

BMJ Open Powerful together with diabetes, a group-based self-management intervention for patients with type 2 diabetes from lower educational groups: study protocol for a hybrid type 2 evaluation

Bedra Horreh ¹, Femke van Nassau,² Lorraine Landais,³ Charlotte Vissenberg,⁴ Johanna M van Dongen,⁵ Hidde P van der Ploeg,² Karien Stronks⁶

To cite: Horreh B, van Nassau F, Landais L, *et al.* Powerful together with diabetes, a group-based self-management intervention for patients with type 2 diabetes from lower educational groups: study protocol for a hybrid type 2 evaluation. *BMJ Open* 2025;**15**:e087767. doi:10.1136/bmjopen-2024-087767

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2024-087767>).

Received 23 April 2024

Accepted 02 December 2024



© Author(s) (or their employer(s)) 2025. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ Group.

For numbered affiliations see end of article.

Correspondence to

Bedra Horreh;
b.horreh@amsterdamumc.nl

ABSTRACT

Introduction Type 2 diabetes mellitus (T2DM) is a major burden on public health worldwide. To reduce adverse events and complications, effective T2DM self-management is required. Self-management and glycaemic control are generally poorer in lower educated people compared with higher educated people. This study aims to assess the (cost-)effectiveness and to conduct a process evaluation of a diabetes self-management programme, 'Powerful Together With Diabetes' (PTWD), which is specifically developed for patients from lower educational groups.

Methods and analysis The PTWD programme is focused on attaining basic knowledge and skills for effective diabetes self-management. In a previous study (the Diabetes in Social Context (DISC) study), lower-educated participants enjoyed the PTWD programme as well as improved their T2DM-related behaviours. The design of the study is an effectiveness-implementation hybrid type 2 trial. We will conduct mixed methods effectiveness, process and economic evaluations. To investigate the (cost-)effectiveness, a two-arm quasi-experimental trial will be conducted with a parallel mixed method process evaluation. The primary outcome of the study is change in haemoglobin A1c levels from baseline to 12 months. Secondary outcomes include use of primary and secondary care, medication use, blood biomarkers, T2DM self-management health behaviours, anthropometrics, and quality of life. Data will be collected with questionnaires, physical activity trackers and registration data from general practitioner registries. To see if the results are maintained, we will also measure the outcomes 24 months after baseline. Study participants are patients from lower educational groups living with T2DM between 35 and 70 years old. Participants will be recruited through general practices, and the intervention will be held in community centres. Our aim is to include 114 participants in the intervention group and 570 participants in the control group.

Ethics and dissemination This study has been approved by the Medical Ethics Committee of the Academic Medical

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ In research on interventions to promote diabetes self-management, patients from lower educated groups are an understudied population; this study will contribute to the evidence base for interventions specifically designed for this population.
- ⇒ The study design is a hybrid type 2 trial, which will include effectiveness, economic and process evaluations.
- ⇒ This is a pragmatic real-world trial rather than a randomised controlled trial, which allows it to better study the integration of the intervention programme into regular care while including a more representative sample.
- ⇒ Another strength of this study is that we will also examine historical data from up to 8 years before baseline to get a better sense of the development of type 2 diabetes mellitus over time and the influence of the intervention programme.
- ⇒ A possible limitation is the lack of randomisation; however, this will allow us to observe a more realistic, real-world implementation.

Center in Amsterdam (#2021_222). Participants will sign an informed consent form prior to enrolment. Manuscripts with the results of the effectiveness, economic and process evaluations will be published in peer-reviewed journals.

Trial registration number [ISRCTN12982302](https://www.isrctn.com/ISRCTN12982302) ISRCTN registry (registered on 29 March 2022).

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic disease associated with several health complications and contributes to an increasing disease burden in all European countries, including the Netherlands.¹ To reduce the chances of adverse events and complications

related to diabetes and consequently maintain quality of life and keep healthcare costs manageable, effective diabetes self-management is required.² Effective diabetes self-management consists of a healthy diet, physical activity, monitoring of blood sugar levels, adherence to prescribed medication, good problem-solving skills, and healthy coping with stress.³ According to a meta-analysis, patients with T2DM adhering to at least one healthy behaviour (eg, a favourable diet or physical activity) had a 57% lower mortality as compared with patients adhering to none.⁴ A meta-analysis, covering studies that investigate the effects of interventions promoting diabetes self-management, showed improvement of glycaemic control in T2DM patients.⁵ Furthermore, a systematic review showed that interventions for T2DM patients, focusing on a healthy diet and physical activity, have a significant effect on blood glucose and improving quality of life of these patients.⁶

Research has shown that educational level is an enabler of effective diabetes self-management; patients with a higher educational level have better self-management skills.⁷ On the contrary, patients with lower educational levels show less glycaemic control (haemoglobin A1c (HbA1c) <7%).⁸ Patients with lower educational levels also have a higher risk of complications and lower health-related quality of life. In order to improve patients' self-management, guidelines recommend that every patient should receive self-management education in a format which is appropriate for the patient's cultural, socio-economic and literacy characteristics.⁹ These guidelines show a need for more targeted and tailored diabetes care, in which patient characteristics are used to adjust their self-management education.¹⁰ However, current programmes, promoting diabetes self-management, are often tailored to the needs of patients with a higher educational level. In fact, diabetes management education in these programmes is highly standardised and does not account for the heterogeneity of diabetes patients.⁸

Another point of interest is that healthcare professionals struggle to provide effective care and support for patients with lower educational levels with regard to their diabetes self-management.¹¹ These struggles consist of difficulties when they provide care to patients with low motivation and involvement. Healthcare professionals stated they have given up the support of these patients after many years without achieving any success.^{8 11}

In view of patients' lower control rates and the struggles of healthcare professionals,^{12 13} it is important to develop tailored programmes that fit the specific needs of patients with lower educational levels. In order to meet these needs, the tailored Powerful Together With Diabetes (PTWD) programme was developed. This programme employs adapted learning strategies and strategies to mobilise social support, based on the importance of social networks and social network interventions for glycaemic control.¹⁴ In a previous study (the DISC study), lower-educated participants enjoyed the PTWD programme, improved their T2DM-related behaviours

and significantly increased their physical activity.^{15 16} The qualitative evaluation showed that patients in the intervention group showed more advanced diabetes self-management behaviours, including better medication adherence.^{15 16}

However, although the previous study showed positive outcomes of the programme, the effectiveness on glycaemic control could not be studied due to the absence of registration data. Furthermore, the previous study showed that the programme required some improvement and additions on certain components. In the current study, the (cost-)effectiveness on HbA1c of the improved programme compared with usual care will be studied in a quasi-experimental trial. Furthermore, a process evaluation will be conducted to study the implementation process, mechanisms of impact and contextual factors influencing implementation of PTWD.

Aims and objectives

This hybrid type 2 study has two aims: (1) to assess the (cost-)effectiveness of the strengthened PTWD programme compared with two control groups and (2) to specify the conditions under which the programme works and evaluate the implementation process. The primary outcome of the effectiveness study is HbA1c; the secondary outcomes are use of primary and secondary care, medication use, blood biomarkers, T2DM self-management health behaviours, anthropometrics and quality of life. Costs of the PTWD participants during the 12-month follow-up will be described from the societal perspective. The full economic evaluation comparing PTWD with usual care will be performed from the healthcare perspective. The process evaluation will evaluate the implementation process (ie, recruitment, reach, fidelity, feasibility, dosage), mechanisms of impact (ie, suitability, satisfaction, perceived effectiveness), and contextual factors hindering or facilitating implementation of PTWD.

