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# Evaluation of a a weight management program for young people

**Submission date**
14/03/2013

**Recruitment status**
No longer recruiting

**Registration date**
10/04/2013

**Overall study status**
Completed

**Last Edited**
25/06/2020

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The recently released National Secondary Students Diet and Activity (NaSSDA) survey revealed excessive prevalence of overweight and obesity among students in Australia. The report also showed that young people have inadequate rates of physical activity and do not eat enough fruit and vegetables. Obesity-related illnesses occur in overweight and obese adolescents. Furthermore, adolescent obesity tracks into adulthood and disease risk markers in obese adolescents can predict illnesses that will occur in adulthood. Commercial weight loss programs have been shown to be successful in initiating and maintaining long term weight loss in adults, such as the Lighten Up trial, which demonstrated the superiority of commercially delivered programs when compared to the health service system in the UK.
To date, there have been no studies that have assessed a commercial weight management program for adolescents. Jenny Craig, a leading commercial weight loss company, have updated and refreshed their adolescent program with the assistance of consultants with expertise in nutrition and psychology. We are not sure how well JenMe works for weight management in young people and that is the aim of this study.

What does the study involve?
The participants will be randomly allocated to one of two groups: the 'JenMe' treatment group or a wait-listed group. Both groups will complete questionnaires on attitudes to eating, physical activity and self-esteem as well as 4-day activity and food diaries prior to study initiation. Measures of body composition will also be assessed and participants will also have the option to provide a blood sample for analysis of cardio-metabolic biomarkers and participate in a dual energy x-ray absorptiometry (DXA) scan for more accurate body composition. The treatment group will then receive the JenMe program for 12 weeks, whereas the wait-listed group will delay their enrolment into the program for 12 weeks. The wait-listed group will be asked to maintain their current diet and activity patterns. At the end of 12 weeks participants will again complete the questionnaires and diaries and have their body composition measurements reassessed. The treatment group will be followed-up at 6 months post completion of the program where the same questionnaires, diaries and body composition measures will be collected.

Who can participate?
Young people aged 13 to 17 years (adolescents) with a BMI z-score equal or above 1.282, which places them above the 90th percentile for BMI in their age and gender group.

What are the possible benefits and risks of participating?
All participants will eventually receive the weight management program. It is anticipated that all participants who complete the program will have modified eating and physical activity behaviours resulting in weight loss or weight stabilisation, which will decrease their risk of diseases associated with overweight and obesity. The food provided as part of the program will be subsidised (50%) for a 12 month period after starting the trial and membership fees to join Jenny Craig will be waived.
Lack of treatment for the obese child is not ideal and we are asking permission to delay treatment in the wait listed group by 12 weeks only to ensure an accurate evaluation of Jenny Craig's adolescent program. Wait-listed participants will be offered the program on completion of the wait-listed period.
The blood sample procedure will be brief but mild to moderate discomfort may be experienced by the participants during this short period and there may be a residual amount of bruising. Standard procedures are in place and will be performed by paediatric nurses. The DXA scan that will be performed in this study involves a very small amount of radiation. At the dose level given by the DXA, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is minimal. To ensure risk minimisation, procedures outlined in the Exposure of Humans to Ionizing Radiation for Research Purposes code of practice have been adopted.

Where is the study run from?
The Department of Nutrition & Dietetics at Monash University, Notting Hill, VIC Australia will be responsible for conducting the study. Participants will receive the JenMe program and have their height, weight, waist and body composition measurements recorded at their nearest Victorian Jenny Craig centre. Blood collection and DXA scans will be performed at the Department of Nutrition & Dietetics at Monash University, Notting Hill, VIC Australia

When is study starting and how long is it expected to run for?
The study will start in March or April 2013 and will run for 2 years or until the required number of 140 adolescents have been recruited and evaluated.

Who is funding the study?
Jenny Craig Weight Loss Centres Pty Ltd (Australia)

Who is the main contact?
Dr Maxine Bonham
maxine.bonham@monash.edu

# Contact information

### Type(s)
Scientific

### Contact name
Dr Maxine Bonham

### Contact details

Level 1, 264 Ferntree Gully Rd
Notting Hill
Australia
3168
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# Additional identifiers

# Study information

### Scientific Title
Evaluation of a 12 week commercial weight management program for adolescents

### Study objectives
A weight management program that incorporates diet, physical activity and personal counselling sessions will increase program compliance and result in weight loss related to behaviour change in overweight and obese adolescents.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Monash University Human Research Ethics Committee ¨C conditional approval - Project Number - CF11/3687 - 2011001940

### Primary study design
Interventional

### Study design
Randomised parallel design

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Overweight and obesity in adolescents

### Interventions
The intervention group will engage in the 12 week JenMe program, whereas the wait-listed group will delay their enrolment for 12 weeks.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)

1. Change in body mass index z-score
2. Change in weight to height ratio
Measured at baseline, 12 weeks and nine months from baseline

### Key secondary outcome(s)
1. Change in activity levels will be measured using pedometers and an activity diary
2. Change in behaviour and self esteem will be measured using validated questionnaires
3. Changes in body composition will be measured using DXA
4. Changes in cardiometabolic risk factors in blood plasma will be measured in blood and will include fasting glucose, triacylglycerols and cholesterol

### Completion date
18/03/2015

## Eligibility

### Key inclusion criteria
1. Adolescents seeking weight management aged 13 to 17 years
2. BMI z-score  1.282
3. Available to complete the 12 week program in a maximum of 14 weeks

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
13 Years

### Upper age limit
17 Years

### Sex
All

### Key exclusion criteria
1. Less than 13 years of age
2. Over 17 years and 2 months of age at time of commencement in study
3. Pregnant or breastfeeding
4. A health condition - Adolescents joining the Jenny Craig program are screened by a company doctor and a health checklist completed. Potential clients are not permitted to enrol in the program if they have a health condition that that requires medication or ongoing health screening. If necessary, the company doctor will liaise between the company and the potential client's GP in order to ascertain medical history and thus advise Jenny Craig as to an individual's suitability to join the program.

**Date of first enrolment**
18/03/2013

**Date of final enrolment**
18/03/2015

# Locations

**Countries of recruitment**
Australia

**Study participating centre**
**Level 1, 264 Ferntree Gully Rd**
Notting Hill
Australia
3168

# Sponsor information

**Organisation**
Monash University (Australia)

**ROR**
https://ror.org/02bfwt286

# Funder(s)

**Funder type**
Industry

**Funder Name**
Jenny Craig Weight Loss Centres Pty Ltd.

# 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 | 01/06/2017 | 25/06/2020 | Yes | No |
| Protocol article | protocol | 19/06/2015 | | Yes | No |