Supplemental material

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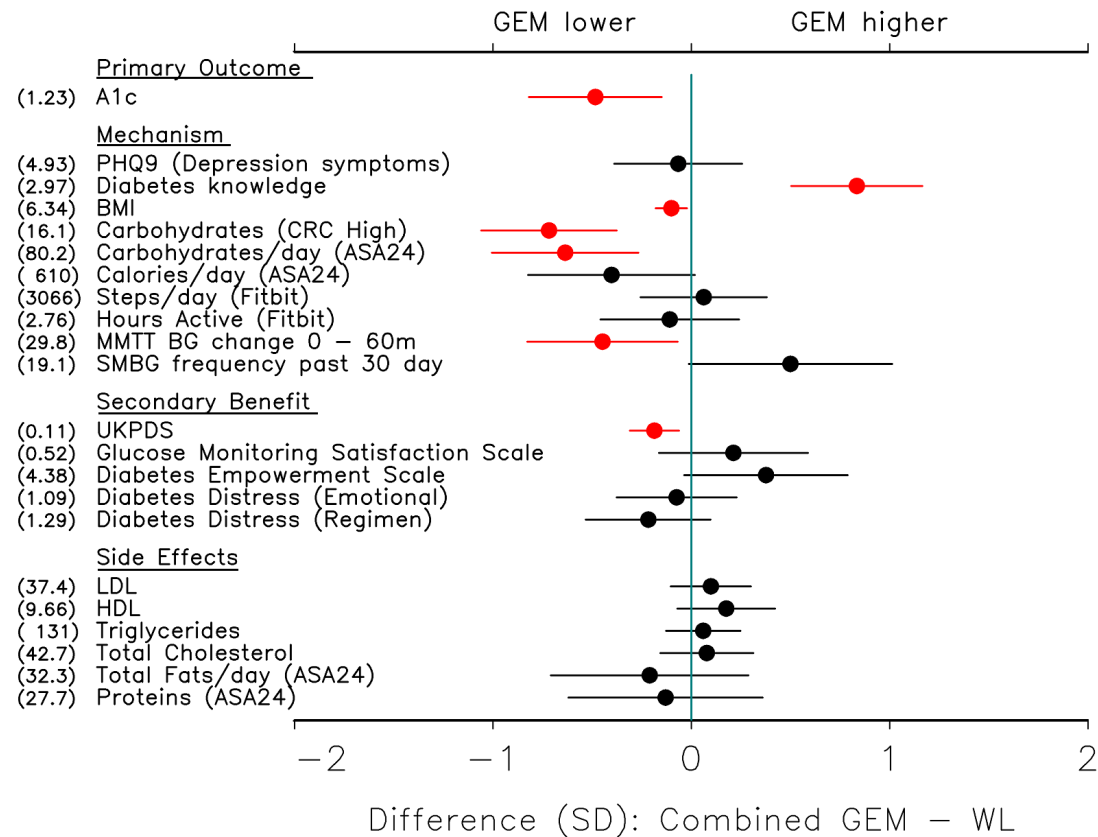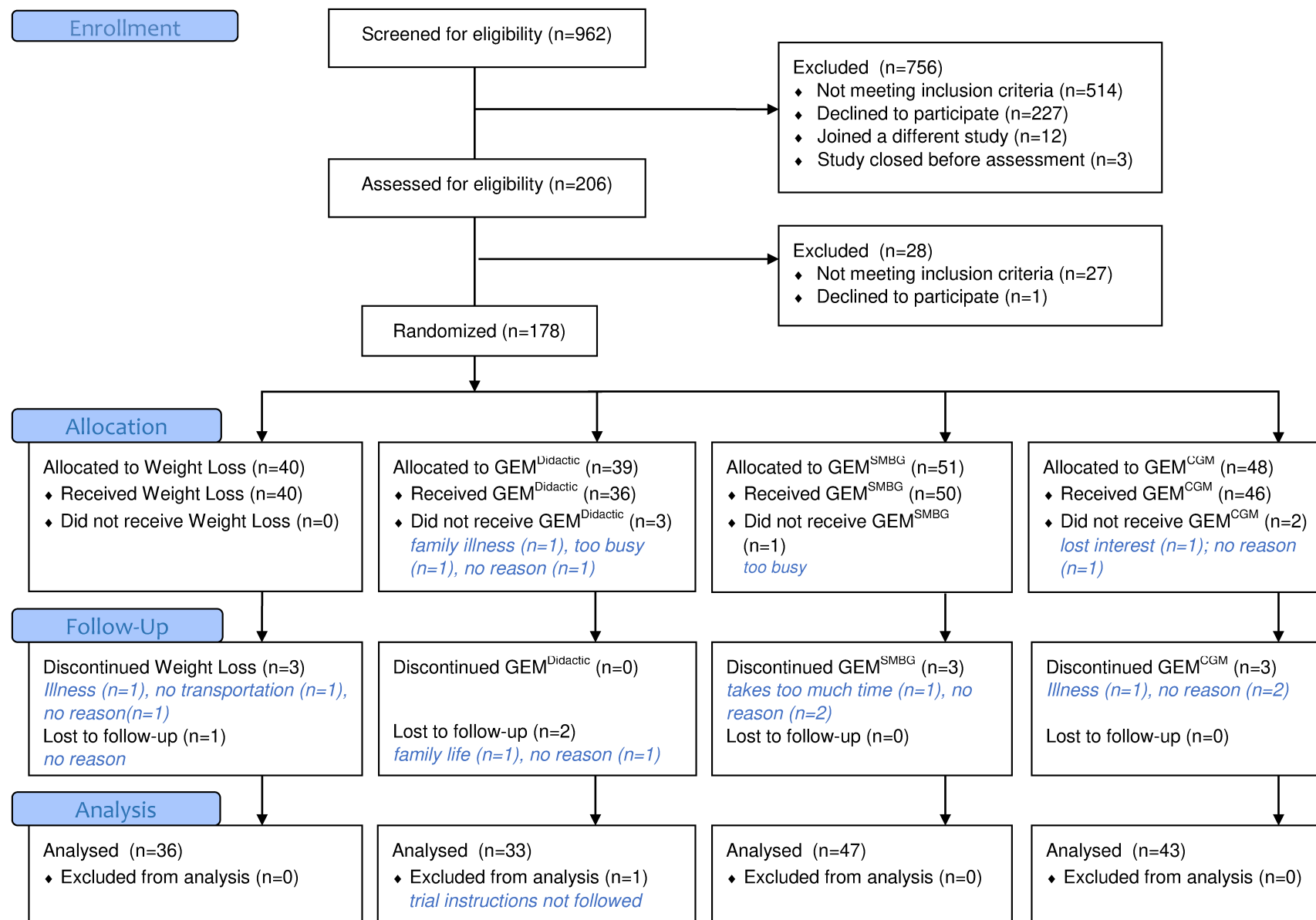
BMJ Open Diab Res Care