METHODS AND ANALYSIS

Study design

The design of our study is an effectiveness-implementation hybrid type 2 trial, to equally focus on the (cost-) effectiveness and the process of implementing the intervention.¹⁷ To investigate the intervention effectiveness on HbA1c, we will conduct a two-arm quasi-experimental effect study comparing the intervention group with two control groups. Additionally, an observational pretest post-test study will be conducted in the intervention arm only to evaluate changes in secondary outcomes: anthropometrics, health behaviours, psychological outcomes, T2DM self-management behaviours and other health behaviours. [Figure 1](#) summarises the study design in a flow chart based on the Consolidated Standards of Reporting Trials template. Online supplemental file 3 provides the completed Standard Protocol Items: Recommendations for Interventional Trials checklist.

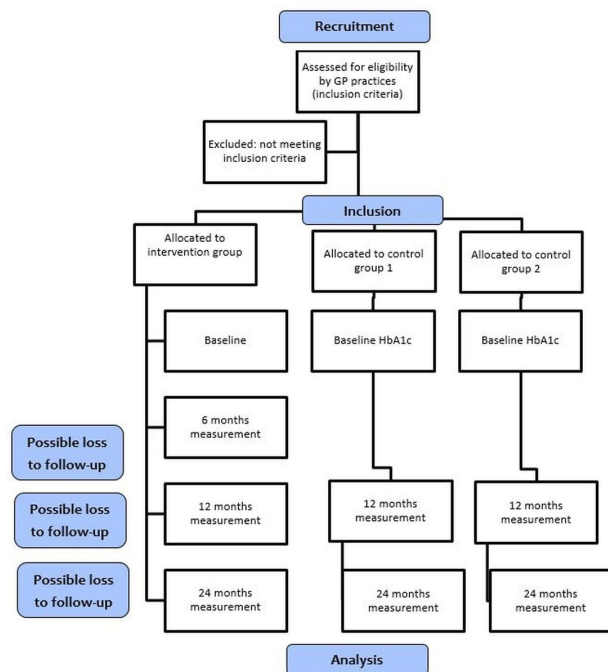


Figure 1 Flow chart of the study.

The process evaluation will evaluate the implementation process (ie, recruitment, reach, fidelity, feasibility, dosage), mechanisms of impact (ie, suitability, satisfaction, perceived effectiveness) and contextual factors hindering or facilitating implementation of PTWD in the intervention arm only, according to the UK Medical Research Council (MRC) guidance for process evaluations¹⁸

Study participants

The study population will include lower educated patients between 35 and 70 years old who are being treated for T2DM and diagnosed at least 1 year before inclusion. The educational level of patients is not registered in general practitioner records. Whether patients belong to the target group will be assessed by the general practitioner (GP) based on the following inclusion criteria: a lack of adequate diabetes self-management, suboptimal results with standard diabetes care, a need for extra or different support in their diabetes self-management, a low overall health literacy or mild intellectual disabilities. Patients will be excluded when the general practitioner has objections against participation of the patient, patients with a serious psychiatric condition that prevents participation in the intervention, patients who cannot independently come to the location where the intervention is offered and patients who plan to go abroad for a long time during the programme.

Recruitment process

For the intervention group, T2DM patients will be selected from general practices in lower socioeconomic neighbourhoods in Amsterdam, the Netherlands. Participants will be invited by their GP to participate in the trial and the PTWD programme. The general practitioner or

practice nurse will select patients from their own practice based on the inclusion criteria described above.

Eligible patients will be invited by their general practitioner to a 'welcome meeting' about PTWD. To do so, they will receive a letter from their GP practice, and then they will be invited by telephone by the researcher. At the welcome meetings, patients will receive detailed information on the programme; they will get introduced to the group leaders and other potential participants, and study procedures. The meeting will also include a PTWD taster session guided by the group leaders, which will be a small interactive component of the intervention to get a good sense of the content of the programme. This meeting is aimed to lower potential barriers to participation and to increase trust.¹⁹ After the welcome meeting, patients will have 1 week to consider their participation. The researcher will call all patients who were invited after the welcome meeting. During this call, they will be asked to participate in the PTWD programme and give their informed consent for the study procedures. Participants will sign a written informed consent, see online supplemental file 1.

We will use two different control groups. The first control group will consist of patients who are selected for the intervention group in the same general practices as the intervention group, but did not participate. For the second control group, we will make use of general practice registries in similar neighbourhoods as those from which we selected the general practices for the intervention group. The patients for this second control group will again be selected by their general practice using the same criteria as were used for the intervention group. During the study period, they will not participate in the programme.

Sample size calculation

Our aim is to demonstrate a clinically relevant 5% decrease in the HbA1c level (primary study outcome) from baseline (T0) to the 12 months (T2) follow-up assessment in the intervention group compared with the second control group. At T0, we expect the average HbA1c level in our study population to be 7.5% (=58 mmol/L). With $\alpha=0.05$ and a power of 80%, we will need 114 respondents in the intervention group with valid HbA1c data and 570 patients in the second control group at T2. For every included participant in the intervention and both control groups, the primary outcome (HbA1c level) will be taken from registration data from their general practice, including for participants who drop out of the programme. Therefore, we anticipate minimal patient drop out and hence have not taken this into account for the sample size calculation.

Powerful Together with Diabetes (PTWD) intervention

The intervention consists of an improved version of the previously developed Powerful Together with Diabetes (PTWD) programme.^{16 20} The current PTWD programme consists of two phases with 27 weekly meetings in total. A

trained group leader will deliver the programme to groups of up to 10 participants. The PTWD programme is aimed at enhancing diabetes self-management by improving behaviours related to diabetes self-management. These behaviours consist of monitoring blood glucose levels, taking medications, a healthy diet, sufficient physical activity, managing stress and healthy sleep habits. Another aim is to increase social support to perform these behaviours and to deal better with unhelpful influences of significant others.¹⁶ Furthermore, the intervention strategies in PTWD are tailored to patients from lower educated groups with low health literacy.¹⁶

Methods of change (theoretical framework) and practical applications of Powerful Together With Diabetes (PTWD)

PTWD is developed using the I-Change model combined with the social network model of Berkman *et al.*^{20–22} The core elements of the PTWD programme consist of a group-based approach, inductive learning, self-affirmation and practical education.¹⁶

The PTWD programme is aimed at increasing autonomy among participants. It adopts the learning method ‘learning from within’, also known as inductive learning, which starts with participants’ experiential knowledge.²³ This learning method promotes involvement and continued participation. In addition, PTWD strives for more connection and social support between

participants. Therefore, a core element of PTWD is the group-based approach. Group education promotes the embedding of participants in a closer social network and the exchange of experiences and mutual support.²⁴ Furthermore, autonomy and connectedness are further strengthened through the use of positive education.²⁵ This learning method also offers participants the self-affirmation they need to further develop their competencies. The three learning methods provide a context that optimally facilitates the improvement of T2DM self-management for patients from lower educated groups.

To achieve behavioural change, the active, practical and interactive working methods in the programme (ie, practical applications) contain a diversity of theoretical and empirically substantiated methods for change.^{26–27} The working methods often contain game elements and are aimed at a variety of determinants of T2DM self-management (I-Change Model²¹). In this way, participants first increase their motivation and skills for self-management. Second, they gradually convert that motivation into healthier self-management behaviour. The content-related themes that are discussed include medication, nutrition, exercise, stress, and sleep.

Figure 2 shows a logic model with the programme theory, the components and the goals.

