ABSTRACT

Background

Overweight and obesity are major public health problems and an increasing global challenge. In lieu of wider policy changes to tackle the obesogenic environment we presently reside in, improving the design of individual-level weight loss interventions is important.

Aim

To identify which aspects of the CAMWEL randomised controlled trial (RCT) weight loss intervention participants engaged with, with the aim of improving the design of future studies and maximising retention.

Methods

A qualitative study comprised of semi-structured interviews (n=18) and a focus group (n=5) with intervention participants.

Results

Two important aspects of participant engagement with the intervention consistently emerged from interviews and focus group; the advisor-participant relationship, and the programme structure. Some materials used during the programme sessions were important in supporting the intervention, however others were not well received by participants.

Conclusion

An individual-level weight loss intervention should be acceptable from the patient perspective in order to ensure participants are engaged with the programme for as long as possible to maximise favourable results. Providing ongoing support in a long-term

22 programme with a trained empathetic advisor may be effective at engaging with people trying
23 to lose weight in a weight loss intervention.

24

1. INTRODUCTION

Overweight and obesity are major public health problems (Whitlock et al., 2009) and an increasing global challenge. A raised Body Mass Index (BMI) ≥25 kg/m^2) can have severe impacts on health, increasing the risk of type 2 diabetes, hypertension, some cancers, heart and liver disease (Haslam D, 2005; Whitlock, Lewington, & Mhurchu, 2002; Whitlock et al., 2009). In England, overweight including obese adults increased from 57.6% to 67.1% in men and from 48.6% to 57.2% in women between 1993 and 2013 (Health and Social Care Information Centre, 2014). It is estimated that obesity-related ill health annually cost the National Health Service over £5 billion (Scarborough et al., 2011).

Public health experts advocate for strong policy initiatives to tackle social and environmental factors perceived to inhibit active living and encourage overconsumption of calories (Finkelstein, Ruhm, & Kosa, 2005; Greener, Douglas, & van Teijlingen, 2010; Swinburn et al., 2011), as well as cautioning that changes in public policy would take considerable time to implement in the current political landscape (Greener et al., 2010; Lang & Rayner, 2007; Teixeira, Silva, Mata, Palmeira, & Markland, 2012). With governments largely abdicating the responsibility for addressing obesity to individuals (Swinburn et al., 2011), the rationale for continuing to study and improve individual-level weight loss interventions continues.

Overweight people often perceive obesity as arising from their personal motivational and physical shortcomings and view it as a 'pathological' state that can be cured with externally supplied interventions (Greener et al., 2010). Yet most obese individuals in clinical weight loss trials have a history of unsuccessful weight loss attempts (Hammarstrom, Wiklund, Lindahl, Larsson, & Ahlgren, 2014) and rely on 'quick fix' strategies in their ongoing and often life-long efforts to lose weight (Thomas, Hyde, Karunaratne, Kausman, & Komesaroff, 2008). Behavioural weight loss interventions undertaken in primary care with a 12 month

follow up provided no strong evidence of differences in weight loss between the intervention and control groups (Booth, Prevost, Wright, & Gulliford, 2014; Nanchahal et al., 2012), and attrition rates of programmes are often high (Dansinger, Gleason, Griffith, Selker, & Schaefer, 2005). It is challenging to discern what makes an 'effective' intervention; however it has been shown that participants who remain in programmes for a longer period of time or attend a greater number sessions have more favourable outcomes than those who are not retained (Ahern, Olson, Aston, & Jebb, 2011; Hollis et al., 2008; Ross, Laws, Reckless, Lean, & Counterweight Project, 2008). A qualitative approach to weight loss research can investigate which aspects of interventions may or may not be effective in engaging with and be acceptable to participants. The CAMWEL randomised controlled trial (RCT) is a 12 month one-to-one lifestyle intervention delivered to overweight/obese patients in UK primary care (Nanchahal et al., 2012). Its aim was to develop and evaluate the efficacy of an intervention programme for an ethnically diverse overweight/obese population recruited from general practices in a pragmatic RCT. To our knowledge, there are currently no other published RCTs of one-to-one lifestyle interventions delivered in UK general practice to overweight/ obese patients without comorbidities. Here, we report findings from a qualitative study conducted in conjunction with the main study to identify which aspects of the intervention were 'effective' from the participant perspective with the aim of informing the design of future weight loss interventions and maximising retention.