Supplemental Figure 1

Supplemental Figure 1. Differences in mean outcomes, along with 95% confidence intervals, between the GEM and WL interventions. Points to the right of zero are outcomes that, on average, are greater for GEM than WL. Values to the left of 0 are, on average, lower for GEM than WL. Confidence intervals for outcomes that differ significantly (p < 0.05) between the interventions are shown in red. In order for outcomes with different scales to be displayed on the same set of axes, the estimated between-group differences were divided by the baseline standard deviation (SD), shown in parentheses on the left. For example, dividing by the SD allows for differences in HbA1c (values between 5.5 and 13%) to be plotted on the same axis as daily steps (values in the thousands).

Supplemental Table 1. CONSORT 2010 Flow Diagram

Enrollment

Screened for eligibility (n=962)

Excluded (n=756)
- Not meeting inclusion criteria (n=514)
- Declined to participate (n=227)
- Joined a different study (n=12)
- Study closed before assessment (n=3)

Assessed for eligibility (n=206)

Excluded (n=28)
- Not meeting inclusion criteria (n=27)
- Declined to participate (n=1)

Randomized (n=178)

Allocation

Allocated to Weight Loss (n=40)
- Received Weight Loss (n=40)
- Did not receive Weight Loss (n=0)

Allocated to GEM^{Didactic} (n=39)
- Received GEM^{Didactic} (n=36)
- Did not receive GEM^{Didactic} (n=3)
  family illness (n=1), too busy (n=1), no reason (n=1)

Allocated to GEM^{SMBG} (n=51)
- Received GEM^{SMBG} (n=50)
- Did not receive GEM^{SMBG} (n=1)
  too busy

Allocated to GEM^{CGM} (n=48)
- Received GEM^{CGM} (n=46)
- Did not receive GEM^{CGM} (n=2)
  lost interest (n=1); no reason (n=1)

Follow-Up

Discontinued Weight Loss (n=3)
Illness (n=1), no transportation (n=1), no reason(n=1)
Lost to follow-up (n=1)
no reason

Discontinued GEM^{Didactic} (n=0)

Lost to follow-up (n=2)
family life (n=1), no reason (n=1)

Discontinued GEM^{SMBG} (n=3)
takes too much time (n=1), no reason (n=2)
Lost to follow-up (n=0)

Discontinued GEM^{CGM} (n=3)
Illness (n=1), no reason (n=2)

Lost to follow-up (n=0)

Analysis

Analysed (n=36)
- Excluded from analysis (n=0)

Analysed (n=33)
- Excluded from analysis (n=1)
  trial instructions not followed

Analysed (n=47)
- Excluded from analysis (n=0)

Analysed (n=43)
- Excluded from analysis (n=0)

Supplemental Table 2. Pre- to follow-up-assessment change scores and F values for WL and GEM

	Estimate: GEM - WL	95% CI	F GEM vs WL	P GEM vs WL	Within WL Followup -Pre (n=36)	P Within WL	Within GEM Followup-Pre (n=123)	P Within GEM
Primary Outcome Variable								
HbA1c mean/SD change (%)	-0.59	(-1.01, -0.18)	8.17	0.005	-0.35	0.055	-0.95	< 0.001
Mechanism Variables								
PHQ9 (Depression symptoms)	-0.33	(-1.91, 1.26)	0.17	0.683	-0.44	0.541	-0.77	0.038
Diabetes knowledge	2.48	(1.49, 3.46)	24.83	< 0.001	0.18	0.690	2.65	< 0.001
BMI	-0.64	(-1.14, -0.14)	6.30	0.013	-0.63	0.005	-1.27	< 0.001
Carbohydrates (g) [CRC]	-11.6	(-17.19, -6.1)	17.23	< 0.001	-4.88	0.050	-16.45	< 0.001
Carbohydrates (g/day) [ASA24]	-51.0	(-80.7, -21.4)	11.70	0.001	-18.09	0.178	-69.13	< 0.001
Calories/day (ASA24)	-245.38	(-501.94, 11.18)	3.60	0.061	-35.82	0.756	-281.21	< 0.001
Steps/day (Fitbit)	191.90	(-784.41, 1168.21)	0.15	0.698	393.90	0.368	585.80	0.012
Hours Active (Fitbit)	-0.30	(-1.27, 0.66)	0.38	0.538	0.91	0.041	0.61	0.006
ΔBG MMTT [0-60 min] (mmol/L)	-0.7	(-1.4, -0.1)	5.48	0.021	0.5	0.082	-0.3	0.090
SMBG frequency past 30 day	9.54	(-0.24, 19.32)	3.71	0.056	6.40	0.143	15.94	< 0.001
Secondary Benefit Variables								
UKPDS (%)	-2	(-3, -1)	8.88	0.003	-1	0.171	-3	< 0.001
Glucose Monitoring Satisfaction Scale	0.11	(-0.09, 0.31)	1.24	0.267	0.26	0.003	0.37	< 0.001
Diabetes Empowerment Scale	1.65	(-0.16, 3.45)	3.26	0.073	1.36	0.096	3.01	< 0.001
Diabetes Distress (Emotional)	-0.08	(-0.41, 0.25)	0.23	0.629	-0.15	0.303	-0.23	0.002
Diabetes Distress (Regimen)	-0.28	(-0.69, 0.13)	1.86	0.175	-0.33	0.078	-0.61	< 0.001
Side Effect Variables								
LDL (mmol/L)	0.20	(-0.21, 0.62)	0.93	0.335	-0.15	0.427	0.06	0.579
HDL (mmol/L)	0.09	(-0.04, 0.23)	1.98	0.162	0.06	0.346	0.15	< 0.001
Triglycerides (mmol/L)	0.43	(-0.92, 1.79)	0.40	0.528	-1.87	0.002	-1.43	< 0.001
Total Cholesterol (mmol/L)	0.18	(-0.37, 0.74)	0.43	0.513	-0.22	0.383	-0.03	0.816
Total Fats/day (g) [ASA24]	-6.80	(-22.88, 9.28)	0.71	0.403	6.06	0.402	-0.74	0.832
Proteins (g) [ASA24]	-3.62	(-17.18, 9.94)	0.28	0.598	2.65	0.664	-0.97	0.741

