Clinical evidence for high-risk CE-marked medical devices for glucose management: a systematic review and meta-analysis

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Abbreviations: AID system, automated insulin delivery system; HbA1c, glycated hemoglobin; TAR, time with sensor values above target range; TBR, time with sensor values below target range; TIR, time with sensor values in target range.

Supplemental table 1

Main baseline characteristics of included studies												
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)***	**Mean age (±sd) or median (IQR)**	**Age category (Age range)**	**Reported outcome**		
										HbA1c	**Other glycemic outcomes (CGM or blood glucose metrics)†**	**Safety**
Implantable CGM devices												
RCTs												
34984786	Renard, E.	2022	RCT: Parallel	26	239	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM‡	43.9 (NR)	Adults (≥18)	+	+	+
34196924	Boscari, F.	2022	RCT: Crossover	12	16	Eversense® CGM System (90 days)	Dexcom G5	48.8 (10.1)	Adults (≥18)	-	+	+
Observational studies												
31418587	Deiss, D.	2020	Longitudinal	111	3023	Eversense® CGM System (90 days) or Eversense® XL CGM System (180 days)		NR	Adults (≥18)	-	-	+
32037699	Irace, C.	2020	Longitudinal	26	100	Eversense® XL CGM System (180 days)		36 (12)	Adults (18-69)	+	+	+
31385732	Sanchez, P.	2019	Longitudinal	13	205	Eversense® CGM System (90 days)		NR	NR	-	-	+
Non-RIS												
30938036	Aronson, R.	2019	Non-RIS	26	36	Eversense® XL CGM System (180 days)		16.9 (9.2)	Adolescents, adults (≥12)	+	-	+
29381090	Christiansen, M. P.	2018	Non-RIS	13	90	Eversense® CGM System (90 days)		45.1 (16.2)	Adults (≥18)	-	-	+
30925083	Christiansen, M. P.	2019	Non-RIS	13	36	Eversense® CGM System (90 days)		51.6 (15.7)	Adults (≥18)	+	-	+

34515521	Garg, S. K.	2022	Non-RIS	26	181	Eversense® XL CGM System (180 days)		48.6 (14.9)	Adults (18-77)	+	-	+
27815290	Kropff, J.	2017	Non-RIS	26	71	Eversense® CGM System (90 days)		41.7 (12.6)	Adults (≥18)	+	-	+
Implantable insulin pumps												
RCTs												
24735100	Schaepelynck, P.	2014	RCT: Parallel	26	168	MiniMed MIP 2007C (+Insuman implantable 400 U/ml [recombinant human insulin])	MiniMed MIP 2007C (+Insuplant 400 U/ml [semisynthetic insulin])	53.4 (10.8)	Adults (≥18)	NA	NA	+
19740082	Liebl, A.	2009	RCT: Crossover	NR	60	DiaPort	CSII	47.9 (11.5)	Adults (≥18)	+	-	+
19429874	Logtenberg, S. J.	2009	RCT: Crossover	26	24	MiniMed MIP 2007C	ST: MDI or CSII	43.6 (11.8)	Adults (18-70)	+	+	+
Observational studies												
19048281	Haveman, J. W.	2010	Longitudinal	520	63	MiniMed MIP 2007C	MiniMed MIP 2001	37.4 (13.6)	NR	-	-	+
22912916	van Dijk, P. R.	2012	Longitudinal	NR	56	MiniMed MIP 2007C		37.6 (14.5)	Adults (NR)	-	-	+
26582805	van Dijk, P. R.	2015	Case-control	26	183	MiniMed MIP 2007C	MDI or CSII	50 (11.9)	Adults (18-70)	+	+	-
Automated insulin delivery systems: Hybrid closed loop systems												
RCTs												
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM#	15.3 (3.1)	Children, adolescents (12-25)	+	+	+
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps[1], with Dexcom G6 CGM	11.2 (2.09)	Children (6-13)	+	+	+
31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps[2], with CGM sensor#	33 (16.3)	Adolescents, adults (14-71)	+	+	+
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	33 (15.5)	Adolescents, adults (14-72)	+	+	+
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	40.6 (12.4)	Adults (19-69)	+	+	+
37551542	Edd, S. N.	2023	RCT: Parallel [###]	26	39	Medtronic 780G	MDI and isCGM	40.6 (12.7)	Adults (≥18)	+	+	+

31099946	Ekhlaspour, L.	2019	RCT: Parallel	0.29	48	Tandem Control-IQ	SAP: Personal insulin pump[3] with Dexcom G5 CGM	12.2 (3.1)	Children (6-12), adolescents (13-18)	-	+	-
30888835	Forlenza, G. P.	2019	RCT: Parallel	0.43	24	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	9.6 (1.8)	Children (6-12)	-	+	-
36472543	Garg, S. K.	2023	RCT: Parallel	26	302	Medtronic 670G	CSII	37.8 (19.2)	Children, adolescents, adults (2-80)	+	+	+
33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps[4], with Dexcom G6 CGM	17 (2.9)	Adolescents, adults (14-24)	+	+	+
33355258	Kanapka, L. G.	2021	RCT: Parallel	12	100	Tandem Control-IQ (after 16 weeks of SAP use)	Tandem Control-IQ (after 16 weeks of Control-IQ use)	11.5 (2.1)	Children (6-13)	NA	NA	+
37796241	Lee, T. M.	2023	RCT: Parallel	36	124 ¥¥¥	CamAPS FX	ST: MDI or CSII	31.1 (5.3)	Adults (18-45)	+	+	+
26049550	Ly, T. T.	2015	RCT: Parallel	0.85	21	Medtronic 670G	PLGS: Medtronic 530G with threshold suspend and Enlite sensor	18.6 (3.7)	Adolescents, adults (15-31)	-	+	+
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	40.3 (8)	Adults (26-60)	+	+	+
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	44.2 (11.7)	Adults (25-70)	+	+	+
38386437	Polsky, S.	2024	RCT: Parallel	32	24 †††	Medtronic 670G	SAP	31.1 (4.2)	Adults (18-45)	-	-	+
34816597	Renard, E.	2022	RCT: Parallel	36	119	Tandem Control-IQ (extended 24/7 use)	Tandem Control-IQ (evening/night use)	8.6 (1.6)	Children (6-12)	NA	NA	+
37729080	Renard, E.	2023	RCT: Parallel	12	72 ¥¥	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	47.2 (12.7)	Adults (19-74)	+	+	+
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	69.5 (8.7)	Adults (≥18)	+	+	+
32119790	Schoelwer, M. J.	2020	RCT: Parallel	1	18	Tandem Control-IQ (reinitialized with new parameters based on protocol)	Tandem Control-IQ (with home settings)	14.5 (1.6)	Adolescents (12-17)	NA	NA	+
36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	41.8 (14.4)	Adults (18-61)	+	+	+
36920756	Wadwa, R. P.	2023	RCT: Parallel	13	102	Tandem Control-IQ	ST: MDI or CSII	3.9 (1.2)	Children (2-6)	+	+	+

35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	13 (2.8)	Children, adolescents (6-18)	+	+	+
33323237	Benhamou, P.	2019	RCT: Crossover	32	63	Diabeloop DBLG1	SAP	48.2 (13.4)	Adults (≥18)	+	+	+
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	19 (4)	Adolescents (14-20), adults (21-29)	+	+	+
34270335	Bode, B.	2021	RCT: Crossover	4	42	Medtronic 670G (+ Ultrarapid lispro)	Medtronic 670G (+ lispro [Humalog®])	47.8 (13.8)	Adults (≥18)	NA	NA	+
33606901	Boughton, C. K.	2021	RCT: Crossover	8	25	CamAPS FX (+ fast-acting insulin aspart [FIASP])	CamAPS FX (+ standard insulin aspart)	38 (9)	Adults (≥18)	NA	NA	+
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	68 (63-70)	Adults (≥60)	+	+	+
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	35.8 (11.2)	Adolescents, adults (12-55)***	+	+	-
33579715	Collyns, O. J.	2021	RCT: Crossover	4	60	Medtronic 670G pump in advanced hybrid closed loop mode	PLGS: Medtronic 670G pump in SAP with PLGS mode	23.5	Children, adolescents, adults (7-80)	-	+	+
37404205	Dovc, K.	2023	RCT: Crossover	8	30	Medtronic 670G + faster acting insulin aspart	Medtronic 670G + standard insulin aspart	15 (1.7)	Children, adolescents (10-18)	NA	NA	+
32520594	Hsu, L.	2021	RCT: Crossover	2	19	Medtronic 670G (+ standard insulin aspart [Novolog®])	Medtronic 670G (+ fast-acting insulin aspart [FIASP®])	40.4 (17.7)	Adults (18-76)	NA	NA	+
31796571	Lee, M. H.	2020	RCT: Crossover	0.14	12	Medtronic 670G (with high intense exercise)	Medtronic 670G (with moderate intense exercise)	53 (42-57)	Adults (>18)	NA	NA	+
34362816	Lee, M. H.	2021	RCT: Crossover	6	25	Medtronic 780G (+ fast-acting insulin aspart)	Medtronic 780G (+ standard insulin aspart)	48 (37-57)	Adults (≥18)	NA	NA	+
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	67 (5)	Adults (60-75)	+	+	+
34524022	Morrison, D.	2022	RCT: Crossover	6	16	Medtronic 780G (+ fast-acting insulin aspart)	Medtronic 780G (+ standard insulin aspart)	48 (37-57)	Adults (≥18)	NA	NA	+

37823892	Nwokolo, M.	2023	RCT: Crossover	16	28	CamAPS FX + ultra-rapid insulin lispro	CamAPS FX + standard insulin lispro	44.5 (10.7)	Adults (≥18)	NA	NA	+
33090016	Ozer, K.	2021	RCT: Crossover	7	37	Medtronic 670G (+ fast-acting insulin aspart)	Medtronic 670G (+ standard insulin aspart)	45.7 (12.9)	Adults (>18)	NA	NA	+
34789504	Paldus, B.	2022	RCT: Crossover	0.08	32	Medtronic 670G (combined with high intensity exercise, moderate intensity exercise, resistance exercise in random order)		38 (9)	Adults (24-60)	NA	NA	+
30620641	Paldus, B.	2019	RCT: Crossover	1	11	Medtronic 770G	Medtronic 670G	51 (15)	Adults (≥18)	-	+	+
35373894	von dem Berge, T.	2022	RCT: Crossover	18	38	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	8.7 (3.5)	Children (7-14)	+	+	+
35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP[#]	5.6 (1.6)	Children (1-7)	+	+	+
36880866	Ware, J.	2023	RCT: Crossover	20	25	CamAPS FX and Fiasp	CamAPS FX and standard insulin aspart	5.1 (1.3)	Children (2-6)	NA	NA	+
Observational studies												
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		41 (12)	Adults (21-68)	+	+	-
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		44.7 (11.1)	Adults (≥18)	+	+	+
35136338	Amole, M.	2021	Longitudinal	26	37	Medtronic 670G		59.1 (14.4)	Adults (NR)##	+	-	-
35414272	Arunachalum, S.	2023	Longitudinal	52	2627	Medtronic 670G		NR	Children, adolescents, adults (≥7)	-	+	-
38459160	Atik-Altinok, Y.	2024	Longitudinal	24	29	Medtronic 780G		12.7 (4.3)	Children, adolescents, adults (5-22)	+	-	-
35116007	Bassi, M.	2022	Longitudinal	4	90	Tandem Control-IQ	Medtronic 780G	20.8 (13.2)	Children, adults (NR)	-	+	-
36777356	Bassi, M.	2023	Longitudinal	52	32	Tandem Control-IQ		15.5 (10.5; 19.9)	Children, adults (NR)	-	+	-
31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		28 (15)	Children, adults (7-63)	+	+	+

36030902	Beato-Vibora, P. I.	2022	Longitudinal	52	135	Medtronic 780G		35 (15)	Children, adults (NR)	-	+	+
30862242	Berget, C.	2020	Longitudinal	4	72	Medtronic 670G		14 (4.3)	Children (NR)	-	+	-
31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		15.7 (3.6)	Children, adults (2-25)	+	+	-
33784196	Breton, M. D.	2021	Longitudinal	52	9451	Tandem Control-IQ		41.9 (20.8)	Children, adolescents, adults (6-91)	-	+	-
34227214	Cherubini, V.	2021	Longitudinal	12	43	Tandem Control-IQ		12 (9-13)	Children, adolescents (7-16)	+	+	+
36724301	Chico, A.	2023	Longitudinal	12	62	Diabeloop DBLG1		44.2 (11)	Adults (>18)	+	+	+
32212971	Cobry, E. C.	2020	Longitudinal	13	37	Medtronic 670G		13.9 (2.3)	Children, adolescents (10-17)	+	-	-
37252734	Cordero, T. L.	2023	Longitudinal	12	176	Medtronic 780G		24.2 (19.1)	Children, adolescents, adults (≥7)	NA	NA	+
33961340	Da Silva, J.	2021	Longitudinal	52	880	Medtronic 670G		NR	NR	-	+	-
DOI in footnote	Del Valle Rolón, M.E.	2023	Longitudinal	52	136	Tandem Control-IQ		13.3 (NR)	Children, adolescents, adults (<25)	+	+	-
34524023	Dubose, S. N.	2021	Longitudinal	52	80	Medtronic 670G		31.8 (17.1-51.0)	Children, adults (7.2–74)	+	+	+
37845757	Elbarbary, N. S.	2023	Longitudinal	24	107	Medtronic 780G		16.01 (8.9)	Children, adolescents, adults (3-71)	-	+	+
30865545	Faulds, E. R.	2019	Longitudinal	12	34	Medtronic 670G		45.9 (11.8)	Adults (22-69)	+	+	-
33450533	Gomez, A. M.	2021	Longitudinal	2	91	Medtronic 670G		33 (17–71)	Adolescents, adults (>14)	-	+	+
DOI in footnote	Gouet, D.	2022	Longitudinal	52	83	Medtronic 780G		47.5 (14.6)	Adults (19-74)	-	+	+
37782904	Graham, R.	2024	Longitudinal	52	3157	Tandem Control IQ		29 (16-45)	Children, adolescents, adults (≥6)	-	-	+
36789699	Grassi, B.	2023	Longitudinal	19	459	Medtronic 780G		NR	Children, adolescents, adults (NR)	-	+	-
37956265	Guibert, C	2023	Longitudinal	37	13	Medtronic 780G		33.1 (3.2)	Adults (NR)	-	-	+
38444313	Halim, B.	2024	Longitudinal	52	1501	Medtronic 780G		NR	Children, adolescents, adults (NR)	-	+	-
37905353	Henry, Z.	2024	Longitudinal	52	231	Medtronic 780G (72%), Tandem Control IQ (28%)		34.6 (32.5-36.8)	Children, adolescents, adults (10-77)	+	+	+
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		41 (13.6)	Adolescents, adults (16-60)	+	+	+
35099298	Jacobsen, S. S.	2022	Longitudinal	52	55	Medtronic 670G		45.6 (12.6)	Adults (NR)	+	+	-
33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	44.2 (12.1)	Adults (NR)	+	+	+

34569850	Ju, Z.	2022	Longitudinal	52	22	Medtronic 670 G		36.7 (9.4)	Adults	+	-	-
36126177	Kovatchev B. P.	2022	Longitudinal	12	19354	Tandem Control-IQ		39 (19-58)	Children, adolescents, adults (1-92)	-	+	-
38236643	Lablanche, S.	2024	Longitudinal	52	220	Medtronic 780G		43 (17)	NR	+	+	+
31548247	Lal, R. A.	2019	Longitudinal	52	79	Medtronic 670G		27.2 (15.3)	Children, adolescents, adults (>7)	+	-	-
38225516	Landau, Z.	2024	Longitudinal	52	46	Medtronic 780G	Open source automated insulin delivery system	12.2 (3.6)	Children, adolescents, adults (7-21)	+	+	+
38579305	Lehmann, V.	2023	Longitudinal	36	44	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G		38.5 (28.5-51)	Adults (>18)	+	+	-
37959415	Lendínez-Jurado, A.	2023	Longitudinal	12	28	Medtronic 780G		12 (2.43)	Children, adolescents (7-17)	+	+	-
37337407	Lendínez-Jurado, A.	2023	Longitudinal	24	28	Medtronic 780G		NR	Children, adolescents (6-17)	+	+	-
37902785	Lepore, G.	2024	Longitudinal	104	296	Medtronic 780G		42.8 (16.5)	Adults (≥18)	-	+	+
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		13.1 (3.1)	Children, adolescents (7-18)	+	+	-
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		58	Adults (25-70)	+	+	-
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		11.7 (9.4, 14.6)	Children, adolescents, adults (2-21)	+	+	-
37184526	Matejko, B.	2023	Longitudinal	52	18	Medtronic 780G		40.9 (7.6)	Adults (26-60)	+	-	-
34096789	Messer, L. H.	2021	Longitudinal	26	191	Tandem Control-IQ		14 (10-16)	Children, adolescents, adults (NR)	-	+	+
DOI in footnote	Mutlu, G. Y.	2023	Longitudinal	12	25	Medtronic 780G		10.5 (2.5)	Children, adolescents (6-19)	-	+	+
36940793	Nattero-Chavez, L.	2023	Longitudinal	24	46	Medtronic 780G		37 (15)	Adults (>18)	+	+	-
35488481	Ng, S. M.	2022	Longitudinal	12	39	Tandem Control-IQ (91%), CamAPS FX (9%)		11.8 (4.4)	Children, adolescents (2.6-18)	+	+	+
36424877	Ng, S. M.	2023	Longitudinal	24	251	Tandem Control-IQ (78%), Medtronic 780G (11%), CamAPS FX (11%)		12.3 (3.5)	Children, adolescents (2-19)	+	+	-
37902713	Nigi, L.	2024	Longitudinal	52	22	Medtronic 780G		43.9 (12.2)	Adults (≥18)	+	-	+
37708979	Papa, G.	2023	Longitudinal	52	54	Medtronic 670G (41%), Medtronic 780G (59%)		38.2 (14.5)	Adults (18-65)	+	+	+

33044604	Petrovski, G.	2021	Longitudinal	52	30	Medtronic 670G		10.2 (2.6)	Children, adolescents (7-18)	+	+	+
36317539	Piccini, B.	2022	Longitudinal	24	44	Medtronic 780G		14.2 (4)	Children, adolescents (6.1; 21.9)	+	+	+
38068733	Piccini, B.	2023	Longitudinal	24	83	Medtronic 780G		13 (4.5)	Children, adolescents, adults (3.3-22.3)	+	+	+
32846114	Pinsker, J. E.	2021	Longitudinal	4	1127¥	Tandem Control-IQ		45.5 (16.6)	Adolescents, adults (≥14)	-	+	-
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		43.4 (14.2)	Adults (≥18)	+	+	+
34668782	Proietti, A.	2022	Longitudinal	26	30	Medtronic 670G		31.5 (15.4); 31.5 (9–57)	Children, adults (NR)	-	+	+
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		48 (40-57)	Adults (NR)	+	+	+
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		13.9 (11-18)	Children, adolescents, adults (7.7-24)	+	+	-
37956944	Rossi, A.	2023	Longitudinal	12	60	Medtronic 780G	PLGS	45.7 (2.4)	Adults (≥18)	-	+	+
31166801	Salehi, P.	2019	Longitudinal	27	16	Medtronic 670G in auto-mode	Medtronic 670G in manual mode with low glucose suspend	4.3 (1.2)	Children (2-6)	+	+	+
35451679	Schiaffini, R.	2022	Longitudinal	4	31	Tandem Control-IQ (55%), Medtronic 780G (45%)		13.05 (2.4)	Children, adolescents (7.6-18)	-	+	-
35020476	Scully, K. J.	2022	Longitudinal	13	13	Tandem Control-IQ		38.5 (4.1)	Adolescents, adults (15.5–64.6)	-	+	-
34524003	Silva, J. D.	2022	Longitudinal	NR	4120	Medtronic 780G		NR	NR	-	+	-
30160523	Stone, M. P.	2018	Longitudinal	13	3141	Medtronic 670G		NR	Children, adolescents, adults (≥7)	-	+	-
34725723	Thivolet, C.	2021	Longitudinal	13	121	Medtronic 780G	SAP with standalone CGM or SAP with PLGS (Tandem t:slim X2 insulin pump with Basal-IQ and Dexcom G6 CGM)	32 (20.2-41.4)	Adolescents, adults (NR)	+	+	+
38377317	Thrasher, J.R.	2024	Longitudinal	5	3851	Medtronic 780G		NR	NR	-	+	-
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	13.3 (2- 21)	Children, adolescents (NR)	+	+	-
34609917	Toschi, E.	2022	Longitudinal	13	48	Tandem Control-IQ		70 (4)	Adults (≥65)	-	+	-
33430621	Usoh, C. O.	2021	Longitudinal	4	80	Medtronic 670G		42.5 (16.2)	Children, adults (NR)	+	+	-

36280026	Usoh, C. O.	2023	Longitudinal	78	66	Tandem Control IQ		42 (18)	Adults (≥18)	+	+	-
34015178	Varimo, T.	2021	Longitudinal	52	111	Medtronic 670G		9.7 (3.2)	Children, adolescents (3-16)	+	+	+
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		12.2 (3.2)	Children (NR)	+	+	-
33958309	Wang, L. R.	2021	Longitudinal	NR	21	Medtronic 670G		50 (13)	Adults (NR)	+	-	+
DOI in footnote	Zuijdwijk, C.	2023	Longitudinal	16	59	Tandem Control IQ		13.8 (11.1; 15.7)	Children, adolescents (6-18)	-	+	-
33838993	Beato-Vibora, P. I.	2021	Cross-sectional	NA	302	Medtronic 670G	Group 1: CGM and MDI; Group 2: FGM and MDI; Group 3: SAP with PLGS	39.4 (12)	Adults (NR)	-	+	-
34058303	Horowitz, M. E.	2021	Cross-sectional	NA	84	Medtronic 670G		51 (21-77)	Adults (≥18)	+	+	-
31347928	Kaur, H.	2019	Case-control	26	14	Medtronic 670G (in adults with T1D with gastroparesis)	Medtronic 670G (in adults with T1D without gastroparesis)	49.6 (5.3)	Adults (≥18)	NA	NA	+
31617752	Lepore, G.	2020	Case-control	26	40	Medtronic 670G	PLGS: Medtronic 640G with Guardian 3	44 (15.6)	Adults (NR)	+	+	+
Non-RIS												
30239219	Adams, R. N.	2018	Non-RIS	0.71	29	Medtronic 670G		23 (7.7)	Adolescents, adults (14-40)	-	+	-
33431420	Amadou, C.	2021	Non-RIS	26	25	Diabeloop DBLG1		43 (13.8)	Adults (25-72)	+	+	+
33784187	Beato-Vibora, P. I.	2021	Non-RIS	4	52	Medtronic 780G		43 (12)	Adolescents, adults (15-65)	-	+	+
34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		43 (12)	Adolescents, adults (15-65)	+	+	+
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	9.1 (0.9)	Children (7-10)	+	+	-
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	68.7 (3.3)	Adults (65-75)	+	+	-
36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		18.8 (13.3–25.7)	Adolescents, adults (13-25)	+	+	+
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		24.5 (16.8)	Children (6-13.9), adults (14-70)	+	+	+
34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		38.3 (17.6)	Adolescents (14-21), adults (22-75)	+	+	+

38439656	Carlson, A. L.	2024	Non-RIS	13	34	Tandem Control-IQ		39.9 (11.9)	Adults (20-66)	+	-	+
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		23.8 (16.6)	Children, adolescents, adults (6-70)	+	+	+
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		60.6 (8.1)	Adults (18-75)	+	+	+
37578778	Davis, G. M.	2023	Non-RIS	1.42	18	Omnipod 5		59 (14)	Adults (32-83)	-	-	+
37598004	Delgado, A. M.	2023	Non-RIS	52	71	Tandem Control-IQ		12.7 (3.2)	Children, adolescents (6-18)	+	+	+
38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		4.7 (1)	Children (2-5.9)	+	+	+
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		34.3 (11.1)	Adults (>18)	+	+	+
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		10.8 (1.8)	Children (7-13)	+	+	+
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		4.6 (1.4)	Children (2-6)	+	+	+
33325779	Forlenza, G. P.	2021	Non-RIS	3	36	Omnipod 5		22.8 (14.7)	Children (6-13.9), adults (14-70)	-	+	+
28134564	Garg, S. K.	2017	Non-RIS	13	124	Medtronic 670G		37.8 (16.5)	Adolescents (14-21), adults (22-75)	+	+	+
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		14.5 (1.7)	Children, adolescents (10-18)	+	+	+
31264889	Lee, M. H.	2019	Non-RIS	5	12	Medtronic 670G‡‡		48 (39-57)	Adults (≥18)	-	+	+
27191182	Ly, T. T.	2017	Non-RIS	0.71	24	Medtronic 670G		21.1 (7.2)	Adolescents, adults (14-40)	-	+	-
38032850	Mameli, C.	2024	Non-RIS	0.28	24	Tandem Control-IQ (first endurance workout, followed by power workout)	Tandem Control-IQ (first power workout, followed by endurance workout)	14.1 (2)	Children, adolescents (9.8; 17.7)	NA	NA	+
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		14.8 (12.3; 18)	Children, adolescents, adults (6-21)	+	+	+
29444895	Messer, L. H.	2018	Non-RIS	13	31	Medtronic 670G		17.8 (3.9)	Adolescents, adults (14-75)	+	+	-
37823890	Michaels, V. R.	2024	Non-RIS	52	20	Medtronic 780G		18.8 (13.3–25.7)	Adolescents, adults (13-25)	+	+	+
34120699	Nally, L. M.	2021	Non-RIS	24	17	Medtronic 670G		15.9 (2.5)	Adolescents, adults (13-26)	-	-	+
33185480	Nimri, R.	2021	Non-RIS	4	12	Medtronic 780G		16.6 (15.9-18.2)	Adolescents, adults (14-40)	-	+	+
31953687	Petrovski, G.	2020	Non-RIS	12	30	Medtronic 670G		10.2 (2.6)	Children, adolescents (7-18)	+	+	+
35072781	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		12.5 (3.7)	Children, adolescents (7-17)	+	+	+

35351095	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		12.5 (3.7)	Children, adolescents (7-17)	+	+	+
37782145	Pinhoker, C.	2023	Non-RIS	12	160	Medtronic 670G		11.3 (2.5)	Children, adolescents (7-17)	+	+	+
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		4.3 (1.3)	Children (2-6)	+	+	+
38514384	Pulkkinen, M.	2024	Non-RIS	39	35	Medtronic 780G		4.3 (1.3)	Children (2-6)	-	+	+
35852811	Seget, S	2022	Non-RIS	4	50	Medtronic 780G		11 (3.4)	Children, adolescents (5.5-19.6)	-	+	-
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		4.7 (1)	Children (2-5.9)	+	+	+
Automated insulin delivery systems: Fully closed loop systems												
RCTs												
35880252	Herzig, D.	2022	RCT: Parallel	2.8	44 [‡‡‡]	CamAPS HX	Standard insulin therapy	68.4 (12.6)	Adults (≥18)	-	+	+
33397767	Blauw, H.	2021	RCT: Crossover	2	23	Inreda AP (closed loop period)	Personal insulin pump therapy with CGM# (if present), with masked CGM (Dexcom G6) (open loop period)	43 (26.5-51)	Adults (18-75)	-	+	+
34349267	Boughton, C.	2021	RCT: Crossover	3	26	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	68.3 (11.2)	Adults (≥18)	-	+	+
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	59 (11)	Adults (≥18)	+	+	+
36069928	Van Veldhuisen, C.L.	2022	RCT: Crossover	2	12 [††]	Inreda AP	ST: MDI or CSII	62.5 (43.1; 74)	Adults (≥18)	-	+	+
Observational studies												
36947090	Boughton, C. K.	2023	Longitudinal	52	32	CamAPS HX		61 (16)	Adults (NR)	-	-	+
Non-RIS												
38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		47.7 (12.4)	Adults (18-75)	+	+	+

Rows highlighted in blue indicate studies comparing several approaches (eg, different insulin compounds, different physical activity levels) in combination with the same medical device or studies comparing different characteristics of the same medical device (eg, different times of use, different settings). These studies are relevant for safety outcomes, but not for efficacy outcomes.
The term “Standard therapy” refers to participants` usual treatment modalities.
*For studies in which no comparison group is specified, only pre-post intervention analysis was performed.
**Follow-up over multiple cycles of sensor use
***With impaired hypoglycaemia awareness

†including time with sensor values within, above and below the target range
†† after total pancreatectomy
††† Women followed-up during second and third trimesters of pregnancy and early postpartum
‡ Usual glucose monitoring system used by participants
‡‡ including refinements
‡‡‡ Patients who underwent elective surgery were followed-up in the hospital
#Manufacturer not specified
##Older veterans
Results of the 6 months continuation phase are shown for participants in the control arm (MDI plus isCGM) who switched to the AID system (referred in the study as the SWITCH group).
¥Number of participants who had data before and after applying Tandem Control-IQ.
¥¥ Participants at high risk of hypoglycemia.
¥¥¥ Pregnant women who were recruited as soon as possible after confirmation by ultrasonography of a viable pregnancy and before 14 weeks' gestation
[1] Personal insulin pump or (for those not on pump before trial) t:slim X2 pump with PLGS.
[2] Personal insulin pump or (for those not on pump before trial) insulin pump without PLGS feature.
[3] Personal insulin pumps included Tandem t:slim, Insulet Omnipod, Medtronic pumps. Animas Ping.
[4] Personal insulin pump or (for those not on pump before trial) t:slim X2 insulin pump without Control-IQ technology.
Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; HbA1c, glycated hemoglobin; MDI, multiple daily insulin injection therapy; non-RIS, non-randomized interventional study; NA, not applicable; NR, not reported; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy: +, Yes; -, No.

Supplemental table 2

Additional characteristics of included studies										
PMID	**First author**	**Year of publication**	**Study setting**	**Age-specific subgroup analysis**	**Sex-specific subgroup analysis**	**% Males**	**Type of diabetes**	**Diabetes duration (years), mean**	**HbA1c (%), mean**	**Baseline treatment against diabetes**
Implantable CGM devices										
RCTs										
34984786	Renard, E.	2022	Outpatient / Home	-	-	55.1	T1DM and T2DM	21.6	8.3	MDI or CSII
34196924	Boscari, F.	2022	Outpatient / Home	-	-	81	T1DM	29.8	7.4	ST
Observational studies										
31418587	Deiss, D.	2020	Outpatient / Home	-	-	NR	T1DM and T2DM	NR	NR	NR
32037699	Irace, C.	2020	Outpatient / Home	-	-	53	T1DM	16	7.4	ST
31385732	Sanchez, P.	2019	Outpatient / Home	-	-	54	T1DM and T2DM	NR	NR	NR
Non-RIS										
30938036	Aronson, R.	2019	Outpatient / Home	+	-	64.1	T1DM	8.3	8	ST
29381090	Christiansen, M. P.	2018	Outpatient / Home	-	-	60	T1DM and T2DM	20.1	7.6	ST
30925083	Christiansen, M. P.	2019	Outpatient / Home	-	-	51.4	T1DM and T2DM	26	7.8	ST
34515521	Garg, S. K.	2022	Outpatient / Home	-	-	47	T1DM and T2DM	22	7.6	ST
27815290	Kropff, J.	2017	Outpatient / Home	-	-	59.2	T1DM and T2DM	22.2	7.6	ST
Implantable insulin pumps										
RCTs										
24735100	Schaepelynck, P.	2014	Outpatient / Home	-	-	50.6	T1DM	32.4	7.7	MiniMed MIP 2007C + Insuplant
19740082	Liebl, A.	2009	Outpatient / Home	-	-	58	T1DM	25.7	8.3	CSII
19429874	Logtenberg, S. J.	2009	Outpatient / Home	-	-	46	T1DM	22.6	8.6	ST
Observational studies										
19048281	Haveman, J. W.	2010	Outpatient / Home	-	-	25.3	T1DM	16.7	NR	NR
22912916	van Dijk, P. R.	2012	Outpatient / Home	-	-	32	T1DM	17.6	NR	NR
26582805	van Dijk, P. R.	2015	Outpatient / Home	-	-	36.8	T1DM	26.6	8	ST
Automated insulin delivery systems: Hybrid closed loop systems										

RCTs										
34633418	Abraham, M. B.	2021	Outpatient / Home	-	-	44	T1DM	7.7	7.7	ST
32846062	Breton, M. D.	2020	Outpatient / Home	+	+	50.3	T1DM	5.2	7.7	ST
31618560	Brown, S. A.	2019	Outpatient / Home	+	+	50	T1DM	16.8	7.4	CSII
32471910	Brown, S. A.	2020	Outpatient / Home	+	+	51.5	T1DM	18.1	7.1	Tandem Control-IQ (applied during an RCT performed 6 months before study start)
36058207	Choudhary, P.	2022	Outpatient / Home	-	-	53.7	T1DM	18.5	9	ST
37551542	Edd, S.N.	2023	Outpatient / Home	-	-	49	T1DM	18.6	9	MDI
31099946	Ekhlaspour, L.	2019	Diabetes camp	+	-	50	T1DM	5.4	7.8	CSII
30888835	Forlenza, G. P.	2019	Outpatient / Home	-	-	50	T1DM	4.6	7.4	ST
36472543	Garg, S.K.	2022	Outpatient / Home	-	-	45.5	T1DM	20.5	8.2	CSII
33216667	Isganaitis, E.	2021	Outpatient / Home	+	-	57	T1DM	7.2	7.9	CSII
33355258	Kanapka, L. G.	2021	Outpatient / Home	-	-	50.8	T1DM	5.5	7.6	SAP
37796241	Lee, T. M.	2023	Outpatient / Home	-	NA	0	T1DM	17.4	7	MDI or CSII
26049550	Ly, T. T.	2015	Diabetes camp	-	-	NR	T1DM	9.1	8.6	ST
35972259	Matejko, B.	2022	Outpatient / Home	-	-	57	T1DM	18.5	7.2	MDI and self-monitoring of blood glucose
33055139	McAuley, S. A.	2020	Outpatient / Home	-	-	46.5	T1DM	24	7.4	ST
38386437	Polsky, S.	2024	Outpatient / Home	-	NA	0	T1DM	19.3	6.8	SAP
34816597	Renard, E.	2022	Outpatient / Home	-	-	58.8	T1DM	5.2	7.7	CSII
37729080	Renard, E	2023	Outpatient / Home	-	-	28	T1DM	27.9	7.2	CSII
37921083	Reznik, Y.	2023	Outpatient / Home	-	-	30.8	T1DM	18.7	9.1	MDI
32119790	Schoelwer, M. J.	2020	60 h Skicamp, 5 days outpatient follow-up	-	-	50	T1DM	NR	7.7	Tandem Control-IQ (with home settings, 5 days before study start)
36949671	Van den Heuvel, T.	2023	Outpatient / Home	-	-	54	T1DM	15.9	9.1	MDI and real time CGM
36920756	Wadwa, R. P.	2023	Outpatient / Home	-	-	49	T1DM	2.4	7.2	ST: MDI or CSII
35272971	Ware, J.	2022	Outpatient / Home	-	-	43	T1DM	6.5	8.3	CSII
33323237	Benhamou, P. Y.	2019	Outpatient / Home	-	-	38	T1DM	28	7.6	CSII
33453783	Bergenstal, R. M.	2021	Outpatient / Home	+	+	38	T1DM	11.3	7.9	CSII or MDI

34270335	Bode, B.	2021	Outpatient / Home	-	-	35.7	T1DM	29.6	7.1	ST
33606901	Boughton, C. K.	2021	Outpatient / Home	-	-	48	T1DM	22	7.4	CSII
35359882	Boughton, C. K.	2922	Outpatient / Home	-	-	21	T1DM	38	7.4	CSII
33555982	Burckhardt, M. A.	2021	Outpatient / Home	-	-	29	T1DM	24.2	7.8	ST
33579715	Collyns, O. J.	2021	Outpatient / Home	+	-	42	T1DM	13.2	7.6	PLGS
37404205	Dovc, K.	2023	Outpatient / Home	+	+	47	T1DM	7.8	7.5	CSII
32520594	Hsu, L.	2021	Outpatient / Home	-	-	53	T1DM	26.6	NR	ST
31796571	Lee, M. H.	2020	Outpatient / Home	-	-	50	T1DM	28	NR	ST
34362816	Lee, M. H.	2021	Outpatient / Home	-	-	52	T1DM	25.7	NR	ST
34844995	McAuley, S. A.	2022	Outpatient / Home	-	-	37	T1DM	35	7.6	CSII
34524022	Morrison, D.	2022	Outpatient / Home	-	-	56	T1DM	29.3	NR	ST
37823892	Nwokolo, M.	2023	Outpatient / Home	-	-	64	T1DM	29.6	7.1	CSII
33090016	Ozer, K.	2021	Outpatient / Home	-	-	67.6	T1DM	NR	7	Medtronic 670G + Insulin analogue
34789504	Paldus, B.	2022	Exercise: Clinical research facility. Follow-up: Home	-	-	53	T1DM	22.6	7.1	CSII
30620641	Paldus, B.	2019	Hotel	-	-	18	T1DM	26.4	7.5	ST
35373894	von dem Berge, T.	2022	Outpatient / Home	+	-	44.7	T1DM	4.3	7.4	CSII
35045227	Ware, J.	2022	Outpatient / Home	-	-	58	T1DM	2.6	7.3	ST
36880866	Ware, J.	2023	Outpatient / Home	-	-	68	T1DM	2.4	7.2	CSII
Observational studies										
31789447	Akturk, H. K.	2020	Outpatient / Home	-	+	39.4	T1DM	NR	7.6	SAP
37236365	Amigo, J.	2023	Outpatient / Home	+	+	25.8	T1DM	27.2	7.4	Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6
35136338	Amole, M.	2021	Outpatient / Home	-	-	94.6	T1DM	25.3	7.6	ST
35414272	Arunachalum, S.	2023	Outpatient / Home	-	-	NR	T1DM	NR	NR	ST
38459160	Atik-Altinok, Y.	2024	Outpatient / Home	+	+	51.7	T1DM	2.2	6.9	Medtronic 780G in manual mode
35116007	Bassi, M.	2022	Outpatient / Home	+	-	52.2	T1DM	11	7.5	ST