2. METHODS

2.1.Study setting

This study was conducted in general practice in the London Borough of Camden in association with the CAMWEL RCT, which recruited 381 adults from 28 practices with BMI ≥ 25 kg/m^2 and randomly assigned them to the intervention (n=191) or control (n=190) group. The study was approved by the London School of Hygiene & Tropical Medicine Ethics Committee, the Camden and Islington Community Research Ethics Committee (reference number 09/H0722/22) and the North Central London Research Consortium.

2.2. The intervention

The intervention took a long-term approach to behaviour change for weight loss, and was based on tailored one-to-one advice sessions with a trained advisor. The participants were invited to attend 14 sessions over a 12 month period. The programme was delivered in three primary care centres and compared to a control group receiving usual care in general practice. The CAMWEL programme (Nanchahal et al., 2012) combined evidence-based components recognized as essential for behaviour change and successful weight loss (Jones & Wadden, 2006) - healthier eating advice, how to increase physical activity in everyday lifestyles, tailored goal setting, keeping food and activity diaries, self-monitoring, positive reinforcement, coping with lapses and high-risk situations, and long-term support. The CAMWEL programme utilised theoretical frameworks such as social cognitive theory, outcome expectations, self-efficacy, self-regulation, diet and physical activity monitoring which underpin health promotion interventions that have an emphasis on long-term changes in habits. As participants progressed through the programme, the frequency of meetings with their advisor decreased. The CAMWEL weight loss advisors were trained in the principles

and techniques behind behaviour change including social cognitive theory, goal setting, motivational interviewing, counselling approaches, and systems thinking in their initial two-day training course, and used these techniques in each session of the programme. The full trial methodology and results are reported elsewhere (Nanchahal et al., 2012).

2.3.Qualitative study design and sample

The qualitative data collection comprised of semi-structured face-to-face interviews with CAMWEL intervention participants, and a focus group with additional intervention participants who had successfully achieved their 5% weight loss goal after their halfway 6 month follow up appointment. For the interviews, eighteen participants from the intervention arm of the CAMWEL RCT (9.4% of all intervention participants) were recruited, and were interviewed by AS up to three times over the course of the 12 month intervention period. We used a purposive sampling strategy to include a mixture of participants by age, gender, ethnicity and BMI. A total of 37 interviews were conducted with the aim of discussing their experiences of taking part in the trial (Box 1). Interview participants' characteristics were comparable to all intervention participants except a higher proportion of interviewees were employed (Table 1). The interviews lasted approximately 30 minutes, and were audio taped with participants' permission. For the focus group, all eligible participants (n=35) were invited to take part by letter, and a convenience sample of five were recruited. The group discussion was convened by the research team, and ran for 90 minutes. Participants were given £15 of shopping vouchers as compensation for their time.

2.4. Data analysis

All interviews and the focus group discussion were recorded and transcribed verbatim. A thematic analysis (Braun & Clarke, 2014) was undertaken by EH and NT. Transcripts were initially reviewed independently for emergent themes and concepts and then coded against

these themes using qualitative data analysis software (NVivo). These initial findings were discussed by all authors over several meetings to agree the main themes, and all authors participated in the interpretation of the results.

RESULTS

Two important aspects of participant engagement with the intervention consistently emerged from the interviews; the advisor-participant relationship, and the programme structure. Secondarily, some features of the tangible materials used during the programme sessions were important in supporting the intervention, however others were not well received by participants. There was no evidence of systematic differences in findings between participants in terms of demographic characteristics (e.g. age group, gender, employment status, BMI).

2.5.The advisor-participant relationship

For many participants, the relationship they formed with their advisor was the most important aspect of the programme. Regular meetings with a trained advisor in a confidential healthcare environment was seen to correspond to the therapeutic relationship of a counselling setting. Our data suggest, regardless of the weight loss outcome, it was this regular, consistent, individually tailored, one-to-one relationship with an advisor that participants valued (n=17/18 endorsed this theme).

"I said before, it's knowing that you're going to come and see someone every two or so weeks to talk about is and, you know, tell them your shortfall and where you might think you've gone wrong you can probably do better and also change this and that. That's the most important thing." Man, 43, interview 1/1.

