Check for updates

STUDY PROTOCOL

REVISED Barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes: a protocol for a systematic review and qualitative evidence synthesis [version 2; peer review: 2 approved, 1 approved with reservations]

Previously titled: 'Barriers and enablers to sustaining self-management behaviours after completing a self-management support intervention for type 2 diabetes: a protocol for a systematic review and qualitative evidence synthesis'

Márcia Carvalho [ID][1], Pauline Dunne[2], Dominika Kwasnicka [ID][3,4], Molly Byrne [ID][1], Jenny McSharry [ID][1]

[1]Health Behaviour Change Research Group, School of Psychology, National University of Ireland, Galway, Galway, Ireland
[2]School of Agriculture and Food Science, University College Dublin, Dublin, Ireland
[3]Faculty of Psychology, SWPS University of Social Sciences and Humanities, Aleksandra Ostrowskiego, Wrocław, Poland
[4]NHMRC CRE in Digital Technology to Transform Chronic Disease Outcomes, Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Melbourne, Australia

Abstract

Background: Attendance at self-management support interventions is associated with improved outcomes for people with type 2 diabetes. However, initial improvements are often not sustained beyond one year, which may be a result of difficulties in sustaining positive changes made to self-management behaviours. The aim of this systematic review is to synthesise qualitative research on the barriers and enablers to sustaining self-management behaviours following attendance at a self-management support intervention for type 2 diabetes.
Methods: The review will use the "best fit" framework synthesis method to develop a new conceptual model of sustained behaviour change in type 2 diabetes. MEDLINE (Ovid), EMBASE (Elsevier), CINAHL (EBSCO), PsycINFO (Ovid), SCOPUS, ProQuest Dissertations and Theses, WorldCat and Open Grey will be searched to identify primary qualitative studies. A parallel search will be conducted in Google Scholar to identify relevant theories for the development of an *a priori* framework to synthesise findings across studies. Methodological

Open Peer Review

Approval Status ? ✓ ✓

	1	2	3
version 2 (revision) 13 Jun 2022			✓ view
version 1 14 Dec 2021	? view	✓ view	✓ view

1. **Leah Avery** [ID], Newcastle University, Newcastle upon Tyne, UK
   Teesside University, Middlesbrough, UK

2. **Angela M. Rodrigues**, Northumbria University, Newcastle upon Tyne, UK

limitations of included studies will be assessed using an adapted version of the Critical Appraisal Skills Programme tool for Qualitative Studies. A sensitivity analysis will be conducted to examine the impact of studies with methodological limitations on synthesis findings. Confidence in the synthesis findings will be assessed using the GRADE-CERQual tool. Screening, data extraction, methodological limitation assessment, synthesis and GRADE-CERQual assessment will be conducted by one author with a second author independently verifying a randomly selected 20% sample.

Discussion: This review will develop a new model of sustained behaviour change in type 2 diabetes self-management. The findings can be used to inform the development of new interventions or revision of existing interventions to better support sustained engagement in type 2 diabetes self-management behaviours.

Keywords
type 2 diabetes, self-management, self-management support interventions, behaviour change, behaviour maintenance, sustained behaviour change, systematic review, qualitative evidence synthesis

3. **Pauline Meskell** (iD), University of Limerick, Limerick, Ireland

Any reports and responses or comments on the article can be found at the end of the article.

REVISED **Amendments from Version 1**

The protocol has been revised in response to the reviewer's comments on Version 1 of the protocol:

- The title and body of the protocol have been changed to highlight our focus on intervention attendance rather than completion.

- The section on eligibility criteria now includes additional information about the inclusion of multi-methods or mixed-methods studies, screening the time gap between intervention attendance and data collection, and the inclusion of studies published in English only.

- The section on information sources and search strategy now includes additional information about the use of search filters.

- The section on data analysis and synthesis now includes additional information about the sensitivity analysis and subgroup analysis.

- The section on reflexivity has been refined to provide more specific detail regarding the approach to reflexivity.

- The section dissemination has been changed to clarify the number of papers we anticipate publishing based on the review.

Any further responses from the reviewers can be found at the end of the article

Introduction

Type 2 diabetes is a progressive, chronic metabolic disease characterised by beta-cell dysfunction and insulin resistance[1,2]. The prevalence of type 2 diabetes and associated health and economic burden is rising worldwide[1]. Approximately 462 million people (6.28% of the world's population) live with type 2 diabetes worldwide[3], with this number expected to increase over the coming years[1,3]. Without adequate management, type 2 diabetes is associated with microvascular and macrovascular health complications, such as cardiovascular disease, blindness, neuropathy, kidney failure, and lower-limb amputation, and an increased risk of premature death and morbidity[1,2]. Achieving good glycaemic control through appropriate self-management is critical to prevent the progression of the disease and avoid health complications[4,5].

Self-management is a broad concept encompassing all cognitive and emotional self-regulatory processes and behaviours an individual needs to perform to manage the physical and psychosocial consequences of living with type 2 diabetes[6,7]. Self-management of type 2 diabetes can be complex and demanding, as it can require significant lifestyle changes (i.e., diet and physical activity) and involves multiple self-management behaviours, such as medication taking and blood glucose monitoring, which individuals need to implement and sustain in their daily lives[4,8]. As a result, many people struggle to achieve and sustain optimal glycaemic management. Real-world evidence of patient profiles and diabetes care practices in developed countries demonstrate that less than 20% of people with type 2 diabetes achieve target blood glucose levels (<53 mmol/mol [<7%])[9,10].

Self-management support interventions aimed at assisting individuals in self-managing their condition are therefore a central component of type 2 diabetes care[11,12]. Attendance at self-management support interventions is recommended internationally for people with type 2 diabetes[1,11,13] and a wide range of self-management support interventions have been developed and implemented[4,8,14,15]. Although self-management support interventions vary in terms of mode of delivery, duration, intensity, type of provider, and content[8,15], in general, interventions focus on one or any combination of the following components: education (providing information and developing self-management skills such as blood glucose monitoring), lifestyle (promoting and supporting changes in health behaviours relevant to type 2 diabetes, such as diet and physical activity), and psychosocial aspects (promoting and supporting the development of psychosocial skills to facilitate coping and management)[8,15].

Several randomised controlled trials and systematic reviews indicate benefits from attendance at type 2 diabetes self-management interventions, such as improved biomedical (e.g., weight and glycaemic control), behavioural (e.g., dietary management, and physical activity), and psychosocial (e.g., diabetes knowledge, and quality of life) outcomes[4,14,16,17]. However, long-term follow-ups tend to show that while improvements in psychosocial outcomes are maintained, frequently people experience a decline in glycaemic management over time, particularly from six months to one-year post-intervention[14,17,18]. Although the reasons for this decline in glycaemic management are poorly understood[14,18], challenges in sustaining positive changes made to self-management behaviours are assumed to be an underlying cause[14,15].

For the purpose of this review, in line with a published definition[19], the term sustained behaviour change is used to describe the continuous performance of self-management behaviours following an initial intentional change (during intervention) at a level that significantly differs from the baseline performance (pre-intervention) in the intended direction. Although there is lack of consensus on the timeframe used in defining sustained health behaviour change with definitions ranging from three-months to one-year post-intervention[20], the criterion of at least 3 months post-intervention will be used in this review.

To design interventions that effectively support sustained engagement in type 2 diabetes self-management behaviours, it is necessary to identify factors that influence the maintenance of self-management behaviours following attendance at a self-management support intervention. A number of primary qualitative studies have been undertaken to explore the experiences of self-management of people with type 2 diabetes post-intervention[21–25]. However, to our best knowledge, available evidence has not yet been synthesised. Individual qualitative studies offer important insights into the individual's experiences and perceptions and perceived barriers and enablers, but a synthesis of qualitative literature can facilitate the development of overarching insights that go beyond individual study findings[26].

Therefore, the main aim of this systematic review is to synthesise qualitative research on barriers and enablers to sustaining

self-management behaviours following attendance at a self-management support intervention for type 2 diabetes.

Methods

This protocol has been prospectively registered on the International Prospective Register of Systematic Reviews (PROSPERO) to ensure the transparency of the research process (CRD42021281374). This systematic review and qualitative evidence synthesis protocol is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P)[27] (See *Extended data*: Supplementary File 1[28]).

The "best fit" framework synthesis method will be used[29]. This is a flexible, transparent, and pragmatic method that builds on one or more existing theories to develop a new context-specific conceptual model to explain or describe a health behaviour[29]. The choice of this analytical approach was informed by the RETREAT (Review question – Epistemology – Time/Timescale – Resources – Expertise – Audience and purpose – Type of Data) framework, which offers a criterion-based approach to guide the selection of most appropriate analytical approach for a review[30] (See *Extended data*: Supplementary File 2[28]).

The "best fit" framework synthesis method involves the identification of a foundation theory or theories referred to as the *a priori* framework, the coding of the data from the primary studies included in the review against this *a priori* framework, and the secondary thematic analysis of the data that do not fit into the *a priori* framework[29]. The process includes seven steps and can be conceptualised as divided into two stages (See Figure 1).

In the first stage, the review question(s) is determined and the primary studies for inclusion and the *a priori* framework are identified. The identification and selection of primary studies for inclusion in the review and the identification and generation of the *a priori* framework occur simultaneously but independently. These two strands then join together at the second stage where the synthesis process begins.

