



WE INVITE YOU TO TAKE PART IN A RESEARCH STUDY

- The Women's Wellness with Type 2 Diabetes Programme (WWDP) is a 12-week structured lifestyle program. The WWDP offers an e-book, a peer support group and two peer supporters to help women with type 2 diabetes to achieve a healthy lifestyle, and better confidence with managing their diabetes.
- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide not to take part. This will not affect the care you get from your own doctors.
- Please ask us if there is anything that is not clear or if you would like more information.

WHAT IS THE PURPOSE OF THE STUDY?

Feeling and living well is key to having a healthy life with type 2 diabetes. Diabetes can lead to many health problems in the eyes, kidneys, nerves, and circulation if it is not well managed. Diabetes can result in people being emotionally overwhelmed by the demands of managing it. The Women's Wellness with Diabetes Programme aims to help midlife women to feel well in their life and approach their diabetes positively so that these complications and negative feelings are avoided. The Women's Wellness with Diabetes Programme has merged two successful programmes called The Diabetes Manual and the Women's Wellness programme for midlife women. This research will evaluate what midlife women with type 2 diabetes think of this newly designed programme and if it improves their physical and emotional wellbeing as well as explore your experiences with the content and delivery of the new online intervention. The study will be carried out in the UK. We will see whether women join the programme, stick with it and are happy to complete the study questionnaires and how it

impacts on their health. This small study will help us plan for a bigger study to see whether the WWDP should be offered by the NHS.

WHY HAVE I BEEN INVITED?

All individuals who identify as a woman are eligible to take part in this study because they have type 2 diabetes and are a woman aged between 45 to 65 years. We want to invite up to 40 women who are already feeling emotionally stressed about their diabetes.

DO I HAVE TO TAKE PART?

It is up to you whether to join the study. If you agree to take part, we will ask you to sign a consent form. A research assistant will contact you after 24 hours receiving your email about that includes you would like to participate to study or filling the survey on the KCL website. They will contact you by phone to address any questions and confirm eligibility, you will then complete a consent form online.

WHAT IF I CHANGE MY MIND ABOUT TAKING PART?

For study 1 (questionnaires), you are free to withdraw without giving a reason until end of day 10 following the survey completion. For study 2 (interviews), if the interviews have been conducted, you will have ten days post interview to withdraw your data. After these timeframes, we will begin data analysis and it will not be possible to remove your data from the study. If you wish to withdraw from the study and request that your data, be withdrawn will be able to reach the principal investigator through the email provided at the bottom of the information sheet.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Firstly, you will fill out the survey called screening questionnaire that asks your age, your type of diabetes, residency, your stress level of diabetes etc...on the KCL website. After your eligibility confirmed, the researcher will contact you via email or by phone in 24 hours. Then, you will receive another online survey link to be completed in 7 days for consent form with baseline questionnaire that includes demographic questionnaire such as health and life information (for example age, income, ethnicity and your time since diabetes diagnosis) and standard questionnaires including diet, diabetes distress, physical activity, menopause, sleep quality, quality of life as well as self-efficacy prior to intervention. This will also include measuring your weight and waist circumference by yourself. If you need more information about how to measure waist circumference, you will find a video link on the questionnaire align with this question. Once this has been completed, you will receive a Women's Wellness with Diabetes Programme website log in details for your electronic devices or smartphones.

Women's Wellness Type 2 Diabetes Programme is a 12-week program that will help you a) understand more about your diabetes, b) set in place positive lifestyle changes and habits to make a difference to your overall health and wellbeing. There are four steps to this program with each step taking three weeks to complete. In step 1, we talk about type 2 diabetes, get you started on the program and provide you with practical healthy lifestyle information to strengthen your confidence

and motivation. You will complete a personal goal/s form which is a self-guided tool to help you set up your goals regarding your diabetes health habit interests. Step 2 is about consolidating the changes you have made in the first few weeks through practising and self-monitoring your new habits. In step 3, you will learn about important health issues for midlife women, and you will be encouraged to maintain the healthy lifestyle habits you have started. Finally in step 4, we want you to retain the confidence and motivation you have to develop your own strategies to maintain your healthy lifestyle behaviours for the rest of your life. The intervention includes an online website (to log in from any smart device using the User ID and password), eBook (weekly reading in order of different content related to their type 2 diabetes health journey for 12 weeks), Factsheets (include different topics on key information on type 2 diabetes, Logbook (to save and make notes of your daily activities intervention duration). You will be expected to enter the website weekly to read the eBook that includes information and record the daily activities on your e-Logbook which only you have access to.

One of the topics on eBook is exercise and you will read about exercise recommendations in the physical activity section. You make commence exercise activity that is too strenuous at first and feel out of breath or have sore muscles afterwards. If you have any concerns about commencing or continuing with physical activity during the programme, please talk to your diabetes nurse or GP. You can listen to podcasts related to your own specific interests and participate in an online peer support group through a private Facebook group. The personal goal form is a self-guided tool that will help you to set up your goals regarding your interest on type 2 diabetes during intervention. You will be expected to choose your 1 or 2 goals independently; however, the online content on the WWDP website, of weeks, 1, 2 and 3 of eBook will support this process.

