BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

**ARTICLE DETAILS**

| TITLE (PROVISIONAL) | An individual goal-based plan based on nursing theory for adults with type 2 diabetes and self-care deficits: a study protocol of a randomized controlled trial |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| AUTHORS             | Rosman, Jessica; Eriksson, Jan; Martinell, Mats; Lindholm Olinder, Anna; Leksell, Janeth |

**VERSION 1 – REVIEW**

| REVIEWER            | Kumar, Ramesh  |
|---------------------|----------------|
|                     | Health Services Academy, Health Systems & Policy Department |
| REVIEW RETURNED     | 01-Oct-2021    |

**GENERAL COMMENTS**

Please explain the strong rationale of this tool design. How the randomisation will be done? Explain how these 5 management skills has been developed? what is the justification?? Any theoretical background support is used for this?? How these patients will be selected? Please specify the objectives for qualitative approach and quantitative approaches. Please see this latest research with similar objectives: 2. Nooseisai M, Wiwattanakulvanid P, Kumar R, Viriyautsahakul N, Muhammad Baloch G, Somrongthong R. (2021) Effects of diabetes self-management education program on lowering blood glucose level, stress, and quality of life among females with type 2 diabetes mellitus in Thailand. Primary Health Care Research & Development 22(e46): 1–6.

You can use this paper in your research.

Moreover, there are tools available for self management efficacy for DM, Please give strong justification for the readers; why you want to design this tool? Tool validation process should be explained in detail.

| REVIEWER            | Iyngkaran, Pupalan |
|---------------------|-------------------|
|                     | The University of Notre Dame Australia |
| REVIEW RETURNED     | 18-Oct-2021       |

**GENERAL COMMENTS**

Thank for the chance to review this. The topic is straightforward and the article very neat. In regards to aesthetics there are no major criticisms. I have some comments:

1. Use of self-management and self-care. Please define term.
2. Individualised - please explain the generic CDSM tool being used or is this short format what the patients will get?
3. It seems hard to work out how patients will address the 5 self-management skills unless they are prompted. Thus a session on how to use it, or prior experience could influence the tool. Please address these issue in limitations - no doubt simplicity is vital but lack of it leaves gap. It is vital that knowledge of these gaps and how they will be addressed be important.
4. DM often have comorbid conditions. How does this tool integrate with CDSM for many conditions? If this is a pilot of this tool to be tested in larger study please specify.
5. Confounders and Bias - The study is powered well - can you expand on on treatment received e.g CV treatment like SGLT2-i for HF can improved HBAic. Are there potential confounders to HBAic that are not accounted for.
6. No discussion provided.

REVIEWER
Othman, Manal
Qatar University, College of Medicine

REVIEW RETURNED
23-Oct-2021

GENERAL COMMENTS
The intervention is not well explained and clearly written. also, the theory used is not related to self-management, it is more related to nursing practice.

REVIEWER
Cheng, Li
Sun Yat-Sen University

REVIEW RETURNED
24-Oct-2021

GENERAL COMMENTS
This study is worthwhile because it focuses on patients with type 2 diabetes and this is particularly important given that the number of such individuals is expected to increase in the future. The authors aimed to develop a written theory-based individual care plan for patients with type 2 diabetes and self-management deficit. However, there are several major concerns regarding the manuscript that need to be addressed.
1. The methodology described in the abstract is insufficient. Little information regarding the intervention design is provided.
2. How to use the Self-care theory to guide the intervention development need further elaboration.
3. Please elaborate more about how to develop the individualized plan for each patient. The dosage, duration, and intensity of the intervention is required to facilitate the maintenance of the intervention fidelity. How to facilitate patients to integrate such plan into daily life need further description.
4. What are the essence of the intervention? If it is a written plan, what is difference between the current intervention and the existing ones?
5. Who did the intervention implementation? Who collected the data? Are the data collectors blinded to the group assignment?
6. How to improve and measure patients’ adherence to the intervention protocol? How to deal with the missing data? T-test is not appropriate to deal the repeated measures and please use the appropriate method to address the research question.
7. The quantitative and qualitative parts seems separate. Please elaborate more about how to integrate the quanti and quali data from a methodological perspective.
Reviewer: 1

