Author's response to reviews

Title: Determining how best to support overweight adults to adhere to effective lifestyle change: Protocol for the SWIFT study

Authors:

Rachael W Taylor (rachael.taylor@otago.ac.nz)
Melyssa Roy (melyssa.roy@otago.ac.nz)
Michelle R Jospe (michelle.jospe@otago.ac.nz)
Hamish R Osborne (hamish.osborne@otago.ac.nz)
Kim Meredith-Jones (kim.meredith-jones@otago.ac.nz)
Sheila M Williams (sheila.williams@otago.ac.nz)
Rachel C Brown (rachel.brown@otago.ac.nz)

Version: 3
Date: 23 July 2015

Author's response to reviews: see over
Victorino Silvestre
on behalf of Natalie Pafitis MSc
Executive Editor
BMC-series Journals
BioMed Central
Floor 6, 236 Gray’s Inn Road
London, WC1X 8HL

23rd July 2015

Re: MS: 1033096798158453. Determining how best to support overweight adults to adhere to effective lifestyle change: Protocol for the SWIFT study

Dear Mr Silvestre,

Thank you for your email of 23rd June requesting a revised version of our manuscript as detailed above. We have carefully considered the comments of each reviewer and provide a point-by-point response to the concerns below. Changes to our revised manuscript have been highlighted in red text.

Reviewer 1: Clemens Drenowatz

1. The role of physical activity (PA)/exercise) should be considered more thoroughly in the introduction as there is considerable research on the benefits of exercise/PA, particularly regarding weight loss maintenance.

We have provided additional review in our introduction on the benefits of exercise (lines 169-179 of revised manuscript).

2. It should be addressed that fat loss, rather than weight loss, provides key health benefits. While the assessment of body composition (measurement of fat mass and lean mass) may not be feasible on a regular basis for individuals in self-monitoring, a stronger emphasis on the role of body composition on health should be put in the manuscript.

We acknowledge the reviewer’s point, but are also cognisant of the length of the manuscript. However, we have added a small comment to the revised introduction addressing this issue (lines 107-109 of revised manuscript).
3. There is not really a selection on the exercise intervention as participants can only opt in to the HIIT. HIIT is also in accordance with current exercise guidelines (i.e. 75 min of vigorous PA).

We understand the reviewers comment that HIIT could be considered part of current exercise recommendations since vigorous activity is one option to meet these guidelines. However in New Zealand, the types of activities promoted as part of these recommendations do NOT include HIIT type regimes which concentrate on very high intensity brief spurts of vigorous exercise. We have modified our methods section to make this clearer (lines 297-332 of revised manuscript).

4. How will participants be encouraged to achieve 30 minutes of MVPA? Will they be provided with several choices based on their current lifestyle and activity levels. As mentioned previously HIIT can be one choice for meeting current guidelines.

Please see response to point 3.

5. Please provide a reference for the meta-analysis regarding the evidence for little difference in outcomes from different treatments. The authors may want to specify which outcome they are referring to. It should also be considered that at this time there is only limited information on the effect of HIIT.

References for five meta-analyses regarding the evidence for little difference in outcomes were included in the original manuscript (Wycherley 2012, Ajala 2013, Johnston 2014, Dutton 2014, Atallah 2014, line 53). We have now added “weight and health” to the text (line 52 of revised manuscript).

6. The discussion should address PA as well as a recent study has shown that MVPA is more consistently associated with body weight than is diet quality (Pate et al. MSSE, 2015).

We have modified the text as requested (lines 506-509).

Minor Essential Revisions:

1. Abstract: evidence that higher levels of physical activity are associated with better weight maintenance is strong as well in addition to adherence to dietary interventions.

We have modified the text as requested (lines 2-3 of revised manuscript).

2. Please specify whether there is a specific age range that will be targeted as age may be an important aspect in the reception and adherence to different protocols.

We did not specify a maximum age range as we wanted to keep recruitment open. However, our baseline analyses demonstrated that there is no significant difference in age between any of the diet (P = 0.752) or exercise (P = 0.595) groups with a mean (SD) age of 43.7 (11.0) years in our 250 participants (20-74 range).
3. Please specify how long the intervention will last (6-12 months?) with an additional follow-up period to examine sustainability.

As outlined in our original manuscript, our study is a 12 month intervention with a further 12 months of follow-up (lines 219-220 of revised manuscript).