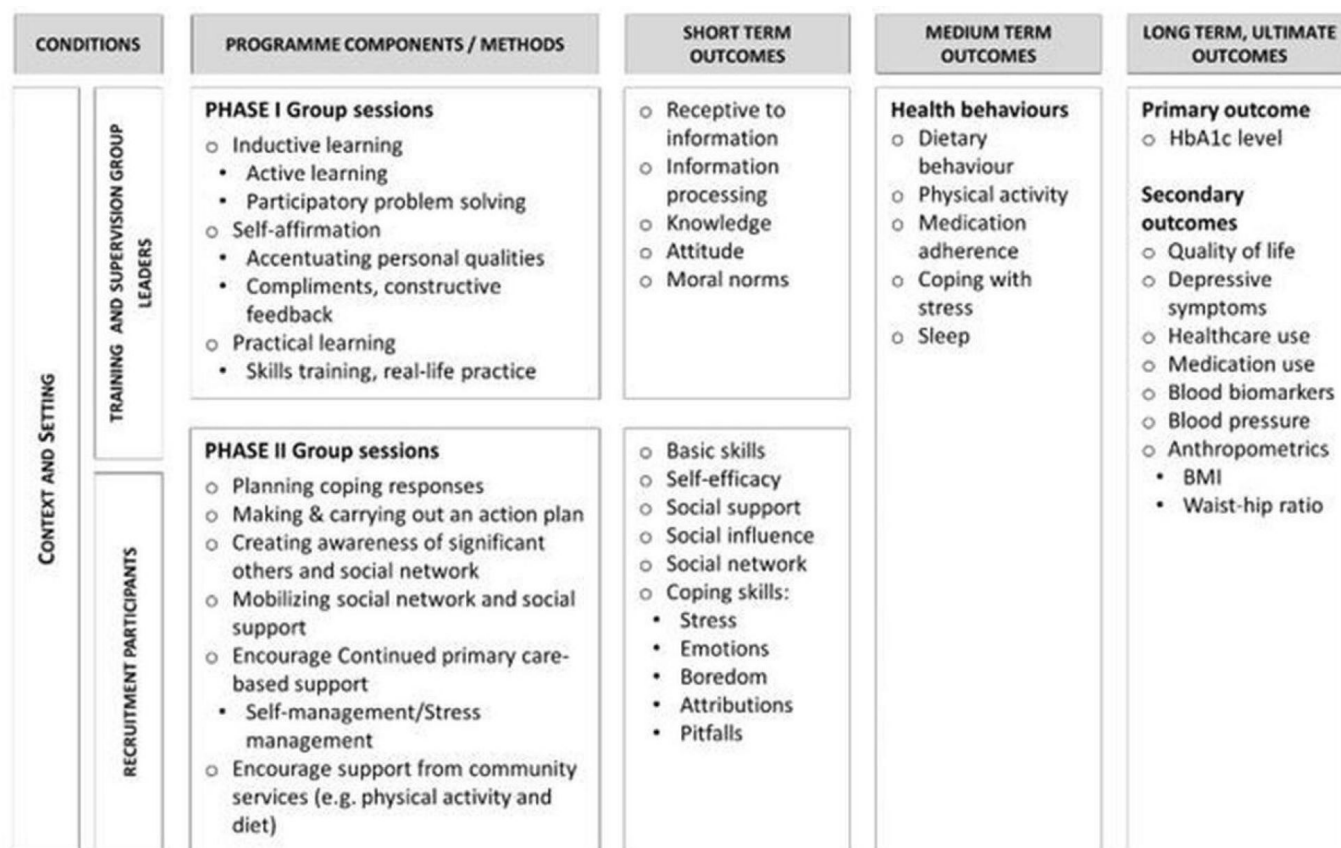


Figure 2 Logic model of the updated Powerful Together with Diabetes programme (21). BMI, body mass index; HbA1c, haemoglobin A1c.

Phase 1

Phase 1 consists of 15 weekly meetings of 2 hours. The focus of this phase is on increasing motivation by improving determinants such as positive outcome expectations, moral norms, knowledge, skills, self-efficacy, stimulating social support, and recognising and dealing with psychosocial mechanisms that hinder optimal diabetes self-management.¹⁹ Furthermore, this phase focuses on learning healthier self-management behaviours by practicing these behaviours in the meetings and small homework assignments to try out at home.

The meetings will be held in local community centres and will be led by a group leader. Each meeting will focus on one topic related to diabetes self-management, and the order and content of the meetings are fixed.

In this phase, methods such as awareness and individualisation (eg, through collecting questions and in a do-it-yourself (DIY) task) will contribute to participants' self-insight and autonomy. Convincing communication, arguments and discussion (eg, in a knowledge game and a video with discussion) aim to increase participants' knowledge. Positive attitudes are expected from methods such as further elaboration, selecting views, and weighing pros and cons (eg, in a statements game). A more positive moral standard can emerge when participants re-evaluate themselves and discuss their standards (eg, in response to a letter of the week or a role play). By planning and directly experiencing coping responses (eg, in a role play), participants will expand their behavioural repertoire and strengthen their self-confidence and skills. The same applies to gaining direct experience with, and monitoring and evaluating healthier self-management behaviour (eg, in a homework assignment).²⁰

Each meeting will have a fixed structure, and the emphasis is on increasing motivation for healthy behaviour and experimenting with these healthy behaviours. The general structure of each meeting will consist of welcoming participants, a reflection on the previous meeting, collecting questions, a positive news round, energisers, homework, a conclusion and a group exercise. See online supplemental tables 1 and 2 for an overview of phase 1 with the themes, subthemes, and the corresponding educational approaches and a selection of the content of this phase.

Phase 2

Phase 2 consists of 12 weekly meetings of 2 hours. This phase will start with the participants' social networks, and then the theme of medication will be revisited. Afterwards, the group leader and/or participants will choose from 20 prestructured sessions. In the sessions on nutrition, exercise, stress and sleep, participants will be guided through a cycle of behaviour change as described below. Other sessions cover topics such as diabetes and holidays, Ramadan and smoking. In addition to the theme, the group leader can also select one of the 15 methods aimed at creating opportunities for or dealing with barriers to healthy self-management behaviours.

In this phase, aimed at converting motivation into behaviour, participants will explore their social networks (eg, in a DIY task) and will mobilise social support for their behaviour change. The work cycle that follows focuses on active learning, a method that increases intrinsic motivation and promotes learning through goal-oriented and practical experiences. The fact that participants will set goals and formulate implementation intentions themselves (step 1) will contribute to the relevance, specificity and feasibility of their 'healthy intentions'. Methods such as public commitment and behavioural contracts (eg, by recording an intention or choosing a symbol) will increase the involvement of participants in their behavioural goal. Through instructions, gaining direct experience and monitoring behaviour (step 2), participants will increase their self-confidence and skills. Repeated behaviour also contributes to habit formation.²⁸ When participants share their experiences (step 3), they re-evaluate themselves and their environment. This facilitates positive reinforcement and favourable attribution of failure and success. This contributes to self-affirmation and to the commitment and motivation needed to maintain the initiated behaviour change. In addition, participants will choose, practice and plan different coping responses (step 4). These result in implementation intentions ('if-then' plans), with which they will increase their options for healthy behaviour and reduce barriers to this.²⁹ Online supplemental tables 3 and 4 present an overview of phase two with themes, subthemes, and corresponding educational approaches and a selection of the content of phase 2.

Follow-up support

As part of the cycle of behaviour change, the participants and the group leader can also get acquainted with local neighbourhood initiatives, such as a local walking group. For each of the self-management themes in PTWD, the group leader is provided with a number of suggestions for this purpose. The aim is that participants will make more use of these services as additional support for their diabetes self-management or for assistance with issues in other life areas. This will also serve as a bridge to future support for participants once PTWD is concluded.

