The trial plus 12-month observational follow-up data showed that glycated haemoglobin was statistically significantly lower (−0.56 mmol/mol, 95% confidence interval −0.71 to −0.42; −0.05, 95% confidence interval −0.06% to −0.04%; $p < 0.001$) and self-management programme attendance higher (adjusted odds ratio 1.13, 95% confidence interval 1.02 to 1.25; $p = 0.017$) in intervention than control conditions, although it should be noted that the difference was not clinically significant. The qualitative substudy indicated that virtual programmes have a place in future self-management programme delivery, with highly positive feedback, particularly around financial and logistical benefits.

Limitations: The COVID-19 pandemic affected this research. A delayed start to the feasibility study prevented all learnings being taken into the wait-list trial, particularly around implementing the intervention at provider, not practice level. Practice engagement with the intervention was limited and variable. National Health Service commissioning restructures in England meant that, for many localities, changes to the provision of diabetes self-management programme commissioning included funding and capacity to co-ordinate and promote uptake in a similar way to the Embedding Package. With the wait-list design, a proxy primary outcome for self-management programme attendance was used, which may have affected the sensitivity of results. Finally, baseline structured self-management education programme attendance was higher than expected, and data sources were between 39% and 66% complete.

Conclusions: There were difficulties implementing the intervention, which probably contributed to the trial showing that, overall, the Embedding Package was unlikely to have affected glycated haemoglobin, self-management programme referrals and attendance or most other secondary outcomes.

Future work: Focus should be on which organisation(s)/role(s) can best drive change around embedding type 2 diabetes self-management programmes into routine care, and the role of blended face-to-face and virtual programmes.

Trial registration: This trial is registered as Current Controlled Trials ISRCTN23474120.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-1212-20004) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 2. See the NIHR Funding and Awards website for further award information.

Contents

List of tables

List of figures

List of boxes

List of supplementary material

Report Supplementary Material 1	PDF version of toolkit
Report Supplementary Material 2	Study materials
Report Supplementary Material 3	Statistical analysis plan
Report Supplementary Material 4	Health economics analysis plan
Report Supplementary Material 5	Health state utility value update

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/KWYF5914).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

CCG	Clinical Commissioning Group
CFIR	Consolidated Framework for Implementation Research
eGFR	estimated glomerular filtration rate
GP	general practitioner
HDL	high-density lipoprotein
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
iNMB	incremental net monetary benefit
IT	information technology
ITT	intention to treat
LDL	low-density lipoprotein
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NPT	normalisation process theory
PPG	Patient Participant Group
PPI	patient and public involvement
QALY	quality-adjusted life-year
QISMET	Quality Institute for Self-Management Education and Training
RCT	randomised controlled trial
SSME	structured self-management education
T2DM	type 2 diabetes mellitus
UKPDS	UK Prospective Diabetes Study
WS	workstream

Plain language summary

The problem: Self-management education and support programmes help people with type 2 diabetes to manage their diabetes. National Health Service guidelines recommend these programmes, but many people are not offered them and most do not attend.

What we did: We tried to increase attendance at type 2 diabetes self-management programmes.

We created an evidence-based 'package' of practical solutions, which included a website with useful resources and a person to encourage organisations to use these resources. We also created a patient digital self-management programme (MyDESMOND) as another way to receive support.

We used the package in a small study and improved it based on what we learnt. We then carried out a large study to see whether the package worked and provided value-for-money.

What we found: The package did not increase attendance at self-management programmes or improve patient glucose levels. There were many reasons for this; for example, many organisations did not use the package. However, there were small improvements in glucose levels among people from ethnic minority backgrounds, who are generally less likely to access self-management programmes. Also, glucose levels and programme attendance improved slightly when we looked at a longer period than the main study. The package was very low cost (52 pence per person).

What does this mean? This package is a starting point for helping more people with type 2 diabetes access support to manage their diabetes, but more work is needed.

Scientific summary

Background

Type 2 diabetes mellitus (T2DM) remains a major health challenge in the United Kingdom. Structured self-management education (SSME) programmes help people with T2DM to manage their diabetes. These programmes are typically designed to engage people in developing and maintaining healthy habits (e.g. food, physical activity, medication taking, glucose monitoring) through peer and professional support and education. Evidence shows that SSME programmes are effective and cost-effective. T2DM SSME programmes are therefore recommended in national and international guidelines.

Uptake of SSME programmes is poor, however, with the latest National Diabetes Audit figures showing that, within 12 months of diagnosis, 75% of people with T2DM were offered SSME but only 11% attended.

Aim

We aimed to develop and test an intervention ('Embedding Package') to increase T2DM SSME uptake by addressing barriers and supporting enablers to uptake at patient, healthcare professional and organisational levels.

Objectives

There were four workstreams. Public involvement underpinned the programme.

Workstream 1: develop and tailor Embedding Package, including further development of a digital SSME programme (MyDESMOND); build capacity and develop resources; establish public involvement reference groups.

Workstream 2: pilot Embedding Package to assess feasibility and suitability of components; Assess feasibility of collecting data with sufficient accuracy and completeness; refine Embedding Package.

Workstream 3: conduct a wait-list cluster randomised controlled trial (RCT) with ethnographic study to compare and understand impact of Embedding Package with usual care on glycated haemoglobin (HbA1c) and SSME attendance [minimum clinically significant difference in HbA1c: 1.1 mmol/mol (0.1 %); target sample size: 66 practices].

Workstream 4: assess cost-effectiveness and sustainability of Embedding Package; conduct qualitative substudy to understand the impact of virtual SSME programmes.

Methods

Workstream 1: developing Embedding Package

Mixed-methods development work for the Embedding Package, including: (1) secondary analysis of existing qualitative data, systematic literature review and the merging of the resulting coded data with further analysis; (2) stakeholder consultation through workshops and interviews; and (3) analysis of all collected data. This resulted in a list of evidence-based components needed by an intervention to increase SSME uptake. The multifaceted Embedding Package was then designed by a specialist education team based on this list.

Workstream 2: feasibility study

A single-arm, mixed-methods feasibility study in six practices across two Clinical Commissioning Groups (CCGs; East Midlands) piloted two patient recruitment approaches, data collection methods and intervention delivery in three

participant groups: patients, practice staff, staff in SSME providers. Quantitative data were collected from primary care electronic medical records (extracted data, 2877 patients) and self-completed patient questionnaires (self-reported data, 423 participants). Health economics data were collected from SSME provider databases and questionnaires and interviews with practice managers and CCG staff. An integrated ethnographic study included observations, interviews and document analysis.

Workstream 3: randomised controlled trial

Using a wait-list cluster randomised design, with practice-level randomisation, we compared the Embedding Package with usual care (i.e. practices referred patients to SSME following their current standards). All practices provided usual care for 3 months (baseline, months −3–0). Practices were then randomised (1 : 1) to receive the Embedding Package for steps one and two of the RCT (months 1–18; immediate group; 33 practices; 16,340 patients) or for step two only (months 10–18; wait-list group; 31 practices; 18,393 patients). The primary outcome was patient-level HbA1c compared between intervention and control conditions as a proxy for SSME attendance, which was not suitable as a primary outcome due to the wait-list design. The main secondary outcomes were patient-level referral to and attendance at SSME (binary yes/no). Analysis used mixed models to account for patient- and practice-level clustering. Secondary analyses compared the completeness of SSME referral and attendance data from three sources (self-report, practice, SSME provider).

The ethnography study used e-mail communications between the embedders (a key role introduced as part of the Embedding Package) and practices/providers, an intervention 'tracker' (database completed by the embedders to track embedding activities), embedder-generated documents, interviews with the embedders and one SSME provider, and observations of meetings between embedders and practices. Interpretive thematic analysis informed by normalisation process theory (NPT) was conducted.

Workstream 4: assess cost-effectiveness and sustainability and enable implementation

For the health economics, the primary (base-case) analysis estimated the costs of embedding activities as implemented across all practices within the RCT, and the discounted quality-adjusted life-years (QALYs) and costs in the intervention and control conditions.

To assess sustainability, a 12-month observational follow-up took place immediately after the RCT during which the study team no longer actively reinforced the Embedding Package, but practices and providers could continue using it (minus the embedder). The RCT models for HbA1c, SSME referral and SSME attendance were repeated using the RCT data plus the observational data.

The qualitative substudy (two primary care practices) comprised one-to-one telephone or video calls with practice staff (who were also virtual SSME educators) and people with T2DM who attended virtual SSME ('attendees'). Topic schedules were mapped on the NPT and theoretical domains framework. Thematic analysis informed the data analysis.

Intervention

The Embedding Package comprised the key components of an intervention to embed SSME (see *Results*) delivered through a 'toolkit' and 'embedder'.

The toolkit was an online portal of resources, including tools, how-to guides and sample resources for anyone actively involved in implementing SSME (e.g. commissioners, providers, primary care staff). There were 88 live toolkit accounts, which could be accessed by multiple individuals. There were 19 page views on average per week for the toolkit (including by study staff as data could not be separated).

The embedder also formed part of the intervention and was a new/amended role to work with practices and programme providers to embed support programmes into routine practice locally. The most and least common embedder activities were 'promoting to patients' (41% of activities) and 'increasing referrals' (3% of activities), respectively.

Additionally, a patient digital support programme (MyDESMOND) was developed due to the absence of an online option at the time. The comparator was usual care.

Results

Workstream 1: developing the Embedding Package

We developed the intervention as planned. Key components of an intervention to embed SSME into primary care were identified as:

- A clear marketing strategy for SSME.
- A user-friendly and effective referral pathway.
- New/amended professional roles.
- A toolkit of resources.

Workstream 2: feasibility study

The feasibility study showed that the RCT would be feasible, albeit with design improvements. Key findings included that the RCT primary outcome data (HbA1c) were over 90% complete in primary care, and 91% of patient-participants completing questionnaires consented to their responses being linked with their extracted primary care data. There was limited engagement from most participating practices and focusing the intervention implementation on practice staff was not feasible given capacity constraints in practices. It was therefore planned that, in the RCT, the focus of intervention implementation would be SSME providers. However, this proved difficult because RCT data were collected at the practice level, therefore embedders had to maintain a practice-level focus.

Workstream 3: randomised controlled trial

Baseline SSME attendance was higher than expected, at 64% and 38% in the wait-list and immediate groups, respectively. While providers were included in the RCT, much of the embedding activities remained focused at the practice level. The practices interacted minimally with both the embedder and the toolkit. Of the 66 RCT practices, 17 did not engage and 4 only used display boards in waiting areas. The remaining 45 practices had at least an initial meeting with an embedder.

The primary outcome (HbA1c) was not significantly different (p = 0.503) between intervention and control conditions [adjusted mean difference, −0.10 mmol/mol, 95% confidence interval (CI) −0.38 to 0.18; −0.01%, 95% CI −0.03% to 0.02%]. There was also no significant difference in most of the secondary outcomes. Prespecified analyses indicated that HbA1c was statistically significantly lower (p = 0.004) among ethnic minority individuals during intervention than control conditions (adjusted mean difference −0.64 mmol/mol, 95% CI −1.08 to −0.20 or −0.06%, 95% CI −0.10% to −0.02%). This difference was not clinically significant and SSME attendance was not significantly different between intervention and control conditions. There was no difference in HbA1c among white individuals between the intervention and control periods.

The three data sources for SSME referral and attendance data (practice, self-report and provider data) ranged from 39% to 66% complete.

The ethnography component found that the attractiveness and usefulness of the Embedding Package were not self-evident to participating practices and providers, and most activity was led by the embedder, with much less active engagement from practice/provider staff. The analysis showed the importance of adapting the Embedding Package to local contexts, and that an embedder covering multiple localities was not necessarily best placed to undertake this.

Workstream 4: assess cost-effectiveness and sustainability and enable implementation

The pooled cost per patient of the Embedding Package was £0.52. There was no evidence of a difference in costs (−£33, 95% CI −£2195 to +£2171) or QALYs (+0.002, 95% CI −0.100 to +0.098) in the base-case analysis.

The sustainability analyses (18-month trial data plus 12-month observational follow-up data) showed that HbA1c was statistically significantly lower (−0.56 mmol/mol, 95% CI −0.71 to −0.42, or −0.05%, 95% CI −0.06% to −0.04%; $p < 0.001$) and support programme attendance higher (adjusted odds ratio 1.13, 95% CI 1.02 to 1.25; $p = 0.017$) during intervention than control conditions. There was no statistically significant difference in SSME referrals.

The qualitative substudy strongly indicated that virtual SSME programmes have a place in future education delivery. Feedback on virtual programmes was highly positive, particularly for the financial and logistical benefits. Negative perceptions included information technology challenges, a lack of interaction and informal conversations with fellow attendees, and difficulties in reading body language and visual cues during virtual delivery.

Conclusions

This programme was designed to address a gap in understanding how to improve uptake to T2DM SSME. We found that, although there was initial enthusiasm for the Embedding Package in some practices, there were difficulties in implementing it, and so many practices did not receive the intervention as it was intended. These were in part due to the embedder role sitting centrally with the study team, rather than in the locations where the package was being implemented or with the local provider organisation. Furthermore, since the proposal for this programme, the structure of NHS commissioning was reformed within England, which meant that, for many localities, changes to the provision of diabetes self-management programme in commissioning plans included funding and capacity to co-ordinate and promote uptake in a similar way to the Embedding Package. This limited uptake of the Embedding Package likely contributed to it having no overall effect on the primary or main secondary outcomes. It is also important to consider the impact of the COVID-19 pandemic, as this started during the latter step of the RCT and meant that all activities by the embedder were stopped prematurely.

There were, nevertheless, some promising results. First, HbA1c (primary outcome) improved among ethnic minority groups during the periods when the Embedding Package was being implemented. However, recorded SSME attendance did not improve among this group, and so this may not have been due to the Embedding Package. Second, during the longer-term analyses, HbA1c was lower and SSME attendance higher during the intervention than control periods. This finding suggests that the positive impact of the Embedding Package may have taken longer than expected to realise highlighting that system-wide change such as this may require longer to be realised. However, other external factors could have also brought about this improvement.

Implications for health care

National roll-out of the Embedding Package in its current format is not suitable given the findings of this programme. However, given the low per-patient cost of the intervention and that the results were indicative of positive changes in the long term, we will instead create a PDF version of the toolkit so that the information contained within it can still be accessed by practices and SSME providers.

The potential improvement in HbA1c among ethnic minority groups is of note. T2DM is known to disproportionately impact ethnic minority groups. It is therefore imperative that any initiatives to increase uptake to T2DM SSME do not further widen inequalities around access to support, which is the case with most initiatives in the UK and other industrialised countries. Conversely, implementation of the Embedding Package was associated with improvements in HbA1c in people in an ethnic minority population. This suggests that the Embedding Package, or parts of it, may have a role in future efforts to increase SSME uptake among ethnic minority groups.

MyDESMOND became more important during the COVID-19 pandemic and is now among the top four diabetes applications (apps) on the ORCHA app library. Further evaluation is needed.

The qualitative substudy findings suggest that patient choice could be important, particularly around having the option to attend SSME face-to-face and/or virtually.

Key recommendations for research

1. Consider how best to increase uptake to SSME within the new context of increased focus on digital/virtual modalities due in part to the COVID-19 pandemic, while maintaining the benefits to some underserved populations without alienating others and widening disparities (e.g. those without internet access).
2. Consider how to tailor initiatives to embed SSME into routine care for underserved populations.
3. Consider how best to embed SSME into routine care, particularly whether a local embedder working within a provider organisation is best placed to drive change.
4. Evaluate blended approaches that combine face-to-face and virtual SSME delivery.
5. Further evaluate MyDESMOND.

Patient and public involvement

The purpose of patient and public involvement was to involve people affected by the research and potential outcomes of the research at all levels of the project. The public involvement plan comprised five main areas of work: (1) public contributors involvement in study groups; (2) oversight and wider involvement through practice Patient Participant Groups (PPGs) and other local groups; (3) support via a local stakeholder group; (4) MyDESMOND development and consultation; and (5) dissemination of findings. Contributors provided governance and oversight of the project, offered advice on recruitment, publicity, local culture and dissemination, and acted as a critical friend giving feedback on project delivery in the local context. Public involvement was challenging because we needed to grow new networks in the localities involved in the RCT. The PPGs at participating primary care practices offered a potential solution to this that could be a useful approach in other research studies.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN23474120.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-1212-20004) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 2. See the NIHR Funding and Awards website for further award information.

Synopsis

Background

Structured self-management education programmes help to manage type 2 diabetes mellitus

While pharmacological interventions can support people with type 2 diabetes mellitus (T2DM) management, lifestyle and self-care behaviours are critical to achieving and maintaining glucose control.[1]

Structured self-management education (SSME) programmes include support and upskilling in T2DM to empower people to engage with healthier behaviours. They are cost-effective and result in improved outcomes, including glycated haemoglobin (HbA1c), weight, blood pressure, depression, quality of life and smoking cessation.[2–7] SSME for people with T2DM is recommended by the UK National Institute for Health and Care Excellence (NICE), the American Diabetes Association and the European Association for the Study of Diabetes.[8,9]

In England, a Clinical Commissioning Group (CCG) commissions a provider organisation to provide T2DM SSME in their local population. The choice of SSME programme rests with the provider. Primary care healthcare professionals then refer people with T2DM to the locally provided SSME programme. In some areas, people with T2DM can also self-refer to SSME.

There are established criteria for high-quality SSME programmes to fulfil NICE requirements (*Box 1*).[10] SSME programmes should be deliverable in a group by default, in addition to routine support from healthcare teams.[9] NICE recognises several UK programmes for people with T2DM as meeting these criteria (e.g. DESMOND, X-PERT, Diabetes Manual).[2,3,11] Additionally, since this research programme began, Quality Institute for Self-Management Education and Training (QISMET) accreditation for SSME was introduced in the UK. This focuses on accrediting providers and commissioners and not the education programme.

Throughout this report, the term SSME includes all programmes for people with T2DM meeting the criteria in *Box 1* or delivered by providers with QISMET accreditation, regardless of delivery modality.

Uptake of structured self-management education is poor

When this research was planned, an indicator for SSME referral had been recently added to the NHS Quality and Outcomes Framework.[12] We assumed that this might improve referrals but was unlikely to impact uptake. This was evident in the latest National Diabetes Audit figures, which, using primary care data, suggest that while 75% of people with T2DM were offered SSME within 12 months of diagnosis, only 11% attended within 12 months.[13] Attendance any time from diagnosis is not routinely reported for primary care data, but self-report data suggest a higher, albeit still suboptimal, figure of 49%.[14]

BOX 1 Patient Education Working Group criteria for structured education programmes[10]

- Be evidence-based.
- Have a structured, written curriculum that is:
  - person-centred
  - reliable, valid, relevant and comprehensive
  - theory driven
  - flexible and able to cope with diversity
  - uses different teaching media
  - resource effective with supporting materials.
- Be delivered by educators:
  - with an understanding of education theory appropriate to the age and needs of the participants
  - who are trained and competent in the delivery of the programme being offered.
- Be quality assured by trained, independent assessors against agreed criteria.
- Be audited for outcomes.

Multiple patient, healthcare professional and organisation factors probably drive poor referrals/uptake, including:[15]

- insufficient investment/trained educators
- lack of staff capacity
- absence of public health marketing for diabetes awareness
- lack of integration into patient pathways
- healthcare professionals not advocating for, or recognising, positive SSME outcomes
- misperception that education is expensive
- lack of consideration of patient access issues
- inconvenient locations/timings of sessions.

Such situations may arise from competing funding priorities, absence of clinical engagement, or lack of knowledge about available programmes or benefits. Even when SSME programmes are available/offered, data on uptake and effectiveness are often not routinely collected, which makes evaluation challenging. Consequently, SSME is often regarded negatively among commissioning priorities, due to a lack of information on costs and benefits.

How to embed or 'routinise' improvements in everyday healthcare practice remains poorly understood, and is as much a matter of networks of influence and knowledge of priorities and incentives frameworks as of clinical or cost-effectiveness in themselves.[16]

Aim

Develop and test an intervention ('Embedding Package') to increase SSME uptake by people with T2DM in primary care by addressing barriers and supporting enablers to uptake at patient, healthcare professional and organisational levels.

Objectives

The following original objectives, were delivered through four workstreams (WS), aligned with the Medical Research Council (MRC) framework for complex interventions.[17,18] These objectives developed over the programme as described in later sections. *Figure 1* shows the final set of tasks.

Workstream 1 (develop intervention)

1.1. Synthesise evidence from existing literature and data sets, and identify experiential practices, procedures, strategies and plans that represent best practice.
1.2. Develop and tailor intervention.
1.3. Build capacity and develop resources.
1.4. Establish stakeholder and public involvement reference groups.

Workstream 2 (feasibility study)

2.1. Pilot the intervention to assess feasibility and suitability of components.
2.2. Assess feasibility of collecting data with sufficient accuracy and completeness.
2.3. Conduct an ethnographic study to evaluate the intervention and inform its refinement.
2.4. Refine the intervention.
2.5. Assess progress of research and report to funders on agreed milestones.

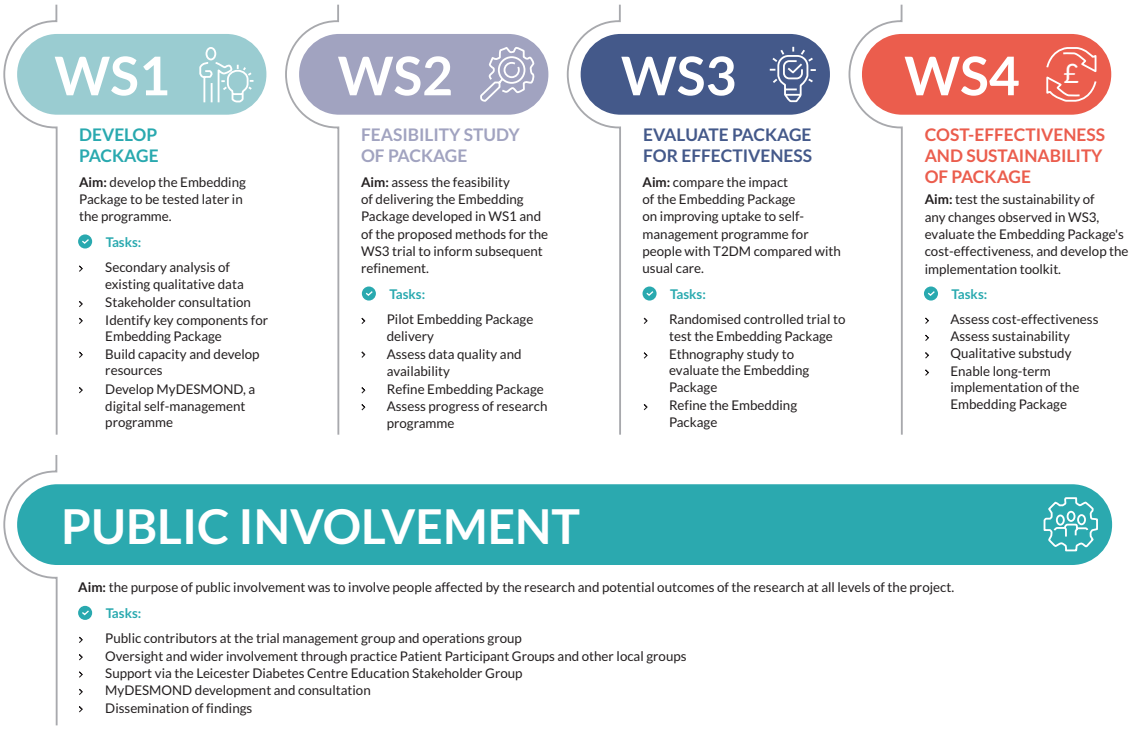

FIGURE 1 Research pathway diagram showing the development, refinement and evaluation of an intervention ('Embedding Package') to improve uptake to SSME for people with T2DM.

Workstream 3 (evaluate intervention for effectiveness)

3.1. Conduct a wait-list randomised controlled trial (RCT) to compare impact of the intervention on uptake to SSME with usual care.
3.2. Continue ethnographic study to evaluate the intervention and inform the implementation toolkit.

Workstream 4 (evaluate cost-effectiveness and sustainability of intervention)

4.1. Assess cost-effectiveness of the intervention.
4.2. Assess sustainability of intervention.
4.3. Conduct final stage of ethnographic study.
4.4. Develop a 'toolkit' to enable widespread implementation of the intervention.

Workstream 1: developing the intervention

Aim

Develop the intervention to be tested in WS3.