4. It would be helpful to clarify that the intervention lasts 12 months with a 24-months follow-up period in order to evaluate sustainability of lifestyle changes.

The text has been modified as requested (lines 220-221 of revised manuscript).

5. Please specify whether randomization will be stratified based on the selection of diet and exercise programs – this may affect adherence as well as selected outcomes rather than the type of strategy to promote the changes.

Randomisation is stratified only by sex (see line 341 of revised manuscript) and not on the basis of diet and exercise programmes. As we outlined in our background, dietary composition seems to have relatively little effect on body weight long-term, and we currently have no information on HIIT versus conventional exercise long-term. However, our two-year study will provide much needed information on adherence to each of these strategies.

6. What about participants who have engaged in dietary or exercise intervention previously – can they opt for a similar intervention as one performed previously?

Participants can have tried these dietary and exercise approaches before and information on this is collected at baseline.

7. Please specify that participants will have to choose a dietary and exercise program prior to starting the program.

As outlined in our manuscript (line 339) participants are only randomised to intervention groups “once they have chosen their diet and exercise approach”.

8. Please specify the clothing requirements for weight measurements on the outcome measure (i.e. surgical scrubs). Also provide a timeline of the measurements and how many visits at each time point will be required to complete all measurements.

The clothing requirements have now been specified (line 405 of revised manuscript). Table 1 shows the timeline of the measurements but a footnote has been added to illustrate that two visits are required at each time point in order to complete all measurements.

Discretionary Revisions:

1. Please specify how the study will be advertised – flyers, radio, internet, TV, ...

The text has been modified as requested (line 230 of revised manuscript).

2. Access to the internet should be an inclusion criteria as this is one option for the intervention.

The text has been modified as requested (line 234 of revised manuscript).

3. What is the rationale for a BMI cutpoint of 27 rather than 25? Is there an upper BMI
We decided to use a BMI cutpoint of 27 rather than 25 to make it more likely that participants had high levels of body fat (as well as being overweight). Gallagher et al published healthy body fat percentages several years ago (Am J Clin Nutr 2000;72:694) for which the maximums range from 21% in young men to 43% in older women. In our sample of 250 adults at baseline, only 3 men and 5 women (3.2% of the total) had body fat percentages (measured by dual-energy x-ray absorptiometry) below these values which supports our decision to use a BMI of 27 rather than 25.

We agree that the most severely obese may struggle with HIIT but this is one of the questions we hope to answer over our two-year study. For this (and other) reasons we chose not to have an upper limit for BMI. Interestingly, there was no significant difference in mean BMI by exercise group (33 kg/m²) at baseline, with a similar range observed in both groups (27-48 kg/m²) indicating that initial body size did not stop them wanting to try this type of exercise.

4. Are there any restrictions regarding baseline activity levels for study participation (i.e. sedentary participants only)?

There were no restrictions on physical activity at baseline for entry to the study. We have purposely collected objective measures of both physical activity (7-day accelerometer) and fitness (submaximal YMCA fitness test) so that we can determine if baseline activity or fitness influences our findings.

5. Please specify that diet records and PA assessment are performed during the same week.

The manuscript has been modified as requested (line 250 of revised manuscript).

Reviewer 2: Brenda Davy

1. The stated primary aim is "to determine the effectiveness of different support strategies on weight loss at 12 and 24 months". The two stated aims suggest that two RCT are needed, however. One RCT would randomly assign individuals to one of the six possible combinations of diet/exercise strategies, or to a "choice" condition which would allow individuals to choose their diet/exercise strategies. This RCT would address the role of choice in promoting lifestyle change, if support strategies were consistent across all study groups. The second RCT would randomly assign individuals to one of five lifestyle change support conditions, while keeping the diet and exercise plan consistent across conditions (stated as the primary aim).

We acknowledge the reviewer’s point that an alternative RCT could be to compare randomisation with choice of diet/exercise and indeed some studies have started to examine this. However, choice is not the primary aim of our RCT – we want to evaluate different support strategies in the real world i.e. when people are following a variety of different exercise and diet approaches. This is actually not that different to studies which do randomise participants to certain diets because we know “randomised” participants do not have a “consistent” diet (as inferred above) because adherence is so variable. Our primary aim (as stated on lines 203-205) is to “determine the effectiveness of different support strategies (control condition, brief support, daily self-weighing, app use, hunger training) on weight loss
at 12 and 24 months” and does not mention keeping diet and exercise consistent. As in other RCTs, an intention to treat analysis will estimate the effectiveness of the different support strategies.