The two-stage seven-step method of "best fit" framework synthesis that will be followed in this review is described in detail below (See Figure 1). The terminology adopted throughout the protocol is consistent with existing literature[29] and published examples of "best fit" framework synthesis[31]. The systematic review and synthesis of the findings will be completed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[32] and the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ)[33] reporting guidelines.

Review question (Stage 1 – Step 1)

A scoping search was conducted to explore the amount and nature of the evidence and to inform the review aim and question. The following review question was developed using the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research Type) framework[34]:

• What are the barriers and enablers perceived by adults with type 2 diabetes to sustaining self-management behaviours after attending a diabetes self-management support intervention?

Eligibility criteria

The following eligibility criteria were informed by the SPIDER framework[34].

Sample. Studies including adults (aged ≥ 18 years) with a diagnosis of type 2 diabetes who have attended a self-management support intervention will be included. If the study also contains participants with type 1 diabetes, individuals with type 2 diabetes aged under 18 years, women with gestational diabetes or adults with type 2 diabetes who did not attend a self-management support intervention, studies will be included only if it is possible to extract the barriers and enablers perceived by the relevant participants.

Phenomenon of interest. Studies will be included if they focus on barriers and enablers to sustaining self-management behaviours at least three months after attending a self-management support intervention. For the purpose of this review, a barrier is defined as any factor that impedes or obstructs sustaining self-management behaviours. An enabler is defined as any factor that facilitates or helps sustain self-management behaviours. The data collection timing will be verified in the study abstract or full text to ascertain the data reported in the study was collected at least 3-months post-intervention. If the study is focused on barriers and enablers to sustaining self-management behaviours, but the data collection timing is not reported in the abstract, the study will be retrieved for full-text screening. When the time gap between intervention attendance and data collection is not reported in the study, the research team will contact the corresponding author(s) for clarification and further information. If it is not possible to ascertain the time gap between intervention attendance and data collection, the study will be excluded. Consistent with a previous review[14], a self-management support intervention for type 2 diabetes is defined as any intervention that aims to support or facilitate self-management of type 2 diabetes. In accordance with the available literature on self-management support for type 2 diabetes, interventions should explicitly focus on self-management support of type 2 diabetes and target one or more of the following self-management domains to be included in the review[17,35]:

Cognitive skills

- Education about the disease process, progression, management, and treatments available.

- Goal setting to promote health and facilitate health behaviour change.

- Empowerment or self-efficacy.

Behavioural skills

- Nutritional education and management.

- Physical activity.

Stage 1

STEP 1	Definition of the review question(s)

STEP 2a	Systematic identification of primary qualitative studies using the SPIDER framework

STEP 2b	Identification of potentially relevant frameworks, models or theories for *a priori* framework

STEP 3a	Study screening, data extraction and assessment of methodological limitations of the included studies

STEP 3b	Selection and generation of the *a priori* framework using thematic analysis

Stage 2

STEP 4	Code data from included studies against the *a priori* framework

STEP 5	Refine *a priori* framework based on secondary thematic analysis of themes that cannot be coded against the *a priori* framework

STEP 6	Produce a new framework composed of *a priori* and new themes supported by evidence

STEP 7	Revisit evidence to explore relationship between themes or concepts of the framework to create a model Test the synthesis and the model by exploring issues of dissonance and the impact of bodies of evidence deemed of poorer quality through a sensitive analysis

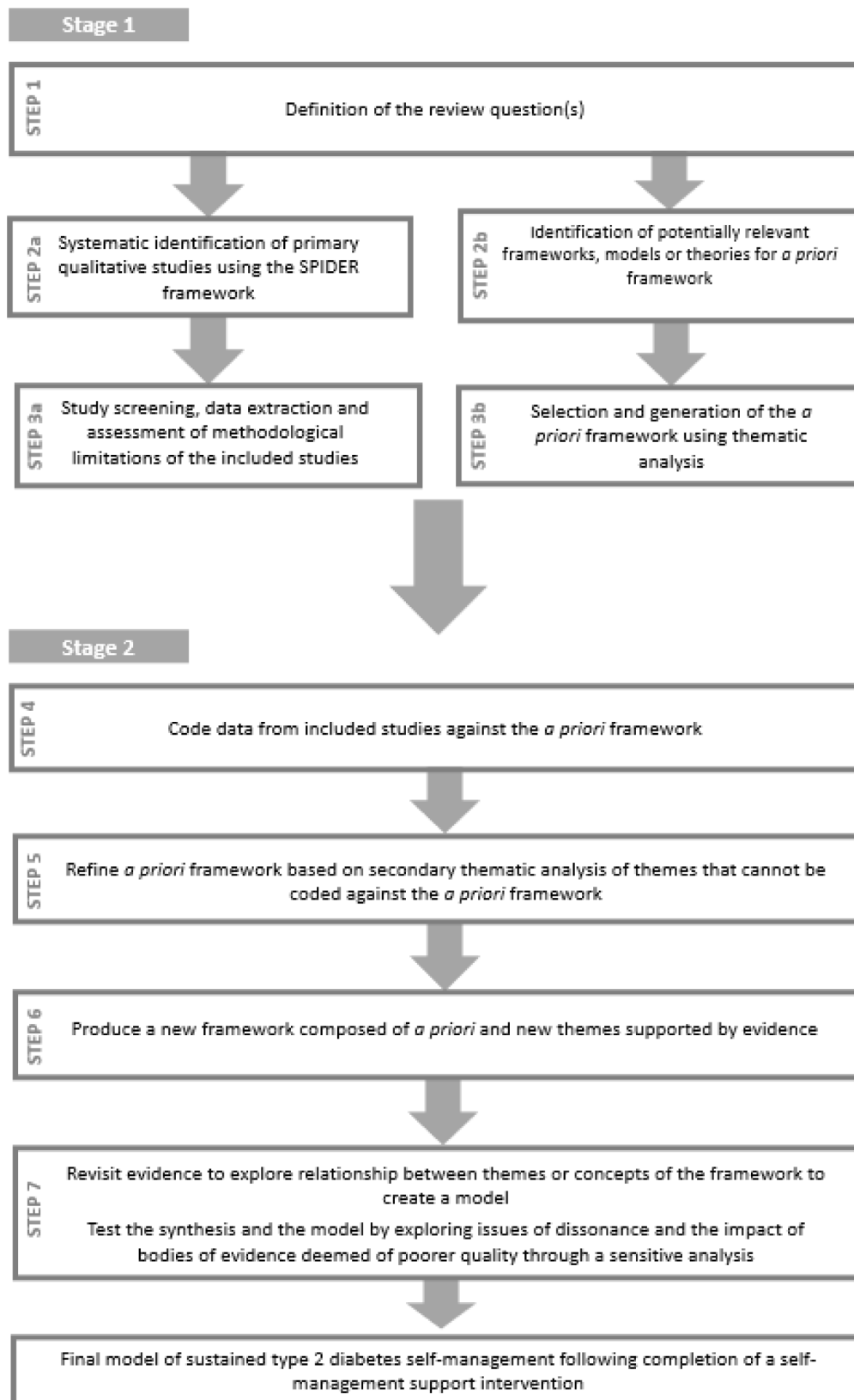|	Final model of sustained type 2 diabetes self-management following completion of a self-management support intervention

Figure 1. Two-stage review design (based on 29).

- Medication intake.
- Blood glucose monitoring.
- Prevention, management, and treatment of health complications.

Emotional skills
- Psychosocial adjustment.
- Distress, anxiety, and depression management.
- Social support.

There will be no restrictions for inclusion based on the intervention setting, mode of delivery, type of facilitator, intensity, duration, and theoretical basis of the intervention. Studies that include carers or family relatives will be included in the review, as long as the intervention is primarily intended for the person with type 2 diabetes. If the study includes both individuals still attending the intervention and individuals who have attended the intervention, studies will only be include if it is possible to extract data from individuals who attended the intervention and have experiences of self-management for at least three months post-intervention at the time of the study. If studies explore sustaining self-management behaviours and other concept(s) in self-management, it must be possible to extract the information specific to sustaining self-management behaviours to be included in the review. Studies examining other aspects of living with type 2 diabetes (e.g., coping, emotional distress) where it is impossible to extract the data on barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention will be excluded.

Design and Research Type. Primary qualitative and mixed-methods research studies will be considered for inclusion. Although grey literature can be difficult to search and retrieve, non-peer reviewed studies will be considered for inclusion as there is a growing consensus that the inclusion of grey literature can widen the scope of reviews, thus providing a more complete picture of the evidence available[36,37]. Studies will be included if a qualitative method is used for data collection (e.g., focus groups or interviews) and analysis (e.g., thematic analysis or grounded theory). The data collection and analysis methods should be clearly reported in the studies to be included in the review. Studies that collect data using qualitative methods but analyse it quantitatively (e.g., descriptive statistics) will not be included in the review. Mixed-methods or multi-methods studies will be included in the review if the qualitative data is reported separately and is relevant and of sufficient depth to be synthesised in the review. Both mixed and multi-methods studies that report qualitative findings in either a separate linked publication that was cited in the study retrieved in the search, or as a separate section of a study retrieved in the search will be considered for inclusion. Studies will be included if there is a focus on barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes. Studies will be deemed relevant and of sufficient depth to be synthesised in the review if relevant findings are supported by at least one quote from participants. Only articles published in English will be included in the review to avoid issues with language translation of qualitative studies as meaning may be lost in translation[38], as well as pragmatic constraints including a limited timeframe for the review, and limited access to translation services. Quantitative studies, literature reviews, qualitative evidence syntheses, editorials, commentaries, opinion pieces, and abstracts in proceedings will be excluded. Where the full text article is not available online, the corresponding author(s) will be contacted by email with one follow-up. If the corresponding author(s) do not reply within one week after the follow-up, the article will be excluded.