Develop intervention

The development details are published elsewhere.[19,20] In brief, development comprised three phases using normalisation process theory (NPT) as the underpinning, flexible framework. This was only the third time that NPT has been used to develop a primary care intervention.[20]

Phase 1 comprised secondary analysis of existing qualitative data (3 data sets; 31 SSME recipients, 30 frontline delivery staff, 3 commissioners) and a systematic literature review[20] of NPT applications for informing and assessing implementation processes in UK primary care settings (23 articles). The coded data were merged and analysed resulting in 46 attributes influencing SSME referral and uptake and the implementation processes involved. We produced a list of resources (pre-existing or in need of creation) needed to realise each attribute, for example, training for referrers and example referral pathways (for the full list, see Turner *et al*.[19]).

Phase 2 organised the 46 attributes into a viable intervention and ensured relevance to the current organisational context of primary care. A stakeholder workshop (n = 13) condensed the attributes to 11 priority attributes with explanatory notes and a refined compendium of resources needed to implement these attributes (see Turner *et al*.[19] for a full list). A second set of stakeholders ranked the 11 priority attributes via a 'diabetes update' meeting (n = 26) and individual interviews (n = 16). The attributes ranked as most important were the need for:

- increased SSME awareness among primary care staff
- increased SSME awareness among patients and the public
- improved referral processes and booking systems
- tailored SSME for a range of audiences
- increased SSME accessibility for patients.

Phase 3 identified key intervention components based on the top five attributes through fortnightly meetings between the phase 1 and 2 analysis team and the intervention development team. This led to identification of four key intervention components (*Box 2*).

Build capacity and develop resources

Following completion of this mixed-methods work, the analysis and intervention development teams designed an intervention focused on the evidence-based components in *Box 2*. The development team then translated this into materials. Full details of the methodology used to develop the intervention are provided elsewhere.[19] The intervention is described in the next section.

BOX 2 Key components of an intervention to embed SSME into primary care

Clear marketing strategy for SSME.
User-friendly and effective referral pathway.
New/amended professional roles.
Toolkit of resources.

Changes from workstream 1 original plan

We intended to use two conceptual frameworks: NPT[21,22] and the Consolidated Framework for Implementation Research (CFIR).[23] However, early examination of the papers identified in the literature review indicated that the focus of these papers, and the level of detail they included, meant that coding according to the detailed domains of CFIR would add limited value. We therefore only used NPT due its flexibility for our approach to, and analysis of, data relating to the contextual issues impacting implementation and embedding. A description of NPT and the rationale for using it in WS1 is published elsewhere.[20]

We planned to review literature on implementing change in complex systems pertaining to SSME interventions in primary care (phase 1). To specifically inform intervention development, we narrowed the search to focus on the application of NPT in informing and assessing implementation processes in UK primary care settings.

We planned to involve people with T2DM in phase 3. However, phase 1 paid specific attention to this group's views, while the views of those working in primary care (potential referrers to SSME) and service provision were underexplored. We were keen to explore how an intervention would fit with the realities of primary care, so we recruited accordingly. We had planned to facilitate stakeholder consultations using nominal group technique. Instead, we used a more flexible and semistructured brainstorming approach for our first stakeholder meeting and a ranking task conducted individually for our second set of stakeholder consultations for pragmatic reasons (e.g. the challenge of bringing all stakeholders together at the same time).

Intervention description

A Template for Intervention Description and Replication description of the intervention follows. All data relate to the RCT (WS3).

Name

Embedding Package.

Why

Structured self-management education improves outcomes for people with T2DM, but SSME uptake in England remains low. This intervention aims to increase SSME uptake by embedding SSME within routine care.

What

Embedding Package

The Embedding Package comprises the components in *Box 2* delivered through a new/amended role ('embedder') and an online portal with a range of supporting resources ('toolkit'; see *Report Supplementary Material 1*). The embedder role can be described as an 'engagement officer'; however, we named it 'embedder' as traditionally engagement officers focus on direct patient engagement, whereas this role focused on the organisational level.

A planned local clinical champion role was not developed due to difficulties with intervention engagement.

MyDESMOND

When this research programme started, there were no online SSME programmes meeting NICE criteria. This was deemed essential for increasing SSME uptake by offering people with T2DM a 'menu' of attendance options to fit their lifestyles.

Before starting this research, a prototype of a digital version of the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed programme, for which we hold the intellectual property) was developed. To have an online modality ready for the Embedding Package, further work was needed to refine the prototype and develop robust analytics to enable data collection on how the digital programme is used.

Consequently, this research programme developed this prototype digital programme into MyDESMOND for people with T2DM. MyDESMOND is a self-directed, web-based, interactive SSME programme based on the NICE-approved face-to-face DESMOND SSME programmes (www.mydesmond.com).

While MyDESMOND was not a formal part of the Embedding Package, it was made available to participating providers (and their patients) to increase SSME accessibility. It has also been made available nationally outside of this research programme.

Materials

The toolkit was a password-protected web-based portal for anyone involved in implementing SSME to help them consider embedding strategies, including:

- commissioners: aiding development of detail for service specifications during tendering processes

- providers (e.g. service leads, SSME educators, co-ordinators, administrators): supporting provision of SSME services across their locality
- primary care staff: providing ideas and resources on promoting their local SSME to patients.

Toolkit access was granted dependent on randomisation and login information sent directly to the relevant recipient. Additional access could be requested through a registration form. Alongside this, where it was welcomed, embedders provided an in-person guided tour of the toolkit.

The toolkit comprised three sections with a range of tools, guidance and sample resources (see *Report Supplementary Material 1* for PDF version):

1. How to guides: provided a wide range of strategies for increasing SSME uptake, such as carrying out a needs assessment and working with public involvement groups to adapt programmes.
2. Promoting to patients: tools for designing and implementing marketing and communications plans.
3. Increasing referrals: detailed activities to strengthen the referral process, such as engagement events and evaluation of existing referral pathways and administration systems.

Under 'promoting to patients', example patient-facing marketing materials were available to raise public awareness of SSME that could be tailored for each practice/provider. During the RCT, the following marketing materials were available (number that engaged with material):

- Sample letter templates including invitation letters with opt-in return slips (two providers).
- Promotional animation/PowerPoint® (Microsoft Corporation, Redmond, WA, USA) for waiting room television screens in practices and other waiting areas (e.g. hospitals; 34 providers/practices).
- Waiting-room display boards highlighting the patient benefits of SSME and quotes from patients who had previously taken part (49 practices).
- Banner stand (two providers) and leaflets/posters (49 providers/practices), including easy-to-read versions (one provider/6 practices), showcasing local SSME programme.
- Text and images describing the local SSME programme for the practice's website and social media (41 practices).
- A health fair/event on World Diabetes Day (3 practices).
- Information packs for practices (49), providers (5), and pharmacists (~ 40) for World Diabetes Day and Diabetes Week, including posters, stickers and flyers designed and supplied to nearby pharmacies.
- Laminate cards for clinic spaces about local SSME and referral details (49 providers/practices).

Procedures

Two embedders were employed to liaise between stakeholders and promote toolkit use via in-person meetings, e-mail communications, telephone calls and health fair attendance. Additionally, embedders listened to practice and provider needs and suggested the introduction and designing of locally specific materials (e.g. those listed above) and liaising with providers/practices to ensure any newly designed resources were fit for purpose before organisation of production and distribution. This also meant organising, designing and delivering presentations at local faith centres to begin discussions about improving access to SSME for ethnic minority populations.

Importantly, the embedders also formed part of the intervention.

Who provided the intervention

The embedder was a new role that evolved based on experience and feedback. It was established that the embedders would require:

- detailed understanding of SSME benefits and ability to communicate this to all staff levels

- experience of quickly building and retaining strong working relationships
- knowledge of toolkit content and ability to implement this at practice and provider level.

The wide-ranging tasks associated with the embedder role are listed below.

- First point of contact for promoting diabetes education within the region.
- Designs new/adapts existing local referral pathways and reports on referral flow.
- Has a working knowledge of and fosters good working relationships with all referral sources.
- Understands the best communication channels to create a network across the region to create a sense of community.
- Understands issues relating to referral mechanisms and is the first point of contact, ensuring that concerns are alleviated.
- Promotes chosen SSME service as an integral aspect of all care pathways and offers solutions to areas of concern.
- Negotiates with patient groups on their rights to receive SSME.
- Develops and sustains good relations and buy-in with team members, stakeholder groups (including patients/service users) and on all organisational levels.
- Presents updates back to commissioners on the impact of their work.
- Prepares and distributes information back to the sources of referral so they are updated and appraised of their patients' progress.
- Maintains oversight of the income and expenditure related to patient SSME and embedding activities to ensure that costs are within contracted value.
- Understands the value of non-cost-based activities and where costs can be saved.
- Liaises with service commissioners to negotiate on increase in referral numbers based on evidence of attendance and audit of outcomes.
- Is innovative in the approach to SSME helping commissioners to understand its and how this can help save money elsewhere across the diabetes pathway.
- Works closely with community leaders to ensure any vulnerable groups or those who disengage with other care providers are included in the offer of SSME.
- Where appropriate, assists in the recruitment of local administrator/s and champions.
- Uses the toolkit as a guide to:

    - Prepare and implement local marketing and communications strategies.
    - Ensure that available SSME offers are appropriate and accessible to the whole community, including any cultural adaptations required.
    - Develop and maintain a locally appropriate referral pathway and administration/booking system.
    - Develop locally appropriate referrer engagement materials and training events.
    - Create and maintain a community awareness package.
    - Develop/link and consult with existing patient and public involvement (PPI) groups and other groups for people with long-term conditions.
    - Build an online and physical resource of local signposting opportunities to other available services that would support patients' self-management.

One embedder focused on SSME providers, while the other focused on practices. While the embedders were involved with research-related activities (e.g. recording activity), they were also an integral part of the intervention and therefore most of their time was focused on intervention delivery [see *Appendix 1* which includes a summary of initiatives undertaken within an embedder role (see *Appendix 1*, *Table 3*), tool articles used with an embedder (see *Appendix 1*, *Table 4*), usage data for the toolkit (see *Appendix 1*, *Table 5*) and the number of page views for the toolkit (see *Appendix 1*, *Figure 5*)]. Therefore, a separate study co-ordinator was mainly responsible for the study-related tasks.

How

Initially, an embedder held a face-to-face toolkit action planning meeting with a provider representative to determine which toolkit elements could be implemented. The embedder then circulated this action plan, including assigning tasks to relevant personnel. Review meetings were scheduled to discuss progress and further tailor the intervention for each locality.

The following activities took place at provider-level (number of providers taking up each activity of eight in total):

- Expansion/addition of a digital SSME offer; MyDESMOND used in areas without online SSME (3).
- Increased focus on or instigation of self-referral mechanism (4).
- Newsletter to referrers from local provider showcasing the SSME offer, attendance figures, recent changes to the service and upcoming availability (1).
- Press releases to showcase new service elements, such as MyDESMOND and self-referral (6).
- Social media templates devised and shared with communication teams (2).
- Health stands and promotional events (2).
- Embedders provided practice feedback to providers, which increased convenient venues for group sessions (3) and alternative days/times for group sessions (3).
- Embedders began discussions regarding adapting SSME programmes to ensure they met local needs, for example, in relation to cultural adaptations (1), learning disabilities (2) and separate sessions for different age groups (1).

Actions relating to practices were disseminated by the embedder to practice staff and, in face-to-face meetings with each practice (45/66 participating practices), the embedder presented the toolkit, embedding ideas were tabled, and/or the practice received or implemented at least one patient-facing marketing material. The practice personnel that led this work varied greatly but were typically the practice manager or a practice nurse, especially those specialising in diabetes. In some practices, existing practice staff meetings were attended and a mixture of staff took part.

Where

- Face-to-face meetings: practice or provider offices.
- Toolkit: online.
- Patient-facing marketing materials: practices, pharmacies, online.

When and how much

Embedder

Embedders recorded all activities with providers and practices in 'trackers' (Excel®, Microsoft Corporation, Redmond, WA, USA) to inform the intervention costing (see *Appendix 1*). Overall, the most and least common activities were in the categories 'promoting to patients' (41% of activities) and 'increasing referrals' (3%), respectively. The most common activities with providers involved the 'how-to' guides (44%), and with practices involved 'promoting to patients' (52%).

Three articles (Top tips for marketing; Increasing practice staff engagement; Providing choice for patients) and general activity (e.g. home page) accounted for over 90% of toolkit use with the embedder (e.g. during toolkit action planning meeting). The toolkit components least engaged in with the embedder were: collect and report audit data; education champions; evaluating your programme; how to work with public involvement.

While these data indicate how the embedder part of the intervention was used, caution is required. First, an increase in activities may reflect the fact that, sometimes, embedders had to follow up more actively due to difficulties in toolkit engagement. Second, trackers only included activities involving an embedder, and providers and practices may have undertaken additional activities.

Toolkit

Appendix 1 summarises the toolkit website data. The 88 live accounts could potentially be accessed by multiple individuals. The average number of page views per week for the toolkit was 19 (including those by study staff as the data could not be separated). *Figure 2* shows that most general practitioner (GP) practices used 7–12 tool articles under all initiatives.

Tailoring

The intervention was tailored to each locality through embedder meetings with practices/providers and specifically designed resources resulting from meetings and communications.

Modifications

The intervention was refined based on feasibility study learnings (WS2) before entering the RCT (WS3). Toolkit improvements included streamlining text, creating new articles and adding functionality to contact an embedder. Additionally, a 'roles' function (practice, provider, commissioner) was added to allow individuals to easily access relevant content. Changes were made to the embedder role, including introducing a second embedder to support implementation across practices. It was planned to focus more on providers with actions filtering down to practices, as it was understood that this would be better for instigating change. A clearer distinction was made between the study team and the embedders so that embedders could focus on toolkit implementation, rather than study-specific issues, although this continued to be problematic throughout the RCT. Other changes included naming the different meetings with providers/practices to provide clarity, improving feedback mechanisms and shortening communications to practices.

In March 2020, when the COVID-19 pandemic began, all embedder activities stopped. Practices and providers could still access the toolkit.

How well the intervention was delivered

Planned

A fidelity assessment was not planned.

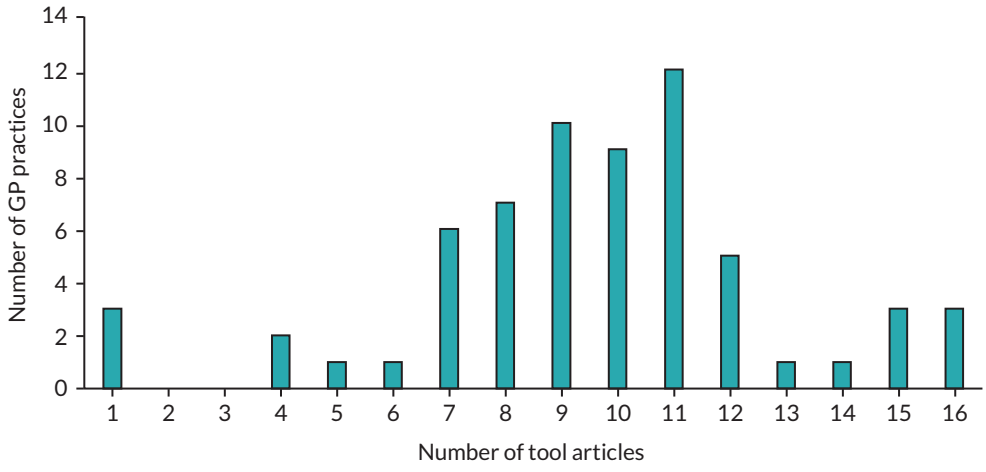

FIGURE 2 Engagement of general practices assessed by the number of tool articles used at practice level.

Actual

Based on feasibility study learnings, it was intended that, during the RCT, the intervention would be aimed at providers and filtered down to practices. This proved difficult to implement because the RCT collected practice-level data, so embedders had to maintain a practice-level focus to ensure that their work with providers did not involve non-study practices, otherwise the effect could not be measured. The intervention in the RCT did not therefore reflect the expected real-world implementation of the intervention based on the feasibility study learnings.

Practice engagement was limited during the feasibility study and RCT (see *Appendix 1*). Of the 66 RCT practices, 45 had at least an initial meeting with an embedder, 17 did not engage and 4 only used waiting-area display boards. Uptake of some marketing elements was very low (e.g. two practices added details of local SSME programmes to their websites; four practices implemented the waiting room animations).

Workstream 2: feasibility study

Aim

Assess the feasibility of intervention delivery and the proposed RCT methods to inform refinement.

Pilot intervention delivery and assess data quality/availability

A summary follows, with detail elsewhere.[24]

A single-arm, mixed-methods feasibility study (six practices; two East Midlands CCGs; May 2017–January 2018) tested two patient recruitment approaches (postal invitations; GP prompts) and the feasibility of intervention delivery and data collection methods.

Three participant groups were involved: patients, practice staff and SSME provider staff. Quantitative data were collected from primary care electronic medical records (extracted data; 2877 patients) and self-completed patient questionnaires (self-reported data; 423 participants). Health economics data were collected from providers and a questionnaire and interview with practice managers and CCG staff. An integrated ethnographic study included observations, interviews and document analysis.

Key findings were:

- HbA1c (RCT primary outcome) was over 90% complete in extracted data.
- More patient participants completed the questionnaire via postal invite (85%) than GP prompt (15%).
- Ninety-one per cent of patient participants consented to linkage of self-reported and extracted data.
- Ethnographic and interview methods were appropriate.
- Intervention costing was possible based on the resource use data collected.

It was therefore concluded that the RCT was feasible with design improvements, including the following:

- There was limited engagement and capacity constraints from most feasibility practices and staff, so it was planned that the RCT intervention implementation would focus on providers, while maintaining relationships with practices and CCGs. However, while the RCT included providers, much of the embedding activity remained at practice level because the primary outcome was extracted from practices, so the focus needed to be on study practices. This may not have happened with a provider-level focus, as providers worked across study and non-study practices. Furthermore, randomisation was at practice level, not provider level. With more time between the feasibility study and RCT, the RCT could have been redesigned to facilitate this change of intervention focus.
- The sample size calculation was updated based on feasibility study recruitment figures.
- SSME information and preferences and biomedical data were removed from the self-report questionnaire due to poor reporting.
- A preassigned participant number was added to the patient questionnaire to reduce the quantity of missing NHS numbers for data linkage.
- CCG staff and practice managers were removed as sources for resource use data because this proved unfeasible. This came from the embedder and provider staff in the RCT.
- The ethnographic study identified challenges around the intervention and feasibility study, including organisational factors (e.g. safety and burden of data extraction, and confusion among stakeholders in duality of project manager and embedder role), intervention features (e.g. uncertainty on how to assess the toolkit and misunderstandings around language used to describe the intervention) and characteristics of local research teams (e.g. logistical and capacity issues within the qualitative team and duality of project manager and embedder role meant that study

issues detracted from intervention activities).[24] Learnings from these challenges were taken into improving the design of the intervention and the RCT.
- Not all findings could be readily incorporated into the domains included in NPT, so we adjusted those constructs (see *Appendix 1*, *Table 5*; see also Davies *et al*.[24]).

Refine intervention

See *Modifications*.

Assess progress of research programme

The following pre-agreed stop/go criteria were met:

1. Completion of evidence synthesis (WS1) and feasibility study (WS2).
2. Tailored Embedding Package for practices and CCGs tested and ready for the trial.
3. Improvements made in the recording of structured education uptake to the satisfactory level for analysis within the RCT.
4. Stakeholder and PPI groups established.
5. Core team for phase 2 WS3 and WS4 appointed.
6. Trial protocol completed and ethical approval gained.
7. Study submitted for adoption on the Clinical Research Network portfolio.
8. Interim statement on intellectual property.

Changes from workstream 2 original plan

There were no major changes. The feasibility study started late (see *Challenges*), which shortened the planned gap before the RCT started.

Workstream 3: randomised controlled trial

Aim

Evaluate whether the Embedding Package improves SSME uptake for people with T2DM compared with usual care.

Conduct a randomised controlled trial

Methods

An overview follows, with detail elsewhere[25] and study materials available in *Report Supplementary Material 2*.

Study design

The Embedding Package was compared with usual care (practices referred patients to SSME following their current standards) using a wait-list cluster randomised design (*Figure 3*), with one-to-one practice-level randomisation stratified by the CCG (May 2018–August 2020). All practices provided usual care for 3 months (months −3–0; baseline) and were then randomised by an independent statistician (study team informed practices of their allocation) to receive the intervention for steps one and two (months 1–18; immediate group) or step two only (months 10–18; wait-list group). Patient-level data were extracted for all patients with T2DM registered at a participating practice. The trial ran to

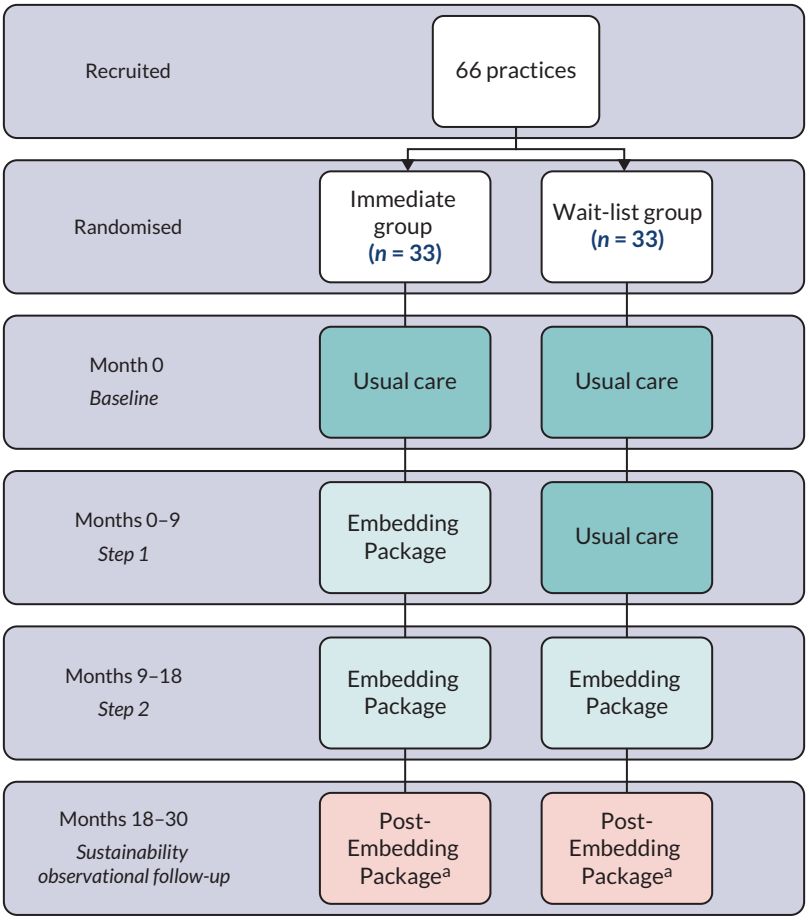

FIGURE 3 Wait-list design used in the RCT (WS3) and observational follow-up (WS4). a, Embedding Package not actively implemented by study team, but practices/providers could continue to use the Package (apart from the study-provided embedder) themselves.

completion, although all embedder activities stopped prematurely due to the COVID-19 pandemic, when all practices were at least 4 months into step two.

Outcomes

The primary outcome was patient-level HbA1c compared between control and intervention conditions. HbA1c was a proxy for SSME attendance, which was the intervention's focus. SSME attendance is a terminal outcome because most people only attend SSME once, so if a person attended before the study started or during a control condition then it would not be possible for them to attend during the intervention condition. HbA1c was selected as it can change continually and SSME attendance is related to reduced HbA1c. SSME referrals and attendance were the main secondary outcomes (binary outcomes coded 1 if the participant was referred/attended, 0 otherwise), with sensitivity analyses to account for their terminal nature. See Davies *et al*. for other secondary outcomes, including quality of attendance data and patient-reported outcome measures.[26]

Data sources

The main source was patient-level data from routine primary care records (extracted data). Notably, primary care SSME data only cover traditional modalities (or virtual equivalents of these post-COVID-19). There is no standard mechanism to feedback uptake of digital SSME (e.g. MyDESMOND) into primary care records, so primary care SSME data do not generally include digital SSME.

Referral and attendance data were additionally available from postal questionnaires completed by patients in step one (self-reported data) and SSME providers.

Sample size

Recruiting 58 practices (29 per group) would give over 90% power to detect a population-level difference in HbA1c of 1.1 mmol/mol (0.1%), which could represent a 2.1% decrease in micro and macrovascular events.[27] This assumed a standard deviation (SD) of 16.4 mmol/mol (1.5%),[27] an intracluster correlation coefficient (ICC) of 0.05 and one baseline HbA1c measurement with one more HbA1c measurement at each randomisation point. This calculation does not account for potential variation in cluster size, as it has been shown that the power of wait-list studies is robust to cluster size variations. Sensitivity of this calculation to changes in average cluster size was assessed. There would be 80% power to detect a difference as small as 0.7 mmol/mol (0.06%). If the average cluster size was larger than 174, there would be 80% power to detect a 1.1 mmol/mol (0.1%) difference. The recruitment target was 66 practices allowing for 10% cluster drop-out.