The meetings provided participants with more than monitoring progress in weight loss terms, and advisors were sources of empathy and unconditional positive regard:

"I get solace here... [Advisor] lets me off-load my guilt and, you know, to me it's much more about you're going to have to do it yourself so it's more there as a support, you know, I see him once every now two, now three weeks, you know, there's no way I can rely on him to do it for me." Man, 42, interview 2/2

For some participants, it was the first time that anyone had invested attention and interest in their lives and became "lifestyle management", rather than just an attempt at weight loss:

"No-one's ever spent, had that interest in my life...it became a bit of lifestyle management which, you know, you just don't ever get." Man, 43, focus group participant.

Participants sought understanding and compassion from their advisor about aspects of their day-to-day lives aside from their weight loss effort, and some explained how their wider life experiences interacted with their weight loss progress and ability to attend meetings:

[Of her husband] "I'm his carer, really. Like if anything goes wrong with him, I'm the first one that's got to be there if anything happens, I can't even leave him" Woman, 62, interview 2/2.

"The few times I had to cancel I was working hard to get ready for the craft fair...and my ceiling collapsed" Woman, 37, interview 2/2.

Having sessions with the same person was important, in order to build a relationship and strong working alliance. As a result of the relationship, an accountability to the advisor was possible that would not have been with inconsistent personnel.

"I think the point was that it's the same person there…had it been a machine on its own I would have been motivated to a point but not that much of a point, whereas if it's a different person every time…that wouldn't have been as effective, but if it's the same person…" Man, 43, focus group participant.

"My counsellor did leave, and I'd have preferred my counsellor to stay obviously…I wouldn't say it's quite the same…It's 'cos you'd like to see it through together almost." Woman, 51, focus group participant.

2.6.Programme structure

The structure of regular meetings with the advisor provided routine for participants, and acted as a framework for their weight loss effort. The frequency and regularity of sessions during the early phase of the intervention were regarded as an important mechanism in maintaining the lifestyle changes participants were making, and to keep them "on track" to achieve their weight loss goal. With the next session due in two to three weeks, participants felt they were being "monitored" and that they would not have had time to "slip up" and reverse any good habits that had been formed before their next session (n=14/18).

"There was no escape; I knew it was coming up so I got back on track. So that does help.having someone..where your own willpower falters occasionally, you have this power overlooking you." Man, 42, interview 2/2.

"I'm a bit slow about losing weight, but it's the fact that someone's going to weigh me, that is a constant reminder." Woman, 53, interview 2/3.

However, participants were critical of the change in regularity in the later phase of the intervention when meetings with the advisor became less frequent.

"You have to look at any slimming club. They have regular meetings once a week because they actually know that those people, people like us, need regular control." Woman, 37, interview 2/2.

Participants who had not yet switched to less frequent meetings but who were anticipating them in future were anxious about the change, as they had become accustomed to regular monitoring.

"Fortnight's good. I'm worried about later on. The gaps in between." Woman, 56, interview 1/2.

"But then it goes I think to three weeks. I'm a bit more concerned that three weeks may not be a good idea…I get too relaxed" Woman, 53, interview 2/3.

2.7.Perceptions of trial materials

The sessions were supported with tangible materials (e.g. leaflets, a pedometer, and portion pots) which were distributed to participants via their advisors. The purpose of the materials was to provide the participant with a motivator between sessions, and the leaflets were a record of what had been discussed during the sessions. Some materials were liked more than others, such as the pedometer (n=12/18):

"The scheme has thrown up some useful tools, like the pedometer, I've got something to measure against." Man, 63, interview 1/2.

Participants were impressed with the quality of the item:

"It's much nicer than the pedometers I've had before." Woman, 31, interview 1/3.

The pedometer helped participants to monitor their activity in between sessions with the advisor, and the pedometer acted as a reminder that they were taking part in the intervention:

"By wearing this, I sort of keep an eye on how I'm doing on a daily basis." Man, 60, interview 1/3.

"I wear the pedometer religiously every day, more as a reminder to me that I'm doing this." Man, 42, interview 1/2.

Participants were asked to record their daily steps and daily food intake in a diary. This allowed them to self-monitor their activity and food intake, and was intended as a goal setting and feedback (Locke & Latham, 2002) component of the intervention programme, however both diaries were regarded as somewhat of a chore (n=6/18):

"I've filled in the forms for a period until the habit has been formed but..it's a bit off putting the amount of recording you've got to do" Man, 60, interview 1/3.

At each session, new topics were introduced with the help of generic leaflets and handouts. The leaflets were generally negatively regarded (n=13/18), as it was often felt that they had heard everything before during previous weight loss attempts, that they offered no new information, and were considered patronising by participants:

"Those leaflets, I don't know, it's like we're stupid... a lot of people know everything about weight loss yet we can't maintain it." Woman, 37, interview 2/2.

"I mean, I think my wife has put them in front of me probably ten years ago, so I know most of the stuff." Man, 42, interview 1/2.

"I suppose they are targeted at the lowest common denominator" Man, 42, interview 2/2.

Further materials included portion pots, and a '100 calorie kit', which was devised by CAMWEL researchers as a visual aide to show participants what a 100 calorie portion of a variety of foods looked like. These materials provided visual representations and an objective perspective on portion sizes which participants found particularly helpful (n=5/18):

"When I saw that, I was quite shocked because I was probably putting twice as many oats." Woman, 37, focus group participant.

"What was useful is... that knowing, the realisation of the quantities which you never really quite accept until you see it and that is very eye opening." Woman, 67, focus group participant.

4. DISCUSSION AND CONCLUSION

4.1. Discussion

With over 60% of adults overweight or obese in the UK, the importance of continuing to study and improve individual-level weight loss interventions is high. The CAMWEL intervention programme is unique because, to our knowledge, there have been no other published RCTs of one-to-one weight loss interventions in UK primary care which were delivered in general practice to patients without specific co-morbidities. The programme was available to an overweight or obese ethnically diverse general population, and therefore the findings presented in this paper are applicable to a general population.

The aspects of the programme we found to be particularly effective at encouraging participant engagement was an ongoing relationship with a trained and empathetic advisor; a regularly structured programme with short periods of time between meetings; a health

technology device such as a pedometer for participants to use between meetings; and a tailored individual programme rather than generic information.

The one-to-one meeting with the trained advisor mirrored a counselling setting, and the advisors were able to provide some of the core components of a classic therapeutic relationship; in particular, empathy and unconditional positive regard (Rogers, 1951), underpinned by a strong working alliance (Gelso & Carter, 1985). If overeating is understood as a way of meeting complex emotional needs and the problem of obesity is not simply one of changing the balance of 'calories in to calories out' but one of affect management and regulation (Buchholz & Schoeller, 2004; Timmerman & Acton, 2001), then a supportive, non-judgemental relationship with an empathic advisor may be a valuable component of interventions to support weight loss. Participants reported managing their weight loss journey in the wider context of their lives, which may include traumatic or emotional events and circumstances. The advisor, by providing regular 'emotional feeds' in a holding environment in which a client is 'safe' to explore the emotional issues that are connected to their eating habits and patterns, enabled them to do this (Kahn, 1997; Rogers, 1951; Stern, 1985).

Our data shows that, in line with other studies, the regular, consistent structure of the intervention programme was valued by participants (Chugh, Friedman, Clemow, & Ferrante, 2013; Cox et al., 2011; Greener et al., 2010; Reyes et al., 2012). A recent review of primary care behavioural treatment programmes found that whilst a variety of weight loss programmes are used, ranging from offering specific diet advice in isolation or taking a more holistic approach with patients, a common feature among the programmes was the structure and frequency of the monitoring by a person in a weight loss 'counsellor' role (Wadden, Butryn, Hong, & Tsai, 2014). This preference for regular, and frequent, sessions also mirrors the therapeutic setting where fixed regular sessions are understood to provide containment

(Miller-pietroni, 1999) and to be a key aspect of fostering a strong working alliance (Gelso & Carter, 1985). Some of our participants expressed anxiety about reduced meeting frequency over the 12 month programme, highlighting the importance of ongoing support. This accords with Reyes (2012), who notes that diminishing support over time is an unfortunate but predictable aspect of many weight loss programmes, and calls for weight maintenance to be treated as a separate issue from weight loss.