36777356	Bassi, M.	2023	Outpatient / Home	-	-	51	T1DM	9.8	7.4	MDI, SAP, PLGS
31855446	Beato-Vibora, P. I.	2020	Outpatient / Home	-	-	41	T1DM	15	7.4	ST
36030902	Beato-Vibora, P. I.	2022	Outpatient / Home	+	-	36	T1DM	21	7.3	MDI or CSII
30862242	Berget, C.	2020	Outpatient / Home	-	-	54	T1DM	NR	8.7	Medtronic 670G in MM (during 1 week run-in period)
31837064	Berget, C.	2020	Outpatient / Home	+	-	50	T1DM	7	8.8	Medtronic 670G in MM (during 1-2 weeks run-in period)
33784196	Breton, M. D.	2021	Outpatient / Home	+	-	48	T1DM and T2DM	NR	NR	PLGS
34227214	Cherubini, V.	2021	Outpatient / Home	-	-	46.5	T1DM	NR	NR	PLGS Basal-IQ
36724301	Chico, A.	2023	Outpatient / Home	-	-	31	T1DM	24.6	7.47	CSII or MDI
32212971	Cobry, E. C.	2020	Outpatient / Home	-	-	37.9	T1DM	6.5	8.3	ST
37252734	Cordero, T. L.	2023	Outpatient / Home	+	-	NR	T1DM	6.6 children and 27.1 adults	7.2 children and 6.8 adults	HCL and Guardian 3 sensor
33961340	Da Silva, J.	2021	Outpatient / Home	-	-	NR	NR	NR	NR	Medtronic 670G in MM (during ≥10 days run-in period)
DOI in footnote	Del Valle Rolón, M. E.	2023	Outpatient / Home	-	-	50	T1DM	5 nonminority, 4.7 minority youth	7.9 nonminority, 9.8 minority youth	MDI or CSII
34524023	Dubose, S. N.	2021	Outpatient / Home	-	-	41	T1DM	18.2	8.4	ST
37845757	Elbarbary, N. S.	2023	Outpatient / Home	+	-	48	T1DM	5.0	NR	MDI or PLGS
30865545	Faulds, E. R.	2019	Outpatient / Home	-	-	50	T1DM	27.8	7.5	ST (for outcome HbA1c); Medtronic 670G in MM, 2 weeks run-in period (for other glycemic outcomes)
33450533	Gomez, A. M.	2021	Outpatient / Home	-	-	43.4	T1DM	18.2	7.1	Medtronic 670G in MM (during 2 weeks run-in period)
DOI in footnote	Gouet, D.	2022	Outpatient / Home	-	-	40	T1DM	23.1	NR	CSII
37782904	Graham, R.	2024	Outpatient / Home	+	-	44.3	T1DM	NR	7.7	ST
36789699	Grassi, B.	2023	Outpatient / Home	+	-	NR	T1DM	NR	NR	Cohort 1: Minimed 640G Cohort 2: Minimed 670G
37956265	Guibert, C.	2023	Outpatient / Home	-	NA	0	T1DM	19	6.4	Medtronic 780

38444313	Halim, B.	2024	Outpatient / Home	+	-	NR	T1DM	NR	NR	Medtronic 670G/770G
37905353	Henry, Z.	2023	Outpatient / Home	+		45	T1DM	20.7	7.86	SAP or PLGS
36108305	Herguido, N. G.	2023	Outpatient / Home	-	-	40	T1DM	28	7.2	CSII
35099298	Jacobsen, S. S.	2022	Outpatient / Home	-	-	42	T1DM	28.2	7.4	ST
33999488	Jeyaventhan, R.	2021	Outpatient / Home	-	-	48.5	T1DM	28.2	7.5	SAP
34569850	Ju, Z.	2022	Outpatient / Home	-	-	31.25	T1DM	20	7.75	ST
36126177	Kovatchev, B. P.	2022	Outpatient / Home	+	+	44.6	T1DM	NR	7.5	PLGS: Basal-IQ with CGM
38236643	Lablanche, S.	2024	Outpatient / Home	-	-	NR	T1DM	26	7.6	CSII
31548247	Lal, R. A.	2019	Outpatient / Home	+	+	57	T1DM	14.2	8	ST
38225516	Landau, Z.	2024	Outpatient / Home	-	-	57.7	T1DM	2.9	6.8	ST
38579305	Lehmann, V.	2023	Outpatient / Home	-	-	63.6	T1DM	22.2	6.9	Cohort 1: Medtronic 640G; Cohort 2: Medtronic 670G
37959415	Lendínez-Jurado, A.	2023	Outpatient / Home	+	-	57	T1DM	7.84	7.34 younger, 6.68 oldest	CSII
37337407	Lendínez-Jurado, A.	2023	Outpatient / Home	+	-	57	T1DM	NR	7.02	CSII
37902785	Lepore, G.	2024	Outpatient / Home	+	-	41.9	T1DM	8.0	22.5	MDI or CSII or SAP/PLGS or HCL (Medtronic 760G)
36763343	Lombardo, F.	2023	Outpatient / Home	+	-	45.9	T1DM	7.2	5.4	MDI or CSII
33628834	Malone, S. K.	2021	Outpatient / Home	-	-	33	T1DM	41	7.3	ST
37646634	Marks, B. E.	2023	Outpatient / Home	+	-	49.7	T1DM	7.5	3.3	MDI or CSII
37184526	Matejko, B.	2023	Outpatient / Home	-	-	55.5	T1DM	NR	7.1	MDI
34096789	Messer, L. H.	2021	Outpatient / Home	-	-	52.6	T1DM	NR	NR	ST
DOI in footnote	Mutlu, G. Y.	2023	Outpatient / Home	+	-	52	T1DM	6.1	NR	Medtronic 640G
36940793	Nattero-Chavez, L.	2023	Outpatient / Home	-	-	33	T1DM	20	6.9	MDI or CSII or SAP
36424877	Ng, S. M.	2023	Outpatient / Home	+	-	58	T1DM	6.6	7.0	MDI
35488481	Ng, S. M.	2022	Outpatient / Home	+	-	56	T1DM	3.8	7.9	CSII
37902713	Nigi, L.	2024	Outpatient / Home	-	+	41	T1DM	27.18	7.35	MDI or CSII or SAP with PLGS or hybrid closed-loop system with automatic basal insulin infusion but without corrective bolus delivery

37708979	Papa, G.	2023	Outpatient / Home	-	-	53.7	T1DM	21.0	8.3	MDI or CSII
33044604	Petrovski, G.	2021	Outpatient / Home	-	-	50	TD1M	2.8	8.2	MDI
38068733	Piccini, B.	2023	Outpatient / Home	-	+	45.8	T1DM	7.0	7.1	Medtronic 780G in manual mode
36317539	Piccini, B.	2022	Outpatient / Home	-	+	50	T1DM	8.0	7.3	Medtronic 780G in manual mode
32846114	Pinsker, J. E.	2021	Outpatient / Home	+	-	48.6	TD1M	25.4	NR	ST
35599092	Pintaudi, B.	2022	Outpatient / Home	-	+	27	T1DM	27.9	7.5	Medtronic 780G in manual mode
34668782	Proietti, A.	2022	Outpatient / Home	-	-	36.7	TD1M	18.1	7.4	ST
36925230	Quiros, C.	2022	Outpatient / Home	-	+	34	T1DM	20	7.6	Medtronic 640G or PLGS
37219952	Rachmiel, M.	2023	Outpatient / Home	-	+	41	T1DM	5.5	7.4	MDI or CSII
37956944	Rossi, A.	2023	Outpatient / Home	-	+	40	T1DM	28.4	7.3	*
31166801	Salehi, P.	2019	Outpatient / Home	-	-	62.5	TD1M	NR	7.9	NR
35451679	Schiaffini, R.	2022	Outpatient / Home	+	+	48.4	T1DM	1.0	NR	Medtronic 640G or Tandem Basal IQ with PLGS
35020476	Scully, K. J.	2022	Outpatient / Home	-	-	38.5	Cystic fibrosis-related diabetes	14.9	8.7	ST
34524003	Silva, J. D.	2022	Outpatient / Home	-	-	NR	T1DM	NR	NR	ST
30160523	Stone, M. P.	2018	Outpatient / Home	+	-	NR	T1DM	NR	NR	Medtronic 670G in MM (during 2 weeks run-in period)
34725723	Thivolet, C.	2021	Outpatient / Home	+	-	42.2	T1DM	18.6	7.9	ST
38377317	Thrasher, J. R.	2024	Outpatient / Home	-	-	NR	T1DM	NR	NR	Medtronic 770G
34858339	Tornese, G.	2021	Outpatient / Home	+	-	38.4	T1DM	4.4	NR	ST (for outcome HbA1c); HCL system in MM (2 weeks training) (for other glycemic outcomes)
34609917	Toschi, E.	2022	Outpatient / Home	-	-	NR	T1DM	42	7.3	CSII
33430621	Usoh, C. O.	2021	Outpatient / Home	-	-	50	T1DM	NR	8.1	Medtronic 670G in MM (during 2 weeks run-in period)
36280026	Usoh, C. O.	2022	Outpatient / Home	-	+	45.4	T1DM	NR	7.7	MDI or CSII
34015178	Varimo, T.	2021	Outpatient / Home	+	+	60.4	T1DM	5.1	7.4	ST
35642299	Vijayanand, S,	2022	Outpatient / Home	-	+	52	T1DM	5.5	7.6	CSII

33958309	Wang, L. R.	2021	Outpatient / Home	-	-	43	T1DM	27.5	7.9	ST
DOI in footnote	Zuijdwijk, C.	2023	Outpatient / Home	+	+	47.5	T1DM	6.3	NR	CSII
33838993	Beato-Vibora, P. I.	2021	Outpatient / Home	-	-	38.3	T1DM	21	NR	ST
34058303	Horowitz, M. E.	2021	Outpatient / Home	-	-	40	T1DM	32	7.4	ST
31347928	Kaur, H.	2019	Outpatient / Home	-	-	42.6	T1DM	30.3	NR	ST
31617752	Lepore, G.	2020	Outpatient / Home	-	-	55	T1DM	21.1	7.4	ST
Non-RIS										
30239219	Adams, R. N.	2018	Hotel	-	-	28	T1DM	14	8	ST
33431420	Amadou, C.	2021	Outpatient / Home	-	-	24	T1DM	19	7.9	CSII
33784187	Beato-Vibora, P. I.	2021	Outpatient / Home	-	-	27	T1DM	27	7.2	PLGS
34329691	Beato-Vibora, P. I.	2021	Outpatient / Home	-	-	27	T1DM	27	7.2	PLGS
33289242	Bisio, A.	2021	Outpatient / Home	-	-	38	T1DM	5.6	7.6	ST
33451264	Bisio, A.	2021	Outpatient / Home	-	-	60	T1DM	35.2	7	ST
36689621	Boucsein, A.	2023	Outpatient / Home	-	-	40	T1DM	9.7	10.5	MDI
34099518	Brown, S. A.	2021	Outpatient / Home	+	+	42.5	T1DM	11.7	7.4	ST
34694909	Carlson, A. L.	2021	Outpatient / Home	+	-	45.2	T1DM	22.6	7.5	SAP, PLGS or automated basal use (during 2 weeks run-in period)
38439656	Carlson, A.L.	2024	Outpatient / Home	-	-	48.8	T1DM	21.8	7.69	CSII
37850941	Criego, A.B.	2024	Outpatient / Home	+	-	43	T1DM	22.6	7.45	ST
36787903	Davis, G.M.	2023	Outpatient / Home	-	-	50	T2DM	19	9.4	Basal or Basal-bolus
37578778	Davis, G.M.	2023	Outpatient / Home	-	-	72	T1DM and T2DM	18	8.2	ST (no insulin pump)
37598004	Delgado, A. M.	2023	Outpatient / Home	-	-	50.7	T1DM	7.1	6.9	PLGS
38277156	DeSalvo, D. J.	2023	Outpatient / Home	-	-	47.5	T1DM	2.3	7.4	ST
37743832	Do, Q. D.	2024	Outpatient / Home	-	-	76	T1DM	17.4	6.4	Open-source AndroidAPS
30585770	Forlenza, G. P.	2019	6 days hotel, remaining outpatient	-	-	53.3	T1DM	5.6	7.9	Medtronic 670G in MM (during 2 weeks run-in period)
35001477	Forlenza, G. P.	2022	Outpatient / Home	-	-	57	T1DM	2.9	8	Medtronic 670G in MM (during 2 weeks run-in period)

33325779	Forlenza, G. P.	2021	Outpatient / Home	+	-	30.5	T1DM	11	7.5	ST
28134564	Garg, S. K.	2017	6 days hotel, remaining outpatient	+	-	44.35	T1DM	21.9	7.4	Medtronic 670G in MM (during 2 weeks run-in period)
36060958	Gianini, A.	2022	Outpatient / Home	-	-	42.6	T1DM	7.2	NR	CSII or PLGS
31264889	Lee, M. H.	2019	1 week run-in, 1 week hotel, 3 weeks home	-	-	58	T1DM	28.3	NR	Medtronic 670G in Open Loop (during 1 week run-in period)
27191182	Ly, T. T.	2017	Hotel	+	-	NR	T1DM	12.2	8.3	SAP
38032850	Mameli, C.	2024	Sport event	-	-	62.5	T1DM	5.3	6.5	Tandem Control-IQ
38444316	Marks, B. E.	2024	Outpatient / Home	-	-	47.7	T1DM	8.1	11.7	MDI
29444895	Messer, L. H.	2018	Outpatient / Home	-	-	52	T1DM	9.3	7.8	Medtronic 670G in Open Loop MM (during 2 weeks run-in period)
37823890	Michaels, V. R.	2024	Outpatient / Home	-	-	40	T1DM	9.7	10.5	MDI
34120699	Nally, L. M.	2021	Outpatient / Home	-	-	29	T1DM	8.7	8.6	ST
33185480	Nimri, R.	2021	6 days hotel, 3 weeks outpatient	-	-	33	T1DM	6.9	NR	Medtronic 780G in MM during 6 days run-in period)
31953687	Petrovski, G.	2020	Outpatient / Home	-	-	50	T1DM	2.8	8.2	MDI
35072781	Petrovski, G.	2022	Outpatient / Home	-	-	47	T1DM	4.3	8.6	MDI
35351095	Petrovski, G.	2022	Outpatient / Home	-	-	47	T1DM	4.3	8.6	MDI
37782145	Pihoker, C.	2023	Outpatient / Home	-	-	48.1	T1DM	6.2	7.9	SAP with/without PLGS or HCL (Auto Basal only) without Auto Correction turned on
36511831	Pulkkinen, M.	2023	Outpatient / Home	-	-	51.4	T1DM	2.6	7.3	MDI or Medtronic 640G or Medtronic 670G
38514384	Pulkkinen, M. D.	2024	Outpatient / Home	-	-	68	T1DM	2.4	7.2	MDI or Medtronic 640G or Medtronic 670G
35852811	Saget, S.	2022	Outpatient / Home	-	-	44	T1DM	4.7	NR	PLGS or CSII
35678724	Sherr, J.	2022	Outpatient / Home	+	-	47.5	T1DM	3	7.4	ST
Automated insulin delivery systems: Fully closed loop systems										
RCTs										
35880252	Herzig, D.	2022	Hospital	-	-	34	T2DM and other forms of non-T1DM diabetes	10.2	7.5	ST: basal insulin, basal-bolus, oral antidiabetic medications

33397767	Blauw, H.	2021	Outpatient / Home	-	-	65	T1DM	23.8	NR	ST
34349267	Boughton, C. K.	2021	Outpatient / Home	-	-	63	T2DM	20	7.2	MDI
36631592	Daly, A.	2023	Outpatient / Home	-	-	73	T2DM	17.5	9	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications
36069928	Van Veldhuisen, C. L.	2022	Outpatient / Home	-	-	70	Pancreatogenic diabetes	4.5	7.5	ST: MDI or CSII
Observational studies										
36947090	Boughton, C. K.	2023	Inpatient/hospital	-	-	75	T2DM	11	8.6	ST
Non-RIS										
38443309	Van Bon, A. C.	2024	Outpatient / Home	-	-	51	T1DM	26	7.8	MDI (18%), CSII (75%), HCL (6%)

The term "Standard therapy" refers to participants` usual treatment modalities.
* Regular use of the studied systems for at least six months prior to enrollment.
Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; HbA1c, glycated hemoglobin; MDI, multiple daily insulin injection therapy; MM, manual mode; non-RIS, non-randomized interventional study; NA, not applicable; NR, not reported; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; +, Yes; -, No.

Supplemental table 3

Additional characteristics of included studies								
PMID	**First author**	**Year of publication**	**Country**	**Study funding**	**Power calculation reported**	**Race/Ethnicity reported**	**%Time in auto mode (AID) reported**	**Patient Reported Outcome (PRO) reported**
Implantable CGM devices								
RCTs								
34984786	Renard, E.	2022	France (Multicenter)	Both*	+	-	NA	-
34196924	Boscari, F.	2022	Italy	Not declared	+	-	NA	+
Observational studies								
31418587	Deiss, D.	2020	Europe and South Africa (Multicenter)	Industry-funded	-	-	NA	-
32037699	Irace, C.	2020	Italy (Multicenter)	None	-	-	NA	-
31385732	Sanchez, P.	2019	United States	Industry-funded	-	-	NA	-
Non-RIS								
30938036	Aronson, R.	2019	Canada	Both*	+	+	NA	-
29381090	Christiansen, M. P.	2018	United States (Multicenter)	Industry-funded	-	+	NA	-
30925083	Christiansen, M. P.	2019	United States (Multicenter)	Industry-funded	-	+	NA	-
34515521	Garg, S. K.	2022	United States (Multicenter)	Industry-funded	-	+	NA	-
27815290	Kropff, J.	2017	Europe (Multicenter)	Industry-funded	+	-	NA	+
Implantable insulin pumps								
RCTs								
24735100	Schaepelynck, P.	2014	France (Multicenter)	Industry-funded	+	-	NA	-
19740082	Liebl, A.	2009	Europe (Multicenter)	Not declared	-	+	NA	+
19429874	Logtenberg, S. J.	2009	Netherlands	Industry-funded	+	-	NA	-
Observational studies								
19048281	Haveman, J. W.	2010	Netherlands	Not declared	-	-	NA	+
22912916	van Dijk, P. R.	2012	Netherlands (Multicenter)	Not declared	-	-	NA	-
26582805	van Dijk, P. R.	2015	Netherlands (Multicenter)	Not declared	-	-	NA	+
Automated insulin delivery systems: Hybrid closed loop systems								
RCTs								
34633418	Abraham, M. B.	2021	Australia	Both*	+	-	-	+
32846062	Breton, M. D.	2020	United States (Multicenter)	Both*	+	+	-	-
31618560	Brown, S. A.	2019	United States (Multicenter)	Non Industry-funded	+	+	+	-
32471910	Brown, S. A.	2020	United States	Non Industry-funded	-	+	+	-

36058207	Choudhary, P.	2022	France, Germany, United Kingdom	Industry-funded	+	-	+	+
37551542	Edd, S.N.	2023	France, Germany, United Kingdom	Industry-funded	-	-	+	+
31099946	Ekhlaspour, L.	2019	United States (Multicenter)	Both*	-	-	+	-
30888835	Forlenza, G. P.	2019	United States	Both*	+	-	-	+
36472543	Garg, S.K.	2022	United States, Canada	Industry-funded	-	+	+	+
33216667	Isganaitis, E.	2021	United States	Non Industry-funded	-	+	+	-
33355258	Kanapka, L. G.	2021	United States (Multicenter)	Both*	-	-	+	+
37796241	Lee, T.T.M.	2023	United States (Multicenter)	Both*	+	+	-	-
26049550	Ly, T. T.	2015	United States	Industry-funded	+	-	+	-
35972259	Matejko, B.	2022	Poland	Industry-funded	+	-	-	-
33055139	McAuley, S. A.	2020	Australia	Non Industry-funded	+	-	-	+
38386437	Polsky, S.	2024	United States	Both*	+	+	+	-
34816597	Renard, E.	2022	France (Multicenter)	Non Industry-funded	-	-	+	+
37729080	Renard, E	2023	France	Non Industry-funded	+	-	-	+
37921083	Reznik, Y.	2023	France (Multicenter)	Non Industry-funded	+	-	+	+
32119790	Schoelwer, M. J.	2020	United States	Industry-funded	+	-	+	-
36949671	Van den Heuvel, T.	2023	United Kingdom, Germany, France	Industry-funded	-	-	+	-
36920756	Wadwa, R. P.	2023	United States (Multicenter)	Both*	+	+	+	-
35272971	Ware, J.	2022	United Kingdom, USA	Both*	+	+	+	-
33323237	Benhamou, P. Y.	2019	France (Multicenter)	Both*	+	.	+	-
33453783	Bergenstal, R. M.	2021	United States, Germany, Israel, and Slovenia	Non Industry-funded	+	+	+	-
34270335	Bode, B.	2021	United States	Industry-funded	+	+	-	-
33606901	Boughton, C. K.	2021	United Kingdom, Austria and Switzerland (Multicenter)	Non Industry-funded	-	+	+	-
35359882	Boughton, C. K.	2022	United Kingdom, Austria	Non Industry-funded	+	+	-	-
33555982	Burckhardt, M. A.	2021	Australia	Non Industry-funded	-	-	+	+
33579715	Collyns, O. J.	2021	New Zealand	Industry-funded	+	+	+	-
37404205	Dovc, K.	2023	Slovenia, Austria	Both*	+	+	+	+
32520594	Hsu, L.	2021	United States	Industry-funded	-	-	+	-
31796571	Lee, M. H.	2020	Australia	Non Industry-funded	-	-	-	+
34362816	Lee, M. H.	2021	Australia	Non Industry-funded	+	-	+	-
34844995	McAuley, S. A.	2022	Australia (Multicenter)	Both*	+	-	+	+
34524022	Morrison, D.	2022	Australia	Both*	+	-	+	-
3782382	Nwokolo, M.	2023	United Kingdom	Both*	-	+	+	-
33090016	Ozer, K.	2021	United States	None	+	+	+	-
34789504	Paldus, B.	2022	Australia and Canada	Both*	+	-	-	-
30620641	Paldus, B.	2019	NR	Industry-funded	-	-	+	-

35373894	von dem Berge, T.	2022	Germany	Both	-	-	+	+
35045227	Ware, J.	2022	Austria, Germany, Luxembourg, United Kingdom (Multicenter)	Non Industry-funded	+	-	+	-
36880866	Ware, J.	2023	United Kingdom (Multicenter)	Both*	-	+	+	-
Observational studies								
31789447	Akturk, H. K.	2020	United States	Non Industry-funded	-	-	+	-
37236365	Amigo,´ J.	2023	Spain	None	-	-	+	+
35136338	Amole, M.	2021	United States	Not declared	-	-	+	-
35414272	Arunachalum, S.	2023	United States	Industry-funded	-	-	+	-
38459160	Atik-Altinok, Y.	2024	Turkey	Industry-funded	+	-	+	-
35116007	Bassi, M.	2022	Italy	Not declared	-	-	-	-
36777356	Bassi, M.	2023	Italy	Not declared	-	-	-	-
31855446	Beato-Vibora, P. I.	2020	NR	None	-	-	+	+
36030902	Beato-Vibora, P. I.	2022	Spain	Non Industry-funded	-	-	+	-
30862242	Berget, C.	2020	United States	Not declared, but there is a conflict of interest	-	-	+	-
31837064	Berget, C.	2020	United States	Non Industry-funded	-	+	+	+
33784196	Breton, M. D.	2021	United States	Non Industry-funded	-	-	+	-
34227214	Cherubini, V.	2021	Italy (Multicenter)	Not declared	+	-	-	-
36724301	Chico, A.	2023	Spain	None	-	-	-	+
32212971	Cobry, E. C.	2020	United States	Non Industry-funded	+	+	+	+
37252734	Cordero, T. L.	2023	Europe, Middle East, Africa	Industry-funded	-	-	-	-
33961340	Da Silva, J.	2021	13 European countries	Industry-funded	-	-	+	-
DOI in footnote	Del Valle Rolón, M. E.	2023	United States	Not declared	+	+	-	-
34524023	Dubose, S. N.	2021	United States (Multicenter)	Non Industry-funded	-	+	-	+
37845757	Elbarbary, N. S.	2023	Egypt	Non-Industry funded	-	-	+	-
30865545	Faulds, E. R.	2019	United States	Not declared	-	-	+	-
33450533	Gomez, A. M.	2021	Colombia	Not declared	-	-	+	-
DOI in footnote	Gouet, D.	2022	France	Not declared	-	-	-	-
37956265	Guibert, C.	2023	France	None	-	-	+	-
38444313	Halim, B.	2024	Australia	None	+	-	+	+
37905353	Henry, Z.	2023	France	None	-	-	+	-
37782904	Graham, R.	2024	United States	Industry-funded	+	+	-	+
36789699	Grassi, B.	2023	Argentina, Brazil, Chile and Colombia	Industry-funded	-	-	+	-
36108305	Herguido, N. G.	2023	Spain	None	-	+	+	+
35099298	Jacobsen, S. S.	2022	Denmark	None	-	-	+	-
33999488	Jeyaventhan, R.	2021	England (Multicenter)	Not declared	-	+	-	+
34569850	Ju, Z.	2022	United States	None	-	+	-	-

36126177	Kovatchev, B. P.	2022	United States	Non-Industry funded	-	-	--	-
38236643	Lablanche, S.	2024	France	Non-Industry funded	-	-	+	-
31548247	Lal, R. A.	2019	United States	Non Industry-funded	-	+	-	-
38225516	Landau, Z.	2024	Israel	None	-	-	-	-
38579305	Lehmann, V.	2023	Switzerland	None	-	-	+	-
37959415	Lendínez-Jurado, A.	2023	Spain	Non-Industry funded	-	-	+	+
37337407	Lendínez-Jurado, A.	2023	Spain	Not declared	-	-	+	+
37902785	Lepore, G.	2024	Italy	None	-	-	+	-
36763343	Lombardo, F.	2023	Italy	None	-	-	+	-
33628834	Malone, S. K.	2021	United States (Multicenter)	Not declared	-	+	-	+
37646634	Marks, B. E.	2023	United States	None	+	+	+	-
37184526	Matejko, B.	2023	Poland	Industry-funded	-	-	+	+
34096789	Messer, L. H.	2021	United States	Non Industry-funded	-	+	+	-
DOI in footnote	Mutlu, G. Y.	2023	Turkey	None	-	-	+	+
36940793	Nattero-Chavez, L.	2023	Spain	Non-Industry funded	-	-	+	+
36424877	Ng, S. M.	2023	England	Non-Industry funded	-	+	+	+
35488481	Ng, S. M.	2022	United Kingdom	Not declared	-	-	+	+
37902713	Nigi, L.	2024	Italy	None	-	-	+	-
37708979	Papa, G.	2023	Italy	None	-	-	+	+
33044604	Petrovski, G.	2021	Qatar	Non Industry-funded	-	-	+	-
38068733	Piccini, B.	2023	Italy	None	-	-	+	-
36317539	Piccini, B.	2022	Italy	None	-	-	+	-
32846114	Pinsker, J. E.	2021	United States	Industry-funded	-	+	+	+
35599092	Pintaudi, B.	2022	Italy	None	-	-	+	-
34668782	Proietti, A.	2022	Argentina	Industry-funded	-	-	+	-
36925230	Quiros, C.	2022	Spain	None	-	-	+	-
37219952	Rachmiel, M.	2023	Israel	None	-	-	+	-
37956944	Rossi, A.	2023	Italy	None	+	-	+	+
31166801	Salehi, P.	2019	United States	Non Industry-funded	-	-	+	-
35451679	Schiaffini, R.	2022	Italy	None	-	-	+	-
35020476	Scully, K. J.	2022	United States (Multicenter)	Non Industry-funded	-	+	-	-
34524003	Silva, J. D.	2022	Belgium, Finland, Italy, the Netherlands, Qatar, South Africa, Sweden, Switzerland, United Kingdom	Industry-funded	-	-	+	-
30160523	Stone, M. P.	2018	NR	Industry-funded	-	-	+	-
34725723	Thivolet, C.	2021	France	Not declared	-	-	-	-
38377317	Thrasher, J. R.	2024	USA	Industry-funded	-	-	+	-
34858339	Tornese, G.	2021	Italy	Not declared	-	-	+	-
34609917	Toschi, E.	2022	NR	Non Industry-funded	-	-	-	-

33430621	Usoh, C. O.	2021	United States	None	-	+	-	-
36280026	Usoh, C. O.	2022	United States	Not declared	-	+	+	-
34015178	Varimo, T.	2021	Finland (Multicenter)	Non Industry-funded	-	-	+	-
35642299	Vijayanand, S.	2022	Australia	Not declared	-	-	+	+
33958309	Wang, L. R.	2021	Canada	Not declared	-	-	+	-
DOI in footnote	Zuijdwijk, C.	2023	Canada	Industry-funded	+	+	+	+
33838993	Beato-Vibora, P. I.	2021	Spain	None	+	-	-	-
34058303	Horowitz, M. E.	2021	NR	Industry-funded	-	-	+	+
31347928	Kaur, H.	2019	United States	None	-	-	-	-
31617752	Lepore, G.	2020	Italy	None	-	-	+	-
Non-RIS								
30239219	Adams, R. N.	2018	United States (Multicenter)	Non Industry-funded	-	-	-	+
33431420	Amadou, C.	2021	France	Both*	-	-	+	-
33784187	Beato-Vibora, P. I.	2021	NR	None	-	-	+	+
34329691	Beato-Vibora, P. I.	2021	NR	Not declared	-	-	+	+
33289242	Bisio, A.	2021	United States	Non Industry-funded	-	+	+	+
33451264	Bisio, A.	2021	United States	Both*	-	-	+	+
36689621	Boucsein, A.	2023	New Zeland (Multicenter)	Both*	+	+	+	-
34099518	Brown, S. A.	2021	United States (Multicenter)	Both*	+	+	+	-
34694909	Carlson, A. L.	2021	United States (Multicenter)	Industry-funded	-	-	+	-
38439656	Carlson, A.L.	2024	United States (Multicenter)	Industry-funded	-	+	-	-
37850941	Criego, A.B.	2024	United States	Industry-funded	-	+	+	-
36787903	Davis, G.M.	2023	United States	Industry-funded	-	+	+	+
37578778	Davis, G.M.	2023	United States	Both*	-	+	+	+
37598004	Delgado, A. M.	2023	Spain	None	-	-	+	-
38277156	DeSalvo, D. J.	2023	United States (Multicenter)	Industry-funded	-	+	+	-
37743832	Do, Q. D.	2024	Czech Reupublic	Non Industry-funded	-	-	-	+
30585770	Forlenza, G. P.	2019	United States and Israel (Multicenter)	Industry-funded	-	-	+	-
35001477	Forlenza, G. P.	2022	United States (Multicenter)	Industry-funded	-	-	+	-
33325779	Forlenza, G. P.	2021	United States (Multicenter)	Industry-funded	-	+	-	-
28134564	Garg, S. K.	2017	United States and Israel (Multicenter)	Industry-funded	-	-	+	-
36060958	Gianini, A.	2022	Slovenia	Non Industry-funded	-	-	-	+
31264889	Lee, M. H.	2019	Australia	Both*	+	-	+	+
27191182	Ly, T. T.	2017	United States (Multicenter)	Non Industry-funded	-	-	-	-
38032850	Mameli, C.	2024	Italy	None	-	-	-	-
38444316	Marks, B. E.	2024	United States	Industry-funded	+	+	+	+
29444895	Messer, L. H.	2018	United States	Not declared	-	-	+	-
37823890	Michaels, V. R.	2024	New Zeland	Non Industry-funded	-	+	+	+

34120699	Nally, L. M.	2021	United States	Not declared	-	+	+	-
33185480	Nimri, R.	2021	Israel	Both*	-	-	-	-
31953687	Petrovski, G.	2020	Qatar	Non Industry-funded	-	-	+	-
35072781	Petrovski, G.	2022	Qatar	Non Industry-funded	-	-	+	-
35351095	Petrovski, G.	2022	Qatar	Both*	-	-	+	+
37782145	Pihoker, C.	2023	United States	Industry-funded	-	+	-	-
36511831	Pulkkinen, M.	2023	Finland	Industry-funded	+	-	+	+
38514384	Pulkkinen, M. D.	2024	Finland	Industry-funded	+	-	-	+
35852811	Saget, S.	2022	Poland	Non Industry-funded	-	-	-	-
35678724	Sherr, J.	2022	United States (Multicenter)	Both*	-	+	+	
Automated insulin delivery systems: Fully closed loop systems								
RCTs								
35880252	Herzig, D.	2022	Switzerland	Both*	+	-	+	-
33397767	Blauw, H.	2021	Netherlands	Industry-funded	+	-	-	-
34349267	Boughton, C. K.	2021	United Kingdom and Switzerland	Both*	-	-	+	-
36631592	Daly, A.	2023	United Kingdom	Non Industry-funded	-	+	+	-
36069928	Van Veldhuisen, C. L.	2022	Netherlands	Both*	+	-	+	-
Observational studies								
36947090	Boughton, C. K.	2023	UK	Non-Industry funded	-	+	-	-
Non-RIS								
38443309	Van Bon, A. C.	2024	Netherlands (Multicenter)	Industry-funded	-	-	+	+

*"Both" indicates industry-related and non industry-related funding.
Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: CGM, continuous glucose monitoring; non-RIS, non-randomized interventional study; NA, not applicable; NR, not reported; RCT, randomized clinical trial; +, Yes; -, No.