Adjustments from original Powerful Together With Diabetes (PTWD) programme

Based on the previous evaluation, we made the following improvements to the PTWD programme.²⁰

General adjustments

1. Ethnically homogeneous groups and ethnically matched group leaders:

In the original PTWD programme, many materials have been adapted for use by/with participants from different ethnic backgrounds. Additionally, part of the groups were ethnically homogeneous and in these groups, the group leader always shared the same ethnic background as the participants. However, the

quality of the implementation varied among the different groups, and the added value of ethnic homogeneous groups and ethnic matching of the group leader was unclear. Considering the complication of these aspects for the broader implementation of PTWD, we decided we will recruit group leaders based on their qualities and skills instead of their ethnicity.

2. The original PTWD programme was developed based on a needs assessment with patients with different cultural backgrounds, including Turkish, Moroccan and Surinamese. For example, we have developed the meetings about nutrition based on different products that are used in these different groups, so they recognise it and can apply the advices. Another example is that sociocultural values and barriers to diabetes self-management were incorporated into the programme (eg, in the letter of the week and statement games). This original programme therefore contained flexible cultural adjustments for participants of Turkish, Moroccan and Surinamese origin. The strengthened version will also contain additional cultural adjustments for participants of Ghanaian origin.
3. Group leaders will be specifically trained in conducting the programme according to the core elements: positive education, learning from within (inductive learning) and learning with each other (group education). During the training of the group leaders, these elements will be put into practice, and educational approaches used in the programme will be practiced by group leaders. This will enable group leaders to use their own experience to master the specific working method in order to adequately guide participants.

Adjustments in phase 1

1. Extension of the programme with new themes: the process evaluation from the initial DISC study showed that the themes stress, sleep and alcohol would be valuable additions to the programme.³⁰ Therefore, they will be included in the group sessions of the strengthened version of the programme.³⁰ Before modifying the programme, a brief needs assessment about these themes will be performed by conducting interviews with representatives of the target group. The results of the interviews will further underline the relevance of these themes for the target group and the importance to incorporate these themes into the existing programme.
2. Meetings for and with significant others and generating social support: the original programme components involving significant others will also be adapted in the strengthened version. The previous process evaluation showed that participation of significant others in the meetings was low and participants were hesitant to invite their significant others because of several reasons, including that the participants did not want to burden them, or did not want them to interfere in their self-management, or the participants experienced shame.³⁰ Due to these reasons, the meetings with significant others and the original home visits will

be replaced by incorporating ways to receive support from significant others in the group meetings and to strengthen the social network and social support without inviting any significant others. This will be partly achieved in the new meeting in phase 2 where the social network of participants is drawn up. In addition, the role of the group leader in this will be further strengthened in their training. They will be trained to have more attention for facilitating group processes and their own role as supporter and role model for the participants. The group leader will also have one-on-one contact with participants during breaks, walking and at the start and ending of meetings.

Adjustments in phase 2

1. The meetings will be extended from 9 to 12 meetings, because of the more optional meetings for phase 2 and the extension of the length of the programme to achieve continuing behavioural change.
2. Realisation of behavioural change: the evaluation showed that in the previous version of this phase, participants implemented relatively few changes in self-management behaviour and had difficulties with action plans.¹⁶ In the adapted version of this phase, there will be a stronger emphasis on actual behaviour change. Participants will go through a cycle of behaviour change for all self-management behaviours. This involves setting goals, creating implementation intentions and providing coping strategies that address various types of factors that may hinder the translation of intention into behaviour.
3. Weekly meetings: the process evaluation of the initial DISC study³⁰ also showed that the drop-out rate increased in the original second phase of the programme. This phase started biweekly and ended with meetings once a month. In this updated version, we decided to make the meetings weekly to keep participants more involved and motivated. A better recollection of the planned behavioural change is another reason for weekly meetings.
4. Community support: the follow-up community support in this phase will also be improved, by optimising the options for support offered by primary care and community services. These are existing programmes or initiatives offered by primary care or within the neighbourhoods of patients, for example, inviting a practical assistant for well-being in a meeting. A qualitative study showed that people living in disadvantaged neighbourhoods in the Netherlands attribute their health problems to the social circumstances they live in.³¹ Our target group generally struggles with social circumstances and multiple other problems, which are often connected to poor diabetes self-management. The aim of the community follow-up support is to improve participants' stress management and lessen the high levels of daily stress which are caused by structural conditions. These changes will contribute to

the programme goals, by improving and maintaining diabetes self-management behaviours and thereby improving HbA1c levels (see *phase 2* in the logic model, figure 2).

Group leaders

The group leaders will be recruited through an advertisement and selected based on their experience with group-based interventions and the target group. They should have a paramedical/psychological higher vocational education diploma or an obtained comparable working and thinking level. The group leaders can have different backgrounds, including lifestyle coaches, dieticians, physiotherapists, and other medical professionals or teachers.

Training group leaders

Before the start, the group leaders will receive an 8-hour training for phase 1 and an 8-hour training for phase 2. The training sessions will be focused on the implementation of the intervention and guidance of the participants. Furthermore, during the training sessions, the group leaders will practice parts of the PTWD programme. During the programme, group leaders will attend bimonthly intervention meetings.

In the training of phase 1, attention will be paid to effective communication, positive feedback and dealing with resistance, as well as to the professional development of the group leaders. For phase 2, group leaders will learn reasoned and habitual behaviour and master the process of behavioural change.²⁶ With their own behavioural examples, they will go through a cycle of behavioural change.³² In doing so, they will be introduced to, among other things, implementation intentions (goal setting), (re)attributions (growth mindset) and different coping responses (dealing with controllable and non-controllable factors).^{26 27}

Data collection and follow-up

For the intervention and control groups, we will receive data from the participating general practitioner registries, for baseline (T0), at 12 months follow-up (T2) and 24 months follow-up (T3). We will also receive historical data up to 8 years before baseline from the registries. For the intervention group, we will collect additional data at all three time points and collect additional data at 6 months (T1). Details on the measurements are provided below. Table 1 shows an overview of the measurements.

Effectiveness evaluation

Primary outcome

The primary outcome is change in HbA1c levels from baseline to 12 months follow-up compared with the control groups. The data on HbA1c, for both the intervention and control groups, will be retrieved from routinely collected data from patient registries in the participating GP practices. These data will be retrieved from a database owned by the academic network of general practice medicine of the Amsterdam University Medical Center in the Netherlands. For a secondary trend analysis of HbA1c

over time, we will retrieve HbA1c data up to 8 years before baseline and at each time point of the study (T0, T2, T3) for both groups.

Secondary outcomes

Blood outcomes (intervention group and control group) (T0, T2, T3)

Data on fasting glucose and lipids (low-density lipoprotein, high-density lipoprotein, triglycerides) will be retrieved from routinely collected data from patient registries in the participating GP practices.

Medication and healthcare use (intervention group and control group) (T0, T2, T3)

Data on prescribed T2DM medication and the use of primary and specialist care will be retrieved from routinely collected data from patient registries in GP practices.