Statistical analysis

See Davies *et al*.[26]

Results

Davies *et al*.[26] gives the full results, with key findings summarised here.

Population

The intention-to-treat (ITT; randomised practices with baseline data) and complete-case populations included 64 (31 wait-list; 33 immediate) and 57 (29 wait-list; 28 immediate) practices, respectively, from 10 CCGs across England (*Figure 4*). The ITT practices used eight SSME providers, covering four SSME programmes (DESMOND, Diabetes 2gether/Diabetes 4ward, Spotlight, Xpert Health).

At baseline, 29,849 eligible patients were registered with ITT practices (wait-list: 15,527 total, 501 mean per practice; immediate: 14,322 total, 434 mean per practice). Patient populations were very similar between the two randomisation groups.[26] The exception was that, at baseline, 19% of wait-list group patients had not been referred to SSME, 16% had been referred but not attended and 64% had attended, while in the immediate group, non-referral (42%) and referral without attendance (20%) were higher, with lower attendance (38%).

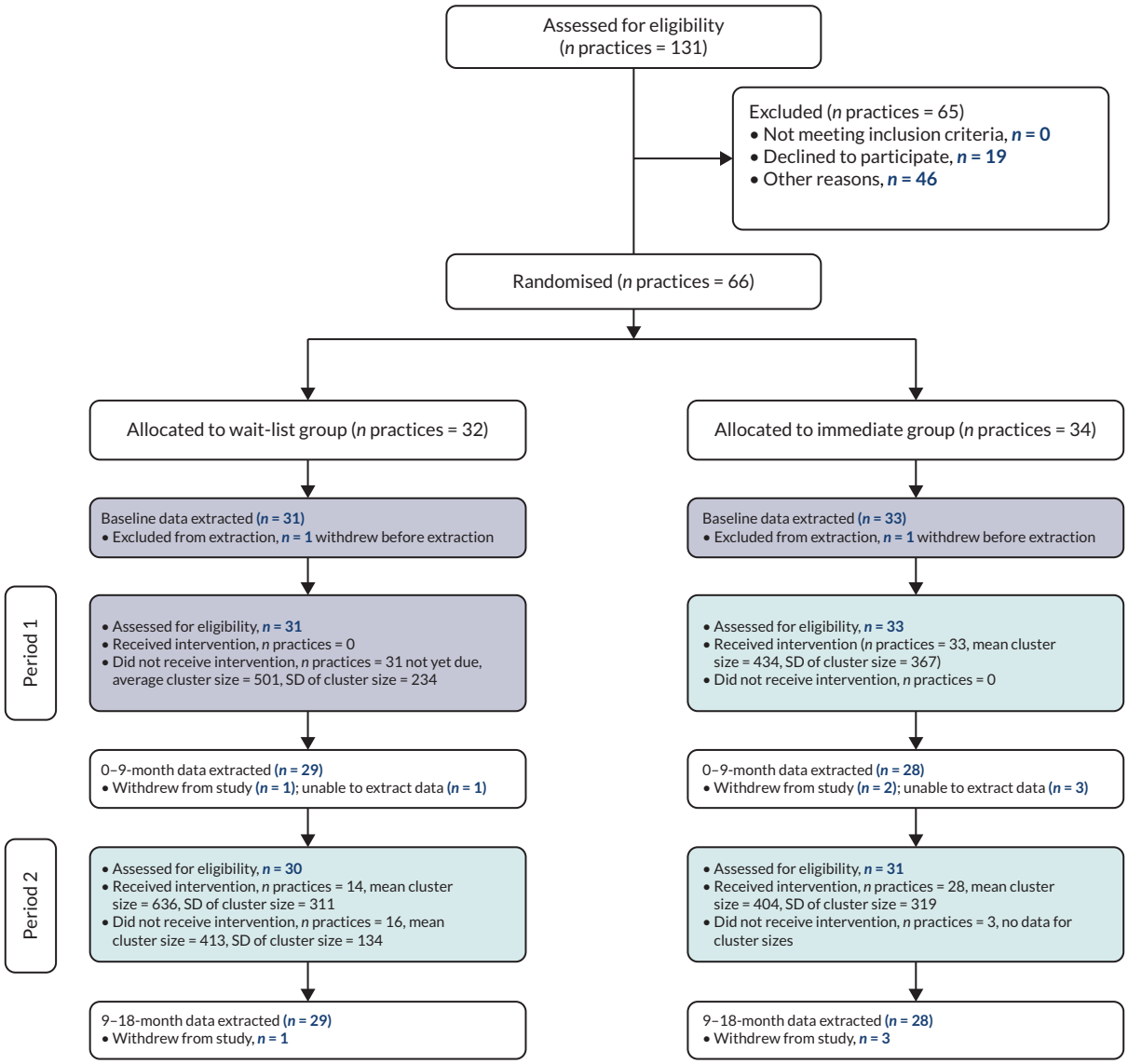

FIGURE 4 Consolidated Standards of Reporting Trials diagram (receiving the intervention was defined as participating in at least one aspect of the intervention).

Primary outcome

There was no significant difference (p = 0.503) in HbA1c between the intervention (immediate: steps one and two; wait-list: step two) and control (immediate: baseline; wait-list: baseline and step one) conditions after accounting for clustering and time effects. The mean difference was −0.10 mmol/mol [95% confidence interval (CI) −0.38 to 0.18 mmol/mol; HbA1c units −0.01%, 95% CI −0.03 to 0.02], so the 95% CI was wholly below the minimum clinically important difference (*Table 1*; practice-level ICC 0.02).

There was a statistically significant interaction with ethnicity (p = 0.001). Among ethnic minority individuals, mean HbA1c was 59.13 mmol/mol (SD 17.77; 7.6%, SD 1.6%) in the control condition and 59.06 mmol/mol (SD 16.98; 7.6%, SD 1.6%) in the intervention condition; the adjusted average difference was −0.64 mmol/mol (95% CI −1.08 to −0.20; HbA1c units −0.06%; 95% CI −0.10% to −0.02%). This does not meet the minimum clinically significant threshold in the sample size calculation and SSME attendance did not increase in these ethnic groups.[26] HbA1c did not significantly differ between the treatment conditions among white individuals (mean difference −0.02 mmol/mol, 95% CI −0.33 to 0.29; 0.00%, 95% CI −0.03% to 0.03%) or in any of the sensitivity analyses.[26] including subgroup analyses by type of SSME programme or local MyDESMOND availability.

TABLE 1 Intervention impact in the intention-to-treat population (64 practices; 35,155 patients; 92,977 observations)

	Complete cases[a]				Intention to treat[a]	
	Observations (*n*)		Mean (SD)			
Outcome	Control (*N* = 45,940)	Intervention (*N* = 47,037)	Control	Intervention	Mean difference (95% CI)	*p*-value
HbA1c, mmol/mol[b]	40,112	31,601	57.37 (16.21)	58.09 (16.50)	−0.10 (−0.38 to 0.18)	0.503
Body mass index, kg/m^2	35,422	25,133	31.58 (6.72)	31.68 (6.78)	−0.10 (−0.31 to 0.10)	0.295
Weight, kg	25,985	24,782	88.71 (21.68)	89.93 (21.42)	−0.15 (−0.78 to 0.48)	0.633
Total cholesterol, mmol/l	37,092	26,517	3.81 (1.20)	4.22 (1.10)	−0.12 (−0.15 to −0.08)	< 0.001
LDL cholesterol, mmol/l	21,442	16,503	2.07 (0.88)	2.08 (0.89)	0.00 (−0.02 to 0.03)	0.879
HDL cholesterol, mmol/l	36,553	26,170	1.22 (0.34)	1.23 (0.35)	0.00 (−0.01 to 0.01)	0.674
Systolic blood pressure, mmHg	40,347	29,304	131.64 (14.21)	131.42 (16.13)	−0.30 (−0.72 to 0.13)	0.168
Diastolic blood pressure, mmHg	40,347	29,020	74.92 (9.54)	75.35 (9.52)	−0.02 (−0.29 to 0.25)	0.897
Cardiovascular risk score (QRisk)	7137	3789	24.64 (14.68)	24.05 (14.58)	−0.01 (−0.38 to 0.35)	0.937
			n (%)		Odds ratio (95% CI)	*p*-value
Referred	40,619	39,368	23,237 (57.2)	21,981 (55.8)	0.85 (0.73 to 0.99)	0.038
Attended	40,619	39,368	23,376 (57.6)	20,470 (52.0)	0.82 (0.66 to 1.01)	0.063
Current smoker	45,294	46,906	7455 (16.5)	6460 (13.8)	1.18 (1.09 to 1.28)	< 0.001
Any hospital admissions	44,249	38,798	1916 (4.3)	1393 (3.6)	0.91 (0.77 to 1.08)	0.279

HDL, high-density lipoprotein; LDL, low-density lipoprotein.

a The intention-to-treat population was used for the analysis with multiple imputation to impute missing values. However, means for the intention-to-treat population could not be generated using multiple imputation, so the complete-cases population was used for the summary statistics. The summary data are crude data and do not account for factors included in the model (imputation of missing data, nested random effects to account for non-independence of data, adjustment for covariates); therefore the crude estimates and model estimates are not directly comparable, which is why some effect sizes are in the opposite direction to the summary data.

b Prespecified primary outcome.

Secondary outcomes

The main secondary outcomes were patient-level referral to, and attendance at, SSME. Both were lower or similar during the intervention than control conditions, with an odds ratio (OR; 95% CI) of 0.85 (0.73 to 0.99; $p = 0.038$) for referrals and 0.82 (0.66 to 1.01; $p = 0.063$) for attendance (see *Table 1*).

During the intervention condition, total cholesterol was lower by 0.12 mmol/l (95% CI 0.08 to 0.15) on average, while there were more current smokers (OR 1.18, 95% CI 1.09 to 1.28; $p < 0.001$) compared with the control condition. There were no other important differences (see *Table 1*).

Quality of referral/attendance data

Agreement between self-report, practice and provider data ranged from 70% (self-report vs. practice) to 79% (practice vs. provider) for referrals, and from 60% (self-report vs. practice) to 77% (self-report vs. provider) for attendance. Combined, the sources were approximately 69% and 77% complete for referral and attendance, respectively.

Patient-reported outcomes

There was no statistically significant difference in Patient Activation Measure® 13 (Insignia Health, Norwich, UK) W-BQ12 well-being questionnaire or Problem Areas in Diabetes questionnaire scores between the groups.

Conclusions

Overall, the intervention did not improve the primary or most secondary outcomes. While the intervention was associated with a slightly reduced HbA1c in a subgroup analysis of people in ethnic minority groups, SSME attendance did not appear to increase. This group may have increased SSME uptake through MyDESMOND, which was made available over the study period; however, use of digital SSME programmes is not routinely recorded in primary care.

There were statistical issues with the binary outcome analyses (e.g. SSME referral, SSME attendance, smoking), as models were unstable and may not fit the data well, so binary outcomes should be interpreted with caution.

Baseline SSME attendance and referrals were imbalanced between the study groups, with very high attendance in the wait-list group (64%) meaning that attendance under the control condition was high with little room for improvement. This could partly explain the negative trial results. Baseline attendance was 38% in the immediate group in primary care data and 41% overall in self-reported data, aligning with previous self-reports showing 49% of people with T2DM have attended SSME.[14] These data suggest that the 11% attendance within 12 months of diagnosis reported by the National Diabetes Audit only shows part of the picture around SSME attendance.[13]

Conduct an ethnography study

Context

Informed by NPT,[28,29] WS1 and WS2, this component focused on understanding implementation at patient, practice, CCG and provider levels, assessing sustainability of the Embedding Package and contextualising the implementation process, sustainability of the change and the 'fit' of the intervention within routine practice.

Methods

Details of the methods are provided in Davies *et al*., including a description of the ethnographic sample, example extracts from the tracker and an example draft press release.[26] Briefly, in-person interviews and observations were planned at 12 sites, including primary care practices, CCGs and SSME providers. Additionally, documentary evidence would provide context around meetings, events and virtual communications. However, study-level factors (including limited intervention engagement) combined with the COVID-19 pandemic severely curtailed face-to-face data collection. Data collection was therefore redesigned to use a larger range of documentary and digital data sources:

- E-mail communications between embedders and practices/providers (2051 individual items).
- Intervention 'tracker': database recording embedder actions and time spent on each activity (928 entries).
- Embedder-generated documents (e.g. practice action plans; $n = 49$).

- Series of debrief interviews with embedders (seven interviews; two embedders) and one interview with an SSME provider.
- Observations of meetings between embedders and practices.

The analysis was informed by interpretive thematic analysis[30] and NPT.

Findings

Findings covered three themes:

- Making and sustaining contact with practices and providers.
- Interaction with the toolkit.
- The role of MyDESMOND.

A summary follows, with detail provided in Davies *et al.*[26]

Making and sustaining contact: interactions with embedders

Embedders faced obstacles in initiating and sustaining contact with providers and practices, especially a lack of, or substantially delayed, responses to correspondence and conducting agreed actions. While face-to-face meetings evoked interest, enthusiasm and buy-in, once the embedder left, often little action followed from participating organisations.

Interviews suggested that sporadic and delayed communication from practices and providers was due to lack of capacity, staff leaving post or being on (extended) leave and poor or no role handover (so embedders had to restart with newly appointed personnel). Providers and staff were perceived to be anxious about additional workload, therefore seeming hesitant to engage in correspondence. Another reflection from the interviews was a potential lack of clarity in early communications with practices, especially regarding their required capacity and commitment.

These challenges were addressed by consistent chasing e-mails, reminders of actions and continued proactivity in communication by embedders. Prior contact with key individuals in localities appeared to affect the reception of the intervention. However, trying to achieve engagement consumed a substantial amount of time, with very mixed success across CCG localities. In particular, a common feature across several localities was uncertainty about the intervention costs and benefits. Put simply, practices and providers were often unsure about what the intervention would do for their provision locally in terms of potential increase in provision of spaces on education groups, and about the level of input it would require from busy individuals. With the onset of the COVID-19 pandemic, communication with CCG localities became even more challenging.

Interaction with the toolkit

Providers and practices were concerned that they lacked time to implement and use the toolkit. Embedders offered diverse initiatives to address these concerns (e.g. structuring action plans; tailoring promotional print material to local needs; drafting press releases; preparing digital material; offering mentoring).

Analyses highlighted a proactive approach to facilitating local activity, especially when there was a delay in, or lack of, response to embedder's communication.

Challenges with toolkit implementation were more frequently encountered than successes. A great deal of time and effort went into tailoring initiatives to local need, and this fell significantly on embedders, not just local stakeholders.

Also apparent was how divergent the participating localities were regarding existing provision and infrastructure for SSME, and how consequential these differences could be. While the intervention was designed to account for such differences, local stakeholders were perceived to lack the time and willingness to lead on tailoring activities and, for most CCG localities, embedders lacked specific local knowledge to navigate them.

Providers were perceived as often reluctant to interact with the toolkit in their day-to-day work, despite encouragement to do so. While some could see the toolkit's merit in discussions with the team, this did not translate into further engagement, let alone embedding into routine practice.

The first COVID-19 lockdown saw an increase in social media use, particularly Twitter® (now X®; X Corp., San Fransisco, CA, USA) to advertise and encourage toolkit adoption. Functionality, such as hashtags and retweets, seemed important in Twitter's popularity among providers and practices, as it made the interaction straightforward. However, while there was some apparent engagement with social media among practices and providers, this did not clearly result in greater toolkit use.

In short, time and capacity constraints, along with behaviours/procedures associated with existing infrastructure, limited toolkit interaction. The embedders perceived that the toolkit alone would be insufficient to bring about the desired change, especially given the challenges involved in incorporating them into existing behaviours and processes. Rather, a fundamental change in attitudes and individuals' behaviours was needed.

Role of MyDESMOND

In some locations, MyDESMOND was used as an additional modality via which patients could access SSME. While 4 of the 10 CCG localities had MyDESMOND available (with a further 2 localities using it when the COVID-19 pandemic started), other localities did not use it, partly due to its compatibility and workability with existing infrastructure.

Where CCG localities took up MyDESMOND, practical difficulties could confound its inclusion in routine care. Interviews showed that, for areas already running DESMOND, MYDESMOND expanded their offer to reach underserved populations.

Yet, while MyDESMOND supported people who struggled to access in-person sessions, some rural areas lacked broadband to access the digital sessions. Moreover, compared with in-person approaches, MyDESMOND was felt to rely more heavily on the user navigating their way through SSME without an educator's assistance. Not all patients appeared comfortable with this approach.

Conclusions

Although data collection was limited by access and participant engagement challenges, combined with the COVID-19 pandemic, qualitative data offered useful understanding around the intervention implementation process and some context for the negative RCT results.

First, despite efforts to develop an intervention that would resonate with, and be adaptable to, local SSME challenges, the attractiveness and usefulness of the package were not self-evident to all practices and providers. There was initial engagement and enthusiasm among local leads, but in many CCG localities this was short-lived, and embedders required much effort to maintain communication and encourage uptake following initial meetings. While this might be partly attributed to time constraints of local staff, the package (especially the toolkit) clearly did not have sufficient immediate appeal, regarding purpose or usability, to become a priority.

Consequently, a very uneven process of cognitive participation was evident across CCG localities, with much activity led by embedders and less evidence of active work from local CCG, practice or provider stakeholders. Indeed, in some areas, some important groups were not involved in intervention implementation, for example due to scepticism about its added value, the presence of other potentially competing practices (e.g. alternative online programmes and recruitment approaches) or ongoing local disagreements about issues such as eligibility and reimbursement. Accordingly, operationalising the intervention locally (orchestrating collective action to implement it) proved challenging in several CCG localities. A good deal of this work related to tailoring the intervention and its materials (e.g. pathways, publicity) to the local context. Often, limited stakeholder engagement meant that this fell primarily to embedders, but it was not clear that an embedder, at least a centrally located one, was best placed to lead this work, as they were not integrated into provider teams and lacked local knowledge.

Overall, the high volume and nature of work by embedders, and sometimes local stakeholders, indicate the importance of adapting the intervention to local contexts, and how divergent those local contexts could be. While much work went into developing an intervention that would be malleable and adaptable and would build on existing infrastructure to encourage SSME uptake, localities differed greatly in existing approaches to provision and in the maturity and sophistication of existing infrastructure for identification, referral and monitoring. Consequently, the work of translating the intervention into divergent local contexts was significant: as Harvey and Kitson have noted, 'the success or otherwise of implementation [rests] upon the ability of the facilitator and the facilitation process to enable recipients within their particular context to adopt and apply the innovation by tailoring their intervention appropriately'.[31] However, our findings suggest that this work was not easily undertaken by an embedder covering multiple CCG localities and lacking detailed local knowledge of infrastructure, relationships and politics.

Refine the intervention

It was anticipated that intervention refinement may be needed during the RCT based on ongoing learnings from intervention delivery and the ethnographic study. Only two minor amendments were made. The self-referral article was updated with figures from the feasibility work. Further details about ensuring accessibility were added around having venues for groups aligned to larger practices/health centres.

Changes from workstream 3 original plan

Ethnography methodology was adapted as described above.

It was planned that embedders would be local to participating CCGs. However, this was not possible due to sustainability and transformation partnerships being introduced (see *Challenges*), meaning that CCGs appointed staff into roles similar to the embedder. Furthermore, the CCG pool was increased to 10 from 2 to 3 to aid practice recruitment. Centralised roles were therefore more feasible from a study perspective and to try to join up activity by the sustainability and transformation partnerships roles.

All practices were expected to be recruited before randomisation and therefore randomised simultaneously. However, practice recruitment took longer than expected, so practices were randomised in batches with staggered study start times.

Data extraction was planned to take place at the end of each step. However, this was difficult to arrange with some practices and so data extraction took place over several months. Data were extracted retrospectively, so this did not affect the results.

Self-report questionnaires were going to be mailed out immediately after practice randomisation, but for practical reasons this mail-out happened over the duration of the first step.

Workstream 4: assess cost-effectiveness and sustainability and enable implementation

Aim

Evaluate the intervention's cost-effectiveness compared with usual care, evaluate the sustainability of changes observed in WS3, understand virtual SSME implementation and develop an implementation toolkit.

Assess cost-effectiveness

The first health economic section reports implementation costs. The second reports the modelling of costs and effects over the lifetime of patients. A summary follows, with details in *Appendix 2*, including costs (see *Appendix 2*, *Tables 6–8*), *Appendix 3*, including costs (see *Appendix 3*, *Table 9*), expected value of information (see *Appendix 3*, *Table 10*), cost-effectiveness planes (see *Appendix 3*, *Figures 6* and *7*) and meta-analysis results (see *Appendix 3*, *Figures 8–13*), model results (see *Appendix 3*, *Table 11*) and cost-effectiveness acceptability curve (see *Appendix 3*, *Figures 14* and *15*)].

Estimate implementation costs

Methods

Data collection
Embedders recorded all embedding-related activities in 'trackers' (Excel spreadsheet). Unit costs were applied to this measure of resource use to estimate intervention costs. Estimated costs were considered to be the incremental costs of embedding activities.

Analysis
The primary (base-case) analysis estimated embedding activity costs across ITT practices (n = 64) within the RCT (33 immediate; 31 wait-list). Secondary analyses used the 57 complete-case practices (ITT practices that had not withdrawn or missed a data extraction; 28 immediate; 29 wait-list) and separated randomisation groups (wait-list and immediate) to explore implementation length.

Costing the intervention
Intervention costs fell into six categories: embedder costs; practice costs (staff); provider costs (staff); toolkit costs (initial and recurrent); marketing materials costs; travel and subsistence. Staff costs were for the financial year 2019–20, with unit costs from published figures.[32] Non-staff costs were taken from actual study expenditure and adjusted for inflation where appropriate. Initial toolkit costs were annuitised at a rate of 3.5% assuming a lifetime of 5 years for the website. As the costs for each practice occurred within 1 year of the intervention going live, no discounting was applied.

Trackers were available for all ITT practices. The only missing data were for time spent on some embedding-related activities (< 3%), for which the mean value for that activity from complete trackers was imputed.

Sensitivity analysis
The principal area of uncertainty for embedding costs was how it would be rolled out in standard practice, as opposed to within a research project. Sensitivity analyses accounted for this by assuming that: (1) embedders would be based more locally to the SSME provider and (2) the lead embedder would have a lower band as they would not need considerable research experience.

Results

Mean time from the first to last embedding activity was longer in immediate (204 days) than wait-list (134 days) practices; costs were adjusted to the longer period for comparability. The cost/patient for the ITT and complete-case practices for the scenario analysis was £0.521 and £0.585, respectively. In the sensitivity analyses, the cost/patient for the ITT and complete-case practices was £0.363 and £0.404, respectively.

Embedder costs amounted to 71% of total intervention costs, demonstrating their central role to intervention delivery. The next most significant costs were the combined costs of provider and practice staff directly incurred for them to attend meetings and follow up on activities initiated by embedders.

Conclusion

Intervention costs were calculated, with sensitivity analyses accounting for uncertainties around real-world implementation. Costs in wait-list and immediate practices were very similar, suggesting that the Embedding Package implementation was similar across the two waves and reasonably constant over time. Consequently, for the purposes of the cost-effectiveness modelling, the pooled cost per patient of £0.521 could be used (£0.363 for sensitivity analysis as this figure corresponds to the ITT analyses).

Estimate cost-effectiveness

Methods

Approach

We used an NHS and Personal Social Services perspective and the NIHR School for Public Health Research T2DM treatment model version 2 (an individual-level simulation of diabetes-related complications for people with T2DM). We obtained our individual-level population from NICE simulation distributions.[9] Discounting aligned with NICE's 2013 methods guide with future costs and quality-adjusted life-years (QALYs) discounted at 3.5% per annum.[33]

Costs

Implementation costs were costs of the intervention and of SSME attendance. Intervention costs were obtained from the costing analyses in the previous section and SSME costs from Gillett *et al.*[7] All costs were in 2019–20 prices.

Effects (base case)

Structured self-management education uptake and changes in risk factors [HbA1c, body mass index, systolic blood pressure, high- and low-density lipoprotein (HDL and LDL) cholesterol levels] were from the RCT analyses for the control and intervention conditions.[26] We assumed that all individuals under the intervention condition received these mean effects. In year 1 of the model, change estimates were obtained from the RCT results, which on average occurred 13.5 months into the intervention period. Year 2 outcomes and beyond were based on the analyses with the observational follow-up period for HbA1c and SSME uptake and on the RCT analyses for the other risk factors, as these were not analysed in the observational follow-up data. We assumed that intervention effects were fully maintained for 3 years.