Supplemental Table 3. Comparison of the three GEM versions on primary and secondary outcome variables.

Variables (Change)	GEM^D Mean (SD)		GEM^S Mean (SD)		GEM^C Mean (SD)		P
Primary Outcome Variable							
HbA1c (%)	-0.85	(1.54)	-1.11	(1.08)	-0.93	(0.96)	0.13
Mechanism Variables							
PHQ9 (Depression symptoms)	-0.55	(4.11)	0.00	(4.42)	-1.74	(5.13)	0.298
Diabetes knowledge	2.58	(2.61)	2.18	(2.70)	3.14	(2.44)	0.448
BMI	-1.33	(1.51)	-1.32	(1.32)	-1.16	(1.37)	0.844
Carbohydrates (g) [CRC]	-21.28	(23.83)	-14.17	(17.49)	-15.80	(14.06)	0.785
Total Carbohydrates (g/day) [ASA24]	-85.70	(81.50)	-46.90	(70.00)	-67.50	(73.70)	0.19
Calories/day (ASA24)	-382	(575)	-171	(572)	-183	(616)	0.293
Steps/day (Fitbit)	1461	(3614)	250	(2320)	210	(2246)	0.1
Hours Active (Fitbit)	0.75	(2.71)	0.66	(2.41)	0.38	(1.94)	0.622
ΔBG MMTT [0-60 min] (mmol/L)	0.09	(1.96)	-0.40	(1.93)	-0.30	(1.89)	0.922
SMBG frequency past 30 day	1.21	(22.38)	27.62	(34.99)	21.30	(30.41)	0.001
Secondary Benefit Variables							
UKPDS (%)	-2	(4)	-3	(5)	-4	(7)	0.431
Glucose Monitoring Satisfaction Scale	0.32	(0.52)	0.33	(0.57)	0.46	(0.57)	0.272
Diabetes Empowerment Scale	2.70	(4.35)	3.30	(6.17)	3.24	(4.89)	0.824
Diabetes Distress (Emotional)	-0.27	(1.13)	-0.03	(0.70)	-0.44	(0.96)	0.344
Diabetes Distress (Regimen)	-0.74	(1.42)	-0.43	(1.14)	-0.67	(1.17)	0.817
Side Effect Variables							
LDL (mmol/L)	0.03	(1.16)	0.10	(1.31)	0.08	(1.18)	0.792
HDL (mmol/L)	0.18	(0.33)	0.12	(0.25)	0.15	(0.46)	0.803
Triglycerides (mmol/L)	-0.93	(3.80)	-1.19	(3.55)	-2.95	(10.40)	0.816
Total Cholesterol (mmol/L)	0.10	(1.28)	0.09	(1.52)	-0.30	(2.16)	0.617
Total Fats/day (g) [ASA24]	-2.29	(33.27)	1.91	(35.34)	5.43	(33.01)	0.778
Proteins (g) [ASA24]	-4.30	(23.63)	0.72	(33.91)	7.79	(29.89)	0.305