Information sources and search strategy (Stage 1 – Step 2a)

A combination of systematic searching of the literature of electronic databases and supplementary searching techniques will be used to maximise the identification of relevant papers for inclusion in the review[34]. A comprehensive search will be conducted on the following databases: MEDLINE (Ovid), EMBASE (Elsevier), CINAHL (EBSCO), PsycINFO (Ovid) and SCOPUS from inception to September 2021. An expert librarian provided support on the selection of the databases and development of the search strategy.

The search strategy was informed by the SPIDER framework[34] (See Table 1 for further details) in consultation with an information specialist. The search combines free-text

Table 1. Inclusion criteria.

SPIDER	Description
S: Sample	Adults aged 18+ with a diagnosis of type 2 diabetes mellitus
P of I: Phenomenon of interest	Sustaining type 2 diabetes self-management behaviours at least 3 months after attending a self-management support intervention
D: Design	Qualitative research methods (data collection and analysis), including interviews, focus groups, case study, observational study, grounded theory, phenomenology, ethnography, thematic analysis, constant comparison, open-ended questions, content analysis, themes, category
E: Evaluation	Experiences, views, perspectives, perceptions, beliefs, opinions, barriers and enablers or facilitators
R: Research	Primary qualitative studies of any design and mixed-methods that report qualitative findings separately

terms with index terms (e.g., Medical Subject Headings) for type 2 diabetes, self-management support interventions, sustained behaviour change, and qualitative research. The search strategy was developed iteratively and informed by existing reviews[14,19,39–42] to ensure the search was as comprehensive as possible. Methodological filters for qualitative research were also used where available in specific databases to enhance the specificity of the search[43,44]. Using validated search filters in qualitative research can result in the omission of potentially relevant studies due to the diversity of terms used to index qualitative research within electronic databases[37]. Therefore, search filters have been combined with other synonymous free-text terms in qualitative research to ensure potentially relevant studies were not missed[37]. Search terms were truncated where relevant to ensure all spellings are captured (e.g., behavio*). In addition, Boolean terms, such as OR and AND were included in the search to enhance specificity and sensitivity. A sample search strategy for the MEDLINE (Ovid) database is presented in *Extended data:* Supplementary File 3[28].

A search of grey literature will also be undertaken on ProQuest Dissertations and Theses, WorldCat via the Online Computer Library Center (OCLC) and Open Grey in September 2021. To counteract common challenges in identifying qualitative literature through systematic searching of electronic databases alone[37], forward, and backward citation searches will be conducted on all included studies.

Screening (Stage 1 – Step 3a)
The lead author will import all references to the electronic reference manager EndNote X20 and remove duplicates. The eligibility criteria will be pilot tested with a random sample of 6 papers by two authors (MC and PD) and the criteria clarified if needed. The lead author will then screen the titles and abstracts and full texts of the identified articles against the eligibility criteria using Rayyan QCRI software[45]. A second author (PD) will independently screen a random sample of 20% of the articles at both stages. A chance-corrected Kappa statistic will be calculated to assess inter-reviewer agreement[46] at both stages. Disagreements will be discussed between the authors and, if necessary, with a third author until consensus is achieved. When the abstract is not available or does not contain enough information to make an informed decision about the inclusion of an article, the article will be retrieved for full text screening. If necessary, authors of primary studies will be contacted for clarification and further information. All the studies identified as potentially relevant by one or both authors will be retrieved for full text screening. A table listing studies excluded from the review and the main reasons for exclusion will be recorded by the research team and presented in the review using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram[32].

Data extraction and management (Stage 1 – Step 3a)
Full-text articles will be imported to QSR International's NVivo v12 software[47]. This software will be used to store the data and to assist in the data extraction and synthesis to ensure clarity and transparency[47]. A data extraction form (See *Extended data*: Supplementary File 4) will be created for the purpose of this synthesis within NVivo[48,49]. The following data will be extracted from each study[48]: study information (e.g., authors, year of publication), study characteristics (e.g., aims and objectives, sample size), participants' characteristics (e.g., age, gender, time living with the diagnosis), intervention characteristics (e.g., intervention components, duration, and mode of delivery), data collection and analysis methods. Findings, including participants' verbatim quotes and reported interpretations by the primary study authors will be extracted as "best fit" framework synthesis allows the analysis, synthesis and integration of primary and secondary data[31,50]. Reported strengths, limitations and implications of the study will also be extracted.

The data extraction form will be initially pre-tested with a random sample of three papers by two authors (MC and PD). One author (MC) will extract data from all included articles and a second author (PD) will cross-check 20% of the articles to ensure consistency and minimise potential bias during the data extraction process. Any disagreement will be discussed between the authors and, if necessary, with a third author until consensus is achieved.

Assessment of methodological limitations of the included studies (Stage 1 – Step 3a)
An adapted version of the Critical Appraisal Skills Programme (CASP) Tool[51] for qualitative studies will be used to assess the methodological limitations of the included studies. The following domains will be considered: context, sampling strategy, data collection, data analysis, support of individual study findings in data, reflexivity, and ethical considerations. Each domain will be judged as yes (i.e., the domain is sufficiently, clearly, and appropriately described in the study), no (i.e., the domain is not described in the study) or unclear (i.e., the study only offers a limited or unclear description of the domain). MC will appraise all the included studies. PD will independently appraise 20% of the included studies. Disagreements will be discussed, and a third author will be consulted if necessary. Studies will not be excluded based on this assessment[52], in line with recommendations[53], but this information will be considered in the analysis of the findings, assessment of confidence in the review findings and the reporting of the review.

Identification and development of the a priori framework (Stage 1 – Steps 2b and 3b)
The *a priori* framework for this review will be selected through a combination of literature search, expert consultation, and research team consensus[29]. Potential *a priori* theories will be identified by the review team opportunistically from within the topic-relevant searches and articles selected for full text screening, and purposively from an independent parallel search in Google Scholar combining the search terms 'model*' or 'framework*'or 'theoretical' or 'theory' or 'concept' or 'conceptual'[31] with the terms 'type 2 diabetes self-management' and 'sustained behaviour change'. A list of relevant candidate

theories will be developed based on the results of this search. This approach has been previously used to identify an appropriate existing conceptual model in a worked example of "best Fit" framework synthesis[31]. Google Scholar has the advantages of covering mainstream and non-mainstream academic literature and ability to sort the results of the search by relevance. Records retrieved will be read to identify relevant candidate theories. The aim is to build a comprehensive list of candidate theories. For each new record, the theory or theories identified will be matched to ones previously identified and added to the list if not previously identified. The search will be terminated when no new theories are identified after five new records have been read[54].

As it is anticipated that the number of hits for the initial search will be high with a large number of records of very low relevance, the search results will be ordered by relevance using the Google algorithm 'sort by relevance'[54].

When a list of potential theories is identified, the review team will meet to discuss the suitability of the candidate theories, and to determine if a single comprehensive theory can be used, or if it is necessary to develop a meta-framework using concepts or constructs from different theories in the existing literature[50]. The list of candidate theories will be circulated by the research team in advance of the meeting. Additionally, the three senior research team members (DK, MB, JMS) with extensive knowledge of and experience using behavioural theories will be consulted to identify any potentially relevant additional theories they are aware of which are not included in it the list.

The review team will discuss the conceptual fit of each of the candidate theories until consensus is achieved. The three criteria outlined by Damschroder and colleagues[55] will be considered by the review team when evaluating candidate theories, as suggested by Booth and Carroll[50] (See Table 2). The assumption by Booth and Carroll[50] that a priori theoretical framework does not need to be "a perfect match for the question or evidence", but only offer "a 'good enough' starting point as designated by the phrase "best fit" (p. 701) will be taken into consideration by the research team. After identifying the most suitable theory, secondary thematic analysis[29] will be

employed to create the *a priori* framework. Thematic analysis will be used to generate a set of explanatory constructs and theoretical propositions, referred in the "best fit" synthesis method as themes, which represent patterns of theoretical explanations. The theoretical themes identified might be further organised by subthemes if appropriate.

Based on the information available in the primary studies and original papers of the selected theory, definitions will be created for each theme[29]. As the suitability of a theory or theories also depends on the proportion of the data that can be accommodated within it, the choice of the *a priori* framework will be revisited during the data analysis and synthesis process to ensure the framework selected is the most appropriate[29]. The *a priori* framework will be considered appropriate if it accommodates at least 50% of the data extracted from the included primary studies.

Data analysis and synthesis (Stage 2 – Steps 4 to 8)
The lead author will develop a coding tree on NVivo with the themes and constructs identified to facilitate the coding of the data against the *a priori* framework. A second author (PD) will cross-check the final list of themes to ensure different authors can consistently code data from primary studies with a sample of three studies[29]. The findings from the included studies will be coded against the themes generated based on the *a priori* framework (Step 4). New themes will be generated to code data that cannot be coded against the *a priori* framework secondary thematic analysis[29]. New themes will be based on the author's interpretation of the data and constant comparison of such data across studies[29] (Step 5). The new themes resulting from this analysis will be added to the *a priori* framework.