Measurements for intervention group only

Physical measurements and anthropometrics (T0, T1, T2, T3)

Blood pressure (systolic and diastolic blood pressure) will be measured twice with an Omron M-6 Comfort monitor after 5 min of rest. A mean blood pressure will be calculated from the two measurements. Body height will be measured (accurate to 0.1 cm) with a stadiometer (SECA 217). Body weight will be measured (accurate to 0.1 kg) without shoes using a calibrated electronic scale (Seca 877). Both measurements will be performed twice, and if there is a difference of more than 0.5 kilograms or centimetres, a third measurement is performed. For the analyses, we will calculate the average of the two closest measurements. BMI will be calculated as weight in kilograms divided by the square of body height in metres (kg/m^2). Waist and hip circumference will be measured twice (accurate to 0.1 cm) using a standard measuring tape. The waist circumference will be measured in the middle of the lowest ribcage and the iliac crest. The hip circumference will be measured at the greater trochanter. Waist and hip circumference will be used to calculate the waist-to-hip ratio. All of these measurements will be conducted by trained research assistants using standard operating procedures and protocols.

Physical activity (T0, T1, T2, T3)

Physical activity will be objectively measured with the activPAL (model activPAL micro; PAL Technologies Ltd., Glasgow, UK). ActivPAL is an activity monitor that weighs 9g and will be taped to the front of the right thigh for at least seven consecutive days. The activPAL has shown to have good measurement properties for adults to assess sedentary time, standing time and stepping time as well as steps per day.³³

Questionnaire: self-management behaviours, health behaviours and quality of life (T0, T1, T2, T3)

For the data collection on self-management behaviour, health-related behaviours, health and quality of life, participants will be asked to complete a questionnaire at each time point. These questionnaires are composed of brief measurement instruments and as much as possible

Table 1 Overview of measures and instruments used in the effectiveness and economic evaluations

Outcomes	Source/method	T0 (baseline)	T1 (6 months)	T2 (12 months)	T3 (24 months)
Blood biomarker and care usage (intervention and control groups)					
HbA1c (primary outcome)	GP database	X		X	X
Fasting glucose	GP database	X		X	X
Lipids (LDL, HDL, triglycerides)	GP database	X		X	X
Use of medication (GP database (intervention and control group))	GP database	X		X	X
Use of primary and specialist care	GP database and questionnaires	X		X	X
Anthropometrics (intervention group only)					
Body height	Stadiometer	X	X	X	X
Body weight	Scale	X	X	X	X
Waist and hip circumference	Measuring tape	X	X	X	X
Resting blood pressure (systolic, diastolic)	Blood pressure monitor	X	X	X	X
Health behaviours (intervention group only)					
Food intake with respect to T2DM (DHD-FFQ)	Questionnaire	X	X	X	X
Sleep pattern and sleep hygiene (PSQI and ISI)	Questionnaire	X	X	X	X
Smoking (CBS, MTSS)	Questionnaire	X	X	X	X
Physical activity (activPAL)	Activity tracker	X	X	X	X
Psychological (intervention group only)					
Quality of life (WHO-5)	Questionnaire	X	X	X	X
Depression (4DSQ)	Questionnaire	X	X	X	X
Loneliness and social isolation (Loneliness scale of DeJong-Gierveld)	Questionnaire	X	X	X	X
Coping skills (DPSI)	Questionnaire	X	X	X	X
Disease-specific (intervention group only)					
Diabetes distress (PAID-5)	Questionnaire	X	X	X	X
Medication adherence (MMAS)	Questionnaire	X	X	X	X
Self-reported sociodemographics (intervention group only)					
Age	Questionnaire	X			
Gender	Questionnaire	X			
Ethnicity	Questionnaire	X			
Marital status	Questionnaire	X			
Household composition	Questionnaire	X			
Education	Questionnaire	X			
Employment status	Questionnaire	X			
Health literacy (SBSQ)	Questionnaire	X			
Co-interventions	Questionnaire		X	X	X
Cost-effectiveness	GP database		X	X	X
Healthcare costs (intervention and control group)					
Societal costs (modified iPCQ, iMCQ, iVICQ)	Questionnaire		X	X	X

CBS, the Dutch Central Statistical Office; DHD-FFQ, Dutch Healthy Diet Index-Food Frequency Questionnaire; DPSI, Diabetes Problem-Solving Inventory; 4DSQ, Four-Dimensional Symptom Questionnaire; GP, general practitioner; HDL, high-density lipoprotein; iMCQ, iMTA Medical Consumption Questionnaire; iPCQ, iMTA Productivity Cost Questionnaire; ISI, Insomnia Severity Index; iVICQ, iMTA Valuation of Informal Care Questionnaire; LDL, low-density lipoprotein; MMAS, Morisky Medication Adherence Scale; MTSS, Motivation To Stop Smoking; PAID-5, 5-item Problem Areas in Diabetes scale; PSQI, Pittsburgh Sleep Quality Index; SBSQ, Set of Brief Screening Questions; WHO-5, World Health Organization-Five Well-Being Index.

have been validated in study populations that are comparable with our target populations and have shown to be reliable in these populations. Furthermore, due to the experience with the too extensive questionnaires in the previous study, these questionnaires are kept more

limited and less complicated.¹⁶ Data will be collected face-to-face with trained research assistants at the same location as the programme. Below we provide details on the different outcomes, and [table 1](#) shows an overview of the questionnaires that will be used.

Sociodemographic measures (T0)

Demographic characteristics will be assessed at baseline, including age, gender, ethnicity, marital status, household composition, education and employment status.

Health behaviours (T0, T1, T2, T3)

Self-reported dietary behaviour will be measured with 19 items selected from the Dutch Healthy Diet Index-Food Frequency Questionnaire, related to the dietary guideline for diabetes patients.³⁴ The frequency of intake of the following foods and drinks will be measured: cereals, bread, toppings, fats, dairy, legumes, fruit and vegetables, pasta, rice, meat, chicken, fish, nuts, drinks and alcohol.

Sleep patterns and sleep hygiene will be measured with 11 items of a combination of two instruments: the Pittsburgh Sleep Quality Index and the Insomnia Severity Index. This combination of questions has been validated in low literate patients.³⁵

Smoking behaviour will be assessed by asking the amount of current consumption, and motivation to stop smoking will be assessed with the validated Motivation To Stop Smoking (MTSS) scale.³⁶

Medication adherence will be assessed with the Morisky Medication Adherence Scale of eight items.³⁷

Self-reported health and psychological measures (T0, T1, T2, T3)

Self-reported health will be assessed with the validated one-item general health measure.³⁸ Quality of life will be assessed using the World Health Organization-Five Well-Being Index.³⁹ Depression will be assessed with the six-item depression scale from the Four-Dimensional Symptom Questionnaire.⁴⁰ Diabetes distress will be assessed with the 5-item Problem Areas in Diabetes scale.⁴¹ Coping skills will be assessed with 14 items of the Diabetes Problem-Solving Inventory.⁴² Loneliness will be assessed with a shortened scale for overall, emotional and social loneliness of six items.⁴³ Health literacy will be assessed with the 3-item Set of Brief Screening Questions.⁴⁴

Economic evaluation

We will conduct an evaluation of the cost-effectiveness of the PTWD programme in comparison to usual care. Costs of the PTWD participants during 24-month follow-up will be described from the societal perspective, and a full economic evaluation comparing PTWD with usual care will be performed from the healthcare perspective.

