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Women’s Wellness Type 2 Diabetes Programme in the UK

Submission date
31/05/2025

Recruitment status
No longer recruiting

Registration date
02/06/2025

Overall study status
Completed

Last Edited
02/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a significant disease among women as they are more vulnerable than men due to biological differences, social marginalisation, and gender roles. Its impacts are also more severe as diabetes ranks in ninth position among the causes of death in this gender. Therefore, it is important to focus on the prevention and management of type 2 diabetes (T2DM) in women. Especially, midlife is an important stage for women to implement lifestyle changes as they are most likely to improve their health status and lower their mortality risk. The Women's Wellness with Type 2 Diabetes Programme (WWDP) is highly relevant, as it aligns with the standard principles of diabetes care and is a 12-week e-Health lifestyle initiative designed for midlife women with type 2 diabetes. Therefore, the primary aim of the study is to gather information on whether it is possible to evaluate the revised WWDP (WWDP+) to gain insight into whether the WWDP+ is acceptable for midlife women with T2DM and improves physical, psychosocial and behavioural outcomes over a 3-month and 6-month period. A secondary aim is to explore the participants' experiences with the content and delivery of the new online intervention and three peer supporters who have been involved 12-week WWDP to facilitate online peer group to explore their experiences and challenges as peer supporter in online setting and to understand aspects of online peer supporter, hence we would analyse deeply that what type of training, resources and sustainability of engagement in online interventions need and its impact on the programme.

Who can participate?
Midlife women aged 45 to 65 years with T2DM in the UK

What does the study involve?
Participants will be asked to complete the intervention over a 3-month period, and tasks over a 3-month and 6-month period. Before agreeing to take part, participants will be asked some questions to check that they are eligible to participate in this research through an online screening questionnaire. If they are eligible and they have agreed to take part with a written consent online form, they will be asked to complete a baseline survey such as questions on height, weight, ethnicity, education, income, distress, sleep quality, and self-efficacy through outcome measure questions before registration to the intervention. Once participants have completed in 7 days, they will be registered within 48 hours to the intervention and their

registration details will be sent to their email address.
Participants will be sent a special link to this with further instructions on how to access the website and peer support group in a private Facebook group. The website requires participants to read weekly health topics from a 12-week e-Book, fill out the logbook for daily activities and watch the podcast for 12 weeks. The peer support group also requires sharing participants' experiences with each other. Participants will also be asked to complete a duplicate form of their goal-setting/evaluation form and return it by email to the researcher within seven days of receiving the form at Week 3 and at Week 12. Each goal-setting sheet will be given a unique identifier so that goal-setting sheets can be linked to participants' questionnaires. Overall, participants will set up their personal goals, read weekly information on the website, listen to podcasts, record weekly schedules, and share experiences in the peer support group during the 12-week intervention. The Logbook is a downloadable and fillable PDF version; thus, participants will be able to download their smart devices. Participants will record their weekly schedule from Monday to Sunday for diet and exercise and at the end of each week, they will be able to review and put a 'tick' for what they have done during the week on the review of past week page for each week.
We are interested in getting participants' opinions about WWDP+. Those who engaged with WWDP+ and peer group will be contacted at the 4-month throughout email for an interview to answer interview topic questions on their use of the WWDP+ and peer group, as well as their feedback and experience of using it. For this reason, it is essential that all participants have access to a smartphone/device and the internet. In addition, we will also invite three moderators who will facilitate the WWDP+ peer support group over 12 weeks about their experiences.
Three and six months into the study, all participants will be asked to complete an online survey. Some of the survey questions will be familiar what was previously asked at the start of the study. All communication will be made through email. Participants will be sent the survey links via email and will be asked to begin completing them within 7 days of receiving them. Participants will need to follow the unique links sent to them to complete surveys.