A new updated framework composed of *a priori* and new themes supported by the evidence will result from this process[29,50] (Step 6). One author (MC) will conduct all stages of data analysis and synthesis from coding to interpretation with continuous input from the rest of the research team. A second author (PD) will independently analyse and synthesise 20% of the articles. Any discrepancies will be discussed between the two authors and if necessary, with a third author until consensus is achieved.

Table 2. Criteria outlined by Damschroder and colleagues[55] to evaluate candidate theories.

Criteria	Description
Clarity and coherence of the terminology used by the framework	External validity: Are the concepts readily understandable to the research team? Internal validity: Can the concepts be consistently operationalised by different authors?
Transferability	Does the framework enable comparison of results across studies?
Room for new theoretical developments	Does the framework allow new theoretical developments?

The potential ways in which themes may relate to each other will then be explored using constant comparison method[56,57], facilitating the generation of a new conceptual model describing the process of sustaining type 2 diabetes self-management behaviours after attending a self-management support intervention[29,50] (Step 7).

Finally, a sensitivity analysis[29,58] will be performed to examine the contribution of studies with methodological limitations to the review findings[29,48,58] (Step 7). Query tools within NVivo, such as matrix-coding queries, will be used to conduct the sensitivity analysis following the guidance provided by Houghton and colleagues (2017)[48]. Matrix-coding queries allow comparing multiple nodes/codes and attributes as a numeric matrix table with different shading colours, which indicates whether studies with methodological limitations skewed the findings in any particular way based on their contribution to the finding[48]. Each study will be assessed for methodological limitations based on the CASP tool criteria to facilitate the analysis[51]. Subgroup analyses will be conducted where appropriate and if possible, comparing studies based on intervention characteristics, time gap between attendance at the intervention and data collection, participants' characteristics, and study context, including continent and income level of country where the study was carried out.

Confidence in the review findings

The Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual)[59] approach will be used to assess confidence in each theme included in the final model. GRADE-CERQual assesses confidence in review findings, based on the following key components: methodological limitations (i.e., the extent to which there are concerns about the design or conduct of the primary studies that contributed to the review finding); relevance (i.e., the extent to which findings from the primary studies are relevant to the review question), coherence (i.e., the extent to which the review findings are grounded in data from the primary studies), and adequacy of the data (i.e., the extent to which a review findings are supported by rich data and a large number of studies)[59]. After assessing each of the four components, a judgement about the overall confidence in the review finding will be made. The confidence in each review finding will be graded as high (i.e., it is highly likely), moderate (i.e., it is likely), low (i.e., it is possible) or very low (i.e., it is unclear) dependant on whether the review finding is judged to a reasonable representation of the phenomenon of interest[59]. All findings will initially be graded as high confidence and will then be graded down if there are important concerns regarding any of the GRADE-CERQual components[59]. The final assessment will be based on consensus among the two authors (MC and PD) involved in the confidence assessment with discussion with the full review team if needed.

Reflexivity

To ensure rigour and quality, the research team members will maintain a reflexive stance throughout all stages of the review process, from study selection to data synthesis and interpretation of the findings. A team-based reflexive approach will be adopted involving individual critical reflection on assumptions and potential biases and reflexive group discussions[60]. The research team will continuously reflect on their background and how their personal views and beliefs could influence their choices regarding methods to use, data extraction, coding synthesis, and interpretation of the review findings. MC, JMS, DK and MB have a background in Health Psychology and primarily work in research focused on health behaviour change. MB is a professor, JMS a lecturer, DK is a senior research fellow, and MC is a PhD candidate. PD is a PhD candidate with a background in nutrition/dietetics and has extensive clinical experience delivering self-management support interventions for people with Type 2 diabetes. MB and JMS have experience in conducting qualitative evidence synthesis and primary qualitative research focused on type 2 diabetes mellitus. MC and PD have previous experience in conducting primary qualitative research. DK has experience and expertise in theory review and synthesis. All authors believe that sustaining self-management behaviours is challenging, and people might struggle to integrate these behaviours into their daily lives.

During the screening, data extraction, coding and synthesis, and assessment of confidence in the review findings, the team will regularly meet to discuss progress and potential disagreements. The two authors (MC and PD) who will conduct the study screening, data coding, extraction and synthesis, and assessment of confidence in the review findings, will meet regularly to discuss how their background, experiences and presumptions on the review topic may be influencing their assessments and analysis and will both record and reflect on their decisions in memos. Both MC and PD will keep reflexive diaries and fieldnotes to document and critically reflect on the research process, which will be recorded in memos and form the basis for ongoing discussion in research team meetings. The authors will use the seven questions orientating for team-reflexive accounts proposed by Barry *et al.* (1999)[60] to guide their reflexive accounts. Examples of questions proposed by Barry *et al.* (1999)[60] include: (1) 'in what way might my experience colour my participation in the project?', (2) 'what is my orientation to qualitative research?', and (3) 'what results do I expect to come out of this project?'. By keeping this reflexive stance, the research team hopes to reduce potential threats to rigour and any potential negative impact of any personal or professionals' beliefs or biases on the interpretation of the findings. As suggested by Flemming and Noyes (2017)[61], the following aspects relevant to author reflexivity will be reported on the final manuscript of the review: (a) the funder and their potential involvement and influence on the development and editing of the review findings; (b) the composition of the review team and the key positions or beliefs about the review question and the phenomenon of interest that could influence the interpretation of the findings; (c) potential conflicts of interest both financial and non-financial; (d) team governance procedures and processes to ensure internal validity; (e) procedures for processing evidence when one of the review authors is also an author of a primary qualitative study; and (f) procedures and processes to engage with key stakeholders ensuring no potential undue influence on the review and interpretation of the findings[61].

Public and Patient Involvement

The involvement of key stakeholders in systematic reviews is increasingly recognised as fundamental to the quality, relevance, and impact of the review findings[62,63]. Patient and public representatives of people with type 2 diabetes who attended a self-management support intervention for type 2 diabetes will be involved in the review from the point of data synthesis. Patient and public representatives will be asked to review the *a priori* framework and the new themes that are generated by the research team and contribute to the new updated framework and interpretation of the synthesis findings. In addition, they will also be invited to contribute to the development of dissemination strategies and assist in the preparation of dissemination documents, such as the lay summary, to ensure clarity and readability. The involvement of the members from the advisory panel in the systematic review process will be guided by the ACTIVE (Authors and Consumers Together Impacting on eVidencE) framework, which outlines a range of methods and approaches to guide both the involvement of stakeholders in systematic reviews and the reporting of their involvement in the review process[63]. The activities and contributions of the advisory panel will be reported in line with the Guidance for Reporting Involvement of Patients and the Public Version 2 (GRIPP2) Checklist[64] and the ACTIVE framework[63].

Study status

The review is currently underway. The database searches, title and abstract screening and full text screening, data analysis and synthesis, and assessment of in confidence in the review findings have been completed.

Discussion

Given the decline in glycaemic control over time following attendance at a self-management support intervention, there is a need to better understand 'how' (and why) people self-manage their diabetes post-interventions. This review will be the first to explore barriers and enablers experienced by people with type 2 diabetes to sustaining self-management behaviours after attending a self-management support intervention. By adopting the "best-fit" framework synthesis method, the review will result in a comprehensive model of the maintenance of type 2 diabetes self-management behaviours after attendance at a self-management support intervention. The model is anticipated to identify factors that influence the self-management of type 2 diabetes over time and might contribute to the variability in the long-term effectiveness of this type of interventions[14]. The evidence-informed conceptual model resulting from this review will be useful to guide future intervention revision or design. In addition, the model resulting from this review will provide important theoretical insights into the process of sustained behaviour change, a key priority area in behavioural science[19].

The planned review has several strengths and limitations. The review methods are transparent, rigorous and will be reported in accordance with published guidelines[27,32,33]. An audit trail detailing the decisions made and methodological steps taken will be kept throughout the research process. Due to

practical reasons, we will not include non-English articles whose findings could provide interesting additional insights. Despite the best efforts of the research team, it is also possible that not all relevant articles will be retrieved during the search for primary studies and/or selected during the screening process due to the myriad of terms used in the literature to describe self-management support interventions, sustained self-management and qualitative research. This review will also reflect the limitations of the included studies as the review findings will be limited to what is reported in the included primary studies. Another potential limitation relates to the heterogeneity of the self-management support interventions described in the primary studies and the time gap between attendance at the intervention and data collection. Differences between interventions and the amount of time since intervention attendance have potential to make the synthesis across studies and the drawing of appropriate conclusions more difficult.

Dissemination

A systematic review article will be submitted to a peer-reviewed journal for publication and the final review results will be promoted in social media outlets, including Twitter, to reach a wider public audience. The findings will also be disseminated to key stakeholders at relevant national and international conferences, and a policy brief and a lay summary will be created to communicate the findings to policymakers, people with type 2 diabetes and the general public. In addition, alternative dissemination strategies suggested by the members of the public and patient advisory panel will also be considered.

Data availability

Underlying data

No data are associated with this article. However, dataset associated with the review will be published Open Access online on the Open Science Framework review page.

Extended data

Open Science Framework: SUSTAIN T2DM: Supporting people with type 2 diabetes to sustain self-management behaviours, https://doi.org/10.17605/OSF.IO/KJVGU[28].

The project contains the following extended data (under Work Package 1: Barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes: A systematic review and qualitative evidence synthesis):

- Supplementary file 2 - RETREAT Framework.docx
- Supplementary file 3 – MEDLINE Search Sample.doc
- Supplementary file 4 - Data Extraction Form.doc

Reporting guidelines

Open Science Framework: Supplementary File 1. PRISMA-P checklist, https://doi.org/10.17605/OSF.IO/KJVGU[28].