In the intervention group, we will collect data on costs concerning the intervention, other healthcare, medication, absenteeism, presenteeism, unpaid productivity and informal care. Intervention costs will be micro-costed and will include costs for hosting (eg, locations for the PTWD programme), organising (eg, intervention materials) and providing (eg, hiring group leaders) the PTWD programme. Other resource use data will be measured every 6 months using questionnaires based on the iMTA Productivity Cost, Medical Consumption and Valuation of Informal Care questionnaires,^{45–47} supplemented by data retrieved from patient registries from the GP database. In

the control group, only other healthcare and medication costs will be measured using data from the GP database. All resource use will be valued in accordance with the Dutch Manual for Costing Studies.⁴⁸

Process evaluation

Design

The design of the process evaluation is based on the UK MRC guidance for process evaluation of complex interventions,¹⁸ the Consolidated Framework For Implementation Research,⁴⁹ Linnan and Steckler,⁵⁰ and Baranowski and Stables.⁵¹ The process evaluation will evaluate the implementation process (ie, recruitment, reach, fidelity, feasibility, dosage), mechanisms of impact (ie, suitability, satisfaction, perceived effectiveness) and contextual factors hindering or facilitating implementation of PTWD. Data will be collected from participants, group leaders and referring GPs. The research team will keep field notes of relevant information of the study process. Table 2 presents an overview of the research objectives and methods that will be used in the process evaluation.

Context

To investigate the context, facilitators and barriers for adoption, implementation and continuation of PTWD will be evaluated.

Implementation process

Recruitment will be evaluated by looking at what procedures were followed for recruiting participants and group leaders and reasons for not participating.

Reach will be evaluated by looking at the characteristics of individuals, group leaders and participating GP practices.

To evaluate the intervention delivery, the extent to which PTWD has been implemented and delivered as intended (fidelity) will be measured. Also, to what extent components of PTWD are delivered (dose delivered), participation and involvement among participants (dose received), and the retention rate will be measured.

Also, all costs related to the implementation of PTWD will be measured.

Mechanisms of impact

To investigate the mechanisms of impact, we will look at the views, experiences and useful elements of PTWD, including suitability, feasibility according to group leaders and participants. Also, the perceived effectiveness of PTWD on the diabetes self-management of participants. We will look at the extent to which the core elements and newly added components (eg, stress and sleep) of PTWD are appropriate for the target group (suitability) and how satisfied the participants are with PTWD (satisfaction). This is also extensively researched in the previous process evaluation, and in this study, we will build on the information obtained from that study.³⁰

Table 2 Overview of the process evaluation and measurements

Research objectives	Quantitative methods				Qualitative methods			
	Q P Baseline	Q P 6M	Q P 12M	Log GL During implementation	FG GL After intervention	FG P After intervention	I GP After intervention	Field notes researcher
Context								
Facilitators and barriers for adoption, implementation and continuation					X	X	X	
Implementation								
Recruitment								
Sources and procedures for recruitment of group leaders					X			X
Sources and procedures for recruitment of participants and reasons for (non-)participation						X	X	X
Reach								
Characteristics of participating GP practices for recruiting participants							X	X
Characteristics of group leaders (eg, background, demographics and experience)					X			
Characteristics of participants recruited (eg, demographics and health profile)	X							
Intervention delivery								
Dose delivered The extent to which components of PTWD are delivered				X	X			X
Dose received Participation in PTWD and the level of involvement among participants and reasons for stopping with PTWD				X	X	X		X
Fidelity The extent to which PTWD has been delivered as intended				X	X			X
Costs All costs related to the implementation of PTWD							X	X
Mechanisms of impact								
Group leaders								
Views, experiences and useful elements of PTWD including suitability, feasibility				X	X			
Perceived effectiveness of PTWD					X			
Participants								
Views, experiences and useful elements of PTWD including satisfaction, suitability and feasibility			X			X		
Perceived effectiveness of PTWD			X			X		
FG, focus group; GL, group leaders; GP, general practitioner; I, interview; P, participants; PTWD, Powerful Together With Diabetes; Q, questionnaire.								

Quantitative data collection

Participant questionnaires

Twelve months after baseline (T2), we will ask participants about their experiences with the programme, their group leader and sustainment of behavioural changes. These questions are added to the T2 questionnaire of the intervention group.

Attendance sheets and log of meetings delivered

During the programme, group leaders will keep a log with attendance sheets and the extent to which components

of the meetings are delivered. The attendance sheets are used to calculate the participation and retention of participants.

Qualitative data collection

Interviews and focus groups with participants

We will conduct these after the programme with a purposive sample of participants. The sample will include participants who completed the whole programme and participants who dropped out, to incorporate all views.

The interviews and focus groups will be carried out with topic lists based on the research objectives in [table 2](#).

Focus groups with group leaders

We will reflect on their experiences with leading the programme, facilitators and barriers in implementing the programme and the feasibility and suitability of the programme. See the topic list for group leaders in online supplemental file 2.

Interviews with referring general practitioners (GPs)

We will reflect on facilitators and barriers for adoption, implementation and continuation, their characteristics, the recruitment of participants and costs related to the implementation of PTWD.

Logs group leaders

During the programme, group leaders will keep a log in which they are asked for each programme component, if it was delivered and what went well and what went less well. In addition, they will be asked to report how the meetings were in terms of atmosphere, interactions between participants and how they deal with issues during the meetings.

Field notes researcher

The researcher will keep field notes of all relevant processes and conversations with general practitioners and other relevant stakeholders. Also, we will make field notes on observations of a sample of meetings, which will focus on how participants interact with each other, how they interact with the group leaders, how they respond to components of the programme and other elements that may influence programme effects.

Participant retention

Once a patient is enrolled, the study site will make every reasonable effort to follow the participant the entire study period.

Data forms and data entry

All data forms will be entered electronically in Castor Electronic Data Capture at the coordinating centre. Original study forms will be kept on file at the coordinating centre. A data management plan is filled in and kept in a trial master file at the coordinating centre. Also data management experts of the Research Data Management section of the coordinating centre are consulted for setting up the data management plan (see online supplemental file 4).

Oversight and monitoring

Amsterdam UMC is the study coordinating centre. The trial supervision and day-to-day trial management will be conducted by the principal investigator of the coordinating centre. The Clinical Monitoring Center of the Amsterdam UMC will conduct auditing and monitoring of the trial. The clinical research associates of this centre are independent from the study, the study team and the sponsor.

Data analysis plan

Effectiveness evaluation

To describe the changes in the primary outcome (HbA1c level) and secondary outcomes, within and between the intervention and control groups, we will use multiple linear and logistic regression analyses. The primary analysis will focus on the HbA1c level change from baseline to 12 months compared with the intervention and the two control groups. Secondary analyses on HbA1c will focus on the comparison with the control groups as well as the follow-up measurements at 12 and 24 months and time trends over the duration of the study and including historical data, to determine whether changes in trend have occurred. Secondary analyses for all other outcomes will focus on changes within the intervention group from baseline to 6, 12 and 24 months follow-up. The group of the participant in the intervention will be used as a level in the model. Analysis will be performed using SPSS (V.28). Effect estimates will be presented with 95% CIs.

Economic evaluation

First, the costs of the PTWD participants during 24-month follow-up will be described from the societal perspective. Second, cost-effectiveness analyses will be performed for the primary outcome HbA1c as well as health-related quality of life from the healthcare perspective. Missing data will be handled using multivariate imputation by chained equations.⁵² Incremental cost-effectiveness ratios will be calculated by dividing the differences in costs by those in effects. Uncertainty surrounding the cost-effectiveness outcomes will be graphically illustrated using cost-effectiveness planes and cost-effectiveness acceptability curves. Sensitivity analyses will be performed to assess the robustness of the results.⁵³

Process evaluation

For the quantitative process data, descriptive statistics (mean, SD, proportions) will be used to report participants' and group leaders' characteristics, questions from the process questionnaires and data from the attendance sheets and group leaders logs.

