**Analysis Plan**

**Title:** How do behavioural change techniques relate to the mean weight loss seen in patients in the control arm of the BWeL trial at the 12-month review.

**Authors:** Eleanor Ayre, Joseph Lee, Kerstin Frie, Paul Aveyard, Charlotte Albury

**Introduction:**

The Brief Interventions for Weight Loss (BWeL) trial was a two-armed parallel randomised study with an intervention and a control arm. In this trial, patients with a BMI>30 who were not actively seeking to lose weight were randomized to receive either a brief free referral to a commercial weight management programme (the intervention arm), or brief weight loss advice (the control arm). The intervention was conducted at the end of a typical consultation with their GP.

In this trial both the control group and the active intervention group lost more weight than is lost on average by people with a BMI >30 over a year (300g)3 . Whilst the control arm showed a mean weight loss of 1.04kg in the 12-month follow up1, no research has yet examined aspects of their referral which may have contributed to changes in patient behaviour which resulted in this weight loss. This project aims to identify the Behavioural Change Techniques (BCTs) used by GPs in the control arm of the study and to examine associations between these BCTs and patient weight loss 12 months after the first consultation. We will use Michie’s v1 behavioural change taxonomy4 and the CALO-RE taxonomy of behaviour change techniques5.

The following questions will be investigated:

* any or BCT domains12
* Are any BCTs or BCT domains used by GPs in the control arm of the BWeL trial associated with significant mean weight loss at 12 months?
* Are any BCTs or BCT domains associated with patients losing ≥5% of their bodyweight?
* Was GP fidelity to the training video associated with greater patient mean weight loss?
* Was the number of individual BCTs used associated with patient weight loss, or action on their weight?

**Methods:**

**Exclusion criteria**

In the BWeL trial the exclusion criteria excluded those who were pregnant/planning pregnancy, those who had undergone bariatric surgery, those who had completed a weight management plan or had used pharmacotherapy in the last three months or were currently enrolled and those attending to discuss weight3.

**Data sources and processing**

In the BWeL trial half of all patients were randomly selected for audio recording. Our research examines 224 intervention recordings of interactions between GPs and patients in the control arm, where GPs delivered brief weight loss advice. Participants were telephoned after 3 months, where they self-reported weight loss, and were seen by a researcher at 12 months, where they were weighed using the Tanita SC-240MA Body Composition Analyser. This was also used to measure weight at the beginning of the trial. Height was also measured, and from these measurements BMI was calculated. At both 3 and 12 months the researchers determined whether participants had tried to lose weight and how they had had done this, recording whether it was effective or not.

We will use the BWeL audio recordings to code behavioural change techniques using Michie’s behavioural change taxonomy v14 alongside the CALO-RE taxonomy3 . Initially two of the authors (EA and CA) will independently code the first 12 transcripts to develop a coder’s handbook. Discrepancies will be resolved through discussion and referral to Michie’s coding guide. Two authors (EA and KF) will then use this handbook to code 10 transcripts. Any disparities will be discussed, and the handbook will be modified. From then on one coder (EA) will continue to code the rest of the transcripts. During this time another coder (CA) will code another 10 transcripts at random comparing and discussing results with the first coder, to mitigate coder drift. Coders will be blinded to associated patient data. For each transcript BCTs will be coded as 1 (present) or 0 (absent). As the BCTs in the v1 taxonomy are grouped by domain for part of this analysis, the number of BCTs used per domain will also be recorded.

**Exposure:**

The exposures in this study are the BCTs which were used in more used at a frequency that allows statistical analysis and, for the v1 taxonomy, the domains under which the BCTs used are categorised. All BCTs in the v1 taxonomy are grouped under domains, for example the domain of natural consequences consists of giving information to the patient as well as monitoring the effect of this information, but it is broken down into more specific BCTs such as salience of information, information about emotional consequences, information about health consequences etc.

We are also examining fidelity as an exposure. GPs were given a 90-minute training video before the trial. We have identified 1 BCT that was used in the BWeL training video. We intend to analyse how well the BCTs used in the consultations reflect those that were recommended, by scoring consultations either 1 or 0 according to their use of the recommended BCT.

**Outcomes:**

Primary outcome:

The primary outcome is mean weight loss at 12 months.

Secondary outcomes:

* weight loss ≥5% of body weight at 12 months
* Patients reporting taking effective action on their weight at 12 months

**Covariates:**

The covariates for this study are age, gender, index of multiple deprivation (IMD) score, and baseline weight.

**Statistical Analysis plan:**

We will perform descriptive statistical analysis on the population including age, gender, mean baseline weight in each gender, and mean weight loss across the data set, as well as on the initial results of the coding. We will also examine what types of effective action patients reported taking on their weight. Effective action was coded as 1) visiting the GP to discuss weight in more detail, 2) attending a weight management programme, 3) increasing exercise, 4) changed eating habits and 5) the use of pharmacotherapy.

We will examine the BCTs for co-linearity. The highly co-linear BCTs will be examined further by uni-variate analysis and bi-variate analysis, combining the correlated BCTs. Where necessary, highly correlated BCTs will be grouped or omitted. Those with missing data for the 12-month follow up will have baseline weight carried forward (therefore inputting no weight change), and we will report data as missing for whether they took effective action.

We will then perform regression analyses to assess the relationship between the behavioural change techniques used and our outcomes. Our sample size of 224 cases allows detection of an effect size of 1.22kg weight change with power of 80% and alpha (or p value) of 5%. We will use Stata to perform linear regressions for outcomes with continuous variables and logistic regressions for those outcomes with binary outcomes. This will produce odds ratios with 95% confidence intervals and p values. We will also perform sensitivity analyses to test robustness by clustering by domain for the v1 taxonomy due to the number of BCTs, and by clustering by GP.

1. Overview | Weight management: lifestyle services for overweight or obese adults | Guidance | NICE.

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3. Aveyard, P. *et al.* Screening and brief intervention for obesity in primary care: a parallel, two-arm, randomised trial. *Lancet* **388**, 2492–2500 (2016).

4. Michie, S. *et al.* The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. *Ann. Behav. Med.* **46**, 81–95 (2013).

5. Michie, S. *et al.* A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychol. Health* **26**, 1479–1498 (2011).

6. Ward, S., Gray, A. & Paranjape, A. African Americans’ Perceptions of Physician Attempts to Address Obesity in the Primary Care Setting. *J. Gen. Intern. Med.* **24**, 579–584 (2009).

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8. Rössner, S. Intermittent vs continuous VLCD therapy in obesity treatment. *Int. J. Obes.* **22**, 190–192 (1998).

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