2. With the current design, the results could leave uncertainty about which lifestyle support approach is most effective, given that the choice of diet and exercise plan could vary across participants and across conditions. In addition, some of the diet and exercise plans have not clearly demonstrated efficacy for weight loss. This design problem could possibly be addressed with a moderation or mediation analysis, if statistical power were sufficient, or with a randomization procedure that assigned the selected diet and exercise approaches evenly across the support approach groups.

As highlighted in point 1, we are interested in real world conditions where people do choose their own diet, so did not want to randomise or stratify by diet/exercise. Our baseline results indicate that each diet and exercise group are split reasonably well across each support group, such that moderation/mediation analyses will indeed be possible. We agree that some of the diet and exercise approaches require further work to examine their efficacy – but this was a stated aim of our project.

Major compulsory revisions:

1. The title states “..adhere to effective lifestyle change..”, yet the diet and exercise approaches targeted have not all clearly demonstrated efficacy, in prior studies.

We acknowledge the reviewer’s point that it could be argued that some of these approaches (assuming they mean HIIT, paleo and intermittent fasting) have not clearly demonstrated efficacy. Yet intriguing research exists to support their potential effectiveness (as outlined in our background), at least in the short term, which warrants further study. As outlined, our secondary aim 3 is to determine whether these approaches have any sustainability long-term so that we can add to this growing literature base.

2. Abstract: whether or not the diet and exercise approaches proposed to be used in this trial are "suitable" is subjective.

We have removed the word “suitable” from our abstract (line 26 of revised manuscript).

3. Pages 7-8: the authors state that it seems "obvious that giving participants choice over which particular dietary pattern they follow should generally improve adherence and thus enhance weight loss", yet the discussion which follows this statement cites several studies that do not support this point. This section should be revised to more clearly and objectively present what is, and is not, known about the role of choice in promoting weight loss.

We have altered the manuscript to reflect that behavioural choice theory would suggest that choice would result in better outcomes, but that the limited existing research does not support this theory. As outlined, very few studies however have directly examined this question (lines 133-137 of revised manuscript).

4. Reference 46 (page 7) does not appear to support the statement about choice.

This reference was indeed incorrect and has now been corrected (Sacks et al 2009, now reference 48, lines 135-137 of revised manuscript).
5. **Page 10: is there adequate statistical power to address the third secondary aim?**

Now that we have finished recruiting, we know that the minimum number of participants in any of the diet and exercise groups is $n = 46$. On the basis of mean (SD) values for body weight and percentage fat of 93 kg (16 kg) and 42% (4.6%) respectively (NEJM 2009;360:859 and J Nutr Metab 2014;13), and a correlation between repeat measures of at least 0.85, a sample of this size allows us to detect a difference of at least 4kg in weight, and 2% in percentage body fat (80% power, $P < 0.05$, 20% drop-out). We recognise that at this point, our study is an observational study rather than an RCT. Differences between diet or exercise groups will have to be examined in the context of a regression model which adjusts for support strategies and other possible confounders or a structural equation model which will consider possible moderators or mediators.

**Reviewer 3: Stephen Boutcher**

**Major Points:**

1. **Although this study will involve an enormous time commitment by the authors, that they have successfully carried out a large trial in the past (Dale et al., 2009), suggests that it is feasible. The focus on a range of adherence strategies concerning eating behaviours appears thematic. The inclusion of an exercise arm, however, does not seem thematic and is the major weakness of the proposed trial.**

We have indeed undertaken a multitude of long-term trials in a variety of population groups including children (Am J Clin Nutr 2008;88:1371 and Pediatrics 2015 doi: 10.1542/peds.2008-1536), and adults (Canad Med J 2009;180:E39, J Nutr 2013;143:1254). We are unsure what the reviewer means by exercise not seeming “thematic” given exercise is one of the cornerstones of weight management. Current research on HIIT is promising yet we know almost nothing about the ability of overweight individuals to attempt HIIT by themselves without supervision, particularly over the long-term. Our novel project provides an excellent opportunity to assess this.