Scenario analyses

All analyses were probabilistic. We ran the model with 5000 patients and 2000 probabilistic analysis runs. Scenario analyses were based on uncertainties in the model:

1. Future costs and QALYs discounted at 1.5% per annum.[34,35]
2. Assume that all statistically insignificant secondary RCT outcomes have no effect.
3. Take change in HbA1c and uptake of SSME in year 2 onwards from RCT results.
4. Use only effect data on SSME uptake from the RCT and base effect of SSME uptake on HbA1c on meta-analysis of published studies (see *Appendix 3*). Effect of SSME uptake is directly given to individuals who attend SSME, rather than giving all individuals mean effects estimated from the RCT. We assumed that SSME is effective for 6 years in full with waning by the 10th year.[5,36]
5. Scenario 3 and 4 combined.

6. Duration of effect is assumed longer than the base case:

    a. 5 years where the effect is fully maintained and no effect afterwards.
    b. 10 years full maintenance of effect and no effect afterwards.

7. Duration of effect is assumed longer than in scenario 4:

    a. 10 years where the effect is maintained in full, with gradual waning by the end of year 15.
    b. Lifetime effect.

Outcome measures

The primary outcome was incremental cost-effectiveness ratio (ICER), which is the difference in cost between intervention and control divided by the differences in QALYs between intervention and control. If one of intervention or control was more effective and cheaper than the other, then that condition was deemed dominant and an ICER was not calculated.

Results

Base case

The Embedding Package dominated usual care (it produced more QALYs at a lower cost; see *Table 2*). The differences in costs and QALYs were very small. However, using the Hatswell *et al.*[37] method for assessing whether sufficient probabilistic sensitivity analysis runs had been conducted suggested that 2000 probabilistic sensitivity analysis runs were sufficient for the stability of the results as the 95% CI around the mean incremental net monetary benefit (iNMB) did not contain £0.

The results were highly uncertain; the cost-effectiveness plane had probabilistic analysis runs scattered either side of the ICER equals £20,000 per QALY line and the intervention had just over a 50% chance of providing the most net benefit at all thresholds between £0 per QALY gained and £50,000 per QALY gained.

Value of information

The expected value of information (total health economic value of having no uncertainty in the results) at a decision-making threshold of £20,000 per QALY gained was £445 per person. The value of conducting further research into the intervention effectiveness was relatively small at £24 per person.

Scenario analyses

The intervention was dominant or had an ICER < £20,000 per QALY gained in seven of nine scenarios (see *Table 2*).

Updated analyses post peer review

Post peer review, we identified errors in the model code relating to the implementation of estimated glomerular filtration rate (eGFR). Revised results have been run in an updated model correcting these errors and are available in *Updated results*. These results are similar to the original results, with the differences in costs and QALYs being small and uncertain and the intervention being dominant or having an ICER < £20,000 per QALY gained in eight of the nine scenarios. The model used to generate these results is under a General Public Licence version 2 or later.[38]

Conclusion

The Embedding Package dominated usual care (it was more effective and lower cost) in the base-case analyses and in six of nine scenario analyses, with the intervention having an ICER of < £20,000 per QALY in one further scenario analysis. However, the differences in cost and QALYs between the intervention and control were very small and highly uncertain with very wide CIs, suggesting no evidence of a difference in costs and QALYs. The value of information analyses indicated the biggest driver of uncertainty were the risk functions used in the model, rather than the effectiveness estimates from the RCT.

TABLE 2 Cost-effectiveness results

	Life years	Discounted QALYs	Discounted costs (£)	Incremental QALYs	Incremental costs (£)	ICERncremental cost-effectiveness ratio	iNMB (95% CI)[a] (£)
Base case							
Usual care	14.273	7.400	44,585	–	–	–	
Embedding	14.277	7.403	44,553	0.002	−33	Embedding dominant	78 (24 to 132)
Scenario 1: 1.5% discounting							
Usual care	14.273	8.812	57,652	–	–	–	–
Embedding	14.277	8.814	57,618	0.003	−34	Embedding dominant	92
Scenario 2: statistically insignificant secondary outcomes removed from the analysis							
Usual care	14.273	7.400	44,585	–	–	–	–
Embedding	14.275	7.401	44,570	0.0011	−15	Embedding dominant	38
Scenario 3: no observational follow–up results in the economic model							
Usual care	14.273	7.400	44,585	–	–	–	–
Embedding	14.272	7.400	44,554	0.0001	−31	Embedding dominant	34
Scenario 4: meta-analysis results							
Usual care	14.315	7.42183	44,534	–	–	–	–
Embedding	14.312	7.42185	44,556	0.00002	22	1,099,530	−21
Scenario 5: meta-analysis and no observational follow-up evidence on uptake							
Usual care	14.315	7.42183	44,534	–	–	–	–
Embedding	14.305	7.41853	44,540	−0.0033	6	Usual Care dominant	−72
Scenario 6a: duration of effect is 5 years instead of 3 years							
Usual care	14.273	7.400	44,585	–	–	–	–
Embedding	14.281	7.405	44,567	0.005	−19	Embedding dominant	112
Scenario 6b: duration of effect is 10 years							
Usual care	14.273	7.400	44,585	–	–	–	–
Embedding	14.290	7.409	44,569	0.01	−16	Embedding dominant	187
Scenario 7a: meta-analysis and SSME effect lasts 10 years in full and wanes after 15 years							
Usual care	14.333	7.42886	44,559	–	–	–	–
Embedding	14.336	7.43017	44,567	0.00130	8	6140	18
Scenario 7b: meta-analysis and SSME effect lasts for a lifetime							
Usual care	14.370	7.43846	44,641	–	–	–	–
Embedding	14.376	7.44041	44,595	0.0020	−46	Embedding dominant	85

a Estimated using the Hatswell *et al.* method, so is 95% CI around the mean Incremental net monetary benefit, rather than uncertainty observed across all probabilistic sensitivity analysis runs.[37]

Note
Incremental net monetary benefit at £20,000 per QALY gained.

Assess sustainability of the intervention

We planned to investigate whether improvements in SSME uptake were maintained beyond WS3 through a 12-month observational follow-up in both arms during which the study team no longer reinforced the intervention, but practices and providers could continue using it if they chose to do so (without a study-provided embedder). The same outcomes were measured as in the RCT. However, the RCT results suggested that the intervention did not improve uptake, so assessing the maintenance of effects was inappropriate.

Instead, the primary RCT analysis (mean difference between control and intervention states estimated using mixed-effects linear regression) was repeated using the RCT and observational data combined to assess whether there was a difference in HbA1c between control and intervention conditions when allowing for more time to realise changes. Similarly, analyses for the main secondary RCT outcomes (referral and attendance) were repeated with the observational data included. All analyses in this subsection were exploratory and not prespecified.

This analysis included 37,825 eligible patients in the ITT practices (20,352 wait-list; 17,473 immediate). After accounting for clustering and time effects, mean HbA1c was −0.56 mmol/mol (95% CI −0.71 to −0.42 mmol/mol; −0.05%, 95% CI −0.06% to −0.04%) lower in intervention than control conditions ($p < 0.001$). This result was statistically significant but not clinically significant based on the predetermined threshold in the RCT sample size calculation.

Structured self-management education referrals did not differ between treatment conditions (OR 0.97, 95% CI 0.90 to 1.04; $p = 0.414$). However, SSME attendance was higher during intervention than control conditions (adjusted OR 1.13, 95% CI 1.02 to 1.25; $p = 0.017$).

We hypothesised that this longer-term improvement may be partly due to increased uptake of MyDESMOND (digital SSME programme) during the COVID-19 pandemic. Therefore, we repeated these analyses within subgroups of providers who did and did not make MyDESMOND available. HbA1c reductions were similar whether MyDESMOND was not available [−0.81 mmol/mol, 95% CI −1.08 to −0.54 mmol/mol; −0.07%, 95% CI −0.10% to −0.05%; $p < 0.001$] or MyDESMOND was available (−0.45 mmol/mol, 95% CI −0.61 to −0.28 mmol/mol; −0.04%, 95% CI −0.06% to −0.03%; $p < 0.001$). Again, these findings were not clinically significant. Similarly, attendance improvements were similar whether MyDESMOND was not available (1.27, 95% CI 0.92 to 1.76; $p = 0.149$) or MyDESMOND was available (1.11, 95% CI 1.00 to 1.24; $p = 0.042$). MyDESMOND was therefore unlikely to be the sole driver of this improvement.

These results suggest that SSME attendance and HbA1c improved compared with control conditions over a longer time period than the main RCT results, which showed no change in SSME attendance or HbA1c. While these results are promising, they should be interpreted with caution as differences were not clinically significant and ethnographic analyses and implementation data (see *Appendix 1*) suggest that implementation of the Embedding Package was limited in most settings. Furthermore, the observational follow-up took place during the COVID-19 pandemic when there was a substantial shift to online T2DM SSME and global messaging about the negative impact of COVID-19 in people with diabetes; both of which likely affected SSME attendance and HbA1c levels. However, these results suggest that the Embedding Package could be effective with the inclusion of a longer period over which to realise the intervention's impact, perhaps reflecting that system-wide change may take longer to realise than allowed for within the RCT design.

Understand implementation of virtual self-management programmes

Context

A qualitative substudy, replacing the ethnographic element of WS4, focused on SSME delivery changes, particularly the move to virtual delivery, which was accelerated by COVID-19.

Due to COVID-19, we adapted our face-to-face DESMOND programme for virtual delivery in real time, via group sessions on Microsoft Teams® (Microsoft Corporation, Redmond, WA, USA), where educators delivered the usual face-to-face content. Other SSME programmes were similarly delivered virtually during the pandemic. This is different

to MyDESMOND, which is an asynchronous, self-directed digital-based programme comprising educational materials, animations and videos on T2DM and self-management, with functions including a chat forum and 'ask the expert'.

Aim

To understand patient- and practice-level barriers and facilitators to virtual SSME uptake and implementation.

Objectives

- Understand the impact of the COVID-19 pandemic on SSME uptake.
- Explore views and experiences of virtual SSME attendees and of online educators.

Methods and results

Data analysis of one-to-one interviews (11 staff and 19 SSME attendees from 2 providers) generated three themes:

- Need for an established infrastructure.
- Staff and user experience.
- The future of virtual SSME programmes.

Appendix 4 provides more detail including characteristics of staff (see *Appendix 4*, *Table 12*) and SSME attendee (see *Appendix 4*, *Table 13*) participants.

Conclusions

This qualitative substudy explored barriers and facilitators to virtual SSME uptake and implementation at organisational and individual levels. Theoretical domains framework (to explore behavioural aspects of delivery and attendance) and NPT (to explore structural and organisational features of SSME uptake) guided data collection.

Staff from both sites expressed information technology (IT) challenges around setting up and delivering SSME programmes, indicating that an established infrastructure is fundamental for the future of virtual SSME. One locality reported enabling support via an established 'academy' that was freely available to educators and provider services, which seemed to level challenges around delivery.

Preference seemed to favour face-to-face SSME; however, participants who attended virtual SSME were originally invited to a face-to-face programme before the pandemic and would not have been exposed in the same way to a virtual format. This finding reiterates results from our cross-sectional study (n > 3500), which concluded that people tend to prefer modalities they have previously experienced.[39]

Regardless of people's preference, all participants stated they would recommend virtual SSME to friends and family, based on the positive experience of staff and attendees. Delivering and attending a programme remotely fits with people's life commitments, saving time and finances on transport to, and delivery of, sessions. This was deemed one of the biggest advantages of virtual SSME, as it addresses many factors that prevent people from attending in-person programmes (e.g. depending on others for transport, cost of public transport, physical barriers, inability to take time off work or time away from family commitments).

Although the convenience factor was a huge positive for virtual SSME, staff and attendees experienced practical and logistical challenges. The ability to join a session remotely resulted in unavoidable distractions and reduced attention span, adding to educators' challenges in delivering virtual sessions. Difficulties were also expressed around not being able to read the group's body language or visual cues, which often aid the flow and depth of group discussions. Barriers to maintaining engagement with attendees were connectivity issues from both parties and the inability to use tangible resources, which were often key to the interactive nature of face-to-face programmes.

We adopted purposive sampling for the attendees' cohort; however, only one person from a minority ethnic group was interviewed. The sample size was small and so this potentially reflects the demographic characteristics of the two localities.

This study offers insight into barriers and enablers to virtual SSME delivery and uptake and suggests acceptability of virtual SSME from both staff and attendees. With appropriate infrastructure and support, SSME programmes could be delivered in a blended approach, face to face or virtually, offering tailored education format and patient choice.

Enable long-term intervention implementation

We planned to generalise the Embedding Package into an implementation toolkit for widespread adoption. However, WS3 results suggest that it is inappropriate to implement the package widely in its current format. Despite this, the package showed some promise. A PDF version of the toolkit was therefore produced (see *Implications for practice and lessons learnt*).

Changes from workstream 4 original plan

As described above, a qualitative substudy replaced the ethnographic work and the implementation toolkit was scaled back.

Instead of using a tick-box tracker for cost-effectiveness data collection and only calculating costs for 12 practices, embedders entered detailed entries in Excel, enabling calculation of costs for all practices, making costings more robust and accurate without needing to impute. Planned interviews with SSME providers were not undertaken (see *Appendix 2*).

Public involvement

Public involvement aim

The purpose was to involve people affected by the research and its outcomes at all levels of the programme. We strived to include meaningful public involvement/engagement and involve 'the relevant people, not just the available people'. We worked with patient groups across the country close to where the research was being conducted.

Methods

This programme had excellent public involvement resourcing and a team-wide commitment to public involvement/engagement. This section describes work conducted for public involvement/engagement purposes.

An initial focus group discussed the programme and recruited interested local volunteers to help with steering. The programme was supported. Much of the discussion focused on themes already identified in focus groups exploring SSME. The public involvement plan subsequently included the following five areas of work.

Public contributors (research champions) in study groups

Our public contributors were stalwarts throughout the programme and are established as colleagues, providing a foundation for continued collaborative work. Over the programme, we worked with five team members, sustaining three active contributors embedded within the governance structure (operational, management, steering).

Reimbursements followed evolving reward and recognition guidance. One public contributor was recruited later in the programme from a particularly engaged Patient Participant Group (PPG) from a RCT practice, underpinning the interaction of the WS and development of relationships and networks throughout the programme.

Oversight and wider involvement through practice and local groups

To work with communities proximal to research sites where we had no existing networks, we engaged with local Diabetes UK groups and PPGs of feasibility study and RCT practices. The public involvement manager offered to visit every practice, attending 12 PPGs; a further 8 visits were cancelled owing to COVID-19.

Two online sessions were offered to PPGs from all practices. Attendance was sufficient but underwhelming (11 people in total). As we needed to communicate with PPGs via practices, we infer that this was not a priority for practices during the pandemic.

Support via the education stakeholders group

The Leicester Diabetes Centre (co-ordinating centre; Leicester, UK) Education Stakeholders Group, comprising people affected by T2DM with an interest in education, maintained a governance and oversight function for the programme, which was a standing agenda item with programme updates shared.

MyDESMOND development

MyDESMOND predevelopment work (see *Intervention description*) included 4 focus groups in 2016–7, comprising 12 people with T2DM. An early version of MyDESMOND was subsequently tested by nine people with T2DM and adapted using their feedback.

Dissemination

Dissemination of programme findings comprised in-person and electronic approaches.

An animation of the findings was created in Gujarati, Punjabi, Hindi, Polish and English (with subtitles) and shared via the website of the co-ordinating centre (www.leicesterdiabetescentre.org.uk/research-blog/embedding).

Two public engagement events were held in participating localities with Diabetes UK (eight visitors in total). Two dissemination talks were also held; one in-person (36 attendees; all Asian women) and one remotely (20 attendees).

Results/public involvement outcomes

Patient Participant Groups provided project governance and oversight, acted as a critical friend regarding project delivery in the local context and offered advice on recruitment, publicity, local culture and dissemination.

MyDESMOND focus groups led to adaptations, including:

- making the chat forum optional
- developing a non-judgemental section on diabetes distress and negative emotions
- inclusion of new weekly content on important topics
- development of user videos sharing their experiences.

Discussion/impact of public involvement

MyDESMOND was made available to over 25,000 individuals free of charge. Feedback continues to be collected, with content and functionality refined accordingly.

A rewarding element of the public involvement was developing positive working relationships with all of the research champions. For example, David joined the trial management group in early 2019 and provided useful guidance throughout on making T2DM SSME accessible in his role as 'critical friend'. This was a useful, supportive and encouraging function for the team. David also feels that it impacted on his own life and perspective:

> *I was both pleased and a little scared to have been asked to be a part of the Embedding study team as a PPI. Pleased because it was something new to me and would add to my experience. A little scared I was the only person there that had not been to university, I need not have worried as the team accepted me and helped me to understand the things I did not know.*

> *I learned about ethnography, I even went to an event at Leicester University about the subject and came away understanding it better. I had done courses about clinical research but, they do not show the amount of work involved in good data collection. That was an eye opener. I enjoyed it and I found it interesting. The next time, if there is one, I would like to be involved again.*

Reflection and critical perspective

This public involvement was unusually challenging, owing partly to the intervention's concept (people often assumed we were testing SSME effectiveness, rather than an intervention to increase SSME uptake), and because we needed to grow new networks in the RCT localities, which needed clinical and educational colleagues to leverage their local connections. This would be extra work for our colleagues under normal circumstances, let alone during a global pandemic.

Our approach to involvement was efficient, effective and provided ready access to local populations. However, PPGs may lack diversity and be unrepresentative of local populations; the PPG model is potentially ethnocentric. Furthermore, we needed to depend on practices for contact, and the priority afforded to public involvement differed between practices. However, as a starting point to engage communities, leveraging PPGs has potential and, in less challenging circumstances, may have led to further contacts in the wider community.

Changes from original plan for public involvement

A programme-specific public involvement group was planned, but initial public involvement showed the homogeneity of themes in education focus groups so, to avoid duplication, a general education public involvement group was established for the co-ordinating centre.

Key findings

Workstream 1

An iterative, mixed-methods approach enabled design of an intervention for primary care. NPT usefully informed the design process (assimilating literature and qualitative data; conducting stakeholder consultations). Key intervention components for embedding SSME into primary care were:

- clear marketing strategy for SSME
- user-friendly and effective referral pathway
- new/amended professional roles
- toolkit of resources.

Workstream 2

We found that the RCT was feasible with design improvements, HbA1c (RCT primary outcome) was over 90% complete in primary care data, and 91% of patient questionnaire respondents consented to linking their questionnaire and primary care data. Most practices had limited intervention engagement, so it was planned that the RCT intervention implementation would focus on SSME providers.

Workstream 3

Baseline SSME attendance was higher than expected in wait-list (64%) and immediate (38%) practices. Most embedding activities remained at practice-level due to study-related logistical reasons. Practices interacted minimally with the intervention.

Overall, the Embedding Package did not affect HbA1c, SSME referrals and attendance, or most other secondary outcomes. HbA1c was statistically, but not clinically, significantly lower among ethnic minority individuals in intervention than control conditions; SSME attendance did not improve.

Practice, self-report and provider data were 39–66% complete for SSME referral and attendance. Each source used a different SSME definition.

Ethnography data showed that the intervention's attractiveness and usefulness were not self-evident to practices and providers, despite efforts to ensure this during development. Most activity was embedder-led, with much less active work (sometimes none) by local stakeholders, who were better integrated with greater local knowledge than embedders, and thus may have been better placed to integrate the package into local practice. Finally, adapting the intervention to (often divergent) local contexts was important, and an embedder covering multiple localities was not necessarily best placed to undertake this.

Workstream 4

Intervention costs were calculated, with sensitivity analyses accounting for uncertainties around real-world implementation. The intervention cost per patient was £0.52 (£0.36 for sensitivity analysis).

Longer-term analyses (RCT and 12-month observational follow-up data) showed that HbA1c was lower and SSME attendance higher during intervention than control conditions. These results require caution, as ethnographic and implementation data suggest limited intervention implementation in most settings. Furthermore, the observational

follow-up occurred during the COVID-19 pandemic when there was a substantial shift to online SSME and global messaging about the negative impact of COVID-19 in people with diabetes. However, these results suggest that the package could be effective with a longer period over which to realise its impact, perhaps reflecting that system-wide change may take longer than allowed for within the RCT design, and that the intervention was not patient facing so the indirect effect could take longer to materialise.

The qualitative substudy suggests acceptability of virtual SSME programmes. Despite IT challenges, feedback on virtual programme delivery was highly positive, particularly regarding financial and logistical benefits. Attendees and staff noted the lack of interaction and informal conversations with fellow attendees, and the inability to read body language and visual cues, were negative compared with face-to-face sessions. There was a strong indication that virtual SSME programmes have a place in future education delivery. The vision for SSME delivery is to progress with a blended approach, providing people with T2DM with a choice of format where virtual SSME complements face-to-face SSME.

Public involvement

Patient Participant Groups showed promise as a starting point for recruiting public involvement participants in new localities; however, they may lack diversity and rely on practices for initial engagement.

Programme execution successes and challenges

Successes

Successes include developing an evidence-based intervention, cohesive and inclusive public involvement, and completion of the work to time with minor adaptations given major hurdles due to COVID-19 and national restructures in logistics around recharging and organising research funding in 2018. This was one of the first programmes affected by this change.

Data collection involved co-ordinating data extraction through a third-party across practices at various time points and collecting provider data and self-report patient questionnaires via mailouts, which were linked through pseudonymised NHS numbers. To our knowledge, this is the first time that such data linkage has assessed agreement in SSME referral and attendance data demonstrating the completeness of data sources.

MyDESMOND was made available to study sites during the RCT, thereby increasing SSME availability for local populations. COVID-19 brought a greater, unintended benefit as face-to-face SSME access for people with T2DM was severely and quickly restricted. Attention on online SSME rapidly escalated and we made MyDESMOND available free of charge nationally to meet this need. Within the RCT CCGs, MyDESMOND users increased 4.2-fold from March 2020 (n = 746; when embedder activity ceased) to August 2021 (n = 3154; end of observational follow-up).

Nationally, > 25,000 diverse people have accessed MyDESMOND outside this research (46% male; 24% < 50 years; 15% ethnic minorities). MyDESMOND has a high retention rate; of those who use it for ≥ 1 day, 56% continue to use it for ≥ 3 months and 24% for ≥ 12 months (average = 107 minutes/person/week on MyDESMOND). Further evaluation of MyDESMOND is underway.

Challenges

Sustainability and transformation partnerships

After this programme began, NHS commissioning was restructured within England and sustainability and transformation partnerships introduced. These groups provide collaboration opportunities for NHS organisations and local government to identify local priorities and develop a plan to meet them. For many localities, this meant changes to diabetes SSME provision in commissioning plans, including additional funding and capacity to co-ordinate and promote uptake in a similar way to the Embedding Package, meaning that the package was sometimes deemed unnecessary. As the RCT began, it was hoped that embedders could focus on working with local CCGs and their providers to better understand current provision of diabetes SSME. However, this was not realised due to the somewhat limited impact of the embedders and the practice-level focus of the intervention implementation.

COVID-19 pandemic

When the COVID-19 pandemic started, the study sponsor paused non-COVID-19 research, leading to a rapid and significant reduction in embedding programme activity and cessation of intervention work with practices and providers. Practice and provider staff were redeployed to COVID-19 care, research and testing.

Throughout the pandemic, various options were considered to continue this project with the least disruption following the current guidance. We worked continuously with all partners and participating sites to establish which organisations could continue with the programme and in what capacity. A study extension or additional funding was not needed. A protocol amendment ensured participant and staff safety and delivery of the outcomes.

The remaining qualitative work saw the largest change. The COVID-19 outbreak led to significant changes in the landscape of group education provision, with rapidly increased demand for digital/virtual provisions, instead of face-to-face sessions. The local study team had expertise in digital programmes and qualitative work, so the

involvement of another qualitative researcher was extended to conduct research into implementation of virtual self-management programmes.

The study may have had different outcomes if it were conducted outside a pandemic; however, this is unlikely, as many of the challenges/limitations were already observed before the COVID-19 pandemic.

Practice engagement

For intervention delivery, communication between practices and embedders relied almost entirely on electronic methods following initial face-to-face meetings. When this became apparently ineffective in drawing engagement from practices, phone calls were made, which also had little to no engagement as, often, the previously engaged personnel became uncontactable. This affected the ethnographic work, as low engagement made it difficult for observations and interviews to take place. It is hard to consider how this could have been overcome.

As well as the limited practice-level engagement with the intervention, there were also challenges around practice-level engagement with study activities. For example, some practices replied immediately to communications regarding study-related activities and intervention delivery, while others did not respond after multiple e-mails and phone calls.