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 Public domain dedication).

References

1. International Diabetes Federation (IDF): **International Diabetes Federation: Diabetes Atlas 9th Edition**. 2019.
   Reference Source

2. Khunti S, Khunti K, Seidu S: **Therapeutic inertia in type 2 diabetes: prevalence, causes, consequences and methods to overcome inertia.** *Ther Adv Endocrinol Metab.* 2019; **10**: 2042018819844694.
   PubMed Abstract | **Publisher Full Text** | **Free Full Text**

3. Khan MAB, Hashim MJ, King JK, *et al.*: **Epidemiology of Type 2 Diabetes - Global Burden of Disease and Forecasted Trends.** *J Epidemiol Glob Health.* 2020; **10**(1): 107–111.
   PubMed Abstract | **Publisher Full Text** | **Free Full Text**

4. Lambrinou E, Hansen TB, Beulens JW: **Lifestyle factors, self-management and patient empowerment in diabetes care.** *Eur J Prev Cardiol.* 2019; **26**(2_suppl): 55–63.
   PubMed Abstract | **Publisher Full Text**

5. Shrivastava SR, Shrivastava PS, Ramasamy J: **Role of self-care in management of diabetes mellitus.** *J Diabetes Metab Disord.* 2013; **12**(1): 14.
   PubMed Abstract | **Publisher Full Text** | **Free Full Text**

6. Barlow J: **How to use education as an intervention in osteoarthritis.** *Best Pract Res Clin Rheumatol.* 2001; **15**(4): 545–558.
   PubMed Abstract | **Publisher Full Text**

7. Stanton-Fay SH, Hamilton K, Chadwick PM, *et al.*: **The DAFNE*plus* programme for sustained type 1 diabetes self management: Intervention development using the Behaviour Change Wheel.** *Diabet Med.* 2021; **38**(5): e14548.
   PubMed Abstract | **Publisher Full Text**

8. Carpenter R, DiChiacchio T, Barker K: **Interventions for self-management of type 2 diabetes: An integrative review.** *Int J Nurs Sci.* 2018; **6**(1): 70–91.
   PubMed Abstract | **Publisher Full Text** | **Free Full Text**

9. Aschner P, Gagliardino JJ, Ilkova H, *et al.*: **Correction to: Persistent poor glycaemic control in individuals with type 2 diabetes in developing countries: 12 years of real-world evidence of the International Diabetes Management Practices Study (IDMPS).** *Diabetologia.* 2020; **63**(5): 1088–1089.
   PubMed Abstract | **Publisher Full Text** | **Free Full Text**

10. Mannucci E, Monami M, Dicembrini I, *et al.*: **Achieving HbA1c targets in clinical trials and in the real world: a systematic review and meta-analysis.** *J Endocrinol Invest.* 2014; **37**(5): 477–495.
    PubMed Abstract | **Publisher Full Text**

11. Beck J, Greenwood DA, Blanton L, *et al.*: **2017 National Standards for Diabetes Self-Management Education and Support.** *Diabetes Educ.* 2017; **43**(5): 449–464.
    PubMed Abstract | **Publisher Full Text**

12. Health Information and Quality Authority (HIQA): **Health technology assessment of chronic disease self- management support intervention - Diabetes**. 2015.
    Reference Source

13. National Institute for Health and Care Excellence (NICE): **Diabetes in adults**. 2011.
    Reference Source

14. Captieux M, Pearce G, Parke HL, *et al.*: **Supported self-management for people with type 2 diabetes: a meta-review of quantitative systematic reviews.** *BMJ open.* 2018; **8**(12): e024262.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

15. Chatterjee S, Davies MJ, Heller S, *et al.*: **Diabetes structured self-management education programmes: a narrative review and current innovations.** *Lancet Diabetes Endocrinol.* 2018; **6**(2): 130–142.
    PubMed Abstract | **Publisher Full Text**

16. Deakin T, McShane CE, Cade JE, *et al.*: **Group based training for self-management strategies in people with type 2 diabetes mellitus.** *Cochrane Database Syst Rev.* 2005; (2): CD003417.
    PubMed Abstract | **Publisher Full Text**

17. Norris SL, Engelgau MM, Narayan KM: **Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials.** *Diabetes Care.* 2001; **24**(3): 561–587.

18. Khunti K, Gray LJ, Skinner T, *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.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

19. Kwasnicka D, Dombrowski SU, White M, *et al.*: **Theoretical explanations for maintenance of behaviour change: a systematic review of behaviour theories.** *Health Psychol Rev.* 2016; **10**(3): 277–296.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

20. Loef M, Walach H: **How applicable are results of systematic reviews and meta-analyses of health behaviour maintenance? A critical evaluation.** *Public Health.* 2015; **129**(4): 377–384.
    PubMed Abstract | **Publisher Full Text**

21. Gildea CM, Lantaff WM, Olenik NL: **Identifying barriers to glycemic control in patients with type 2 diabetes after completion of an accredited education program.** *J Am Pharm Assoc (2003).* 2017; **57**(3S): S211–S216.
    PubMed Abstract | **Publisher Full Text**

22. Rise MB, Pellerud A, Rygg LØ, *et al.*: **Making and maintaining lifestyle changes after participating in group based type 2 diabetes self-management educations: a qualitative study.** *PLoS One.* 2013; **8**(5): e64009.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

23. Schmidt SK, Hemmestad L, MacDonald CS, *et al.*: **Motivation and Barriers to Maintaining Lifestyle Changes in Patients with Type 2 Diabetes after an Intensive Lifestyle Intervention (The U-TURN Trial): A Longitudinal Qualitative Study.** *Int J Environ Res Public Health.* 2020; **17**(20): 7454.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

24. Song M, Lee M, Shim B: **Barriers to and facilitators of self-management adherence in Korean older adults with type 2 diabetes.** *Int J Older People Nurs.* 2010; **5**(3): 211–218.
    PubMed Abstract | **Publisher Full Text**

25. Moses M, Olenik NL: **Perceived impact of caregiver's participation in diabetes education classes on implementation of self-care behaviors.** *J Am Pharm Assoc (2003).* 2019; **59**(4S): S47–S51.e1.
    PubMed Abstract | **Publisher Full Text**

26. Pope C, Mays N: **Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research.** *BMJ.* 1995; **311**(6996): 42–45.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

27. Moher D, Shamseer L, Clarke M, *et al.*: **Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement.** *Syst Rev.* 2015; **4**(1): 1.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

28. Carvalho M, Dunne P, Kwasnicka D, *et al.*: **SUSTAIN T2DM: Supporting people with type 2 diabetes to sustain self-management behaviours.** *Open Science Framework.* 2021.

29. Carroll C, Booth A, Leaviss J, *et al.*: **"Best fit" framework synthesis: refining the method.** *BMC Med Res Methodol.* 2013; **13**: 37.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

30. Booth A, Noyes J, Flemming K, *et al.*: **Structured methodology review identified seven (RETREAT) criteria for selecting qualitative evidence synthesis approaches.** *J Clin Epidemiol.* 2018; **99**: 41–52.
    PubMed Abstract | **Publisher Full Text**

31. Carroll C, Booth A, Cooper K: **A worked example of "best fit" framework synthesis: a systematic review of views concerning the taking of some potential chemopreventive agents.** *BMC Med Res Methodol.* 2011; **11**: 29.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

32. Moher D, Liberati A, Tetzlaff J, *et al.*: **Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement.** *PLoS Med.* 2009; **6**(7): e1000097.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

33. Tong A, Flemming K, McInnes E, *et al.*: **Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ.** *BMC Med Res Methodol.* 2012; **12**: 181.
    PubMed Abstract | **Publisher Full Text** | **Free Full Text**

34. Cooke A, Smith D, Booth A: **Beyond PICO: the SPIDER tool for qualitative evidence synthesis.** *Qual Health Res.* 2012; **22**(10): 1435–1443.
PubMed Abstract | **Publisher Full Text**

35. Pal K, Eastwood SV, Michie S, *et al.*: **Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus.** *Cochrane Database Syst Rev.* 2013; **2013**(3): CD008776.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

36. Mahood Q, Van Eerd D, Irvin E: **Searching for grey literature for systematic reviews: Challenges and benefits.** *Res Synth Methods.* 2014; **5**(3): 221–234.
PubMed Abstract | **Publisher Full Text**

37. Booth A: **Searching for qualitative research for inclusion in systematic reviews: a structured methodological review.** *Syst Rev.* 2016; **5**: 74.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

38. van Nes F, Abma T, Jonsson H, *et al.*: **Language differences in qualitative research: is meaning lost in translation?.** *Eur J Ageing.* 2010; **7**(4): 313–316.
PubMed Abstract | |**Publisher Full Text** | |**Free Full Text**

39. Campbell F, Lawton J, Rankin D, *et al.*: **Follow-Up Support for Effective type 1 Diabetes self-management (The FUSED Model): A systematic review and meta-ethnography of the barriers, facilitators and recommendations for sustaining self-management skills after attending a structured education programme.** *BMC Health Serv Res.* 2018; **18**(1): 898.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

40. Greaves C, Poltawski L, Garside R, *et al.*: **Understanding the challenge of weight loss maintenance: a systematic review and synthesis of qualitative research on weight loss maintenance.** *Health Psychol Rev.* 2017; **11**(2): 145–163.
PubMed Abstract | **Publisher Full Text**