Supplemental table 4

Supplemental table 4. Pre-market and post-market studies (a)							
PMID	**First author**	**Year of publication**	**Device**	**Previous study registration (if reported)**	**CE-mark approval date of the device (b)**	**Date of recruitment ending**	**Pre- or post- market study**
Implantable CGM devices							
RCTs							
34984786	Renard, E.	2022	Eversense® XL CGM System (180 days)	NCT03445065	2017	20/08/2020*	Post-market
34196924	Boscari, F.	2022	Eversense® CGM System (90 days)	NCT03613805	2016	01/09/2019*	Post-market
Observational studies							
31418587	Deiss, D.	2020	Eversense® CGM System (90 days) or Eversense® XL CGM System (180 days)	NR	2016, 2017	30/08/2018	Post-market
32037699	Irace, C.	2020	Eversense® XL CGM System (180 days)	NCT04160156	2017	30/06/2019*	Post-market
31385732	Sanchez, P.	2019	Eversense® CGM System (90 days)	NR	2016	03/03/2021	Post-market
Non-RIS							
30938036	Aronson, R.	2019	Eversense® XL CGM System (180 days)	NCT02933164	09/2017	08/2017**	Pre-market
29381090	Christiansen, M. P.	2018	Eversense® CGM System (90 days)	NCT02647905	06/2016	07/2016*	Post-market
30925083	Christiansen, M. P.	2019	Eversense® CGM System (90 days)	NR	2016	02/2018	Post-market
34515521	Garg, S. K.	2022	Eversense® XL CGM System (180 days)	NCT03808376	2017	08/05/2020*	Post-market
27815290	Kropff, J.	2017	Eversense® CGM System (90 days)	NCT02154126	2016	11/2015*	Pre-market
Implantable insulin pumps							
RCTs							
24735100	Schaepelynck, P.	2014	MiniMed MIP 2007C	NCT01194882	2013	01/02/2018*	Post-market
19740082	Liebl, A.	2009	DiaPort	NR	2012	NR	Pre-market #
19429874	Logtenberg, S. J.	2009	MiniMed MIP 2007C	NCT00286962	2013	04/2008*	Pre-market
Observational studies							
19048281	Haveman, J. W.	2010	MiniMed MIP 2007C	NR	2013	31/12/2006	Pre-market
22912916	van Dijk, P. R.	2012	MiniMed MIP 2007C	NR	2013	01/06/2011	Pre-market

26582805	van Dijk, P. R.	2015	MiniMed MIP 2007C	NCT01621308 and NL41037.075.12	2013	03/2014*	Post-market
Automated insulin delivery systems: Hybrid closed loop systems							
RCTs							
34633418	Abraham, M. B.	2021	Medtronic 670G	ACTRN12616000753459	2018	04/10/2019	Post-market
32846062	Breton, M. D.	2020	Tandem Control-IQ	NCT03844789	2020	30/08/2019	Pre-market
31618560	Brown, S. A.	2019	Tandem Control-IQ	NCT03563313	2020	09/10/2018	Pre-market
32471910	Brown, S. A.	2020	Tandem Control-IQ	NCT03591354	2020	09/04/2019	Pre-market
36058207	Choudhary, P.	2022	Medtronic 780G	NCT04235504	2020	12/03/2021	Post-market
37551542	Edd, S.N.	2023	Medtronic 670G	NCT04235504	2018	30/05/2022*	Post-market
31099946	Ekhlaspour, L.	2019	Tandem Control-IQ	NCT03369067	2020	15/04/2018*	Pre-market
30888835	Forlenza, G. P.	2019	Tandem Control-IQ	NCT03369067	2020	15/04/2018*	Pre-market
36472543	Garg, S.K.	2022	Medtronic 670G	NCT02748018	2018	06/10/2020	Post-market
33216667	Isganaitis, E.	2021	Tandem Control-IQ	NCT03563313	2020	09/10/2018	Pre-market
33355258	Kanapka, L. G.	2021	Tandem Control-IQ	NCT03844789	07/2020	20/03/2020*	Pre-market
37796241	Lee, T.T.M.	2023	CamAPS FX	ISRCTN56898625	2020	05/2022	Post-market
26049550	Ly, T. T.	2015	Medtronic 670G	NCT02366767	2018	09/2014	Pre-market
35972259	Matejko, B.	2022	Medtronic 780G	NCT04616391	2020	20/04/2021	Post-market
33055139	McAuley, S. A.	2020	Medtronic 670G	ACTRN12617000520336	2018	24/01/2019	Post-market
38386437	Polsky, S.	2024	Medtronic 670G	NCT03774186	2018	03/2022	Post-market
34816597	Renard, E.	2022	Tandem Control-IQ	NCT03739099	2020	05/05/2023**	Post-market
37729080	Renard, E	2023	Tandem Control-IQ	NCT04266379	07/2020	15/10/2020	Post-market
37921083	Reznik, Y.	2023	Tandem Control-IQ	NCT04233229	2020	30/05/2022*	Post-market
32119790	Schoelwer, M. J.	2020	Tandem Control-IQ	NCT03804983	2020	16/02/2019*	Pre-market
36949671	Van den Heuvel, T.	2023	Medtronic 780G	NCT04235504	2020	12/03/2021	Post-market
36920756	Wadwa, R. P.	2023	Tandem Control-IQ	NCT04796779	2020	13/01/2022	Post-market
35272971	Ware, J.	2022	CamAPS FX	NCT02925299	03/2020	27/08/2020*	Post-market
33323237	Benhamou, P. Y.	2019	Diabeloop DBLG1	NCT02987556	2018	19/06/2017	Pre-market
33453783	Bergenstal, R. M.	2021	Medtronic 780G	NCT03040414	2020	22/08/2019	Pre-market
34270335	Bode, B.	2021	Medtronic 670G	NCT03760640	2018	07/10/2019*	Post-market

33606901	Boughton, C. K.	2021	CamAPS FX	NCT04055480	03/2020	30/08/2020*	Post-market
35359882	Boughton, C. K.	2022	CamAPS FX	NCT04025762	03/2020	02/10/2020	Post-market
33555982	Burckhardt, M. A.	2021	Medtronic 670G	ACTRN12616000909426	06/2018	30/09/2018†	Post-market
33579715	Collyns, O. J.	2021	Medtronic 670G	NCT04073576	2018	07/10/2019	Post-market
37404205	Dovc, K.	2023	Medtronic 670G	NCT0485303	2018	28/01/2021	Post-market
32520594	Hsu, L.	2021	Medtronic 670G	NCT03554486	2018	30/03/2019	Post-market
31796571	Lee, M. H.	2020	Medtronic 670G	ACTRN12618000070235	06/2018	17/09/2018†	Post-market
34362816	Lee, M. H.	2021	Medtronic 780G	ACTRN12619000469112	06/2020	31/03/2020	Pre-market
34844995	McAuley, S. A.	2022	Medtronic 670G	ACTRN12619000515190	2018	16/04/2020	Post-market
34524022	Morrison, D.	2022	Medtronic 780G	ACTRN12619000469112	06/2020	30/11/2020	Post-market
37823892	Nwokolo, M.	2023	CamAPS FX	NCT05257460	2020	08/2022	Post-market
33090016	Ozer, K.	2021	Medtronic 670G	NCT03977727	2018	20/04/2020*	Post-market
34789504	Paldus, B.	2022	Medtronic 670G	ACTRN12618000905268	2018	10/12/2019	Post-market
30620641	Paldus, B.	2019	Medtronic 670G	NR	2018	16/11/2017	Pre-market
35373894	von dem Berge, T.	2022	Medtronic 670G	NCT03815487	2018	2020	Post-market
35045227	Ware, J.	2022	CamAPS FX	NCT03784027	03/2020	03/10/2022*	Post-market
36880866	Ware, J.	2023	CamAPS FX	NCT04759144	2020	03/2022	Post-market
Observational studies							
31789447	Akturk, H. K.	2020	Medtronic 670G	NR	25/06/2018	01/06/2018	Pre-market
37236365	Amigo,´ J.	2023	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)	NR	2020	06/2022	Post-market
35136338	Amole, M.	2021	Medtronic 670G	NR	06/2018	31/12/2018	Post-market
35414272	Arunachalum, S.	2023	Medtronic 670G	NR	2018	11/2020	Post-market
38459160	Atik-Altinok, Y.	2024	Medtronic 780G	NR	2020	05/2022	Post-market
35116007	Bassi, M.	2022	Tandem Control-IQ	NR	2020	30/04/2021	Post-market
36777356	Bassi, M.	2023	Tandem Control-IQ	NR	2020	10/2021	Post-market
31855446	Beato-Vibora, P. I.	2020	Medtronic 670G	NR	2018	NR	Post-market††
36030902	Beato-Vibora, P. I.	2022	Medtronic 780G	NR	2020	NR	NR
30862242	Berget, C.	2020	Medtronic 670G	NR	2018	NR	NR
31837064	Berget, C.	2020	Medtronic 670G	NR	06/2018	31/05/2018	Pre-market

33784196	Breton, M. D.	2021	Tandem Control-IQ	NR	2020	11/02/2021	Post-market
34227214	Cherubini, V.	2021	Tandem Control-IQ	NR	2020	NR	NR
36724301	Chico, A.	2023	Diabeloop DBLG1	NR	2018	NR	NR
32212971	Cobry, E. C.	2020	Medtronic 670G	NR	2018	NR	NR
37252734	Cordero, T. L	2023	Medtronic 780G	NCT03959423	2020	02/12/2022	Post-market
33961340	Da Silva, J.	2021	Medtronic 670G	NR	2018	31/07/2020	Post-market
DOI in footnote	Del Valle Rolón, M. E.	2023	Tandem Control-IQ	NR	2020	27/04/2022	Post-market
34524023	Dubose, S. N.	2021	Medtronic 670G	NR	2018	31/03/2019	Post-market
37845757	Elbarbary, N. S.	2023	Medtronic 780G	NR	2020	NR	NR
30865545	Faulds, E. R.	2019	Medtronic 670G	NR	2018	31/12/2017	Pre-market
33450533	Gomez, A. M.	2021	Medtronic 670G	NR	2018	31/07/2020	Post-market
DOI in footnote	Gouet, D.	2022	Minimed 780 G	NR	2020	11/2021	Post-market
37782904	Graham, R.	2024	Tandem Control IQ	NR	2020	03/2022	Post-market
36789699	Grassi, B.	2023	Medtronic 780G	NR	2020	09/2022	Post-market
37956265	Guibert, C.	2023	Medtronic 780G	CE-2022-55	2020	09/2022	Post-market
38444313	Halim, B.	2024	Medtronic 780G	NR	2020	12/2022	Post-market
37905353	Henry, Z.	2023	Medtronic 780G (72%), Tandem Control IQ (28%)	NR	2020	02/2023	Post-market
36108305	Herguido, N. G.	2023	Medtronic 780G	NR	2020	11/2021	Post-market
35099298	Jacobsen, S. S.	2022	Medtronic 670G	P-2020-795	2018	NR	NR
33999488	Jeyaventhan, R.	2021	Medtronic 670G	NR	2018	NR	NR
34569850	Ju, Z.	2022	Minimed Medtronic 670G	NR	2018	01/2020	Post-market
36126177	Kovatchev, B. P.	2022	Tandem Control-IQ	NR	2020	NR	NR
38236643	Lablanche, S.	2024	Medtronic 780G	NR	2020	03/2022	Post-market
31548247	Lal, R. A.	2019	Medtronic 670G	NCT03017482	2018	30/08/2019*	Post-market
38225516	Landau, Z.	2024	Medtronic 780G	NR	2020	12/2021	Post-market
38579305	Lehmann, V.	2023	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G	NR	2018, 2020	12/2021	Post-market
37959415	Lendínez-Jurado, A.	2023	Medtronic 780G	NR	2020	04/2022	Post-market
37337407	Lendínez-Jurado, A.	2023	Medtronic 780G	NR	2020	04/2022	Post-market

37902785	Lepore, G.	2024	Medtronic 780G	NR	2020	09/2022	Post-market
36763343	Lombardo, F.	2023	Medtronic 780G	NR	2020	03/2022	Post-market
38225516	Landau, Z.	2024	Medtronic 780G	NR	2020	12/2021	Post-market
33628834	Malone, S. K.	2021	Medtronic 670G	NCT03215914	2018	31/12/2020	Post-market
37646634	Marks, B. E.	2023	Omnipod 5	NR	09/2022	01/11/2022	Post-market
37184526	Matejko, B.	2023	Medtronic 780G	NR	2020	08/2022	Post-market
DOI in footnote	Mutlu, G. Y.	2023	Medtronic 780G	NR	2020	10/2021	Post-market
36940793	Nattero-Chavez, L.	2023	Medtronic 780G	NCT04900636	2020	NR	NR
36424877	Ng, S. M.	2023	Tandem Control-IQ (78%), Medtronic 780G (11%), CamAPS FX (11%)	NR	2020	10/12/2022	Post-market
35488481	Ng, S. M.	2022	Tandem Control-IQ (91%), CamAPS FX (9%)	NR	2020	NR	NR
37902713	Nigi, L.	2024	Medtronic 780G	NR	2020	01/2021	Post-market
37708979	Papa, G.	2023	Medtronic 670G (41%), Medtronic 780G (59%)	NR	2018, 2020	04/2022	Post-market
34096789	Messer, L. H.	2021	Tandem Control-IQ	NR	2020	NR	NR
33044604	Petrovski, G.	2021	Medtronic 670G	NCT03755479	2018	NR	Post-market[##]
38068733	Piccini, B.	2023	Medtronic 780G	NR	2020	NR	NR
36317539	Piccini, B.	2022	Medtronic 780G	NR	2020	NR	NR
32846114	Pinsker, J. E.	2021	Tandem Control-IQ	NR	07/2020	24/03/2020	Pre-market
35599092	Pintaudi, B.	2022	Medtronic 780G	NR	2020	04/2021	Post-market
34668782	Proietti, A.	2022	Medtronic 670G	NR	2018	NR	Post-market[###]
36925230	Quiros, C.	2022	Medtronic 780G	NR	2020	NR	NR
37219952	Rachmiel, M.	2023	Medtronic 780G	NR	2020	NR	NR
37956944	Rossi, A.	2023	Medtronic 780G	NR	2020	NR	NR
31166801	Salehi, P.	2019	Medtronic 670G	NR	2018	NR	NR
35451679	Schiaffini, R.	2022	Tandem Control-IQ (55%), Medtronic 780G (45%)	NR	2020	03/2021	Post-market
35020476	Scully, K. J.	2022	Tandem Control-IQ	NR	2020	07/2021	Post-market
34524003	Silva, J. D.	2022	Medtronic 780G	NR	2020	03/03/2021	Post-market
30160523	Stone, M. P.	2018	Medtronic 670G	NR	2018	NR	NR

34725723	Thivolet, C.	2021	Medtronic 780G	NR	2020	31/05/2021	Post-market
38377317	Thrasher, J. R.	2024	Medtronic 780G	NR	2020	22/08/2023	Post-market
34858339	Tornese, G.	2021	Medtronic 780G	NR	2020	01/04/2021	Post-market
34609917	Toschi, E.	2022	Tandem Control-IQ	NR	07/2020	31/12/2020	Post-market
33430621	Usoh, C. O.	2021	Medtronic 670G	NR	2018	29/02/2020	Post-market
36280026	Usoh, C. O.	2022	Tandem Control IQ	NR	2020	06/2021	Post-market
34015178	Varimo, T.	2021	Medtronic 670G	NR	2018	01/12/2019	Post-market
35642299	Vijayanand, S.	2022	Medtronic 670G	NR	2018	07/2021	Post-market
33958309	Wang, L. R.	2021	Medtronic 670G	NR	2018	31/03/2020	Post-market
DOI in footnote	Zuijdwijk, C.	2023	Tandem Control IQ	NR	2020	NR	NR
33838993	Beato-Vibora, P. I.	2021	Medtronic 670G	NR	2018	31/03/2020	Post-market
34058303	Horowitz, M. E.	2021	Medtronic 670G	NR	2018	NR	NR
31347928	Kaur, H.	2019	Medtronic 670G	NR	2018	NR	NR
31617752	Lepore, G.	2020	Medtronic 670G	NR	2018	NR	Post-market[####]
Non-RIS							
30239219	Adams, R. N.	2018	Medtronic 670G	NCT02280863	2018	05/2015	Pre-market
33431420	Amadou, C.	2021	Diabeloop DBLG1	NR	2018	NR	NR
33784187	Beato-Vibora, P. I.	2021	Medtronic 780G	NR	2020	NR	Post-market[#####]
34329691	Beato-Vibora, P. I.	2021	Medtronic 780G	NR	2020	NR	Post-market[######]
33289242	Bisio, A.	2021	Tandem Control-IQ	NCT03674281	2020	30/11/2019	Pre-market
33451264	Bisio, A.	2021	Tandem Control-IQ	NCT03674281	2020	30/11/2019	Pre-market
36689621	Boucsein, A.	2023	Medtronic 780G	ACTRN12621000556842	2020	02/2022	Post-market
34099518	Brown, S. A.	2021	Omnipod 5	NCT04196140	2022	28/02/2020	Pre-market
34694909	Carlson, A. L.	2021	Medtronic 780G	NCT03959423	2020	27/10/2023	Post-market
38439656	Carlson, A.L.	2024	Tandem Control-IQ	NCT05422053	2020	01/06/2023*	Post-market
37850941	Criego, A.B.	2024	Omipod 5	NCT04196140	09/2022	20/04/2022*	Pre-market
36787903	Davis, G.M.	2023	Omipod 5	NCT04617795	09/2022	06/03/2022*	Pre-market
37578778	Davis, G.M.	2023	Omipod 5	NCT04714216	09/2022	11/08/2022*	Pre-market
37598004	Delgado, A. M.	2023	Tandem Control-IQ	NR	2020	NR	NR

38277156	DeSalvo, D. J.	2023	Omipod 5	NCT04476472	09/2022	12/10/2022*	Post-market
37743832	Do, Q. D.	2024	Tandem Control-IQ	NCT0516561	2020	21/12/2022	Post-market
30585770	Forlenza, G. P.	2019	Medtronic 670G	NCT02660827	2018	01/02/2021*	Post-market
35001477	Forlenza, G. P.	2022	Medtronic 670G	NCT02660827	2018	01/02/2021*	Post-market
33325779	Forlenza, G. P.	2021	Omnipod 5	NCT04176731	2022	31/01/2020*	Pre-market
28134564	Garg, S. K.	2017	Medtronic 670G	NCT02463097	06/2018	10/2018*	Post-market
36060958	Gianini, A.	2022	Medtronic 780G	NR	2020	NR	NR
31264889	Lee, M. H.	2019	Medtronic 670G	ACTRN12618000840280	06/2018	24/07/2018	Post-market
27191182	Ly, T. T.	2017	Medtronic 670G	NCT02463097	06/2018	10/2018*	Post-market
38032850	Mameli, C.	2024	Tandem Control-IQ	NR	2020	25/10/2022	Post-market
38444316	Marks, B. E.	2024	Tandem Control-IQ	NCT04807374	2020	24/05/2022	Post-market
29444895	Messer, L. H.	2018	Medtronic 670G	NCT02463097	06/2018	10/2018*	Post-market
37823890	Michaels, V. R.	2024	Medtronic 780G	NR	2020	01/02/2022*	Post-market
34120699	Nally, L. M.	2021	Medtronic 670G	NR	2018	NR	NR
33185480	Nimri, R.	2021	Medtronic 780G	NCT02776696	2020	14/08/2019*	Pre-market
31953687	Petrovski, G.	2020	Medtronic 670G	NCT03755479	2018	11/08/2019*	Post-market
35072781	Petrovski, G.	2022	Medtronic 780G	NR ‡	2020	NR	NR
35351095	Petrovski, G.	2022	Medtronic 780G	NCT03755479	2020	02/05/2021	Post-market
37782145	Pihoker, C.	2023	Medtronic 670G	NCT03959423	2018	17/03/2021	Post-market
36511831	Pulkkinen, M.	2023	Medtronic 780G	NCT04949022	2020	31/12/2023*	Post-market
38514384	Pulkkinen, M. D.	2024	Medtronic 780G	NCT04949022	2020	31/12/2023*	Post-market
35852811	Saget, S.	2022	Medtronic 780G	NR	2020	NR	NR
35678724	Sherr, J.	2022	Omipod 5	NCT04476472	2022	01/2021	Pre-market
Automated insulin delivery systems: Fully closed loop systems							
RCTs							
35880252	Herzig, D.	2022	CamAPS HX	NCT04361799	2020	20/08/2021	Post-market
33397767	Blauw, H.	2021	Inreda AP	NCT03858062	2020	12/09/2019*	Pre-market
34349267	Boughton, C. K.	2021	CamAPS HX	NCT04025775	2020	01/03/2021*	Post-market
36631592	Daly, A.	2023	CamAPS HX	NCT04701424	2020	24/01/2021	Post-market
36069928	Van Veldhuisen, C. L.	2022	Inreda AP	NL8871	02/2020	11/2020	Post-market

Observational studies							
36947090	Boughton, C. K.	2023	CamAPS HX	NR	2020	07/2022	Post-market
Non-RIS							
38443309	Van Bon, A. C.	2024	Inreda AP	NL9578	2020	03/2022	Post-market

(a) The studies were defined as pre-market if the study completion date was before the CE-mark approval date. The studies were defined as post-market if the study completion date was after the CE-mark approval date.
(b) The year of CE-mark approval is provided. If the year of CE-mark approval is the same as the year of recruitment ending, the month of CE-mark approval is additionally provided. If the year and month of CE-mark approval are the same as the year and month of recruitment ending, the day of CE-mark approval is additionally provided.
*Actual study completion date according to clinicaltrial.gov website (Defined as the date on which the last participant in a clinical study was examined or received an intervention/treatment to collect final data for the primary outcome measures, secondary outcome measures, secondary outcome measures, and adverse events [that is, the last participant`s visit]).
**Estimated study completion date according to clinicaltrial.gov website (Defined as the date that the researchers think will be the study completion date).
†Anticipated date of last participant enrolment: https://anzctr.org.au/TrialSearch.aspx.
††In the Introduction section of the study, it is stated that the study was performed after the commercialization of Medtronic 670G in Europe.
#The study was classified as pre-market, because the publication date was before the date of CE-mark approval.
##This observational study with a 1 year follow-up was performed as a continuation of a non-RIS by Petrovski et al (PMID 31953687).
###The study starting date (March 2020) is after the CE mark approval date.
####In the Methods section, it is stated that the study took place after September 2018, namely after the CE mark approval date of the device.
#####In the Methods section, it is stated that the study protocol was approved in 2020, namely after the CE mark approval date of the device.
######Same population as the study by Beato Vibora et al (PMID 33784187), but with followed-up over a longer time period.
‡The protocol number of a previous similar study is mentioned (NCT03755479), but it does not correspond to the actual study.
Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: NR, not reported.

Supplemental table 5

Results on high-risk medical devices for diabetes and HbA1c*											
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)**	**Baseline treatment against diabetes**	**HbA1c (%) at baseline, mean***	**HbA1c (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention vs comparison [Reference])**	**HbA1c (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention, final vs baseline [Reference])**
Implantable CGM devices											
RCTs											
34984786	Renard, E.	2022	RCT: Parallel	26	239	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM	MDI or CSII	8.3	Cohort 1: -0.1 (-0.4; 0.1) Cohort 2: 0.1 (-0.2; 0.4)† Overall: -0.02 (-0.21; 0.17)	
Observational studies											
32037699	Irace, C.	2020	Longitudinal	26	100	Eversense® XL CGM System (180 days)		ST	7.4		**-0.43 (-0.64; -0.22)**
Non-RIS											
30938036	Aronson, R.	2019	Non-RIS	26	Pediatric: n, 30 Adults: n, 6	Eversense® XL CGM System (180 days)		ST	8		Pediatric: -0.2 (-0.54; 0.14) Adults: 0.1 (-0.53; 0.73) Overall: -0.13 (-0.43; 0.17)
30925083	Christiansen, M. P.	2019	Non-RIS	13	36	Eversense® CGM System (90 days)		ST	7.8		**-0.30 (-0.57; -0.03)**
34515521	Garg, S. K.	2022	Non-RIS	26	181	Eversense® XL CGM System (180 days)		ST	7.6		-0.3
27815290	Kropff, J.	2017	Non-RIS	26	71	Eversense® CGM System (90 days)		ST	7.6		**-0.35 (-0.55; -0.21)**
Implantable insulin pumps											
RCTs											
19740082	Liebl, A.	2009	RCT: Crossover	NR	60	DiaPort	CSII	CSII	8.3	0.1 (-0.12; 0.32)	
19429874	Logtenberg, S. J.	2009	RCT: Crossover	26	24	MiniMed MIP 2007C	ST: MDI or CSII	ST	8.6	**-0.76 (-1.41; -0.11)**	

Observational studies											
26582805	van Dijk, P. R.	2015	Case-control	26	184	MiniMed MIP 2007C	MDI or CSII	ST	8	**0.27 (0.46; -0.09)**	
Automated insulin delivery systems											
RCTs											
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM	ST	7.7	**-0.3 (-0.5; -0.0)**	**-0.3 (-0.46; -0.14)**
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	ST	7.7	-0.4 (-0.9; 0.1)	**-0.6 (-0.74; -0.46)**
31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	CSII	7.4	**-0.33 (-0.53; -0.13)**	**-0.34 (-0.45; -0.23)**
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	Tandem Control-IQ (applied during an RCT performed 6 months before study start)	7.1	**-0.34 (-0.57; -0.11)**	
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	ST	9	**-1.42 (-1.74; -1.1)**	**-1.54 (-1.77; -1.31)**
37551542	Edd, S. N.	2023	RCT: Parallel	26	39	Medtronic 780G	MDI and isCGM	MDI	8.9		**-1.4 (-1.7; -1.1)**
36472543	Garg, S. K.	2023	RCT: Parallel	26	302	Medtronic 670G	CSII	CSII	8.2	**-0.6 (-0.8; -0.3)**	**-1 (-1.14; -0.85)**
33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	CSII	7.9	-0.30 (-0.67; 0.08)	**-0.46 (-0.64; -0.28)**
37796241	Lee, T. M.	2023	RCT: Parallel	36	124	CamAPS FX	ST: MDI or CSII	ST: MDI or CSII	7.7	**-0.3 (-0.5; -0.1)**	**-1.6 (-1.79; -1.40)**
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	MDI and self-monitoring of blood glucose	7.2	**-0.6 (-0.9; -0.2)**	**-0.35 (-0.6; -0.09)**
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	ST	7.4	**-0.4 (-0.6; -0.2)**	**-0.4 (-0.54; -0.26)**
37729080	Renard, E.	2023	RCT: Parallel	12	72	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	CSII	7.2	-0.1 (-0.4; 0.2)	**-0.3 (-0.42; -0.18)**
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	MDI	9.1	**-1.3 (-1.9; -0.7)**	**-1.6 (-2.2; -0.99)**

36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	MDI and real time CGM	9.1	-1.1 (-2.2; 0)	**-1.7 (-2.26; -1.14)**
36920756	Wadwa, R. P.	2023	RCT: Parallel	13	102	Tandem Control-IQ	ST: MDI or CSII	ST: MDI or CSII	7.6	**-0.42 (-0.62; -0.22)**	**-0.5 (-0.68; -0.32)**
35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	CSII	8.2	**-1.05 (-1.43; -0.67)**	**-1.1 (-1.36; -0.83)**
33323237	Benhamou, P.	2019	RCT: Crossover	32	63	Diabeloop DBLG1	SAP	CSII	7.6	-0.15 (-0.33; 0.03)	**-0.29 (-0.44; -0.13)**
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	CSII or MDI	7.9	**-0.2 (-0.37; -0.03)**	**-0.5 (-0.63; -0.37)**
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	CSII	6.7	**-0.2 (-0.4; -0.1)**	
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	ST	7.8	-0.1 (-0.21; 0.01)	**-0.5 (-0.89; -0.11)**
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	CSII	7.6	-0.2 (-0.3; 0)	
35373894	von dem Berge, T.	2022	RCT: Crossover	18	38	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	CSII	7.4	-0.2 (-0.45; 0.05)	**-0.5 (-0.69; -0.30)**
35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP	ST	7.3	**-0.4 (-0.5; -0.3)**	**-0.7 (-0.8; -0.60)**
Observational studies											
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		SAP	7.6		**-0.41 (-0.65; -0.17)**
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6			**-0.4 (-0.51; -0.28)**
35136338	Amole, M.	2021	Longitudinal	26	37	Medtronic 670G		ST	7.6		**-0.3 (-0.47; -0.13)**
38459160	Atik-Altinok, Y.	2023	Longitudinal	24	29	Medtronic 780G		Medtronic 780G in manual mode			-0.2 (-0.5; 0.1)
31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		ST	7.4		**-0.4 (-0.6; -0.2)**

31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		Medtronic 670G in MM (during 1-2 weeks run-in period)	8.8		**-0.3 (-0.33; -0.27)**
34227214	Cherubini, V.	2021	Longitudinal	12	43	Tandem Control-IQ		PLGS Basal-IQ			**-0.5 (-0.7; -0.3)**
36724301	Chico, A.	2023	Longitudinal	12	62	Diabeloop DBLG1		CSII or MDI			**-0.52 (-0.68; -0.36)**
32212971	Cobry, E. C.	2020	Longitudinal	13	37	Medtronic 670G		ST	8.3		-0.2 (-0.41; 0.01)
DOI in footnote	Del Valle Rolón, M.E.	2023	Longitudinal	52	136	Tandem Control-IQ		CSII or MDI			Non-minority**: -0.7 (-0.98; -0.42)** Minority**: -2 (-2.59; -1.41)** Overall**: -0.94 (-1.19; -0.69)**
34524023	Dubose, S. N.	2021	Longitudinal	52	80	Medtronic 670G		ST	8.4		-0.4
30865545	Faulds, E. R.	2019	Longitudinal	12	34	Medtronic 670G		ST	7.5		**-0.5 (-0.71; -0.29)**
37905353	Henry, Z.	2023	Longitudinal	52	231	Medtronic 780G (72%), Tandem Control IQ (28%)		SAP or PLGS	7.8		Medtronic 780G: **-0.89 (-1.41; -0.37)** Tandem Control IQ**: -0.63 (-0.99; -0.27)** Overall**: -0.71 (-1.01; -0.42)**
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		CSII			-0.1 (-0.23; 0.03)
35099298	Jacobsen, S. S.	2022	Longitudinal	52	55	Medtronic 670G		ST	7.4		**-0.3 (-0.41; -0.19)**
33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	SAP	7.5	**0.8 (0.59; 1.01)**	
34569850	Ju, Z.	2022	Longitudinal	52	22	Medtronic 670 G		ST	7.6		**-0.49 (-0.76; -0.22)**
38236643	Lablanche, S.	2023	Longitudinal	52	220	Medtronic 780G		CSII	7.6		**-0.5 (-0.6; -0.4)**
31548247	Lal, R. A.	2019	Longitudinal	52	79	Medtronic 670G		ST	8		-0.1 (-0.35; 0.15)
38225516	Landau, Z.	2023	Longitudinal	52	46	Medtronic 780G	Open source automated insulin delivery system	ST	7	-0.05 (-0.47; 0.37)	
38579305	Lehmann, V.	2023	Longitudinal	36	44	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G		Cohort 1: Medtronic 640G; Cohort 2: Medtronic 670G	Cohort 1: 7.3 Cohort 2: 6.95		Cohort 1: -0.3 (-1.06; 0.46) Cohort 2: 0 (0; 0)
37959415	Lendínez-Jurado, A.	2023	Longitudinal	12	28	Medtronic 780G		CSII	Cohort 1: 7.34		Cohort 1**: -0.4 (-0.6; -0.19)**

									Cohort 2: 6.68		Cohort 2: -0.03 (-0.3; 0.23)
37337407	Lendínez-Jurado, A.	2023	Longitudinal	24	28	Medtronic 780G		CSII	7.02		-0.5 (-1.4; 0.4)
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		MDI or CSII	7.2		**-0.3 (-0.4; -0.2)**
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		ST	7.3		0.23 (-0.6; 1.06)
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		MDI or CSII	7.5		**-0.45 (-0.67; -0.23)**
37184526	Matejko, B.	2023	Longitudinal	52	18	Medtronic 780G		MDI	7.1		**-0.6 (-0.85; -0.35)**
36940793	Nattero-Chavez, L.	2023	Longitudinal	24	46	Medtronic 780G		MDI or CSII or SAP	6.9		**-0.2 (-0.31; -0.09)**
37902713	Nigi, L.	2023	Longitudinal	52	22	Medtronic 780G		MDI or CSII or SAP with PLGS or hybrid closed-loop system with automatic basal insulin infusion but without corrective bolus delivery	7.4		**-0.53 (-0.76; -0.3)**
35488481	Ng, S. M.	2022	Longitudinal	12	39	Tandem Control-IQ (91%), CamAPS FX (9%)		CSII	7.9		**-2.7 (-3.2; -2.2)**
36424877	Ng, S. M.	2023	Longitudinal	24	251	Tandem Control-IQ (78%), Medtronic 780G (11%), CamAPS FX (11%)		MDI	7.9		**-2.8 (-2.9; -2.7)**
37708979	Papa, G.	2023	Longitudinal	52	54	Medtronic 670G (41%), Medtronic 780G (59%)		MDI or CSII	8.3		**-1 (-1.6; -0.7)**
33044604	Petrovski, G.	2021	Longitudinal	52	30	Medtronic 670G		MDI	8.2		**-1.1 (-1.47; -0.73)**
36317539	Piccini, B.	2022	Longitudinal	24	44	Medtronic 780G		Medtronic 780G in manual mode	7.2		**-0.6 (-0.73; -0.47)**
38068733	Piccini, B.	2023	Longitudinal	24	83	Medtronic 780G		Medtronic 780G in manual mode	7.2		**-0.3 (-0.39; -0.21)**
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		Medtronic 780G in manual mode	7.5		**-0.8 (-0.93; -0.67)**
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		Medtronic 640G or PLGS	7.6		**-0.6 (-0.69; -0.51)**
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		MDI or CSII	7.4		-0.1 (-0.36; 0.16)

31166801	Salehi, P.	2019	Longitudinal	27	16	Medtronic 670G in auto mode	Medtronic 670G in MM with low glucose suspend	NR	7.9	**-0.5 (-0.85; -0.15)**	
34725723	Thivolet, C.	2021	Longitudinal	13	121	Medtronic 780G	SAP with standalone CGM or SAP with PLGS (Tandem t:slim X2 insulin pump with Basal-IQ and Dexcom G6 CGM)	ST	7.9	**-0.48 (-0.76; -0.20)**	**-0.86 (-0.89; -0.83)**
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	ST			**-0.5 (-1.4; -0.1)[#]**
33430621	Usoh, C. O.	2021	Longitudinal	4	80	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)	8.1		**-0.69 (-1.02: -0.36)**
36280026	Usoh, C. O.	2023	Longitudinal	78	66	Tandem Control IQ		MDI or CSII	7.7		**-0.6 (-1.08; -0.12)**
34015178	Varimo, T.	2021	Longitudinal	52	111	Medtronic 670G		ST	7.4		**-0.1 (-0.19; -0.009)**
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		CSII	7.6		0 (-0.18; 0.18)
33958309	Wang, L. R.	2021	Longitudinal	NR	21	Medtronic 670G		ST	7.9		**-0.9 (-1.19; -0.61)**
34058303	Horowitz, M. E.	2021	Cross-sectional	NA	84	Medtronic 670G		ST	7.4		0 (-0.13; 0.13)
31617752	Lepore, G.	2020	Case-control	26	40	Medtronic 670G	PLGS: Medtronic 640G with Guardian 3	ST	7.4	**-0.5 (-0.86; -0.14)**	**-0.4 (-0.7; -0.1)**
Non-RIS											
33431420	Amadou, C.	2021	Non-RIS	26	25	Diabeloop DBLG1		CSII	7.9		**-0.8 (-1.22; 0.38)**
34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		PLGS	7.2		**-0.56 (-0.7; -0.41)**
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	7.6		**-0.6 (-1.05; -0.15)**
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	7		**-0.3 (-0.58; -0.02)**
36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		MDI	10.5		**-2.9 (-3.8; -1.9)**
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		ST	7.4		Children: **-0.71 (-1.06; -0.37)** Adults: **-0.38 (-0.57; -0.20)**

											Overall: **-0.45 (-0.62; -0.29)**
34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		SAP, PLGS or automated basal use (during 2 weeks run-in period)	7.5		**-0.5 (-0.58; -0.42)**
38439656	Carlson, A. L.	2024	Non-RIS	13	34	Tandem Control-IQ		CSII	7.7		**-0.82 (-1.08; -0.57)**
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		ST	7.4		Children: **-0.5 (-0.6; -0.4)** Adolescents/adults: **-0.3 (-0.4; -0.2)** Overall: **-0.4 (-0.47; -0.33)**
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		Basal or basal-bolus	9.4		**-1.3 (-1.53; -1.07)**
37598004	Delgado, A. M.	2023	Non-RIS	52	71	Tandem Control-IQ		PLGS	6.9		**-0.33 (-0.44; -0.22)**
38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		ST	7.4		**-0.4 (-0.54; -0.26)**
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		Open-source AndroidAPS	6.4		-0.1 (-0.88; 0.68)
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)	7.9		**-0.4 (-0.49; -0.3)**
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)	8		**-0.5 (-0.66; -0.33)**
28134564	Garg, S. K.	2017	Non-RIS	13	124	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)	7.4		Adolescents: **-0.6 (-0.79; -0.41)** Adults: **-0.5 (-0.61; -0.39)** Overall: **-0.53 (-0.62; -0.43)**
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		CSII or PLGS	8.5		**-0.81 (-1.25; -0.37)**
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		MDI	11.7		**-2.1 (-3.1; -1.1)**
29444895	Messer, L. H.	2018	Non-RIS	13	31	Medtronic 670G		Medtronic 670G in Open Loop MM (during 2 weeks run-in period)	7.8		**-0.75 (-1-08; -0.42)**
37823890	Michaels, V. R.	2024	Non-RIS	52	20	Medtronic 780G		MDI	10.5		**-2.5 (-3.57; -1.5)**
31953687	Petrovski, G.	2020	Non-RIS	12	30	Medtronic 670G		MDI	8.2		**-1.5 (-1.89; -1.11)**

35072781	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI	8.6		**-2.1 (-2.52; -1.68)**
35351095	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI	8.6		**-2.1 (-2.52; -1.68)**
37782145	Pinhoker, C.	2023	Non-RIS	12	160	Medtronic 670G		SAP with/without PLGS or HCL (Auto Basal only) without Auto Correction turned on	7.9		**-0.5 (-0.58; -0.42)**
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G	7.4		**-2.4 (-4.12; -0.68)**
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		ST	7.4		**-0.4 (-0.85; -0.1)**
Automated insulin delivery systems: Fully closed loop systems											
RCTs											
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications	9	**-1.4 (-1.8; -1)**	
Non-RIS											
38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		MDI (18%), CSII (75%), HCL (6%)	7.8		**-0.9 (-1.32; -0.48)**

*Results from the longest follow-up time are reported. Statistically significant results are bolded. In green areas, mean differences (95%CI) are calculated based on the values provided in the study. In orange areas, there is an incomplete reporting of the results from the studies.

**For all participants

†(Cohort 1) T1D or T2D with HbA1c > 8% (64 mmol/mol) (Cohort 2) T1D with a time spent with glucose values below 70 mg/dL (3.8 mmol/l) (TBR<70) for >1.5 h/d during the previous 28 days.

#In participants using Medtronic 780G, HbA1c measured at baseline was compared with HbA1c measured after 6 months of auto mode.

Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706

Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion (pump therapy); HbA1c, glycated hemoglobin; MDI, multiple daily insulin injection therapy; MM, manual mode; NA, not applicable; non-RIS, non-randomized interventional study; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy.

Supplemental table 6

Meta-regression of clinical variables on pooled effect estimates					
Parameter	**Parameter**	**Univariable**		**Multivariable**	
		β	**p**	**β**	**p**
HbA1c (n=21 studies)					
Age	continuous	-0.003	0.5	-0.03	0.001
Sex (% males)	continuous	-0.011	0.04	-0.004	0.4
Diabetes duration	continuous	0.008	0.4	0.06	0.001
TIR (n=27 studies)					
Age	continuous	0.14	0.07	0.22	0.03
Sex (% males)	continuous	0.32	0.007	0.32	0.01
Diabetes duration	continuous	0.02	0.9	-0.19	0.3
TAR (n=26 studies)					
Age	continuous	-0.13	0.12	-0.31	0.01
Sex (% males)	continuous	-0.28	0.01	-0.23	0.02
Diabetes duration	continuous	0.05	0.8	0.45	0.1
TBR (n=26 studies)					
Age	continuous	-0.006	0.7	0.01	0.4
Sex (% males)	continuous	0.02	0.5	-0.002	0.9
Diabetes duration	continuous	-0.05	0.12	-0.07	0.16
Time below 3 mmol/l (n=23 studies)					
Age	continuous	-0.002	0.5	0.0007	0.9
Sex (% males)	continuous	0.003	0.6	0.0003	0.9
Diabetes duration	continuous	-0.006	0.3	-0.008	0.6

Abbreviations: HbA1c, glycated hemoglobin; n, total number of studies; TIR, time in range; TAR, time above range; TBR, time below range.

