THE SLIMMING CLINIC[™]

Doctor Led Personal Weight Loss

The Slimming Clinic

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Introduction

- There is a global obesity epidemic.
- According to WHO there are around 2 billion adults overweight, of those 650 million are considered to be obese¹.
- The worldwide prevalence of obesity has neatly tripled between 1975 and the present.
- In the UK, currently 67% of men and 60% of women are overweight or obese².
- The UK weight loss market is rapidly growing, further heightened by the Covid-19 pandemic.
- The Slimming Clinic is proud to be the UK's largest provider of private non-surgical medical weight management solutions, specialising in doctor-led and patient-centred weight loss programmes for those with overweight or obesity.
- The company, founded in 1984, helps patients achieve their weight loss goals through medical consultation, behavioural change, and prescription medication.
- With over 35,000 patients on our database, we help thousands of patients each year looking for additional support to lifestyle change alone. Currently we have nearly 3000 currently active patients.

History of The Slimming Clinic

Founded in 1984 in Bournemouth as National Slimming and Cosmetic Clinics.

Regulated by CQC in England, HIS in Scotland and HIW in Wales.

23 UK-wide clinics were acquired in 2018 by Harwood with new management team introduced.

Cosmetic services ceased in 2019 to focus on weight management. Rebranded to The Slimming Clinic.

Initial business plan was to:

- Change patient interaction from transactional weekly prescription of medication to a programme of care supporting patient education, lifestyle review and behavioural change.
- Establish a multi-disciplinary treatment programme offering the most comprehensive support of diet, body and mind.
- Introduce monthly membership programmes encouraging 12 week minimum treatment.
- Expand to >100 clinics nationwide by 2022.

Current Status

The Slimming Clinic remains the UK's largest provider of private non-surgical doctor-led medical weight management programmes.

In response to the Covid-19 lockdown in March 2020, the business was adapted and transformed to a remote service. This remote service proved popular with both patients and staff alike and allowed nationwide provision of our services. In August 2020, it was decided continue solely as a remote provider and not to reopen the clinics. All patient care since 31st March 2020 has been delivered remotely via phone and video consultations.

Our Team

- Medical workforce of employed motivated and engaged clinicians (20 doctors and 2 nurses).
- Multi-disciplinary team of a Registered Dietitian, Level 4 Personal Trainer and Counsellor.
- Team of patient and clinician support staff working alongside practitioners to assist the delivery of high-quality care.
- Dispense and dispatch staff supporting the delivery of discreet patient programme material and medication.
- Patient services team managing patient feedback, comments and complaints.
- Head office team covering Operations, Marketing, Finance, HR and IT.

Our Aims

- Provide support to those with overweight and obesity to lose weight through diet, exercise and lifestyle behavioural changes alongside the use of pharmacotherapy, to improve their health, well-being and reduce weight-related risk factors.
- To be at the forefront of the Independent Healthcare medical weight loss sector by developing a Gold Standard of Care across the organisation.
- Deliver patient-centred care at the core of our treatment programmes.
- Offer patients a personal service, integrating the highest quality products with the latest proven techniques and protocols and the support of qualified medical staff.
- To invest in people, equipment and technology and innovate processes based on a measured business case.
- To encourage and develop innovation, ambition, enterprise and continuous improvement.
- To maintain the highest professional and ethical standards.

Our Company Values

Will help people to look better, feel better and achieve their dreams

Believe in simple science - proven effective treatments, delivered without overcomplication

Will take personal responsibility for being the best I can be - every day is a fresh start, another chance to be better than yesterday

Will be brilliant in working with the people around me - to have open, honest conversations and really listen

Believe that for us, it's personal - your success is ours

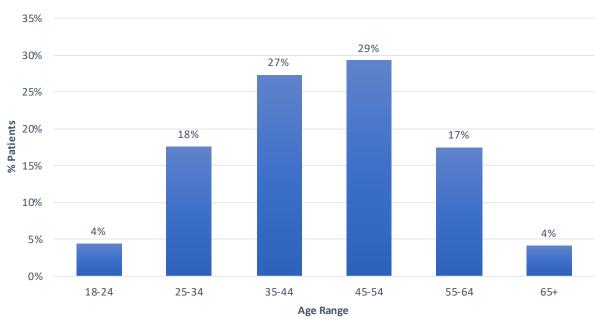
Patient Selection

- At The Slimming Clinic, our clinicians will consult with any patient with a BMI>24.9 kg/m².
- Our treatment programmes are suitable for patients with a BMI 24.9-26.9 kg/m², however the addition of prescription medication to the treatment programme is only for clinically suitable patients with a BMI > 30 kg/m² or BMI > 27 kg/m² with a medical comorbidity.
- We have no upper limit of BMI we can treat.
- We will consult with any patient with a qualifying BMI from the age of 18 years upwards. Through the variety of prescription medication we offer, we can treat patients up to the age of 75 years if deemed medically suitable by our medical team.
- Patients medical examination results and medical history are considered alongside BMI to decide on suitability for addition of prescriptive medication.
- Patients with a BMI 24.9-26.9 kg/m² can be considered for treatment without medication, using the clinical team support and the supplements.