41. McSharry J, McGowan L, Farmer AJ, *et al.*: **Perceptions and experiences of taking oral medications for the treatment of Type 2 diabetes mellitus: a systematic review and meta-synthesis of qualitative studies.** *Diabet Med.* 2016; **33**(10): 1330–1338.
PubMed Abstract | **Publisher Full Text**

42. O'Neill M, Houghton C, Crilly G, *et al.*: **A qualitative evidence synthesis of users' experience of mobile health applications in the self-management of type 2 diabetes.** *Chronic Illn.* Advance online publication, 2021; 1742395320983877.
PubMed Abstract | **Publisher Full Text**

43. McKibbon KA, Wilczynski NL, Haynes RB: **Developing optimal search strategies for retrieving qualitative studies in PsycINFO.** *Eval Health Prof.* 2006; **29**(4): 440–454.
PubMed Abstract | **Publisher Full Text**

44. Wong SS, Wilczynski NL, Haynes RB, *et al.*: **Developing optimal search strategies for detecting clinically relevant qualitative studies in MEDLINE.** *Stud Health Technol Inform.* 2004; **107**(Pt 1): 311–316.
PubMed Abstract

45. Ouzzani M, Hammady H, Fedorowicz Z, *et al.*: **Rayyan-a web and mobile app for systematic reviews.** *Syst Rev.* 2016; **5**(1): 210.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

46. Viera AJ, Garrett JM: **Understanding interobserver agreement: the kappa statistic.** *Fam Med.* 2005; **37**(5): 360–363.
PubMed Abstract

47. **QSR International Pty Ltd. (2921). NVivo**.
Reference Source

48. Houghton C, Murphy K, Meehan B, *et al.*: **From screening to synthesis: using nvivo to enhance transparency in qualitative evidence synthesis.** *J Clin Nurs.* 2017; **26**(5–6): 873–881.
PubMed Abstract | **Publisher Full Text**

49. McGrath N, McHugh S, Kearney PM, *et al.*: **Barriers and enablers to screening and diagnosing depression and diabetes distress in people with type 2 diabetes mellitus; protocol of a qualitative evidence synthesis.** *HRB Open*

Res. 2020; **2**: 26.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

50. Booth A, Carroll C: **How to build up the actionable knowledge base: the role of 'best fit' framework synthesis for studies of improvement in healthcare.** *BMJ Qual Saf.* 2015; **24**(11): 700–708.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

51. Critical Appraisal Skills Programme (CASP): **Critical Appraisal Skills Programme.** 2021.
Reference Source

52. Dixon-Woods M, Sutton A, Shaw R, *et al.*: **Appraising qualitative research for inclusion in systematic reviews: a quantitative and qualitative comparison of three methods.** *J Health Serv Res Policy.* 2007; **12**(1): 42–47.
PubMed Abstract | **Publisher Full Text**

53. Carroll C, Booth A: **Quality assessment of qualitative evidence for systematic review and synthesis: Is it meaningful, and if so, how should it be performed?** *Res Synth Methods.* 2015; **6**(2): 149–154.
PubMed Abstract | **Publisher Full Text**

54. Michie S, West R, Pidgeon N, *et al.*: **Staying 'Covid-safe': Proposals for embedding behaviours that protect against Covid-19 transmission in the UK.** *Br J Health Psychol.* 2021; **26**(4): 1238–1257.
PubMed Abstract | **Publisher Full Text**

55. Damschroder LJ, Aron DC, Keith RE, *et al.*: **Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science.** *Implement Sci.* 2009; **4**: 50.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

56. Strauss AL, Corbin JM: **Basics of qualitative research: Grounded theory procedures and techniques.** Sage Publications. 1990.
Reference Source

57. McGrath N, McHugh S, Racine E, *et al.*: **Barriers and enablers to screening and diagnosing diabetes distress and depression in people with type 2 diabetes mellitus: A qualitative evidence synthesis.** *Prim Care Diabetes.* 2021; S1751-9918(21)00162-5.
PubMed Abstract | **Publisher Full Text**

58. Carroll C, Booth A, Lloyd-Jones M: **Should we exclude inadequately reported studies from qualitative systematic reviews? An evaluation of sensitivity analyses in two case study reviews.** *Qual Health Res.* 2012; **22**(10): 1425–1434.
PubMed Abstract | **Publisher Full Text**

59. Lewin S, Glenton C, Munthe-Kaas H, *et al.*: **Using qualitative evidence in decision making for health and social interventions: an approach to assess confidence in findings from qualitative evidence syntheses (GRADE-CERQual).** *PLoS Med.* 2015; **12**(10): e1001895.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

60. Barry CA, Britten N, Barber N, *et al.*: **Using reflexivity to optimize teamwork in qualitative research.** *Qual Health Res.* 1999; **9**(1): 26–44.
PubMed Abstract | **Publisher Full Text**

61. Flemming K, Noyes J: **Qualitative Evidence Synthesis: Where Are We at?.** *International Journal of Qualitative Methods.* 2021.
Publisher Full Text

62. Park S, Khan N, Stevenson F: **Patient and Public Involvement (PPI) in evidence synthesis: how the PatMed study approached embedding audience responses into the expression of a meta-ethnography.** *BMC Med Res Methodol.* 2020; **20**(1): 29.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

63. Pollock A, Campbell P, Struthers C, *et al.*: **Development of the ACTIVE framework to describe stakeholder involvement in systematic reviews.** *J Health Serv Res Policy.* 2019; **24**(4): 245–255.
PubMed Abstract | **Publisher Full Text**

64. Staniszewska S, Brett J, Simera I, *et al.*: **GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research.** *BMJ.* (Clinical research ed.) 2017; **358**: j3453.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Open Peer Review

Current Peer Review Status: ❓ ✔️ ✔️

Version 2

Reviewer Report 13 June 2022

https://doi.org/10.21956/hrbopenres.14822.r32307

✔️ **Pauline Meskell** iD

Department of Nursing and Midwifery, University of Limerick, Limerick, Ireland

Highlighted areas for review have been addressed appropriately.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Qualitative Evidence Synthesis methodology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 28 February 2022

https://doi.org/10.21956/hrbopenres.14677.r31087

✔️ **Pauline Meskell** iD

Department of Nursing and Midwifery, University of Limerick, Limerick, Ireland

The protocol gives background and context to the issues around the complexities of sustaining self management behaviors for individuals living with T2 Diabetes Mellitus. People that undergo educational interventions in self management often do not sustain the behaviors long term and this can have negative consequences on their overall health and diabetes management, The aim

of the review was to synthesis qualitative evidence on the barriers and facilitators to sustaining self management behaviors following completion of a self management support intervention for T2DM.

The review authors detail the planned methodology of the QES using a Best Fit Framework synthesis approach. Good detail is provided in relation to the development of the review question, and the intended format of the best fit framework approach. Clear descriptions of the criteria is outlined. The design and research type of studies is well detailed. No justification of why only articles in English is given, this is a potential limitation of the review. Appropriate level details is included for searching and screening both for the review and the best fit framework. The approach to identify a best fit framework appears particularly complex, and would appear to complicate the process of apriori coding rather than facilitate it. If the framework is sufficiently well developed it should not require secondary thematic analysis and perhaps the choice of framework needs to be cognizant of this.

The subgroup analysis could include socioeconomic factors, such as income level of country where research was carried out as this may have an influence on outcomes of a self management intervention. Good reflexive account of review authors positions in the topic area and review. Inclusion of PPI is a positive step towards meaningful inclusion of patients/public.

Overall a well detailed protocol, that evidences good understanding of the processes and requirements of a QES.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Qualitative Evidence Synthesis methodology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

> Author Response 01 Jun 2022
> **Márcia Carvalho**, National University of Ireland, Galway, Galway, Ireland
>
> **C3.1. The protocol gives background and context to the issues around the complexities of sustaining self management behaviors for individuals living with T2 Diabetes**

Mellitus. People that undergo educational interventions in self management often do not sustain the behaviors long term and this can have negative consequences on their overall health and diabetes management, The aim of the review was to synthesis qualitative evidence on the barriers and facilitators to sustaining self management behaviors following completion of a self management support intervention for T2DM.

R3.1.: We thank the reviewer for the comments on our manuscript.

C3.2. The review authors detail the planned methodology of the QES using a Best Fit Framework synthesis approach. Good detail is provided in relation to the development of the review question, and the intended format of the best fit framework approach. Clear descriptions of the criteria is outlined. The design and research type of studies is well detailed. No justification of why only articles in English is given, this is a potential limitation of the review. Appropriate level details is included for searching and screening both for the review and the best fit framework.

R3.2.: The research team agrees that the inclusion of articles in English only is a limitation of the review and has reflected on the potential impact of this decision in the discussion section of the protocol.

The team decided to only include studies in English to avoid issues with language translation of qualitative studies as meaning may be lost in translation (van Nes et al., 2010). This decision was also made for practical reasons, including limited access to translation services and a limited timeframe as this review is being conducted as part of a wider PhD project. The protocol has been amended to clarify why only articles in English will be included. The following sentences and reference have been added to page 7 (phenomenon of interest):

"Only articles published in English will be included in the review to avoid issues with language translation of qualitative studies as meaning may be lost in translation [38], as well as pragmatic constraints including a limited timeframe for the review, and limited access to translation services".

We will also reflect on this limitation in the final manuscript reporting the findings of the review.