In our study, participant perceptions of the programme materials were mixed. Materials that provided objective visual representations for participants such as the portion pots and 100 Calorie Kit were better received than leaflets providing generic information. The pedometer was very well received, and participants' continuing use of the pedometer may be because the device was a reminder of their participation in a weight loss intervention in between their regular meetings with the advisor. It may also have been a symbol of their health endeavour, to themselves and to others. Current literature on health technology highlights how the boundaries between health, aesthetics, and consumption of products are becoming blurred, and the use of these products is increasingly about the presentation of an ideal self, not just the prevention of disease (Carter, Green, & Thorogood, 2013). Participants were dissatisfied with the 'generic' nature of the leaflets. The intervention programme used behaviour change techniques derived from motivational interviewing, which emphasises a client-centred approach to counselling, and it may be that the leaflets did not accord with this approach and did not reflect how the relationship with the advisor made participants feel - valued. This finding is concurrent with other studies, where participants expressed a desire for personalised weight management plans and generalised nonspecific weight loss advice was equated with a lack of concern, attention, and support (Chugh et al., 2013), were viewed as condescending (Teychenne, Ball, & Salmon, 2012), and led to participants feeling stigmatised and blamed by the simplicity of the messages (Lewis et al., 2010).

To our knowledge, no other qualitative studies have been carried out examining patient engagement with a weight loss intervention in UK primary care. Providing ongoing support in a tailored long-term programme with a trained empathetic advisor which mirrors a counselling setting and also uses a health technology device, may be effective at engaging with people trying to lose weight. In terms of implications for the clinical care of obesity, our findings lend support for obesity to be reframed as a chronic health condition (Rippe, 1998) which requires long-term, possibly lifelong, treatment. Access to a trained advisor or counsellor over the long term as part of an established weight management team available to patients wishing to lose weight through general practice should be explored as a model of care in future research.

4.2. Limitations of the study

Not all trial participants took part in interviews, therefore may not be representative of all participants. Those who did take part may not have completed all three interviews.

4.3. Conclusion

In lieu of wider policy changes to tackle the obesogenic environment we presently reside in, improving the design of individual-level weight loss interventions is important. An individual-level weight loss intervention needs to be acceptable from the patient perspective in order to ensure participants are engaged with the programme for as long as possible to maximise favourable results. Reframing the problem of obesity as a chronic condition which needs long term and possibly lifelong management is necessary.

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421 Box 1: Topic guide for semi-structured interviews

Theme	**Questions/prompts**
Participation in the study (Only for first interview)	▪ How did you first hear of the weight management study? ▪ When did you first hear of the CAMWEL study? ▪ What were your first thoughts when you learned about it? ▪ How did you feel about your weight before this? ▪ What was your main reason for deciding to take part? ▪ Had you thought of taking action with regard to your weight prior to this? ▪ What are your hopes for taking part in the study?
The intervention	▪ Who is your health advisor? ▪ When was your last session? ▪ What happened in this appointment? ▪ How do you find the timing of the meeting? Length and frequency? ▪ Have you had to miss any appointments? ▪ How do you find the timing of the meeting? Length and frequency? ▪ How do you feel about the health advisor? Are they helpful? Is there anything they could do differently? ▪ What do you think of the leaflets/handouts you are given in the study?
Acceptability	▪ What do you think/how do you feel about the weight management programme? ▪ What aspects do you like best? ▪ What aspects do you like least? ▪ Are you satisfied with what has happened with your weight since starting the programme? ▪ Has the programme met your expectations? ▪ Are there things you would change about how it is delivered or experienced? If so, what?
Generalisability	▪ Would you recommend the programme to a friend? Why or why not?

Impact	▪ Has your lifestyle changed since starting the programme? If so how, ▪ How do you feel about your weight at the moment? ▪ Has this changed since you started the programme? If so, in what ways? ▪ Has your weight?
Follow-up questions	▪ Have you changed the amount of weight that you'd like to lose? Why?

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424 Table 1: Baseline characteristics of CAMWEL RCT intervention participants compared to

425 qualitative study intervention participants

	CAMWEL RCT		Qualitative study sample		P value
	%	n	%	N	
Allocation: Intervention	50.13	191	9.4	18	
Age group (years)					
18- <35	20.9	40	5.6	1	
35- <50	31.4	60	44.4	8	
50- <60	24.1	46	22.2	4	
≥60	23.6	45	27.8	5	0.32
Body mass index (kg/m^2)					
BMI 25-<30	25.6	49	27.8	5	
BMI ≥30	74.4	142	72.2	13	0.82
Gender: Female	71.7	137	61.1	11	0.29
Ethnicity: White	74.2	124	88.9	16	0.08
Education: No qualifications	8.8	15	11.1	2	0.66
Employed: Yes	63.2	108	33.3	6	0.03
Area Deprivation (IMD): Lowest quartile (deprived)	23.9	45	11.1	2	0.18
Lost 5% of initial weight	18.3	35	22.2	4	0.52

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