Supplemental table 7

Subgroup and sensitivity analyses for the meta-analyses of RCTs on the impact of AID systems on HbA1c and CGM parameters				
	N	**Mean difference (95% CI)**	**I^2**	**Univariate meta-regression p-value**
All RCTs				
HbA1c†	21	**-0.46 (-0.59; -0.34)**	85.5%	
TIR†	27	**13.40 (11.13; 15.67)**	89.5%	
TAR†	26	**-11.67 (-13.87; -9.47)**	86.2%	
TBR†	26	**-0.82 (-1.14; -0.49)**	91%	
Time below 3 mmol/l†	23	**-0.12 (-0.19; -0.06)**	80.3%	
Stratification by age categories				
HbA1c				
Children and/or adolescents	5	**-0.46 (-0.65; -0.26)**	70.7%	0.5
Adults	11	**-0.57 (-0.81; -0.34)**	89.8%	
Mixed	5	**-0.32 (-0.49; -0.14)**	74.8%	
TIR				
Children and/or adolescents	6	**10.7 (8.71; 12.68)**	43%	0.07
Adults	14	**18.38 (13.94; 22.82)**	92.6%	
Mixed	7	**7.94 (3.94; 11-95)**	87.6%	
TAR				
Children and/or adolescents	5	**-10.06 (-12.47; -7.65)**	34.1%	0.12
Adults	15	**-15.28 (-19.27; -11.30)**	91.1%	
Mixed	6	**-6.78 (-9.65; -3.91)**	62.3%	
TBR				
Children and/or adolescents	5	-0.04 (-0.48; 0.39)	49.2%	0.6
Adults	14	**-0.97 (-1.42; -0.52)**	91.6%	
Mixed	7	**-1.17 (-1.92; -0.42)**	94.3%	
Time below 3 mmol/l				
Children and/or adolescents	6	-0.0 (-0.03; 0.03)	0%	0.5
Adults	12	**-0.20 (-0.32; -0.09)**	81%	
Mixed	5	**-0.28 (-0.49; -0.07)**	83.6%	
Stratification by funding source				
HbA1c				
Non-industry funded	9	**-0.42 (-0.59; -0.24)**	86.9%	0.07
Industry-funded	4	**-0.90 (-1.37; -0.42)**	83.5%	
Industry and non-industry funded	8	**-0.33 (-0.48; -0.19)**	67.3%	
TIR				

Non-industry funded	9	**12.79 (9.56; 16.02)**	89.6%	0.2
Industry-funded	7	**17.67 (8.26; 27.07)**	95.3%	
Industry and non-industry funded	11	**10.71 (8.34; 13.08)**	65.8%	
TAR				
Non-industry funded	9	**-10.90 (-13.97; -7.82**	88.3%	0.1
Industry-funded	6	**-17.61 (-26.16; -9.05)**	85.4%	
Industry and non-industry funded	11	**-8.13 (-10.34; -5.92)**	56.7%	
TBR				
Non-industry funded	9	**-0.80 (-1.39; -0.21)**	93.5%	0.3
Industry-funded	7	**-1.26 (-2.08; -0.44)**	88.8%	
Industry and non-industry funded	10	**-0.64 (-1.18; -0.10)**	90.9%	
Time below 3 mmol/l				
Non-industry funded	9	**-0.19 (-0.33; -0.05)**	85.2%	0.4
Industry-funded	4	-0.25 (-0.54; 0.05)	53.8%	
Industry and non-industry funded	10	**-0.09 (-0.17; -0.00)**	80.9%	
Stratification by study setting*				
HbA1c				
Unsupervised	21	**-0.46 (-0.59; -0.34)**	85.5%	NA
TIR				
Unsupervised	24	**13.91 (11.69; 16.13)**	88.7%	0.5
Supervised	3	8.96 (-6.73; 24.66)	88.6%	
TAR				
Unsupervised	23	**-11.88 (-14.16; -9.6)**	87.3%	0.8
Supervised	3	-8.83 (-20.68; 3.01)	73%	
TBR				
Unsupervised	23	**-0.98 (-1.37; -0.58)**	91.2%	0.2
Supervised	3	-0.06 (-0.42; 0.29)	62.5%	
Time below 3 mmol/l				
Unsupervised	22	**-0.14 (-0.22; -0.07)**	78.6%	0.5
Supervised	1	0 (-0.03; 0.03)	-	
Stratification by RCT design				
HbA1c				
Parallel	14	**-0.55 (-0.73; -0.38)**	80.7%	0.3
Cross-over	7	**-0.32 (-0.49; -0.14)**	87.9%	
TIR				
Parallel	16	**13.00 (9.75; 16.24)**	88.8%	0.7
Cross-over	11	**14.23 (10.71; 17.75)**	91.0%	
TAR				
Parallel	15	**-11.50 (-14.65; -8.35)**	84.4%	0.8

Cross-over	11	**-12.16 (-15.58; -8.74)**	89%	
TBR				
Parallel	16	**-0.85 (-1.35; -0.35)**	92.5%	0.9
Cross-over	10	**-0.75 (-1.18; -0.32)**	88.5%	
Time below 3 mmol/l				
Parallel	14	**-0.22 (-0.33; -0.10)**	83.3%	0.3
Cross-over	9	-0.05 (-0.13; 0.03)	75.8%	
Stratification pre- vs post-market				
HbA1c				
Pre-market	4	**-0.27 (-0.38; -0.15)**	0%	0.3
Post-market	17	**-0.51 (-0.67; -0.36)**	88%	
TIR				
Pre-market	7	**10.09 (5.12; 15.47)**	93.4%	0.2
Post-market	20	**14.62 (12.03; 17.21)**	87.6%	
TAR				
Pre-market	7	**-9.93 (-13.88; -5.98)**	85.3%	0.4
Post-market	19	**-12.59 (-15.37; -9.80)**	87.1%	
TBR				
Pre-market	7	-0.58 (-1.26; 0.10)	92.6%	0.5
Post-market	19	**-0.91 (-1.30; -0.52)**	90.7%	
Time below 3 mmol/l				
Pre-market	4	-0.04 (-0.11; 0.02)	48.8%	0.4
Post-market	19	**-0.16 (-0.25; -0.07)**	81.6%	
Stratification by geographical region				
HbA1c				
Europe	10	**-0.61 (-0.86; -0.36)**	90.5%	**0.04**
North America	6	**-0.39 (-0.48; -0.29)**	0%	
Australia or New Zealand	4	**-0.23 (-0.36; -0.09)**	60.4%	
Mixed	1	**-1.05 (-1.43; -0.67)**	-	
TIR				
Europe	14	**18.08 (14.03; 22.13)**	91.8%	**0.03**
North America	7	**8.56 (4.71; 12.41)**	89.2%	
Australia or New Zealand	5	**10.19 (5.98; 14.40)**	79.9%	
Mixed	1	**15.00 (7.95; 22.05)**	-	
TAR				
Europe	14	**-16.41 (-20.47; -12.35)**	90.1%	**0.01**
North America	6	**-7.38 (-10.00; -4.75)**	66.8%	
Australia or New Zealand	5	**-7.42 (-10.62; -4.22)**	66.4%	
Mixed	1	**-18.40 (-26.95; -9.85)**	-	

TBR				
Europe	13	**-0.80 (-1.24; -0.36)**	90.2%	0.4
North America	7	-0.50 (-1.16; 0.16)	92.5%	
Australia or New Zealand	5	**-1.42 (-2.24; -0.60)**	90.8%	
Mixed	1	3.13 (-1.25; 7.51)	-	
Time below 3 mmol/l				
Europe	11	-0.10 (-0.21; 0.02)	74.1%	0.2
North America	6	-0.04 (-0.09; 0.01)	36.1%	
Australia or New Zealand	5	**-0.35 (-0.54; -0.15)**	89.3%	
Mixed	1	0.91 (-0.81; 2.63)	-	
Stratification by diabetes type				
HbA1c				
Type 1 diabetes	20	**-0.42 (-0.54; -0.30)**	82.7%	**0.027**
Type 2 diabetes	1	**-1.40 (-1.80; -1.00)**	-	
TIR				
Type 1 diabetes	23	**12.06 (9.89; 14.23)**	88.6%	**0.03**
Type 2 or pancreatogenic diabetes	4	**23.30 (13.13; 33.38)**	75.1%	
TAR				
Type 1 diabetes	22	**-10.33 (-12.34; -8.32)**	83.8%	**0.03**
Type 2 or pancreatogenic diabetes	4	**-22.63 (-34.68; -10.59)**	70.7%	
TBR				
Type 1 diabetes	22	**-0.95 (-1.36; -0.53)**	91.2%	0.4
Type 2 or pancreatogenic diabetes	4	-0.24 (-0.63; 0.14)	79.3%	
Time below 3 mmol/l				
Type 1 diabetes	20	**-0.14 (-0.21; -0.06)**	81.4%	0.8
Type 2 or pancreatogenic diabetes	3	-0.06 (-0.22; 0.10)	75%	
Stratification by medical device				
HbA1c				
Medtronic 670G	6	**-0.28 (-0.42; -0.14)**	70.6%	0.06
Medtronic 780G	3	**-1.03 (-1.68; -0.38)**	82.6%	
Tandem Control-IQ	6	**-0.39 (-0.58; -0.20)**	60.9%	
,Diabeloop DBLG1	1	-0.15 (-0.33; 0.03)	-	
CampAPS FX	4	**-0.42 (-0.64; -0.21)**	83.3%	
CamAPS HX	1	**-1.40 (-1.80; -1.00)**	-	
TIR				
Medtronic 670G	8	**8.80 (4.86; 12.74)**	87.8%	**0.003**
Medtronic 780G	3	**24.79 (20.28; 29.29)**	13.4%	
Tandem Control-IQ	7	**10.59 (7.78; 13.41)**	74.3%	
Diabeloop DBLG1	1	**9.20 (6.45; 11.95)**	-	

CampAPS FX	3	**9.02 (7.30; 10.73)**	33.8%	
CamAPS HX	3	**23.85 (10.29; 37.41)**	81.9%	
Inreda AP	2	**26.23 (19.57; 32.88)**	27.9%	
TAR				
Medtronic 670G	7	**-7.28 (-10.31; -4.26)**	64.9%	**0.007**
Medtronic 780G	3	**-22.85 (-33.18; -12.52)**	76.5%	
Tandem Control-IQ	6	**-9.12 (-12.25; -5.99)**	72.6%	
Diabeloop DBLG1	1	**-6.80 (-9.70; -3.90)**	-	
CampAPS FX	4	**-8.26 (-10.90; -5.62)**	74.7%	
CamAPS HX	3	**-23.47 (-37.49; -9.44)**	79.1%	
Inreda AP	2	**-25.58 (-31.85; -19.31)**	0%	
TBR				
Medtronic 670G	7	**-1.53 (-2.27; -0.79)**	92.8%	0.8
Medtronic 780G	3	-1.36 (-3.66; 0.95)	80.2%	
Tandem Control-IQ	7	-0.45 (-1.22; 0.31)	92.1%	
Diabeloop DBLG1	1	**-2.40 (-3.05; -1.75)**	-	
CampAPS FX	3	-0.02 (-0.32; 0.29)	23.2%	
CamAPS HX	3	-0.02 (-0.16; 0.11)	0%	
Inreda AP	2	**-1.64 (-2.29; -1.00)**	0%	
Time below 3 mmol/l				
Medtronic 670G	6	**-0.27 (-0.45; -0.08)**	88.4%	0.8
Medtronic 780G	3	-0.48 (-1.08; 0.13)	59.1%	
Tandem Control-IQ	7	-0.08 (-0.17; 0.01)	76.4%	
CampAPS FX	4	-0.00 (-0.08; 0.07)	6.5%	
CamAPS HX	2	0.01 (-0.06; 0.07)	0%	
Inreda AP	1	**-0.62 (-1.05; -0.19)**	-	
Stratification by AID system				
HbA1c				
Hybrid closed-loop system	20	**-0.42 (-0.54; -0.30)**	82.7%	**0.027**
Fully closed-loop system	1	**-1.40 (-1.80; -1.00)**	-	
TIR				
Hybrid closed-loop system	22	**11.18 (9.19; 13.17)**	85.9%	**0.002**
Fully closed-loop system	5	**24.90 (17.87; 31.93)**	67.8%	
TAR				
Hybrid closed-loop system	21	**-9.49 (-11.32; -7.65)**	79.9%	**0.002**
Fully closed-loop system	5	**-24.35 (-32.15; -16.55)**	61.1%	
TBR				
Hybrid closed-loop system	21	**-0.91 (-1.33; -0.49)**	91.4%	0.6
Fully closed-loop system	5	**-0.44 (-0.88; 0)**	83.1%	

Time below 3 mmol/l				
Hybrid closed-loop system	20	**-0.14 (-0.21; -0.06)**	81.4%	0.8
Fully closed-loop system	3	-0.06 (-0.22; 0.10)	75%	
After removing poor quality studies				
HbA1c	19	**-0.48 (-0.61; -0.28)**	86.2%	NA
TIR	24	**12.98 (10.63; 15.33)**	88.7%	NA
TAR	24	**-11.28 (-13.46; -9.10)**	84.5%	NA
TBR	23	**-0.55 (-0.85; -0.26)**	88.7%	NA
Time below 3 mmol/l	22	**-0.10 (-0.16; -0.04)**	77.6%	NA
After restricting the analyses to studies within pseudo 95% CI of the funnel plot				
HbA1c	16	**-0.32 (-0.39; -0.25)**	39.4%	NA
TIR	17	**10.32 (9.18; 11.46)**	33.9%	NA
TAR	17	**-8.53 (-9.79; -7.27)**	41.4%	NA
TBR	14	**-0.18 (-0.31; -0.06)**	9.2%	NA
Time below 3 mmol/l	17	**-0.04 (-0.07; -0.00)**	41.2%	NA

†RCTs evaluating the effect of AID systems on the outcome (including HbA1c, TIR, TAR, TBR, or time below 3 mmol/l). The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices.
*Study settings were classified into unsupervised outpatient setting vs controlled environments or combined settings.
Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; 95% CI, 95% confidence interval; HbA1c, glycated hemoglobin; I^2, heterogeneity; N, total number of studies; NA, not applicable; RCT, randomized clinical trial; TAR, time with sensor values above target range; TBR, time with sensor values below target range; TIR, time with sensor values in target range; Time below 3 mmol/l, time with sensor values below 3 mmol/l.

Supplemental table 8

Results on high-risk medical devices for diabetes and TIR *										
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)**	**Baseline treatment against diabetes**	**TIR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention vs comparison [Reference])**	**TIR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention, final vs baseline [Reference])**
Implantable CGM devices										
RCTs										
34984786	Renard, E.	2022	RCT: Parallel	26	239	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM	MDI, CSII	Cohort 1: -0.9 (-6.7; 4.8) Cohort 2: -0.4 (-4.6; 3.8) Overall: -0.57 (-3.97; 2.82)	Cohort 1: **6 (4.1; 7.9)** Cohort 2: **2 (0.2; 3.7)** Overall: **3.84 (2.55; 5.12)**
34196924	Boscari, F.	2022	RCT: Crossover	12	16	Eversense® CGM System (90 days)	Dexcom G5	ST	**4.15 (1.02; 7.28)¶**	
Observational studies										
32037699	Irace, C.	2020	Longitudinal	26	100	Eversense® XL CGM System (180 days)		ST		**5.3 (2.74; 7.86)**
Implantable insulin pumps										
RCTs										
19429874	Logtenberg, S. J.	2009	RCT: Crossover	26	24	MiniMed MIP 2007C	ST: MDI or CSII	ST	**10.9 (4.6; 17.3)**	
Observational studies										
26582805	van Dijk, P. R.	2015	Case-control	26	184	MiniMed MIP 2007C	MDI or CSII	ST	**-6.9 (-12.5; -1.2)**	
Automated insulin delivery systems: Hybrid closed loop systems										
RCTs										
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM	ST	**6.7 (2.7; 10.8)**	**9.4 (7.5; 11.3)**
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	ST	**11 (7; 14)**	**14 (12.48; 15.51)**

31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	CSII	**11 (9; 14)**	**10 (8; 12)**
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	Tandem Control-IQ (applied during an RCT performed 6 months before study start)	**5.9 (3.6; 8.3)**	
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	ST	**27.6 (21.63; 33.6)**	**34.2 (31.6; 36.8)**
37551542	Edd, S. N.	2023	RCT: Parallel	26	39	Medtronic 780G	MDI and isCGM	MDI		**28.1 (22.8; 33.4)**
31099946	Ekhlaspour, L.	2019	RCT: Parallel	0.29	48	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	CSII	**12.5 (0.28; 24.72)†**	
30888835	Forlenza, G. P.	2019	RCT: Parallel	0.43	24	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	ST	**18.4 (9.5; 27.3)†**	
36472543	Garg, S. K.	2023	RCT: Parallel	26	302	Medtronic 670G	CSII	CSII	**12 (8.8; 15.1)**	**14.9 (13.31; 16.49)**
33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	CSII	**13 (9; 16)**	**13 (9.57; 16.43)**
26049550	Ly, T. T.	2015	RCT: Parallel	0.85	21	Medtronic 670G	PLGS: Medtronic 530G with threshold suspend and Enlite sensor	ST	-3.2 (-7.18; 0.78)†	
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	MDI and self-monitoring of blood glucose	**21.5 (15.7; 27.3)**	**15.7 (11.87; 19.53)**
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	ST	**14.8 (11; 18.5)**	**14.7 (12.61; 16.78)**
37729080	Renard, E.	2023	RCT: Parallel	12	72	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	CSII	**8.6 (5.2; 12.1)**	**13.2 (11.14; 15.26)**
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	MDI	**27.4 (15; 39.8)**	**28.6 (18.6; 38.6)**
36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	MDI and real time CGM	**28.8 (12.3; 45.3)**	**31.5 (23.72; 39.27)**
36920756	Wadwa, R. P.	2023	RCT: Parallel	13	102	Tandem Control-IQ	ST: MDI or CSII	ST: MDI or CSII	**12.4 (9.5; 15.3)**	**12.6 (9.87; 15.33)**

35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	CSII	**15 (8; 22.1)**	**13 (9.99; 16)**
33323237	Benhamou, P.	2019	RCT: Crossover	32	63	Diabeloop DBLG1	SAP	CSII	**9.2 (6.4; 11.9)**	
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	CSII or MDI	**4 (1.9; 6.1)†**	**10 (8.63; 11.37)**
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	CSII	**8.6 (6.3; 11)**	
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	ST	**13.6 (4.67; 22.53)†**	**8.6 (5.3; 11.8)**
33579715	Collyns, O. J.	2021	RCT: Crossover	4	60	Medtronic 670G pump in advanced hybrid closed loop mode	PLGS: Medtronic 670G pump in SAP with PLGS mode	PLGS	**12.5 (5.43; 19.57)**	**11.4 (9.79; 13)**
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	CSII	**6.2 (4.4; 8)**	
30620641	Paldus, B.	2019	RCT: Crossover	1	11	Medtronic 770G	Medtronic 670G	ST	5 (-4.35; 14.35)†	
35373894	von dem Berge, T.	2022	RCT: Crossover	18	38	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	CSII	**10.5 (5.44; 15.56)**	**10.4 (7.82; 12.97)**
35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP	ST	**8.7 (7.4; 9.9)**	**10.4 (8.91; 11.89)**
Observational studies										
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		SAP		**10.7 (4.48; 16.9)**
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6		**11.6 (11.3; 11.9)**
35414272	Arunachalum, S.	2023	Longitudinal	52	2627	Medtronic 670G		ST		**8.3 (7.96; 8.64)**
35116007	Bassi, M.	2022	Longitudinal	4	90	Tandem Control-IQ	Medtronic 780G	ST	**-9.3 (-15.5, -3.1)**	

36777356	Bassi, M.	2023	Longitudinal	52	32	Tandem Control-IQ		MDI, SAP, PLGS		**12.5 (9.8; 15.2)**
31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		ST		**9.7 (7.3; 12.1)**
36030902	Beato-Vibora, P. I.	2022	Longitudinal	52	135	Medtronic 780G		MDI or CSII		**10.15 (8.94; 11.36)**
30862242	Berget, C.	2020	Longitudinal	4	72	Medtronic 670G		Medtronic 670G in MM (during 1 week run-in period)		**13.1 (10.77; 15.43)**
31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		Medtronic 670G in MM (during 1-2 weeks run-in period)		**6.2 (5.94; 6.46)**
33784196	Breton, M. D.	2021	Longitudinal	52	9451	Tandem Control-IQ		PLGS		**10 (9.77; 10.23)**
34227214	Cherubini, V.	2021	Longitudinal	12	43	Tandem Control-IQ		PLGS Basal-IQ		**11 (9;14)**
36724301	Chico, A.	2023	Longitudinal	12	62	Diabeloop DBLG1		CSII or MDI		**16.34 (13.56; 19.12)**
33961340	Da Silva, J.	2021	Longitudinal	52	880	Medtronic 670G		Medtronic 670G in MM (during ≥10 days run-in period)		**9.8 (4.89; 14.71)**
DOI in footnote	Del Valle Rolón, M.E.	2023	Longitudinal	52	136	Tandem Control-IQ		CSII or MDI		Non-minority**: 11 (5.2; 16.78)** Minority: 9 (-10.61; 28.62) Overall: **10.84 (5.29; 16.39)**
34524023	Dubose, S. N.	2021	Longitudinal	52	80	Medtronic 670G		ST		2
37845757	Elbarbary, N. S.	2023	Longitudinal	24	107	Medtronic 780G		MDI or PLGS		**18.06 (16.89; 19.23)**
30865545	Faulds, E. R.	2019	Longitudinal	12	34	Medtronic 670G		Medtronic 670G in MM (2 weeks run-in period)		3.8 (-0.32; 7.92)
33450533	Gomez, A. M.	2021	Longitudinal	2	91	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**4.3 (2.86; 5.74)**
DOI in footnote	Gouet, D.	2022	Longitudinal	52 ¥	83	Medtronic 780G		CSII		**7 (5.42; 8.58)**
36789699	Grassi, B.	2023	Longitudinal	19	459	Medtronic 780G		Cohort 1: Minimed 640G. Cohort 2: Minimed 670G		Cohort 1**: 10.6 (9.7; 11.6)** Cohort 2**: 4.7 (3.6; 5.9)**
38444313	Halim, B.	2024	Longitudinal		1501	Medtronic 780G		Medtronic 670G/770G		**4 (3.59; 4.4)**

37905353	Henry, Z.	2023	Longitudinal	52	231	Medtronic 780G (72%), Tandem Control IQ (28%)		SAP or PLGS		Medtronic 780G: **14.84 (6.16; 23.52)** Tandem Control IQ: **14.3 (6.18; 22.42)** Overall: **14.55 (8.62; 20.48)**
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		CSII		**8.5 (4.96; 12.04)**
35099298	Jacobsen, S. S.	2022	Longitudinal	52	55	Medtronic 670G		ST		**12.7 (10.47; 14.93)**
33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	SAP	**-10.3 (-16.9; -3.7)**†	
36126177	Kovatchev B. P.	2022	Longitudinal	12	19354	Tandem Control-IQ		PLGS: Basal-IQ with CGM		**11.6 (11.44; 11.75)**
38236643	Lablanche, S.	2023	Longitudinal	52	220	Medtronic 780G		CSII		**9.1 (7.6; 10.5)**
38225516	Landau, Z.	2023	Longitudinal	52	46	Medtronic 780G	Open-source automated insulin delivery system	ST	5.4 (-5.02; 15.82)	
38579305	Lehmann, V.	2023	Longitudinal	36	44	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G		Cohort 1: Medtronic 640G; Cohort 2: Medtronic 670G		Cohort 1: **6.6 (2.6; 12.7)** Cohort 2: **1.6 (0.5; 4.5)**
37959415	Lendínez-Jurado, A.	2023	Longitudinal	12	28	Medtronic 780G		CSII		Cohort 1: **18.8 (15.74; 21.86)** Cohort 2: **11.33 (7.95; 14.71)**
37337407	Lendínez-Jurado, A.	2023	Longitudinal	24	28	Medtronic 780G		CSII		**14.52 (10.9; 18.1)**
37902785	Lepore, G.	2023	Longitudinal	104	296	Medtronic 780G		MDI or CSII or SAP/PLGS or HCL (Medtronic 760G)		**12.2 (10.89; 13.51)**
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		MDI or CSII		**11.3 (9.72; 12.88)**
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		ST		3.4 (-12.66; 19.46)
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		MDI or CSII		**11 (5.58; 16.42)**
34096789	Messer, L. H.	2021	Longitudinal	26	191	Tandem Control-IQ		ST		**9.4 (9.29; 9.51)**
DOI in footnote	Mutlu, G. Y.	2023	Longitudinal	12	25	Medtronic 780G		Medtronic 640G		**4.5 (1.91; 7.08)**
36940793	Nattero-Chavez, L.	2023	Longitudinal	24	46	Medtronic 780G		MDI or CSII or SAP		**13 (10.2; 15.79)**
35488481	Ng, S. M.	2022	Longitudinal	12	39	Tandem Control-IQ (91%),		CSII		**16.5 (5.8; 21)**

						CamAPS FX (9%)				
36424877	Ng, S. M.	2023	Longitudinal	24	251	Tandem Control-IQ (78%), Medtronic 780G (11%), CamAPS FX (11%)		MDI		**14.3 (12.4; 15.9)**
37708979	Papa, G.	2023	Longitudinal	52	54	Medtronic 670G (41%), Medtronic 780G (59%)		MDI or CSII		**24.4 (17.3; 33.3)**
33044604	Petrovski, G.	2021	Longitudinal	52	30	Medtronic 670G		MDI		**26.5 (7.66; 45.3)**
36317539	Piccini, B.	2022	Longitudinal	24	44	Medtronic 780G		Medtronic 780G in manual mode		**8.7 (5.3; 11.2)**
38068733	Piccini, B.	2023	Longitudinal	24	83	Medtronic 780G		Medtronic 780G in manual mode		**9 (7.17; 10.83)**
32846114	Pinsker, J. E.	2021	Longitudinal	4	1435	Tandem Control-IQ		ST		**10.5 (9.89; 11.1)**
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		Medtronic 780G in manual mode		**15.5 (13.27; 17.72)**
34668782	Proietti, A.	2022	Longitudinal	26	30	Medtronic 670G		ST		**10.1 (6.47; 13.73)**
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		Medtronic 640G or PLGS		**5 (2.78; 7.22)**
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		MDI or CSII		**10 (6.05; 13.95)**
37956944	Rossi, A.	2023	Longitudinal	12	60	Medtronic 780G	PLGS	‡‡	**12.2 (11.38; 13.02)**	
31166801	Salehi, P.	2019	Longitudinal	27	16	Medtronic 670G in auto mode	Medtronic 670G in MM with low glucose suspend	NR	**13.4 (3.22; 23.58)**†	
35451679	Schiaffini, R.	2022	Longitudinal	4	31	Tandem Control-IQ (55%), Medtronic 780G (45%)		Medtronic 640G or Tandem Basal IQ with PLGS		Tandem Control-IQ: **5.3 (1.29; 9.31)** Medtronic 780G: 4.8 (-1.4; 11) Overall: **5.15 (1.79; 8.52)**
35020476	Scully, K. J.	2022	Longitudinal	13	13	Tandem Control-IQ		ST		**15.2 (13.25; 17.14)**
34524003	Silva, J. D.	2022	Longitudinal		4120	Medtronic 780G		ST		**12.1 (11.49; 12.7)**
30160523	Stone, M. P.	2018	Longitudinal	13	3141	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**7.3 (2.96; 11.6)**
34725723	Thivolet, C.	2021	Longitudinal	13	121	Medtronic 780G	SAP with standalone CGM or	ST	**17.5 (7.33; 27.67)**	**21.2 (20.84; 21.46)**

							SAP with PLGS (Tandem t:slim X2 insulin pump with Basal-IQ and Dexcom G6 CGM)			
38377317	Thrasher, J.R.	2024	Longitudinal	5	3851	Medtronic 780G		Medtronic 770G		**5.1 (4.88; 5.32)**
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	HCL system in MM (2 weeks training)		**14 (9.33; 18.67)**[#] Comparison, final vs baseline**: 9 (2.14; 15.86)**
34609917	Toschi, E.	2022	Longitudinal	13	48	Tandem Control-IQ		CSII		**14 (11.48; 16.52)**
33430621	Usoh, C. O.	2021	Longitudinal	4	80	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**10.8 (4.88; 16.72)**
36280026	Usoh, C. O.	2023	Longitudinal	78	66	Tandem Control IQ		MDI or CSII		**13.8 (6.72; 20.87)**
34015178	Varimo, T.	2021	Longitudinal	52	111	Medtronic 670G		ST		**11.6 (10.09; 13.11)**
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		CSII		**5.5 (1.4; 9.5)**
DOI in footnote	Zuijdwijk, C.	2023	Longitudinal	16	59	Tandem Control IQ		CSII		**8.9 (6.5; 11.3)**
33838993	Beato-Vibora, P. I.	2021	Cross-sectional	NA	302	Medtronic 670G	Group 1: CGM and MDI; Group 2: FGM and MDI; Group 3: SAP with PLGS	PLGS	Medtronic 670G vs CGM+MDI: **12 (7.03; 16.97)** Medtronic 670G vs FGM+MDI: **13 (8.27; 17.73)** Medtronic 670G vs SAP+PLGS: 4 (-0.01; 8.01)	
34058303	Horowitz, M. E.	2021	Cross-sectional	NA	84	Medtronic 670G		ST		**27.7 (25.17; 30.23)**
31617752	Lepore, G.	2020	Case-control	26	40	Medtronic 670G	PLGS; Medtronic 640G	ST	**10 (3.41; 16.6)**	**12.4 (7.69; 17.11)**
Non-RIS										
30239219	Adams, R. N.	2018	Non-RIS	0.71	29	Medtronic 670G		ST		**8.6 (5.52; 11.68)**
33431420	Amadou, C.	2021	Non-RIS	26	25	Diabeloop DBLG1		CSII		**33 (19.1; 46.9)**
33784187	Beato-Vibora, P. I.	2021	Non-RIS	4	52	Medtronic 780G		PLGS		**8.6 (5.52; 11.68)**

34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		PLGS		**12.8 (10.34; 15.26)**
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	**18.3 (9.64; 26.96)**†	
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	**10 (1.43; 18.57)**†	
36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		MDI		**38.9 (31.2; 46.5)**
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		ST		Children**: 15.6 (8.03; 23.17)** Adults**: 9.3 (4.77; 13.8)** Overall**: 10.95 (7.08; 14.83)**
34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		SAP, PLGS or automated basal use (during 2 weeks run-in period)		**5.7 (4.68; 6.72)**
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		ST		Children**: 13.5 (11.6; 15.39)** Adolescents/adults**: 9.3 (7.43; 11.17)** Overall**: 11.37 (10.04; 12.7)**
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		Basal or basal-bolus		**22 (17.03; 26.97)**
37598004	Delgado, A. M.	2023	Non-RIS	52	71	Tandem Control-IQ		PLGS		**8 (5.74; 10.26)**
38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		ST		**10 (7.85; 12.15)**
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		Open-source AndroidAPS		1.48 (-3.11; 6.07)
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**8.8 (7.45; 10.15)**
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**8.1 (5.68; 10.52)**
33325779	Forlenza, G. P.	2021	Non-RIS	3	36	Omnipod 5		ST		Children: **13.9 (4.5; 23.3)**; Adults: 6.9; P-value > 0.05
28134564	Garg, S. K.	2017	Non-RIS	13	124	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		Adolescents: **6.8 (4.35; 9.25)** Adults: **5 (3.52; 6.48)** Overall**: 5.48 (4.21; 6.75)**
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		CSII or PLGS		**10.4 (5.97; 14,11)**
31264889	Lee, M. H.	2019	Non-RIS	5	12	Medtronic 670G‡		Medtronic 670G‡ in Open Loop (during 1 week run-in period)		**10.3 (4.89; 15.7)**

27191182	Ly, T. T.	2017	Non-RIS	0.71	24	Medtronic 670G		SAP		Adults: 4.1 (-1.84; 10.04) Adolescents: **14.6 (9.79; 19.41)** Overall: **10.44 (6.7; 14.18)**
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		MDI		**23.7 (16.9; 30.5)**
29444895	Messer, L. H.	2018	Non-RIS	13	31	Medtronic 670G		Medtronic 670G in Open Loop MM (during 2 weeks run-in period)		**13.7 (10.42; 16.97)**
37823890	Michaels, V. R.	2024	Non-RIS	52	20	Medtronic 780G		MDI		**34.9 (26.9; 42.9)**
33185480	Nimri, R.	2021	Non-RIS	4	12	Medtronic 780G		Medtronic 780G in MM (during 6 days run-in period)		**5.6 (0.36; 10.84)**
31953687	Petrovski, G.	2020	Non-RIS	12	30	Medtronic 670G		MDI		**27.9 (22.86; 32.94)**
35072781	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI		**36.7 (31.71; 41.69)**
35351095	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI		**36.7 (31.71; 41.69)**
37782145	Pinhoker, C.	2023	Non-RIS	12	160	Medtronic 670G		SAP with/without PLGS or HCL (Auto Basal only) without Auto Correction turned on		**10.9 (9.7; 12.09)**
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		**8.3 (5.6; 10.99)**
38514384	Pulkkinen, M.	2024	Non-RIS	39	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		**8.7 (5.92; 11.48)**
35852811	Seget, S	2022	Non-RIS	4	50	Medtronic 780G		PLGS or CSII		**5.31 (3.55; 7.07)**
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		ST		**8.9 (4.9; 13.8)**
Automated insulin delivery systems: Fully closed loop systems										
RCTs										
35880252	Herzig, D.	2022	RCT: Parallel	2.8	44	CamAPS HX	Standard insulin therapy	ST: basal insulin, basal-bolus, oral antidiabetic medications	**19.9 (8.2; 31.7)**	
33397767	Blauw, H.	2021	RCT: Crossover	2	23	Inreda AP (closed loop period)	Personal insulin pump therapy with CGM (if present),	ST	**28.4 (23.4; 34.8)**	

							with masked CGM (Dexcom G6) (open loop period)			
34349267	Boughton, C.	2021	RCT: Crossover	3	26	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	MDI	**14.6 (3.36; 25.84)†**	
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications	**35.3 (28; 42.6)**	
36069928	Van Veldhuisen, C.L.	2022	RCT: Crossover	2	10	Inreda AP	ST: MDI or CSII	ST: MDI or CSII	**20.92 (9.85; 31.99)**	
Non-RIS										
38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		MDI (18%), CSII (75%), HCL (6%)		**24.8 (21.8; 27.79)**

*Time in range is the percentage of time that the glucose level is within the target range of 3.9 to 10 mmol/l.
Results from the longest follow-up are reported. Statistically significant results are bolded. In green areas, mean differences (95%CI are calculated based on the values provided in the study. In orange areas, there is an incomplete reporting of the results from the studies
¶ TIR (sd): Intervention 71.14 (12.29); Comparison: 66.99 (11.8)
†Difference between intervention and comparison at follow-up, baseline data not reported.
#In participants using Medtronic 780G, TIR measured when in manual mode (2 weeks training) was compared with TIR measured after 6 months of auto mode.
‡including refinements
¥ Because of the large loss of follow-up at 52 weeks, the results are provided for a follow-up of 26 weeks.
‡‡ Regular use of the studied systems for at least six months prior to enrollment.
Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion (pump therapy); HCL, hybrid closed loop; HbA1c, glycated hemoglobin; MDI, multiple daily insulin injection therapy; MM, manual mode; NA, not applicable; non-RIS, non-randomized interventional study; NR, not reported; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; sd, standard deviation; ST, standard therapy.