We undertook a substantial amount of work to try and overcome the challenge of poor practice engagement with study-related activities including, but not limited to:

- Constructing a practice manager contact database to avoid delays in clinical research network contacting practices.
- Working closely with clinical research network contacts to prompt practices as necessary.
- Maintaining a careful balance of prompting practices and giving them the space that they requested to maintain GP practice retention rate.
- Providing practical support to limit practice study-related workload, such as providing prepacked questionnaire packs for mailouts.

Limitations

Delayed start to feasibility study

Several challenges delayed feasibility practice recruitment, mainly finalising the practice-level data collection process (which impacted protocol completion) and the NHS cyber attack in May 2017 (causing reduced practice capacity for research, heightened awareness of information governance and delays in testing data extraction). Attempts to improve this included approaching research site initiative practices and federations, and diabetes and research leads and prominent local professors providing letters of endorsement for the study that were sent to practices. The trial manager also tried to visit CCGs, but only one CCG facilitated a visit.

These delays shortened the timeline between the feasibility study and RCT. Consequently, all feasibility study learnings could not be implemented into the RCT, particularly implementing the intervention at provider level. It may have been preferable to maintain the planned timeline between the feasibility study and RCT to allow implementation of feasibility study learnings by extending the programme length or attempting to gain the time back elsewhere.

Study design complexity

Participating practices had sizable requirements regarding study-related activities (e.g. questionnaire postage; enabling data extractions), which was compounded by embedders sometimes undertaking study-related activities, so the distinction was not always clear. This impacted on intervention engagement in some practices that could not separate the two activities, and on the ability of embedders to deliver the intervention as intended. This may have been reduced if the intervention was wholly at provider-level, thus a step removed from the research data collection.

Embedding of the embedders

Ethnography analyses showed that embedders found it difficult to get 'buy-in' and commitment for embedding activities, partly due to physical distance (neither embedder were local to where the intervention was implemented) and not being employed by local providers. Therefore, a lot of embedder availability was spent travelling, rather than continuing work and building better relationships. Furthermore, embedders embedded or employed within provider teams may have needed less regular reintroductions to themselves and the toolkit. This highlights the importance of considering study delivery practicalities when recruiting study-specific roles.

Primary outcome choice

During RCT planning, the primary outcome was much discussed. SSME attendance (the intervention's primary target) would be a natural choice, but had limitations within a wait-list design because local commissioning rules often prevented an individual attending SSME multiple times. Additionally, our findings show that SSME attendance data are only moderately complete, which would affect their validity as a primary outcome.

The primary outcome of HbA1c was chosen because attending SSME is associated with reduced HbA1c, and this outcome could change within each step of the wait-list design. This outcome is, however, a proxy and is one step removed from the intervention's primary purpose, meaning that it may be insensitive to change.

Potential contamination

Some of the intervention was delivered at provider level, conferring a potential contamination risk (i.e. control practices may have unintentionally received some of the intervention early via their provider). To limit contamination, we requested that the provider-level aspects of the intervention were targeted at practices participating in the Embedding Package as far as possible, and only aimed at wait-list practices when they were receiving the intervention. This in itself may have hindered intervention engagement as it may have been deemed too complicated. A rationale for embedders maintaining a practice-level focus (despite feasibility study findings that provider level would be preferable) was to limit contamination. With more time between the feasibility study and RCT (see *Delayed start to feasibility study*), the RCT could have been redesigned to facilitate this change without contamination. The likely impact of any contamination would have been to reduce the effect size estimating the intervention versus control difference.

Lack of fidelity assessment

An intervention delivery fidelity assessment was not planned. The data in *Appendix 1* partly mitigate this limitation by providing some understanding of delivery.

Conclusions

To improve T2DM SSME uptake, an intervention that could be tailored to the local context was designed through a comprehensive, mixed-methods approach involving stakeholders. This intervention was evaluated through a feasibility study and RCT with qualitative and health economics work.

Despite initial enthusiasm for the intervention, there were implementation difficulties, partly due to embedders sitting centrally with the study team, which probably contributed to it having no effect on HbA1c or the main secondary outcomes (referrals and attendance). Other contributing factors may have been that baseline SSME attendance was higher than expected, a proxy outcome was used for the primary outcome, and COVID-19 caused all embedder activities to stop prematurely.

There were some promising results. First, HbA1c improved among ethnic minority groups during intervention conditions. This result was not clinically significant and SSME attendance did not improve so other factors likely caused the HbA1c improvement. Second, during longer-term analyses, HbA1c was (statistically but not clinically) significantly lower, and SSME attendance higher, during intervention than control conditions, suggesting that the intervention's positive impacts and system-wide change may take longer than expected to realise. However, other external factors could have caused this improvement, such as the pandemic and the move to more online SSME. Finally, the intervention was very low cost (£0.52 per person with T2DM) and was more effective and lower cost than usual case in the base-case analyses and six out of nine scenario analyses, albeit these results were highly uncertain.

Finally, virtual SSME is acceptable to both patients and healthcare professionals, and SSME referral and attendance data are only moderately complete.

Recommendations for future research

Priority 1

The intervention had limited success and nationally SSME attendance remains fairly low at 11% within 12 months of T2DM diagnosis[13] and 38–64% in the longer term (based on this study and Nicolucci *et al.*[14]). Research into embedding SSME therefore remains a priority and some of the original research questions remain, particularly:

- Which organisation(s) and role(s) can best drive change regarding SSME uptake?
- Would a local embedder and/or one within SSME provider(s) have more traction?
- Would integrating a behaviour change theory with an implementation theory/model into the intervention development and delivery be beneficial in addition to focusing on intervention content?
- How do direct-to-patient approaches (e.g. ability to self-refer) impact SSME attendance?

Future research should consider how initiatives around embedding SSME into routine care should be tailored for different populations, otherwise SSME referrals may inadvertently exclude some populations.

Priority 2

COVID-19 affected face-to-face, group-based SSME delivery, with greater emphasis on online modalities. This increased SSME access for some underserved populations (e.g. individuals who cannot take time off work for SSME). Future research should consider how to increase SSME uptake within this new context, maintaining the benefits to some underserved populations without alienating others (e.g. those without internet access).

Priority 3

Establishing reliable SSME referral and attendance data is key to obtaining reliable data for research to better evaluate these programmes and fully embed them within primary care.

Priority 4

Evaluation of virtual and blended (face-to-face and virtual) SSME delivery is needed.

Priority 5

Regarding public involvement, future research should continue to build methodology for engaging diverse communities in new locations close to where research is being conducted, rather than where investigators are based.

Priority 6

Further investigation would benefit wait-list design methodology challenges:

- Choice of primary outcome when the desired end point is terminal.
- How best to analyse terminal end points.
- Challenges around model fit when a high proportion of participants have only one observation across the steps.

Implications for practice and lessons learnt

Embedding Package

Our findings highlight how knowledge gaps can arise when logistical barriers prevent the study design from reflecting intended real-world delivery.

While our findings do not support national roll-out of the intervention, providers and practices engaged well with parts of it (e.g. 'how-to' guides and 'promoting to patients') and the intervention was very low cost per patient. Furthermore, the national DESMOND Programme Office found that an adapted version of the toolkit was well accessed by their providers, signalling that a SSME programme-specific toolkit may have more real-world utility. Finally, similar toolkits are available in PDF format.[40,41] We therefore developed a PDF format for initial intervention roll-out (see *Report Supplementary Material 1*), with the same content as the online toolkit and an added focus on online SSME delivery. The PDF toolkit was made available free-of-charge to participating practices and via the DESMOND website.

Online self-management programmes

A core part of the original proposal was developing a digital SSME programme because, at the time, no such programmes were available. MyDESMOND became more important during the COVID-19 pandemic and is now among the top four diabetes applications on the ORCHA application library. Further evaluation is needed.

Real-time, group-based, virtual SSME delivery by an educator was also shown as acceptable to people with T2DM and delivery staff. Virtual SSME delivery was viewed as key going forward to ensure that people with T2DM have choices around accessing SSME, and to increase availability.

Ethnic minority groups

The Embedding Package was associated with a small HbA1c reduction among ethnic minority populations, which cannot necessarily be attributed to the intervention. Nevertheless, this potential improvement is notable and may relate to activities focused on ethnic minority populations. For example, the embedder attended a gathering at a Hindu temple and delivered a presentation on diabetes and SSME, with attendees encouraged to self-refer on the day. A local dietitian answered questions, and the embedder sought volunteers to work with the local provider to adapt their SSME programme to ensure cultural appropriateness. Unfortunately, the pandemic stopped this work.

Type 2 diabetes mellitus disproportionately impacts ethnic minority groups,[42] so it is imperative that strategies to increase SSME uptake do not further widen inequalities around accessing support. This is the case with most UK-based initiatives because, for example, majority ethnic populations may be more able to navigate systems or have English as their first language. Conversely, the intervention seemed to either benefit people in ethnic minority populations or at least did not increase existing inequalities.

The findings suggest that the Embedding Package, or parts of it, could be usefully applied to explore how to increase SSME uptake among underserved populations, particularly ethnic minority groups.

Other lessons learnt

COVID-19 affected the programme's practical delivery and research focus and brought into stark focus the ability to adapt in a long programme of work.

A strong evidence base for an intervention does not always translate into effectiveness. Therefore, while interventions should be based on best possible evidence, robust testing is necessary.

To really understand the effectiveness of initiatives to increase SSME uptake, work is needed to improve SSME data quality, availability and linkage, which is currently of moderate standard.

Finally, implementing change around SSME uptake takes time to change stakeholder mindsets and embed SSME as part of routine care. While ambitious, with content grounded in comprehensive research, the Embedding Package did not draw upon theories of change management for systems or of behaviour change, which could be the next step towards creating real change.

Additional information

Contributions of authors

Melanie J Davies (https://orcid.org/0000-0002-9987-9371) Professor, Diabetes Medicine, was the chief investigator, developed the research questions and the original proposal and grant submission, has had oversight and input into the overall programme of research, and inputted and commented on each of the WS. She worked closely with the project manager to have oversight of the overall programme.

Shona Agarwal (https://orcid.org/0000-0002-1650-4356) Research Associate, Qualitative Research. Conducted the data collection and analysis for the qualitative substudy.

Danielle H Bodicoat (https://orcid.org/0000-0002-2184-4865) Medical Statistician and Writer, Biostatistics. Conducted the analysis of the RCT and observational data.

Alan Brennan (https://orcid.org/0000-0002-1025-312X) Professor, Health Economics and Decision Modelling. Provided oversight of the health economics modelling.

Simon Dixon (https://orcid.org/0000-0001-7394-7009) Professor, Health Economics. Provided oversight of the health economics costing analysis.

Helen Eborall (https://orcid.org/0000-0002-6023-3661) Lecturer, Qualitative Research. Provided oversight of the intervention development and ethnography study.

Agnieszka Glab (https://orcid.org/0000-0003-2738-8829) Trial Manager, Trial Management. Was the programme manager.

Laura J Gray (https://orcid.org/0000-0002-9284-9321) Professor, Medical Statistics. Contributed to the design and analysis of the feasibility study, RCT and observational data.

Michelle Hadjiconstantinou (https://orcid.org/0000-0003-2827-0988) Research Fellow, Behavioural Science. Led and conducted the analysis for the qualitative substudy.

Lisa Huddlestone (https://orcid.org/0000-0002-8054-4475) Research Associate, Qualitative Research. Conducted the ethnography research within the feasibility study and the first part of the RCT.

Nicky Hudson (https://orcid.org/0000-0003-4091-1493) Professor, Medical Sociology. Provided oversight of the intervention development and ethnography study.

Anju Keetharuth (https://orcid.org/0000-0001-8889-6806) Senior Research Fellow, Health Economics. Conducted the health economics costing analysis and the quantitative analysis of the intervention delivery.

Kamlesh Khunti (https://orcid.org/0000-0003-2343-7099) Professor, Primary Care Diabetes and Vascular Medicine. Provided primary care expertise.

Caroline Kristunas (https://orcid.org/0000-0001-8945-4671) Biomedical Statistician, Biostatistics. Conducted the analysis of the feasibility study.

Graham Martin (https://orcid.org/0000-0003-1979-7577) Director of Research, Qualitative Research. Provided oversight of the intervention development and ethnography study.

Alison Northern (https://orcid.org/0000-0001-8193-3934) Implementation Manager, Diabetes SSME. Contributed to the intervention developments and was the lead embedder.

Mike Patterson (https://orcid.org/0000-0003-2888-2407) Public Involvement Representative, Lived Experience of Diabetes. Provided expertise regarding lived experience of diabetes and SSME.

Daniel Pollard (https://orcid.org/0000-0001-5630-0115) Research Fellow, Health Economics. Conducted the health economics modelling.

Rebecca Pritchard (https://orcid.org/0000-0002-2655-7312) Patient and Public Involvement Manager, Public Involvement. Led the public involvement aspects of the research programme.

Sally Schreder (https://orcid.org/0000-0002-4394-9764) Assistant Director of Operations for Research, Diabetes SSME. Contributed to the intervention development and provided expertise around implementation of diabetes SSME programmes.

Jane Speight (https://orcid.org/0000-0002-1204-6896) Foundation Director, Health Psychology. Contributed towards the intervention development and provided expertise in psychological instruments and evaluation.

Bernie Stribling (https://orcid.org/0000-0003-1426-1132) Assistant Director of International and External Business Development, Diabetes SSME. Provided expertise around implementation of diabetes SSME programmes.

Jackie Sturt (https://orcid.org/0000-0003-1281-1401) Professor, Behavioural Medicine in Nursing. Contributed towards the intervention development and provided expertise in diabetes SSME.

Jess Turner (https://orcid.org/0000-0002-4458-5528) Research Assistant, Qualitative Research. Conducted the intervention development research and the ethnography study.

Christina Weis (https://orcid.org/0000-0002-8447-0039) Lecturer, Qualitative Research. Contributed to the ethnography study.

Danielle Bodicoat, Helen Eborall, Michelle Hadjiconstantinou, Nicky Hudson, Anju Keetharuth, Graham Martin, Alison Northern, Daniel Pollard, Rebecca Pritchard and Christina Weis produced initial drafts of sections of the reports. All authors inputted into the design of the overall programme, its WS and its studies (as relevant), and reviewed and revised the report.

Acknowledgements

The authors would like to thank all of the study participants; the investigators and researchers involved in the studies which created the qualitative data sets for secondary analysis in WS1 phase 1; the stakeholders that took part in WS1 phase 2; Liz Shaw for undertaking the secondary analysis and stakeholder interviews in WS1.

Questionnaire acknowledgements

The following licensed questionnaires were included in the patient self-completed questionnaire booklet:

- ©2022 Patient Activation Measure® (PAM®) from Insignia Health, a Phreesia company. All rights reserved.
- W-BQ12 © Clare Bradley www.healthpsychologyresearch.com.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used *#datasaveslives*. You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

This research was conducted in accordance with the Declaration of Helsinki. Ethical approval was sought and received from West Midlands – Edgbaston Research Ethics Committee (reference number: 18/WM/0036; approval date: 25 January 2018) and the Health Research Authority (reference number: 238291; approval date: 5 February 2018). The University of Leicester Research Ethics Committee granted approval for the secondary analysis of qualitative data and the stakeholder workshop elements of WS1.

Information governance statement

The University of Leicester is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, University of Leicester is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here https://le.ac.uk/ias/data-protection.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KWYF5914.

Primary conflicts of interest: All authors received funding from the National Institute for Health Research for the current manuscript and the work underpinning it. University Hospitals of Leicester NHS Trust (Melanie Davies, Shona Agarwal, Agnieszka Glab, Michelle Hadjiconstantinou, Kamlesh Khunti, Alison Northern, Rebecca Pritchard, Sally Schreder, Bernie Stribling) received not-for-profit income through licensing fees to support implementation of a diabetes structured education programme (DESMOND and its online counterpart MyDESMOND) in CCGs in the UK, Ireland and Australia; all payments were made to the trust. Jackie Sturt manages the licensing, via University of Warwick, for a diabetes structured education programme (Diabetes Manual) that is commercially available; royalties have been paid to University of Warwick but not to Jackie Sturt personally. Danielle Bodicoat has undertaken paid consultancy work for the University of Leicester for this programme and other projects. Alan Brennan and Daniel Pollard have received funding for projects from the European Union and National Institute for Health Research. Kamlesh Khunti was a member of the HS&DR Funding Committee 2019–22. Graham Martin has received consulting fees from the Health Foundation and has participated in or chaired advisory groups and steering groups for work funded by the Health Foundation, City University, National Institute for Health Research and Leicester Centre for Ethnic Health Research.

Martin has also been a trustee for the Foundation for the Sociology of Health and Illness and a member of the National Institute for Health Research NETSCC National Stakeholder Advisory Group. Daniel Pollard has received personal payment from Novo Nordisk for a market research interview and is receiving in-kind support for other projects from Abbott Diabetes Care, Eli Lilly and Company, Medtronic International Trading, Novo Nordisk, and Sanofi. Sally Schreder has received funding for projects from the National Institute of Health Research. The other authors have no other potential conflicts of interest to disclose.

Publications

Peer-reviewed journal articles

Davies MJ, Kristunas CA, Alshreef A, Dixon S, Eborall H, Glab A, *et al*. The impact of an intervention to increase uptake to structured self-management education for people with type 2 diabetes mellitus in primary care (the embedding package), compared to usual care, on glycaemic control: study protocol for a mixed methods study incorporating a wait-list cluster randomised controlled trial. *BMC Fam Pract* 2019;**20**:152. https://doi.org/10.1186/s12875-019-1038-0

Davies M, Kristunas CA, Huddlestone L, Alshreef A, Bodicoat D, Dixon S, *et al*. Increasing uptake of structured self-management education programmes for type 2 diabetes in a primary care setting: a feasibility study. *Pilot Feasibility Stud* 2020;**6**:71. https://doi.org/10.1186/s40814-020-00606-0

Huddlestone L, Turner J, Eborall H, Hudson N, Davies M, Martin G. Application of normalisation process theory in understanding implementation processes in primary care settings in the UK: a systematic review. *BMC Fam Pract* 2020;**21**:52. https://doi.org/10.1186/s12875-020-01107-y

Turner J, Martin G, Hudson N, Shaw L, Huddlestone L, Weis C, *et al*. Using normalisation process theory (NPT) to develop an intervention to improve referral and uptake rates for self-management education for patients with type 2 diabetes in UK primary care. *BMC Health Serv Res* 2022;**22**:1206. https://doi.org/10.1186/s12913-022-08553-7

Davies MJ, Bodicoat DH, Brennan A, Dixon S, Eborall H, Glab A, *et al*. Uptake of self-management education programmes for people with type 2 diabetes in primary care through the embedding package: a cluster randomised control trial and ethnographic study. *BMC Prim Care* 2024;**25**:136. https://doi.org/10.1186/s12875-024-02372-x

Pollard DJ, Keetharuth A, Brennan A, Bodicoat DH, Glab A, Hadjiconstantinou M, *et al*. A model based cost-utility analysis of Embedding referral to structured self-management education into standard practice (Embedding) compared to usual care for people with type 2 diabetes diagnosis in the last 12 months in England. *BMJ Open* 2025;**15**:e093327. https://doi.org/10.1136/bmjopen-2024-093327

Other publications

Embedding structured education for self-management of type 2 diabetes in primary care: an NPT informed analysis. Presented at the British Sociological Association Medical Sociology Group Annual Conference, York, 13 September 2017.

Factors influencing the implementation of an intervention to increase uptake of type-2 diabetes structured management education in NHS primary care: an ethnographic study using normalisation process theory. Poster presentation, College of Life Sciences (University of Leicester) Early Career Researcher Symposium, 12 September 2019.

The feasibility of using routinely collected primary care data in a trial testing approaches to increase uptake to education programmes for type 2 diabetes. Poster presentation, 5th International Clinical Trials Methodology Conference, 7 October 2019.

Seeing the wood and the trees. University of Leicester Doctoral College 'Images of Research' exhibition, 27 November 2019.

References

1. van den Arend IJ, Stolk RP, Krans HM, Grobbee DE, Schrijvers AJ. Management of type 2 diabetes: a challenge for patient and physician. *Patient Educ Couns* 2000;**40**:187–94. https://doi.org/10.1016/s0738-3991(99)00067-1
2. Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Cradock S, *et al.*; Diabetes Education and Self Management for Ongoing and Newly Diagnosed Collaborative. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ* 2008;**336**:491–5. https://doi.org/10.1136/bmj.39474.922025.BE
3. Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the diabetes X-PERT Programme makes a difference. *Diabet Med* 2006;**23**:944–54. https://doi.org/10.1111/j.1464-5491.2006.01906.x
4. Jacobs-van der Bruggen MA, van Baal PH, Hoogenveen RT, Feenstra TL, Briggs AH, Lawson K, *et al*. Cost-effectiveness of lifestyle modification in diabetic patients. *Diabetes Care* 2009;**32**:1453–8. https://doi.org/10.2337/dc09-0363
5. Khunti K, Gray LJ, Skinner T, Carey ME, Realf K, Dallosso H, *et al*. Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *BMJ* 2012;**344**:e2333. https://doi.org/10.1136/bmj.e2333
6. Trento M, Gamba S, Gentile L, Grassi G, Miselli V, Morone G, *et al.*; ROMEO Investigators. Rethink Organization to iMprove Education and Outcomes (ROMEO): a multicenter randomized trial of lifestyle intervention by group care to manage type 2 diabetes. *Diabetes Care* 2010;**33**:745–7. https://doi.org/10.2337/dc09-2024
7. Gillett M, Dallosso HM, Dixon S, Brennan A, Carey ME, Campbell MJ, *et al*. Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis. *BMJ* 2010;**341**:c4093. https://doi.org/10.1136/bmj.c4093
8. Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, *et al*. Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2018;**41**:2669–701. https://doi.org/10.2337/dci18-0033
9. National Institute for Health and Care Excellence. *Type 2 Diabetes in Adults: Management*. NICE Guideline NG28. London: NICE; 2022. URL: www.nice.org.uk/guidance/ng28 (accessed 4 May 2023).
10. Department of Health and Diabetes UK. *Structured Patient Education in Diabetes: Report from the Patient Education Working Group*. London: Department of Health; 2005.
11. Sturt AS, Dokubo EK, Sint TT. Antiretroviral therapy (ART) for treating HIV infection in ART-eligible pregnant women. *Cochrane Database Syst Rev* 2010;**2010**:CD008440. https://doi.org/10.1002/14651858.cd008440
12. NHS Employers, General Practitioners Committee (British Medical Association), NHS England. *2014/2015 General Medical Services (GMS) Contract Quality and Outcomes Framework (QOF): Guidance for GMS Contract 2014/15*. URL: www.england.nhs.uk/gp/investment/gp-contract/2014-2015 (accessed 4 May 2023).
13. NHS Digital. *National Diabetes Audit, 2020–21 Quarterly Report*. URL: https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/e4-data (accessed 4 May 2023).
14. Nicolucci A, Kovacs Burns K, Holt RI, Comaschi M, Hermanns N, Ishii H, *et al.*; DAWN2 Study Group. Diabetes attitudes, wishes and needs second study (DAWN2™): cross-national benchmarking of diabetes-related

psychosocial outcomes for people with diabetes. *Diabet Med* 2013;**30**:767–77. https://doi.org/10.1111/dme.12245

15. Funnell MM, Bootle S, Stuckey HL. The diabetes attitudes, wishes and needs second study. *Clin Diabetes* 2015;**33**:32–6. https://doi.org/10.2337/diaclin.33.1.32
16. Martin GP, Weaver S, Currie G, Finn R, McDonald R. Innovation sustainability in challenging health-care contexts: embedding clinically led change in routine practice. *Health Serv Manage Res* 2012;**25**:190–9. https://doi.org/10.1177/0951484812474246
17. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and Evaluating Complex Interventions*. URL: https://mrc.ukri.org/documents/pdf/complex-interventions-guidance (accessed 20 December 2021).
18. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al*. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. *Health Technol Assess* 2021;**25**:1–132. https://doi.org/10.3310/hta25570
19. Turner J, Martin G, Hudson N, Shaw L, Huddlestone L, Weis C, *et al*. Using Normalisation Process Theory (NPT) to develop an intervention to improve referral and uptake rates for self-management education for patients with type 2 diabetes in UK primary care. *BMC Health Serv Res* 2022;**22**:1206. https://doi.org/10.1186/s12913-022-08553-7
20. Huddlestone L, Turner J, Eborall H, Hudson N, Davies M, Martin G. Application of normalisation process theory in understanding implementation processes in primary care settings in the UK: a systematic review. *BMC Fam Pract* 2020;**21**:52. https://doi.org/10.1186/s12875-020-01107-y
21. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology* 2009;**43**:535–54.
22. May C. Towards a general theory of implementation. *Implement Sci* 2013;**8**:18. https://doi.org/10.1186/1748-5908-8-18
23. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;**4**:50. https://doi.org/10.1186/1748-5908-4-50
24. Davies M, Kristunas CA, Huddlestone L, Alshreef A, Bodicoat D, Dixon S, *et al*. Increasing uptake of structured self-management education programmes for type 2 diabetes in a primary care setting: a feasibility study. *Pilot Feasibility Stud* 2020;**6**:71. https://doi.org/10.1186/s40814-020-00606-0
25. Davies MJ, Kristunas CA, Alshreef A, Dixon S, Eborall H, Glab A, *et al*. The impact of an intervention to increase uptake to structured self-management education for people with type 2 diabetes mellitus in primary care (the embedding package), compared to usual care, on glycaemic control: study protocol for a mixed methods study incorporating a wait-list cluster randomised controlled trial. *BMC Fam Pract* 2019;**20**:152. https://doi.org/10.1186/s12875-019-1038-0
26. Davies MJ, Bodicoat DH, Brennan A, Dixon S, Eborall H, Glab A, *et al*. Uptake of self-management education programmes for people with type 2 diabetes in primary care through the embedding package: a cluster randomised control trial and ethnographic study. *BMC Prim Care* 2024;**25**:136. https://doi.org/10.1186/s12875-024-02372-x
27. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med* 2008;**359**:1577–89. https://doi.org/10.1056/NEJMoa0806470
28. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC Health Serv Res* 2006;**6**:86. https://doi.org/10.1186/1472-6963-6-86
29. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, *et al*. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* 2010;**8**:63. https://doi.org/10.1186/1741-7015-8-63

30. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Health* 2019;**11**:589–97. https://doi.org/10.1080/2159676X.2019.1628806

31. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implement Sci* 2016;**11**:33. https://doi.org/10.1186/s13012-016-0398-2

32. Curtis L, Burns A. *Unit Costs of Health and Social Care 2020*. Canterbury: Personal Social Services Research Unit (PSSRU), University of Kent; 2020. https://doi.org/10.22024/UniKent/01.02.84818

33. National Institute for Health and Care Excellence. *Guide to the Methods of Technology Appraisal 2013*. NICE Process and Methods PMG9. London: NICE; 2013. URL: www.nice.org.uk/process/pmg9/chapter/foreword (accessed 9 April 2019).