WWDP WEEK 1-PREPARATION you will read information to understand your diabetes, self-care activities, and goals. Following this, WEEK 2-3 CHANGING LIFESTYLE will provide information about healthy eating with type 2 diabetes, understanding more about glucose, alcohol and smoking, healthy shopping, and meal planning, changing eating behaviours, stretching and flexibility, strength training exercise, diabetes distress and strategies for managing stress, better sleep, and goal setting recommendations. On the first day of the WEEK 3, you will receive the Personal Goal Form via email, and you will be expected to independently set up 1 or 2 Goal at the end of the WEEK 3; to have discussions about how everyone is approaching this goal setting and form completion. Overall, you will be ready to set up your goals using the personal goal form instructions at the end of week 3.

The peer support group is an online private Facebook group (12) comprising two 2 moderators who will facilitate Monday to Friday between 9:00 am to 5:00 pm. The moderators are volunteer midlife women living with type 2 diabetes who have been purposely fully recruited through Diabetes UK and have undertaken five hours of training. The moderators will be supervised by the PI and supervisors Prof Sturt, Dr Duaso and Dr Nadal. The peer support group will help you to engage with, and learn from, other participants during 12-weeks. In this space, you can share and learn from others' experiences, post questions, and discuss topics related to weekly content provided on our website. While the group is moderated to ensure a supportive environment, please be aware that real-time interaction is not guaranteed. To enrich your experience, you are

encouraged to participate in activities such as quizzes, message boards, and direct questions at your convenience. You are expected to post or comment at least three times a week to foster a vibrant community dialogue.

To join the group, you will receive an email invitation by the research team. Upon requesting access to the Facebook group, you'll need to enter a unique ID number provided to you. Before participating, we will ask you to review the peer support guidelines on the resources page of our website. You will be asked whether you would like the FB group to remain open, unmoderated, following the study. Please see below chart for a summary of intervention process 12 weeks.

At the end of the study, there will be an optional feedback interview with the researcher. Interview participants will be purposively selected based on your engagement with the program. Minimum requirements to engage with the programme for 12 weeks; Log in to website ≥ 3 times and attendance of peer group ≥ 3 times. This feedback interview will take place by video call and be recorded via Microsoft Teams program. The research team will help you to access these. This record will be transcribed as given unique ID number and then deleted.



Screening Questionnaire to be confirmed eligibility via email.

eBook Contents –
Each week you will
read...

Online interaction

Week 1 Refresh your knowledge about type 2 diabetes, treatment, your feelings, your self-care plan, and your goals for health.

Week 2 & 3 Changing Lifestyle, Healthy Eating, Glucose, Alcohol and Smoking, Physical Activity and Exercise, Stress, Diabetes Distress, Sleeping

Week 4 Healthy weight week

Week 5 Strong Bones Week Osteoporosis Prevention, Calcium and Vitamin D, Exercises Examples

Week 6 Menopause, Sexuality and Menopause

Week 7 Healthy Heart Week

Week 8 Diabetes Complications Prevention Week, Your regular tests and check-ups, Preventing complications of diabetes, Short and long term complications

Week 9 Cancer Prevention Week

Week 10 Reviewing what you have learned

Week 11 Motivation and change, Overcoming obstacles to change

Week 12 Looking forward – goal setting

Week 0 Online questionnaire

Week 0 Receiving an invitation for private Facebook group via email and send request to attend group. Download peer support handbook from the website and read what you need to know before attend.

Week 1 until week 3, thinking about possible goals through intervention duration 12 weeks and discussing with peers on the group.

Week 1 Downloading Logbook from website and record daily activities for 12 weeks.

Week 3 Receive personal goal form via email to set up 1 or 2 goals with following instructions, and record on the sheet at the end of Week 3.

Week 12 Online questionnaire including reviewing goal setting process and evaluation.

Week 12 Receiving consent form via email for feedback interview via Microsoft Teams.

Week 16 Interviews will be conducted as approximately 60 minutes via Teams.

CAN I TAKE BREAKS DURING THE 12 WEEK PROGRAM?

IS IT POSSIBLE?

Sometimes life gets in the way of our newly developing habits and healthy lifestyle behaviours. For example, this might be because we take a holiday, we have a celebration, we get busy at work, or someone gets ill. The Women's Wellness with Diabetes Programme is realistic about these life events, and we will ask you before you start whether you are expecting any of these events. If you are we will suggest you commence the programme once the event is over. For unexpected events, the programme can accommodate a break of up to two weeks.

As it is a research study, we hope that everyone will be able to complete the WWDP by the time the study ends. However, if you have not been able to do so because of personal events like those above, you will have unlimited access to the workbook and access to the website until week 14 even though we may not be collecting information from you.

During any periods when you take a break from the 12-week programme, you will retain access to the peer support FB group and will be encouraged to continue your engagement with it.

CAN I ATTEND ROUTINE APPOINTMENTS WITH MY GP AND OTHER HEALTH CARE PROFESSIONALS?