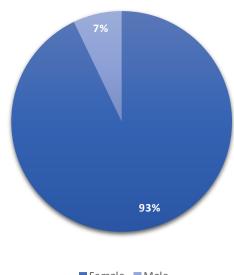
Current Patient Demographics

From a recent analysis of our active patient list, 93% of our current patients are female and 7% are male.

The age distribution of our current patients is as shown below, with 56% of our patients between the ages of 35-54 years of age.







Active Patients - Gender Split

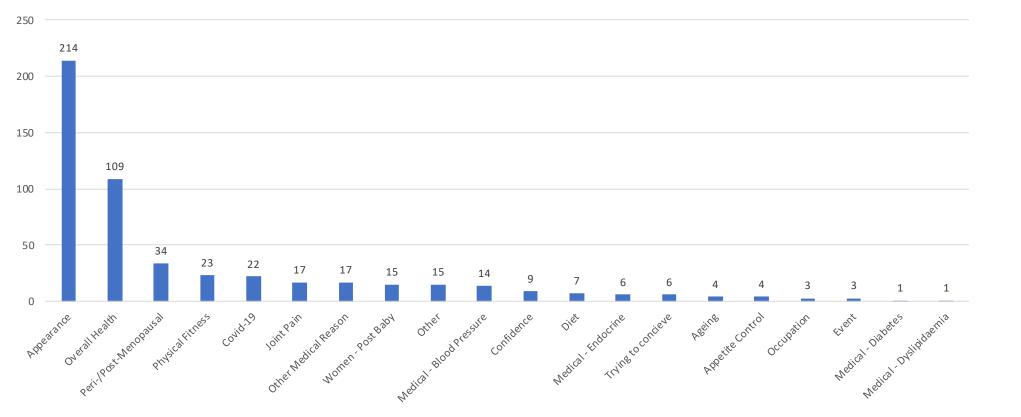
Female Male



Current Patient Demographics

From a recent survey of active patients, we explored the reasons they had sought our services to lose weight. The top 5 reasons were:

- Appearance
- Overall improvement in health
- Peri-/Post-Menopausal
- Level of physical fitness
- Covid-19 pandemic



Treatment Programmes

We offer a range of different treatment programmes alongside which the patient can be considered for anti-obesity medicines as adjuncts to the lifestyle and behavioural changes.

Our clinicians advise patients on realistic and achievable dietary and lifestyle changes which are reviewed and adjusted weekly as the patient progresses.

Dependent on the treatment programme chosen by the patient, their care will be overseen by a doctor plus the additional multidisciplinary practitioners.

All programmes 3 month minimum duration.

Foundation	Change	iChange Elite	Transform
 Clinician-led Care Prescriptive Medication* 	 Clinician-led Care Prescriptive Medication* Supplements FB Group Support 	 Clinician-led Care Prescriptive Medication* Supplements Smart Scales & BP Monitor FB Group Support 	 MDT-led Care Prescriptive Medication* Supplements Smart Scales & BP Monitor Blood Testing FB Group Support

*Prescriptive medication included only after patient clinical suitability assessment

Treatment Programmes - Results

Below are results from a recent audit of patients completing 12 weeks treatment in the remote service from Nov 2020 - Jan 2021. The comparative standard is the Weight Watchers NHS Referral Programme where 33% of all patients achieve at least 5% TBWL.

		Change	
	Foundation	iChange Elite	Transform
Achieved 5% TBWL	26%	32%	56%
Achieved 10% TBWL	4%	9%	12%
Average % TBWL	4.3%	5.1%	6.5%
Average weight lost (kg)	3.6	4.8	6.7

New Patient Pathway

New patients or those lapsed to the service of more than 12 months, require medical examination before prescription.

These patients enter our Explore 14 day programme consisting of:

- Online learning modules and getting started resources.
- Pre-Consultation appointment with a clinician to discuss medical history and medication suitability.
- Medical Examination appointment.

Medical Examination Appointment

Provided by third-party medical practitioners in established clinical settings across the UK.

Provided by an at Home Assessment, using telemedicine and digital stethoscope to allow examination over video call.

On completion of Explore programme and the pre-consultation and medical examination appointment, patients begin treatment on one of the aforementioned treatment programmes.