2. **With regard to diet and behavioural change strategies there may be two important omissions. For example, there is evidence that long term low carbohydrate ketogenic diets are more effective than other diets (Bueno et al., Brit J Med, 110, 1178-87). Also there is good evidence to indicate that regular motivational interviewing successfully increases both adherence and the effectiveness of interventions. As there will be monthly meeting with participants it appears that some form of motivational interviewing will take place in SWIFT. However, it does not seem to be structured, quantified, or assessed in any way.**

We acknowledge the reviewers point that very low carbohydrate diets may have been an alternative option on the basis of the meta-analysis listed above. However, we are particularly interested in long-term adherence and this meta-analysis clearly showed that adherence to the very low carbohydrate diet was not apparent at study end in virtually all of the included studies (see Table 1 of the meta-analysis). Furthermore, the difference in weight, while statistically significant, was unlikely to be clinically significant at only 0.9kg (Bueno et al, Brit J Nutr 2013;110:1178). We agree that motivational interviewing is interesting and have expertise in this area (Dawson et al, J Pediatr Child Health 2014;50:461). However, our SWIFT intervention does not include motivational interviewing and should not be interpreted
in this way. We acknowledge that our brief support group could be construed as addressing motivation to some degree, but only in that good listening skills and an interest in participant progress are also part of good MI practice.

3. It is not clear how participant’s choice of intervention will affect randomisation. For example, it is possible that the majority of participants may choose one of the diets or the easier form of exercise.

Please see responses to point 5 of minor essential revisions for Reviewer 1, point 2 for Reviewer 2, and point 5 of major compulsory revisions for Reviewer 2.

4. The large age range may be problematic as motivational factors of older individuals are likely to be different to those of the young.

Please see the response to point 2, minor essential revisions, Reviewer 1.

5. The weakest component of the proposed trial, in my view, is the inclusion of exercise. There is insufficient information regarding the HIIT component. For example, how many times will they exercise?; at what intensity will they exercise?; and on what modality? Will they all perform HIIT on a stationary bike? If so how will they have access to the bike? How will you know if they carry out the exercise training? The proposed HIIT is for a flat out 30-second sprint followed by a rest period. But what is the resistance that participants will pedal against. For example, the 30-second Wingate test involves a very high resistance and high pedal rate that typically exhausts individuals.

Additional information has now been provided in the revised manuscript (lines 304-332). Adherence measures are outlined on lines 453-468.

The choice of the HIIT is problematic as there are no reported trials lasting more than 6 weeks (typically 2 weeks) using the 30-second protocol and the clinical markers proposed in SWIFT have not been significantly changed by this form of interval sprinting (e.g., body fat). This form of exercise is so challenging that it is inappropriate for sedentary overweight individuals. The other exercise option (walking, gardening) is very unlikely to result in a change in the markers proposed in SWIFT. Thus, my suggestion would be cut the exercise options.

As outlined in point 5, we have provided additional information which illustrates that our HIIT protocol is not restricted to the Wingate protocol which we agree is problematic for this population. Participants actually receive information on a variety of submaximal and maximal HIIT protocols, starting at a beginner level and progressing to harder options. Participants have the opportunity to trial different ones, receive feedback and determine which HIIT protocol is actually most suitable for them. We believe this individual approach is a critical strength of our study, which aims to assess whether adherence is possible in the real world. As the reviewer highlights, existing research in this area is typically very short-term.

If authors are keen to include exercise then they should recruit an exercise physiologist as part of the research team who is knowledgeable in the interval sprinting and metabolic health area. For example, there are a number of randomised controlled trials examining similar clinical markers to SWIFT that have been published (see below). Also a review in this area has been published as well as a self-help book which provides details and information of how to perform interval sprinting
exercise for fat loss and metabolic health (see below).

We thank the reviewer for references to his own and other’s work in this area. While we acknowledge the view that an exercise physiologist could provide additional expertise, our team members already include a fellow of the Australasian College of Sports Physicians who is a vocationally registered sport and exercise medicine specialist (Osborne), and another medic (Roy) with general practice training, and an industry qualification and experience in exercise prescription. As SWIFT is intended to be suitable for a primary health physician to offer as an alternative to standard exercise recommendations, it is appropriate that doctors with this level of training should be able to assess cardiovascular risk and recommend HIIT programmes without further exercise physiology or prescription specialisation. However, experienced colleagues (Associate Professor Jim Cotter, exercise physiology and Professor Gerry Wilkins, cardiology) have also provided a considerable level of expert advice.

We hope that the revised manuscript may be deemed suitable for publication in *BMC Public Health* and we look forward to hearing from you in due course.

Yours sincerely

Associate Professor Rachael Taylor
*Karitane Senior Research Fellow in Early Childhood Obesity*