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International feasibility study for the Women’s Wellness with Type 2 Diabetes Programme (WWDP): An eHealth enabled 12-week intervention programme for midlife women with type 2 diabetes.

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Structured Abstract

Aims: The current study aimed to examine feasibility of participant recruitment and retention rates for the Women's Wellness with Type 2 Diabetes program (WWDP), and to assess initial efficacy of the program in improving wellbeing outcomes.

Methods: 70 midlife women with type 2 diabetes mellitus (T2DM) participated in a 12-week wellness-focused intervention, the WWDP. The WWDP involved a structured book (with participatory activities), an interactive website and nurse consultations. This study had an Australian and a UK arm. Analyses were conducted using chi-square, McNemar, paired t-test, and Wilcoxon signed-ranks tests.

Results: The attrition rate for the sample was 22.2%. Overall, significant improvement was observed in diabetes distress (DD), diabetes self-efficacy, weight, BMI, menopausal symptoms and sleep symptoms from baseline to program completion at 12 weeks. Australian participants were also more likely to meet fruit recommendation guidelines and had significant waist- and hip-circumference reductions.

Conclusions: Good retention rates and initial efficacy findings indicated feasibility of the WWDP as a promising 12-week health and wellness program for women with T2DM. They also suggest incorporating a focus on self-efficacy and gendered information may be important in improving wellness and health outcomes related to distress and menopause.

Keywords: type 2 diabetes mellitus; women; menopause; wellness; intervention; feasibility

1. Introduction.

Recent prevalence reports show more than 450,000 women have Type 2 diabetes mellitus (T2DM) in Australia, and approximately 1.4 million in the United Kingdom (UK)^{1,2}. This creates a considerable health burden for health providers and for individuals with diabetes, as they face increased risks of complications such as cardiovascular disease and reduced quality of life (QOL)^{3,4}. Women also experience more elevated, clinically significant diabetes distress (DD), an emotional response to ones perceived health threats balanced against an appraisal of available coping resources^{5,6}.

Lifestyle modification programs can reduce risk of complications for those already diagnosed^{7,8}. However, it is key such programs incorporate overall wellbeing, including both physical and mental wellness. Indeed, research has shown that without psychological components, participants in self-management interventions evidence less improvement in clinical outcomes⁹ and individuals with elevated DD participate less⁷. Conversely where DD is targeted, outcomes improve¹⁰.

Importantly, sex-related differences have been found in both the experience and management of diabetes, and in risk of other chronic disease or poor QOL outcomes. Compared to men, women with diabetes have greater risk of chronic disease outcomes and report poorer QOL and mental well-being, including increased embarrassment, greater perceived stigma and burdens, greater social restrictions and increased fatalistic perspectives^{6,11-16}. Women also experience unique health concerns and information needs due to reproductive physiology^{11,17}. As such, there is a need for wellness programs tailored specifically for women with T2DM.

For women, midlife represents an important time for health consideration due to menopause. Menopause is often a time when health problems arise, due to age or accumulated effects of previously less healthy lifestyle behaviours¹⁸. Many women are now diagnosed with

T2DM when also experiencing menopause or perimenopause, which together may promote motivation for lifestyle change and a focus on health¹⁸⁻²¹.

The Women's Wellness with T2DM Programme (WWDP) was developed from existing online Women's Wellness Programme's (WWP)²²⁻²⁴, and the Diabetes Manual²⁵. The WWP are 12-week structured, multi-modal lifestyle interventions for chronic disease prevention in women and have found QOL increases and menopausal symptoms decreases for midlife women, and women with cancer^{22,24}. The Diabetes Manual is a UK 12-week T2DM Education Programme which compared to usual care found decreases in DD and increased self-efficacy²⁵. From these programs the online WWDP aims to improve lifestyle behaviours and health outcomes in midlife women with T2DM, including reduced distress, increased exercise, healthy eating, better sleep and increased diabetes management self-efficacy. The aims of the current study were to examine feasibility of participant recruitment and retention for the WWDP and assess initial efficacy to inform a future randomised controlled trial. The study was multi-national, delivered in Australia from Griffith University and in the UK from Kings College London.