Clinical Guidelines for Management of Obesity

EASO Clinical Guidelines³

BMI ≥25 kg/m² or waist circumference ≥94 cm (men) ≥80 cm (women)

- Set goals and propose realistic lifestyle changes; weight loss goal of 5–15% body weight or 0.5–1kg/week
- Reduce nutrient intake by 500/1000 kcal/day
- 30 min of moderate intensity exercise 3–5 times/week

BMI \geq 30 kg/m² or \geq 27 kg/m² with risk factors

Pharmacotherapy (as an adjunct to diet and lifestyle modifications)

BMI \geq 40 kg/m² or BMI \geq 35 kg/m² with risk factors

• Consider bariatric surgery if other weight loss attempts have failed. Requires lifelong medical monitoring



Prescriptive Medication at The Slimming Clinic

Xenical (orlistat)

Lipase inhibitor. MHRA licensed and approved by NICE for use on the NHS.

Phentermine Hydrochloride

Sympathomimetic amine in β -phenethylamine family.

Influences noradrenergic and dopaminergic signalling in arcuate nucleus of hypothalamus.

Class C/Schedule 3 controlled drug.

In 2000 EMA advised withdrawal from market but legally challenged in 2003 allowing use in UK. Prescribed as a 'Special'.

Diethylpropion Hydrocholirde

Phenylethylamine ring with minor sympathomimetic properties.

Increases noradrenaline in synaptic cleft of hypothalamic neurones. Less stimulant effects than phentermine.

Class C/Schedule 3 controlled drug.

Unlicensed medication. Prescribed as a 'Special'.

Saxenda® (liraglutide)

GLP-1 receptor agonist.

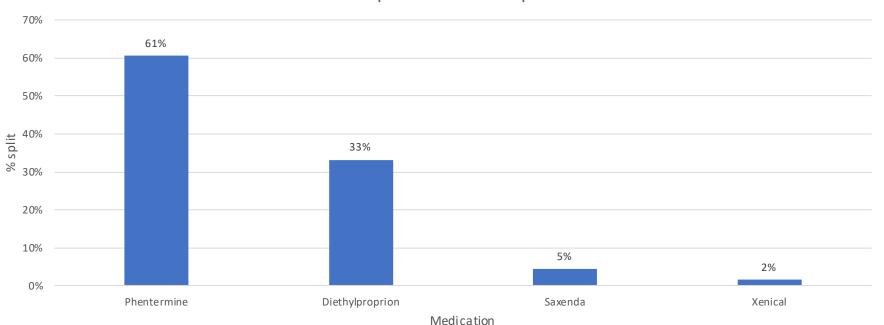
European Marketing Authorisation granted in 2015. NICE approved in specialist centres.



Prescriptive Medication at The Slimming Clinic - Split

Our current split across the prescriptive medications at The Slimming Clinic are as shown in the graph below.

- Phentermine and Diethylpropion remain our most popular medication option (93%).
- Saxenda is becoming a more popular option but still remains a low volume of prescriptions (5%)
- Xenical prescriptive rates have been between 1-3% over the last 5 years.



Prescription Medication Split

Specials

The Medicines Act (1968) allows manufacture and supply of unlicensed medicinal products for individual patients ("Specials") if clinical needs of the patient cannot be met by a licensed medication provided that:

- 1. There is a bona-fide unsolicited order
- 2. Product is manufactured in accordance with the requirements of a doctor licensed to practice in the UK
- 3. Product is for use by the individual patient under the direct personal responsibility of the doctor

Our patients are informed that Phentermine and Diethylpropion are prescribed as a 'Special' at their initial consultation and this is supplied in a written format by email and the PIL sent with every carton of medication.

Licensing of Phentermine and Diethylpropion

- The worldwide withdrawal of fenfluramine and dexfenfluramine prompted the European regulators to withdraw licenses for older products on the premise that they lacked proof of clinical benefits and explains the paucity of antiobesity agents in Europe compared with the US.
- The potential for mental health and cardiovascular disease comorbidities are relatively high in the obese population and, on a practical level, this translates into a high risk for inappropriate prescribing.
- On 26 November 2002, the European Court of First Instance annulled previous European Commission decisions (2000) to withdraw the licences (Marketing Authorisations) for two anorectic agents phentermine and diethylpropion.
- In accordance with this, the Medicines Control Agency reinstated the relevant marketing authorisations for diethylpropion and phentermine, which can be legally prescribed.
- The decision related to longstanding legal action and was not based on any new safety or new efficacy information relating to drugs.
- Both drugs were evaluated and originally licensed by criteria less stringent than those that are required since 1997 by both the EU Committee for Proprietary Medicinal Products and the US Food and Drugs Administration.
- Our patients are informed that Phentermine and Diethylpropion are unlicensed medications at their initial consultation and this is supplied in a written format by email and the PIL sent with every carton of medication.