What are the possible benefits and risks of participating?
Benefits of taking part in the study will include access to an intervention that has been found to increase knowledge about general health, improve health-related quality of life, reduce BMI, improve understanding of diet, development of regular exercise habits, and also greater confidence in managing type 2 diabetes through peer support.
The use of the intervention is associated with potential risks. It is important to be aware of any possibilities for injury during exercise, especially if the participant does not exercise regularly. To minimise the risk of injury from exercise, intervention programs depend on the usage as much as they could as individuals. The intervention advises participants to gradually increase their exercise levels over time; they do not overexert themselves at the beginning. To prevent stiffness and promote flexibility, participants are also encouraged to stretch regularly. Due to the participant's involvement in reading the eBook every day, there may be a risk of tiredness in their eyes and stiffness in their shoulders. During the program, the participants might like to incorporate some exercise into their daily routine, which could potentially reduce this risk. The eBook on the WWDP website includes information about physical activity. Participant may choose to increase their levels of PA as a result of taking part in the intervention. Psychological risks for intervention: The topics that participants could find uncomfortable are the section on cancer and type 2 diabetes related complications. However, if this should happen, participants will be informed in the participant information sheet that they may choose not to speak about topics or questions that make them uncomfortable. If they remain upset, they should contact their usual diabetes provider, Diabetes UK 0345 123 2399 or Samaritans 116 123 to get counseling support. Psychological risks for peer support group: online moderated peer support groups aim to provide a supportive environment but there are still potential risks. Online communication can be prone to misinterpretation and misunderstandings. Failure to address

harmful or disruptive behaviour can lead to a decline in the quality of the group and participants' well-being. To mitigate this, we will ensure moderators have adequate expertise, establish clear guidelines, and prioritise participant well-being. If they remain upset, they should contact their usual diabetes provider, Diabetes UK 0345 123 2399 or Samaritans 116 123 to get counselling support. Researchers will also monitor the peer support group messages daily and follow the study protocol for management of distressed participants during intervention in need of immediate and non-immediate support.
Study 2 involves midlife women with T2DM, and interview topics cover general, health and diabetes questions. There is no evidence to suggest that participating will be upsetting or distressing. However, if this should happen, participants will be informed in the participant information sheet that they may choose not to speak about topics or questions that make them uncomfortable or that they can stop participating at any time without giving a reason. If they remain upset, they should talk to the principal investigator or their usual diabetes provider to get counselling support.
To thank participants and moderators for sharing their experiences, those who participated in the interview will be rewarded with a £35 multi-use gift voucher.

Where is the study run from?
Although the study has been designed and will run from King's College London, participants can take part from the comfort of their own home. Participants will not be required to attend King's College London for the completion of study tasks, and all tasks and outcome measures will be completed online.

When is the study starting and how long is it expected to run for?
February 2021 to January 2025

Who is funding the study?
1. Ministry of Education, Government of Turkiye
2. King's College London (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Women’s Wellness Type 2 Diabetes Programme: a single-arm trial of a newly designed intervention for midlife women

Acronym
WWDP+

Study objectives
The revised Women’s Wellness Type 2 Diabetes Programme is feasible and acceptable among midlife women with type 2 diabetes in the UK.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/03/2024, King’s College London Research Ethics Committee (Room 4.16 Franklin Wilkins Building, Waterloo Bridge Wing, Stamford Street, London, SE1 9NH, United Kingdom; +44 (0)207848 4070/4077/3871; rec@kcl.ac.uk), ref: HR/DP-23/24-34435

Study design
Single-arm feasibility trial

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions

This single-arm feasibility trial is to evaluate a 12-week revised WWDP for midlife women (45 to 65 years) in the UK. A mixed-methods design will be applied to fulfil the evaluation aims. There will be three phases of this study:
Phase 1 refers to the revision process of WWDP through the 2021 Medical Research Council Framework.
Phase 2 hereafter is a non-randomised single-arm study (n = 40) to aid refinement of the intervention for the next phase of the study. In this phase, forty eligible women will receive the revised WWDP (WWDP+).
Phase 3 includes exploring barriers and facilitators through semi-structured interviews with participants who will complete the WWDP+ and moderators who will facilitate the peer group of WWDP+ over 12 weeks.

Social media campaign:
A social media recruitment strategy to reach a diverse group of women with T2DM between the ages of 45 to 65 in the UK. The advertisement is mainly through digital platforms such as Google, Facebook, Twitter and Instagram. The social media campaign was advertised for 4 weeks through Facebook and Google. Those who said on interested in being contacted for research involvement, the PI will email potential participants the project webpage https://www.kcl.ac.uk /research/wwdp, and ask whether they are interested or have any questions.

Screening questionnaire and participant information sheet:
Potential participants will access the PIS form and a survey through https://www.kcl.ac.uk /research/wwdp. Once the PI confirm the participant's eligibility through survey results, then participants will receive further details and informed consent.