2. Subjects, Materials and Methods

2.1 Subjects and Methods

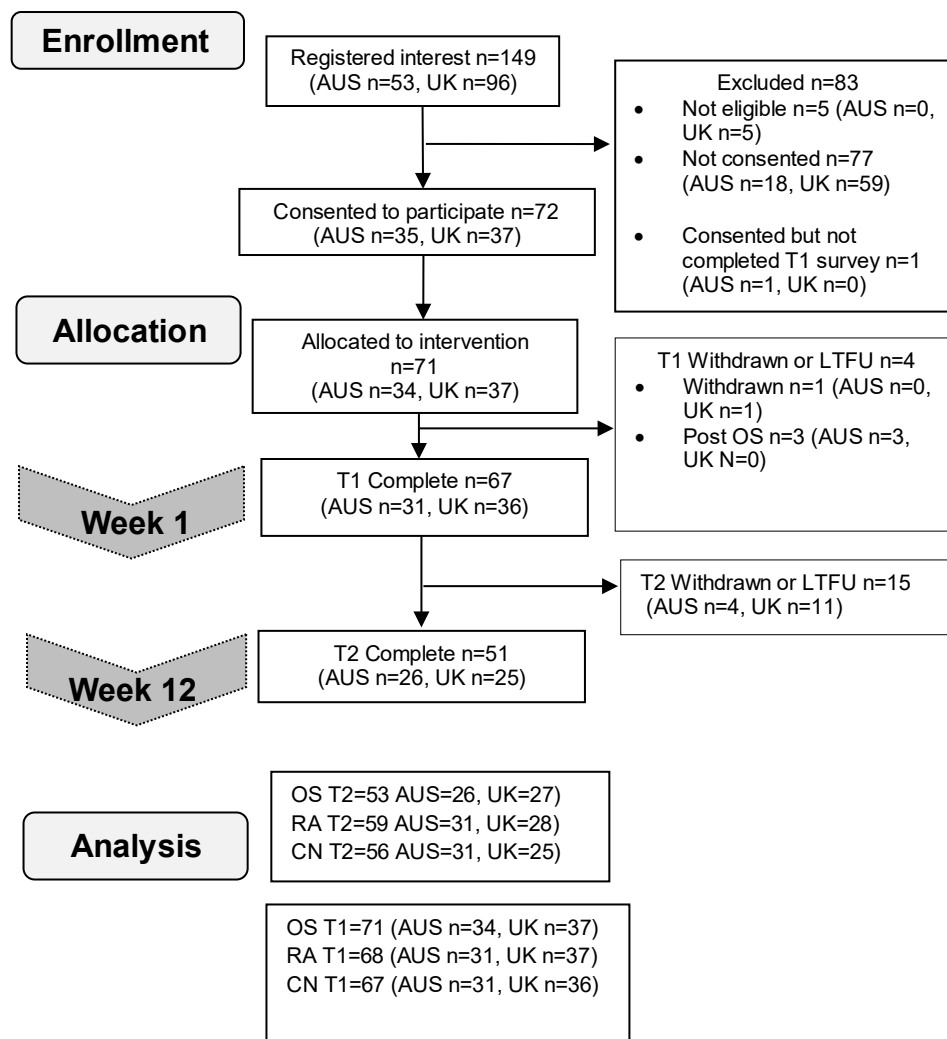
Women aged 45-65 years with T2DM were recruited from Australia and the UK through advertisements using regular and social media, diabetes charities, women's membership organisations and employers between September 2016 and August 2017. The proposed sample size took into account recommendations for feasibility trials which propose a method for determining feasibility sample to minimise sample size for the main RCT.^{26,27} This sample size supports confidence intervals calculations around proportion of eligible participants who agree to participate, and attrition rates from both treatment and research. Our proposed sample size was 70 (35 per arm). Recruitment continued until we reached this.

Participants were screened for inclusion and exclusion criteria by a research assistant (RA) in Australia or UK. Inclusion criteria were: Australian or UK residency, females aged 45-65 years, diagnosis of T2DM, can speak and read English, computer or tablet device access, basic computer literacy, internet service at home address and access to body weight scales. Exclusion criteria were: type 1 diabetes, and any contraindication or condition identified by research staff which may have affected physical participation in the program.

Of the 72 participants who initially consented, 67 commenced the program and 56 completed (**Figure 1**). This represented a 22.2% attrition rate. Participants were registered for the study via direct contact with the research team or study website, which provided inclusion criteria, study information, and contact details. Upon expressing interest, the researcher confirmed eligibility via email and provided the Participant Information and Consent Form.

2.2 Ethical Approval

This study received independent ethical approval for Australian and UK study arms from Griffith University Human Research Ethics Committee (HREC/2016/074) and King's College London's Ethics Committee (LRS-16/17-3670) respectively. Participation was voluntary and women could withdraw at any time. During recruitment, a Participant Information and Consent form describing risks and benefits of the study was provided.



Note 1: OS=Online survey; RA=Research Assistant appointment; CN=Consultation Nurse appointment; LTFU=lost to follow up

Note 2: A withdrawal/LTFU can occur before or after completion of a RA appointment or OS.

Figure 1 Consort diagram for the WWDP study

2.3 Materials

Demographic, biomedical, psychological and behavioural data were collected at two time-points (baseline and post-intervention) through an emailed survey and RA data collection (Skype/FaceTime). Based on previous WWP and Diabetes Manual trials^{22,24,25}, outcomes targeted were DD, diabetes self-efficacy, health-related QOL, menopause symptoms, anthropometry, and modifiable lifestyle factors (e.g. dietary intake, physical activity, sleep).

For psychological measures, the Diabetes Distress Scale (DDS)²⁸ measured DD. Using 17 items, it assessed four subscales: emotional burden, physician-related distress, regimen-related distress and diabetes-related interpersonal distress. Self-efficacy was measured using the UK version of the Diabetes Management Self-Efficacy Scale (DMSES UK), a 15-item scale for T2DM self-management actions and behaviours²⁹. The Short-Form 36 (SF-36)³⁰ assessed health-related QOL across 9 domains: physical functioning, physical health role limitations, emotional problems role limitations, pain, mental health, social functioning, pain, general health, reported health transition and overall mental- and physical-wellbeing scores.

For health behaviours, habitual dietary intake (including fruit, vegetables, and alcohol/tobacco) was assessed using questions from the Food Frequency Questionnaire (FFQ³¹). The 9-item International Physical Activity Questionnaire-Short Form (IPAQ³²) assessed physical activity.