Supplier of CDs

Our CD medication is ordered from one supplier in the UK, Essential Nutrition Ltd (Company number 02407484)

- Full MHRA UK Manufacturers Licence (MIA 16133)
- Specials Licence (MS 16133)
- UK Home Office licence to handle controlled drugs.

All medication is ordered by a GMC-registered doctor via a FP10CDF CD Requisition Form, held by Essential Nutrition Ltd.

Medication is delivered to our Head Office dispensing site overseen by a doctor.

I visited Essential Nutrition Ltd manufacturing site in February 2019 to review their manufacturing methods and processes, compliance to regulatory body and quality control and assurance processes.

We maintain a good relationship with the supplier. In August 2019 we worked with Essential Nutrition Ltd, to put the Phentermine and Diethylpropion medication into blister packs. It was previously supplied in large tubs that required "pilling up" by the consulting doctor into smaller bottles based on the patients requirements.

We had attempted to visit, inspect and develop a similar relationship with Typharm, suppliers of modified release capsule Phentermine and Diethylpropion, however despite our efforts this was no accommodated and so we ceased ordering medication from them in early 2019.

Prescribing of Medication at The Slimming Clinic

We have partnered with a third-party pharmacy CloudRx (Company number 12320974) for dispensing and dispatching the medications Saxenda and Xenical to our patients.

For the Phentermine and Diethylpropion, we presently dispense and dispatch this medication from our Head Office dispensing site, overseen personally by myself and fellow senior doctor, Dr Jane Glazebrook. Both myself and Dr Glazebrook are responsible for the safe storage, supply, ordering, dispensing and destruction of the medication.

Prescriptions are made electronically to allow a timely dispense and dispatch of the medication with signed paper copies held and reconciled at our Head Office dispensing site.

- All prescribing clinicians have PPCD codes.
- We are currently in the process of ordering FP10PCD forms and printers for our remote clinicians to use which we are open to supplying to NHS Prescription Services.

On average per month:

- Our 21 prescribing clinicians write 2600 prescriptions for phentermine and diethylpropion.
- We dispense 9500 cartons of medication to 2500 patients.
- This equates to 1300 weeks of medication and a ratio of 3.8 cartons (roughly 4 weeks supply) per patient.
- Only 2% of all prescriptions each month are for more than 28 days supply which is audited and monitored each month.

Head Office Dispensing Site

Our Head Office dispensing site follows the general guidance on security measures as explained in Home Office "Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants"⁴ guidance.

- All external doors and windows have secure locks.
- External doors are manufactured to the recommended standard.
- An electronic access control system with a clear audit trail (swipe cards) into the Head Office site.
- Access to the dispensing room is via a combination key lock.
- All CD stock is kept in Bristol Maid CD035 safe cabinets, bolted to an external wall.
- Keys for the CD cabinets are kept within a combination key lock cupboard affixed to an external wall.
- We have the below Policies and SOPs governing the management of CDs:
 - o Controlled Drugs
 - o Supply, Storage and Safe Disposal of Medicines
- We follow the below legislative and regulatory documents:
 - o The Misuse of Drugs Act 1971
 - The Misuse of Drugs (Safe Custody) Regulations 1973
 - o The Misuse of Drugs Regulations 2001
 - The Controlled Drugs (Supervision of Management and Use) Regulations 2006
 - o NICE NG46 Controlled drugs: safe use and management 2016

Audit and Management of Prescribing and Dispensing

The Medicines Management Committee meet each month to discuss the ordering, supply, prescribing, dispensing, dispatching and destruction of controlled drug medication.

The key areas discussed are:

- Concerns regarding supply/ordering of stock
- Audit of a sample of prescriptions
- Supply of more than 28 days CD medication
- Current stock level and future ordering requirements
- Lost, damaged and returned medication.
- Dispatch issues with regards to tracking/delivery

In addition we perform the below audits

- Daily, weekly and monthly stock control audit
- Daily CD safe temperature logs
- Quarterly medication control audit

References

- 1. <u>https://www.worldobesity.org/about/about-obesity/prevalence-of-obesity#:~:text=According%20to%20the%20World%20Health,overweight%2C%20with%2013%25%20obese</u>.
- 2. <u>https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/england-2020</u>
- 3. <u>https://easo.org/education/guidelines/</u>
- 4. <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/857591/Security_Gui</u> <u>dance_for_all_Businesses_and_Other_Organisations_v1.4_Jan_2020.pdf</u>