34. National Institute for Health and Care Excellence. *Health Technology Evaluation. Process, Methods and Topic Selection Review: Conclusions and Final Review (Item 7).* Public board meeting agenda and papers: 19 January 2022.

35. National Institute for Health and Care Excellence. *The NICE Methods of Health Technology Evaluation: The Case for Change*. London: NICE; 2020.

36. Gæde P, Oellgaard J, Carstensen B, Rossing P, Lund-Andersen H, Parving HH, Pedersen O. Years of life gained by multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: 21 years follow-up on the Steno-2 randomised trial. *Diabetologia* 2016;**59**:2298–307. https://doi.org/10.1007/s00125-016-4065-6

37. Hatswell AJ, Bullement A, Briggs A, Paulden M, Stevenson MD. Probabilistic sensitivity analysis in cost-effectiveness models: determining model convergence in cohort models. *PharmacoEconomics* 2018;**36**:1421–6. https://doi.org/10.1007/s40273-018-0697-3

38. Pollard D, Pidd K, Breeze P, Brennan A, Thomas C. *Sheffield Type 2 Diabetes Treatment Model Version 3: With the Embedding RCT Health Economic Analyses Implemented*. Sheffield, UK: University of Sheffield; 2023.

39. Quinn LM, Woolley AK, Davies MJ, Bodicoat DH, Seidu S, Khunti K, Hadjiconstantinou M. Educational preferences in individuals with cardiometabolic disease differs with age, ethnicity and educational status. *Patient Educ Couns* 2022;**105**:3479–86. https://doi.org/10.1016/j.pec.2022.08.016

40. Health Innovation Network. *Structured Education for Type 2 Diabetes: A Toolkit for Optimal Delivery*. London: Health Innovation Network; 2014. URL: https://healthinnovationnetwork.com/resources/type-2-diabetes-a-toolkit-for-optimal-delivery-of-structured-education (accessed 25 April 2023).

41. Diabetes UK. *Taking Control HCP Toolkit*. URL: https://shop.diabetes.org.uk/products/taking-control-hcp-toolkit (accessed 25 April 2023).

42. Goff LM. Ethnicity and Type 2 diabetes in the UK. *Diabet Med* 2019;**36**:927–38. https://doi.org/10.1111/dme.13895

43. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes*. Oxford: Oxford University Press; 2015.

44. Pollard DJ, Keetharuth A, Brennan A, Bodicoat DH, Glab A, Hadjiconstantinou M, *et al*. A model based cost-utility analysis of Embedding referral to structured self-management education into standard practice (Embedding) compared to usual care for people with type 2 diabetes diagnosis in the last 12 months in England. *BMJ Open* 2025;**15**:e093327. https://doi.org/10.1136/bmjopen-2024-093327

45. Beaudet A, Clegg J, Thuresson PO, Lloyd A, McEwan P. Review of utility values for economic modeling in type 2 diabetes. *Value Health* 2014;**17**:462–70. https://doi.org/10.1016/j.jval.2014.03.003

46. Alva ML, Gray A, Mihaylova B, Leal J, Holman RR. The impact of diabetes-related complications on healthcare costs: new results from the UKPDS (UKPDS 84). *Diabet Med* 2015;**32**:459–66. https://doi.org/10.1111/dme.12647

47. Breeze P, Thomas C, Thokala P, Lafortune L, Brayne C, Brennan A. The impact of including costs and outcomes of dementia in a health economic model to evaluate lifestyle interventions to prevent diabetes and cardiovascular disease. *Med Decis Making* 2020;**40**:912–23. https://doi.org/10.1177/0272989X20946758

48. Curtis L, Burns A. *Unit Costs of Health and Social Care 2017*. Canterbury: Personal Social Services Research Unit; 2017.

49. Joint Formulary Committee. *BNF Online*. https://bnf.nice.org.uk (accessed 1 June 2021).

50. Tappenden P, Eggington S, Nixon R, Chilcott J, Sakai H, Karnon J. *Colorectal Cancer Screening Options Appraisal: Report to the English Bowel Cancer Screening Working Group*. Sheffield: School of Health and Related Research, University of Sheffield; 2004.

51. Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Searle A, Haase AM, *et al*. A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: the treating depression with physical activity (TREAD) trial. *Health Technol Assess* 2012;**16**:1–164, iii–iv. https://doi.org/10.3310/hta16100

52. National Institute for Health and Care Excellence. *Chronic Kidney Disease (Stage 5). Peritoneal Dialysis*. Clinical Guideline CG125. London: NICE; 2011.

53. Gordois A, Scuffham P, Shearer A, Oglesby A, Tobian JA. The health care costs of diabetic peripheral neuropathy in the US. *Diabetes Care* 2003;**26**:1790–5. https://doi.org/10.2337/diacare.26.6.1790

54. Madan J, Rawdin A, Stevenson M, Tappenden P. A rapid-response economic evaluation of the UK NHS Cancer Reform Strategy breast cancer screening program extension via a plausible bounds approach. *Value Health* 2010;**13**:215–21. https://doi.org/10.1111/j.1524-4733.2009.00667.x

55. National Institute for Health and Care Excellence. *Hypertension in Adults: Diagnosis and Management*. Clinical Guideline CG127. London: NICE; 2011.

56. Curtis L, Burns A. *Unit Costs of Health and Social Care 2020*. Canterbury: Personal Social Services Research Unit; 2020. https://doi.org/10.22024/UniKent/01.02.84818

57. Curtis L. *Unit Costs of Health and Social Care 2011*. Canterbury: Personal Social Services Research Unit; 2011.

58. Winkley K, Upsher R, Stahl D, Pollard D, Kasera A, Brennan A, *et al*. Psychological interventions to improve self-management of type 1 and type 2 diabetes: a systematic review. *Health Technol Assess* 2020;**24**:1–232. https://doi.org/10.3310/hta24280

59. Leal J, Alva M, Gregory V, Hayes A, Mihaylova B, Gray AM, *et al*. Estimating risk factor progression equations for the UKPDS Outcomes Model 2 (UKPDS 90). *Diabet Med* 2021;**38**:e14656. https://doi.org/10.1111/dme.14656

60. Sargeant JA, Brady EM, Zaccardi F, Tippins F, Webb DR, Aroda VR, *et al*. Adults with early-onset type 2 diabetes (aged 18–39 years) are severely underrepresented in diabetes clinical research trials. *Diabetologia* 2020;**63**:1516–20. https://doi.org/10.1007/s00125-020-05174-9

61. Sone H, Katagiri A, Ishibashi S, Abe R, Saito Y, Murase T, *et al*.; JD Study Group. Effects of lifestyle modifications on patients with type 2 diabetes: the Japan Diabetes Complications Study (JDCS) study design, baseline analysis and three year-interim report. *Horm Metab Res* 2002;**34**:509–15. https://doi.org/10.1055/s-2002-34791

62. Young RJ, Taylor J, Friede T, Hollis S, Mason JM, Lee P, *et al*. Pro-active call center treatment support (PACCTS) to improve glucose control in type 2 diabetes: a randomized controlled trial. *Diabetes Care* 2005;**28**:278–82. https://doi.org/10.2337/diacare.28.2.278

63. Adolfsson ET, Walker-Engström ML, Smide B, Wikblad K. Patient education in type 2 diabetes: a randomized controlled 1-year follow-up study. *Diabetes Res Clin Pract* 2007;**76**:341–50. https://doi.org/10.1016/j.diabres.2006.09.018

64. Ko SH, Song KH, Kim SR, Lee JM, Kim JS, Shin JH, *et al*. Long-term effects of a structured intensive diabetes education programme (SIDEP) in patients with Type 2 diabetes mellitus – a 4-year follow-up study. *Diabet Med* 2007;**24**:55–62. https://doi.org/10.1111/j.1464-5491.2007.02013.x

65. Sturt JA, Whitlock S, Fox C, Hearnshaw H, Farmer AJ, Wakelin M, *et al*. Effects of the diabetes manual 1:1 structured education in primary care. *Diabet Med* 2008;**25**:722–31. https://doi.org/10.1111/j.1464-5491.2008.02451.x

66. Gary TL, Batts-Turner M, Yeh HC, Hill-Briggs F, Bone LR, Wang NY, *et al*. The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial. *Arch Intern Med* 2009;**169**:1788–94. https://doi.org/10.1001/archinternmed.2009.338

67. Walker EA, Shmukler C, Ullman R, Blanco E, Scollan-Koliopoulus M, Cohen HW. Results of a successful telephonic intervention to improve diabetes control in urban adults: a randomized trial. *Diabetes Care* 2011;**34**:2–7. https://doi.org/10.2337/dc10-1005

68. Ali MK, Singh K, Kondal D, Devarajan R, Patel SA, Shivashankar R, *et al*.; CARRS Trial Group. Effectiveness of a multicomponent quality improvement strategy to improve achievement of diabetes care goals: a randomized, controlled trial. *Ann Intern Med* 2016;**165**:399–408. https://doi.org/10.7326/M15-2807

69. Odnoletkova I, Goderis G, Nobels F, Fieuws S, Aertgeerts B, Annemans L, Ramaekers D. Optimizing diabetes control in people with Type 2 diabetes through nurse-led telecoaching. *Diabet Med* 2016;**33**:777–85. https://doi.org/10.1111/dme.13092

70. Andrews RC, Cooper AR, Montgomery AA, Norcross AJ, Peters TJ, Sharp DJ, *et al*. Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial. *Lancet* 2011;**378**:129–39. https://doi.org/10.1016/S0140-6736(11)60442-X

71. Strong M, Oakley JE, Brennan A. Estimating multiparameter partial expected value of perfect information from a probabilistic sensitivity analysis sample: a nonparametric regression approach. *Med Decis Making* 2014;**34**:311–26. https://doi.org/10.1177/0272989X13505910

Appendix 1 Intervention delivery

Methods

Tracker data for embedder activity

The embedders recorded all of their activities with the SSME providers and primary care practices in 'trackers' (Excel spreadsheets) to inform the intervention costing.

In the tables, 'all' refers to general activities across the entire toolkit and includes all e-mail correspondence, initial meetings, action plan development, follow-up meetings, etc.

For the costing of the intervention, activities were also recorded under the heading of research costs to represent activities that would not need to be carried out should the intervention be rolled out (e.g. informing practices of start and end dates). The tables do not include research activities.

Toolkit data

Backend analytics data for the toolkit website were available. The available data were number of page views per day, number of active accounts for practices and providers, and page specific data (number of page views and average time on page).

Statistical analysis

Data were analysed using descriptive statistics, namely count (percentage) for categorical variables and median (interquartile range) for continuous variables.

Results

Tracker data for embedder activity

Table 3 summarises initiatives undertaken with an embedder. *Promoting to patients* was most commonly conducted overall, accounting for 41% of the activities. The least commonly conducted initiative was *Increasing referrals* (3%). The *how-to guides* (44%) and *promoting to patients* (52%) were the most common activities that the embedder conducted with providers and practices, respectively.

Table 4 summarises the tool articles used with an embedder. Overall, three articles and general use (e.g. log-in page) account for over 90% of counts of tool articles used. *Top tips for marketing* was the most used article, driven by the Campaign for Diabetes Week and the World Diabetes Day. The toolkit articles mainly used by providers with an embedder were *Providing choice for patients* and *Top tips for marketing*. Practices mainly used *Top tips for marketing* and *Increasing practice staff engagement* with an embedder.

TABLE 3 Number of initiatives undertaken by an embedder with SSME providers or primary care practices

Initiative	Providers, *n* (%)	Practices, *n* (%)	Total, *n* (%)	Total time spent (hours)
Promoting to patients	75 (23.1)	287 (51.5)	362 (41.0)	175.08
How to guide	144 (44.3)	143 (25.7)	287 (32.5)	193.53
All	87 (26.8)	119 (21.4)	206 (23.4)	130.78
Increasing referrals	19 (5.8)	8 (1.4)	27 (3.1)	18.46
Total	325 (100.0)	557 (100.0)	939 (100.0)	517.85

TABLE 4 Tool articles used as part of the intervention with an embedder

Tool/article	Overall, *n* (%)	Provider, *n* (%)	Practice, *n* (%)
Top tips for marketing	342 (38.8)	71 (21.8)	271 (48.7)
General	220 (24.9)	90 (27.7)	130 (23.3)
Increasing practice staff engagement	139 (15.8)	4 (1.2)	135 (24.2)
Providing choice for patients	101 (11.5)	101 (31.1)	0 (0.0)
Referrer engagement event	16 (1.8)	1 (0.3)	15 (2.7)
Self-referral	13 (1.5)	13 (4.0)	0 (0.0)
Adapting your programme to suit local needs	13 (1.5)	13 (4.0)	0 (0.0)
Social media	9 (1.0)	9 (2.8)	0 (0.0)
Advertising on referring practice websites	8 (0.9)	6 (1.8)	2 (0.4)
Ensuring accessibility	7 (0.8)	7 (2.2)	0 (0.0)
Improving patient and referrer discussions	6 (0.7)	6 (1.8)	0 (0.0)
How to work with public involvement	3 (0.3)	0 (0.0)	3 (0.5)
Evaluating your programme	3 (0.3)	3 (0.9)	0 (0.0)
Collect and report audit data	1 (0.1)	1 (0.3)	0 (0.0)
Education champions	1 (0.1)	0 (0.0)	1 (0.2)
Total	882 (100.0)	325 (100.0)	557 (100.0)

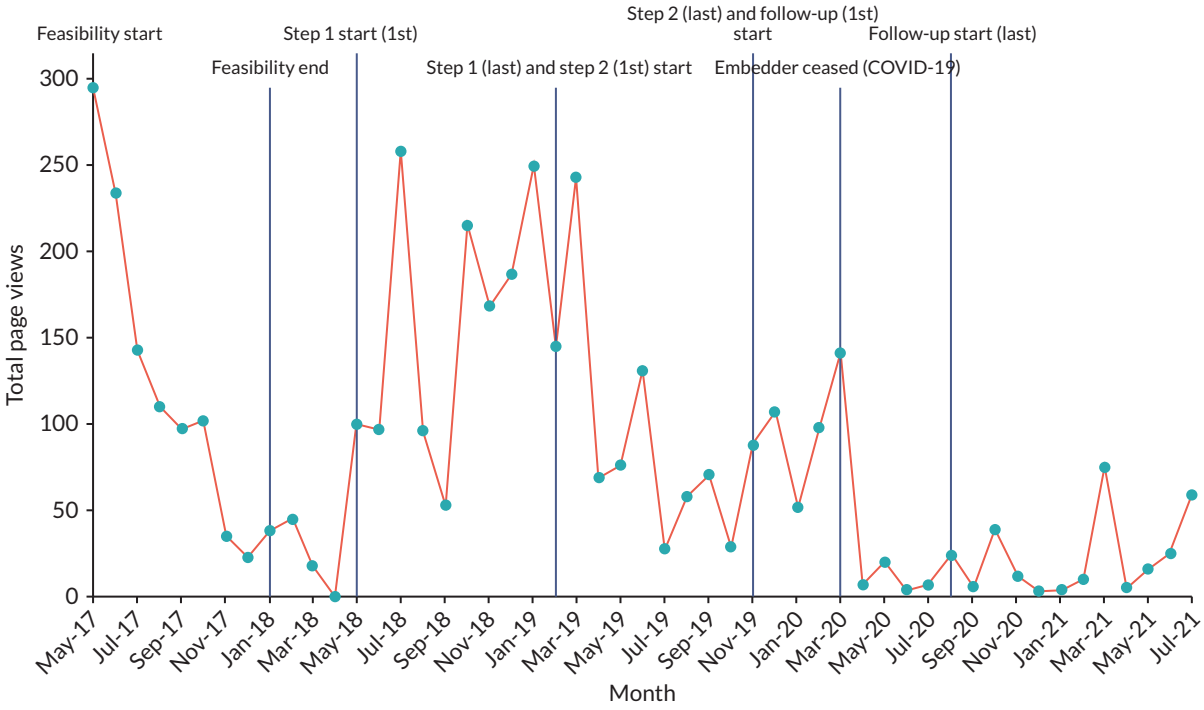

FIGURE 5 Page views of the embedding toolkit by week. Notes: '1st' indicates the first month when at least one practice started that step. 'Last' indicates the last month when a practice started that step.

Toolkit website usage data

There were 88 live accounts for the toolkit; 68 (77.3%) assigned to practices, 18 (20.5%) assigned to providers, and 2 (2.3%) assigned to commissioners. The practice accounts used a generic account name and so were potentially accessed by more than one individual.

Figure 5 shows the number of page views for the toolkit by week. It was not possible to separate these by user, so page views include views by embedders and study staff. Page views peaked at nearly 300 views per week at the start of the feasibility study and then rapidly declined to fewer than 50 views per week by the end of the feasibility study. During step one, page views were variable between around 100–250 views most weeks. However, during step two and the start of the observational follow-up, page views were lower at around 25–140 page views per week. Page views dropped noticeably to fewer than 50 per week once the COVID-19 pandemic started and all embedder activity ceased, although there was an indication that this was starting to rise again towards the end of the follow-up.

Table 5 shows usage data for the toolkit over the study period. Again, it was not possible to separate out usage by study staff, embedders and other users; therefore these data cover all users. The three most viewed pages were navigational pages (*login*, *how to guides*, *promoting to patients*). The three least viewed pages were *adaptation* (of SSME programmes), *setting up a signposting hub* and *providing choice for patients*. However, this last page had the highest average view time (approximately 4.5 minutes) showing that those who did visit the page stayed on it for some time.

TABLE 5 Total page views and average time on page for toolkit website over the feasibility study and wait-list RCT

Page	Page views	Average time on page (mm:ss)
Login	359	00:28
How to guides	345	01:33
Promoting to patients	217	00:50
Increasing referrals	208	00:43
Join us	181	00:54
About us	173	01:17
Why structured education	113	01:34
Roles	76	00:16
Top tips for marketing	68	02:03
Diabetes education – Get in the know campaign	62	02:13
Improving the referrer and patient discussion	57	01:27
Assess your community needs	50	01:47
Referrer engagement events and awareness raising	49	02:01
Improving your referral pathway and admin systems	46	03:07
Increasing staff engagement	44	00:51
Using social media	40	03:32
Designing and implementing a marketing plan	39	00:46
Education champions	37	01:08

continued

TABLE 5 Total page views and average time on page for toolkit website over the feasibility study and wait-list RCT (*continued*)

Page	Page views	Average time on page (mm:ss)
Self-referral	36	01:37
Collecting and reporting audit data	35	01:40
Linking with patient's annual review	33	02:39
Ensuring accessibility	32	03:55
Advertising on referring practice websites	32	03:17
Developing a communications strategy	28	00:34
Cultural adaptation	27	03:10
How to work with public involvement	27	00:36
The role of the co-ordination office	26	00:57
Guidance for local administrators' telephone	24	03:31
Setting up text reminder services	22	01:34
Evaluating your programme	22	01:22
Adaptation	20	02:17
Setting up a signposting hub	16	00:42
Providing choice for patients	15	04:27

Appendix 2 Costing the intervention

Methods

Data collection

The embedders recorded all embedding-related activities at the practice and provider levels in an Excel spreadsheet, henceforth referred to as trackers (see *Appendix 1*). The embedders recorded the initiatives undertaken (toolkit, promoting to patients, increasing referrals), the toolkit articles used (e.g. top tips for marketing, increasing practice staff engagement, providing choice for patients), details of the activities, date and time taken to carry out the activities. In addition to providing an audit of the various activities attempted, the trackers provided a measure of resource use against which unit costs were applied to estimate the costs associated with the Embedding Package.

Updated tackers were discussed with embedders approximately every 3 months to check completion rates and resolve any data queries. Data on travel and subsistence and on production of marketing materials and the toolkit were made available by the research team. No data were collected for activities during the control phases and, as such, the costs associated with the embedding activities are the incremental costs of embedding activities.

Main analysis

The primary (base-case) analysis estimated the costs of Embedding activities as implemented across all practices within the wait-list RCT. Secondary analyses estimated the costs for the complete-case practices and in the two groups of practices to explore possible differences between the two waves, for example, due to learning curve effects or length of implementation.

Intervention costing

The base-case analyses were carried out with costs from the 64 ITT practices. Costs were calculated and reported separately for the 33 immediate and 31 wait-list practices. Aligning with the statistical analyses, costs were also calculated for the 57 complete-case practices (28 immediate; 29 wait-list).

Intervention costs fell into six categories: embedder costs; practice costs (staff); provider costs (staff); toolkit costs (initial and recurrent); marketing materials costs; travel and subsistence.

Based on the activities from the trackers, we attributed costs for practice administrative staff, managers, nurses, GPs and providers for attending meetings and costs of administrative staff to follow up on arranging meetings. Unit costs for staff time were from the *Unit Costs of Health and Social Care* publication.[32] For the embedders, individual staff were matched to Agenda for Change bands, while for other staff, job title was used to identify the most relevant unit cost. Non-staff costs were taken from actual expenditure from the study. Staff costs were for the financial year 2019–20 and are summarised in *Table 6*.

Discounting

Initial costs of the toolkit were annuitised. Otherwise, no discounting was applied as all costs occurred within 1 year of the intervention going live.

Missing data

All ITT practices had a tracker. The only missing data were for time spent on embedding-related activities (< 3%), for which the mean value for that activity from complete trackers was imputed.

Sensitivity analysis

The principal area of uncertainty for the Embedding Package costs was around how it would be rolled out in standard practice, as opposed to within a research project. Two aspects of delivery were identified as likely to change in standard practice. First, the intervention was delivered and facilitated by the embedders who were associated with the project team and based in one location. However, should the intervention be rolled out, it is likely that the embedders would

TABLE 6 Costs used in analyses and sources

Staff costs	Cost (2019–20), £	Source	Details/assumptions
Embedder (senior)	58	Embedders (band) and Agenda for Change rates from Personal Social Services Research Unit[32]	
Embedder (junior)	36		
Practice administrative staff	25		Estimated 12 minutes[a] to follow up on activities such as arranging meetings with embedders
Practice manager	58		
Practice nurse	39		
Diabetes specialist nurse	49		
GPs	156		
Provider staff (lead)	49		
Other costs			
Marketing materials costs	Variable	Provided by the research team	Allocated to practices where stated, or equally if not specified.
Travel and subsistence expenses for embedders	Variable		Allocated equally across all practices only. There was no information to differentiate costs incurred between practice and providers. As the claim or mileage had not changed, this was not adjusted for inflation.
Website	Variable		Includes one-off and recurring costs. The one-off cost was converted to an annual cost using the annuitisation procedure.[43] We used an interest rate of 3.5%, assuming that the website would have a lifetime of 5 years and the costs were incurred upfront. The recurring costs were adjusted for 2019 prices.

a Estimate based on the opinions of the embedders.

be more locally based, potentially as part of the education provider team. Therefore, we have estimated costs excluding travel and subsistence. Second, the embedding staff in the study needed to have considerable research experience as well as the skills needed to deliver the intervention, and as a result, their Agenda for Change banding was probably higher than would be expected for standard practice. Consequently, we costed the intervention using lower Agenda for Change bandings for the lead embedder than those used for this research study (band 5 vs. band 7).