For physiological measures, anthropometry measures included height and weight (from which body mass index (BMI) was derived), and waist-to-hip ratio. BMI was grouped according to the WHO International Classification of adult weight (i.e., <18.5 underweight, 18.5-24.9 in normal weight range, and ≥ 30 obese)³³. These measurements were undertaken according to protocol by participants during video call with a researcher supervising. The standard Greene Climacteric Scale^{34,35} measured menopausal symptoms, with 21 items assessing subscales for vasomotor, somatic, psychological (anxiety and depression), and sexual function symptoms. Sleep activity and quality were measured using the General Sleep Disturbance Scale³⁶. This 21-item scale includes subscales for problems initiating sleep, waking up during sleep, waking too early from sleep, quality of sleep, quantity of sleep, fatigue and alertness at work, and use of substances to induce sleep.

2.4 Program

The WWDP is theoretically underpinned by Social Cognitive Theory³⁷. It targets self-efficacy to promote health behaviour change with additional emphasis on perceived control, and planned behaviour. Developed as a single intervention for both UK and Australian users, the program sourced and listed country-specific health resources, education and recommendations for each country's current practice guidelines (**Table 1**). It was reviewed by diabetes professionals in both countries and adjustments were made for country differences, content and language. Participants additionally received their diabetes usual care.

Table 1 Targeted health knowledge and behaviours

Knowledge / Behaviour	Recommendations
1. Physical activity	<ul style="list-style-type: none"> • Be moderately physically active for at least 30 minutes/day. As fitness improves, aim for 150-300 minutes/week of moderate intensity exercise <u>Or</u> 75-150 minutes/week of vigorous intensity physical activity • Complete strength exercises on two+ days/week working all major muscles³⁸.
2. Diet	<p>Australia</p> <ul style="list-style-type: none"> • Seven serves of fruit and vegetables per day: 2 fruit & 5 veg³⁹ <p>UK</p> <ul style="list-style-type: none"> • At least 5x80gram portions of a combination of fruit and veg⁴⁰. <p>Australia & UK</p> <ul style="list-style-type: none"> • Eat mostly foods of plant-based origin • Limit consumption of energy dense foods • Avoid sugary drinks and snacks • Limit intake of red meat • Manage portion size of meals • Recommended alcohol intake per country guidelines^{41,42}
3. Smoking	<ul style="list-style-type: none"> • Smoking cessation
4. Body fatness	<ul style="list-style-type: none"> • Be as lean as possible within normal weight range • Avoid weight gain and waist circumference increases
5. Stress and psychological wellbeing	<ul style="list-style-type: none"> • Sleep • Develop healthy stress management strategies • Reduce anxiety and depression • Recognise and manage DD
6. Diabetes self-management	<ul style="list-style-type: none"> • Medication concordance • Blood glucose management • Managing clinical appointments

7. Menopausal symptoms	<ul style="list-style-type: none"> • Menopausal symptoms management
8. Preventative health and risk screening	<ul style="list-style-type: none"> • Heart disease, eye, renal, breast and gynaecological health

The intervention contains: a *program e-book* (also provided in hard copy), an *interactive website* and virtually delivered *nurse consultations*.

The *e-book* encourages women to bring together the health topics in 4 stages and incorporate them into their lives over a 12-week period. Chronologically, the 4 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. Fact Sheets also provide further information on key topics. The *interactive website* provides a news feed to enhance knowledge and enabled participation in a moderated participant forum within each country to share knowledge and support.

Women also have access to three personal *nurse consultations* (via online videoconference using Skype/FaceTime) at weeks 1, 6 and 12 with an experienced consultation nurse (CN) trained in the program delivery as well as email-based follow-up and monitoring (**Table 2**).

Table 2 WWDP Intervention Nurse Content

Week/s	Delivery Strategies	Content
1	Virtual consultation delivered by nurse	<ul style="list-style-type: none"> ▪ Background information surrounding diabetes and diagnosis ▪ Medical history and current medications ▪ Anthropometric measures discussion ▪ DD Level ▪ Goal setting of targeted health behaviours and education ▪ Other goals, related health topics (body image, sexuality, menopause)

3 & 9	Email	<ul style="list-style-type: none"> ▪ Progress, review individualised plan and goals ▪ Revise personal action plan ▪ Identify barriers
6	Virtual consultation delivered by nurse	<ul style="list-style-type: none"> • Review plan and goals • Behavioural relapse prevention strategies • DD management and concerns • Ongoing concerns and management strategies of biophysical measurements (e.g. weight, HBA1c)
12	Virtual consultation delivered by nurse	<ul style="list-style-type: none"> • Review plan and goals, set future goals • Biophysical measurements discussion • Relapse prevention, maintenance and self-monitoring

2.5 Data analysis

Analyses were performed using SPSS(v24) software. Descriptive statistics are presented using frequency and percentage for categorical data, mean (M) and standard deviation (SD) for continuous data with normal distribution and median (Mdn) and interquartile range (IQR) for continuous non-normal data. To assess changes over time within groups, paired t-tests were used for normally distributed continuous data, Wilcoxon's signed-rank test was used for non-normally distributed continuous data and the McNemar test was used for dichotomous categorical variables, with statistical significance set at $\alpha=.05$. As the sample was not powered to run multiple imputation analyses, we analysed completer data only.

3. Results

3.1 Baseline Characteristics

Baseline characteristics of the sample (n=70), including women who completed the intervention and women lost to follow-up (LTFU) are presented in **Table 4**. The mean age was 56.46 ± 5.87 years, and most were married or living as a couple (64.3%, n=45). Overall, most women (80.0%) were born in Australia or UK, most worked either full- or part-time (55.7% or 20.0% respectively), and almost half (44.3%) were university educated. The mean time since diagnosis was 8.7 years (range: 1 month-30.6 years). Most participants reported receiving

treatment through oral medication (72%), dietary modification (31%), insulin (18%) or no treatment (5%).

