

5/2 Diet - PRimary care Intermittent versus Continuous Energy restriction (PRINCE) trial



You may have seen the BBC Horizon programme which aired on BBC2 in January this year which looked at intermittent fasting, often called 5/2 dieting, which led huge interest in this approach to weight loss especially since it promised additional health benefits. However it has divided informed opinion for example, NHS Choices suggests people should speak to a doctor before engaging in this form of weight loss with cautionary words about the high fat content of the two days of dieting. This confusion was confirmed by our survey of 167 people with weight problems and most considered this an important topic for study – they had heard reports of success but were wary of the celebrity stories and possible risks. They supported research involving primary care clinicians.

The research proposal:

Losing weight reduces blood pressure, reduces the risk of diabetes or improves or resolves it, and reduces the pain of arthritis so many patients in primary care would benefit from losing weight. It makes sense to prevent the onset of these conditions by weight loss too. Patients would like to discuss their weight and its effect on their health with their clinicians but clinicians are reluctant because there is little they can do to help. Our reviews of published tests of interventions (called trials) for NICE show that referral to commercial weight loss programmes are effective but support from primary care nurses offering apparently similar programmes are not. All commercial programmes have well-worked dietary regimens that advise reducing energy intake each day, but constructing these is complex and perhaps difficult for nurses to convey as they have little or no nutritional training. Intermittent energy restriction here means severely restricting food for two days a week and eating sensibly for five days, so-called 5/2 dieting. The simplicity of this may improve the ability of nurses to convey this and the ability of patients to follow it when

provided without the tools provided in commercial programmes. This would give clinicians another approach to recommend and widen access for patients who might not want to go to a commercial programme, many of which appear very feminine.

The aim of this proposal is to test the effectiveness of intermittent dieting with nurse support compared with continuous energy restriction with nurse support. We will also test whether intermittent dieting leads to a more unhealthy diet than continuous energy restriction. We will capture patients' experiences on video and place these online on a popular website to help people understand what it is like to lose weight using either of these approaches. Initially, we will adapt our existing materials for use by non-specialist primary care clinicians. These will aim to motivate and support patients to follow the two dietary regimens and improve physical activity. We will create written material and online video material and a programme manual for nurses to help them to support their patients. We will then test both programmes to check that they run appropriately, that patients respond favourably, people adhere to the intermittent programme, and that nurses do not inadvertently give advice on intermittent dieting to people who should be using continuous energy restriction. If we meet these criteria, we will test the two weight loss programmes in a randomised trial. In the trial, we will assess the effect on weight at three and 12 months and effect on diet quality at 12 months. We will assess how well patients and nurses adhere to the programme with a view to improving the programme before roll-out in the NHS. We will interview patients about their experience of both methods of losing weight, edit the films with their involvement and consent, and put these online for others who may want to lose weight in these ways.

How did our Weight Management Panel get involved?

In March this year we sent out an email to everyone on our Weight Management Panel asking for people to join us for a meeting to discuss our research proposal as we want to put in a funding request for this trial by October this year.

To make sure our research proposal is asking the right and relevant questions we put some questions to our panel members at the March meeting. We asked the following questions;

- In research, to prove that what you are testing is working, it needs to be compared to something else. The study needs a 'control group'. We asked the group what they thought might be a good 'control' to compare the 5:2 diet against.
- Should the main trial look at other health areas as well as metabolic effects e.g. diabetes, heart disease etc.?
- What issues or concerns should the study focus on and/or be aware of?
- Is it valuable to collect participants' experiences during the trial so this information can be looked at and evaluated after the study?
- Trials are funded by the tax payer. Should the cost of intervention relative to the health benefits be considered and is this important?

So where are we now?

We took our Panel members views into consideration and submitted a first stage application. We were shortlisted and are now in the process of putting together our full detailed application to submit to the funding body, National Institute for Health Research (NIHR) in October.