C3.3. The approach to identify a best fit framework appears particularly complex, and would appear to complicate the process of a priori coding rather than facilitate it. If the framework is sufficiently well developed it should not require secondary thematic analysis and perhaps the choice of framework needs to be cognizant of this.

R3.3.: We have decided to be cautious in the protocol and cover all possibilities in relation to developing the a priori framework including the need for secondary thematic analysis. However, it is anticipated that the a priori framework chosen to guide data coding will be developed enough that it will not require secondary thematic analysis.

C3.4. The subgroup analysis could include socioeconomic factors, such as income level

of country where research was carried out as this may have an influence on outcomes of a self-management intervention.

R3.4.: The protocol has been amended to add further details on the subgroup analysis in response to the suggestion of the reviewer. We have rephrased the last sentence of the data analysis and synthesis section (page 12) to read:

"Subgroup analyses will be conducted where appropriate and if possible, comparing studies based on intervention characteristics, the time gap between the completion of attendance at the intervention and data collection, participants' characteristics, and study context, including continent and income level of the country where the study was carried out".

C3.5. Good reflexive account of review authors positions in the topic area and review. Inclusion of PPI is a positive step towards meaningful inclusion of patients/public. Overall a well detailed protocol, that evidences good understanding of the processes and requirements of a QES.

R3.5.: We thank the reviewer for the comments on our manuscript.

Competing Interests: None declared.

Reviewer Report 01 February 2022

https://doi.org/10.21956/hrbopenres.14677.r31171

✔ **Angela M. Rodrigues**
Department of Psychology, Northumbria University, Newcastle upon Tyne, UK

This paper is an important addition to the literature that will summarise qualitative research on the barriers and enablers to sustaining self-management behaviours. I really like the potential of generating a comprehensive theoretical framework of sustained behaviour change in type 2 diabetes self-management as a result of this work. The paper also provides an excellent description of this systematic review and qualitative evidence synthesis methodology. Some very minor comments below:

- Sensitivity analysis – Further elaboration might be beneficial. Can you detail how exactly you are going to conduct the sensitivity analysis? From your writing, I can sense that you know exactly how you are going to do it but might be worth spelling it out. For readers less familiar with sensitivity analyses in narrative synthesis this information might be particularly relevant.

- Reflexivity – I really like this section and find it very innovative to add this to a narrative

synthesis. Some further details might be needed here. How exactly are you going to do this? Are you going to keep a reflective logbook for every part of the process, for instance? How will you integrate this into your interpretation of the findings?

○ Publication plan – If possible/known, it might be appropriate to specify how many papers you anticipate publishing as a result of this work.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Diabetes prevention, behavioural science, systematic reviews

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 16 Jun 2022
Márcia Carvalho, National University of Ireland, Galway, Galway, Ireland

C2.1. This paper is an important addition to the literature that will summarise qualitative research on the barriers and enablers to sustaining self-management behaviours. I really like the potential of generating a comprehensive theoretical framework of sustained behaviour change in type 2 diabetes self-management as a result of this work. The paper also provides an excellent description of this systematic review and qualitative evidence synthesis methodology. Some very minor comments below:

R2.1.: We thank the reviewer for the comments on our manuscript.

C2.2. Sensitivity analysis – Further elaboration might be beneficial. Can you detail how exactly you are going to conduct the sensitivity analysis? From your writing, I can sense that you know exactly how you are going to do it but might be worth spelling it out. For readers less familiar with sensitivity analyses in narrative synthesis this information might be particularly relevant.

R2.2.: As suggested, we have added the following sentences to the protocol (see page 9 data analysis and synthesis) to provide further details on how we will conduct the sensitivity

analysis:

"The query tools within NVivo, such as matrix-coding queries, will be used to conduct the sensitivity analysis following the guidance provided by Houghton and colleagues (2017) [48]. Matrix-coding queries allow for the comparison of multiple nodes/codes and attributes as a numeric matrix table with different shading colours, which indicates whether studies with methodological limitations skewed the findings in any particular way based on their contribution to the finding [48]. Each study will be assessed for methodological limitations based on the CASP tool criteria to facilitate this analysis [51]".

C2.3. Reflexivity – I really like this section and find it very innovative to add this to a narrative synthesis. Some further details might be needed here. How exactly are you going to do this? Are you going to keep a reflective logbook for every part of the process, for instance? How will you integrate this into your interpretation of the findings?

R2.3.: To ensure we keep a reflective stance throughout the review, the two review authors involved in screening, data extraction and synthesis (MC and PD) have engaged in writing individual reflexive diaries and field notes, which have been recorded in memos on NVivo and form the basis for ongoing discussion in research team meetings. In addition, the two authors have been using the seven questions proposed by Barry et al. (1999) to guide their reflexive accounts. Examples of questions proposed by Barry et al. (1999) include: 'In what way might my experience colour my participation in the project?', 'What is my orientation to qualitative research?', and 'What results do I expect to come out of this project?'. The two authors have reflected on these questions and recorded their thoughts at two-time points so far: at the start of the review before commencing screening, and in the middle of the review before commencing data synthesis. The authors' reflections were recorded in memos on NVivo.
By keeping this reflexive stance, we hope to reduce potential threats to rigour and to articulate any potential impact of personal or professional beliefs or biases on the interpretation of the findings. The team has been considering and discussing any potential conflicts of interests, or biases, carefully as a team and keeping records of reflexive accounts and decisions made throughout the research process, including the rationale for the decisions. As suggested by Flemming et al. (2017), the following aspects related to author reflexivity will be reported on the final manuscript of the review: (a) the funder and their potential involvement and influence on the development and editing of the review findings; (b) the composition of the review team and the key positions or beliefs about the review question and the phenomenon of interest that could influence the interpretation of the findings; (c) potential conflicts of interest both financial and non-financial; (d) team governance procedures and processes to ensure internal validity; (e) procedures for processing evidence when one of the review authors is also an author of a primary qualitative study; and (f) procedures and processes to engage with key stakeholders ensuring no potential undue influence on the review and interpretation of the findings. The protocol has been amended as per below to provide further details on the author's reflexivity and clarify the queries raised by the reviewer on page 9 of the protocol (reflexivity):

"Both MC and PD will keep reflexive diaries and field notes, which will be recorded in memos. The authors will use the questions proposed by Barry et al. (1999) [60] to guide their reflexive accounts. Examples of questions proposed by Barry et al. (1999) [60] include: (1) 'in what way might my experience colour my participation in the project?', (2) 'what is my orientation to qualitative research?', and (3) 'what results do I expect to come out of this project?'. By keeping this reflexive stance, the research team hopes to identify potential threats to rigour and any potential negative impact of any personal or professional beliefs or biases on the interpretation of the findings.

As suggested by Flemming and Noyes (2017) [61], the following aspects relevant to author reflexivity will be reported on the final manuscript of the review: (a) the funder and their potential involvement and influence on the development and editing of the review findings; (b) the composition of the review team and the key positions or beliefs about the review question and the phenomenon of interest that could influence the interpretation of the findings; (c) potential conflicts of interest both financial and non-financial; (d) team governance procedures and processes to ensure internal validity; (e) procedures for processing evidence when one of the review authors is also an author of a primary qualitative study; and (f) procedures and processes to engage with key stakeholders ensuring no potential undue influence on the review and interpretation of the findings [61]".

C2.4. Publication plan – If possible/known, it might be appropriate to specify how many papers you anticipate publishing as a result of this work.

R2.4.: We anticipate publishing only one paper based on this review. This has been specified in the dissemination section on page 10 of the manuscript to enhance clarity.

Competing Interests: No competing interests were disclosed.

Reviewer Report 31 January 2022

https://doi.org/10.21956/hrbopenres.14677.r31085

? **Leah Avery** (ORCID)

[1] Translational and Clinical Research Institute, Newcastle University, Newcastle upon Tyne, UK
[2] Centre for Rehabilitation, School of Health & Life Sciences, Teesside University, Middlesbrough, UK

The aim of this systematic review is to synthesise qualitative research on the barriers and enablers to sustaining self-management behaviours following the completion of a self-management intervention for type 2 diabetes.

It is widely accepted that people with type 2 diabetes experience difficulties in making and sustaining lifestyle behaviour changes to effectively manage their condition. The authors highlight this point, with specific reference to sustaining changes, which provides a strong rationale for undertaking the systematic review. A number of systematic reviews exist that report on the effectiveness of self-management interventions, however, there is a lack of specific evidence reporting on the barriers and enablers. This context is vitally important to optimise existing interventions, to inform the development of new interventions, and in the case of this piece of research, to develop models of sustained behaviour change. The study is clearly described in terms of subject matter, methods, and intended outcomes, and in my view will make a valuable and much needed contribution to the field. I do, however, have a few queries as follows:

The study design is appropriate for the research question, although I have a number of queries regarding the eligibility criteria. The review aims to include qualitative studies and multi-methods studies that report qualitative findings separately. Does that refer to a separate (but linked) publication or a separate section of the mixed-methods publication, or both? As such, would this include a publication reporting on a randomised controlled trial of an intervention with a qualitative sub-study, as long as the findings from the sub-study were reported in sufficient detail within the same paper? I see that the authors have made reference to 'sufficient detail', but in the case of the two situations I have described, the level of detail could be very different. Could the authors perhaps provide further information on what will be sufficient?

In terms of sustained behavioural change at 3-months post-intervention, how will this be verified in a situation where a publication reporting on a primary qualitative study is retained for review?

