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White Paper

Weight Loss Management using Low Calorie Diets – An Effective, Long-Lasting and User-Friendly Solution

Putting the Individual in charge of their weight loss goals

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Executive Summary

One of the greatest challenges facing mankind today is achieving weight loss to reduce major disease and premature death. According to the World Health Organisation (WHO), 650 million adults globally were classified as obese in 2016 and the number of people living with obesity has tripled since 1975 (WHO 2020).
Despite decades of knowledge that obesity and overweight confer a significant health burden from heart disease, stroke, cancer, and type 2 diabetes, the long-standing tools of dietary and lifestyle advice, pharmaceutical agents and surgical interventions have not been sufficient for achieving widescale and effective long-term weight loss.
Recently, the Diabetes Remission Clinical Trial (DiRECT) showed that community-based low-calorie diet programmes delivered using a multidisciplinary approach are a robust and cost-effective solution for achieving significant weight loss and remission of type 2 diabetes. Healthcare providers can offer this accessible and user-friendly approach without overburdening existing NHS resources.
This white paper explores the science behind the concept of community-based total diet replacement programmes and their novel role in achieving and maintaining normal body weight and remission of type 2 diabetes.

Key Messages

- Obesity is an urgent public health problem requiring innovative multi-level strategies to achieve weight loss and reduce future morbidity and mortality.

- Total diet replacement programmes represent a cost-effective, community-based, service user-centred approach to effective weight loss.

- Total diet replacement programmes can enable remission of type 2 diabetes, reducing the risk of long-term cardiovascular and other complications and premature death.

- Total diet replacement weight loss programmes should be considered a primary intervention in the global strategy for combating chronic metabolic diseases relating to overweight and obesity.

Introduction – the Need for Robust Weight Loss Programmes

Challenges of Achieving Weight Loss

Obesity is one of the major global public health challenges affecting people today. The World Health Organisation (WHO) reports that, since 1975, worldwide obesity has tripled with over 1.9 billion adults classed as overweight or obese (WHO 2020). In England, 67% of men and 60% of women are currently overweight or obese and 11,117 hospital admissions were directly attributed to obesity in 2019 (NHS Digital 2020). It is imperative that effective strategies are employed to reduce the incidence and prevalence of overweight and obesity and combat associated morbidity and mortality in the UK population.

Consistent and accurate public messaging and media communications educate the general public on the risks of overweight and obesity so that they understand the importance of accessing and engaging with weight loss and healthy lifestyle community programmes (Cody-Stanford et al 2018).

At the population level, societal changes nudge individuals towards achieving weight loss, for example by encouraging walking, providing green spaces for exercise and recreation and imposing sugar taxes (Kumanyika et al 2008). At the personal level, managing overweight and obesity should be individualised and holistic with the support of a multidisciplinary healthcare team ideally in a community setting.

Weight loss can be achieved with healthy diets, increased physical activity, weight-loss medication, bariatric surgery or a combination of these interventions. While they can all be associated with successful outcomes, their effectiveness is limited by lack of adherence to treatment and/or disabling side-effects and therefore they are not always a longer-term solution.

Other socioeconomic factors that need addressing are barriers to healthcare access such as lack of time, expense, stigma, working hours, and specific issues pertaining to Black and Ethnic Minority (BAME) groups. Literacy and access to education can also impact on achieving healthy lifestyles as well as a tendency towards looking for "quick wins" when tackling obesity and weight management.

Combined behavioural weight management programmes which are delivered by multidisciplinary teams, including registered dietitians, psychologists and physical activity trainers and underpinned by behaviour change methods, are far more effective than physical activity programmes alone especially for achieving long-term weight loss (Johns et al 2014).

Randomised controlled trials have shown the benefits of healthy diets on weight loss for several decades. An extensive selection of diets is currently available including Mediterranean, low-fat, low-carbohydrate, total meal replacement, intermittent fasting and commercial weight loss programmes.

Low-fat, low-carbohydrate and Mediterranean diets are all beneficial on glycaemic and lipid parameters (Shai et al 2008). More recently, very low-calorie diets as part of

total meal replacement have been shown to achieve effective and cost-effective outcomes in glycaemic and lipid parameters in a community setting (Lean et al 2018).

Economic Costs of Obesity and Type 2 Diabetes to the NHS

Obesity has economic costs on populations in terms of physical disability, stigma and co-morbid conditions resulting in work absenteeism (ref).
Type 2 diabetes management, which accounts for more than 90% of all types of diabetes, places a significant cost burden on the NHS. It is widely asserted that 10% of the NHS budget for England and Wales is spent on diabetes care with a significant proportion spent on medication and managing complications. There are also the occupational and social costs of diabetes due to absenteeism, early retirement and social benefits. According to Diabetes UK, there has been a doubling in numbers of people living with type 2 diabetes in the last 20 years, and it is predicted that the UK incidence will be 5 million by 2025. In 2018, glucose-lowering drug prescriptions were £1 billion for the first time in the UK (Stedman et al 2019).

Challenges of User Self-Motivation

The primary challenge in attaining weight loss is difficulty in maintaining adherence to the prescribed diet (Thom & Lean 2017). However, optimal adherence is promoted by application of behaviour change models and regular professional contact with trained healthcare providers such as diabetes practitioners or coaches. Consistent engagement with learning tools and education either face-to-face or digitally enhances the user experience and reduces attrition rate from weight loss programmes. In our increasingly technological world, a multimedia experience which continually engages the users' interest and motivation is more likely to lead to weight loss goals and improved outcomes.

Importance of Relevant Measurable KPIs

There has been some criticism that weight loss studies of healthy diets tend to focus mainly on weight loss outcomes only and not on dietary effects during weight loss maintenance (Yannakoulia et al 2019).
The UK National Institute for Health and Care Excellence (NICE) has recommended that suitable outcomes or measurable key performance indicators (KPI) for weight loss programmes should include anthropometric measures i.e. body mass index (BMI) or waist circumference, dietary intake indicators e.g. fruit and vegetable consumption or intake of sugar sweetened drinks, duration and intensity of physical activity, duration and type of sedentary behaviour, prevalence of obesity-related diseases, and other health indicators such as mental health (NICE PH42 2012). Other suggested and important KPIs are process outcomes including service use, engagement with disadvantaged groups, establishment or expansion of community groups, and indicators of structural changes such as changes to procurement contracts.

These KPIs ensure that a quality service is being provided and can be audited at regular intervals to confirm that service delivery targets and outputs are being fulfilled. Community health teams should also collect data on both quantitative and qualitative patient-reported outcomes (PROs) as part of any weight loss programme. These PROs should include biochemical, clinical, lifestyle and psychosocial parameters.

Accountability and Benchmarking

NICE has emphasised that all stakeholders, including directors of public health and public health teams, academic health networks and academic institutions, local authority, NHS and other local commissioners and provider organisations, should be accountable for implementing monitoring and evaluation of community weight loss programmes thereby ensuring consistency and comparability in delivery across regions (NICE PH42 2012).

Value and Quality in Weight Loss Management Programmes

The value and quality of low-calorie weight loss programmes in the UK has been established following the results of the Diabetes Remission Clinical Trial (DiRECT) which showed that type 2 diabetes remission is both achievable and durable in the community setting with positive effects on glycaemic, lipid, blood pressure and quality of life parameters (Leslie et al 2016, Lean et al 2018, Taylor et al 2018, Lean et al 2019, Xin 2020).

DiRECT showed that, after withdrawing anti-diabetic and anti-hypertensive medication, a 3-month total diet replacement programme followed by food introduction after 2 months led to remission of type 2 diabetes in 36% of participants at 24 months (Xin 2020). In participants who achieved more than 15kg of weight loss, the remission rate increased to 70% at 24 months. The study confirmed the challenge of maintaining weight loss in that only a quarter of the intervention group achieved 10% or more weight loss, but this was improved by ongoing support and relapse management.

This ground-breaking research identified that several key factors predict remission: degree of weight loss, number of baseline diabetes medications and absence of anxiety and depression. In contrast, diabetes duration, fasting insulin and C-peptide levels, and body mass index (BMI) are not predictive of remission.

Based on these findings, the conclusion from DiRECT was that early remission should be a primary management target for people with type 2 diabetes.

Include DROPLET stuy results for LCD in primary obese population (ref).

Education

Education and support with other components of optimal health such as smoking cessation, blood pressure management, sleep hygiene and mental well-being can be incorporated into behavioural programmes whose primary focus is on achieving weight loss. This adds quality, provides a holistic learning and supportive environment, and

promotes the understanding that weight loss has multifactorial causes which are not based solely on unhealthy eating patterns.
The service user should be given objectives and goals which are SMART-aligned, that is, specific, measurable, attainable, realistic, and timely to ensure achievable outcomes.

Digital Opportunities

In a technological era, when many people have access to computers, tablets and smartphones, it is essential that digital methods should be integral to delivering weight-loss programmes. Digital offerings such as web-based modules and smartphone apps are cost-effective and convenient for delivering education and support, while allowing service users to access resources at their own time and convenience. Service users are not constrained by location, access to transport or time zones, thus improving adherence to the intervention and reducing attrition rate, which often reduce effectiveness of behaviour change programmes.

Solutions

Optimising Self-Management using a multidisciplinary approach

NICE recommends that local healthcare commissioners commission multi-component lifestyle weight management programmes that address dietary intake, physical activity levels and behaviour change. These programmes should be developed by a multidisciplinary team comprising registered dietitians and psychologists and a qualified physical activity instructor (NICE PH53 2014).
Complex health behaviour change interventions are necessary to ensure effectiveness and maintenance of weight loss strategies. They should be carefully developed using standardized and validated frameworks, for example the Medical Research Council Framework, to achieve optimal outcomes (Craig et al 2008).
Key components of NICE behaviour change recommendations are problem solving, goal setting, ability to carry out tasks or activities effectively, self-monitoring of weight and other behaviours affecting weight, and feedback on performance. Logistical aspects such as accessibility to venues, men or women-only groups and childcare provision should be implemented as well as tailoring of programmes to suit the needs of high-risk populations e.g. Black and Minority Ethnic (BAME) communities.
Based on the evidence from DiRECT and the NICE recommendations, since September 2020, general practices from ten areas of England have been referring people with type 2 diabetes diagnosed in the last six years to community-based low-calorie total diet replacement. Service users on these programmes will receive enhanced support from a multidisciplinary team of dietitians, psychologists and physical activity specialists and the programme will be delivered by coaches either one-to-one, or in face-to-face or online groups. Additionally, there will be online support with self-learning education

modules, discussion forums and a web-based app through which the service user can communicate with the coach and other users.
Similar programmes are being rolled out in Scotland and Wales as community pilot projects.

Remote Care using Digital Solutions

Digital solutions for providing behavioural weight loss interventions have been shown to achieve and maintain weight loss in the primary care setting which offers a cost-effective solution to delivery. For example, in the Positive Online Weight Reduction (POWeR) programme, a 24 session web-based weight management intervention in 818 individuals over 6 months, 81% achieved an extra 1.5kg of weight loss compared with the control group who maintained nearly 3kg in weight loss (Little et al 2017). However, the difference between the groups for mean weight loss was not maintained at 12 months, suggesting the need for longer duration of intervention and support.

Conclusions

One long-term sustainable solution to the problems of obesity and type 2 diabetes is a community-based total diet replacement programme which has been a highly successful strategy in research studies. Translating positive research outcomes into clinical practice is often challenging but ultimately rewarding for both patients and clinicians. The UK diabetes charity Diabetes UK, which funded DiRECT, has reported that, “People with type 2 diabetes who have put their diabetes into remission frequently tell us how it has changed their lives.”
The success of any clinical programme is reliant on user engagement and satisfaction. Multi-disciplinary community weight management programmes using total diet replacement have been shown to reverse type 2 diabetes and improve health outcomes. Therefore, they should be offered as a first-line intervention to people living with obesity and type 2 diabetes, as they provide a clinical and economic solution to managing this complex and devastating condition.

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