

## 1.2 Flowchart

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Procedure	Protocol section	Screening	Enrolment	D	ose esc	calatio	n	In	nitial	treatr	nent ph	ıase	End of initial treatment phase					Mai	Aaintenance phase				
Visit		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	e P13	V14	e P15	V16	e P17	V18	e P19	V20	P	
Timing of Visit (Weeks)		-2	0	4	8	12	16	20	28	40	52	68	78	82	91	95	104	108	117	121	130	1	
Visit Window (Days)		±7	0	±3	±3	±3	±3	±3	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±	
Informed Assent/Consent	10.1.3	Х																					
Demography <sup>d</sup>		X																				 	
Medical History/Concomitant Illness	<u>8.2</u>	Х																				П	
Weight History	<u>8.2</u>	X																				П	
Concomitant Medication	6.8	X	X	X	X	X	X	X	Х	X	X	X	X	X	X	Х	X	X	X	X	X	П	
Tobacco, Nicotine and e-cigarettes Status	5.3.2	Х																				Π	
Childbearing Potential <sup>e</sup>	10.4.1	Х	Х	Х	Х	Х	X	Х	Х	Х	X	X	X	X	X	Х	X	X	X	X	X	$\sqcap$	
Contraceptive Counselling <sup>f</sup>	10.4.2	X	X	X	X	X	X	Х	Х	X	X	X	X		X		X		X		X	$\sqcap$	
Pregnancy Test <sup>f</sup>	8.2.6	Х	X			X			X	Х	X	X	X		X		X		X		X	Π	
Date of Menarcheg	8.2.6		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	Π	
Pubertal Status (Tanner)	8.2.2	Х						Х		Х			X						X			 	
Eligibility Criteria	<u>5.1</u> ; <u>5.2</u>	Х	Х																			 	
Enrolment			X																			 	
Evaluation of Glycaemic Status	<u>8</u>		X					X		X			X						X			 	
Procedures Form	<u>6.8</u>			X	X	X	X	X	Х	X	X	X	X	X	X	Х	Х	X	X	X	X	 	
Socioeconomic Status (SES)	<u>8</u>		X																			 	
Living with parents/LAR	<u>8</u>		X										X									 	
Allocation to Maintenance Phase Group <sup>h</sup>	<u>4.1; 8.1.1</u>												X										
Discontinuation Criteria	<u>7</u>			Х	X	X	X	X	X	Х	X	X	X	X	X	X	X	X	X	X	X		
1																							

Procedure	Protocol section	olmen	End of initial treatment phase	Maintenance phase
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Visit		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	e P13	V14	e P15	V16	e P17	V18	e P19	V20	P
Timing of Visit (Weeks)		-2	0	4	8	12	16	20	28	40	52	68	78	82	91	95	104	108	117	121	130	1
Visit Window (Days)		±7	0	±3	±3	±3	±3	±3	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	3
Body Weight	<u>8.1.1</u>	X	X	X	X	X	X	X	X	Х	X	Х	X		Х		X		Х		Х	
Height	8.1.1	X	X			X		X		Х	X	X	X		X		X		X		X	П
Waist Circumference	8.1.1		X	П				Х		Х			X						X			Г
DXA Scan <sup>i</sup>	<u>8.1.2</u>	X											X									
End of IMP Treatment																						Г
End of Study																						Г
Biosamples for Future Research <sup>j</sup>	<u>8.9</u>		k X	П				Х					k X									Г
Mental Health Evaluation	8.2.7.1		X	Х	X	Х	X	X	Х	X	X	X	X	X	X	X	X	X	Х	Х	X	П
C-SSRS Baseline	8.2.7.2	Х																				
C-SSRS Since Last Visit	8.2.7.2									Х			X						Х			
Patient Health Questionnaire (PHQ-9)	8.2.7.2	X								Х			X						Х			
Hunger Single-items	<u>8.1.3</u>		X					Х		Х			m X		n X		n X		m X		n X	П
Hand out paper Hunger Single-items	8.1.3	Х																				
IWQOL-Kids	8.1.3		X	П						Х			X						X		$\Box$	П
PGI Status-IWQOL-Kids	8.1.3		X	П						Х			X									Г
PGI Change-IWQOL-Kids	8.1.3									X			X									П
In-trial interview <sup>p</sup>	<u>8.11</u>												X									Г
Study App (e-dosing diary)	8.8		X	X	X	X	X	Х	X	Х	X	X	X		X		X		Х		X	
Diet and Physical Activity Counselling <sup>q</sup>	6.1.1; 6.1.2		Х	х	х	Х	Х	х	Х	Х	X	х	Х		Х		х		Х		х	
Training in Trial Product, Pen-handling	<u>6.1</u>		X	X		X		X		Х			X						Х			
Procedure	Protocol section	Screening	Enrolment	Do	Dose escalation		n	In	Initial treat		nent pl	hase	End of initial treatment phase					Mai	ntenan	ce phas	se	
Visit		V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	e P13	V14	e P15	V16	e P17	V18	e P19	V20	P
Timing of Visit (Weeks)		-2	0	4	8	12	16	20	28	40	52	68	78	82	91	95	104	108	117	121	130	1
Visit Window (Days)		±7	0	±3	±3	±3	±3	±3	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	±5	
Hand Out ID Card	8	X																				

Hand Out Direction for Use	<u>6.1</u>		X										X									
Hand Out Dose Reminder Card	<u>6.1</u>		X	X	X	X	Х															
Vital Signs	8.2.3	Х	X										X									
Physical Examination	8.2.1	X																				
Attend Visit Fasting	5.3.1		X					X		X			X						X			
Laboratory Assessments	10.3;10.2	X	X					X		X			X						X			
Adverse Event	<u>8.3; 10.3</u>		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Medication Error, Misuse and Abuse	10.3.3		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
ECG	8.2.4	X																				
Dose Registration in eCRF	<u>6.5.1</u>		X										X		c X		c X		c X		c X	
Drug Dispensing	<u>6.3</u>		X	X	X	X	X	X	X	X	X	X	X		X		X		X		X	
Drug Accountability	<u>6.2</u>		X	X	X	X	X	X	X	X	X	X	X		X		X		X		X	