Results

Table 7 shows the costs associated with intervention delivery for the ITT practices by wait-list practices, immediate practices and providers (who worked with both sets of practices). The central role of the embedders is demonstrated by their costs amounting to 71% of the total intervention costs. Embedder costs were higher (60%) at the provider-level than the practice-level, highlighting the volume of work that the embedders carried out with providers. The second most significant costs were the combined costs of provider and practice staff directly incurred for them to attend meetings and follow up on activities initiated by embedders. The total costs for immediate practices were 44% and 41% higher than those for wait-list practices for the ITT and complete-case populations, respectively. Results based on the complete-case population were very similar.

The sensitivity analyses showed a 31% reduction in costs from £40,316 to £27,751 in the ITT population and a 32% reduction from £39,188 to £26,744 in the complete-case population (detailed results available on request due to space limitations here).

TABLE 7 Intervention costs based on intention-to-treat population for when the intervention was being delivered

Type of cost	Wait-list, £ (%)	Immediate, £ (%)	Provider, £ (%)	Total costs, £ (%)
Embedder direct costs	3650 (13)	7746 (27)	17,200 (60)	28,596 (71)
Practice costs (staff)	185 (11)	1471 (89)	N/A	1656 (4)
Provider costs (staff)	N/A	N/A	3358 (100)	3358 (8)
Travel and subsistence	551 (13)	3827 (87)	N/A	4378 (11)
Marketing materials costs	600 (47)	687 (53)	N/A	1288 (3)
Toolkit costs	504 (48)	537 (52)	N/A	1041 (3)
Total costs	5490 (14)	14,268 (35)	20,558 (51)	40,316 (100)

The number of days between the first activities and the last activities carried out by the embedders as part of the intervention ranged between 1 and 323. The mean (median) numbers of days between the first and last embedding activities were 170 (174) for all practices, 134 (131) for wait-list practices and 204 (199) for immediate practices.

Given the different periods under consideration for the wait-list and immediate practices, the costs were adjusted to the longer period so that they were comparable (*Table 8*). The adjusted results show that the costs per month between the two waves of practices were very similar.

The difference in cost per patient was slightly larger, proportionately, due to differences in patient population sizes. The costs per patient for the ITT and complete-case practices for the scenario analysis were £0.52 and £0.59, respectively. Similar results are observed in the sensitivity analyses where the costs per patient for the ITT and complete-case practices for the scenario analysis were £0.36 and £0.40, respectively (results available on request).

TABLE 8 Costs of the intervention (base-case and secondary analysis)

	Intention-to-treat population (base case)			Complete-case population (secondary)		
	Wait-list (*n*)	Immediate (*n*)	All practices (*n*)	Wait-list (*n*)	Immediate (*n*)	All practices (*n*)
Total costs (£) for the whole duration of the trial	15,568	24,748	40,316	16,805	22,383	39,188
Practices (*n*)	31	33	64	29	28	57
Mean number of days when intervention was delivered	134	204	170	139	202	170
Mean cost (£) per practice for 204 days	765	750	757	842	799	821
Number of patients with T2DM	48,529	44,448	92,977	45,556	34,431	79,987
Mean cost (£) per T2DM patient for 204 days	0.4884	0.5568	0.5211	0.5361	0.6501	0.5852

Discussion

We calculated the intervention costs for ITT and complete-case practices. Sensitivity analyses were carried out accounting for uncertainties around real-world implementation of the intervention, as opposed to delivery within a research project. Costs in the wait-list and immediate practices were very similar suggesting that the implementation of the Embedding Package was similar across the two waves and reasonably constant over time. Consequently, for the cost-effectiveness modelling, the pooled cost per patient of £0.521 can be used (£0.363 for sensitivity analysis).

Costs were based on practice and provider specific data collected by the embedders. These data were regularly checked and discussed leading to minimal missing data within recorded activities. Unit costs for staff time were based on established sources, although one minor assumption was required about the length of one set of activities. Project expenditure data were used for non-staff expenditure and were considered very accurate.

We consider there to be three potential weakness with our estimates. First, the intervention as delivered in the project may not reflect how we would expect it to be delivered in normal practice. However, we have examined this in our sensitivity analysis by exploring the impact of a less centralised model, with lower grade staff and the embedders being based more locally to SSME providers. This analysis produced a 31% reduction in cost per patient.

Second, while missing data within the activities recorded in the trackers was minimal, it is possible that some activities were not recorded at all. Possible reasons for this could be that the embedders were unaware that the activities took place, or they were not recorded as they were not thought to be embedding activities. We guarded against potential misclassification of activities as being unrelated to embedding, through our regular data checks with embedders. Consequently, the low cost per practice of £757 (ITT practices) appears to be the result of the lower than anticipated engagement of practices within the study, coupled with the general low cost per patient of the intervention.

Third, there were several deviations from the protocol in relation to the data collection methods. The embedders were to complete a simple tick-box tracker of the preidentified implementation activities. We had intended to verify the unit costs through structured interviews undertaken with designated staff at provider organisations within a sub-sample of 12 practices. Three changes were made to this process. Instead of using a simple tick-box tracker, the embedders recorded detailed entries in an Excel spreadsheet. In lieu of obtaining detailed costings for 12 practices only, it was possible to calculate costings for all the practices given the high-quality data recorded in the trackers. This made the costings more robust and accurate without the need to impute. We undertook an interview with one provider organisation, which confirmed that they unaware of what happened at the practice level and were therefore unable to verify the tracker data.

Appendix 3 Cost-effectiveness

Methods

Analyses followed a health economics analysis plan (see *Report Supplementary Material 4*).

Health state utility value update

We updated the searches of Beaudet *et al.* (see *Report Supplementary Material 5*).[45]

Health state costs

We updated the model to use costs in Alva where possible.[46] Other costs were as per Breeze *et al.*[47] *Table 9* summarises the costs used in 2019–20 prices, with costs from previous years inflated using published indices.[56,57]

We assumed:

- Secondary care visits accorded with UK Prospective Diabetes Study (UKPDS) analysis of hospital visits for someone with no diabetes-related complications.[46]
- For people receiving first- or second-line pharmacotherapy, primary care visits included 1 eye screening visit/year, 1 nurse visit, 1 healthcare assistant visit, tests for HbA1c, lipids, liver function test, B12 and urine, and 730 metformin tablets/year. People receiving second-line pharmacotherapy also received 365 sitagliptin tablets and 82 blood glucose self-test kits.
- For people receiving third-line pharmacotherapy, primary care visits included 1 eye screening visit/year, 3 nurse visits, 3 healthcare assistant visits, 3 tests for HbA1c, lipids, liver function test, B12 and urine, treatment with insulin glargine and 82 blood glucose self-test kits.

Evaluation methods

Model used

National Institute for Health and Care Research School for Public Health Research T2DM treatment model version 2, which is an individual level simulation of diabetes-related complications for people with T2DM. Compared with version 1,[58] we have updated risk factor progression and risk equations to use UKPDS 90, updated utilities and updated the costs of diabetes-related complications.[45,46,58,59]

Perspective

National Health Service and Personal Social Services perspective.[33]

Population

Individual-level population from the simulation distributions reported in the NICE guideline.[9]

Discounting

Followed NICE's 2013 methods guide with future costs and QALYs discounted at 3.5% per annum.[33]

Time horizon

Lifetime.

Costs

Intervention costs were obtained from costing analyses (see *Appendix 2*). The cost of SSME courses were obtained from Gillett *et al.*,[7] assuming that all courses have the same cost as DESMOND.

TABLE 9 Summary of health state costs used in School for Public Health Research T2DM model version 2

Cost incurred	Mean		Source
Metformin and primary care	633.94		46,48,49
Metformin, sulfonylurea and primary care	1094.61		
Insulin and primary care	2049.80		
Hypertension treatments	209.81		49
Statins	13.20		
Fatal myocardial infarction[a]	585.84		46
Fatal ischaemic heart disease[a]	3067.36		
Fatal stroke[a]	3275.17		
Osteoarthritis	868.17		50
Depression	595.60		51
Renal failure	24,040.01		52
Foot ulcer	378.28		53
GP	39.12		48
Breast cancer	12,646.68		54
Colorectal cancer	25,362.24		50
Hypertension diagnosis	43.99		55
Adjustments			
Being male	-420.03		46
Being aged > 65 years	46.42		
	Year of event	***Previous year***	
Myocardial Infarction	7010.16	921.87	46
Stroke	7632.48	983.77	46
Chronic heart failure	3513.92	1608.29	46
Ischaemic heart disease	10,655.62	970.50	46
Amputation	12,439.67	2666.12	46
Blindness	2380.94	221.07	46

a As the model risk equations do not attribute death to a particular cause, these costs were assumed to apply if an individual died in the same year that they experienced one of these events.

Prices

All costs were in pounds sterling and 2019–20 prices. Costs from previous years, were inflated using the hospital and community health services pay and prices index (up until 2014–5) and NHS cost inflation index pay and prices index (from 2015 to 2016 onwards).[32,57]

Effects

Base-case analyses used changes in risk factors (HbA1c, body mass index, systolic blood pressure, HDL, lipid cholesterol, low-density lipid, LDL, cholesterol) and SSME uptake under intervention and control conditions from

the RCT analyses. We assumed that all individuals under the intervention condition received these mean effects. In year 1 of the model, these changes were obtained from the RCT results, which on average occurred approximately 13.5 months into the intervention period across all sites. Estimates of mean change in HbA1c and SSME uptake for year 2 of the model were obtained using the observational follow-up analyses. The intervention effect on some risk factors (body mass index, systolic blood pressure, HDL cholesterol, LDL cholesterol) was not estimated in the observational follow-up analyses, so we assumed that the intervention effect on the mean change in these risk factors in year 2 was the same as in year 1.

Duration of effect

In the base case, we assumed that the intervention effects are fully maintained for 3 years because clinical opinion of key trial management group members was that this is the most likely time horizon over which the effects will be maintained.

Probabilistic sensitivity analysis

As the model has been shown to be non-linear, the base-case analysis was probabilistic (i.e. all model parameters are randomly sampled from an associated distribution, the model is run for this set of parameters, the results are recorded, and the process is repeated for a set number of runs). We ran the model with 5000 patients and 2000 probabilistic analysis runs. Two thousand probabilistic runs were assessed as sufficient using the Hatswell *et al.*[37] method at a threshold ICER of £20,000 per QALY gained.

Scenario analyses

1. Discounting: future costs and QALYs discounted at 1.5% per annum. NICE noted that there was a case for using 1.5% as an alternative discount rate.[34,35]
2. Set insignificant secondary outcomes to zero effect: assume that all statistically insignificant secondary outcomes in the RCT have no effect.
3. Only use results from RCT analysis: assume that change in HbA1c and uptake of SSME in year 2 onwards are taken from the main RCT results.
4. Use only effect data on SSME uptake from the RCT and apply effect of SSME uptake on HbA1c based on a meta-analysis of published studies: Effect of SSME uptake is directly given to those individuals who attend SSME, rather than giving all individuals mean effects estimated from the embedding study. The effect of SSME attendance was obtained by conducting a meta-analysis of included studies in a recent review.[60] Thirteen studies were considered for data extraction,[2,3,6,61–70] with data on any effect of SSME programmes on HbA1c, body mass index HDL cholesterol, LDL cholesterol and systolic blood pressure within a 6-month window of 1-year follow-up extracted. Studies with 1-year outcomes, and those with outcomes within a 6-month window of 1-year follow-up, were analysed as subgroups and together. Longer-term outcomes were extracted where available. Random-effects meta-analyses were conducted using RevMan v5.4 (Cochrane Collaboration, UK). We assumed that SSME is effective for 6 years in full with waning by the 10th year based on the DESMOND follow-up and STENO II trial.[5,36]
5. Scenario 3 and 4 combined. Means that individuals under the intervention conditions are less likely overall to receive SSME benefits.
6. Duration of effect is assumed to be longer than the base case:
    a. 5 years where the effect is fully maintained and no effect afterwards.
    b. 10 years full maintenance of effect and no effect afterwards.
7. Duration of effect is assumed longer than in scenario 4:
    a. 10 years where the effect is maintained in full, with gradual waning by the end of year 15.
    b. Lifetime effect.

Outcome measures

The primary outcome was the ICER, calculated as (difference in discounted cost between intervention and control) divided by (differences in discounted QALYs between intervention and control), unless intervention or control is more effective and cheaper than the other, in which case the more effective and cheaper one is deemed dominant and an ICER is not calculated.

To interpret the ICER, we compared calculated ICER with £20,000 per QALY gained (the lower end of NICE's typical range of threshold ICERs).[33] iNMB was calculated as £20,000*incremental QALYs minus incremental costs.

In line with our protocol, we also produced cost-effectiveness acceptability curves and conducted expected value of information analyses using Sheffield Accelerated Value of Information methods.[71] We produced estimates for the following parameter combinations: all effectiveness parameters, all cost parameters and all utility parameters.

Results

Base-case analysis

The intervention dominated usual care (i.e. it produced more QALYs at a lower cost; see *Table 2*). The differences in costs and QALYs were very small; however, the 95% CI for the iNMB did not include £0. The results were highly uncertain, with runs scattered either side of the ICER equals £20,000 per QALY line and the intervention having just over a 50% chance of providing the most net benefit at all thresholds between £0 and £50,000 per QALY gained (*Figures 6* and *7*).

Value of information

The overall expected value of information at a decision-making threshold of £20,000 per QALY gained was £445 per person (*Table 10*). The subset of parameters with the most value for conducting further research was around the model risk equations and risk factor evolution. The value of conducting further research into the intervention effectiveness was relatively small (£24 per person).

Meta-analysis results

Figures 8–13 show the random-effects meta-analyses results.

Scenario analysis results

The results were insensitive to most scenarios, in that the Embedding Package was dominant (see *Table 2*). However, usual care was favoured in two scenarios.

Updated results

We updated the model to version 3.0, which corrected two coding errors for the eGFR variables for UKPDS 82 (tobit for eGFR > 60 now applied to people whose eGFR is > 60 rather than < 60; tobit for eGFR < 60 now applied to people whose eGFR is < 60 rather than > 60). An executable version of the model that produces comma-separated values

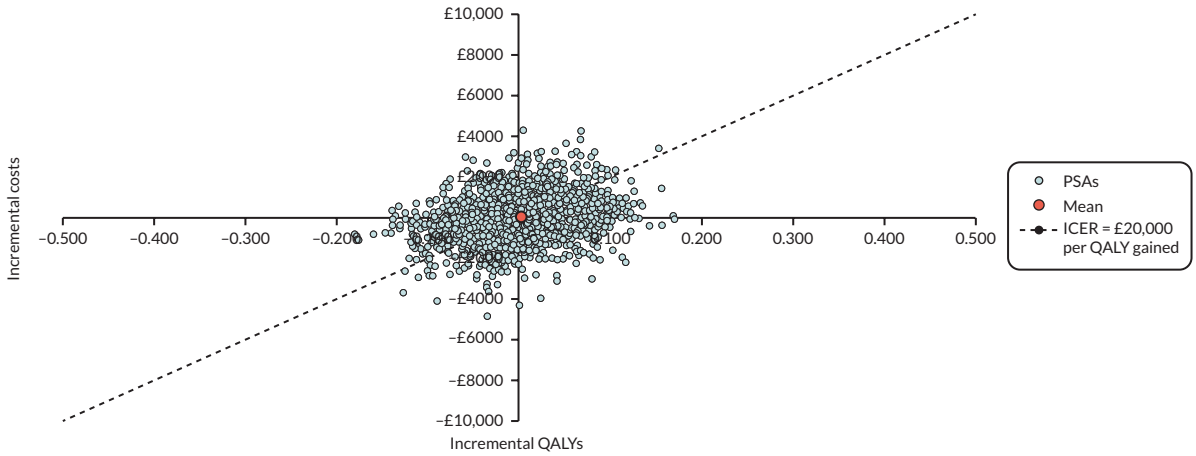

FIGURE 6 Cost-effectiveness plane for base-case analysis. PSA, probabilistic sensitivity analysis.

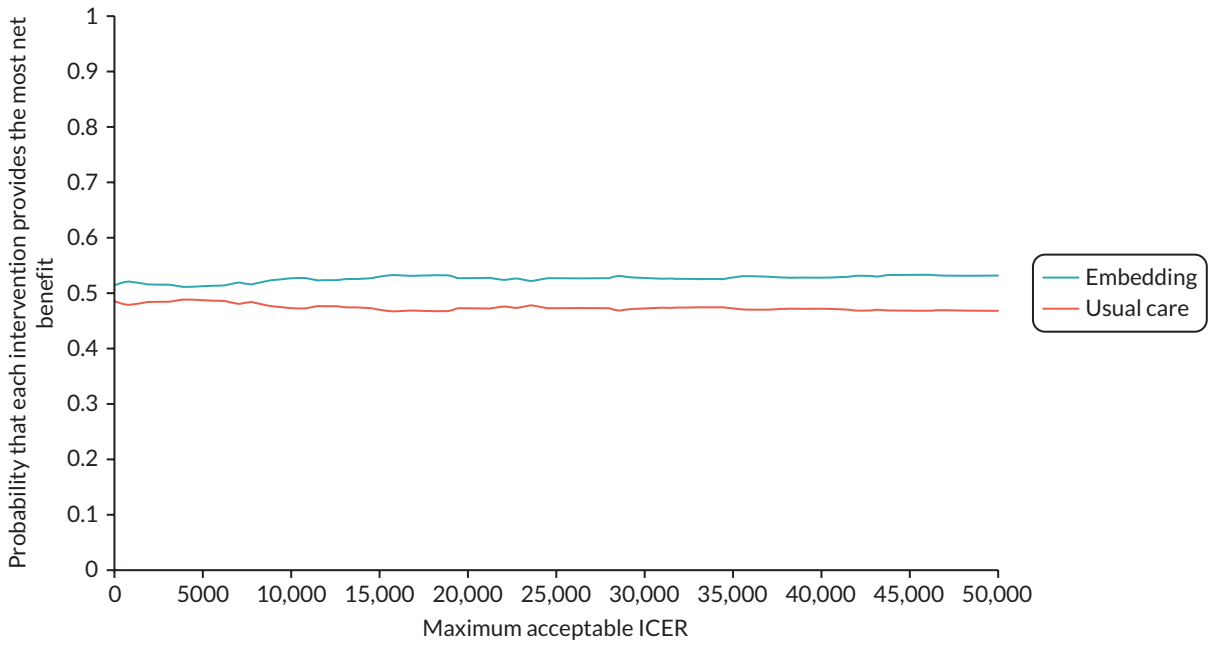

FIGURE 7 Cost-effectiveness acceptability curve for base-case analysis.

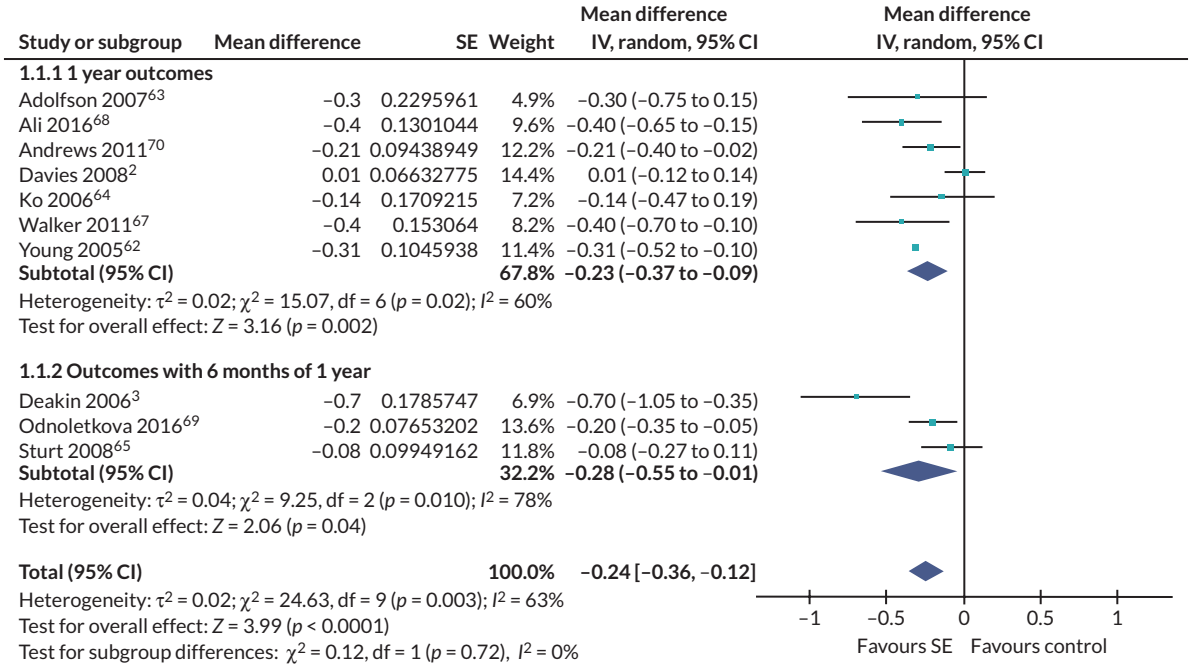

FIGURE 8 Random-effects meta-analysis of HbA1c at 1 year post treatment. SE, standard error.
Reproduced with permission from Pollard *et al.*[44] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

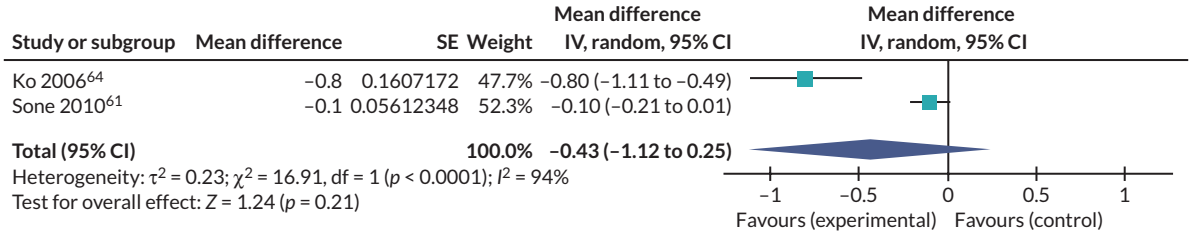

FIGURE 9 Random-effects meta-analysis of HbA1c at 4 years post treatment.
Reproduced with permission from Pollard *et al.*[44] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

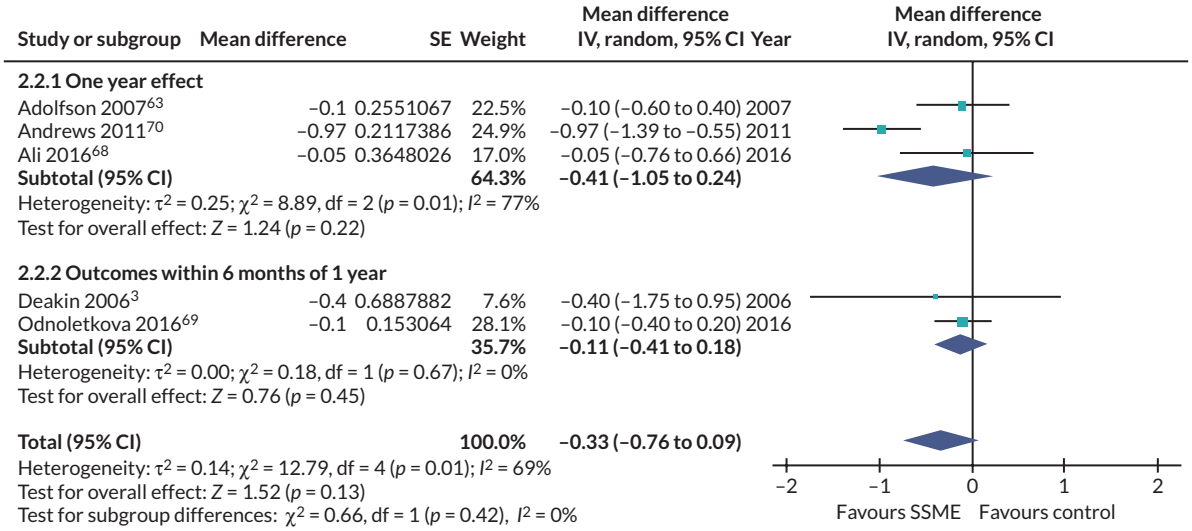

FIGURE 10 Random-effects meta-analysis of body mass index at 1 year post treatment.
Reproduced with permission from Pollard *et al.*[44] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