By sustained, are the authors referring to any change from baseline sustained or change from completion of the intervention sustained (e.g., if a person increases physical activity by 50 minutes per week at the 1-month intervention time point and an additional 30 minutes per week at the 2-month intervention time point, will the changes be considered as 'sustained' if 20 minutes per week is reported upon intervention completion at 4-months)? I appreciate this relates to definitions of maintenance, however, it would be useful to clarify for the purpose of this review.

Will the views of non-completers be included in the review if they sustain a change in behaviour (e.g., those who complete 3-weeks of a 3-month intervention but still provide their views)? I ask because the protocol refers to those who have 'completed' a self-management intervention, however, I suspect including and synthesising the views of non-completers will be advantageous. It is possible that despite not completing the intervention, any changes made early on could still be sustained.

The methods reported are very comprehensive and enable replication, specifically in terms of study selection, data extraction, and assessment of methodological quality. Clarification on the queries highlighted in relation to inclusion criteria will further strengthen replicability and augment understanding.

In relation to the search strategy (page 6), the authors report that methodological filters will be used for qualitative research to enhance specificity where databases provide these filters. While I can understand the merit of doing this, it can sometimes omit relevant studies if the study has not been indexed using the term searched for. It might be worth piloting the search in this regard.

Overall, this is a robust and well-designed systematic review protocol reviewing literature in a very important area and will likely generate outcomes/resources of significant benefit to the field.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Development and evaluation of health behaviour change interventions in the context of type 2 diabetes, NAFLD and other long-term health conditions. Multi-method research/systematic reviews.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

> Author Response 16 Jun 2022
> **Márcia Carvalho**, National University of Ireland, Galway, Galway, Ireland
>
> **C1.1. The aim of this systematic review is to synthesise qualitative research on the barriers and enablers to sustaining self-management behaviours following the completion of a self-management intervention for type 2 diabetes.**
> **It is widely accepted that people with type 2 diabetes experience difficulties in making and sustaining lifestyle behaviour changes to effectively manage their condition. The authors highlight this point, with specific reference to sustaining changes, which provides a strong rationale for undertaking the systematic review. A number of systematic reviews exist that report on the effectiveness of self-management interventions, however, there is a lack of specific evidence reporting on the barriers and enablers. This context is vitally important to optimise existing interventions, to inform the development of new interventions, and in the case of this piece of research, to develop models of sustained behaviour change. The study is clearly described in terms of subject matter, methods, and intended outcomes, and in my view will make a valuable and much needed contribution to the field. I do, however, have a few queries as follows.**
>
> *R1.1.:* We thank the reviewer for the constructive comments on our manuscript.

C1.2. The study design is appropriate for the research question, although I have a number of queries regarding the eligibility criteria. The review aims to include qualitative studies and multi-methods studies that report qualitative findings separately. Does that refer to a separate (but linked) publication or a separate section of the mixed-methods publication, or both? As such, would this include a publication reporting on a randomised controlled trial of an intervention with a qualitative sub-study, as long as the findings from the sub-study were reported in sufficient detail within the same paper? I see that the authors have made reference to 'sufficient detail', but in the case of the two situations I have described, the level of detail could be very different. Could the authors perhaps provide further information on what will be sufficient?

R1.2.: Multi-methods or mixed-methods studies that report qualitative findings separately refer to both a separate (but linked) publication or a separate section of the mixed-methods publication. This can include a publication reporting on a randomised controlled trial of an intervention with a qualitative sub-study relevant and of sufficient depth to be synthesised in the review. However, it is important to note that the search retrieved all potentially relevant studies and, therefore, it was not actually necessary to explore separate but linked publications during the screening.

We considered relevant, and of sufficient depth for inclusion, qualitative data focused on barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes. Studies were included independent of this being the primary or secondary aim of the study, as long as relevant findings were supported by at least one quote from verbatim transcripts. Mixed-methods or multi-method studies that used qualitative data collection methods, but analysed and presented the findings quantitatively (e.g., only code labels and/or descriptive statistics) were not included in the review.

The protocol has been amended to clarify this. We added the following sentences to the eligibility criteria section (design and research type, page 6):

"Both mixed and multi-methods studies that report qualitative findings in either a separate linked publication that was cited in the study retrieved in the search or as a separate section of a study retrieved in the search will be considered for inclusion.

Studies will be included if there is a focus on barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes. Studies will be deemed relevant and of sufficient depth to be synthesised in the review if relevant findings are supported by at least one quote from participants."

C1.3. In terms of sustained behavioural change at 3-months post-intervention, how will this be verified in a situation where a publication reporting on a primary qualitative study is retained for review?

R1.3.: This has been verified by checking the data collection timing in the study abstract or full text. In many studies, the authors reported the data collection timing (e.g., 6 months

post-intervention attendance) in the methods section, specifying the time gap between intervention attendance and data collection. When the authors of the primary studies did not report the time gap between intervention attendance and data collection, the research team contacted the corresponding author(s) for clarification and further information, if contact details were available.

Studies have been excluded from the review when it is impossible to ascertain the time gap between intervention attendance and data collection in the study. This information has been added to the protocol on page 4 (phenomenon of interest):

"The data collection timing will be verified in the study abstract or full text to ascertain that data reported in the study were collected at least 3-months post-intervention. If the study is focused on barriers and enablers to sustaining self-management behaviours, but the data collection timing is not reported in the abstract, the study will be retrieved for full-text screening. When the time gap between intervention attendance and data collection is not reported in the study, the research team will contact the corresponding author(s) for clarification and further information. If it is not possible to ascertain the time gap between intervention attendance and data collection, the study will be excluded".

C1.4. By sustained, are the authors referring to any change from baseline sustained or change from completion of the intervention sustained (e.g., if a person increases physical activity by 50 minutes per week at the 1-month intervention time point and an additional 30 minutes per week at the 2-month intervention time point, will the changes be considered as 'sustained' if 20 minutes per week is reported upon intervention completion at 4-months)? I appreciate this relates to definitions of maintenance, however, it would be useful to clarify for the purpose of this review.

R1.4.: The definition of sustained change is important (and complicated!) both for this study and for the field more generally. For this review, we are focusing on the process of trying to sustain any changes made at least three months after attendance at the intervention, whether that process was successful or not.

As we are looking at qualitative data, we will focus on participants' perceptions of sustaining long-term change and we will not use a specific definition of whether changes are sustained or not as we do not have access to data on quantitative or objective measures of behaviour change. In the example provided by the reviewer, we would not make a decision as to whether this was sustained change or not but would be interested in the participant's view of this process, and the barriers and enablers to maintaining this change to physical activity.

C1.5. Will the views of non-completers be included in the review if they sustain a change in behaviour (e.g., those who complete 3-weeks of a 3-month intervention but still provide their views)? I ask because the protocol refers to those who have 'completed' a self-management intervention, however, I suspect including and synthesising the views of non-completers will be advantageous. It is possible that despite not completing the intervention, any changes made early on could still be sustained.

R1.5.: There is a difficulty in some studies in ascertaining if all the participants have completed the intervention (i.e., attended all intervention sessions), particularly in studies exploring the maintenance of randomised control trial outcomes. In these studies, different definitions of intervention completion (e.g., attendance at 75% of the programme sessions) are commonly reported. In other studies, the authors seem to use the terms intervention attendance and completion interchangeably, not specifying how these concepts were defined and/or how many sessions the study participants attended. In addition, as the reviewer highlights, a person who has attended only 50% or 75% of the sessions might also have made changes to self-management behaviours earlier in the intervention which can still be sustained at 3 months post-intervention.

Therefore, the research team has decided to focus on attendance rather than completion and to consider studies focused on barriers and enablers to sustaining self-management behaviours after attending a self-management support intervention for type 2 diabetes for inclusion in the review. With this change, it is possible that the views of non-completers, or people who did not attend all intervention sessions, will be included in the review. The title of the review and the protocol have been amended to reflect this change.

C1.6. The methods reported are very comprehensive and enable replication, specifically in terms of study selection, data extraction, and assessment of methodological quality. Clarification on the queries highlighted in relation to inclusion criteria will further strengthen replicability and augment understanding.

R1.6.: The protocol has been amended to provide further clarity on the queries highlighted by the reviewer. These changes are outlined below in response R1.7.

C1.7. In relation to the search strategy (page 6), the authors report that methodological filters will be used for qualitative research to enhance specificity where databases provide these filters. While I can understand the merit of doing this, it can sometimes omit relevant studies if the study has not been indexed using the term searched for. It might be worth piloting the search in this regard.

R1.7.: There is evidence that using validated search filters in qualitative research can result in the omission of potentially relevant studies due to the diversity of terms used to index qualitative research within electronic databases (Booth, 2016). Therefore, we have combined search filters with other synonymous free-text terms in qualitative research to enhance the specificity of the search. We have also piloted the search to ensure the retrieval of all potentially relevant studies (Booth, 2016). The protocol has been amended to reflect to clarify this. The following sentences were added to information sources and search strategy:

"Using validated search filters in qualitative research can result in the omission of potentially relevant studies due to the diversity of terms used to index qualitative research within electronic databases 37. Therefore, search filters have been combined with other synonymous free-text terms in qualitative research to ensure potentially relevant studies were not missed [37]".

C1.8. Overall, this is a robust and well-designed systematic review protocol reviewing

literature in a very important area and will likely generate outcomes/resources of significant benefit to the field.

R1.8.: Once again, we thank the reviewer for the constructive comments on our manuscript.

Competing Interests: None declared.