| Question                                                                 | Response                                                                                      |
|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Please explain the strong rationale of this tool design.                 | Added the following section:                                                                  |
|                                                                          | There is a need for further studies regarding individual DSMES. In Sweden, most patients with type 2 diabetes are treated and receive health education in the primary care setting. Diabetes nurses are responsible for DSMES; however, there is a lack of evidence in this area. The aim of the present randomised controlled trial is to evaluate whether an individualized goal-based plan (Figure 1) can reduce this knowledge gap. The purpose of the individual written plan is to set goals in diabetes self-care that are easy to understand and manageable for the patient. Additionally, these goals should be established in a collaboration between patient and diabetes nurse. |
| How the randomisation will be done?                                      | Thank you for an important question. Simple randomisation based on a single sequence of random assignments will be computer-generated using IBM SPSS version 26.0 software. A person who is not involved in the study will prepare and seal opaque envelopes marked and numbered from 1 to 110 containing the group assignment. An envelope will be opened by the diabetes nurse each time a participant is included in the study, and the patient's serial number and personal identification number will then be recorded. |
| Explain how these 5 management skills has been developed? what is the justification?? Any theoretical background support is used for this?? | Thank you for this comment, we have decided to remove this section due to the point that this theories don’t add any importance support neither to the theoretical background nor to the development of the present care-plan. |
| How these patients will be selected?                                     | The following section have been rewritten to clearly this.                                  |
The recruitment and randomisation process will be conducted according to the following:

1. Patients with type 2 diabetes will be invited to participate in the study via a mailed invitation letter, in connection with their annual appointment.
2. If the patient wishes to participate in the study, they will sign the informed consent form and complete the RAND-39 and The Diabetes Questionnaire.
3. Patients will return the signed informed consent form and questionnaires during their annual appointment.
4. A diabetes nurse will ensure that each participant meets the stipulated inclusion criteria.
5. Each patient will be randomised to either the intervention or control group, with a 1:1 allocation.

| ✓ | Please specify the objectives for qualitative approach and quantitative approaches. |
|   | We aim to examine if an individual written goal-based plan based on nursing theory can affect glycaemic control, health-related quality of life and the experiences of living with diabetes and support from the diabetes care. We further aim to get an increased understanding of the patients' experiences of using this goal-based plan. |

| ✓ | Please see this latest research with similar objectives; 2. Nooseisai M, Viwattanakulvanid P, Kumar R, Viriyautsahakul N, Muhammad Baloch G, Somrongthong R. (2021) Effects of diabetes self-management education program on lowering blood glucose level, stress, and quality of life among females with type 2 diabetes mellitus in Thailand. Primary Health Care Research & Development 22(e46): 1–6. |
|   | Thank you for the suggestion, this article is now included in the background. |

| ✓ | Moreover, there are tools available for self-management efficacy for DM. Please give strong justification for the readers; why you want to design this tool? Tool validation process should be explained in detail. |
|   | We have added a rationale and provided additional information about a pilot study that has been previously performed. The intervention has been tested in a pilot study and the instrument has been validated in an unpublished master’s thesis.34 |
There is a need for further studies regarding individual DSMES. In Sweden, most patients with type 2 diabetes are treated and receive health education in the primary care setting. Diabetes nurses are responsible for DSMES; however, there is a lack of evidence in this area. The aim of the present randomised controlled trial is to evaluate whether an individualized goal-based plan (Figure 1) can reduce this knowledge gap. The purpose of the individual written plan is to set goals in diabetes self-care that are easy to understand and manageable for the patient. Additionally, these goals should be established in a collaboration between patient and diabetes nurse.

Reviewer: 2

1. Use of self-management and self-care. Please define term.

Thank you the important comments, we have rearranged the section about the concepts to bring further clarification:

According to the self-care deficit nursing theory by Dorothea Orem, self-care is a human need, and nursing is required in situations of self-care deficits. Self-care deficits can comprise limitations in knowledge, the ability to perform actions, or in making decisions. Self-care and self-management are often understood and used as equivalent concepts, without in-depth explanation. In a concept analysis by Richard and Shea, the relationship among a range of concepts, including self-care and self-management, was described and differentiated. Self-management is defined as a part of self-care. Both self-care and self-management are based on the philosophy that individuals are primarily responsible for their own health. Self-management is defined as “the ability of the individual, in conjunction with family, community, and healthcare professionals to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions”. According to Orem, the role of nurses is to support, teach, guide, and provide an environment that supports personal development.