Supplemental table 9

Results on high-risk medical devices for diabetes and TAR *										
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)**	**Baseline treatment against diabetes**	**TAR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention vs comparison [Reference])**	**TAR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention, final vs baseline [Reference])**
Implantable CGM devices										
RCTs										
34984786	Renard, E.	2022	RCT: Parallel	26	239	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM	MDI or CSII	Cohort 1: 1.3 (-4.9; 7.4) Cohort 2: 3.1 (-1.6; 7.8) Overall: 2.44 (-1.30; 6.17)	Cohort 1: **-5.7 (-8.24; -3.16)** Cohort 2: 0.90 (-1.46; 3.26) Overall: **-2.16 (-3.89; -0.43)**
34196924	Boscari, F.	2022	RCT: Crossover	12	16	Eversense® CGM System (90 days)	Dexcom G5	ST	**-4.52 (-8.08; -0.96)**	
Observational studies										
32037699	Irace, C.	2020	Longitudinal	26	100	Eversense® XL CGM System (180 days)		ST		**-6.00 (-7.92; -4.08)**
Implantable insulin pumps										
RCTs										
19429874	Logtenberg, S. J.	2009	RCT: Crossover	26	24	MiniMed MIP 2007C	ST: MDI or CSII	ST	**-8.9 (-16.7; -1.2)**	
Observational studies										
26582805	van Dijk, P. R.	2015	Case-control	26	184	MiniMed MIP 2007C	MDI or CSII	ST	**9.3 (2.8; 15.8)**	
Automated insulin delivery systems: Hybrid closed loop systems										
RCTs										
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM	ST	-4.3 (-8.8; 0.2)	**-7.40 (-9.66; -5.14)**
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps,	ST	**-10 (-14; -6)**	**-14.00 (-16.63; -11.37)**

							with Dexcom G6 CGM			
31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	CSII	**-10 (-13; -8)**	**-9.00 (-11.22; -6.78)**
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	Tandem Control-IQ (applied during an RCT performed 6 months before study start)	**-6.04 (-8.40; -3.68)**	**3.00 (0.86; 5.14)**
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	ST	**−27.9 (−34.2; −21.6)**	**-34.6 (-37.41; -31.78)**
37551542	Edd, S. N.	2023	RCT: Parallel	26	39	Medtronic 780G	MDI and isCGM	MDI		**-27.2 (-32.9; -21.6)**
31099946	Ekhlaspour, L.	2019	RCT: Parallel	0.29	48	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	CSII	**-11.6 (-20.25; -2.95)**†	
30888835	Forlenza, G. P.	2019	RCT: Parallel	0.43	24	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	ST	**-18.5 (-28.12; -8.88)†**	
33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	CSII	**-12 (-16; -8)**	**-12 (-15.7; -8.28)**
37796241	Lee, T. M.	2023	RCT: Parallel	36	124	CamAPS FX	ST: MDI or CSII	ST: MDI or CSII	**-5 (-8; -3)**	**-15 (-17.92; -12.08)**
26049550	Ly, T. T.	2015	RCT: Parallel	0.85	21	Medtronic 670G	PLGS: Medtronic 530G with threshold suspend and Enlite sensor	ST	3.6 (-7.77; 14.97)†	
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	MDI and self-monitoring of blood glucose	**-14.7 (-21.4; -8)**	**-9.1 (-13.04; -5.16)**
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	ST	**-12.0 (-16.1; -7.9)**	**-11.6 (-14.07; -9.13)**
37729080	Renard, E.	2023	RCT: Parallel	12	72	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	CSII	**-5.3 (-8.7; -1.8)**	**-6.5 (-8.85; -4.15)**
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	MDI	**-27.7 (-40.5; -15)**	**-28.5 (-38.95; -18.05)**
36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	MDI and real time CGM	**-28.5 (-45.3; -11.6)**	**-31.2 (-39.16; -23.24)**

35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	CSII	**-18.4 (-26.9; -9.8)**	**-17 (-21.09; -12.9)**
33323237	Benhamou, P.	2019	RCT: Crossover	32	63	Diabeloop DBLG1	SAP	CSII	**-6.8 (-9.7; -3.9)**	
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	CSII or MDI	**-3 (-1.54; -4.46)**	**-10.0 (-11.52; -8.48)**
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	CSII	**-8.5 (-10.9; -6.1)**	
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	ST	-5.2 (-10.61; 0.21)	-2.30 (-6.95; 2.35)
33579715	Collyns, O. J.	2021	RCT: Crossover	4	60	Medtronic 670G pump in advanced hybrid closed loop mode	PLGS: Medtronic 670G pump in SAP with PLGS mode	PLGS	**-12.1 (-18.95; -5.25)**	**-10.4 (-12.05; -8.75)**
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	CSII	**-5.4 (-7.3; -3.5)**	
30620641	Paldus, B.	2019	RCT: Crossover	1	11	Medtronic 770G	Medtronic 670G	ST	-5 (-15.44; 5.44)†	
35373894	von dem Berge, T.	2022	RCT: Crossover	18	38	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	CSII	**-10.7 (-16.27; -5.13)**	**-10.50 (-13.58; -7.41)**
35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP	ST	**-8.5 (-9.9; -7.1)**	**-11.5 (-13.69; -9.31)**
Observational studies										
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		SAP		**-9.8 (-9.93; -9.67)**
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6		**-8.9 (-9.21; -8.59)**
35414272	Arunachalum, S.	2023	Longitudinal	52	2627	Medtronic 670G		ST		**-8.5 (-8.86; -8.14)**
35116007	Bassi, M.	2022	Longitudinal	4	90	Tandem Control-IQ	Medtronic 780G	ST	**3.5 (-0.8; 7.8)**	

36777356	Bassi, M.	2023	Longitudinal	52	32	Tandem Control-IQ		MDI, SAP, PLGS		**-5 (-6.46; -3.54)**
31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		ST		**-9.3 (-11.8; -6.8)**
31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		Medtronic 670G in MM (during 1-2 weeks run-in period)		**-6.6 (-6.86; -6.34)**
36724301	Chico, A.	2023	Longitudinal	12	62	Diabeloop DBLG1		CSII or MDI		**-14.56 (-18.51; -10.6)**
34524023	Dubose, S. N.	2021	Longitudinal	52	80	Medtronic 670G		ST		-2
37845757	Elbarbary, N. S.	2023	Longitudinal	24	107	Medtronic 780G		MDI or PLGS		**-4.31 (-5.16; -3.46)**
30865545	Faulds, E. R.	2019	Longitudinal	12	34	Medtronic 670G		Medtronic 670G in MM (2 weeks run-in period		-3.70 (-7.85; 0.45)
33450533	Gomez, A. M.	2021	Longitudinal	2	91	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-3.21 (-4.61; -1.81)**
DOI in footnote	Gouet, D.	2022	Longitudinal	52 ¥	83	Medtronic 780G		CSII		**-4 (-4.92; -3.08)**
36789699	Grassi, B.	2023	Longitudinal	19	459	Medtronic 780G		Cohort 1: Minimed 640G. Cohort 2: Minimed 670G		Cohort 1: **-10.5 (-11.5; -9.5)** Cohort 2**: -5 (-6.2; -3.8)**
38444313	Halim, B.	2024	Longitudinal		1501	Medtronic 780G		Medtronic 670G/770G		**-4.1 (-4.51; -3.69)**
37905353	Henry, Z.	2023	Longitudinal	52	231	Medtronic 780G (72%), Tandem Control IQ (28%)		SAP or PLGS		Medtronic 780G: **-14.4 (-22.82; -5.98)** Tandem Control IQ: **-14.41 (-22.59; -6.23)** Overall**: -14.41 (-20.27; -8.54)**
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		CSII		**-7.3 (-10.69; -3.91)**
33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	SAP	**10.81 (1.64; 19.98)**	
36126177	Kovatchev B. P.	2022	Longitudinal	12	19354	Tandem Control-IQ		PLGS: Basal-IQ with CGM		**-11.4 (-11.56; -11.23)**
38236643	Lablanche, S.	2023	Longitudinal	52	220	Medtronic 780G		CSII		**-7.3 (-8.8; -5.7)**
38579305	Lehmann, V.	2023	Longitudinal	36	44	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G		Cohort 1: Medtronic 640G; Cohort 2: Medtronic 670G		Cohort 1: **-5.6 (-12.7; -2.3)** Cohort 2: **-1.5 (-5.6; -1.8)**

37902785	Lepore, G.	2023	Longitudinal	104	296	Medtronic 780G		MDI or CSII or SAP/PLGS or HCL (Medtronic 760G)		**-10.6 (-11.67; -9.52)**
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		MDI or CSII		**-11.6 (-13.3; -9.9)**
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		ST		0.78 (-13.56; 15.12)
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		MDI or CSII		**-10 (-14.93; -5.07)**
34096789	Messer, L. H.	2021	Longitudinal	26	191	Tandem Control-IQ		ST		**-7.8 (-7.9; -7.7)**
DOI in footnote	Mutlu, G. Y.	2023	Longitudinal	12	25	Medtronic 780G		Medtronic 640G		**-2.9 (-4.89; -0.91)**
36940793	Nattero-Chavez, L.	2023	Longitudinal	24	46	Medtronic 780G		MDI or CSII or SAP		**-10 (-12.66; -7.34)**
33044604	Petrovski, G.	2021	Longitudinal	52	30	Medtronic 670G		MDI		**-26 (-44.49; -7.51)**
32846114	Pinsker, J. E.	2021	Longitudinal	4	1435	Tandem Control-IQ		ST		**-9.3 (-9.95; -8.65)**
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		Medtronic 780G in manual mode		**-15.4 (-17.94; -12.86)**
34668782	Proietti, A.	2022	Longitudinal	26	30	Medtronic 670G		ST		**-10.50 (-14.05; -6.95)**
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		Medtronic 640G or PLGS		**-3 (-4.44; -1.56)**
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		MDI or CSII		**-6 (-11.12; -0.87)**
37956944	Rossi, A.	2023	Longitudinal	12	60	Medtronic 780G	PLGS	‡	**-12.6 (-13.48; -11.72)**	
35451679	Schiaffini, R.	2022	Longitudinal	4	31	Tandem Control-IQ (55%), Medtronic 780G (45%)		Medtronic 640G or Tandem Basal IQ with PLGS		Tandem Control-IQ: -1.1 (-3.78; 1.58) Medtronic 780G: -3.7 (-8.66; 1.26) Overall: -1.69 (-4.05; 0.67)
35020476	Scully, K. J.	2022	Longitudinal	13	13	Tandem Control-IQ		ST		**-15.70 (-17.69; -13.71)**
34524003	Silva, J. D.	2022	Longitudinal		4120 812 with pre/post	Medtronic 780G		ST		**-11.70 (-12.35; -11.04)**
30160523	Stone, M. P.	2018	Longitudinal	13	3141	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-6.8 (-10.85; -2.75)**
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	ST (for outcome HbA1c);		**-12 (-16.67; -7.33)**

								HCL system in MM (2 weeks training) (for other glycemic outcomes)		
34609917	Toschi, E.	2022	Longitudinal	13	48	Tandem Control-IQ		CSII		**-10.00 (-11.92; -8.08)**
33430621	Usoh, C. O.	2021	Longitudinal	4	80	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-10.4 (-15.37; -5.42)**
36280026	Usoh, C. O.	2023	Longitudinal	78	66	Tandem Control IQ		MDI or CSII		**-11.9 (-18.84; -4.96;)**
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		CSII		**-3.4 (-6.2; -0.6)**
DOI in footnote	Zuijdwijk, C.	2023	Longitudinal	16	59	Tandem Control IQ		CSII		**-8.7 (-11.1; -6.3)**
33838993	Beato-Vibora, P. I.	2021	Cross-sectional	NA	302	Medtronic 670G	Group 1: CGM and MDI; Group 2: FGM and MDI; Group 3: SAP with PLGS	ST	Medtronic 670G vs CGM+MDI: **-11 (-16.17; -5.83)** Medtronic 670G vs FGM+MDI: **-10 (-15.20; -4.80)** Medtronic 670G vs SAP+PLGS: -3 (-7.17; 1.17)	
34058303	Horowitz, M. E.	2021	Cross-sectional	NA	84	Medtronic 670G		ST		**-24.50 (-27.33; -21.67)**
Non-RIS										
33784187	Beato-Vibora, P. I.	2021	Non-RIS	4	52	Medtronic 780G		PLGS		**-12.1 (-18.89; -5.31)**
34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		PLGS		**-12.6 (-19.67; -5.53)**
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	**-19.8 (-10.81; -28.79)**†	
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	**-7.3 (-11.6; -2.29)**	
36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		MDI		**-37.3 (-45.4; -29.1)**
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		ST		Children: **-15.10 (-22.43; -7.77)** Adults: **-7.7 (-11.46; -3.94)** Overall: **-9.24 (-12.59; -5.9)**

34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		SAP, PLGS or automated basal use (during 2 weeks run-in period)		**-4.80 (-5.87; -3.73)**
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		ST		Children**: -13.2 (-15.21; -11.18)** Adolescents/adults**: -7.8 (-9.74; -5.86)** Overall**: -10.85 (-12.13; -9.57)**
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		Basal or basal-bolus		**-21.5 (-26.54; -16.46)**
38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		ST		**-9.2 (-11.54; -6.86)**
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		Open-source AndroidAPS		-0.12 (-5.07; 4.83)
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-7.10 (-8.67; -5.53)**
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-8.00 (-10.68; -5.32)**
33325779	Forlenza, G. P.	2021	Non-RIS	3	36	Omnipod 5		ST		Children**: -12.7 (-16.96; -8.44)** Adults: -4.10 (-9.54; 1.34) Overall: **-9.43 (-12.78; -6.08)**
28134564	Garg, S. K.	2017	Non-RIS	13	124	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		Adolescents: **-5.3 (-8.14; -2.46)** Adults: **-2.10 (-3.68; -0.53)** Overall**: -2.85 (-4.23; -1.48)**
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		CSII or PLGS		**-9.3 (-13.86; -4.74)**
31264889	Lee, M. H.	2019	Non-RIS	5	12	Medtronic 670G		Medtronic 670G in Open Loop (during 1 week run-in period)		**-11 (-16.36; -5.64)**
27191182	Ly, T. T.	2017	Non-RIS	0.71	24	Medtronic 670G		SAP		Adults: 1.60 (-7.31; 10.51) Adolescents: **-13.2 (-25.2; -1.20)** Overall**:** -3.66 (-10.81; 3.49)
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		MDI		**-23.9 (-31; -16.8)**
37782145	Pinhoker, C.	2023	Non-RIS	12	160	Medtronic 670G		SAP with/without PLGS or HCL (Auto		**-11 (-12.27; -9.73)**

								Basal only) without Auto Correction turned on		
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		**-8.6 (-11.29; -5.9)**
38514384	Pulkkinen, M.	2024	Non-RIS	39	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		**-9.6 (-12.47; -6.73)**
33185480	Nimri, R.	2021	Non-RIS	4	12	Medtronic 780G		Medtronic 780G in MM during 6 days run-in period)		-4.20 (-11.29; 2.89)
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		ST		**-7.6 (-12.8; -3.5)**
Automated insulin delivery systems: Fully closed loop systems										
RCTs										
35880252	Herzig, D.	2022	RCT: Parallel	2.8	44	CamAPS HX	Standard insulin therapy	ST: basal insulin, basal-bolus, oral antidiabetic medications	**-18.5 (-30.7; -6.4)**	
33397767	Blauw, H.	2021	RCT: Crossover	2	23	Inreda AP (closed loop period)	Personal insulin pump therapy with CGM# (if present), with masked CGM (Dexcom G6) (open loop period)	ST	**-26.2 (-32.6; -19.6)†**	
34349267	Boughton, C.	2021	RCT: Crossover	3	26	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	MDI	-14 (-22.35; 5.65) †	
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications	**-35.2 (-42.8; -27.5)**	
36069928	Van Veldhuisen, C.L.	2022	RCT: Crossover	2	10	Inreda AP	ST: MDI or CSII	ST: MDI or CSII	-17.22 (-41.03; 6.59)	
Non-RIS										

38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		MDI (18%), CSII (75%), HCL (6%)		**-23.1 (-26.52; -19.68)**

* Time above range is the percentage of time that the glucose level is above 10 mmol/l.
Results from the longest follow-up are reported. Statistically significant results are bolded. In green areas, mean differences (95%CI are calculated based on the values provided in the study. In orange areas, there is an incomplete reporting of the results from the studies
† Difference between intervention and comparison at follow-up, baseline data not reported
¥ Because of the large loss of follow-up at 52 weeks, the results are provided for a follow-up of 26 weeks.
‡ Regular use of the studied systems for at least six months prior to enrollment.
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion (pump therapy); MDI, multiple daily insulin injection therapy; NA, not applicable; non-RIS, non-randomized interventional study; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy; TAR, time above range.

Supplemental table 10

Results on high-risk medical devices for diabetes and TBR *										
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)**	**Baseline treatment against diabetes**	**TBR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention vs comparison [Reference])**	**TBR (%) mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention, final vs baseline [Reference])**
Implantable CGM devices										
RCTs										
34984786	Renard, E.	2022	RCT: Parallel	26	239	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM	MDI or CSII	Cohort 1: -0.4 (-1.5; 0.8) Cohort 2: **-3.3 (-6.3; -0.3)** Overall: -0.77 (-1.85; 0.30)	Cohort 1: -0.3 (-0.76; 0.16) Cohort 2: **-2.8 (-3.83; -1.77)** Overall: **-0.72 (-1.14; -0.30)**
34196924	Boscari, F.	2022	RCT: Crossover	12	16	Eversense® CGM System (90 days)	Dexcom G5	ST	0.37 (-0.47; 1.20)	
Observational studies										
32037699	Irace, C.	2020	Longitudinal	26	100	Eversense® XL CGM System (180 days)		ST		0.6 (-0.82; 2-02)
Implantable insulin pumps										
RCTs										
19429874	Logtenberg, S. J.	2009	RCT: Crossover	26	24	MiniMed MIP 2007C	ST: MDI or CSII	ST	-2.0 (-5.4; 1.3)	
Observational studies										
26582805	van Dijk, P. R.	2015	Case-control	26	184	MiniMed MIP 2007C	MDI or CSII	ST	-3.2 (-7.4; 1)	
Automated insulin delivery systems: Hybrid closed loop systems										
RCTs										
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM	ST	**-1.9 (-2.5; -1.3)**	**-0.7 (-1.22; -0.17)**
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	ST	**-0.40 (-0.83; -0.02)**	**0.4 (0.21; 0.59)**

31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	CSII	**-0.88 (-1.19; -0.57)**	**-2.00 (-2.48; -1.52)**
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	Tandem Control-IQ (applied during an RCT performed 6 months before study start)	**0.75 (0.31; 1.19)**	**0.40 (0.18; 0.62)**
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	ST	0.1 (−0.7; 1)	0.4 (-0.01; 0.81)
37551542	Edd, S. N.	2023	RCT: Parallel	26	39	Medtronic 780G	MDI and isCGM	MDI		-0.5 (-1.5; 0.1)
31099946	Ekhlaspour, L.	2019	RCT: Parallel	0.29	48	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	CSII	1.2 (-0.31; 2.71)†	
30888835	Forlenza, G. P.	2019	RCT: Parallel	0.43	24	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	ST	0 (-1.95; 1.95)†	
36472543	Garg, S. K.	2023	RCT: Parallel	26	302	Medtronic 670G	CSII	CSII	**-3.6 (-4.6; -2.6)**	**-3.8 (-4.45; -3.15)**
33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	CSII	**-0.7 (-1; -0.2)**	**-1.60 (-2.24; -0.96)**
26049550	Ly, T. T.	2015	RCT: Parallel	0.85	21	Medtronic 670G	PLGS: Medtronic 530G with threshold suspend and Enlite sensor	ST	-0.3 (-0.62; 0.02)†	
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	MDI and self-monitoring of blood glucose	**-4.4 (-7.4; -2.1)**	**-6.6 (-9.42; -3.78)**
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	ST	**-2.0 (-2.5; -1.3)**	**-2.80 (-3.56; -2.04)**
37729080	Renard, E.	2023	RCT: Parallel	12	72	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	CSII	**-3.7 (-4.8; -2.6)**	**-6.6 (-7.52; -5.68)**
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	MDI	0.1 (-1; 1.3)	-0.2 (-0.86; 0.46)
36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	MDI and real time CGM	-0.6 (-2.6; 1.4)	-0.3 (-1.84; 1.24)
36920756	Wadwa, R. P.	2023	RCT: Parallel	13	102	Tandem Control-IQ	ST: MDI or CSII	ST: MDI or CSII	-0.2 (-0.7; 0.4)	0 (-0.31; 0.31)

35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	CSII	3.13 (-1.25; 7.51)	2.2 (-1.62; 6.02)
33323237	Benhamou, P.	2019	RCT: Crossover	32	63	Diabeloop DBLG1	SAP	CSII	**-2.4 (-3; -1.7)**	
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	CSII or MDI	0 (-3.4; 3.4)	0.2 (-0.006; 0.41)
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	CSII	-0.1 (-0.3; 0.2)	
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	ST	**-3.5 (-5.36; -1.64)**	**-2.6 (-3.31; -1.88)**
33579715	Collyns, O. J.	2021	RCT: Crossover	4	60	Medtronic 670G pump in advanced hybrid closed loop mode	PLGS: Medtronic 670G pump in SAP with PLGS mode	PLGS	**-0.4 (-0.75; -0.05)**	**-1.00 (-1.33; -0.67)**
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	CSII	**-0.47 (-1.05; -0.25)**[†]	
30620641	Paldus, B.	2019	RCT: Crossover	1	11	Medtronic 770G	Medtronic 670G	ST	-0.7 (-2.39; 0.99)[†]	
35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP	ST	0.1 (-0.4; 0.5)	**0.50 (0.01; 0.98)**
Observational studies										
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		SAP		**-0.97 (-1.53; -0.41)**
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6		**-1.2 (-1.27; -1.13)**
35414272	Arunachalum, S.	2023	Longitudinal	52	2627	Medtronic 670G		ST		**0.2 (0.14; 0.26)**
35116007	Bassi, M.	2022	Longitudinal	4	90	Tandem Control-IQ	Medtronic 780G	ST	**-1.0 (-1.8, -0.3)**	-0.2 (-0.6; 0.2)
36777356	Bassi, M.	2023	Longitudinal	52	32	Tandem Control-IQ		MDI, SAP, PLGS		0 (-0.69; 0.69)

31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		ST		-0.50 (-1.1; 0.2)
30862242	Berget, C.	2020	Longitudinal	4	72	Medtronic 670G		Medtronic 670G in MM (during 1 week run-in period)		-0.20 (-0.57; 0.16)
31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		Medtronic 670G in MM (during 1-2 weeks run-in period)		0.10 (-0.09; 0.29)
36724301	Chico, A.	2023	Longitudinal	12	62	Diabeloop DBLG1		CSII or MDI		**-4.69 (-7.3; -2.08)**
34524023	Dubose, S. N.	2021	Longitudinal	52	80	Medtronic 670G		ST		-1
37845757	Elbarbary, N. S.	2023	Longitudinal	24	107	Medtronic 780G		MDI or PLGS		**-3.39 (-3.84; -2.93)**
30865545	Faulds, E. R.	2019	Longitudinal	12	34	Medtronic 670G		Medtronic 670G in MM (2 weeks run-in period)		-0.17 (-1.25; 0.91)
DOI in footnote	Gouet, D.	2022	Longitudinal	52 ¥	83	Medtronic 780G		CSII		**-0.3 (-0.53; -0.07)**
36789699	Grassi, B.	2023	Longitudinal	19	459	Medtronic 780G		Cohort 1: Minimed 640G. Cohort 2: Minimed 670G		Cohort 1: -0 (-1; 0.9) Cohort 2**: 0.2 (0; 0.5)**
38444313	Halim, B.	2024	Longitudinal		1501	Medtronic 780G		Medtronic 670G/770G		0 (-0.06; 0.06)
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		CSII		**-2.3 (-3.28; -1.32)**
33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	SAP	**-0.6 (-2.24; 1.04)**	
36126177	Kovatchev B. P.	2022	Longitudinal	12	19354	Tandem Control-IQ		PLGS: Basal-IQ with CGM		**-0.2 (-0.22; -0.18)**
38236643	Lablanche, S.	2023	Longitudinal	52	220	Medtronic 780G		CSII		0 (-2; 0)
38579305	Lehmann, V.	2023	Longitudinal	36	44	Cohort 1: Medtronic 670G. Cohort 2: Medtronic 780G		Cohort 1: Medtronic 640G; Cohort 2: Medtronic 670G		Cohort 1: -1.03 (-2.07; 0.01) Cohort 2: 0.05 (-0.27; 0.37)
37902785	Lepore, G.	2023	Longitudinal	104	296	Medtronic 780G		MDI or CSII or SAP/PLGS or HCL (Medtronic 760G)		**-1.6 (-1.92; -1.28)**
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		MDI or CSII		0.3 (-0.03; 0.63)
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		ST		-2.64 (-7.14; 1.86)
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		MDI or CSII		**-0.2 (-0.3; -0.1)**

34096789	Messer, L. H.	2021	Longitudinal	26	191	Tandem Control-IQ		ST		**-0.40 (-0.42; -0.38)**
36940793	Nattero-Chavez, L.	2023	Longitudinal	24	46	Medtronic 780G		MDI or CSII or SAP		**-3 (-4.64; -1.36)**
32846114	Pinsker, J. E.	2021	Longitudinal	4	1435	Tandem Control-IQ		ST		-0.1 (-0.16; -0.04)
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		Medtronic 780G in manual mode		0.1 (-0.37; 0.57)
34668782	Proietti, A.	2022	Longitudinal	26	30	Medtronic 670G		ST		-0.10 (-0.61; 0.41)
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		Medtronic 640G or PLGS		0 (-0.38; 0.38)
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		MDI or CSII		-1.5 (-3.12; 0.12)
31166801	Salehi, P.	2019	Longitudinal	27	16	Medtronic 670G in auto mode	Medtronic 670G in MM with low glucose suspend	NR	**1.10 (0.32; 1.80)**	
35451679	Schiaffini, R.	2022	Longitudinal	4	31	Tandem Control-IQ (55%), Medtronic 780G (45%)		Medtronic 640G or Tandem Basal IQ with PLGS		Tandem Control-IQ: -0.4 (-1.11; 0.31) Medtronic 780G: 0 (-0.5; 0.5) Overall: -0.13 (-0.54; 0.28)
35020476	Scully, K. J.	2022	Longitudinal	13	13	Tandem Control-IQ		ST		**0.30 (0.19; 0.41)**
34524003	Silva, J. D.	2022	Longitudinal		4120 812 with pre/post	Medtronic 780G		ST		**-0.40 (-0.51; -0.29)**
30160523	Stone, M. P.	2018	Longitudinal	13	3141	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-0.6 (-1; -0.2)**
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	HCL system in MM (2 weeks training)		0 (-0.56; 0.56)
34609917	Toschi, E.	2022	Longitudinal	13	48	Tandem Control-IQ		CSII		**-1.0 (-1.28; -0.71)**
33430621	Usoh, C. O.	2021	Longitudinal	4	80	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		-0.4 (-12.86; 12.06)
36280026	Usoh, C. O.	2023	Longitudinal	78	66	Tandem Control IQ		MDI or CSII		**-2.3 (-4.14; -0.46)**
34015178	Varimo, T.	2021	Longitudinal	52	111	Medtronic 670G		ST		**-2.70 (-3.41; -1.99)**
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		CSII		**-0.8 (-1.4; -0.2)**

DOI in footnote	Zuijdwijk, C.	2023	Longitudinal	16	59	Tandem Control IQ		CSII		-0.2 (-0.6; 0.3)
33838993	Beato-Vibora, P. I.	2021	Cross-sectional	NA	302	Medtronic 670G	Group 1: CGM and MDI; Group 2: FGM and MDI; Group 3: SAP with PLGS	ST	Medtronic 670G vs CGM+MDI: **-1.7 (-3.13; -0.27)** Medtronic 670G vs FGM+MDI: **-2.5 (-3.78; -1.22)** Medtronic 670G vs SAP+PLGS: **-1.4 (-2.48; -0.31**)	
34058303	Horowitz, M. E.	2021	Cross-sectional	NA	84	Medtronic 670G		ST		**-3.00 (-4.05; - 1.95)**
Non-RIS										
30239219	Adams, R. N.	2018	Non-RIS	0.71	29	Medtronic 670G		ST		**-2.70 (-3.88; -1.52)**
33431420	Amadou, C.	2021	Non-RIS	26	25	Diabeloop DBLG1		CSII		**-1.10 (-2.03; -0.17)**
33784187	Beato-Vibora, P. I.	2021	Non-RIS	4	52	Medtronic 780G		PLGS		-0.20 (-0.8; 0.4)
34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		PLGS		-0.3 (-0.87; 0.27)
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	-0.6 (-2.03; 0.83)†	
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	-9.4 (-10.78; -8.02)†	
36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		MDI		-1.3 (-2.7; 0.2)
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		ST		Children: -0.43 (-3.75; 2.89) Adults: **-1.57 (-2.33; -0.80)** Overall**: -1.51 (-2.26; -0.77)**
34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		SAP, PLGS or automated basal use (during 2 weeks run-in period)		**-1.00 (-1.29, -0.71)**
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		ST		Children**: -0.35 (-0.68; -0.02)** Adolescents/adults**: -1.41 (-1.83; -0.99)** Overall**: -0.75 (-1.01; -0.5)**
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		Basal or basal-bolus		-0.07 (-0.2; 0.05)

38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		ST		**-0.82 (-1.41; -0.23)**
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		Open-source AndroidAPS		**-1.48 (-2.44; -0.52)**
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		-1.7 (-2.22; -1.17)
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		-0.10 (-0.56; 0.36)
33325779	Forlenza, G. P.	2021	Non-RIS	3	36	Omnipod 5		ST		Children: **-1.20 (-2.22; -0.18)** Adults: **-2.70 (-3.78; -1.62)** Overall: **-1.91 (-2.65; -1.17)**
28134564	Garg, S. K.	2017	Non-RIS	13	124	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		Adolescents: **-1.50 (-2.25; -0.74)** Adults: **-3.00 (-3.60; -2.40)** Overall**: -2.42 (-2.89; -1.95)**
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		CSII or PLGS		-0.77 (-1.79; 0.25)
31264889	Lee, M. H.	2019	Non-RIS	5	12	Medtronic 670G		Medtronic 670G in Open Loop (during 1 week run-in period)		**1.40 (0.39; 2.41)**
27191182	Ly, T. T.	2017	Non-RIS	0.71	24	Medtronic 670G		SAP		Adults: **-5.60 (-8.95; -2.25)** Adolescents:-0.20 (-1.12; 0.73) Overall: -0.58 (-1.47; 0.31)
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		MDI		0.2 (-0.5; 0.9)
37823890	Michaels, V. R.	2024	Non-RIS	52	20	Medtronic 780G		MDI		**-1.38 (-3.29; -0.38)**
33185480	Nimri, R.	2021	Non-RIS	4	12	Medtronic 780G		Medtronic 780G in MM during 6 days run-in period)		-1.40 (-3.51; 0.71)
37782145	Pinhoker, C.	2023	Non-RIS	12	160	Medtronic 670G		SAP with/without PLGS or HCL (Auto Basal only) without Auto Correction turned on		0 (-0.18; 0.18)
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		0.2 (-0.24; 0.64)

38514384	Pulkkinen, M.	2024	Non-RIS	39	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		0 (-0.41; 0.41)
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		ST		-0.27 (-1.54; 0.46)
Automated insulin delivery systems: Fully closed loop systems										
RCTs										
35880252	Herzig, D.	2022	RCT: Parallel	2.8	44	CamAPS HX	Standard insulin therapy	ST: basal insulin, basal-bolus, oral antidiabetic medications	0 (-0.03; 0.3)	
33397767	Blauw, H.	2021	RCT: Crossover	2	23	Inreda AP (closed loop period)	Personal insulin pump therapy with CGM (if present), with masked CGM (Dexcom G6) (open loop period)	ST	**-1.7 (-2.9; -0.8)†**	
34349267	Boughton, C.	2021	RCT: Crossover	3	26	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	MDI	0.05 (-0.51; 0.61) †	
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications	-0.1 (-0.36; 0.16)	
36069928	Van Veldhuisen, C.L.	2022	RCT: Crossover	2	10	Inreda AP	ST: MDI or CSII	ST: MDI or CSII	**-1.61 (-2.43; -0.79)**	
Non-RIS										
38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		MDI (18%), CSII (75%), HCL (6%)		**-0.95 (-1.36; -0.54)**

* Time below range is the percentage of time that the glucose level is below 3.9 mmol/l.
Results from the longest follow-up are reported. Statistically significant results are bolded. In green areas, mean differences (95%CI are calculated based on the values provided in the study. In orange areas, there is an incomplete reporting of the results from the studies
†Difference between intervention and comparison at follow-up, baseline data not reported
¥ Because of the large loss of follow-up at 52 weeks, the results are provided for a follow-up of 26 weeks.
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110

Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063 Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107 Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion (pump therapy); MDI, multiple daily insulin injection therapy; NA, not applicable; non-RIS, non-randomized interventional study; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy; TBR, time below range.

Supplemental table 11

Results on high-risk medical devices for diabetes and time with sensor values below 3 mmol/l *										
PMID	**First author**	**Publication year**	**Study design**	**Max follow-up (weeks)**	**N**	**Intervention**	**Comparison (if any)**	**Baseline treatment against diabetes**	**%Time<3, mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention vs comparison)**	**%Time<3, mean difference (and [95%CI] or [sd + p-value] or [p-value]) (Intervention, final vs baseline)**
Implantable CGM devices										
RCTs										
34196924	Boscari, F.	2022	RCT: Crossover	12	16	Eversense® CGM System (90 days)	Dexcom G5	ST	0.07 (-2.62; 2.76)	
Automated insulin delivery systems: Hybrid closed loop systems										
RCTs										
34633418	Abraham, M. B.	2021	RCT: Parallel	26	135	Medtronic 670G	ST: MDI or CSII, with or without CGM	ST	**-0.5 (-0.7; -0.3)**	-0.20 (-0.4; 0.002)
32846062	Breton, M. D.	2020	RCT: Parallel	16	101	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	ST	-0.07 (-0.19; 0.02)	**0.10 (0.05; 0.14)**
31618560	Brown, S. A.	2019	RCT: Parallel	26	168	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	CSII	**-0.10 (-0.19; -0.02)**	**-0.61 (-0.82; -0.40)**
32471910	Brown, S. A.	2020	RCT: Parallel	13	109	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	Tandem Control-IQ (applied during an RCT performed 6 months before study start)	0.04 (-20.05; 0.13)	0.08 (0.03; 0.13)
36058207	Choudhary, P.	2022	RCT: Parallel	24	82	Medtronic 780G	MDI and intermittently scanned CGM	ST	-0.1 (-0.4; 0.3)	-0.2 (-0.43; 0.02)
37551542	Edd, S. N.	2023	RCT: Parallel	26	39	Medtronic 780G	MDI and isCGM	MDI		-0.2 (-0.4; 0)
31099946	Ekhlaspour, L.	2019	RCT: Parallel	0.29	48	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	CSII	0 (-0.03; 0.03)	
30888835	Forlenza, G. P.	2019	RCT: Parallel	0.43	24	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G5 CGM	ST	0.1 (-0.24; 0.44)	

33216667	Isganaitis, E.	2021	RCT: Parallel	26	63	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	CSII	-0.09 (-0.2; 0.05)	**-0.60 (-0.88; -0.32)**
37796241	Lee, T. M.	2023	RCT: Parallel	36	124	CamAPS FX	ST: MDI or CSII	ST: MDI or CSII	-0.23 (-0.55; 0.09)	-0.34 (-0.68; 0.01)
35972259	Matejko, B.	2022	RCT: Parallel	12	37	Medtronic 780G	MDI and self-monitoring of blood glucose	MDI and self-monitoring of blood glucose	**-0.9 (-1.6; -0.3)**	**-2.6 (-4.23; -0.97)**
33055139	McAuley, S. A.	2020	RCT: Parallel	26	120	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	ST	**-0.6 (-0.8; -0.3)**	**-0.60 (-0.81; -0.38)**
37729080	Renard, E.	2023	RCT: Parallel	12	72	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	CSII	**-0.8 (-1.2; -0.5)**	**-2.5 (-2.99; -2)**
37921083	Reznik, Y	2024	RCT: Parallel	12	30	Tandem Control-IQ	ST: MDI	MDI	0 (-0.3; 0.4)	-0.4 (-1.23; 0.43)
36949671	Van den Heuvel, T.	2023	RCT: Parallel	24	13	Medtronic 780G	MDI and real time CGM	MDI and real time CGM	-0.7 (-2; 0.6)	-0.4 (-1.19; 0.39)
36920756	Wadwa, R. P.	2023	RCT: Parallel	13	102	Tandem Control-IQ	ST: MDI or CSII	ST: MDI or CSII	0.01 (-0.1; 0.1)	0 (-0.1; 0.1)
35272971	Ware, J.	2022	RCT: Parallel	26	46	CamAPS FX	ST: CSII	CSII	0.91 (-0.96; 2.49)	-0.5 (-1.42; 0.42)
33453783	Bergenstal, R. M.	2021	RCT: Crossover	52	113	Medtronic 780G	Medtronic 670G	CSII or MDI	**-0.06 (-0.11; -0.2)**	0 (-0.04; 0.04)
35359882	Boughton, C	2022	RCT: Crossover	32	37	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	CSII	0 (-0.1; 0.1)	
33555982	Burckhardt, M. A.	2021	RCT: Crossover	8	17	Medtronic 670G	ST: CSII with CGM	ST	**-1.6 (-2.54; -0.75)**	**-0.60 (-0.86; -0.34)**
33579715	Collyns, O. J.	2021	RCT: Crossover	4	60	Medtronic 670G pump in advanced hybrid closed loop mode	PLGS: Medtronic 670G pump in SAP with PLGS mode	PLGS	**-0.1 (-0.19; -0.02)**	0.0 (-0.09; 0.09)
34844995	McAuley, S. A.	2022	RCT: Crossover	17	30	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	CSII	**-0.11 (-0.16; -0.05)**	
35373894	von dem Berge, T.	2022	RCT: Crossover	18	38	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	CSII	0.2 (-0.08; 0.48)	0 (-0.17; 0.17)

35045227	Ware, J.	2022	RCT: Crossover	16	74	CamAPS FX	SAP	ST	0.02 (−0.1; 0.1)	**0.3 (0.16; 0.44)**
Observational studies										
31789447	Akturk, H. K.	2020	Longitudinal	26	127	Medtronic 670G		SAP		**-0.2 (-0.21; -0.19)**
37236365	Amigo, J.	2023	Longitudinal	12	66	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)		Medtronic 640G with Guardian 3 or Tandem t:slim X2 with Basal IQ and Dexcom G6 or Roche Accu-Chek Insight insulin pump with Dexcom G6		**-0.4 (-0.43; -0.36)**
35414272	Arunachalum, S.	2023	Longitudinal	52	2627	Medtronic 670G		ST		**0.1 (0.07; 0.13)**
35116007	Bassi, M.	2022	Longitudinal	4	90	Tandem Control-IQ	Medtronic 780G	ST	**-0.2 (-0.6; 0.2)**	
36777356	Bassi, M.	2023	Longitudinal	52	32	Tandem Control-IQ		MDI, SAP, PLGS		0 (-0.33; 0.33)
31855446	Beato-Vibora, P. I.	2020	Longitudinal	13	58	Medtronic 670G		ST		-0.17 (-0.4; 0.1)
31837064	Berget, C.	2020	Longitudinal	26	92	Medtronic 670G		Medtronic 670G in MM (during 1-2 weeks run-in period)		0.10 (-0.03; 0.23)
33784196	Breton, M. D.	2021	Longitudinal	52	9451	Tandem Control-IQ		PLGS		**0.05 (0.02; 0.08)**
34227214	Cherubini, V.	2021	Longitudinal	12	43	Tandem Control-IQ		PLGS Basal-IQ		0 (-1; 1)
37845757	Elbarbary, N. S.	2023	Longitudinal	24	107	Medtronic 780G		MDI or PLGS		**-1.41 (-1.69; -1.13)**
33450533	Gomez, A. M.	2021	Longitudinal	2	91	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-0.21 (-0.37; -0.05)**
36789699	Grassi, B.	2023	Longitudinal	19	459	Medtronic 780G		Cohort 1: Minimed 640G. Cohort 2: Minimed 670G		Cohort 1: -0 (-0.3; 0.2) Cohort 2: 0 (-0; 0.2)
38444313	Halim, B.	2024	Longitudinal		1501	Medtronic 780G		Medtronic 670G/770G		**-0.1 (-0.12; -0.08)**
36108305	Herguido, N. G.	2023	Longitudinal	24	47	Medtronic 780G		CSII		0 (-0.13; 0.13)
35099298	Jacobsen, S. S.	2022	Longitudinal	52	55	Medtronic 670G		ST		**-0.2 (-0.31; -0.09)**

33999488	Jeyaventhan, R.	2021	Longitudinal	26	68	Medtronic 670G	Loop	SAP	**-0.3 (-0.48; -0.12)**	
36126177	Kovatchev B. P.	2022	Longitudinal	12	19354	Tandem Control-IQ		PLGS: Basal-IQ with CGM		**-0.03 (-0.036; -0.025)**
38225516	Landau, Z.	2023	Longitudinal	52	46	Medtronic 780G	Open source automated insulin delivery system	ST	0.1 (-0.5; 0.7)	
37959415	Lendínez-Jurado, A.	2023	Longitudinal	12	28	Medtronic 780G		CSII		Cohort 1: 0 (-0.26; 0.26) Cohort 2: -0.09 (-0.39; 0.20)
37337407	Lendínez-Jurado, A.	2023	Longitudinal	24	28	Medtronic 780G		CSII		-0.07 (-0.25; 0.11)
37902785	Lepore, G.	2023	Longitudinal	104	296	Medtronic 780G		MDI or CSII or SAP/PLGS or HCL (Medtronic 760G)		**-0.6 (-0.77; -0.43)**
36763343	Lombardo, F.	2023	Longitudinal	24	101	Medtronic 780G		MDI or CSII		0 (-0.12; 0.12)
33628834	Malone, S. K.	2021	Longitudinal	78	6	Medtronic 670G		ST		-0.99 (-2.51; 0.53)
37646634	Marks, B. E.	2023	Longitudinal	13	195	Omnipod 5		MDI or CSII		**-0.2 (-0.3; -0.1)**
34096789	Messer, L. H.	2021	Longitudinal	26	191	Tandem Control-IQ		ST		0 (-0.009; 0.009)
37708979	Papa, G.	2023	Longitudinal	52	54	Medtronic 670G (41%), Medtronic 780G (59%)		MDI or CSII		**-1.7 (-2.4; -1.1)**
36317539	Piccini, B.	2022	Longitudinal	24	44	Medtronic 780G		Medtronic 780G in manual mode		0.2 (-0.0; 0.5)
32846114	Pinsker, J. E.	2021	Longitudinal	4	1435	Tandem Control-IQ		ST		0 (-0.01; 0.01)
35599092	Pintaudi, B.	2022	Longitudinal	24	59	Medtronic 780G		Medtronic 780G in manual mode		0 (-0.11; 0.11)
36925230	Quiros, R.	2023	Longitudinal	24	50	Medtronic 780G		Medtronic 640G or PLGS		0 (-0.18; 0.18)
37219952	Rachmiel, M.	2023	Longitudinal	72	22	Medtronic 780G		MDI or CSII		-0.03 (-0.24; 0.18)
35020476	Scully, K. J.	2022	Longitudinal	13	13	Tandem Control-IQ		ST		**0.10 (0.06; 0.14)**
34524003	Silva, J. D.	2022	Longitudinal		4120 812 with pre/post	Medtronic 780G		ST		**-0.10 (-0.14; -0.06)**
30160523	Stone, M. P.	2018	Longitudinal	13	3141	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-0.1 (-0.16; -0.04)**