Yes, you should continue to attend any routine appointments with your usual healthcare providers and that this program is not intended to replace any treatment they are currently receiving for your type 2 diabetes.

I DO NOT HAVE A MICROSOFT TEAMS ACCOUNT AND FACEBOOK ACCOUNT.

The researcher will help you to set up an account and show you how to use it.

DO I GET PAID?

This is voluntary. There is no payment available.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Physical Risk for Intervention: 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 you do not exercise regularly. To minimise the risk of injury from exercise, intervention programs depend on the usage as much as you could as individual. The intervention advises you gradually increase your exercise levels over time, you do not overexert themselves at the beginning. To prevent stiffness and promote flexibility, you are also encouraged to stretch regularly. Due to your involvement in reading the iBook

every day, there may be a risk of tiredness in your eyes, and stiffness in your shoulders. During the program, you might like to incorporate some exercise into your daily routine, which could potentially reduce this risk.

Psychological risks for intervention: The topics that you could find uncomfortable the section on cancer and type 2 diabetes related complications. You may choose not to speak about topics or questions that make you uncomfortable.

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 your well-being. To mitigate this, we will ensure moderators have adequate expertise, establish clear guidelines, and prioritise participant well-being. Other risks: 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. You may choose not to speak about topics or questions that make you uncomfortable or that you can stop participating at any time without giving a reason.

If you feel uncomfortable with a question or any topic in the eBook, you do not have to answer every question or read the topic. If you have any concerns about research, please email to the researcher. Support resources:

If you are experiencing distress and would like to receive support from a health professional, please contact following resources:

1. Share your concerns making you feel distressed on the peer support online group. The purpose of the group is to facilitate peer support when things are feeling tough and when you experience success.
2. Your usual diabetes provider: They provide a medical diabetes examination, healthcare, diabetes symptom management and when necessary, your diabetes provider can refer you to Mental Health Service for further examination, support, and care.
3. Diabetes UK: Diabetes UK has trained counsellors who provide a free and confidential talk about uneasy emotions. You can get in touch with their highly trained advisors for support, advice or just a chat. You can tell their helpline on 0345 123 2399, Monday to Friday, 9 am to 6pm.
4. Samaritans: It's a 24-hour service that provide confidential telephone support for adults who have difficulties with their emotions. Helpline: 116 123 (UK).

Peer supporters are facilitator and moderator of the online peer support group. Your facilitator is a Peer support, when one or more people like you offer you information, encouragement, and reassurance, is well known to be effective in helping people cope with difficult or challenging situations. Peer support has been used in diabetes communities for decades. Peer support can be even stronger when peers are more like each other in gender, age, and health circumstances for example. The private Facebook peer support group aims to offer this type of support from other women very similar to yourself. Thus, you will be able to see how other women living with type 2 diabetes cope with the management of it in their life and this will guide each other during the peer group. Peer supporters are facilitators and moderators of the online peer support

group. Your facilitator is a non-professional who is between 45-65 age range and living with type 2 diabetes and will provide you with support as motivation during your time on the programme by online messaging. Your facilitator will be able to see your Facebook profile. In order to ensure that their support is relevant and specific to you, and to ensure your wellbeing, your facilitator will be able to see your messages and posts so your conversation on the peer group and i.e. your goals and process. However, if you think your concern is likely to be best addressed by a health professional, then they are the best people to contact. If you share your distress, questions, or concerns on the peer support group, peers or the moderator may suggest that you contact your GP or diabetes nurse.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

If you complete the 12-week program, the earlier Women's Wellness programmes found women experienced: more knowledge about their general health improved health related quality of life; decreased BMI; a better understanding of your diet; a habit of regular exercise. We expect that this programme with peer support group will also leave you with more knowledge and confidence to manage your diabetes.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

With your consent, your participation will be confidential.

All identifiable participant data will be de-identified and stored in line with the Data Protection Act 1998 in the UK and non-identifiable data for Australia and provider and developer DAWN for WWDP. (DAWN is a health research community that brings together all the research, training, and wellness programs being developed by research teams across the world. It is hosted and led by the Women's Wellness Research Collaborative in Australia). The research team manage the WWDP website; however, any technical issues on the website will be resolved by the Dawn IT team. Your confidential data will be stored on a secure server at King's College London research team can access these data. A separate electronic file will hold the identifiable details and access to this will be restricted to 4 members of the King's College London university research teams.

WHAT WILL HAPPEN TO MY DATA IF I WITHDRAW FROM THE STUDY?

With your consent, we will keep and use the data provided. The data will be anonymised. After the specific period, it will no longer be possible to withdraw from the study because the collected data will be anonymised and will be included in the analysis.

HOW IS THE PROJECT BEING FUNDED?

This project is funded by a doctoral fellowship for the main researcher by the Ministry of Education, Turkey.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

We aim to publish the results of this study in peer reviewed scientific journals. It will not be possible to identify any individual participant from the published data. If this study goes well, then we will seek funding to conduct a larger study in the future.

WHO CAN I CONTACT FOR MORE INFORMATION?

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WHAT IF I HAVE FURTHER QUESTIONS, OR IF SOMETHING GOES WRONG?

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