2. Individualised - please explain the generic CDSM tool being used or is there.

Added a rationale to the background:

There is a need for further studies regarding individual DSMES. In Sweden, most patients with type 2 diabetes...
| this short format what the patients will get? | are treated and receive health education in the primary care setting. Diabetes nurses are responsible for DSMES; however, there is a lack of evidence in this area. The aim of the present randomised controlled trial is to evaluate whether an individualized goal-based plan (Figure 1) can reduce this knowledge gap. The purpose of the individual written plan is to set goals in diabetes self-care that are easy to understand and manageable for the patient. Additionally, these goals should be established in a collaboration between patient and diabetes nurse. |
|---|---|
| 3. It seems hard to work out how patients will address the 5 self-management skills unless they are prompted. Thus a session on how to use it, or prior experience could influence the tool. Please address these issue in limitations - no doubt simplicity is vital but lack of it leaves gap. It is vital that knowledge of these gaps and how they will be addressed be important. | Thank you for this comment, we have decided to remove the section regarding the 5 self-management skills section due to the point that this theories don’t add any importance support neither to the theoretical background nor to the development of the present care-plan. 

**Added to the Method:**

The diabetes nurses participating in this study will include registered nurses with higher education training in diabetes care. Nurses will attend a 2-hour educational session regarding the theoretical framework of the intervention and how to apply it in practice. This educational training will be conducted by a doctoral candidate on the research team with knowledge of the nursing theory adopted in this study. Diabetes nurses will be encouraged to discuss and reflect on use of the individual goal based plan among themselves and with the doctoral student so as to complete the educational process. Diabetes nurses are informed that both the intervention and control group should receive equal pharmaceutical treatment for type 2 diabetes in accordance with current guidelines. |
| ✓ | 
| 4. DM often have comorbid conditions. How does this tool integrate with CDSM for many conditions? If this is a pilot of this tool to be tested in larger study please specify. | In this initial study the focus is persons with diabetes. If there will be a positive result of this study there is an interest to apply the same tool regarding other chronic conditions e.g. heart failure and obesity. |
| ✓ | 
| 5. Confounders and Bias - The study is powered well - can you expand on treatment recevied e.g CV treatement like SGLT2-i for HF can improved | Diabetes nurses are informed that both the intervention and control group should receive equal pharmaceutical treatment for type 2 diabetes in accordance with current guidelines. Of course there is potential confounders to |
|   | HBAic. Are there potential confounders to HBAic that are not accounted for. | HbA1c. Due to the research design (RCT) the impact of this confounders will hopefully decrease. |
|---|---|---|
|   | Data will be collected regarding pharmaceutical treatment. |   |

| ✓ | 6. No discussion provided. | Not needed according to template |
|---|---|---|

Reviewer: 3

| ✓ | The intervention is not well explained and clearly written. also, the theory used is not related to self-management, it is more related to nursing practice. | We have clarified the intervention and described the theoretical basis of nursing, in the context in which the study is conducted. |
|---|---|---|

Reviewer: 4

| ✓ | 1. The methodology described in the abstract is insufficient. Little information regarding the intervention design is provided. | Thank you for this important standpoint. The abstract has been rewritten to clarify the methodology and the intervention design. |
|---|---|---|
| ✓ | 2. How to use the Self-care theory to guide the intervention development need further elaboration. | Changed the interventions section in the Method: The present intervention is based on the theoretical framework of Dorothea Orem\(^{11}\) and inspired by the American Association of Diabetes Educators (AADE) 7 Self-Care Behaviours\(^{33}\) regarding healthy eating, being active, taking medications and support problem solving. The underlying assumption is that nurses can facilitate the action of self-care by clarifying the patient’s self-care requisites and can support the patient to express this both verbally and in writing. To inspire the patient to reflect on self-care in a structured way using four predetermined questions, the nurse and the patient in collaboration can determine which available care interventions can increase the patient’s knowledge, ability to perform self-care actions, and capacity to make decisions, in accordance with Orem’s self-care deficit theory. Additionally, using the individual goal based plan, diabetes nurses together with the patient can identify and clarify ways for the patient to overcome self-care deficits. This collaboration can also increase the use of resources that already exist in the primary care setting, such as dietitians, physiotherapists, and counsellors. As a result, the patient can become more self-sufficient regarding self-care. |
|   |   |   |