The qualitative process data will be analysed using a thematic analysis. The interviews and focus groups will be audiotaped and transcribed verbatim. All qualitative research material, including transcripts and field notes, will be imported in MAXQDA. The analysis will follow a direct content analysis approach, whereby the transcripts are deductively analysed using a prespecified codebook. This codebook will be created using the prespecified research objectives. Parts of the transcripts which cannot be categorised within the initial coding scheme will be inductively given a new open code. The open codes will eventually be sorted and grouped together into different themes and categories with a thematic analysis.⁵⁴ This material will be coded in two cycles. For the first cycle, structural coding will be used, following the research objectives. In the second coding cycle, axial coding will

be used, in which similarly coded data will be grouped into conceptual categories.

Patient and public involvement

Patients of the target group will be involved in a needs assessment prior to intervention development. Research participants will receive a summary of study results at the end of the study.

ETHICS AND DISSEMINATION

Ethics approval for this study is obtained in the Netherlands at the Medical Ethics Committee of the Academic Medical Center (AMC) in Amsterdam. This study is registered in the ISRCTN registry with trial ID ISRCTN12982302 on 29 March 2022. Participants will sign an informed consent prior to enrolment.

Manuscripts with the results of the (cost)effectiveness study and the process evaluation will be published in peer-reviewed journals. After completion of the trial, data requests can be submitted to the researchers at the Department of Public and Occupational Health, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam Public Health Research Institute, Amsterdam, the Netherlands.

Study status

The recruitment of the study began in February 2022, and the expected completion of the study is in December 2025.

DISCUSSION

This paper presents the study protocol of the effectiveness, economic and process evaluations of the PTWD intervention programme for T2DM patients from lower educated groups. These patients are not sufficiently included in research and interventions to promote diabetes self-management.⁵⁵ This study aims to include these patients and offer them a tailored diabetes management programme, which will help them to improve their diabetes self-management.

The effectiveness of the PTWD programme will be evaluated in a two-arm quasi-experimental study with two control groups. To limit the potential study burden for patients in the intervention group, part of the data for the intervention group and all of the data of the two control groups will be retrieved from GP registries. This also gives the opportunity to increase the power of the study without increasing the number of intervention patients, and it increases the feasibility of the study as the recruitment of T2DM patients from lower educated groups is limited to those needed in the intervention arm of the study. Another advantage of this study is that we will also retrieve historical data 8 years before baseline, in which the development of the blood biomarker outcomes and the effect of the intervention can be investigated.

A possible limitation of this study is that participants will not be randomised. Research has shown that there

is a greater risk of bias in non-randomised studies of interventions.⁵⁶ However, because this is a pragmatic real-world trial, randomisation could negatively interfere with the recruitment process. In addition, there will be two control groups to study the effectiveness, matched on the general practitioner level. Furthermore, randomisation can have a negative influence on inclusion, because it adds uncertainty and potential disappointment for participants, which might be a reason not to participate or drop out. Lastly, the programme was evaluated in a previous study, which has already yielded many results.

Another limitation is that although the PTWD programme is developed for patients with T2DM from lower educated groups, we are not able to select patients on this indicator based on available data in GP practices. Instead, we will use proxy indicators as described in the inclusion criteria. Furthermore, we will measure educational level during the baseline measurement, and we will adjust for this in the analyses.

Another relevant point is that this study will focus on evaluating the whole process which builds on the previous study but also the conditions for the future and structural implementation of the PTWD programme. If the programme proves to be effective, it is necessary to further investigate the conditions for structural implementation of PTWD outside of the research setting. This will be investigated in a separate study.

Author affiliations

¹Public and Occupational health, Amsterdam UMC Locatie VUmc Divisie 10, Amsterdam, Noord Holland, The Netherlands

²Vrije Universiteit Amsterdam, Department of Public and Occupational health, Amsterdam Public Health Institute, Amsterdam University Medical Centres, Amsterdam, Noord-Holland, The Netherlands

³Amsterdam UMC Locatie VUmc, Amsterdam, Noord-Holland, The Netherlands

⁴Windesheim Flevoland, Almere, Flevoland, The Netherlands

⁵Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

⁶Amsterdam University Medical Centres, Amsterdam, Noord-Holland, The Netherlands

X Femke van Nassau @FemkeVanNassau

Acknowledgements We thank Janneke Harting (Amsterdam University Medical Center, University of Amsterdam) for her valuable input and contribution during the project and updating the programme.

Contributors All authors have contributed to the design of the study. KS conceptualised the study. The first draft of this manuscript was produced by BH. All authors read and approved the final manuscript. BH is the guarantor.

Funding This work was supported by the Netherlands Organization for Health Research and Development (ZonMw) under grant number 555003202. This funding source has no role in the design, execution, analysis of this study and the interpretation of the data, or decision to submit results.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer-reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and

responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iD

Bedra Horreh <http://orcid.org/0000-0002-7659-1180>

REFERENCES

- Andersson E, Persson S, Hallén N, *et al*. Costs of diabetes complications: hospital-based care and absence from work for 392,200 people with type 2 diabetes and matched control participants in Sweden. *Diabetologia* 2020;63:2582–94.
- van Puffelen AL, Rijken M, Heijmans MJWM, *et al*. Living with diabetes: a group-based self-management support programme for T2DM patients in the early phases of illness and their partners, study protocol of a randomised controlled trial. *BMC Health Serv Res* 2014;14:144.
- Aminuddin HB, Jiao N, Jiang Y, *et al*. Effectiveness of smartphone-based self-management interventions on self-efficacy, self-care activities, health-related quality of life and clinical outcomes in patients with type 2 diabetes: A systematic review and meta-analysis. *Int J Nurs Stud* 2021;116:103286.
- Schlesinger S, Neuenschwander M, Ballon A, *et al*. Adherence to healthy lifestyles and incidence of diabetes and mortality among individuals with diabetes: a systematic review and meta-analysis of prospective studies. *J Epidemiol Community Health* 2020;74:481–7.
- 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:e64009.
- Zhang Y, Yang Y, Huang Q, *et al*. The effectiveness of lifestyle interventions for diabetes remission on patients with type 2 diabetes mellitus: A systematic review and meta-analysis. *Worldviews Evid Based Nurs* 2023;20:64–78.
- Adu MD, Malabu UH, Malau-Aduli AEO, *et al*. Enablers and barriers to effective diabetes self-management: A multi-national investigation. *PLoS One* 2019;14:e0217771.
- Elissen AMJ, Hertroijs DFL, Schaper NC, *et al*. Differences in biopsychosocial profiles of diabetes patients by level of glycaemic control and health-related quality of life: The Maastricht Study. *PLoS One* 2017;12:e0182053.
- Abu-Saad K, Murad H, Barid R, *et al*. Development and Efficacy of an Electronic, Culturally Adapted Lifestyle Counseling Tool for Improving Diabetes-Related Dietary Knowledge: Randomized Controlled Trial Among Ethnic Minority Adults With Type 2 Diabetes Mellitus. *J Med Internet Res* 2019;21:e13674.
- Hertroijs DFL, Brouwers MCGJ, Elissen AMJ, *et al*. Relevant patient characteristics for estimating healthcare needs according to healthcare providers and people with type 2 diabetes: a Delphi survey. *BMC Health Serv Res* 2019;19:575.
- Fransen MP, Beune EJAJ, Baim-Lance AM, *et al*. Diabetes self-management support for patients with low health literacy: Perceptions of patients and providers. *J Diabetes* 2015;7:418–25.
- Hertroijs DFL, Elissen AMJ, Brouwers MCGJ, *et al*. Preferences of people with Type 2 diabetes for diabetes care: a discrete choice experiment. *Diabet Med* 2020;37:1807–15.
- Reshma P, Rajkumar E, John R, *et al*. Factors influencing self-care behavior of socio-economically disadvantaged diabetic patients: A systematic review. *Health Psychol Open* 2021;8:20551029211041427.
- Schram MT, Assendelft WJJ, van Tilburg TG, *et al*. Social networks and type 2 diabetes: a narrative review. *Diabetologia* 2021;64:1905–16.
- Vissenberg C, Stronks K, Nijpels G, *et al*. Impact of a social network-based intervention promoting diabetes self-management in socioeconomically deprived patients: a qualitative evaluation of the intervention strategies. *BMJ Open* 2016;6:e010254.
- Vissenberg C, Nierkens V, van Valkengoed I, *et al*. The impact of a social network based intervention on self-management behaviours among patients with type 2 diabetes living in socioeconomically deprived neighbourhoods: a mixed methods approach. *Scand J Public Health* 2017;45:569–83.
- Curran GM, Bauer M, Mittman B, *et al*. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217–26.
- Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258.
- Vissenberg C, Nierkens V, Uitewaal PJM, *et al*. The DISC (Diabetes in Social Context) Study-evaluation of a culturally sensitive social network intervention for diabetic patients in lower socioeconomic groups: a study protocol. *BMC Public Health* 2012;12:199.
- Vissenberg C, Nierkens V, Uitewaal PJM, *et al*. Development of the Social Network-Based Intervention “Powerful Together with Diabetes” Using Intervention Mapping. *Front Public Health* 2017;5:334.
- Vries H de, Mesters I, van de Steeg H, *et al*. The general public’s information needs and perceptions regarding hereditary cancer: an application of the Integrated Change Model. *Patient Educ Couns* 2005;56:154–65.
- Berkman LF, Kawachi I. *Social epidemiology*. USA: Oxford University Press, 2000.
- Korthagen F, Lagerwerf B. *Leren van binnenuit*. In: *Kwaliteit en inspiratie in het onderwijs*. Den Haag: Boom Lemma, 2011.
- Borek AJ, Abraham C. How do Small Groups Promote Behaviour Change? An Integrative Conceptual Review of Explanatory Mechanisms. *Appl Psychol Health Well Being* 2018;10:30–61.
- Pekrun R. Achievement emotions. In: Allen K-A, Furlong MJ, Vella-Brodick E, *et al*, eds. *Handbook of positive psychology in schools*. 3rd edn. New York/London: Routledge Taylor & Francis Group, 2022: 319–45.
- Bartholomew Eldridge LK, Markham CM, Ruiter RAC, *et al*. *Planning health promotion programs: an intervention mapping approach*. 4th edn. Hoboken, NY: Wiley, 2016.
- Kok G, Gottlieb NH, Peters G-JY, *et al*. A taxonomy of behaviour change methods: an Intervention Mapping approach. *Health Psychol Rev* 2016;10:297–312.
- Wood W, Rünger D. *Psychology of Habit*. *Annu Rev Psychol* 2016;67:289–314.
- Gollwitzer PM, Sheeran P. Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Adv Exp Soc Psychol* 2006;69:1–19.
- Vissenberg C, Nierkens V, Uitewaal PJM, *et al*. Recruitment and retention in a 10-month social network-based intervention promoting diabetes self-management in socioeconomically deprived patients: a qualitative process evaluation. *BMJ Open* 2017;7:e012284.
- Berg J, Harting J, Stronks K. Individualisation in public health: reflections from life narratives in a disadvantaged neighbourhood. *Crit Public Health* 2021;31:101–12.
- Schwarzer R. Modeling Health Behavior Change: How to Predict and Modify the Adoption and Maintenance of Health Behaviors. *Appl Psychol* 2008;57:1–29.
- Swartz AM, Rote AE, Cho YI, *et al*. Responsiveness of motion sensors to detect change in sedentary and physical activity behaviour. *Br J Sports Med* 2014;48:1043–7.
- Looman M, Feskens EJ, de Rijk M, *et al*. Development and evaluation of the Dutch Healthy Diet index 2015. *Public Health Nutr* 2017;20:2289–99.
- Chaitra D, Manasa K, Puneem US, *et al*. The Assessment of Sleep Quality and Insomnia Severity in Cardiovascular Diseases. *IJOPP* 2020;13:326–31.
- Hummel K, Brown J, Willemsen MC, *et al*. External validation of the Motivation To Stop Scale (MTSS): findings from the International Tobacco Control (ITC) Netherlands Survey. *Eur J Public Health* 2016;27:ckw105.
- Ahmad NS, Ramli A, Islahudin F, *et al*. Medication adherence in patients with type 2 diabetes mellitus treated at primary health clinics in Malaysia. *Patient Prefer Adherence* 2013;7:525–30.
- DeSalvo KB, Fisher WP, Tran K, *et al*. Assessing measurement properties of two single-item general health measures. *Qual Life Res* 2006;15:191–201.
- Topp CW, Østergaard SD, Søndergaard S, *et al*. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom* 2015;84:167–76.
- Kleinstäuber M, Exner A, Lambert MJ, *et al*. Validation of the Four-Dimensional Symptom Questionnaire (4DSQ) in a mental health setting. *Psychol Health Med* 2021;26:1–19.

- 41 McGuire BE, Morrison TG, Hermanns N, *et al.* Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia* 2010;53:66–9.
- 42 Glasgow RE, Toobert DJ, Barrera M Jr, *et al.* Assessment of problem-solving: a key to successful diabetes self-management. *J Behav Med* 2004;27:477–90.
- 43 de Jong Gierveld J, van Tilburg T. A shortened scale for overall, emotional and social loneliness. *Tijdschr Gerontol Geriatr* 2008;39:4–15.
- 44 Fransen MP, Van Schaik TM, Twickler TB, *et al.* Applicability of internationally available health literacy measures in the Netherlands. *J Health Commun* 2011;16 Suppl 3:134–49.
- 45 Bouwmans C, Krol M, Severens H, *et al.* The iMTA Productivity Cost Questionnaire: A Standardized Instrument for Measuring and Valuing Health-Related Productivity Losses. *V Health* 2015;18:753–8.
- 46 Hoefman R, Al-Janabi H, McCaffrey N, *et al.* Measuring caregiver outcomes in palliative care: a construct validation study of two instruments for use in economic evaluations. *Qual Life Res* 2015;24:1255–73.
- 47 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
- 48 Nederland Z. Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg. 2024.
- 49 Damschroder LJ, Aron DC, Keith RE, *et al.* Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Impl Sci* 2009;4:50.
- 50 Linnan LA, Steckler AB, eds. Chapter one process evaluation for public health interventions and research an overview. 2002.
- 51 Baranowski T, Stables G. Process evaluations of the 5-a-day projects. *Health Educ Behav* 2000;27:157–66.
- 52 White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med* 2011;30:377–99.
- 53 Drummond MF, Sculpher MJ, Claxton K, *et al.* *Methods for the economic evaluation of health care programmes*. OUP Oxford, 2015.
- 54 Castleberry A, Nolen A. Thematic analysis of qualitative research data: Is it as easy as it sounds? *Curr Pharm Teach Learn* 2018;10:807–15.
- 55 Strandberg RB, Nilsen RM, Pouwer F, *et al.* Lower education and immigrant background are associated with lower participation in a diabetes education program - Insights from adult patients in the Outcomes & Multi-morbidity In Type 2 diabetes cohort (OMIT). *Pat Educ Couns* 2023;107:107577.
- 56 Sterne JA, Hernán MA, McAleenan A, *et al.* Assessing risk of bias in a nonrandomized study. In: *Cochrane handbook for systematic reviews of interventions*. 2019: 621–41.