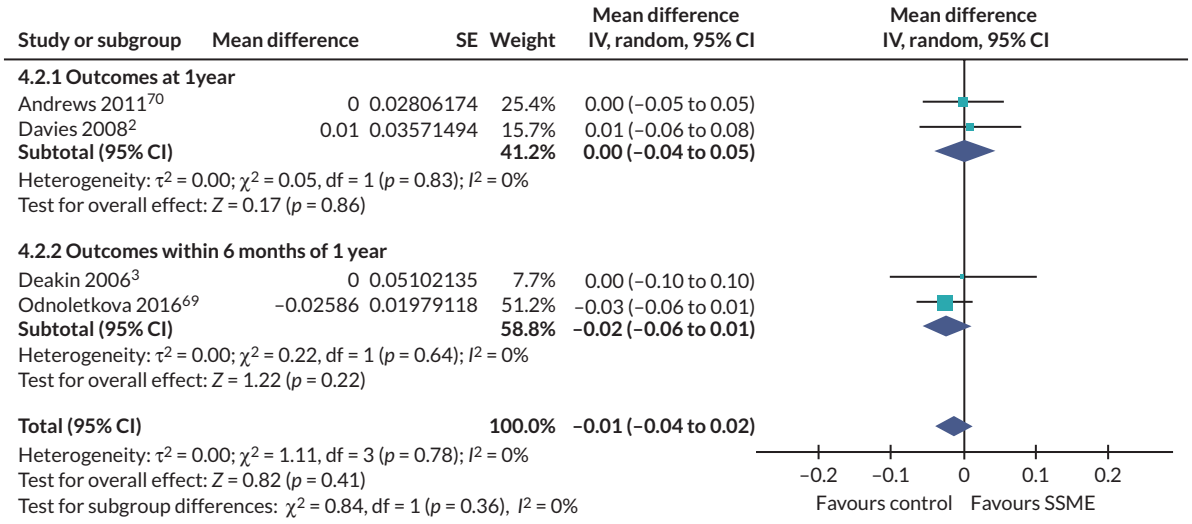

FIGURE 11 Random-effects meta-analysis of HDL at 1 year.
Reproduced with permission from Pollard *et al.*[44] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

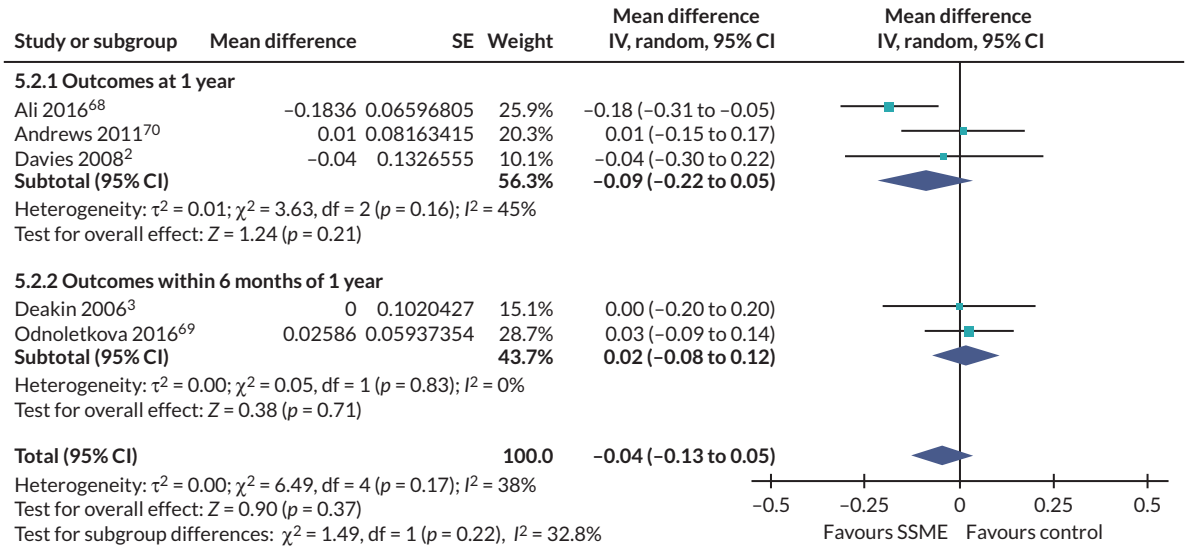

FIGURE 12 Random-effects meta-analysis of LDL cholesterol.

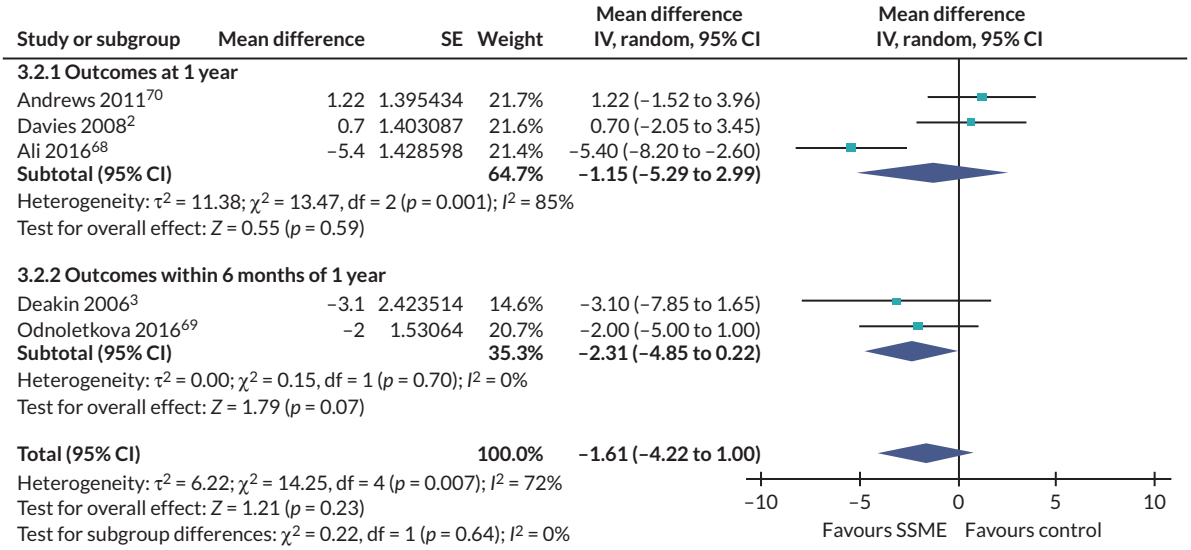

FIGURE 13 Random-effects meta-analysis of systolic blood pressure.

files that can be used to produce these results are available open access.[37] Analyses, run in R version 4.3.0 (The R Foundation for Statistical Computing, Vienna, Austria), used a 50-year time horizon in which 99.2% of patients died in the deterministic model runs.

The results are largely the same as before, with very small cost and QALY differences between the two treatments (*Table 11*). However, the parameter uncertainty is much smaller as seen in the cost-effectiveness plane and the cost-effectiveness acceptability curve (*Figures 14* and *15*). All the same structural uncertainty around the input evidence remains.

TABLE 10 Expected value of parameter information results from the Sheffield Accelerated Value of Information tool

Parameters	Per-person EVPPI	Standard error	Indexed to overall EVPI
Overall EVPI	445	NA	1.00
UKPDS OMv2: mortality equations	202	14.6	0.45
UKPDS OMv2: microvascular complication equations	220	14.3	0.49
UKPDS OMv2: macrovascular complication equations	185	15.6	0.42
UKPDS 90: risk factor progression and risk equations	244	14.1	0.55
Utility parameters	45	13.2	0.10
Cost parameters	187	15.2	0.42
Effectiveness parameters from embedding	24	12.0	0.05

EVPI, expected value of perfect information; EVPPI, expected value of perfect parameter information; OMv2, Outcomes Model version 2.

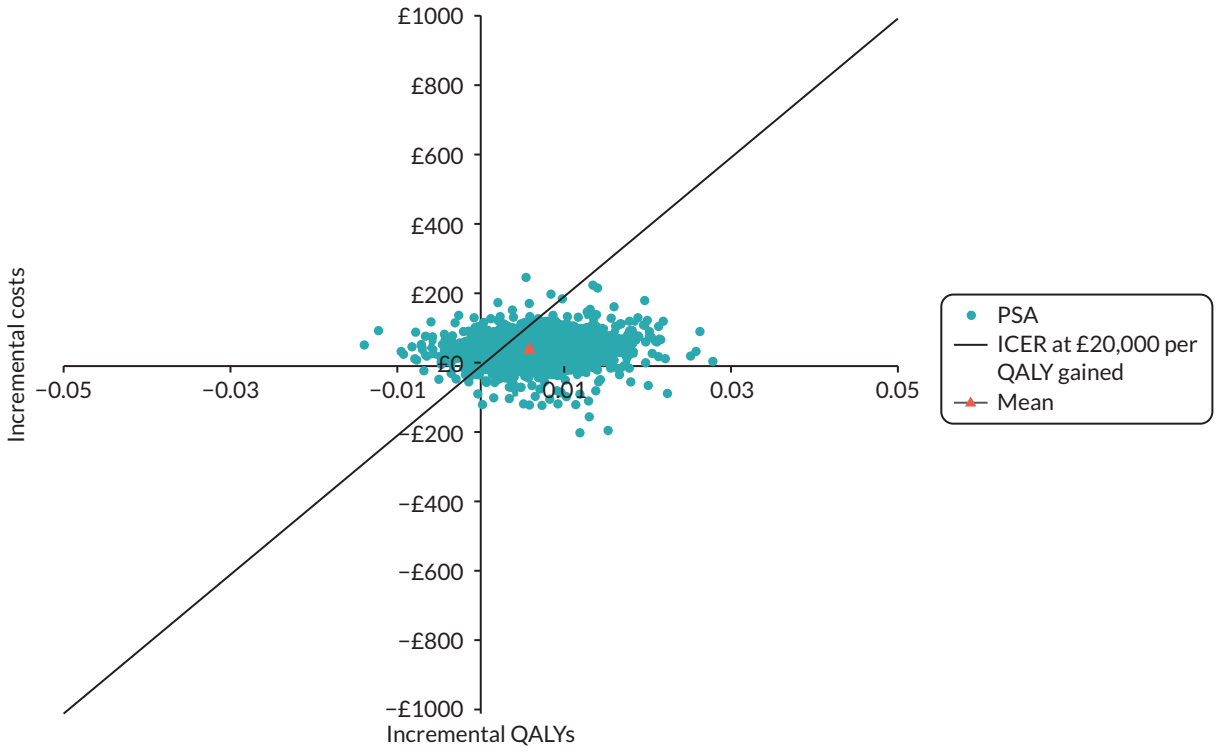

FIGURE 14 Cost-effectiveness plane for revised base-case analysis. PSA, probabilistic sensitivity analysis.

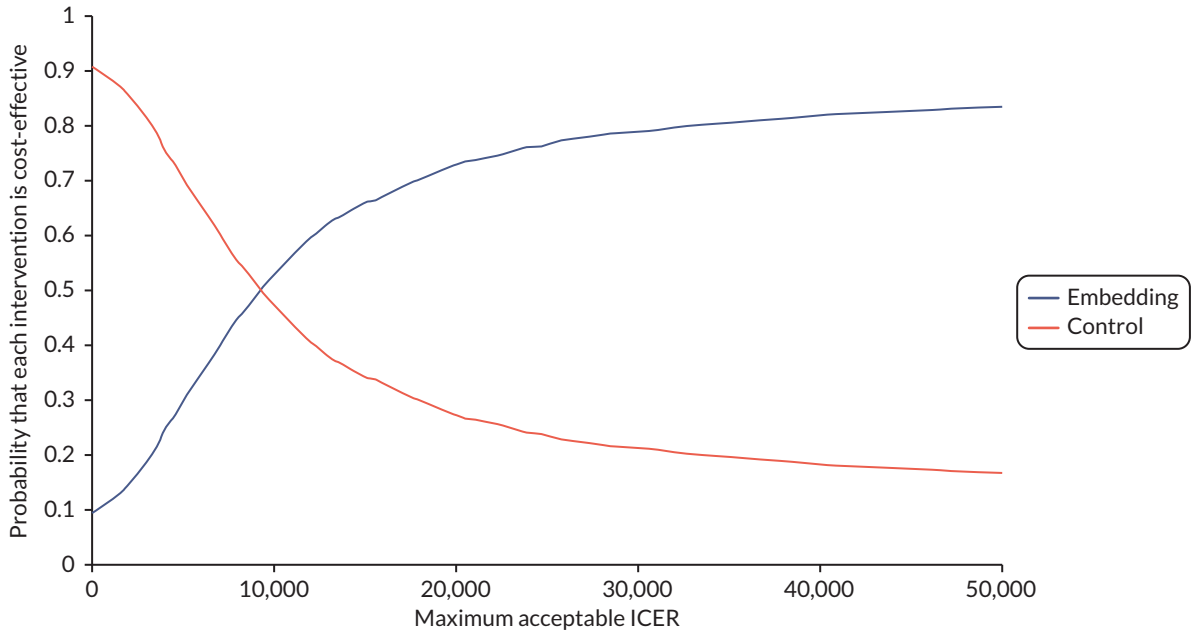

FIGURE 15 Cost-effectiveness acceptability curve for revised base-case analysis.

TABLE 11 Revised cost-effectiveness scenarios

	Incremental costs (£)[a]	Incremental QALYs[a]	Prob Embedding is cost-effective at £20,000 per QALY gained (%)	ICER (£)	iNMB (£)
Base case	49.90	0.0059	72.8	8387	69.09
S1 – discounting at 1.5%	51.27	0.0068	73.3	7511	85.24
S2 – no insignificant secondary outcomes	−3.12	0.0014	80.1	Embedding dominates	31.97
S3 – only use results from main step-wedge	−4.41	0.0049	85.2	Embedding dominates	103.17
S4 – only use SSME uptake from the trial, apply SSME effectiveness from a meta-analysis	3.30	0.002	59.3	2113	27.93
S5 – S3 + S4	1.04	−0.0030	14.4	Control dominates	−60.69
S6a – 5 years of full effect	43.95	0.0093	83.4	4712	142.60
S6b – 10 years of full effect	36.94	0.016	90.6	2333	279.75
S7a – S4 + SSME benefits last in full for 10 years and wane after 15 years	4.29	0.0021	61.5	2069	37.17
S7b – S4 + SSME benefits last in full for a lifetime	1.69	0.0032	66.1	535	61.43

a Calculated as the intervention value – usual care value.

Appendix 4 Qualitative substudy

Methods

The initial plan was to recruit staff involved in virtual SSME provision and delivery, and people with T2DM who attended virtual SSME (referred to as 'attendees') from four providers. However, the COVID-19 pandemic impacted on practice staff capacity and redeployment more than initially expected, so we recruited staff and attendees from two participating providers. Although both sites delivered virtual SSME, these programmes were by different providers. Data collection was via one-to-one telephone and video (Microsoft Teams) calls facilitated by one qualitative researcher.

Recruitment strategy for staff

Using the established relationship between the project manager and the site managers, the project manager made initial contact with the two hospital sites. Practices then shared details of eligible staff who were interested in taking part in the qualitative study. The project manager recorded the details of eligible staff onto a tracker document and this was shared with the qualitative research team. The qualitative researcher sent a stakeholder information sheet to eligible staff by e-mail, and offered several interview dates and times and a choice of telephone or video call for the interview. Once a date was confirmed, the qualitative researcher confirmed the interview date/time by e-mail.

Recruitment strategy for attendees

The project manager and qualitative research team provided a study invitation pack (invitation, participant information sheet, reply slip and stamped return envelope if applicable) to provider sites by post and e-mail, with the intention that the sites would send the study invitation pack to eligible people. One site sent 300 invitation packs by post and the other sent 200. If interested, eligible people returned the reply slip to the project manager. Based on a purposive sample, we invited eligible people who represented a wide range of characteristics based on age, gender, ethnicity and time of T2DM diagnosis. The qualitative researcher contacted the eligible people by telephone to offer interview dates/times and a choice of telephone or video call for the interview. Once a date was confirmed, the qualitative researcher confirmed the interview date/time by post or e-mail.

Topic guides

Topic guides to guide our interviews were informed by two key social and behavioural theories: the NPT and the theoretical domains framework. Taking a pragmatic approach, data were coded by one qualitative researcher and discussed with a second qualitative researcher. Analysis was informed by thematic analysis. NVivo 12 (QSR International, Warrington, UK) software was used to aid data management and analysis.

Results

Participant characteristics

Findings are based on descriptive coding. Of 13 staff who expressed an interest in taking part in the study, 11 were interviewed by telephone/video (*Table 12*) and two were no longer interested. Of 46 eligible attendees, 19 were interviewed by telephone/video (*Table 13*).

Themes

Based on the data collected, we generated the following themes: need for an established infrastructure; staff and user experience; the future of virtual SSME programmes.

Need for an established infrastructure

There was a lack of staff educators to deliver the virtual SSME sessions, creating a reliance on bank staff to help. This led to a heavy workload for those running the virtual sessions.

TABLE 12 Characteristics of staff members

Characteristic	Number (%)
Gender	
Male	0 (0.0)
Female	11 (100.0)
NHS trust/provider[a]	
P1	3 (27.3)
P3	8 (72.7)
Job role	
Dual role (management and diabetes specialist nurse)	3 (27.3)
Diabetes specialist nurse	3 (27.3)
Diabetes dietician	3 (27.3)
Bank nurse	2 (18.2)

a Organisations are anonymised throughout to preserve anonymity.

TABLE 13 Characteristics of attendees

Characteristic	Number (%)
Gender	
Male	11 (57.9)
Female	8 (42.1)
Age (years)	
40–59	9 (47.4)
60–75	8 (42.1)
> 75	2 (10.5)
Ethnic group	
White	18 (94.7)
Asian/Asian British	1 (5.3)
Time since type 2 diabetes diagnosis	
< 6 months	1 (5.3)
6–12 months	2 (10.5)
1–3 years	12 (63.2)
4–10 years	1 (5.3)
Over 10 years	3 (15.8)

> *Instead of simply being a bank member of staff who was employed to come along and deliver some sessions, I was actually much more part of the team and involved in developing something*
>
> *Participant 3, female, bank nurse*

Although administrative staff and support were provided, it was highlighted that the key role was held by the administration staff to 'sell' the virtual SSME to people, set up the online sessions, and provide support to attendees joining the sessions: 'the whole success of the programme has very much depended upon very good admin, those that can sell it and who are able to help people have the confidence to get on the course' (participant 3, female, bank nurse).

More IT support (from the employing trust) was required at the set-up stage, as many had never delivered virtual sessions before, nor did they have the right equipment and skills to use microsoft Teams. Although IT support was not in place, this gradually evolved over time: 'The challenging bit was the IT really because we didn't get any IT support within (the local trust)' (participant 3, female, bank nurse).

Formal training on how to deliver the SSME sessions virtually was reported to be insufficient. Some, particularly those from one of the trusts, reported receiving support from an established SSME Academy initiative, which was launched in 2020 as a new innovative way of supporting existing educators and provider organisations. Other sources of support included peer support among colleagues, helping each other to learn on the job and adapting as necessary.

> *A smaller group of us (educators) did a little pilot with just inviting people in for a connectivity check – plus run through all the lesson plans and with our slide sets – and kind of run it through together and talked it through together. So I think it was just playing around with pretend patients. So I guess we didn't have a robust training programme.*
>
> *Participant 2, female, co-clinical lead and community diabetes specialist nurse*

> *We all attended the DESMOND academy sessions ... I wouldn't call it training really because it wasn't really training. It was support.*
>
> *Participant 3, female, bank nurse*

Staff and user experience

Despite the IT challenges experienced by staff, feedback on the delivery of virtual programmes was highly positive. There was particular attention on the financial and logistical benefits.

> *The pros probably were we weren't travelling around the county, so I didn't have to allow extra time, it was literally a case of sign in at 9am, start registering people in and get going with it rather than drive an hour and a half to a venue.*
>
> *Participant 1, female, community diabetes specialist nurse*

> *Yes, so cost's one thing, like we said. Don't have to pay for petrol, tea, coffee, venue, whatever.*
>
> *Participant 5, female, co-clinical lead and community diabetes specialist nurse*

Similar to the staff feedback, attendees also valued the provision of virtual SSME, describing it as a '*well-structured*' programme, '*useful*' and '*helpful*'. Appreciating the challenges that the educators would have experienced under the current climate, attendees expressed gratitude for having such programmes available to them. The ability to join SSME sessions virtually brought a 'convenience' factor for those who are less independent than others.

> *Obviously I was working from home so it was convenient whereas before I had to take time out, get my husband to take me because I don't drive.*
>
> *Participant 11, female, White British, 60–75 years, diagnosed T2DM 1–3 years*

> *I can't fault the way it was ran, because they did the best they could under the circumstances and they were very prompt and finished in good time and I can't say that you could have had better people running it with better knowledge, they were good.*
>
> *Participant 18, male, White British, 40–59 years, diagnosed T2DM 1–3 years*

What was less appealing for both attendees and staff was the lack of interaction and informal conversations with fellow attendees that would naturally occur prior and during face-to-face sessions. The ability to read body language and visual cues aids human interaction and group dynamics, alas this opportunity was deemed absent when SSME sessions were delivered virtually.

> *I think once you arrive and you're in the face to face, and you're in the lobby before the meeting, like you say, you do have a bit of a chinwag – 'Where have you come from', type conversation, and your experiences – and then it just builds in a face to face session, doesn't it? That was missing because you were just going in cold.*
>
> *Participant 14, female, White British, 60–75 years, diagnosed T2DM 1–3 years*

> *It's that meeting and the greeting and the kind of small talk stuff … I think it feels far more intuitive when you're seeing people face to face and welcoming them and settling them and there is a bit more ability to see people's expression really quickly and then pick up on the nuances – 'oh were you about to ask a question'. You can't quite pick that up so readily online.*
>
> *Participant 13, female, community diabetes specialist nurse*

Although the convenience factor was a hugely positive trait for virtual SSME, this was considered as a negative also. The ability to join a session remotely, or from the comfort of people's homes, resulted in unavoidable distractions and reduced attention span, adding to the educators' list of challenges to deliver the sessions virtually.

> *You can switch on and switch off at your own leisure, whereas you really can't do that when you're in a group of people and it actually spurs you on to a different level.*
>
> *Participant 18, male, White British, 40–59 years, diagnosed T2DM 1–3 years*

> *People don't always take it seriously because I think it's like oh well it's on the end of my phone or the end of my iPad, I can carry that around with me so, you know, I don't necessarily need to sit and listen properly, which makes it really, really difficult.*
>
> *Participant 9, female, bank nurse*

The element of SSME delivery that seemed to be significantly affected by the delivery changes was the adaptation from using tangible resources and materials, to presenting these concepts on slides. One example was the inability to use real food models, which were seen as vital prompts to engage with attendees in a face-to-face environment.

> *It's a little bit interactive in the sense that when we're face to face, we use flipcharts and food models and things like that so I guess in that sense the variety almost is lost because it's all on screen and slides being presented.*
>
> *Participant 11, female, community diabetes specialist nurse*

The future of virtual structured self-management education programmes

There was a strong indication that virtual SSME programmes have a place in future education delivery, suggesting that '*we have the bones for it now*' to carry it forward. Attendees would recommend virtual SSME programmes to family and friends.

> *It's one of those education methods that I don't think we should lose completely [...] And if I think it would stop completely I don't think I would be altogether happy about that.*
>
> *Participant 9, female, bank nurse*

> *Oh yeah, yeah definitely, yeah … I was like unsure for the very first one, but after that it was great and yeah I'd definitely recommend it.*
>
> *Participant 17, male, White British, 60–75 years, diagnosed T2DM 1–3 years*

The vision for SSME delivery is to progress with a blended approach. It was expressed by both staff and attendees that people with T2DM should be given the choice of SSME format, indicating that virtual SSME could be a viable alternative to complement face-to-face SSME.

> *Post Covid, give people the option, if they are young; busy or literate and not afraid of jumping onto these things and can absorb it in that form – there you go – that's an online session.*
>
> *Participant 18, male, White British, 40–59 years, diagnosed T2DM 1–3 years*

> *Actually thinking going back to face to face, I'm going to miss some of the virtual. We're going to keep virtual going as well … Or giving people more choices anyway.*
>
> *Participant 3, female, bank nurse*

EME
HSDR
HTA
PGfAR
PHR

Part of the NIHR Journals Library
www.journalslibrary.nihr.ac.uk

Published by the NIHR Journals Library