| ✓ | 3. Please elaborate more about how to develop the individualized plan for | Thank you for this question. The core of the care-plan is to inspire the patient to reflect on their own self-care |
|---|---|---|
| Question                                                                 | Answer                                                                                                                                                                                                 |
|-------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| each patient. The dosage, duration, and intensity of the intervention is required to facilitate the maintenance of the intervention fidelity. How to facilitate patients to integrate such plan into daily life need further description. | activities in a structured way using the four predetermined questions. After, In accordance with Orem self-care deficits theory, the diabetes nurse support and guides the patient how and in what way these self-care activities can increase the patient's knowledge, ability and capacity to carry out these activities, on a daily basis. Furthermore it becomes clear what patients can manage by their own and what kind of support patient needs from primary care, such as dietitian, physiotherapist or physician. We have clarified this in the paper. |
| 4. What are the essence of the intervention? If it is a written plan, what is difference between the current intervention and the existing ones? | See above.                                                                                                                                                                                               |
| The difference is the structured way of working for the diabetes nurse. There is as today in the Swedish primary care setting no consensus about how to work with individual self-care education and support. |                                                                                                                                                                                                          |
| 5. Who did the intervention implementation?                              | The intervention is conducted by diabetes nurses that are educated on how to use the individual care plan.                                                                                               |
| Who collected the data?                                                  | The data will be collected by the responsible PhD student. Added a section about the Swedish diabetes registry from which data will be collected.                                                        |
| Are the data collectors blinded to the group assignment?                 | The data collectors are not blinded.                                                                                                                                                                     |
| 6. How to improve and measure patients’ adherence to the intervention protocol? | The study is not supposed to be a process evaluation in this earliest phase. The result measured is primarily the HbA1c. The evaluated intervention is the individual care plan, not the self-care change that is a possible consequence of it. |
| How to deal with the missing data?                                       | It has not yet been decided how missing data will be handled. This decision will be made together with an experienced statisticians.                                                                    |
| T-test is not appropriate to deal the repeated measures and please use the appropriate method to address the research question. | Unpaired t-test will be used to compare the groups regarding the difference at baseline and the two measuring points (six months and twelve months).                                                                 |
7. The quantitative and qualitative parts seems separate. Please elaborate more about how to integrate the quanti and quali data from a methodological perspective.

The result of the study described in the study protocol is intended to form the basis for two articles. The result will then be brought together in a doctoral dissertation.

It is an interesting view and we will further ahead reflect around the possibility to join together the quantitative and qualitative data with an analytical process like e.g. joint display.

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### VERSION 2 – REVIEW

| REVIEWER | Iyngkaran, Pupalan  
The University of Notre Dame Australia |
|----------|------------------------------------------------------------------|
|          | I have interest CDSM and have published in the area             |
| REVIEW RETURNED | 09-Feb-2022                                                   |

### GENERAL COMMENTS

Thank you for the opportunity to review this rebuttal. The authors have gone through the manuscript and provided thought to the questions raised. As for the 15 points above (yes/ no replies) I cant see any faults for a negative response. The paper itself:

- The title and topic is highly relevant for today's medical practice. It has a nursing basis which is important for administering meaningful CDSM. The term self-care vs self-management can be used interchangeably or have specific meanings. I am hopefully the editorial team will communicate the authors and ensure the most accurate (and consistent) use.

- General comments - please clarify self-care v self-management differences or use one. HBAic in some areas are given as a percentage - pls clarify your reference; Pt n

The Abstract is of good quality - adding some study details e.g patient numbers could help when readers and scanning to see if article is powered. Some terms are a bit loose - self-care deficit can also mean self-efficacy. There are tools to assess this already. Deficit is a negative view, efficacy positive. Also there are elements of this including monitoring, actioning, interpreting - so it is broad area that may need some explanation.

- Introduction - good
- Rational and objective - please check with Journal the format for where this is best placed
- Methods - eligibility does not factor comorbidities, could this influence study results and pt knowledge; rest of methods are reasonable.

Summary - a good short study. I think there are deficits in your design, its hard to spell it all out. However it is important area and
if presented well and reproducible then it will add something and provide discussions points. Look forward to seeing what you find.