Baseline differences between completers and LTFU were analysed for key socio-demographic variables and outcomes, with only a small difference ($p=.047$) found in greater sleep concerns for LTFU.

Table 3. Socio-Demographic data of Australian and UK participants

Variables	Australia			UK		
	Completers	LTFU	Total	Completers	LTFU	Total
	n=28	n=6	n=34	n=34	n=2	n=36
Age in years M(SD)	57.46 (6.60)	54.17 (4.17)	56.88 (6.31)	45.00 (55.06)	50.00 (8.49)	55.11 (5.45)
Years since Diagnosis M(SD)	9.54 (8.42)	1.5 (1.44)**	8.76 (8.35)**	7.37 (7.16)	15.33 (18.27)	7.66 (7.19)
Treatment for Diabetes*						
No treatment	1 (3.6)	-	1 (3.2)	2 (5.9)	-	2 (5.6)
Dietary modification	10 (35.7)	-	10 (32.3)	10 (29.4)	1 (50.0)	11 (30.6)
Oral medication	23 (82.1)	3 (50.0)	26 (83.9)	20 (58.8)	1 (50.0)	22 (61.1)
Insulin	5 (17.9)	-	5 (11.9)	6 (17.6)	1 (50.0)	7 (19.4)
No response/Missing	-	3 (50.0)	3 (8.8)	1 (2.9)	-	-
Marital status (%)						
Married	15 (53.6)	2 (33.3)	17 (50.0)	19 (55.9)	2 (100.0)	21 (58.3)
De-facto	2 (7.1)	-	2 (5.9)	5 (14.7)	-	5 (13.9)
Separated	1 (3.6)	1 (16.7)	2 (5.9)	-	-	-
Divorced	4 (14.3)	2 (33.3)	6 (17.6)	3 (8.8)	-	3 (8.3)
Widowed	2 (7.1)	-	2 (5.9)	3 (8.8)	-	3 (8.3)
Never married	4 (14.3)	1 (16.7)	5 (14.7)	4 (11.8)	-	4 (11.1)
Employment status (%)						
Employed full-time	12 (42.9)	5 (83.3)	17 (50.0)	21 (61.8)	2 (100.0)	23 (63.9)
Employed part-time	7 (25.0)	-	7 (20.6)	7 (20.6)	-	7 (19.4)
Home duties	3 (10.7)	-	3 (8.8)	4 (11.8)	-	4 (11.1)
Unemployed	1 (3.6)	1 (16.7)	2 (5.9)	-	-	-
Full-time student	1 (3.6)	-	1 (2.9)	-	-	-
Retired	2 (7.1)	-	2 (5.9)	2 (5.9)	-	2 (5.6)
Permanently ill/unable to work	2 (7.1)	-	2 (5.9)	-	-	-
Educational status (%)						
Junior high school/Secondary school	8 (28.6)	1 (16.7)	9 (26.5)	3 (8.8)	-	3 (8.3)
Senior high school/Sixth form	3 (10.7)	-	3 (8.8)	3 (8.8)	-	3 (8.3)
Trade, technical certificate or diploma	6 (21.4)	2 (33.3)	8 (23.5)	12 (35.3)	1 (50.0)	13 (36.1)

University or college degree	7 (25.0)	3 (50.0)	10 (29.4)	8 (23.5)	1 (50.0)	9 (25.0)
Postgraduate degree	4 (14.3)	-	4 (11.8)	8 (23.5)	-	8 (22.2)
Country of Birth						UK
Australia	24 (85.7)	4 (66.7)	28 (82.4)	28 (82.4)	-	28 (77.8)
Other	4 (14.3)	2 (33.3)	6 (17.6)	6 (17.6)	2 (100.0)	8 (22.2)
Ancestry Australia (%)						
Oceania	3 (10.7)	1 (16.7)	4 (11.8)			
North-west European	16 (57.1)	2 (33.3)	18 (52.9)			
Southern and Eastern European	2 (7.1)	-	2 (5.9)			
North-East Asian	1 (3.6)	-	1 (2.9)			
Other	6 (21.4)	3 (50.0)	9 (26.5)			
Ancestry UK (%)						
White English/Welsh/Scottish/Irish/ Northern Irish/British				26 (76.4)	-	26 (72.2)
Black African/Caribbean/Black British-African				2 (5.9)	-	2 (5.6)
Other from Asian background				1 (2.9)	1 (50.0)	2 (5.6)
Asian/Asian British/ Indian				1 (2.9)	-	1 (2.8)
Other				2 (5.9)	1 (50.0)	3 (7.4)

* Multiple response so percentage exceeds 100.

**3 respondents missing response.

3.2 Diabetes Distress and Diabetes self-efficacy findings over time

Diabetes distress. Significant reductions in total DD ($z=-4.88, p<.001$) were observed from baseline. Significant reductions were also noted in regimen-related DD ($z=4.59, p<.001$), emotional burden ($z=-4.28, p<.001$) and physician-related DD ($z=2.05, p<.05$).

When examined by country, these reductions remained significant in total DD (AU: $z=-2.73, p<.01$; UK: $z=-4.04, p<.001$) and regimen-related distress (AU: $z=-2.13, p<.05$; UK: $t(27)=5.59, p<.001$). Reductions also remained significant for the UK sample for emotional burden ($z=-4.00, p<.001$) and physician-related DD ($z=2.32, p<.05$).