34725723	Thivolet, C.	2021	Longitudinal	13	121	Medtronic 780G	SAP with standalone CGM or SAP with PLGS (Tandem t:slim X2 insulin pump with Basal-IQ and Dexcom G6 CGM)	ST		**-0.08 (-0.12; -0.04)**
34858339	Tornese, G.	2021	Longitudinal	26	44	Medtronic 780G	Medtronic 670G	ST (for outcome HbA1c); HCL system in MM (2 weeks training) (for other glycemic outcomes)		0 (-0.31; 0.31)
34609917	Toschi, E.	2022	Longitudinal	13	48	Tandem Control-IQ		CSII		0 (-0.06; 0.06)
35642299	Vijayanand, S.	2022	Longitudinal	24	52	Medtronic 670G		CSII		-0.1 (-0.5; 0.3)
33838993	Beato-Vibora, P. I.	2021	Cross-sectiona l	NA	302	Medtronic 670G	Group 1: CGM and MDI; Group 2: FGM and MDI; Group 3: SAP with PLGS	ST	Medtronic 670G vs CGM+MDI: **0.4 (0.01; 0.79);** Medtronic 670G vs FGM+MDI: **0.2 (0.005; 0.40);** Medtronic 670G vs SAP/PLGS: **0.4 (0.1; 0.71)**	
31617752	Lepore, G.	2020	Case-control	26	40	Medtronic 670G	PLGS: Medtronic 640G with Guardian 3	ST	0 (-0.29; 0.29)	-0.10 (-0.22; 0.02)
Non-RIS										
33431420	Amadou, C.	2021	Non-RIS	26	25	Diabeloop DBLG1		CSII		-0.08 (-0.27; 0.11)
33784187	Beato-Vibora, P. I.	2021	Non-RIS	4	52	Medtronic 780G		PLGS		-0.1 (-0.32; 0.12)
34329691	Beato-Vibora, P. I.	2021	Non-RIS	13	52	Medtronic 780G		PLGS		-0.2 (-0.45; 0.05)
33289242	Bisio, A.	2021	Non-RIS	4	13	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST		0 (-0.22; 0.22)
33451264	Bisio, A.	2021	Non-RIS	4	15	Tandem Control-IQ	SAP: Personal insulin pump with Dexcom G6 CGM	ST	0 (-0.28; 0.28)	

36689621	Boucsein, A.	2023	Non-RIS	12	20	Medtronic 780G		MDI		-0.6 (-1.5; 0.4)
34099518	Brown, S. A.	2021	Non-RIS	13	240	Omnipod 5		ST		Children **-0.08 (-0.18; -0.02)** Adults **-0.39 (-0.58; -0.2)** Overall**: -0.13 (-0.2; -0.05)**
34694909	Carlson, A. L.	2021	Non-RIS	13	157	Medtronic 780G		SAP, PLGS or automated basal use (during 2 weeks run-in period)		**-0.3 (-0.48; -0.13)**
37850941	Criego, A. B.	2024	Non-RIS	104	224	Omnipod 5		ST		Children**:** -0.03 (-0.14; 0.07) Adolescents/adults**:** -0.36 (-0.55; -0.17) Overall: **-0.11 (-0.2; -0.02)**
36787903	Davis, G. M.	2023	Non-RIS	8	24	Omnipod 5		Basal or basal-bolus		0 (-0.01; 0.01)
37598004	Delgado, A. M.	2023	Non-RIS	52	71	Tandem Control-IQ		PLGS		**-0.2 (-0.29; -0.1)**
38277156	DeSalvo, D. J.	2024	Non-RIS	104	80	Omnipod 5		ST		-0.24 (-0.52; 0.04)
37743832	Do, Q. D.	2023	Non-RIS	12	25	Tandem Control-IQ		Open-source AndroidAPS		-0.36 (-0.73; 0.01)
30585770	Forlenza, G. P.	2019	Non-RIS	13	105	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		**-0.5 (-0.79; -0.21)**
35001477	Forlenza, G. P.	2022	Non-RIS	13	46	Medtronic 670G		Medtronic 670G in MM (during 2 weeks run-in period)		0 (-0.14; 0.14)
33325779	Forlenza, G. P.	2021	Non-RIS	3	36	Omnipod 5		ST		Children: -0.2 (-0.44; 0.04) Adults: **-0.7 (-1.12; -0.28)** Overall: **-0.32 (-0.53; -0.11)**
36060958	Gianini, A.	2022	Non-RIS	NR	24	Medtronic 780G		CSII or PLGS		-0.11 (-0.4; 0.18)
31264889	Lee, M. H.	2019	Non-RIS	5	12	Medtronic 770G		Medtronic 670G in Open Loop (during 1 week run-in period)		0.2 (-0.61; 1.01)
38444316	Marks, B. E.	2024	Non-RIS	24	15	Tandem Control-IQ		MDI		0.1 (-0.2; 0.4)

33185480	Nimri, R.	2021	Non-RIS	4	12	Medtronic 780G		Medtronic 780G in MM during 6 days run-in period)		-0.2 (-0.65; 0.25)
35072781	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI		**-0.4 (-0.68; -0.12)**
35351095	Petrovski, G.	2022	Non-RIS	12	34	Medtronic 780G		MDI		**-0.3 (-0.46; -0.14)**
36511831	Pulkkinen, M.	2023	Non-RIS	12	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		0 (-0.2; 0.2)
38514384	Pulkkinen, M.	2024	Non-RIS	39	35	Medtronic 780G		MDI or Medtronic 640G or Medtronic 670G		-0.2 (-0.4; 0.01)
35852811	Seget, S	2022	Non-RIS	4	50	Medtronic 780G		PLGS or CSII		-0.07 (-0.34; 0.2)
35678724	Sherr, J. L.	2022	Non-RIS	13	80	Omnipod 5		ST		0.06 (-0.3; 0.16)
Automated insulin delivery systems: Fully closed loop systems										
RCTs										
35880252	Herzig, D.	2022	RCT: Parallel	2.8	44	CamAPS HX	Standard insulin therapy	ST: basal insulin, basal-bolus, oral antidiabetic medications	0 (0; 0)	
34349267	Boughton, C.	2021	RCT: Crossover	3	26	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	MDI	0 (-0.1; 0.1) [†]	
36631592	Daly, A. B.	2023	RCT: Crossover	20	26	CamAPS HX	Standard insulin therapy	ST: Insulin regimen (basal insulin, basal-bolus, pre-mixed insulin) and/or oral antidiabetic medications	0.01 (-0.07; 0.09)	
36069928	Van Veldhuisen, C.L.	2022	RCT: Crossover	2	10	Inreda AP	ST: MDI or CSII	ST: MDI or CSII	**-0.62 (-1.05; -0.19)**	
Non-RIS										
38443309	Van Bon, A. C.	2024	Non-RIS	52	78	Inreda AP		MDI (18%), CSII (75%), HCL (6%)		-0.1 (-0.21; 0.01)

*Results from the longest follow-up are reported. Statistically significant results are bolded. In green areas, mean differences (95%CI are calculated based on the values provided in the study. In orange areas, there is an incomplete reporting of the results from the studies
¶TIR (sd): Intervention 71.14 (12.29); Comparison: 66.99 (11.8)

†Difference between intervention and comparison at follow-up, baseline data not reported
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Abbreviations: CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion (pump therapy); MDI, multiple daily insulin injection therapy; NA, not applicable; non-RIS, non-randomized interventional study; PLGS, predictive low glucose suspend; RCT, randomized clinical trial; SAP, sensor augmented insulin pump therapy; ST, standard therapy;; %Time<3, time with sensor values below 3 mmol/l.

Supplemental table 12

Results on high-risk medical devices for diabetes and safety-related outcomes

Supplemental table 12a

Studies with comparison arm													
PMID	**First author**	**Publication year**	**Number of participants**		**Max follow-up (weeks)**	**Intervention**	**Comparison**	**Safety-related outcomes (a)** Number of participants (percentage) and/or [Number of events]					
								Diabetic ketoacidosis		**Severe hypoglycemia**		**Other device-related serious adverse events (b)**	**Device deficiencies (c)**
			Intervention	Comparison				Intervention	Comparison	Intervention	Comparison	Intervention	Intervention
Implantable CGM devices													
RCTs													
34984786	Renard, E.	2022	97	52	26	Eversense® XL CGM System (180 days)	Self-monitoring of blood glucose or intermittently scanned CGM	1 (1%) [1]	0	0	1 (2%) [1]	-	-
34196924	Boscari, F.	2022	16*	16*	12	Eversense® CGM System (90 days)	Dexcom G5	-	-	-	-	0	-
Implantable insulin pumps													
RCTs													
24735100	Schaepelynck, P.	2014	84	84	26	MiniMed MIP 2007C (+Insuman implantable 400 U/ml [recombinant human insulin])	MiniMed MIP 2007C (+Insuplant 400 U/ml [semisynthetic insulin])	0	0	12 (14%)	11 (13%)	-	0
19740082	Liebl, A.	2009	60*	60*	NR	DiaPort	CSII	-	-	IR, 0.348 / patient-year	IR, 0.861 / patient-year#	-	-
19429874	Logtenberg, S. J.	2009	24*	24*	26	MiniMed MIP 2007C	ST: MDI or CSII	-	-	1 (8%) [2]	1 (8%) [5]	-	0
Observational studies													

19048281	Haveman, J. W.	2010	35	28	520	MiniMed MIP 2007C	MiniMed MIP 2001	-	-	-	-	1 (4%)	2 (6%)
Automated insulin delivery systems: Hybrid closed loop systems													
RCTs													
34633418	Abraham, M. B.	2021	67	68	26	Medtronic 670G	ST: MDI or CSII, with or without CGM	0	0	0	0	0	[91]
32846062	Breton, M. D.	2020	78	23	16	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	0	0	0	0	0	12 (15%) [12]
31618560	Brown, S. A.	2019	112	56	26	Tandem Control-IQ	SAP: Various insulin pumps, with CGM sensor	1 (1%) [1]	0	0	0	1 (1%) [1]	-
32471910	Brown, S. A.	2020	54	55	13	Tandem Control-IQ	PLGS: Tandem Basal-IQ (t:slim X2 with Basal-IQ and Dexcom G6 CGM)	0	0	0	0	0	-
36058207	Choudhary, P.	2022	41	41	24	Medtronic 780G	MDI and intermittently scanned CGM	0	0	0	0	0	[56]
37551542	Edd, S. N.	2023	39	26		Medtronic 780G (prior Medtronic 780G)	Medtronic 780G (prior MDI and intermittently scanned CGM)	0	0	0	2 (5.1%) [3]	0	-
36472543	Garg, S. K.	2023	151	151	26	Medtronic 670G	CSII	0	0	0	[4] IR, 0.06 events per person -year	0	-
33216667	Isganaitis, E.	2021	40	23	26	Tandem Control-IQ	SAP: Various insulin pumps, with Dexcom G6 CGM	1 (3%) [1]	0	0	0	0	-
33355258	Kanapka, L. G.	2021	22	78	12	Tandem Control-IQ (after 16 weeks of SAP use)	Tandem Control-IQ (after 16 weeks of Control-IQ use)	0	0	0	0	0	1 (5%) [2]
37796241	Lee, T. M.	2023	59	61	36	CamAPS FX	ST: MDI or CSII	1 (1%) [1]	1 (1%) [1]	4 (6.7%) [6] IR, 0.21 events per person -year	5 (8.2%) [5] IR, 0.16 events per person -year	-	-

26049550	Ly, T. T.	2015	21	21	0.85	Medtronic 670G	PLGS: Medtronic 530G with threshold suspend and Enlite sensor	0	0	0	1 (4%) [1]	-	-
35972259	Matejko, B.	2022	20	17	12	Medtronic 780G	MDI and self-monitoring of blood glucose	0	0	0	0	-	-
33055139	McAuley, S. A.	2020	61	59	26	Medtronic 670G	ST: MDI or CSII with masked CGM (Guardian 3)	1 (2%) [1]	2 (3%) [2]	6 (10%) [8]	3 (5%) [7]	[5]	-
38386437	Polsky, S.	2024	12	12	32	Medtronic 670G	SAP	0	0	0	0	0	[4]
34816597	Renard, E.	2022	59	60	36	Tandem Control-IQ (extended 24/7 use)	Tandem Control-IQ (evening/night use)	0	0	0	0	-	-
37729080	Renard, E.	2023	49	12	12	Tandem Control-IQ	Usual insulin pump and Dexcom G6 CGM	[2]	0	[2]	0	0	[1]
37921083	Reznik, Y	2024	11	14	12	Tandem Control-IQ	ST: MDI	0	0	0	0	0	8 (72%) [22]
32119790	Schoelwer, M. J.	2020	9	9	1	Tandem Control-IQ (reinitialized with new parameters based on protocol)	Tandem Control-IQ (with home settings)	-	-	-	-	0	-
36949671	Van den Heuvel, T.	2023	8	5	24	Medtronic 780G	MDI and real time CGM	0	0	0	0	0	0
36920756	Wadwa, R. P.	2023	68	34	13	Tandem Control-IQ	ST: MDI or CSII	1 (1%) [1]	0	[2]	[1]	0	-
35272971	Ware, J.	2022	21	25	26	CamAPS FX	ST: CSII	0	0	3 (14%) [3]	3 (11.5%) [3]	0	-
33323237	Benhamou, P.	2019	63*	63*	32	Diabeloop DBLG1	SAP	0	0	[5]	[3]	-	-
33453783	Bergenstal, R. M.	2021	112*	112*	52	Medtronic 780G	Medtronic 670G	0	0	1 (1%) [1]	0	0	2 (2%) [2]
34270335	Bode, B.	2021	42*	42*	4	Medtronic 670G (+ Ultrarapid lispro)	Medtronic 670G (+ lispro [Humalog®])	-	-	0	[10]	0	-
33606901	Boughton, C. K.	2021	25*	25*	8	CamAPS FX (+ fast-acting insulin aspart [FIASP])	CamAPS FX (+ standard insulin aspart)	0	0	0	0	0	1 (4%) [1]
35359882	Boughton, C	2022	36*	37*	32	CamAPS FX	SAP: same device as intervention but with disabled auto mode function	0	0	0	[2]	0	[5]
33579715	Collyns, O. J.	2021	59*†	59*	4	Medtronic 670G pump in advanced	PLGS: Medtronic 670G pump in SAP with PLGS mode	0	1 (2%) [1]	0	0	-	-

						hybrid closed loop mode							
37404205	Dovc, K.	2023	30*	30*	8	Medtronic 670G + faster acting insulin aspart	Medtronic 670G + standard insulin aspart	0	0	0	0	0	-
32520594	Hsu, L.	2021	19*	19*	2	Medtronic 670G (+ standard insulin aspart [Novolog®])	Medtronic 670G (+ fast-acting insulin aspart [FIASP®])	0	0	0	0	0	[2]
31796571	Lee, M. H.	2020	12*	12*	0.14	Medtronic 670G (with high intense exercise)	Medtronic 670G (with moderate intense exercise)	-	-	0	0	-	-
34362816	Lee, M. H.	2021	25*	25*	6	Medtronic 780G (+ fast-acting insulin aspart)	Medtronic 780G (+ standard insulin aspart)	0	0	0	0	0	6 (24%) [20]
34844995	McAuley, S. A.	2022	30*	30*	17	Medtronic 670G	SAP: Medtronic 670 G in manual mode with CGM alerts and optional low glucose suspend	0	1 (3%) [1]	3 (10%) [3]	2 (7%) [2]	0	-
34524022	Morrison, D.	2022	16*	16*	6	Medtronic 780G (+ fast-acting insulin aspart)	Medtronic 780G (+ standard insulin aspart)	0	0	0	0	0	6 (24%) [20]
37823892	Nwokolo, M.	2023	28*	28*	16	CamAPS FX + ultra-rapid insulin lispro	CamAPS FX + standard insulin lispro	0	0	0	0	0	7 (12%) [10]
33090016	Ozer, K.	2021	37*	37*	7	Medtronic 670G (+ fast-acting insulin aspart)	Medtronic 670G (+ standard insulin aspart)	-	-	0	0	-	[14]
34789504	Paldus, B.	2022	32*	32*	0.08	Medtronic 670G (combined with high intensity exercise, moderate intensity exercise, resistance exercise in random order)		0	0	0	0	-	-
30620641	Paldus, B.	2019	11*	11*	1	Medtronic 770G	Medtronic 670G	0	0	0	0	-	-
35373894	von dem Berge, T.	2022	38*	38*	18	Medtronic 670G in auto mode	PLGS: Medtronic 670G without auto mode, with Guardian sensor	0	0	0	0	1 (2.6%) [1]	-
35045227	Ware, J.	2022	74*	74*	16	CamAPS FX	SAP	0	0	1 (1%) [1]	0	0	-
36880866	Ware, J.	2023	25*	25*	20	CamAPS FX and Fiasp	CamAPS FX and standard insulin aspart	0	0	0	0	0	-

Observational studies											
33999488	Jeyaventhan, R.	2021	38	30	26	Medtronic 670G	Loop	0 0	7 (18%) 0	-	-
31166801	Salehi, P.	2019	16	16	27	Medtronic 670G in auto-mode	Medtronic 670G in manual mode with low glucose suspend	0 0	4 (25%) 0	0	-
34725723	Thivolet, C.	2021	36	85	13	Medtronic 780G	SAP with standalone CGM or SAP with PLGS (Tandem t:slim X2 insulin pump with Basal-IQ and Dexcom G6 CGM)	0 0	0 0	0	-
31347928	Kaur, H.	2019	5	9	26	Medtronic 670G (in adults with T1D with gastroparesis)	Medtronic 670G (in adults with T1D without gastroparesis)	- -	0 0	-	-
38225516	Landau, Z.	2023	20	26	52	Medtronic 780G	Open source automated insulin delivery system	0 0	0 0	-	-
31617752	Lepore, G.	2020	20	20	26	Medtronic 670G	PLGS: Medtronic 640G with Guardian 3	0 0	0 0	-	-
37956944	Rossi, A.	2023	30	30	12	Medtronic 780G	PLGS	- -	0 0	-	-
Non-RIS											
38032850	Mameli, C.	2024	13	11	0.28	Tandem Control-IQ (first endurance workout, followed by power workout)	Tandem Control-IQ (first power workout, followed by endurance workout)	- -	0 0	-	-
Automated insulin delivery systems: Fully closed loop systems											
RCTs											
35880252	Herzig, D.	2022	22	22	2.8	CamAPS HX	Standard insulin therapy	0 0	0 0	0	[6]
33397767	Blauw, H.	2021	23*	23*	2	Inreda AP (closed loop period)	Personal insulin pump therapy with CGM (if present), with masked CGM (Dexcom G6) (open loop period)	0 0	0 0	0	-
34349267	Boughton, C.	2021	26*	26*	3	CamAPS HX	Standard insulin therapy (MDI or basal insulin therapy) with masked Dexcom G6 CGM	- -	1 (4%) [1] 0	0	5 (19%) [5]
36631592	Daly, A. B.	2023	26*	26*	20	CamAPS HX	Standard insulin therapy	- -	0 0	1 (3.8%) [1]	5 (19%) [6]

36069928	Van Veldhuisen, C.L.	2022	5	5	2	Inreda AP	ST: MDI or CSII	0	0	0	0	0	[30]

(a) In the table section of “Safety outcomes”, results are reported as (i) number of participants who experienced a certain event in the specific study arms (percentage), and/or (i) [numbers of events in the specific study arms], depending on what is reported in the study, unless otherwise specified. For the outcomes of diabetic ketoacidosis and severe hypoglycemia, results are provided for the intervention and comparison groups. For the outcomes of device-related serious adverse events and device deficiencies, results are provided for the intervention group. None of the studies reporting on diabetic ketoacidosis and severe hypoglycemia provided effect measures or p-values for the differences between the intervention and comparison arms, except for the study from Liebl et al (see additional information in the footnote, #)

(b) *Device-related serious adverse event* is defined as any serious adverse event that has a causal relationship with the investigational device or where such causal relationship is reasonably possible. A *serious adverse event* is defined as any adverse event that led to death, serious deterioration in the health of the patient requiring medical assistance including emergency medical services and/or hospitalization.

(c) *Device deficiency* is defined as any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer. *Device deficiency with a serious adverse event potential* is defined as any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate. In the table section of “Device deficiency”, examples of reported device deficiencies include device malfunction such as pump failure or occlusion, misuse, and inadequate labeling. Importantly, none of the studies reported on device deficiency with a serious adverse event potential.

*Crossover studies

#Incidence ratio (95% confidence interval): 2.47 (1.11; 5.5); p-value 0.01

†A total of 59 participants completed the study, one participant withdrew during run-in phase

Abbreviations: “-“ indicates that studies did not report events; IR, incidence rate.

Supplemental table 12b

Studies without comparison arm									
PMID	First author	Publication year	N	Max follow-up (weeks)	Intervention	Safety-related outcomes (a) Number of participants (percentage) and/or [number of events]			
						Diabetic ketoacidosis	Severe hypoglycemia	Other device related serious adverse events (b)	Device deficiencies (c)
Implantable CGM devices									
Observational studies									
31418587	Deiss, D.	2020	3023	111	Eversense CGM System (90 days) or Eversense XL CGM System (180 days)	-	-	0	-
32037699	Irace, C.	2020	100	26	Eversense® XL CGM System (180 days)	-	-	0	1 (1%) [1]
31385732	Sanchez, P.	2019	205	13	Eversense® CGM System (90 days)	-	-	0	-
Non-RIS									
30938036	Aronson, R.	2019	36	26	Eversense® XL CGM System (180 days)	-	-	0	-
29381090	Christiansen, M. P.	2018	90	13	Eversense® CGM System (90 days)	-	-	1 (1%) [1]	[2]
30925083	Christiansen, M. P.	2019	36	13	Eversense® CGM System (90 days)	-	-	0	-
34515521	Garg, S. K.	2022	181	26	Eversense® XL CGM System (180 days)	-	-	0	-
27815290	Kropff, J.	2017	71	26	Eversense® CGM System (90 days)	-	-	0	-
Implantable insulin pumps									
Observational studies									
22912916	van Dijk, P. R.	2012	56	NR	MiniMed MIP 2007C	[9]	-	2 (3.5%)	35 (62%)
Automated insulin delivery systems: Hybrid closed loop systems									
Observational studies									
37236365	Amigo, J.	2023	66	12	Tandem Control-IQ (33%), Medtronic 780G (41%), Diabeloop DBLG1 (26%)	0	0	-	-
31855446	Beato-Vibora, P. I.	2020	58	13	Medtronic 670G	0	0	-	-

36030902	Beato-Vibora, P. I.	2022	135	52	Medtronic 780G	-	[11]	-	-
34227214	Cherubini, V.	2021	43	12	Tandem Control-IQ	0	0	-	-
36724301	Chico, A.	2023	62	12	Diabeloop DBLG1	0	0	0	-
37252734	Cordero, T. L.	2023	176	12	Medtronic 780G	0	0	0	-
34524023	Dubose, S. N.	2021	80	52	Medtronic 670G	2 (2.5%) [2]	3 (3.7%) [3]	-	-
37845757	Elbarbary, N. S.	2023	107	24	Medtronic 780G	0	0	0	-
33450533	Gomez, A. M.	2021	91	2	Medtronic 670G	0	0	-	-
DOI in footnote	Gouet, D.	2022	83	52	Medtronic 780G	0	0	-	-
37782904	Graham, R.	2023	3157	52	Tandem Control IQ	IR, 0.01 / patient-year	IR, 0.09 / patient-year	-	-
37956265	Guibert, C	2023	13	37	Medtronic 780G	0	0	-	-
37905353	Henry, Z.	2023	231	52	Medtronic 780G (72%), Tandem Control IQ (28%)	0	0	-	-
36108305	Herguido, N. G.	2023	47	24	Medtronic 780G	0	0	0	-
38236643	Lablanche, S.	2023	220	52	Medtronic 780G	2 (1%)	5 (2.2%)	-	-
37902785	Lepore, G.	2023	296	104	Medtronic 780G	0	0	-	-
34096789	Messer, L. H.	2021	191	26	Tandem Control-IQ	[2]	0	-	-
DOI in footnote	Mutlu, G. Y.	2023	25	12	Medtronic 780G	0	0	-	-
35488481	Ng, S. M.	2022	39	12	Tandem Control-IQ (91%), CamAPS FX (9%)	0	0	-	-
37902713	Nigi, L.	2023	22	52	Medtronic 780G	0	0	-	-
37708979	Papa, G.	2023	54	52	Medtronic 670G (41%), Medtronic 780G (59%)	0	0	-	-
33044604	Petrovski, G.	2021	30	52	Medtronic 670G	0	0	-	-
36317539	Piccini, B.	2022	44	24	Medtronic 780G	0	0	-	-
38068733	Piccini, B.	2023	83	24	Medtronic 780G	0	0	-	-
35599092	Pintaudi, B.	2022	59	24	Medtronic 780G	0	0	-	-
34668782	Proietti, A.	2022	30	26	Medtronic 670G	0	0	-	-
36925230	Quiros, R.	2023	50	24	Medtronic 780G	0	0	-	-
34015178	Varimo, T.	2021	111	52	Medtronic 670G	0	1 (1%) [1]	-	-
33958309	Wang, L. R.	2021	21	NR	Medtronic 670G	1 (5%)	3 (14%)	-	-

Non-RIS									
33431420	Amadou, C.	2021	25	26	Diabeloop DBLG1	-	-	0	-
33784187	Beato-Vibora, P. I.	2021	52	4	Medtronic 780G	0	0	0	-
34329691	Beato-Vibora, P. I.	2021	52	13	Medtronic 780G	0	0	-	-
36689621	Boucsein, A.	2023	20	12	Medtronic 780G	[2] IR, 0.4 events per person-year	0	-	-
34099518	Brown, S. A.	2021	240	13	Omnipod 5	1 (0.4%) [1]	3 (1.2%) [3]	-	-
34694909	Carlson, A. L.	2021	157	13	Medtronic 780G	0	0	-	-
38439656	Carlson, A. L.	2024	34	13	Tandem Control-IQ	0	0	0	-
37850941	Criego, A. B.	2024	224	104	Omnipod 5	1 (0.4%) [1] IR, 0.002 events per person-year	7 (3.1%) [7] IR, 0.02 events per person-year	-	-
37578778	Davis, G. M.	2023	18	1.42	Omnipod 5	0	0	-	-
37598004	Delgado, A. M.	2023	71	52	Tandem Control-IQ	0	0	-	-
38277156	DeSalvo, D. J.	2024	80	104	Omnipod 5	1 (1.2%) [1] IR, 0.009 events per person-year	1 (1.2%) [1] IR, 0.009 events per person-year	[20]	-
37743832	Do, Q. D.	2023	25	12	Tandem Control-IQ	0	0	-	-
30585770	Forlenza, G. P.	2019	105*	13	Medtronic 670G	0	0	0	-
35001477	Forlenza, G. P.	2022	46	13	Medtronic 670G	0	0	0	-
33325779	Forlenza, G. P.	2021	36	3	Omnipod 5	0	0	0	11 (30%) [17]
28134564	Garg, S. K.	2017	124	13	Medtronic 670G	0	0	-	-
36060958	Gianini, A.	2022	24	NR	Medtronic 780G	0	0	-	-
31264889	Lee, M. H.	2019	12	5	Medtronic 770G	0	0	-	-
38444316	Marks, B. E.	2024	15	24	Tandem Control-IQ	4 (26.7%) [5] IR, 0.72 events per person-year	0	-	-
37823890	Michaels, V. R.	2024	20	52	Medtronic 780G	[3] IR, 0.15 events per person-year	1 (0.05%) [1]	0	[3]
34120699	Nally, L. M.	2021	17	24	Medtronic 670G	0	0	-	-
33185480	Nimri, R.	2021	12	4	Medtronic 780G	-	-	0	-

31953687	Petrovski, G.	2020	30	12	Medtronic 670G	0	0	-	-
35072781	Petrovski, G.	2022	34	12	Medtronic 780G	0	0	-	-
35351095	Petrovski, G.	2022	34	12	Medtronic 780G	0	0	0	-
37782145	Pinhoker, C.	2023	160	12	Medtronic 670G	0	0	0	0
36511831	Pulkkinen, M.	2023	35	12	Medtronic 780G	0	0	-	-
38514384	Pulkkinen, M.	2024	35	39	Medtronic 780G	1 (2.8%)	0	-	-
35678724	Sherr, J. L.	2022	80	13	Omnipod 5	0	0	[12]	-
Automated insulin delivery systems: Fully closed loop systems									
Observational studies									
36947090	Boughton, C. K.	2023	32	52	CamAPS HX	0	0	0	16 (50%) [34]
Non-RIS									
38443309	Van Bon, A. C.	2024	78	52	Inreda AP	0	2 (2.5%)	-	-

(a) In the table section of “Safety outcomes”, results are reported as (i) number of participants who experienced a certain event (percentage), and/or (i) [numbers of events], depending on what is reported in the study, unless otherwise specified.
(b) *Device-related serious adverse event* is defined as any serious adverse event that has a causal relationship with the investigational device or where such causal relationship is reasonably possible. A *serious adverse event* is defined as any adverse event that led to death, serious deterioration in the health of the patient requiring medical assistance including emergency medical services and/or hospitalization.
(c) *Device deficiency* is defined as any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer. *Device deficiency with a serious adverse event potential* is defined as any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate. In the table section of “Device deficiency”, examples of reported device deficiencies include device malfunction such as pump failure or occlusion, misuse, and inadequate labeling. Importantly, none of the studies reported on device deficiency with a serious adverse event potential.
*One participant experienced diabetic ketoacidosis before device was implanted. This participant was hospitalized, discharged after one day and withdrawn from the study protocol.
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Abbreviations: “-“ indicates “Not reported”; IR, incidence rate

Supplemental table 13

Quality assessment of included studies

Supplemental table 13a

Randomized clinical trials*								
PMID	**First author**	**Year of publication**	**Domain 1**	**Domain 2**	**Domain 3**	**Domain 4**	**Domain 5**	**Overall risk of bias**
Implantable CGM devices								
34984786	Renard, E.	2022	Some concerns	Some concerns	High	Low	Some concerns	High
34196924	Boscari, F.	2022	Some concerns	Some concerns	Low	Low	High	High
Implantable insulin pumps								
24735100	Schaepelynck, P.	2014	Some concerns	Low	Low	Low	Low	Some concerns
19740082	Liebl, A.	2009	Some concerns	Low	Low	Low	Low	Some concerns
19429874	Logtenberg, S. J.	2009	Some concerns	Low	Low	Low	Low	Some concerns
Automated insulin delivery systems: Hybrid closed loop systems								
34633418	Abraham, M. B.	2021	Low	Low	Low	Low	Low	Low
32846062	Breton, M. D.	2020	Low	Some concerns	Low	Low	Low	Some concerns
31618560	Brown, S. A.	2019	Low	Low	Low	Low	Low	Some concerns
32471910	Brown, S. A.	2020	Some concerns	Low	Low	Low	Low	Some concerns
36058207	Choudhary, P.	2022	Low	Some concerns	Low	Low	Low	Low
37551542	Edd, S.	2023	Some concerns	Some concerns	Low	Low	Low	Some concerns
31099946	Ekhlaspour, L.	2019	Some concerns	Low	Low	Low	Low	Some concerns
30888835	Forlenza, G. P.	2019	Some concerns	Low	Low	Low	Low	Some concerns
36472543	Garg, S.K.	2023	Some concerns	Some concerns	Some concerns	High	Low	High
33216667	Isganaitis, E.	2021	Some concerns	Some concerns	Low	Low	Low	Some concerns
33355258	Kanapka, L. G.	2021	Some concerns	Low	Low	Low	Low	Some concerns
37796241	Lee, T.T.M.	2023	Low	Some concerns	Low	Low	Low	Some concerns
26049550	Ly, T. T.	2015	Some concerns	Some concerns	Low	Low	Low	Some concerns
35972259	Matejko, B.	2022	Low	Some concerns	Some concerns	Low	Low	Some concerns
33055139	McAuley, S. A.	2020	Low	Low	Low	Low	Low	Low
38386437	Polsky, S.	2024	Low	Some concerns	Low	Low	Low	Low

34816597	Renard, E.	2022	Some concerns	Low	Low	Low	Low	Some concerns
37729080	Renard. E.	2023	High	Some concerns	Low	Low	Low	High
37921083	Reznik, Y.	2024	Low	Low	Low	Low	Low	Low
32119790	Schoelwer, M. J.	2020	Some concerns	Low	Low	Low	Low	Some concerns
36949671	Van den Heuvel, T.	2023	Low	Some concerns	Low	Low	Some concerns	Some concerns
36920756	Wadwa, R. P.	2023	Low	Low	Low	Low	Low	Low
35272971	Ware, J.	2022	Low	Some concerns	Low	Low	Low	Low
33323237	Benhamou	2019	Low	Low	Low	Low	Low	Low
33453783	Bergenstal, R. M.	2021	Low	Low	Low	Low	Low	Low
34270335	Bode, B.	2021	Some concerns	Low	Low	Low	High	Some concerns
33606901	Boughton, C. K.	2021	Some concerns	Low	Low	Low	Low	Low
35359882	Boughton, C.	2022	Low	Some concerns	Some concerns	Low	Low	Some concerns
33555982	Burckhardt, M. A.	2021	Some concerns	Low	Low	Low	Low	Some concerns
33579715	Collyns, O. J.	2021	Some concerns	Low	Low	Low	Low	Some concerns
36631592	Daly, A.B.	2023	Low	Low	Low	Low	Low	Low
37404205	Dovc, K.	2023	Some concerns	Low	Low	Low	Low	Some concerns
32520594	Hsu, L.	2021	Some concerns	Low	Low	Low	Low	Some concerns
31796571	Lee, M. H.	2020	Some concerns	High	Low	Low	Low	Some concerns
34362816	Lee, M. H.	2021	Some concerns	Low	Low	Low	Low	Some concerns
34844995	McAuley, S. A.	2022	Low	Low	Low	Low	Low	Low
34524022	Morrison, D.	2022	Low	Low	Low	Low	Low	Low
37823892	Nwokolo	2023	Low	Low	Low	Low	Low	Low
33090016	Ozer, K.	2021	Some concerns	Some concerns	Low	Low	Low	Some concerns
34789504	Paldus, B.	2022	Low	Low	Low	Low	Low	Low
30620641	Paldus, B.	2019	Some concerns	Some concerns	Low	Low	Some concerns	Some concerns
35373894	von dem Berge, T.	2022	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns
35045227	Ware, J.	2022	Low	Low	Low	Low	Low	Low
36880866	Ware, J.	2023	Low	Low	Low	Low	Low	Low
Automated insulin delivery systems: Fully closed loop systems								

35880252	Herzig, D.	2022	Low	Some concerns	Low	Low	Low	Some concerns
33397767	Blauw, H.	2021	Low	Some concerns	Low	High	Low	High
34349267	Boughton, C. K.	2021	Low	Low	Low	Low	Low	Low
36069928	Van Veldhuisen, C.L.	2022	Low	Some concerns	Some concerns	Low	Low	Some concerns

*The quality of evidence of randomized clinical trials was assessed using version 2 of the Cochrane Risk of Bias Assessment Tool, which is based on 5 domains.
(Domain 1) bias arising from the randomization process;
(Domain 2) bias due to deviations from intended interventions;
(Domain 3) bias due to missing outcome data;
(Domain 4) bias in measurement of the outcome;
(Domain 5) bias in selection of the reported result.
Abbreviation: CGM, continuous glucose monitoring.

