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A randomised controlled trial to investigate the effectiveness of two commonly-used lifestyle-based weight-loss programmes across three countries

Submission date 03/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/08/2007	**Overall study status** Completed	
Last Edited 06/07/2018	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6202

Study information

Scientific Title
A randomised controlled trial to investigate the effectiveness of two commonly-used lifestyle-based weight-loss programmes across three countries

Acronym
WW Global Effectiveness Trial

Study objectives
The purpose of the study is to compare the effectiveness of WeightWatchers (WW), a commercial weight-loss programme, with current standard General Practitioner (GP) weight-loss treatment for overweight adults, as informed by national guidelines in three countries (the UK, Australia and Germany).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: Nottingham Research Ethics Committee 2, 30/04/2007, ref: 07/Q2404/40
2. Australia: Sydney SW Area Health Service (RPAH Zone), 14/05/2007, ref. X07-0089
3. Germany: Ethics Committee of Fakultat (Ethikkommission de Fakultat fur Medizin der TUM), 18 /05/2007, ref. 1812/07

Primary study design
Interventional

Study design
12-month multi-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
GP referral to WW for 12 months versus standard GP management for weight loss for 12 months.

Intervention Type
Behavioural

Primary outcome(s)
To examine the differences in weight loss at 12 months between the WW programme and standard GP management for weight loss (as informed by national guidelines) across three countries.

Key secondary outcome(s)
1. To investigate numbers of subjects losing 5% and 10% of baseline weight in each group
2. To investigate changes in a number of indicators of metabolic disease in both groups - to include body composition (bio-impedance analysis), simple indices of insulin sensitivity (HOMA-IR) , lipid profile, liver function and inflammatory markers, measured at baseline and at 6 and 12

months
3. To explore the impact of the treatments on eating behaviour (Three Factor Eating Questionnaire [TFEQ-R21]), physical activity (International Physical Activity Questionnaire short version [IPAQ-short]) and quality of life (Impact of Weight on Quality Of Life [IWQOL-lite]), assessed at baseline and at 6 and 12 months
4. To examine cost of the WW programme vs standard GP care for weight loss
5. To investigate the temporal pattern of change in body weight over all measured time points
6. To qualitatively explore participants' experiences of the two weight-loss programmes (focus groups), assessed at baseline and at 6 and 12 months

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Men and women who are overweight and with evidence of some increased risk of obesity-related disease will be eligible for the trial. Participants will be male and female adults aged 18+ years, with a body mass index of 27 - 35 kg/m^2 and one or more of the following risk factors:
1. Family history of diabetes mellitus
2. Controlled type 2 diabetes mellitus not treated with insulin*
3. Previous gestational diabetes mellitus
4. Impaired glucose tolerance/impaired fasting glycaemia
5. Mild-moderate dyslipidaemia, or treatment for dyslipidaemia
6. Treatment for hypertension
7. Central adiposity (waist circumference greater than 88 cm in women or greater than 102 cm in men)
8. Polycystic ovary syndrome/infertility without apparent cause other than weight
9. Lower limb osteoarthritis
10. Abdominal hernia

* Patients with type 2 diabetes treated with sulphonylureas will be eligible for inclusion but GPs will be advised to instruct them to closely monitor their glucose levels due to the additional risk of hypoglycaemia during weight loss, and to regularly review their medication. The number of people with diabetes recruited to the study will be limited to a maximum of 50% of the total sample.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Factors which may affect weight:
1. Recent weight loss of greater than 5 kg in the previous 3 months
2. History of clinically-diagnosed eating disorder
3. Orthopaedic limitations preventing participation in regular physical activity
4. Untreated thyroid disease or greater than one change in thyroid medication over previous 6 months
5. Taking any prescription medication with known effects on appetite or weight (according to National Medicines Formulary)
6. Taking oral steroids
7. Chronic/inflammatory gastrointestinal disorders (irritable bowel syndrome acceptable)
8. Previous surgical procedure for weight loss
9. Major surgery within previous 3 months
10. Pregnancy or lactation

Co-exisiting disease:
11. Insulin-treated diabetes mellitus
12. HbA1c greater than 9.0%
13. Diagnosis of type 2 diabetes within previous 6 months
14. Heart problems within previous 3 months (e.g. angina, myocardial infarction, stroke) or implanted cardiac defibrillator or pacemaker
15. Uncontrolled hypertension (greater than 160/95 mmHg)
16. Having started taking a new prescription medication within 3 months
17. Change in dosage of a prescription medication within 1 month
18. History or presence of cancer (completely resected basal or squamous cell carcinoma acceptable if treatment completed more than 6 months prior to enrolment)

Participants will also be excluded if they have participated in another clinical trial within 30 days prior to enrolment.

Participants must be willing to be involved in a lifestyle-based weight-loss programme for a 12-month period, and able to attend weekly meetings (free of charge) for the duration if required.

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Australia

Germany

Study participating centre
MRC Human Nutrition Research
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation
Medical Research Council Human Nutrition Research (UK)

ROR
https://ror.org/050pqs331

Funder(s)

Funder type
Industry

Funder Name
WeightWatchers International Inc. (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/10/2011		Yes	No
Results article	cost-effectiveness results	01/06/2013		Yes	No
Results article	results	01/06/2014		Yes	No
Results article	results	04/07/2018		Yes	No