There was also a significant increase in likelihood of being in the non-distressed category ($p<.001$) at post-intervention. When examining findings by country, this remained significant for the UK sample ($p<.01$).

Diabetes self-efficacy. Significant increases were found in diabetes management self-efficacy ($t(52)=3.82, p<.001$) from baseline. When examined by country, these remained significant for the UK sample ($t(26)=4.04, p<.001$).

3.3 Health-Related Quality of Life (SF-36) findings over time

There were significant improvements in self-reported general health ($t(53)=4.24, p<.001$), vitality ($t(53)=3.27, p<.01$), physical function ($z=2.76, p<.01$), reported health transition ($z=4.37, p<.001$), social function ($z=2.20, p<.05$) mental health ($z=2.91, p<.01$) and overall mental component score ($z=2.67, p<.01$) from baseline. Other domains did not differ significantly over time ($p=.08-.38$).

Table 4. Psychological, health behaviour and physiological data of study participants across two points of the study

Study Location	Australia		UK		Total	
	Baseline	Endpoint	Baseline	Endpoint	Baseline	Endpoint
	M(SD) Mdn[IQR]	M(SD) Mdn[IQR]	M(SD) Mdn[IQR]	M(SD) Mdn[IQR]	M(SD) Mdn[IQR]	M(SD) Mdn[IQR]
<u>Psychological Outcomes</u>						
DMSES	n=26		n=27		n=53	
	145.42 (34.25)	153.31 (33.72)	133.78 (36.18)	156.70 (42.73)	139.49 (35.40)	155.04 (38.24)
	150.00 [45.75]	160.00 [60.75]	135.00 [51.00]	176.00 [38.00]	147.0 [49.00]	170 [59.00]
Diabetes Distress	n=28		n=28		n=56	
Total DDS	2.04 (0.90)	1.72 (0.84)	2.89 (1.12)	2.03 (0.64)	2.46 (1.10)	1.88 (0.76)
	1.71 [1.37]	1.32 [1.24]	2.71 [1.67]	2.06 [0.90]	2.16 [1.90]	1.85 [1.21]
Emotional burden subscale	2.03 (1.06)	1.74 (0.88)	2.83 (1.25)	1.92 (0.69)	2.43 (1.22)	1.83 (0.79)
	1.60 [1.70]	1.40 [1.30]	2.50 [1.90]	1.90 [1.10]	2.2 [2.00]	1.8 [1.30]
Physician-related distress subscale	1.54 (1.00)	1.63 (1.26)	2.54 (1.66)	1.86 (1.05)	2.04 (1.45)	1.75 (1.16)
	1.00 [0.50]	1.00 [0.44]	2.00 [2.69]	1.63 [1.25]	1.25 [1.75]	1.13 [1.00]
Regimen-related distress subscale	2.58 (1.33)	2.18 (1.26)	3.34 (1.38)	2.18 (1.03)	2.96 (1.40)	2.18 (1.14)
	2.20 [2.00]	1.90 [1.50]	3.30 [2.20]	1.90 [1.50]	2.80 [2.40]	1.9 [1.60]
Interpersonal distress subscale	1.75 (1.09)	1.69 (1.16)	2.70 (1.54)	2.23 (0.99)	2.23 (1.41)	1.96 (1.10)
	1.33 [1.00]	1.17 [1.00]	2.00 [2.53]	2.00 [1.69]	1.84 [1.70]	1.67 [1.67]
Elevated DD (%)	n=31		n=37		n=16	
	8 (25.8)	3 (10.7)	13 (35.1)	2 (7.1)	11 (16.18)	5 (9.26)
SF-36						
Physical Functioning	70.47 (22.90)	75.33 (20.66)	82.03 (19.14)	85.55 (18.62)	76.25 (21.70)	80.44 (20.15)
	75.00 [31.48]	79.99 [30.00]	89.96 [30.20]	95.00 [15.01]	82.47 [34.98]	85.00 [21.45]
Role-Physical	76.16 (21.09)	79.86 (22.29)	83.56 (20.30)	84.49 (19.18)	79.86 (20.84)	82.18 (20.73)
	81.25 [43.75]	87.50 [25.00]	87.50 [25.00]	93.75 [25.00]	87.50 [37.50]	87.50 [25.00]
Bodily Pain	58.00 (20.37)	61.11 (22.21)	64.89 (22.30)	65.81 (24.01)	61.44 (21.44)	63.46 (23.03)
	62.00 [33.00]	62.00 [23.00]	62.00 [33.00]	62.00 [43.00]	62.00 [33.00]	62.00 [33.00]