Supplemental table 13b

Observational studies*								
PMID	**First author**	**Publication year**	**Selection (maximum 4 stars)**	**Comparability (maximum 2 stars)**	**Outcome (maximum 3 stars)**	**Total number of stars**	**Overall quality**	**Overall risk of bias**
Implantable CGM devices								
31418587	Deiss, D.	2020	2	0	3	5	poor	high
32037699	Irace, C.	2020	3	1	2	6	good	low
31385732	Sanchez, P.	2019	3	1	2	6	good	low
Implantable insulin pumps								
19048281	Haveman, J. W.	2010	2	0	3	5	poor	high
22912916	van Dijk, P. R.	2012	3	0	3	6	poor	high
26582805	van Dijk, P. R.	2015	3	1	3	7	good	low
Automated insulin delivery systems: Hybrid closed loop systems								
31789447	Akturk, H. K.	2020	3	1	3	7	good	low
37236365	Amigo, J.	2023	3	1	3	7	good	low
35136338	Amole, M.	2021	1	1	2	4	poor	high
35414272	Arunachalum, S.	2022	3	1	3	7	good	low
38459160	Atik-Altinok, Y.	2024	3	1	3	7	good	low
35116007	Bassi, M.	2022	3	1	3	7	good	low
36777356	Bassi, M.	2023	2	1	3	6	fair	low
36030902	Beato-Víbora, P.I.	2022	3	2	3	8	good	low
31855446	Beato-Vibora, P. I.	2020	4	1	3	8	good	low
30862242	Berget, C.	2020	4	1	3	8	good	low
31837064	Berget, C.	2020	3	1	3	7	good	low
36947090	Boughton, C.K.	2023	1	0	2	3	poor	high
33784196	Breton, M. D.	2021	4	1	3	8	good	low
34227214	Cherubini, V.	2021	3	2	3	8	good	low
36724301	Chico, A.	2023	4	1	3	8	good	low
32212971	Cobry, E. C.	2020	2	1	3	6	good	low
37252734	Cordero, T.L.	2023	3	2	3	8	good	low
33961340	Da Silva, J.	2021	3	1	3	7	good	low
DOI in footnote	Del Valle Rolón, M.E.	2023	2	2	3	7	good	low

34524023	Dubose, S. N.	2021	4	0	1	5	poor	high
37845757	Elbarbary, N.S.	2023	3	1	3	7	good	low
30865545	Faulds, E. R.	2019	3	0	3	6	poor	high
33450533	Gomez, A. M.	2021	3	0	1	4	poor	high
DOI in footnote	Gouet, D.	2022	2	1	3	6	fair	low
37782904	Graham, R.	2024	3	1	3	7	good	low
36789699	Grassi, B.	2023	3	1	3	7	good	low
37956265	Guibert, C.	2023	1	0	2	3	poor	high
38444313	Halim, B.	2024	3	1	3	7	good	low
37905353	Henry, Z.	2023	3	2	3	8	good	low
36108305	Herguido, N.G.	2022	3	1	3	7	good	low
35099298	Jacobsen, S. S.	2022	4	0	1	5	poor	high
33999488	Jeyaventhan, R.	2021	3	0	3	6	poor	high
34569850	Ju, Z.	2022	3	1	3	7	good	low
36126177	Kovatchev, B.P.	2022	3	2	3	8	good	low
38236643	Lablanche, S.	2024	3	2	3	8	good	low
31548247	Lal, R. A.	2019	4	1	1	6	poor	high
38225516	Landau, Z.	2023	3	1	3	7	good	low
38579305	Lehmann, V.	2023	3	1	3	7	good	low
37959415	Lendínez-Jurado, A.	2023	2	1	3	6	fair	low
37337407	Lendínez-Jurado, A.	2023	2	1	3	6	fair	low
37902785	Lepore, G.	2024	3	2	3	8	good	low
36763343	Lombardo, F.	2023	2	2	3	7	fair	low
33628834	Malone, S. K.	2021	2	0	2	4	poor	high
37646634	Marks, B.	2023	2	2	3	7	fair	low
37184526	Matejko, B.	2023	1	0	3	4	poor	high
34096789	Messer, L. H.	2021	4	0	3	7	poor	high
DOI in footnote	Mutlu, G.Y.	2023	2	1	3	6	fair	low
36940793	Nattero-Chavez, L.	2023	2	2	3	7	fair	low

36424877	Ng, S.M.	2022	2	2	3	7	fair	low
35488481	Ng, S.M.	2021	2	1	3	6	fair	low
37902713	Nigi, L.	2024	2	1	3	6	fair	low
37708979	Papa, G.	2023	3	2	3	8	good	low
33044604	Petrovski, G.	2021	2	0	1	3	poor	high
36317539	Piccini, B.	2022	2	2	3	7	fair	low
38068733	Piccini, B.	2023	2	2	3	7	fair	low
32846114	Pinsker, J. E.	2021	3	1	1	5	poor	high
35599092	Pintaudi, B.	2022	3	2	3	8	good	low
34668782	Proietti, A.	2022	2	0	1	3	poor	high
36925230	Quiros, C.	2022	3	2	3	8	good	low
37219952	Rachmiel, M.	2023	2	2	3	7	fair	low
37956944	Rossi, A.	2023	2	2	3	7	fair	low
31166801	Salehi, P.	2019	1	0	1	2	poor	high
35451679	Schiaffini, R.	2022	2	1	3	6	fair	low
35020476	Scully, K. J.	2022	1	1	3	5	poor	high
34524003	Silva, J. D.	2022	3	1	3	7	good	low
30160523	Stone, M. P.	2018	3	1	3	7	good	low
34725723	Thivolet, C.	2021	4	1	3	8	good	low
38377317	Thrasher, J.R.	2024	3	1	3	7	good	low
34858339	Tornese, G.	2021	2	0	2	4	poor	high
34609917	Toschi, E.	2022	1	0	3	4	poor	high
33430621	Usoh, C. O.	2021	3	1	3	7	good	low
36280026	Usoh, C.O.	2022	3	1	3	7	good	low
34015178	Varimo, T.	2021	4	1	3	8	good	low
35642299	Vijayanand, S.	2022	2	1	2	5	fair	low
33958309	Wang, L. R.	2021	1	0	1	2	poor	high
DOI in footnote	Zuijdwijk, C.	2023	2	1	3	6	fair	low
33838993	Beato-Vibora, P. I.	2021	3	1	3	7	good	low

34058303	Horowitz, M. E.	2021	3	0	2	5	poor	high
31347928	Kaur, H.	2019	1	1	3	5	poor	high
31617752	Lepore, G.	2020	2	0	1	3	poor	high

*The quality of evidence of observational studies was assessed using the Newcastle Ottawa Scale, which is based on three domains, including selection of participants, comparability of study groups, and ascertainment of the outcomes of interest. Each study can be awarded a maximum of nine stars. Based on the thresholds for converting the NOS scores into the Agency for Healthcare Research and Quality (AHRQ) standards, the quality of the studies and risk of bias were categorized as follows: (I) Good quality and low risk of bias: 3 or 4 stars in the selection domain, AND 1 or 2 stars in the comparability domain, AND 2 or 3 stars in the outcome domain. (II) Fair quality and moderate risk of bias: 2 stars in the selection domain, AND 1 or 2 stars in the comparability domain, AND 2 or 3 stars in the outcome domain. (III) Poor quality and high risk of bias: 0 or 1 star in the selection domain, OR 0 star in the comparability domain, OR 0 or 1 stars in the outcome domain.

Del Valle Rolón, M.E.2023 : DOI https://doi.org/10.1155/2023/6621706
Gouet, D. 2022: https://doi.org/10.1016/j.deman.2022.100110
Mutlu, G. Y 2023: DOI: 10.5603/DK.a2022.0063
Zuijdwijk, C. 2023: DOI https://doi.org/10.1155/2023/5106107
Abbreviation: CGM, continuous glucose monitoring.

Supplemental table 13c

Non-randomized interventional studies with no control group*																								
PMID	30239219	33431420	30938036	33784187	34329691	33289242	33451264	34099518	34694909	30925083	29381090	33325779	35001477	30585770	34515521	28134564	31264889	27191182	29444895	34120699	33185480	35072781	31953687	27815290
First author	Adams R. N. 2018	Amadou C. 2021	Aronson, R. 2019	Beato-Vibora, P. I. 2021	Beato-Vibora, P. I. 2021	Bisio, A. 2021	Bisio, A. 2021	Brown, S. 2021	Carlson, A. L. 2021	Christiansen, M. P. 2019	Christiansen, M. P. 2018	Forlenza g. p. 2021	Forlenza g. p. 2022	Forlenza g. p. 2019	Garg, S.K 2022	Garg, S.K 2017	Lee, M.H 2019	Ly. TT 2017	Messer, L. H. 2018	Nally, L. M. 2021	Nimri, R. 2021	Petrovski, G. 2022	Petrovski, G. 2020	Kropff, J. 2017
Device	AID	AID	CGM	AID	AID	AID	AID	AID	AID	CGM	CGM	AID	AID	AID	CGM	AID	AID	AID	AID	AID	AID	AID	AID	CGM
D1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D2	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D4	y	NI	NI	NI	NI	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
D5	N	N	Y	N	N	N	N	Y	Y	N	Y	N	N	Y	Y	Y	N	N	N	N	N	N	N	Y
D6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D7	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D8	N	N	NI	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N

D9	NI	NI	Y	Y	NI	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D10	NA	Y	NA	Y	Y	Y	Y	Y	Y	NA	NA	Y	Y	Y	NA	Y	Y	Y	Y	Y	Y	Y	Y	NA
D11	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
D12	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Overall RoB	**M**	**M**	**M**	**M**	**M**	**L**	**M**	**L**	**L**	**M**	**L**	**L**	**M**	**L**	**L**	**L**	**L**	**L**	**M**	**L**	**L**	**L**	**L**	**L**

*The quality of evidence of non-randomized interventional studies with no control group was assessed using the validated National Institute of Health assessment tool for Before-After (Pre-Post) studies without control group, with is based on 12 domains.
Domain 1 (D1): Was the study question or objective clearly stated?
Domain 2 (D2): Were eligibility criteria for the study population prespecified and clearly described?
Domain 3 (D3): Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?
Domain 4 (D4): Were all eligible participants that met the prespecified entry criteria enrolled?
Domain 5 (D5): Was the sample size sufficiently large to provide confidence in the findings?
Domain 6 (D6): Was the intervention clearly described and delivered consistently across all study participants?
Domain 7 (D7): Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?
Domain 8 (D8): Were the people assessing the outcomes blinded to the participants' intervention?
Domain 9 (D9): Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?
Domain 10 (D10): Did the statistical methods examine changes in outcome measures «from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?
Domain 11 (D11): Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention
Domain 12 (D12): If the intervention was conducted at a group level, did the statistical analysis take into account the use of individual-level data to determine effects at the group level?
Each study can be awarded a maximum of 12 points. Risk of bias was categorized as follows: 8–12 points indicated low risk, 5–7 points indicated moderate and 1–4 indicated high risk of bias.
Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; H, high risk of bias; L, low risk of bias, M, moderate risk of bias; N, no; NA, not available; NI, no information; RoB, risk of bias; Y, yes.

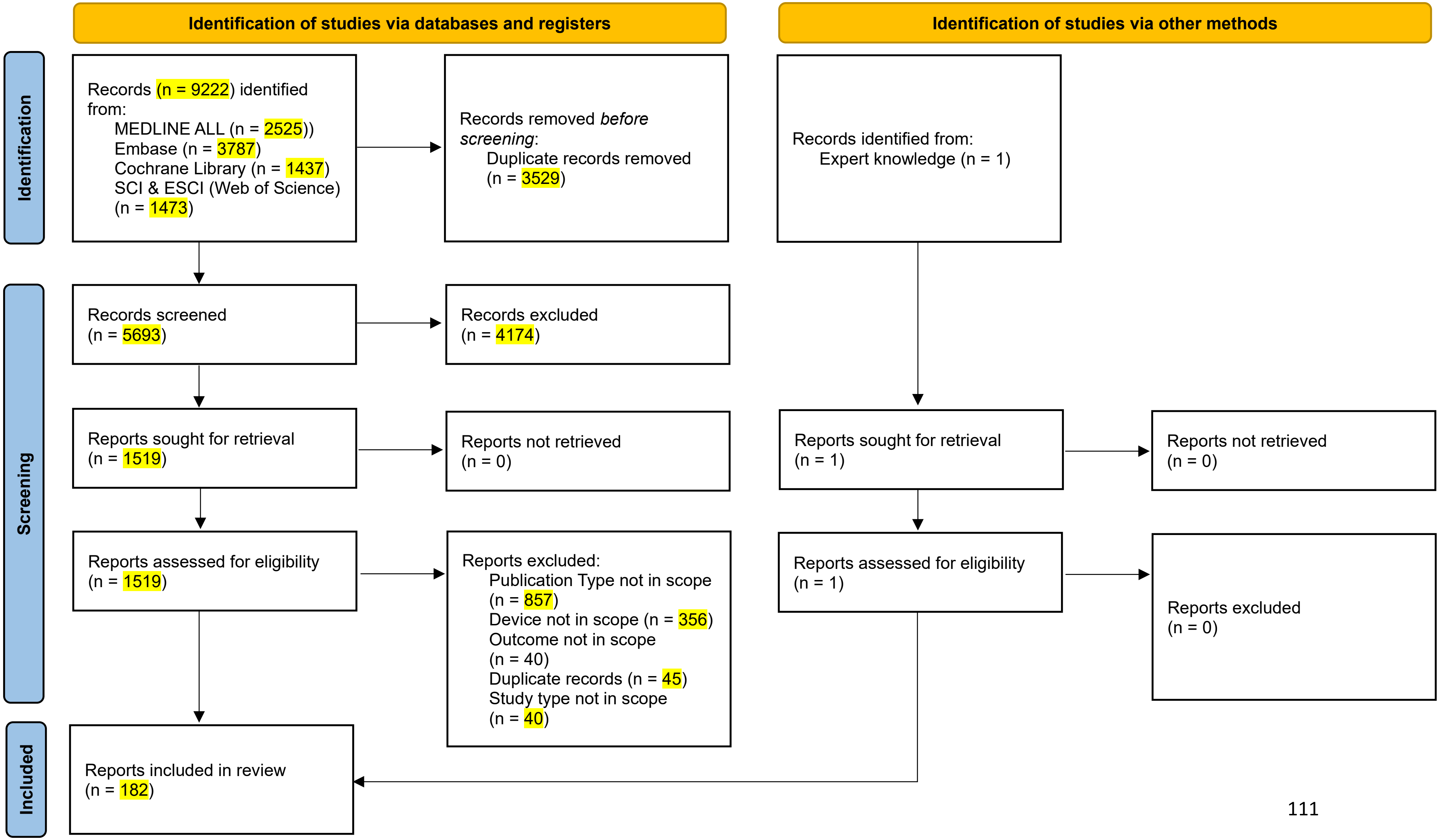
Non-randomized interventional studies with no control group* (continued)																			
PMID	36689621	38439656	37850941	36787903	38277156	37578778	37743832	36060958	38032850	38444316	37823890	37598004	35351095	37782145	38514384	36511831	35852811	35678724	38443309
First author	Boucsein A.	Carlson A. L.	Criego A. B.	Davis M. G.	Desalvo D. J	Davis M. G	DO Q. C	Gianini G.	Mameli C.	Marks B. E.	Michaels V. R.	Mingorance Delgado A.	Petrovski G.	Pihoker C.	Pulkkinen M.	Pulkkinen M.	Seget S.	Sherr J. L.	Van Bon A. C.
D1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D2	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D4	NI	NI	NI	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D5	N	N	Y	N	Y	N	N	N	N	N	N	Y	N	Y	N	N	Y	Y	Y
D6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D7	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D8	NI	NI	NI	NI	Ni	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI	NI
D9	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D10	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

D11	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
D12	NA	NA	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Over all RoB	**M**	**M**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**	**L**

*The quality of evidence of non-randomized interventional studies with no control group was assessed using the validated National Institute of Health assessment tool for Before-After (Pre-Post) studies without control group, with is based on 12 domains.
Domain 1 (D1): Was the study question or objective clearly stated?
Domain 2 (D2): Were eligibility criteria for the study population prespecified and clearly described?
Domain 3 (D3): Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?
Domain 4 (D4): Were all eligible participants that met the prespecified entry criteria enrolled?
Domain 5 (D5): Was the sample size sufficiently large to provide confidence in the findings?
Domain 6 (D6): Was the intervention clearly described and delivered consistently across all study participants?
Domain 7 (D7): Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?
Domain 8 (D8): Were the people assessing the outcomes blinded to the participants' intervention?
Domain 9 (D9): Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?
Domain 10 (D10): Did the statistical methods examine changes in outcome measures «from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?
Domain 11 (D11): Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention
Domain 12 (D12): If the intervention was conducted at a group level, did the statistical analysis take into account the use of individual-level data to determine effects at the group level?
Each study can be awarded a maximum of 12 points. Risk of bias was categorized as follows: 8–12 points indicated low risk, 5–7 points indicated moderate and 1–4 indicated high risk of bias.
Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; H, high risk of bias; L, low risk of bias, M, moderate risk of bias; N, no; NA, not available; NI, no information; RoB, risk of bias; Y, yes.

Supplemental figure 1

Flow chart of study selection for inclusion in the systematic review



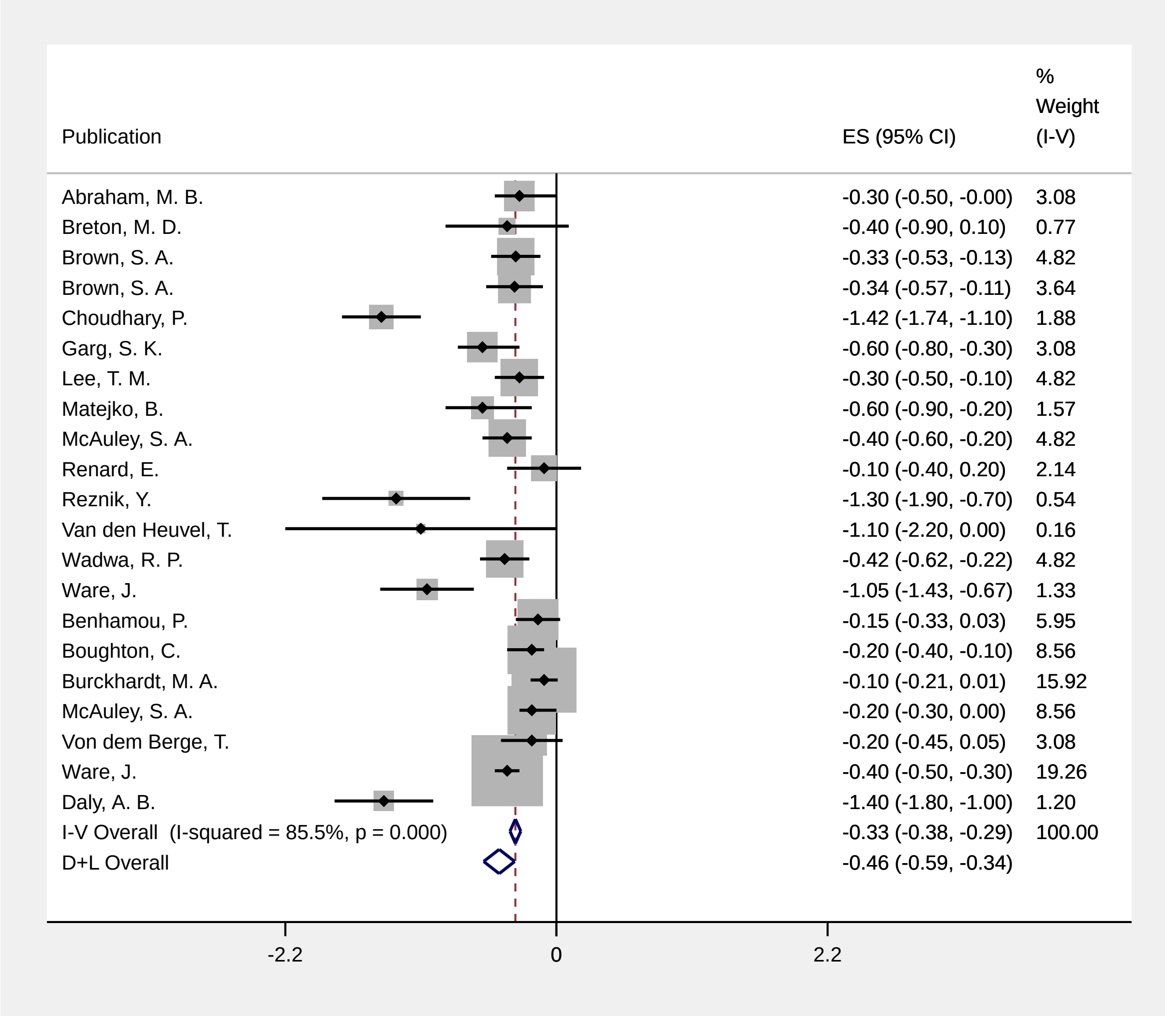
From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Supplemental figure 2

Meta-analysis on AID systems and HbA1c (%). Abbreviations: AID, automated insulin delivery; ES (95%CI), mean difference (95% confidence interval); HbA1c, glycated hemoglobin.

Supplemental figure 2a

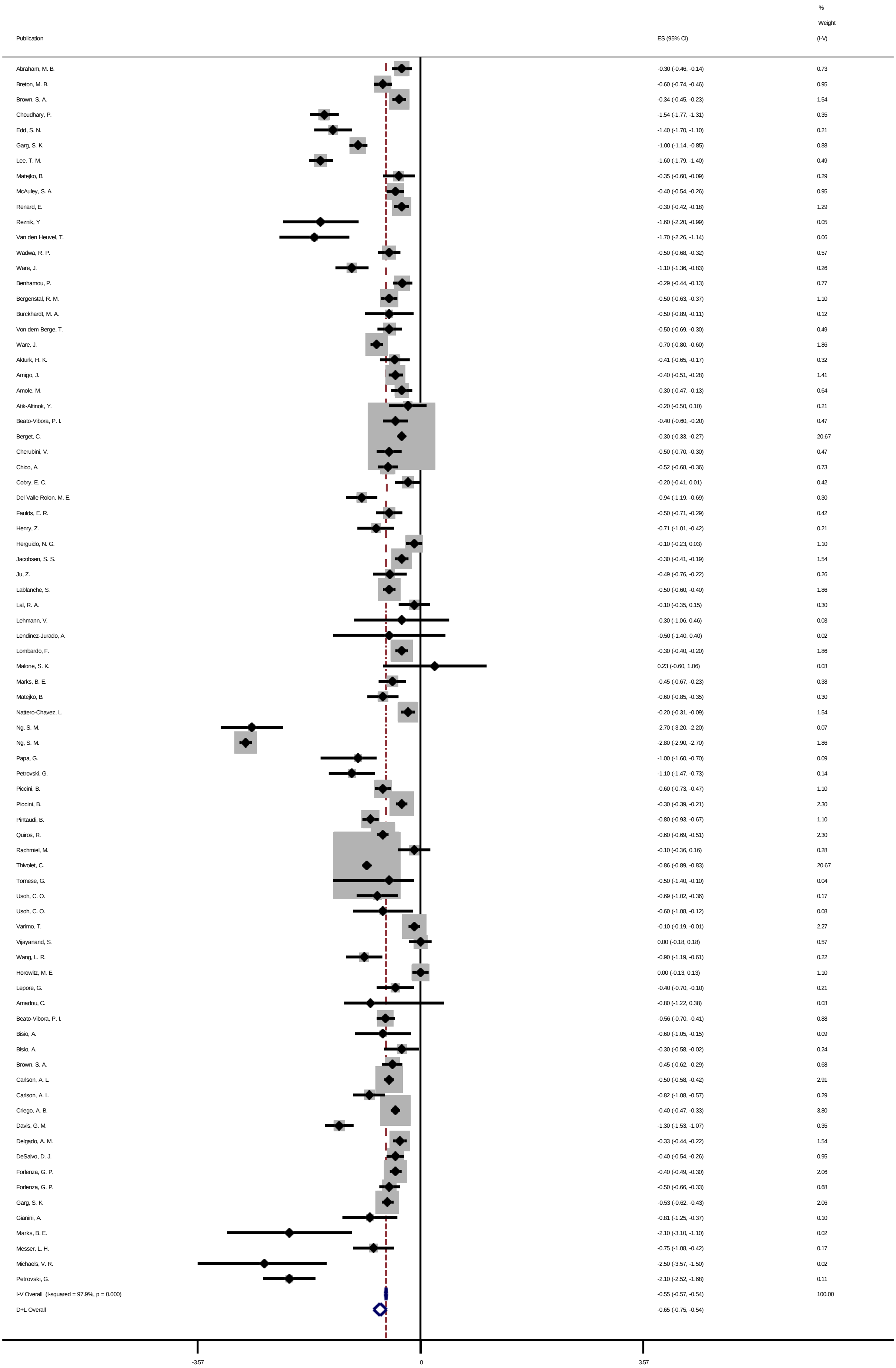
Randomized clinical trials. Randomized clinical trials evaluating the impact of AID systems on HbA1c (%). The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants.



Supplemental figure 2b

Studies of any design. Studies of any design comparing HbA1c (%) before (Reference) vs after utilization of AID systems (i.e., pre-post intervention). Baseline treatment (before utilization of AID system) includes any other diabetes treatment methods (including standard diabetes therapy, multiple daily injection insulin therapy with/without glucose sensing-device, continuous subcutaneous insulin infusion with/without sensor augmentation with/without [predictive] low glucose suspend).

Additional note. Two studies, by Petrovski et al [PMID 33044604] and Petrovski et al [PMID 31953687] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Petrovski et al [PMID 33044604] because of the longer follow-up. Two studies, by Petrovski et al [PMID 35072781] and Petrovski et al [PMID 35351095] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the results of only one of the studies. Two studies, by Lendínez-Jurado et al [PMID 37959415] and Lendínez-Jurado et al [PMID 37337407] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Lendínez-Jurado et al [PMID 37337407] because of the longer follow-up. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants. Two studies, by DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by DeSalvo et al [PMID 38277156] because of the longer follow-up. Two studies, by Boucsein et al [PMID 36689621] and Michaels et al [PMID 37823890] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Michaels et al [PMID 37823890] because of the longer follow-up.

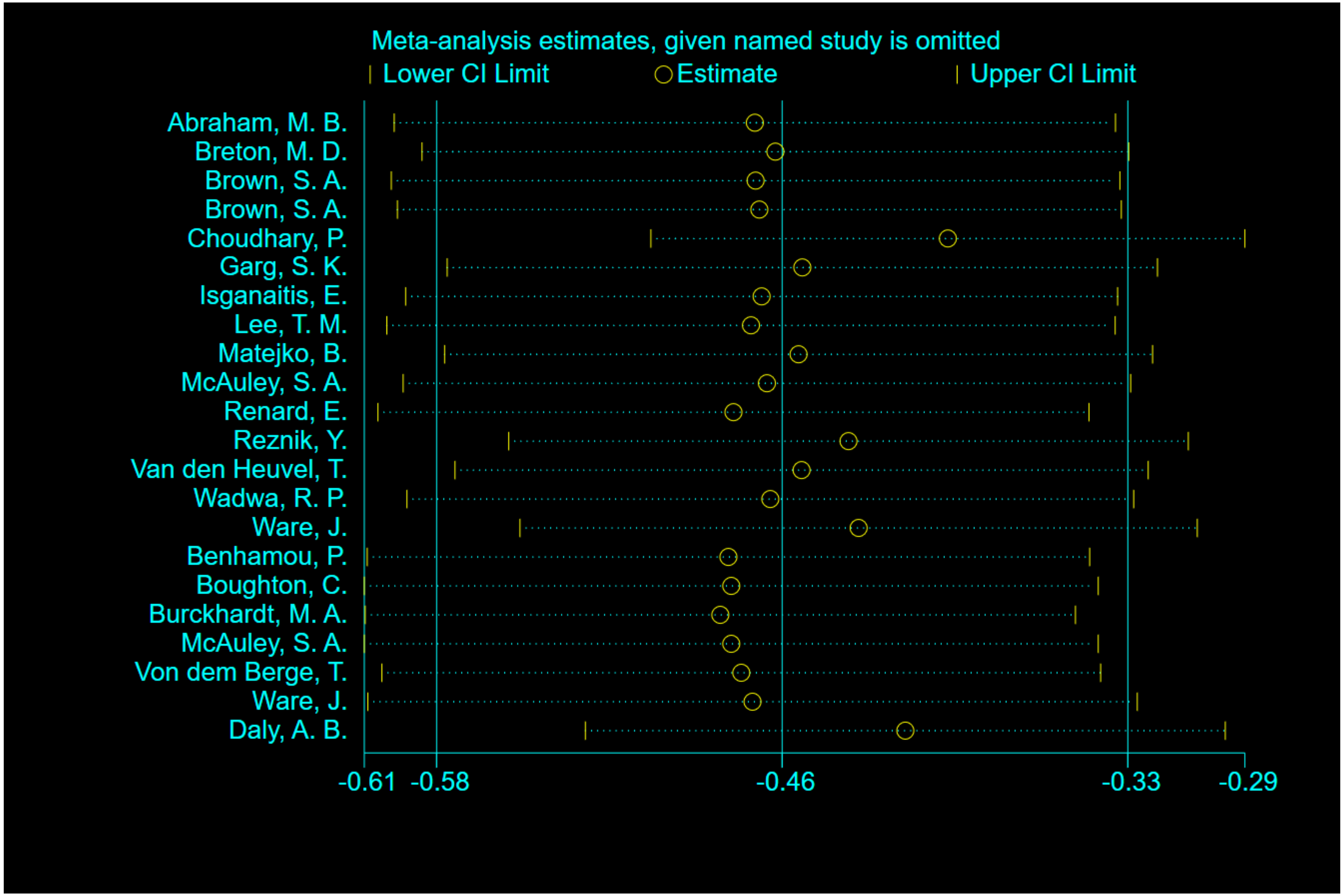

%
Weight
Publication
ES (95% CI)
(I-V)
Abraham, M. B. -0.30 (-0.46, -0.14) 0.73
Breton, M. B. -0.60 (-0.74, -0.46) 0.95
Brown, S. A. -0.34 (-0.45, -0.23) 1.54
Choudhary, P. -1.54 (-1.77, -1.31) 0.35
Edd, S. N. -1.40 (-1.70, -1.10) 0.21
Garg, S. K. -1.00 (-1.14, -0.85) 0.88
Lee, T. M. -1.60 (-1.79, -1.40) 0.49
Matejko, B. -0.35 (-0.60, -0.09) 0.29
McAuley, S. A. -0.40 (-0.54, -0.26) 0.95
Renard, E. -0.30 (-0.42, -0.18) 1.29
Reznik, Y -1.60 (-2.20, -0.99) 0.05
Van den Heuvel, T. -1.70 (-2.26, -1.14) 0.06
Wadwa, R. P. -0.50 (-0.68, -0.32) 0.57
Ware, J. -1.10 (-1.36, -0.83) 0.26
Benhamou, P. -0.29 (-0.44, -0.13) 0.77
Bergenstal, R. M. -0.50 (-0.63, -0.37) 1.10
Burckhardt, M. A. -0.50 (-0.89, -0.11) 0.12
Von dem Berge, T. -0.50 (-0.69, -0.30) 0.49
Ware, J. -0.70 (-0.80, -0.60) 1.86
Akturk, H. K. -0.41 (-0.65, -0.17) 0.32
Amigo, J. -0.40 (-0.51, -0.28) 1.41
Amole, M. -0.30 (-0.47, -0.13) 0.64
Atik-Altinok, Y. -0.20 (-0.50, 0.10) 0.21
Beato-Vibora, P. I. -0.40 (-0.60, -0.20) 0.47
Berget, C. -0.30 (-0.33, -0.27) 20.67
Cherubini, V. -0.50 (-0.70, -0.30) 0.47
Chico, A. -0.52 (-0.68, -0.36) 0.73
Cobry, E. C. -0.20 (-0.41, 0.01) 0.42
Del Valle Rolon, M. E. -0.94 (-1.19, -0.69) 0.30
Faulds, E. R. -0.50 (-0.71, -0.29) 0.42
Henry, Z. -0.71 (-1.01, -0.42) 0.21
Herguido, N. G. -0.10 (-0.23, 0.03) 1.10
Jacobsen, S. S. -0.30 (-0.41, -0.19) 1.54
Ju, Z. -0.49 (-0.76, -0.22) 0.26
Lablanche, S. -0.50 (-0.60, -0.40) 1.86
Lal, R. A. -0.10 (-0.35, 0.15) 0.30
Lehmann, V. -0.30 (-1.06, 0.46) 0.03
Lendinez-Jurado, A. -0.50 (-1.40, 0.40) 0.02
Lombardo, F. -0.30 (-0.40, -0.20) 1.86
Malone, S. K. 0.23 (-0.60, 1.06) 0.03
Marks, B. E. -0.45 (-0.67, -0.23) 0.38
Matejko, B. -0.60 (-0.85, -0.35) 0.30
Nattero-Chavez, L. -0.20 (-0.31, -0.09) 1.54
Ng, S. M. -2.70 (-3.20, -2.20) 0.07
Ng, S. M. -2.80 (-2.90, -2.70) 1.86
Papa, G. -1.00 (-1.60, -0.70) 0.09
Petrovski, G. -1.10 (-1.47, -0.73) 0.14
Piccini, B. -0.60 (-0.73, -0.47) 1.10
Piccini, B. -0.30 (-0.39, -0.21) 2.30
Pintaudi, B. -0.80 (-0.93, -0.67) 1.10
Quiros, R. -0.60 (-0.69, -0.51) 2.30
Rachmiel, M. -0.10 (-0.36, 0.16) 0.28
Thivolet, C. -0.86 (-0.89, -0.83) 20.67
Tornese, G. -0.50 (-1.40, -0.10) 0.04
Usoh, C. O. -0.69 (-1.02, -0.36) 0.17
Usoh, C. O. -0.60 (-1.08, -0.12) 0.08
Varimo, T. -0.10 (-0.19, -0.01) 2.27
Vijayanand, S. 0.00 (-0.18, 0.18) 0.57
Wang, L. R. -0.90 (-1.19, -0.61) 0.22
Horowitz, M. E. 0.00 (-0.13, 0.13) 1.10
Lepore, G. -0.40 (-0.70, -0.10) 0.21
Amadou, C. -0.80 (-1.22, 0.38) 0.03
Beato-Vibora, P. I. -0.56 (-0.70, -0.41) 0.88
Bisio, A. -0.60 (-1.05, -0.15) 0.09
Bisio, A. -0.30 (-0.58, -0.02) 0.24
Brown, S. A. -0.45 (-0.62, -0.29) 0.68
Carlson, A. L. -0.50 (-0.58, -0.42) 2.91
Carlson, A. L. -0.82 (-1.08, -0.57) 0.29
Criego, A. B. -0.40 (-0.47, -0.33) 3.80
Davis, G. M. -1.30 (-1.53, -1.07) 0.35
Delgado, A. M. -0.33 (-0.44, -0.22) 1.54
DeSalvo, D. J. -0.40 (-0.54, -0.26) 0.95
Forlenza, G. P. -0.40 (-0.49, -0.30) 2.06
Forlenza, G. P. -0.50 (-0.66, -0.33) 0.68
Garg, S. K. -0.53 (-0.62, -0.43) 2.06
Gianini, A. -0.81 (-1.25, -0.37) 0.10
Marks, B. E. -2.10 (-3.10, -1.10) 0.02
Messer, L. H. -0.75 (-1.08, -0.42) 0.17
Michaels, V. R. -2.50 (-3.57, -1.50) 0.02
Petrovski, G. -2.10 (-2.52, -1.68) 0.11
I-V Overall (I-squared = 97.9%, p = 0.000) -0.55 (-0.57, -0.54) 100.00
D+L Overall -0.65 (-0.75, -0.54)
-3.57
0
3.57

Supplemental figure 3

Leave-one-out sensitivity analyses for randomized clinical trials.

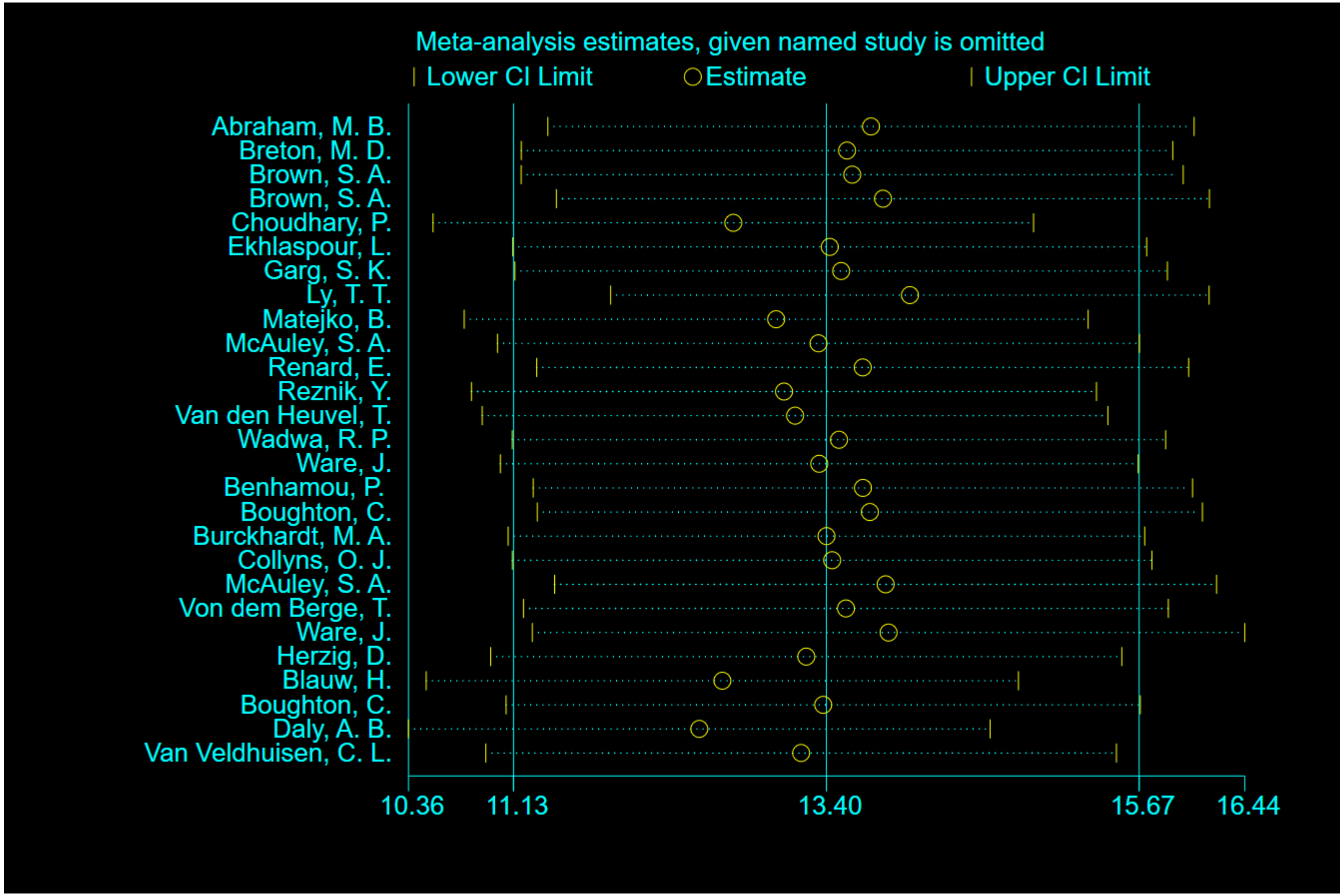
Supplemental figure 3a

Leave-one-out sensitivity analysis for glycated hemoglobin.



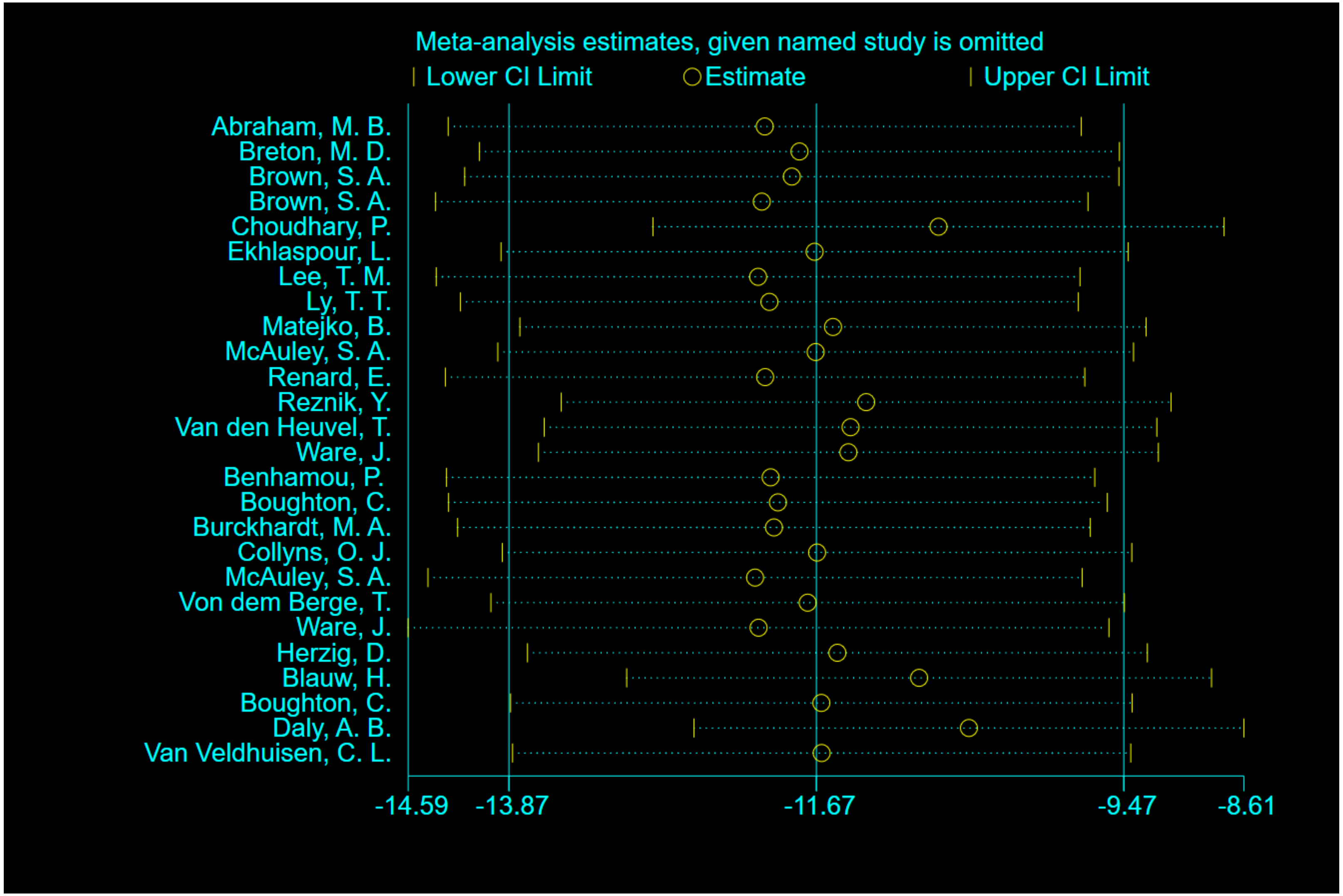
Supplemental figure 3b

Leave-one-out sensitivity analysis for time with sensor values in target range (%).