**VERSION 2 – AUTHOR RESPONSE**

| Editorial requests                                                                 | Authors response                                                                 |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Please note that BMJ Open does not accept declarative titles. Please revise the title to include the research question. For example "An individual goal-based plan based on nursing theory for adults with type 2 diabetes and and self-care deficits: a study protocol of a randomized controlled trial". | Thank you for the suggestion regarding the title. We have now changed the title according to your recommendation. |
| ✅ The recruitment setting is somewhat unclear. The manuscript states that "Recruitment of participants will be conducted at several primary care units in the Region of Uppsala, Sweden" but the trial registry states that this is a single-center interventional randomized controlled trial. Please clarify and amend as necessary. | We have now changed this in the trial registry to a multi-center interventional randomized controlled trial. |
| ✅ You have clarified in your response to reviewer 4 that "the difference between the current intervention and existing interventions is the structured way of working for the diabetes nurse. There is as today in the Swedish primary care setting no consensus about how to work with individual self-care education and support." Please clarify this in the manuscript. | Thank you for suggesting this clarification. We have now clarified this in the rationale. |
| ✅ We note that you cite unpublished work in the manuscript "The intervention has been tested in a pilot study and the instrument has been validated in an unpublished master's thesis". Are you able to add the relevant data within the manuscript, Supporting Information files, or in a public repository? | We have added the following section to the manuscript regarding relevant data from the master’s thesis:

"The intervention has been tested in a pilot study in an unpublished master’s thesis. In the intervention group, HbA1c decreased by 8.8 mmol/mol (SD = 14.7) after three months (p = 0.027) while the control group showed no change in HbA1c. However, no significant difference in HbA1c was demonstrated between the
| Reviewer 4 previously asked about data collection. Please ensure that this information has been added to the manuscript, and not just provided in the author response. | We have now added a section regarding who will perform the data collection and regarding whether data will be blinded or not. |
|---|---|
| We note from your response to reviewer 4 that you haven’t yet decided how to handle missing data. When will this be addressed? If you are planning to publish a separate statistical analysis plan, please state this. Otherwise the statistical plan should be presented in this protocol. | There is now a section regarding missing data included in the manuscript. We have added an table regarding the statistical plan in the manuscript (table 2) for clarification purpose. |

**Reviewer 2**

The title and topic is highly relevant for today’s medical practice. It has a nursing basis which is important for administering meaningful CDSM. The term self-care vs self-management can be used interchangeably or have specific meanings. I am hopefully the editorial team will communicate the authors and ensure the most accurate (and consistent) use. General comments - please clarify self-care v self-management differences or use one.

We would like to argue that we have already clarified the two concepts and the relationship between them. The concept of self-care vs self-management is defined in the following section:

“Self-care and self-management are often understood and used as equivalent concepts, without in-depth explanation. In a concept analysis by Richard and Shea,¹² the relationship among a range of concepts, including self-care and self-management, was described and differentiated. Self-management is defined as a part of self-care. Both self-care and self-management are based on the philosophy that individuals are primarily responsible for their own health. Self-management is defined as “the ability of the individual, in conjunction with family, community, and healthcare professionals to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions”."¹²”

HbA1c in some areas are given as a percentage - pls clarify your reference; Pt n

HbA1c is given in mmol/mol in accordance with the IFCC standard throughout the manuscript.

The Abstract is of good quality - adding some study details e.g. patient numbers could help when readers and scanning to see if article is powered.

Thank you for this comment. We have now added the number of patients that will be included to the abstract.
Some terms are a bit loose - self-care deficit can also mean self-efficacy. There are tools to assess this already. Deficiency is a negative view, efficacy positive. Also there are elements of this including monitoring, actioning, interpreting - so it is broad area that may need some explanation.  

| Rational and objective - please check with Journal the format for where this is best placed | Thank you, we appreciate this comment and intend to inquire were this is best placed. |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|

| Methods - eligibility does not factor comorbidities, could this influence study results and pt knowledge; rest of methods are reasonable. | Thank you so much for this really important statement. We have now added to the manuscript that we have ethical approval for collecting data regarding; diabetes duration, treatment regimen (insulin, oral drugs and/or GLP), other pharmaceutical treatment (antihypertensive, lipid lowering drugs) comorbidity (ischemic heart disease, cerebrovascular disease) and late complications (nephropathy, retinopathy, foot complications) body mass index, blood pressure, low-density lipoprotein, high-density lipoprotein, cholesterol, urine albumin and urine albumin to creatinine ratio. |

| Summary - a good short study. I think there are deficits in your design, its hard to spell it all out. However it is important area and if presented well and reproducible then it will add something and provide discussion points. Look forward to seeing what you find. | We have now clarified the design by adding some important information regarding the design of the study. Hopefully this clarifications now makes the design easier to follow. |

We consider Orem’s definition of self-care deficits more suitable for the aim of this study.