General Health	51.89 (19.49)	60.81 (20.32)	47.41 (20.62)	56.19 (21.48)	49.65 (20.01)	58.50 (20.84)
	52.00 [32.00]	62.00 [35.00]	52.00 [30.00]	57.00 [37.00]	52.00 [28.00]	59.50 [35.50]
Vitality	49.54 (21.08)	54.63 (22.31)	49.07 (19.82)	59.03 (16.11)	49.31 (20.27)	56.83 (19.40)
	50.00 [31.25]	56.25 [25.00]	50.00 [31.25]	56.25 [25.00]	50.00 [26.56]	56.25 [26.56]
Social Functioning	72.22 (25.32)	75.46 (23.12)	76.85 (25.41)	86.11 (17.10)	74.54 (25.23)	80.79 (20.85)
	75.00 [50.00]	75.00 [37.50]	75.00 [37.5]	87.75 [25.00]	75.00 [50.00]	87.50 [37.50]
Role-Emotional	80.56 (26.25)	82.41 (25.56)	83.33 (18.49)	91.05 (15.49)	81.94 (22.53)	86.73 (21.39)
	100.00 [41.67]	91.67 [25.00]	91.67 [25.00]	100.00 [16.67]	91.67 [27.08]	100.00 [25.00]
Mental Health	71.85 (17.98)	74.44 (17.00)	66.67 (16.76)	76.85 (13.67)	69.26 (17.41)	75.64 (15.33)
	75.00 [20.00]	80.00 [25.00]	70.00 [20.00]	80.00 [15.00]	75.00 [20.00]	80.00 [20.00]
Reported Health Transition	3.33 (0.68)	2.33 (1.04)	3.04 (0.71)	2.44 (0.89)	3.19 (0.70)	2.39 (0.96)
	3.00 [1.00]	2.00 [2.00]	3.00 [0.00]	2.00 [1.00]	3.00 [1.00]	2.00 [1.00]
Physical Component Score	45.23 (7.11)	47.55 (8.76)	48.74 (7.15)	48.90 (8.42)	46.98 (7.28)	48.23 (8.39)
	44.96 [8.38]	50.47 [5.53]	49.85 [11.66]	50.73 [13.66]	47.97 [10.22]	50.48 [11.55]
Mental Component Score	48.53 (11.46)	49.67 (10.73)	46.58 (8.42)	52.23 (7.10)	47.56 (10.01)	50.95 (9.11)
	52.26 [15.07]	49.80 [11.29]	48.97 [11.48]	54.19 [5.85]	49.93 [13.76]	53.25 [10.13]
<u>Health Behaviour Outcomes</u>						
Physical activity in minutes per week]	n=28		n=28		n=56	
	565.00	954	1512.00	1298.50	990.00	1107.00
	[1144.00]	[1988.00]	[2299.5]	[1950.5]	[1578.25]	[2192.25]
Mean Fruit and Vegetables	n=26		n=24		n=50	
	4.29 (2.05)	5.88 (1.75)	5.07 (2.47)	5.70 (1.92)	4.66 (2.28)	5.79 (1.82)
Meeting Australian Vegetable Recommendations (n=26)						
Yes	6 (23.1%)	14 (53.8%)				
No	20 (76.9%)	12 (46.2%)				
Meeting Australian Fruit Recommendations (n=26)						
Yes	11 (42.3%)	22 (84.6%)				

No	15 (57.7%)	4 (15.4%)				
Meeting UK Combined Fruit and Vegetable Recommendations (n=24)						
Yes			15 (62.5%)	17 (70.8%)		
No			9 (37.5%)	7 (29.2%)		
<u>Physiological Outcomes</u>						
Weight (kg)	n=25		n=26		n=51	
	93.30 (18.89)	90.79 (18.92)	85.18 (22.65)	83.41 (21.78)	89.16 (21.09)	87.03 (20.56)
	90.20 [38.15]	89.00 [37.30]	81.20 [35.85]	81.35 [32.00]	86.23 [35.10]	85.10 [33.8]
Body Mass Index (BMI)	n=25		n=25		n=50	
	34.62 (7.38)	33.66 (7.22)	32.53 (8.86)	31.89 (8.64)	33.58 (8.14)	32.77 (7.93)
	33.79 [11.78]	33.42 [10.91]	29.53 [12.42]	30.25 [11.75]	33.29 [11.38]	32.59 [10.02]
Waist circumference (cm)	n=25					
	109.06 (15.02)	105.52 (14.33)				
	109.70 [24.80]	109.00 [23.70]				
Hip circumference (cm)	n=25					
	118.09 (15.18)	114.22 (14.15)				
	119.20 [20.75]	116.20 [25.50]				
Waist-Hip Ratio (WHR)	n=25					
	0.93 (0.09)	0.93 (0.10)				
	0.91 [0.10]	0.91 [0.09]				
Menopausal symptoms	n = 27		n=27		n=54	
Psychological	8.22 (5.65)	6.96 (5.16)	8.30 (6.06)	5.63 (3.56)	8.26 (5.80)	6.30 (4.44)
	8.0 [8.00]	6.0 [6.00]	6.0 [6.00]	5.0 [3.00]	7.0 [7.25]	5.5 [6.00]
Psychological anxiety	4.30 (2.85)	3.56 (2.75)	4.04 (3.20)	2.96 (1.74)	4.17 (3.01)	3.26 (2.30)
	4.0 [4.00]	3.0 [3.00]	3.0 [4.00]	3.0 [3.00]	3.0 [4.00]	3.0 [2.25]
Psychological depression	3.93 (3.15)	3.41 (2.89)	4.26 (3.12)	2.67 (2.30)	4.09 (3.11)	3.04 (2.61)
	4.0 [5.00]	3.0 [4.00]	4.0 [4.00]	2.0 [2.00]	4.0 [4.25]	2.5 [4.00]
Somatic	5.48 (3.83)	4.56 (3.26)	3.52 (2.64)	2.52 (2.24)	4.50 (3.40)	3.54 (2.96)
	4.0 [7.00]	5.0 [5.00]	3.0 [3.00]	2.0 [2.00]	3.0 [5.00]	3.0 [4.00]

Vasomotor	1.89 (1.87) 2.0 [3.00]	1.41 (1.62) 1.0 [2.00]	2.00 [4.00] 2.0 [4.00]	1.00 [2.00] 1.0 [2.00]	1.94 (1.77) 2.0 [3.25]	1.28 (1.47) 1.0 [2.00]
Total GCS	16.85 (10.85) 15.0 [15.00]	14.07 (8.58) 12.0 [14.00]	15.11 (9.92) 10.0 [14.00]	10.19 (5.90) 10.0 [9.00]	15.98 (10.33) 13.5 [14.25]	12.13 (7.55) 11.0 [9.00]
Sleep	n=26		n=27		n=53	
Sleep onset latency	2.65 (2.02) 2.0 [3.25]	2.31 (2.29) 2.0 [3.00]	2.11 (2.12) 2.0 [3.00]	1.11 (1.55) 1.0 [2.00]	2.38 (2.07) 2.0 [2.50]	1.70 (2.02) 1.0 [3.0]
Mid sleep awakening	4.31 (2.26) 4.0 [4.00]	3.62 (2.42) 3.0 [5.00]	4.93 (2.34) 6.0 [4.00]	4.63 (2.56) 6.0 [4.00]	4.62 (2.30) 5.0 [4.00]	4.13 (2.52) 3.0 [5.0]
Early awakening	2.35 (2.13) 1.0 [3.25]	2.62 (2.47) 2.0 [4.00]	3.59 (2.58) 3.0 [5.00]	2.78 (2.58) 2.0 [5.00]	2.98 (2.43) 3.0 [4.0]	2.70 (2.50) 2.0 [4.50]
Quality of sleep	9.19 (3.26) 9.0 [4.25]	7.77 (3.68) 8.0 [3.00]	8.22 (4.24) 8.0 [5.00]	8.19 (3.81) 8.0 [4.00]	8.70 (3.79) 9.0 [4.0]	7.98 (3.71) 8.0 [4.00]
Quantity of sleep	4.19 (3.05) 4.0 [4.00]	3.58 (2.56) 3.0 [4.25]	3.93 (2.70) 4.0 [6.00]	2.67 (2.30) 2.0 [4.00]	4.06 (2.85) 4.0 [4.50]	3.11 (2.45) 2.0 [5.00]
Use of sleep substances	2.69 (3.56) 0.5 [6.00]	2.23 (3.35) 0.0 [5.50]	0.59 (1.25) 0.0 [0.0]	0.37 (1.24) 0.0 [0.0]	1.62 (2.83) 0.0 [2.50]	1.28 (2.66) 0.0 [1.00]
Fatigue/alertness at work	14.65 (9.06) 13.0 [10.75]	13.96 (9.55) 13.0 [10.00]	12.89 (7.26) 11.0 [11.0]	12.85 (5.52) 11.0 [8.00]	13.75 (8.16) 11.0 [10.50]	13.40 (7.71) 13.0 [9.00]
Overall GSDS score	40.04 (13.45) 36.0 [20.00]	36.08 (14.75) 35.5 [22.75]	36.26 (13.55) 38.0 [15.00]	32.59 (11.29) 30.0 [19.00]	38.11 (13.50) 37.0 [18.0]	34.30 (13.09) 32.0 [19.50]

When examined by country, significant improvements remained in self-reported general health (AU: $t(26)=2.57$, $p<.05$); $p<.05$; UK: $t(26)=3.66$, $p<.001$) and reported health transition (AU: $z=3.51$, $p<.001$; UK: $z=2.62$, $p<.01$). Significant improvements also remained for the UK sample in vitality ($t(26)=3.27$, $p<.01$), physical function ($z=-2.07$, $p<.05$), mental health ($z=3.22$, $p<.01$) and overall mental component score ($z=3.34$, $p<.01$).

3.4 Health Behaviour findings over time

Physical activity. A trend was observed overall for significant increases in physical activity in minutes/week ($z=1.74$, $p=.08$). This remained for the Australian sub-sample ($z=1.68$, $p=.09$).

Fruit and vegetable consumption. As fruit and vegetable recommendations differ between Australia and the UK, results are reported by country. There was a significant increase in the likelihood of Australian participants meeting fruit consumption ($p<.005$). There was no significant change in combined fruit and vegetable consumption ($p=.63$) for UK participants.

Smoking. Few participants identified as current smokers; therefore, this data is presented descriptively. Overall, 4.0% of participants indicated they were a current smoker at baseline and no participants changed smoking status.

3.5 Physiological findings over time

Weight, waist and hip circumference. Participants significantly reduced weight ($t(50)=5.71$, $p<.001$) and BMI ($t(49)=5.51$, $p<.001$) from baseline. When examined by country, this remained significant for weight (AU: $z=-4.00$, $p<.001$; UK: $t(25)=3.19$, $p<.01$) and BMI (AU: $z=-4.05$, $p<.001$; UK: $t(25)=3.01$, $p<.01$). More anthropometric measures were available for the Australian sample. For these participants, a significant reduction was observed from baseline for waist-circumference ($t(24)=4.23$, $p<.001$) and hip-circumference ($z=-3.42$, $p<.001$). No significant changes were observed for waist-hip ratio.

Menopausal symptoms. Significant reductions were also found in total menopausal symptoms ($z=-3.58, p<.001$) from baseline. Significant reductions were found in all subscales, including the psychological (total: $z=-2.95, p<.01$; anxiety: $z=-2.39, p<.05$; depression: $z=-2.69, p<.01$), somatic ($t(53)=2.52, p<.05$), vasomotor ($z=-3.77, p<.001$), and sexual dysfunction ($t(53)=2.08, p<.05$) symptoms.