Informed consent:
The Informed Consent form will be provided through Qualtrics survey software, which is available to the researcher under the King’s College London licencing. The participants will be asked to provide their written consent to enrol on the WWDP+.

Baseline questionnaire:
Participants will receive a baseline questionnaire before being allocated to the intervention.

Goal setting session:
Participant will receive the form to set their goals at Week 3 and evaluate at Week 12.

3 months and 6 months post baseline:
Participants will receive a follow-up survey through Qualtrics to be completed in 7 days.

Website and iBook Component of WWDP+
WWDP+ is a 12-week multi-modal intervention through an eHealth website. The website has specific terms and conditions and participants will be asked to read this information when logging into the website. It aims to reduce diabetes complications and promote healthy behaviours and is theoretically underpinned by Social Cognitive Theory with an emphasis on perceived control and planned behaviour as concepts that promote health behaviour change. It includes a web interface (including podcasts), and an interactive electronic book (e-Book which is accessible from any device) that offers detailed intervention instructions and guides for participants to record relevant health and lifestyle information based on the UK and includes a peer support group with three peer supporters to engage with each other.

The e-Book encourages women to bring together the health topics in four stages and incorporate them into their lives over a 12-week period. Chronologically, the four stages include:

1) preparation and changing lifestyle (including diabetes specific refresher); 2) establishing healthy lifestyle habits; 3) maintaining health for illness prevention; and 4) becoming independent. Included activities allow participants to record responses and reflections, including a weekly exercise planner and a weekly health behaviour review exercise.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcome measures:
1. Recruitment rate via the social media campaign, calculated as the percentage of eligible participants who enrolled in the study
2. Intervention/peer group attendance, calculated as the proportion of participants who logged into the online peer group site on at least three occasions over the 12 weeks
3. Data quality, calculated as the proportion of participants who provided data at all three timepoints

Key secondary outcome(s))
1. Distress measured using the Diabetes Distress Scale at baseline (within 7 days), 3 months and 6 months post baseline
2. Confidence in self-management using the Diabetes Management Self-Efficacy Scale (DMSES UK) at baseline (within 7 days), 3 months and 6 months post baseline
3. Quality of life measured using the Short-Form health survey (SF-36) at baseline (within 7 days), 3 months and 6 months post baseline
4. Physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline (within 7 days), 3 months and 6 months post baseline
5. Dietary behaviours on diabetes management assessed using the UK version Diabetes and Diet Questionnaire (UKDDQ) at baseline (within 7 days), 3 months and 6 months post baseline
6. Smoking prevalence assessed using a subset of key questions from the Global Adult Tobacco Survey at baseline (within 7 days), 3 months and 6 months post baseline
7. Sleep activity and quality assessed using the 21-item General Sleep Disturbance Scale at baseline (within 7 days), 3 months and 6 months post baseline
8. Menopausal symptoms assessed using the standard Greene Climacteric Scale at baseline (within 7 days), 3 months and 6 months post baseline
9. The Goal Assessment Scale (GAS) was used to assess whether participants had achieved their goals within 7 days of receiving the form in week 12 using a +2 to -2 scale
10. Physiological measures: anthropometric measures including body weight, height, waist and hip circumferences and body mass index (BMI) at at baseline (within 7 days), 3 months and 6 months post baseline

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Women aged ≥45 and ≤65 years
2. A current diagnosis of T2DM
3. Using medication to treat T2DM (insulin or oral medication)
4. Living in the UK and with access to diabetes care in the NHS
5. Able to read and speak English

6. Access to a computer or laptop, reliable internet access and IT literacy (defined as being able to buy a product over the internet, search for a topic and send an email)
7. Not currently participating in other research
8. Have a Facebook account or accepts to open a new Facebook account
9. Receive all diabetes care through GP surgery
10. Diabetes distress score 2 or above on the DDS scale

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
65 years

Sex
Female

Total final enrolment
34

Key exclusion criteria
1. Women diagnosed with type 1 diabetes or GDM
2. Unable to read and understand English
3. Women without computer or internet access
4. Women who currently participate in other research

Date of first enrolment
10/05/2024

Date of final enrolment
15/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

King's College London
Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care
James Clerk Maxwell Building Room 5.40
57 Waterloo Road
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Government of Turkiye

Funder Name
King’s College London

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes