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Treatment of overweight and obesity in general practice: a cluster randomised trial

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ABSTRACT

Overweight and obesity are among the most serious health problems of our time.

A majority of patients with overweight and obesity will first get in touch with health services through primary care. This makes it crucial to develop strategies to enable physicians in primary care to help and treat patients with overweight and obesity. The physicians tend to avoid this subject. The main reason is reported to be lack of knowledge and education, and that they have nothing concrete to offer their patients.

We wanted to examine if a simple method with specific measures could be used in Norwegian general practice and achieve meaningful weight loss.

23 physicians and 210 patients participated in the study. The physicians who participated were cluster randomised into either control group or intervention group. The physicians in the control group were told to follow their usual approach, while the physicians in the intervention group followed a fixed plan with specific diets given orally and in writing to the patients. The inclusion criteria for both groups were: body mass index (BMI)>30 kg/m^2, or BMI>25 kg/m^2 with at least one weight-related condition. Weight was measured at the start, then after 1 year and finally after 2 years in both groups.

We found no significant weight loss in the control group. In the intervention group, there was a weight loss of at least 10% by 25.5% after the first year and 24.2% after the entire observation period. 53.5% of the patients lost at least 5% of their weight in the first year and nearly 45% after the entire observation period. We conclude that a simple tool with a specific diet and activity plan is feasible in general practice and may produce significant weight loss. Trial registration number: NCT03000062.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patients want to discuss overweight/obesity with their general practitioners general practitioners (GPs).
⇒ Many GPs avoid the subject.

WHAT THIS STUDY ADDS

⇒ This study was carried out by GPs for GPs.
⇒ It presents an effective tool for losing weight.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Overweight/obesity should be part of GP specialisation.
⇒ This study could be a start for producing a guideline.

INTRODUCTION

Overweight and obesity are among the greatest health problems of current times and are associated with numerous diseases, such as cardiovascular disease, type 2 diabetes and obstructive sleep apnoea syndrome.[1] Overweight and obesity are linked to several types of cancer[2] and increase the risk of a severe course of infectious diseases, including COVID-19.[3]

Overweight is defined as a body mass index (BMI)>25 kg/m^2, while obesity is a BMI>30 kg/m^2.[1]

A report about causes, incidence and consequences of overweight and obesity in Norway[4] points out that overweight and obesity are strongly associated with underlying demographic and socioeconomic factors, such as level of education and income. There are also large geographical differences. The highest prevalence of obesity is found in districts and among individuals with a low level of education and income, and in certain immigrant groups. Incapacity to work related to overweight and obesity has been calculated to cost Norwegian kroner (NOK) 17 billion annually (€1.6 billion), while the costs to the health service amount to NOK12 billion (€1 billion).[4] Overall, this means that obesity is one of the most expensive chronic diseases in Norway.

Weight stigmatisation towards people with overweight and obesity is widespread, even among healthcare professionals.[5 6] Many think it is a question of willpower and 'pulling yourself together'. This type of attitude not only stops people seeking help, but it can also worsen their physical and mental health and lead to weight gain.[5 6] It is also often referred to as 'fat shaming'.[7] By using an approach in which the main focus is the patient's health, rather than their weight, it is possible that

more people can get help from their general practitioner (GP).

Several drugs have been developed in recent years to treat overweight and obesity. Those with widest use and approval are liraglutide and bupropion/naltrexone combined.

The effect of bupropion/naltrexone combined is that it inhibits the uptake of norepinephrine and dopamine in areas of the brain that regulate feelings of hunger and satiety. Lira, a GLP-1 analogue, is assumed to have a similar effect in the brain, as well as delaying gastric emptying.[8]

The sale of these drugs in Norway has increased considerably,[9] without it being possible so far to draw any definite conclusions about what this means for weight reduction in wider population groups. In Norway, liraglutide was prescribed to 9083 individuals (1.39 defined daily doses (DDD)/1000 inhabitants per day) in 2017, and by 2021, this had increased to 24073 (3.59 DDD/1000 inhabitants per day). It is not known to what extent patients who take these drugs receive follow-up and guidance from their GP.

The primary care service is where most patients with overweight and obesity first get in contact with the health service, so it is important to develop strategies for how GPs interact with and treat people in this patient group.

One study found that although the majority of patients with overweight and obesity wanted their doctor to discuss this subject with them,[10] it was rarely discussed during the consultation.[10 11] According to the same study, the patients would have liked a specific diet plan and exercise advice, as well as a realistic weight reduction plan.[10]

The main reasons for doctors avoiding the subject were inadequate education during their medical studies and specialist training, and the fact that they did not have anything specific to offer the patients.[11 12] Lack of time was also given as an explanation. The doctors found it easier to talk about overweight and obesity if the patients had a weight-related disease. There was also a fear that bringing up overweight and weight reduction might cause offence and lead to increased focus on appearance and physique.[11 12]

Previous research has found the effect of interventions for overweight in the primary care service to be uncertain. A meta-analysis of behavioural therapy given to patients with overweight was unable to demonstrate any definite effect on weight reduction,[13] and no particular diet (eg, low-carb diet) has been found to have any definite advantage over other diets.[14] Many patients who lose weight, regain the weight after the end of the intervention.[15]

Digital tools for weight reduction seem tempting, but a Danish study found that the most important success factor for weight reduction was an empathic and trusting relationship between the patient and GP.[16] Another study confirms that patients prefer to receive advice about weight reduction from their GP.[17] Considerable initial weight reduction[18] and close follow-up, particularly in the early phase,[19] may be significant factors. There is a lack of evidence-based knowledge about effective treatment for patients with overweight and obesity in general practice.

We wanted to conduct an interventional study in patients with overweight and obesity at GP clinics. The objective of this study was to investigate whether a tool of dietary and physical advice could be implemented in a regular GP practice and have an effect on the patients' overweight.

METHOD AND MATERIAL

GPs in the Moss district in Norway were asked to take part in a study on weight reduction in patients with overweight and obesity in their own practice. Those doctors who were interested attended an information meeting and were provided with both verbal and written information about the study. Randomisation to either the intervention group or control group was performed by the Department of General Practice at the University of Oslo. The study was conducted as a cluster randomised trial, in which the doctors were randomised, but the outcomes were measured in the patients who were recruited. Each doctor was expected to be able to recruit ten patients in line with the inclusion and exclusion criteria.

The inclusion criteria for both groups were: BMI>30 kg/m^2 or BMI>25 kg/m^2 with at least one weight-related condition: hypertension, dyslipidaemia, metabolic syndrome, type 2 diabetes, overload in a weight-bearing joint, sleep apnoea syndrome, polycystic ovary syndrome, gastro-oesophageal reflux disease, depression, non-alcoholic steatohepatitis, stress incontinence, venous stasis, leg ulcer, gout, age >18 and <70 years, consent for participation. Sufficient knowledge of Norwegian to be able to understand written and verbal information.

A total of 35 GPs were asked to take part in the study (figure 1), 30 of whom agreed. Of the doctors who initially agreed to take part, seven either subsequently reported that they no longer wished to take part or did not recruit any patients into the study. This left 23 doctors, with 12

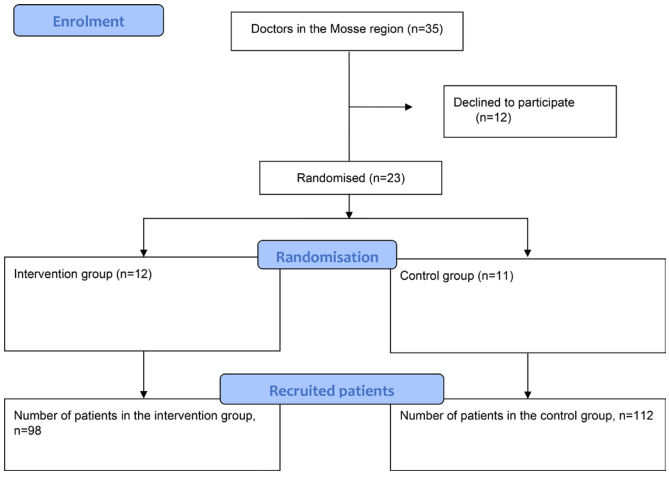

Figure 1 CONSORT 2010 flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

assigned to the intervention group and 11 to the control group. There were 98 patients in the intervention group and 112 in the control group.

Recruitment for this study commenced in January 2017 and ended in January 2018, and the patients were invited consecutively to take part by the doctors. The patients were followed up for 12 months after the end of the intervention (appointments with the GP) with data being collected for 24 months from inclusion. It has been demonstrated that a 5% wt reduction leads to health benefits.[20] The primary outcome measure of this study was a weight reduction of 10% in both control and intervention groups. The secondary outcome measure was a weight reduction of 5% in both groups.

The study was registered in the Clinical Trials registry (NCT03000062)

The intervention group took part in a joint information meeting and received training in the method. The doctors were given a detailed written manual outlining the content of each appointment and what data should be collected. The patients visited their GP six times in the first year and twice in the second year. Data were recorded (see Diet 1: the first 4 weeks), and the patients received detailed advice at each visit. This advice followed a defined plan for diet and exercise in the study period. The plan consists of a relatively significant change in diet with a substantial reduction in calories in the first 4 weeks because a considerable initial weight reduction can lead to better long-term results[18]:

DIET 1: THE FIRST 4 WEEKS

You cannot eat: Potatoes, bread, rice, pasta, confectionary, fruit, dairy products, cereal products or nuts, or drink alcohol for 4 weeks.

You can eat: Fish, meat, eggs, shellfish, vegetables and salad (as much as you want).

Alternatives to fish and meat can be pulses such as chickpeas, beans or lentils.

At least 4 meals a day. It is easiest to make a big salad with, for example, tuna fish and eggs or chicken, keep it in the fridge and take out portions.

For dinner, you can eat fish or meat and vegetables.

Breakfast can consist of 1–2 eggs, ham and tomatoes, or you can eat salad (see above).

You can drink water, tea or coffee.

Feel free to use oil in cooking and salads.

Activity: Walk or cycle 20–30 min per day. Can be divided into several sessions.

After 4 weeks, the diet plan was changed. It became more varied and followed current recommendations from the Norwegian National Council for Nutrition[21]:

DIET 2: THE FOLLOWING 11 MONTHS

Breakfast: Oatmeal or porridge with skimmed milk or water, with a few nuts or berries, or two crispbreads or one slice of wholemeal bread (two slices of wholemeal bread for men) with lean cold cuts, fish or low-fat cheese. Feel free to have salad, tomatoes and/or cucumber on top.

Snack: 3–4 tablespoons of Quark (low-fat) or cottage cheese and 1 apple/pear/orange or a few grapes and a few nuts.

An alternative can be 2–3 slices of low-fat cheese (just cheese) with a few grapes and a few nuts.

Lunch: Salad with, for example, tuna fish and eggs or chicken. No bread.

Alternatives can be soup with 1–2 crispbreads or a hot lunch, for example, omelette with vegetables.

Dinner: Meat or fish and vegetables or salad and a potato or a little rice/pasta.

Alternatives to fish and meat can be pulses such as chickpeas, beans or lentils.

Supper: Two crispbreads or one slice of wholemeal bread with lean cold cuts, fish or low-fat cheese. Feel free to have salad, tomatoes and/or cucumber on top.

Use oil in cooking and salads.

Drink: Water, tea or coffee

Activity: Walk or cycle 30–40 min per day. Can be divided into several sessions.

As mentioned above, the recommended exercise in the first 4 weeks was to walk or cycle 20–30 min per day. After the first 4 weeks, it was recommended to walk or cycle 30–40 min per day. The activity could be divided into sessions of, for example, 10 min.

In the control group, the doctors received general information about the study and, in particular, about recording and collecting data. They were encouraged to use their normal approach to overweight. Furthermore, they were asked to collect and record data. The doctors in the control group were also given a folder describing which examinations and samples were to be carried out on inclusion to the study and at the stipulated time points for measurements. All the required forms were in the folder. The doctors were free to arrange as many visits as they wanted with the patients in the study period.

Recruitment to the study ended in January 2018, and the patients were followed up for 12 months after the end of the intervention (appointments with GP) with data being collected for 24 months from inclusion.

Statistical methods

Descriptive statistics in the form of frequency and percentage distribution were used to summarise categorical data at baseline, while mean with SD was used to summarise numerical variables. Associations between categorical variables were demonstrated using χ^2 tests, and Fisher's exact test was used when the expected cell count was less than five. The independent t-test was used to compare numerical data between the intervention and control groups.

We used the miceadds package in R to perform 10 multilevel imputations of missing data, which we then exported to Stata SE V.16 for further analyses. The data from both primary and secondary outcome measures were collected at three different time points in the study.

Table 1 Patient characteristics in both groups at baseline

Baseline characteristics	Intervention (n=98)	Control (n=112)	P value
Sex: n (%)			0.48
Female	52 (53.1)	54 (48.2)	
Male	46 (46.9)	58 (51.8)	
Age groups (years): n (%)			0.34
18–25	2 (2.0)	1 (0.9)	
26–50	40 (40.8)	56 (50.0)	
51–60	31 (31.6)	36 (32.1)	
61–70	25 (25.5)	19 (17.0)	
Level of education: n (%)			0.14
Secondary school	65 (66.3)	63 (56.3)	
Higher education/ university	33 (33.7)	49 (43.8)	
Proportion of smokers: n (%)			0.70
Smokers	14 (14.3)	14 (12.5)	
Non-smokers	84 (85.7)	98 (87.5)	
Mean±SD			
Weight at baseline	106.8±18.5	101.7±17.3	0.01
BMI at baseline	36.0±6.8	33.4±4.2	<0.01
Waist circumference	118.6±13.3	108.7±11.1	<0.01
Systolic BP	132.4±16.8	130.9±14.8	0.50
Diastolic BP	81.3±11.9	80.9±10.1	0.81
HbA1c (4–6.1)	6.2±1.2	6.0±1.0	0.32
Total cholesterol (3.9–7.8)	5.1±1.3	5.3±1.1	0.20
No of days with physical activity per week	2.9±2.2	3.3±2.2	0.24

BMI, body mass index; BP, blood pressure; HbA1c, glycated hemoglobin A1c.

To account for the clustering of these observations in patients who were in turn nested within GPs, multilevel binary logistic regression models with random effects at patient and GP levels were used. The models were adjusted for variables measured at baseline: sex, age, level of education, smoking and number of days with physical activity per week. We observed differences in weight and waist circumference between the intervention and control groups at baseline (see table 1). Therefore, multilevel regression models for weight and waist circumference were adjusted further for both weight and waist circumference at baseline. All analyses were performed in Stata SE V.16, and the significance level was set at α=0.05. Power of the test was set at 0.8 (80%).

Data at baseline

Patient characteristics in both groups were measured at baseline (see table 1). Mean weight in the intervention group was 106.8 kg compared with 101.7 kg in the control group (p=0.01). The results also showed that mean waist circumference was 118.6 cm in patients in the intervention group and 108.7 cm in the control group (p<0.01). No other significant differences between the two groups were found.

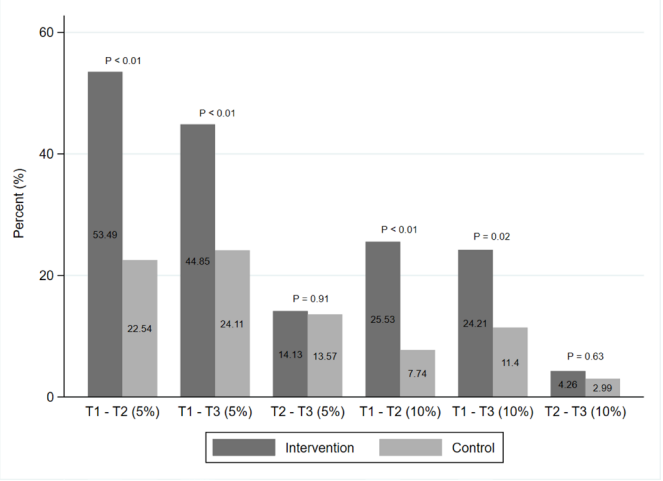

Figure 2 Comparison of the weight change in the groups at various measurement time points.

RESULTS

In the intervention group, 25.5% of participants had a weight reduction of at least 10% during the intervention period (figure 2) while 7.7% of participants in the control group achieved this. In the entire observation period, a total of 24.2% participants in the intervention group achieved a weight reduction of 10%, while the corresponding figure in the control group was 11.4%.

We found no statistically significant differences between the groups as regards HbA1c (glycated hemoglobin A1c), blood pressure or total cholesterol.

Although over half of the participants in the intervention group lost weight in this study, we also found that 44.9% gained weight.

≥5% weight reduction

We found a change in weight of at least 5% and 10% for the intervention and control groups at various measurement time points (figure 2).The proportion of participants who lost at least 5% in weight between T1 and T2 was significantly higher in the intervention group (53.5%) than in the control group (22.5%). We also observed that almost 45% of participants in the intervention group lost at least 5% between T1 and T3. The corresponding figure for the control group was 24.1% (p<0.01). The changes observed between T2 and T3 were not statistically significant.