When examined by country, these reductions remained significant for total menopausal (AU: $t(26)=2.25, p<.05$; UK: $z=-2.63, p<.01$), total psychological (AU: $z=-2.18, p<.05$; UK: $z=-2.04, p<.05$) and vasomotor (AU: $z=-2.37, p<.05$; UK: $z=-2.93, p<.01$) symptoms. Reductions also remained significant for the UK sample for depression ($z=-2.35, p<.05$) and sexual dysfunction ($t(26)=2.10, p<.05$) symptoms.

Sleep. Significant improvements were found in total sleep score ($t(52)=2.68, p<.05$), sleep onset latency ($z=-2.56, p<.05$), and quantity of sleep ($t(52)=2.40, p<.05$). No significant changes were observed for the remaining domains ($p=.06-.69$).

When examined by country, the improvements remained significant for the Australian sample in total sleep score ($t(25)=2.12, p<.05$) and for the UK sample for sleep onset latency ($z=-2.72, p<.01$) and quantity of sleep ($t(26)=2.11, p<.05$).

4. Discussion

This is the first study to examine the feasibility of a wellness program designed for midlife women with T2DM. This study demonstrated promising initial efficacy findings for the WWDP of improved wellbeing and health across a range of outcomes.

DD is an important QOL outcome for women with Type 2 diabetes linked to increased risk for a variety of health concerns²⁸. In this study, improvements were noted in many health-related QOL indicators, including general health, vitality, reported health transition, social functioning and mental health. However, one of the key findings were the improvements for diabetes-specific outcomes (diabetes self-efficacy and DD: regimen-

related, emotional burden and physician-related). These improvements support suggestions from past research that diabetes self-efficacy may be linked to DD, with both often improving together in past mixed-gender interventions^{25,43}. Specifically, distress may be decreased from the sense of control gained from development of health-management skills alongside development of skills in reflection, goal setting and coping/motivational strategies. With an underlying theoretical structure focused on increasing wellness through a self-efficacy framework, this places the WWDP in a unique position to improve DD by addressing this under-targeted area. The improvements on diabetes-specific outcomes also suggest good feasibility for adaptation of this WWP framework for a T2DM population.

Significant improvements were also found for all menopausal symptoms assessed and total sleep dysfunction. This is consistent with other WWP programs for midlife women without illness²², and women who have had cancer²⁴ and further support the applicability of the gendered-wellness framework for those with T2DM.

Similar to other mixed-gender lifestyle interventions⁴⁴, the current study also found significant improvements in weight and BMI for participants. Significant improvements were also found in waist- and hip-circumference for the Australian arm. Partial improvements were observed for some lifestyle behaviours with a trend for physical activity improvement and increases in adherence to fruit and vegetable recommendations for the Australian sample. Data were missing for the UK sample.

The initial efficacy and feasibility for the WWDP outlined in the current study provide an important step forward in care for women with T2DM. The WWDP fills an important gap, by providing gender-specific care that can target key issues for women such as menopause. Further, with its low contact and remote administration the WWDP may provide flexibility and convenience for women to improve their self-efficacy, reduce distress and increase health and wellness outcomes such as sleep and lifestyle behaviours.

The current study has many strengths. Our high level of data completion and relatively low attrition rate provide initial indications this program is acceptable to women with T2DM in Australia and the UK. Further, the preliminary findings support that our primary outcomes in a larger RCT should be DD, health-related QOL and diabetes self-efficacy. The similarity between completers and LTFU is also promising for feasibility and suggests it is unlikely program dropout was motivated by poorer initial wellbeing.

However, there are also limitations. The primary purpose of this study was to examine program feasibility and therefore no control group was included. As such, it is possible some of the change observed may be due to non-program factors. Findings were also sometimes inconsistent between country samples, and some assessment methods (e.g. online anthropometrics) were used with unknown reliability and validity. Furthermore, the current study did not assess clinical outcomes, either physical or mental health, and as such the impact of intervention on these outcomes and resulting health service usage is unknown. The self-selection bias and lessons learned from this feasibility study will impact attention to future recruitment strategies in the larger future trial in order to recruit/reach those women who stand to benefit most from the intervention. The self-selection bias (related to convenience sampling) is acknowledged as this sample might have different baseline characteristics (i.e self-efficacy) or greater resources (i.e food, security) compared to women who did not respond with interest (or were never reached through recruitment methods). The future study will ensure the measurement of social determinants of health that may further impact the women's ability to engage in lifestyle and wellness practices that are addressed in this intervention. These limitations will be addressed in future research conducting larger RCT trials of the WWDP.

Conclusion

In conclusion, good retention rates and good initial efficacy findings indicate feasibility of the WWDP as a promising 12-week health and wellness program for women with T2DM. They also suggest incorporating a focus on self-efficacy and gendered information may be important in improving wellness and health outcomes related to distress and menopause. Overall, these findings provide a good foundation for future trials to provide more definitive results, using larger sample sizes and RCT designs.

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Declarations of interest: none

Contributions

DA and JS are co-leads for the project. DA, JS, NM, JPS, RR, AT, CS, AM, DT, RT and LAK are project members having made substantial contributions to intervention administration and evaluation. DS and CW made contributions to data analysis and manuscript preparation. All authors read and approved the manuscript. DA is the corresponding author.

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