Binary logistic regression

Estimates of OR with 95% CIs obtained from the multilevel binary logistic regression model, comparing the intervention to the control are presented in a forest plot (figure 3).We found that participants in the intervention group had a 4.19-fold higher probability of losing at least 10% and a 4.35-fold higher probability of losing at least

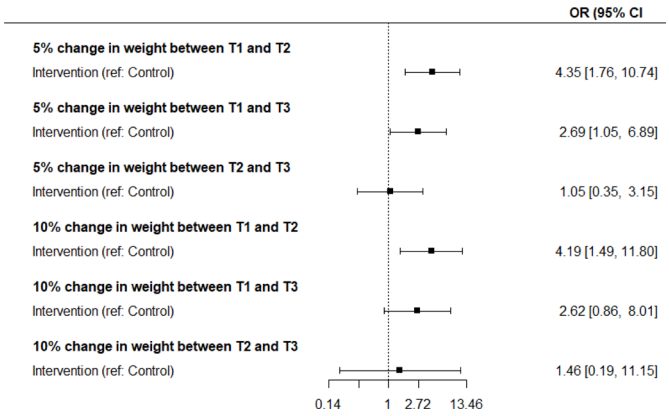

Figure 3 Balance diagram showing the probability of achieving a specific weight reduction in the intervention and control groups.

5% in weight between T1 and T2 compared with participants in the control group. In addition, the probability of a weight reduction of at least 5% between T1 and T3 was significantly higher in the intervention group (OR 2.69 (95% CI 1.05 to 6.89)).

DISCUSSION

This study demonstrates that it is possible to implement appropriate intervention for weight reduction in patients with overweight and obesity in general practice. In the intervention group, 25.5% of participants lost at least 10% in the first year, while the corresponding figure in the control group was 7.7%. A weight reduction of at least 5%was achieved by 53.5% in the intervention group and 22.5% in the control group. Both differences are statistically significant.

It is known that weight reduction is often followed by weight gain.[15] We followed up the patients for 2 years, and the adjusted data indicate that the patients who lost weight in the first year also maintained this in the second year, although a weak non-significant weight gain was seen in the second year. Neither was there a significant difference between the groups as regards the number of patients who achieved 5% or 10% wt reduction in the observation period (between T2 and T3). The study by Nordmo *et al*[15] found that participants were back to their original weight after an observation period of 3 years. No intervention was performed in the observation period. If the observation period in our study had been longer, it is possible that the weight gain would have continued, and after a while a significant weight gain might have been seen.

The continuity in the doctor–patient relationship over a long period of time means that GPs have a unique opportunity to implement individual weight measures over several years. A good doctor–patient relationship, which many people have with their GP, could make this possible. The addition of weighing patients and a structured conversation about weight, diet and exercise at check-ups once or twice a year may be sufficient. In other words, it would be possible to perform the intervention over a number of years.

Specific suggestions for diet and exercise are important. Both patients and doctors report a need for this.[10 11] It is not reasonable to raise the issue without having something specific to offer the patient. The measures used in the intervention group in this study are easy to perform and can be implemented in the everyday clinical practice of a GP.

None of the participants were blinded in this study, and a participant's knowledge that they are taking part in a study may in itself affect the results. We would like to point out again the significance of the fact that a good long-term doctor–patient relationship may represent the best setting for lasting weight reduction. However, a prerequisite for this is that the doctor is motivated, is not prejudiced and has a specific tool for the task. As mentioned above, it has been shown that the majority of patients with overweight and obesity want the doctor to address the subject during a consultation.[10]

The patients in our study did not take drugs to treat overweight and obesity, but it is possible that these drugs might have enhanced the effect of the lifestyle treatment and helped to prevent weight gain. Further research is needed in this field.

Considerable initial weight reduction can lead to better results in the long run,[18] and close follow-up, particularly in the early phase, may be significant for whether the patient achieves their target weight reduction.[19]

Our study was carried out in Norway by Norwegian GPs on Norwegian patients. Our primary care system differs from primary care systems in other countries and this may influence the possibility of implementing our method. Nevertheless, it is our opinion that patients in general practice across the countries share a lot of the same issues and that GPs in different countries have many identical challenges. We believe that trying to help patients with obesity and overweight are among these. Therefore, a local modification of our intervention should be feasible in most practices.

We hope that this study provides a tool that GPs can use to help their patients with overweight and obesity to achieve lasting weight reduction.

Contributors MDN conceived the presented idea and the project. MDN is the guarantor. MDN and ELW developed the idea further. IM did the statistical analysis. All authors discussed the results and contributed to the final manuscript.

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Competing interests None declared.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval The study was approved by the Regional Committee for Medical and Health Research Ethics (REC) (2016/393).

Provenance and peer review Not commissioned; externally peer reviewed by Tatiana Christides, Barts and The London School of Medicine and Dentistry, Turner Street London, United Kingdom of Great Britain and Northern Ireland.

Data availability statement Data are available in a public, open access repository.

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REFERENCES

1 Helsedirektoratet. *IS-1735 Forebygging, utredning og behandling av overvekt og fedme hos voksne Nasjonale retningslinjer for primærhelsetjenesten. Norwegian Health Directorate. IS-1735. Prevention, examination and treatment of overweight and obesity in adults*. 2010.
2 Avgerinos KI, Spyrou N, Mantzoros CS, *et al*. Obesity and cancer risk: emerging biological mechanisms and perspectives. *Metabolism* 2019;92:121–35.
3 Yang J, Hu J, Zhu C. Obesity aggravates COVID-19: a systematic review and meta-analysis. *J Med Virol* 2021;93:257–61.
4 Aamo AAW, Lind LH, Myklebust A. *Overvekt og fedme i Norge: Omfang, utvikling og samfunnskostnader*. MENON-PUBLIKASJON NR, 2019.
5 Puhl RM, Phelan SM, Nadglowski J, *et al*. Overcoming weight bias in the management of patients with diabetes and obesity. *Clin Diabetes* 2016;34:44–50.
6 Alberga AS, Nutter S, MacInnis C, *et al*. Examining weight bias among practicing Canadian family physicians. *Obes Facts* 2019;12:632–8.
7 Chakravorty T. Fat Shaming is stopping doctors from helping overweight patients—here's what medical students can do about it. *BMJ* 2021;375:n2830.
8 Felleskatalogen. *The Norwegian Pharmaceutical Product Compendium*. Oslo: Felleskatalogen AS, 2022. Available: www.felleskatalogen.no
9 Folkehelseinstituttet. *Legemiddelforbruket i Norge 2017–2021 - Data fra Grossistbasert legemiddelstatistikk og Reseptregisteret*. Publikasjoner fra FHI, 2022.
10 Potter MB, Vu JD, Croughan-Minihane M. Weight management: what patients want from their primary care physicians. *J Fam Pract* 2001;50:513–8.
11 Forman-Hoffman V, Little A, Wahls T. Barriers to obesity management: a pilot study of primary care clinicians. *BMC Fam Pract* 2006;7:35.
12 Scott JG, Cohen D, DiCicco-Bloom B, *et al*. Speaking of weight: how patients and primary care clinicians initiate weight loss counseling. *Prev Med* 2004;38:819–27.
13 Booth HP, Prevost TA, Wright AJ, *et al*. Gulliford effectiveness of behavioural weight loss interventions delivered in a primary care setting: a systematic review and meta-analysis family practice. *Fam Pract* 2014;31:643–53.
14 Sacks FM, Bray GA, Carey VJ, *et al*. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med* 2009;360:859–73.
15 Nordmo M, Danielsen YS, Nordmo M. The challenge of keeping it off, a descriptive systematic review of high-quality, follow-up studies of obesity treatments. *Obes Rev* 2020;21:e12949.
16 Christensen JR, Hesseldal L, Olesen TB, *et al*. Long-term weight loss in a 24-month primary care-anchored telehealth lifestyle coaching program: randomized controlled trial. *J Telemed Telecare* 2022;28:764–70.
17 Appel LJ, Clark JM, Yeh H-C, *et al*. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med* 2011;365:1959–68.
18 Astrup A, Rössner S. Lessons from obesity management programmes: greater initial weight loss improves long-term maintenance. *Obes Rev* 2000;1:17–9.
19 Wadden TA, Volger S, Sarwer DB, *et al*. A two-year randomized trial of obesity treatment in primary care practice. *N Engl J Med* 2011;365:1969–79.
20 Blackburn G. Effect of degree of weight loss on health benefits. *Obes Res* 1995;3 Suppl 2:211s–6s.
21 Helsdirektoratet (Norwegian Health Directorate). *Nasjonalt råd for ernæring (National council for nutrition) Kostråd. Kosthåndboken – veileder i ernæringsarbeid i helse- og omsorgstjenesten Utgitt: Utgitt juni 2012, sist endret september 2016 Bestillingsnummer: IS-1972*. 2016.