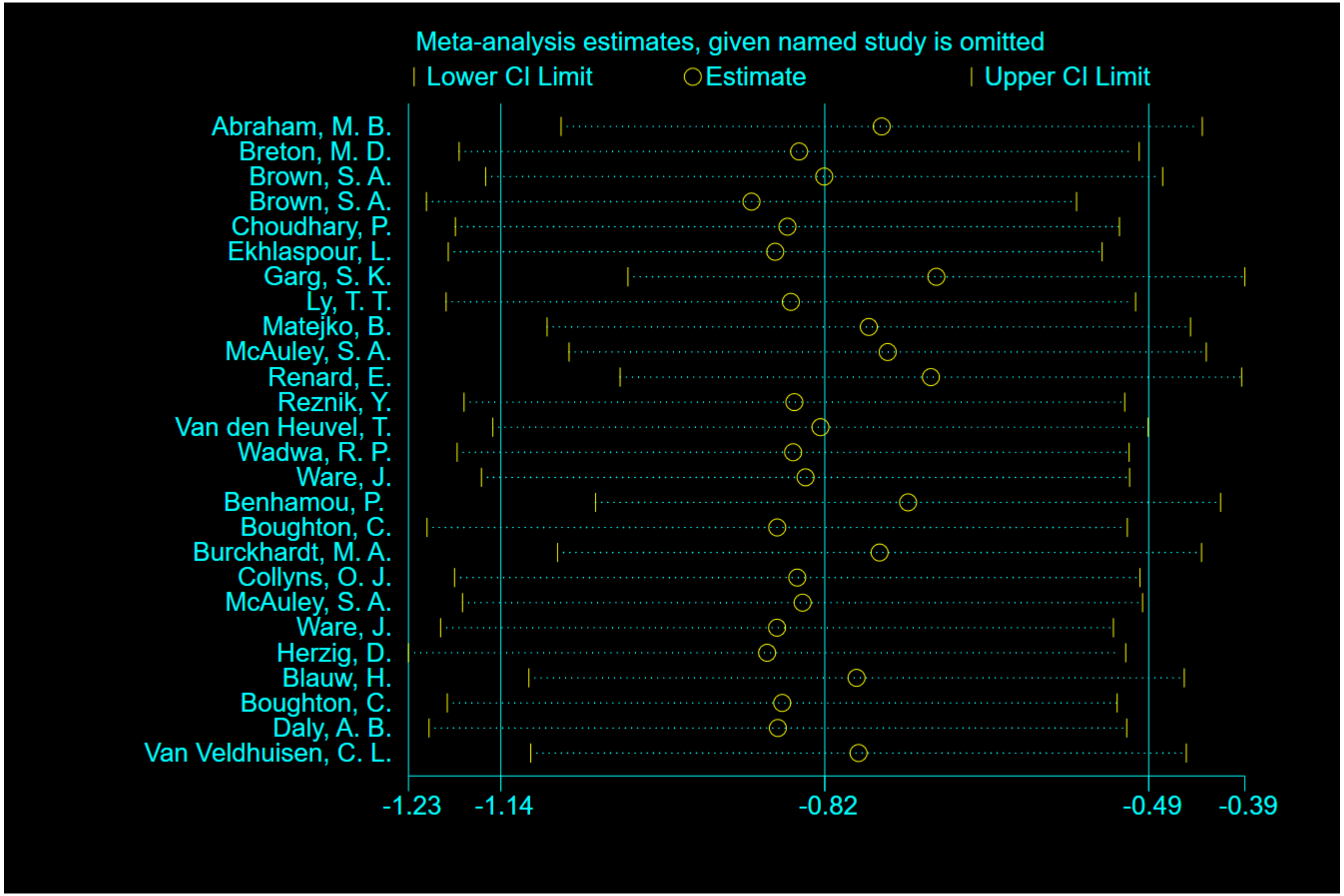
Supplemental figure 3c

Leave-one-out sensitivity analysis for time with sensor values above target range (%).



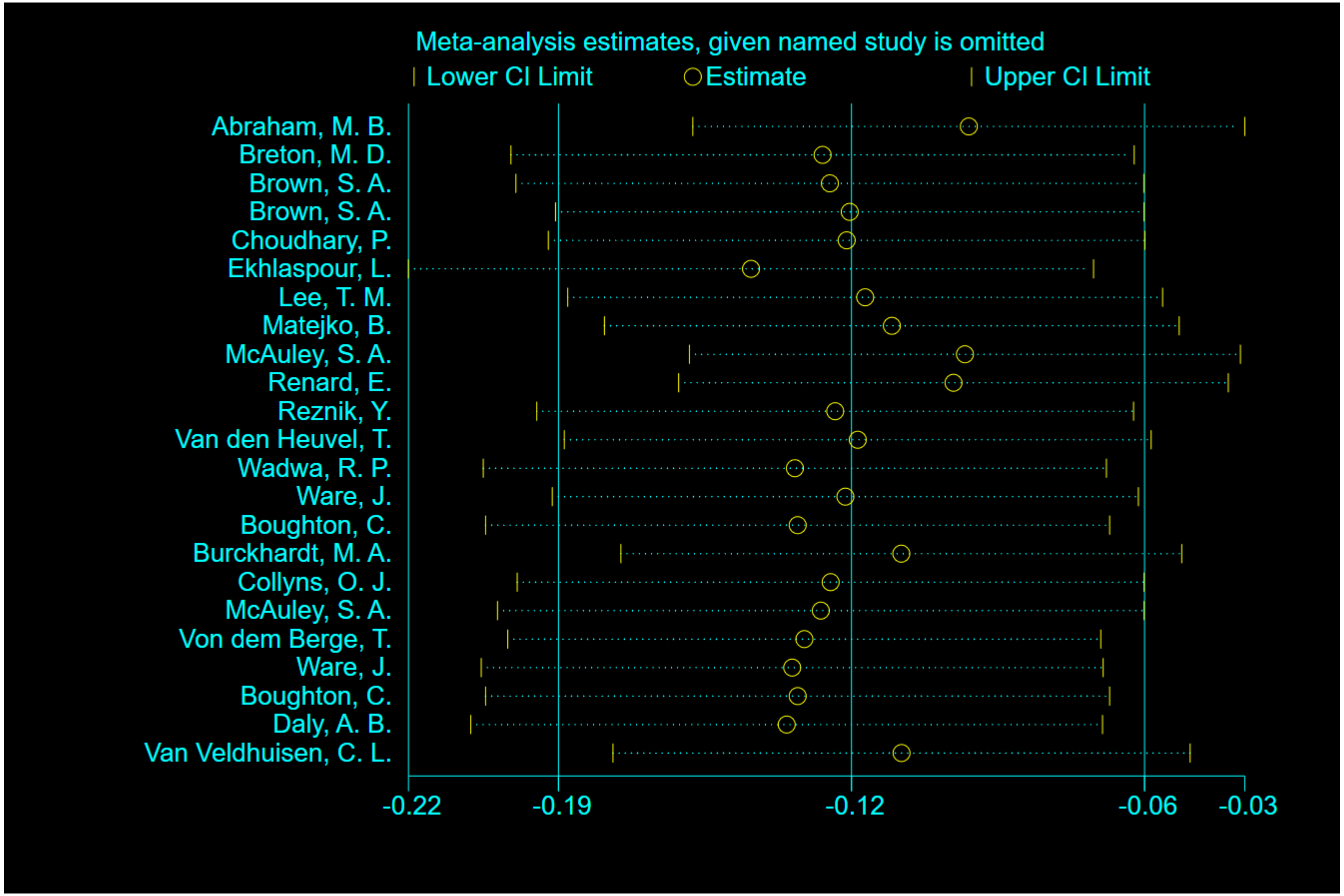
Supplemental figure 3d

Leave-one-out sensitivity analysis for time with sensor values below target range (%).



Supplemental figure 3e

Leave-one-out sensitivity analysis for time with sensor values below 3 mmol/l (%).

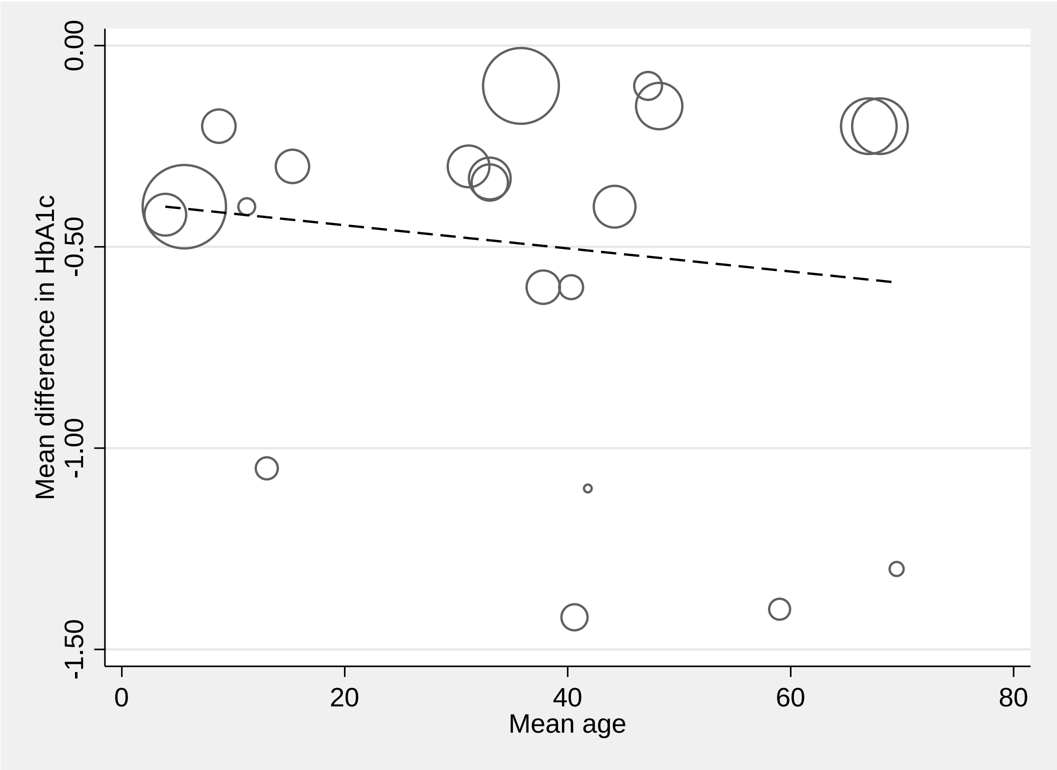


Supplemental figure 4

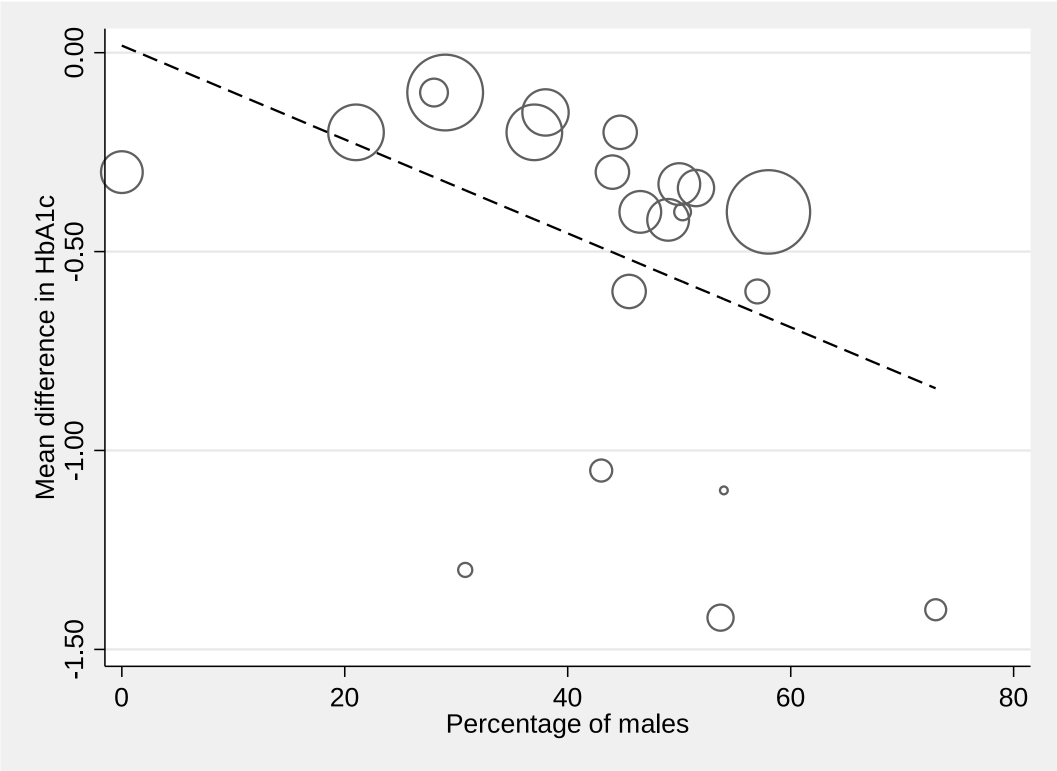
Bubble plot of study characteristics against effect estimates

Supplemental figure 4a

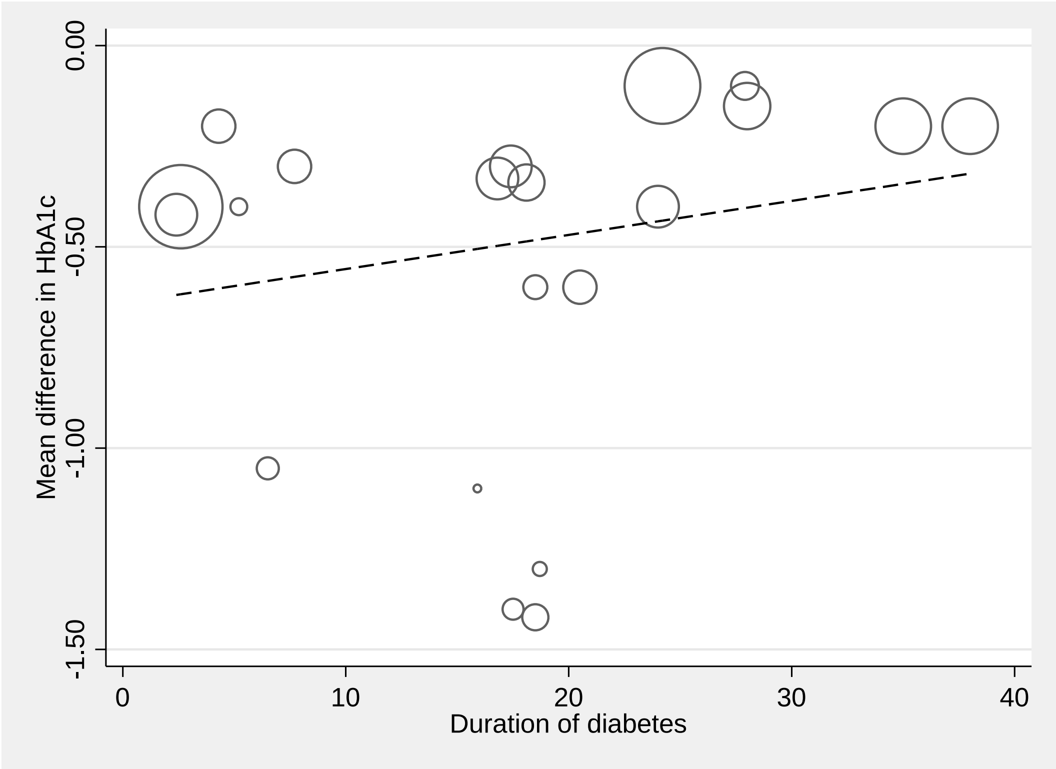
Difference in glycated hemoglobin (HbA1c) (%) by mean age



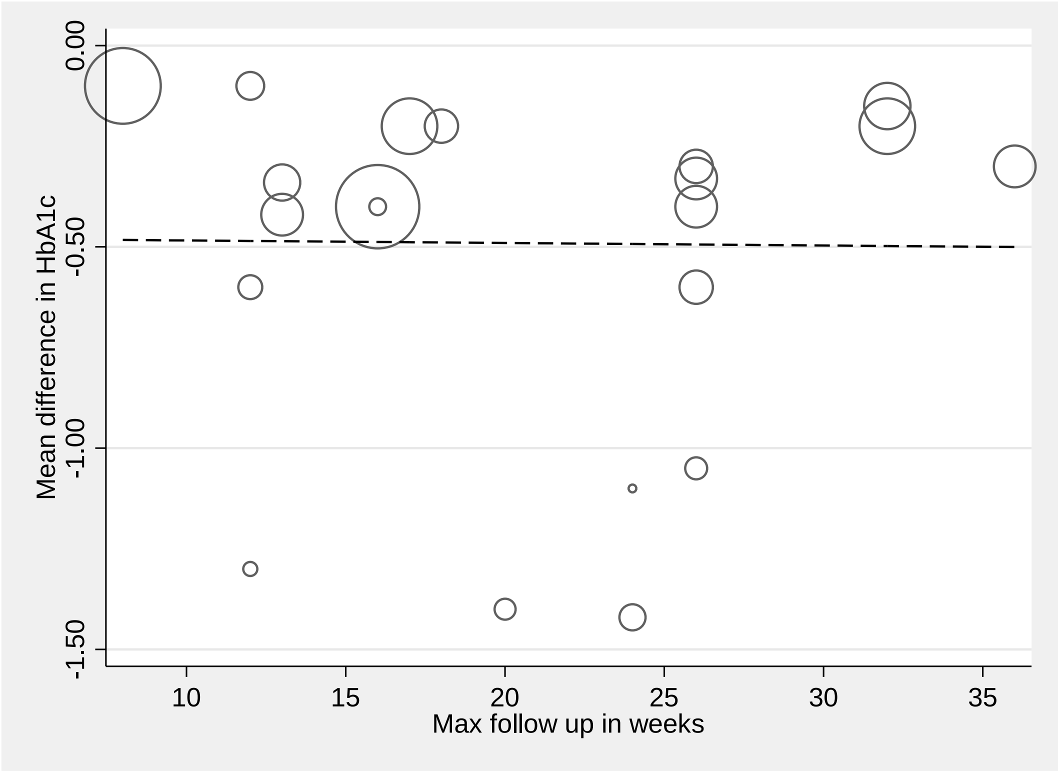
Difference in glycated hemoglobin (HbA1c) (%) by percentage of males



Difference in glycated hemoglobin (HbA1c) (%) by diabetes duration

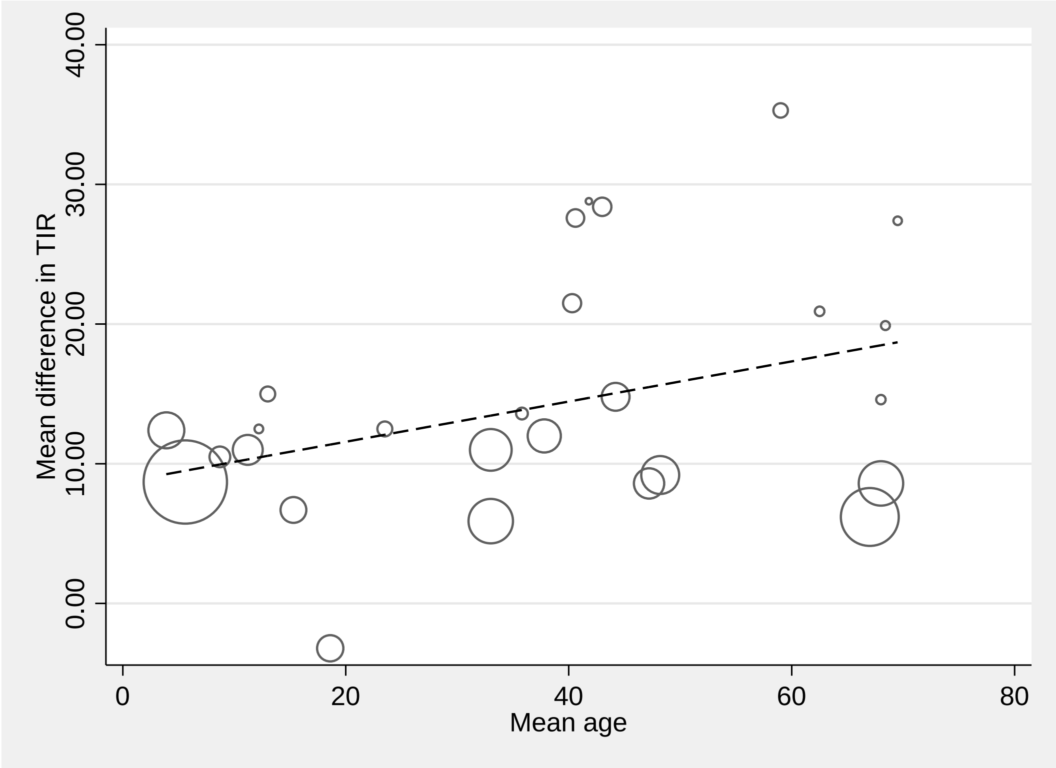


Difference in glycated hemoglobin (HbA1c) (%) by maximum follow-up (in weeks)

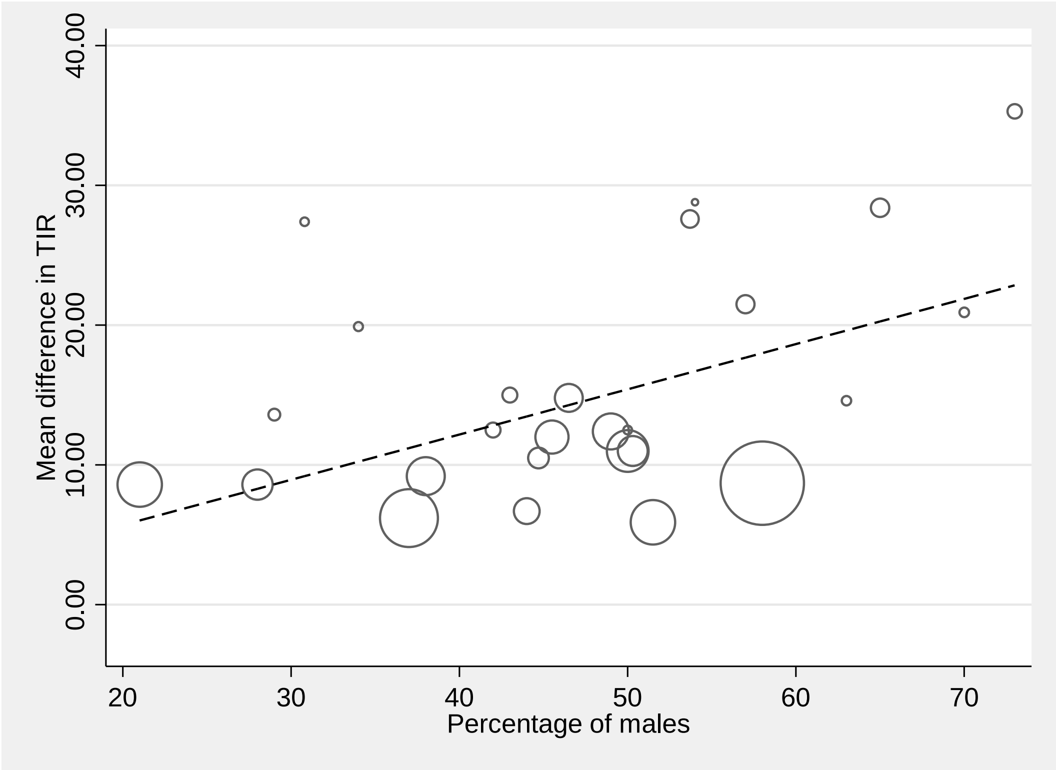


Supplemental figure 4b

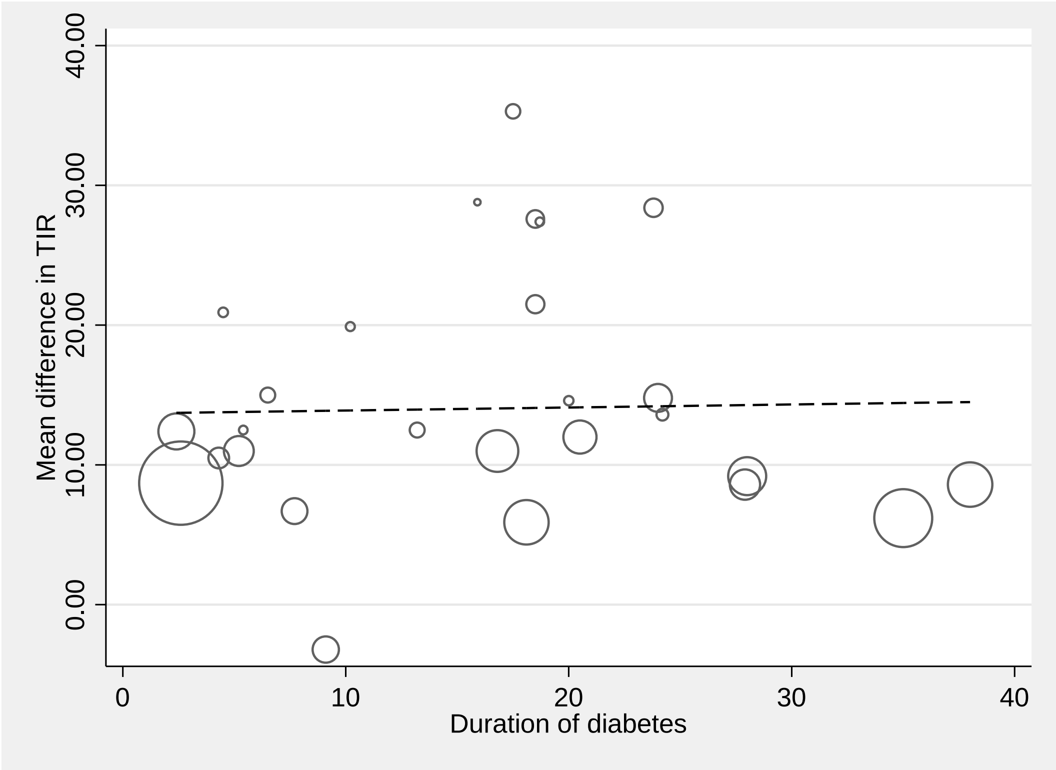
Difference in time with sensor values in target range (TIR) (%) by mean age



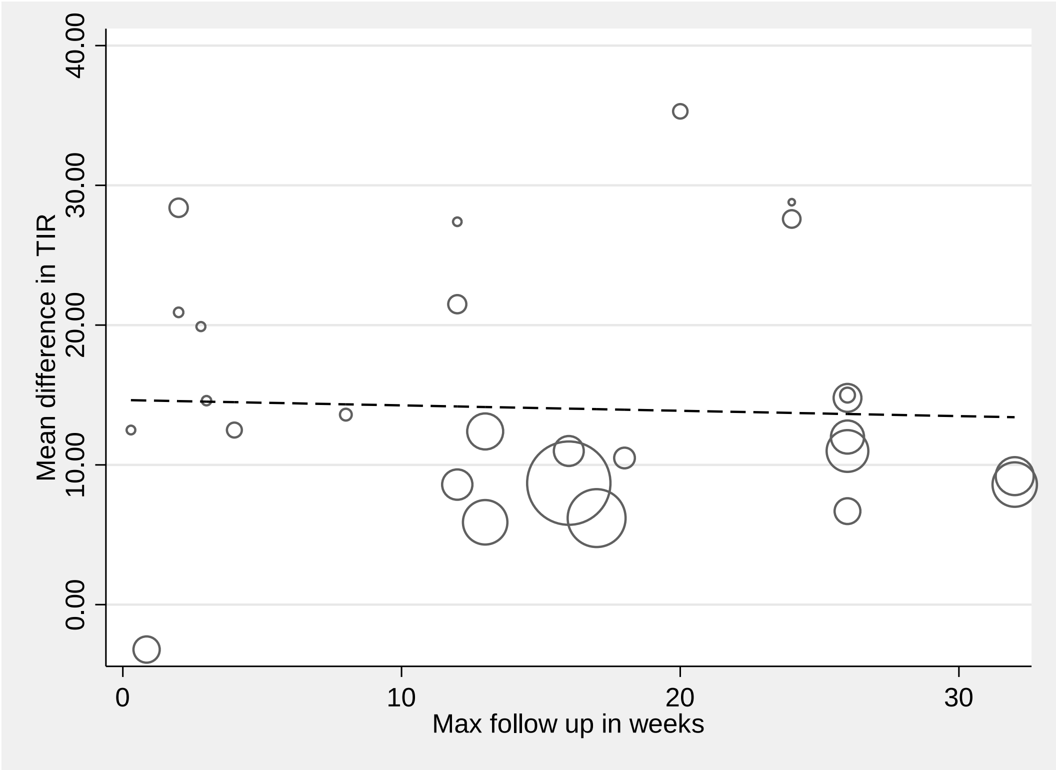
Difference in time with sensor values in target range (TIR) (%) by percentage of males



Difference in time with sensor values in target range (TIR) (%) by diabetes duration

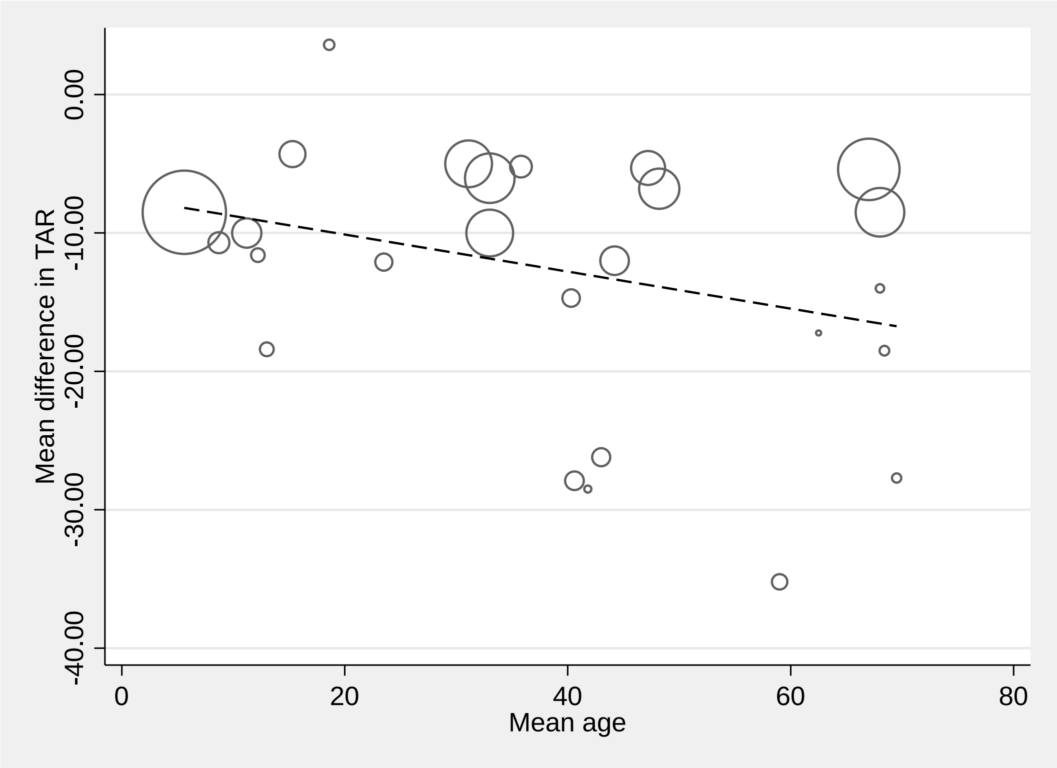


Difference in time with sensor values in target range (TIR) (%) by maximum follow-up (in weeks)

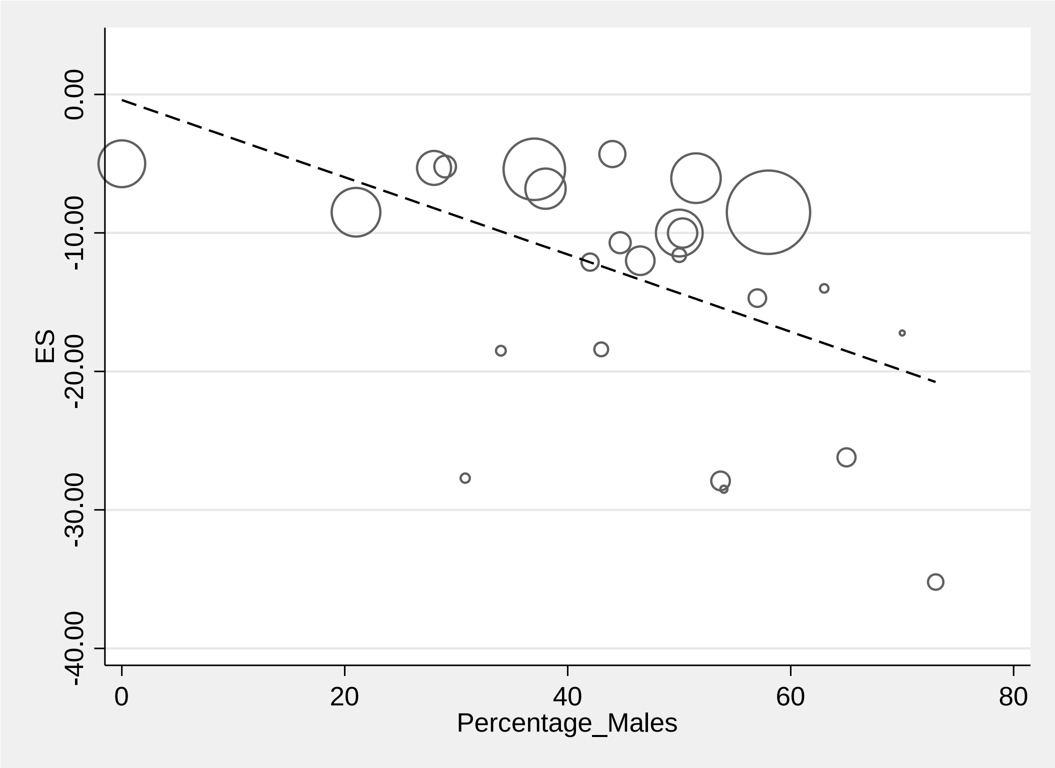


Supplemental figure 4c

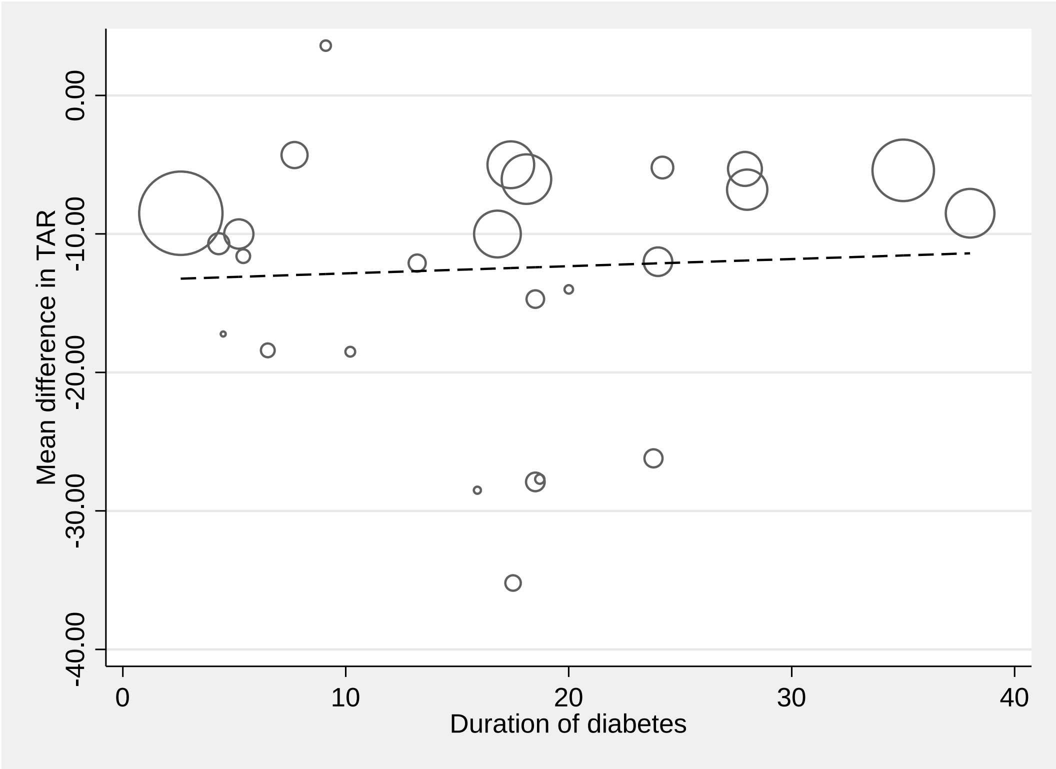
Difference in time with sensor values above target range (TAR) (%) by mean age



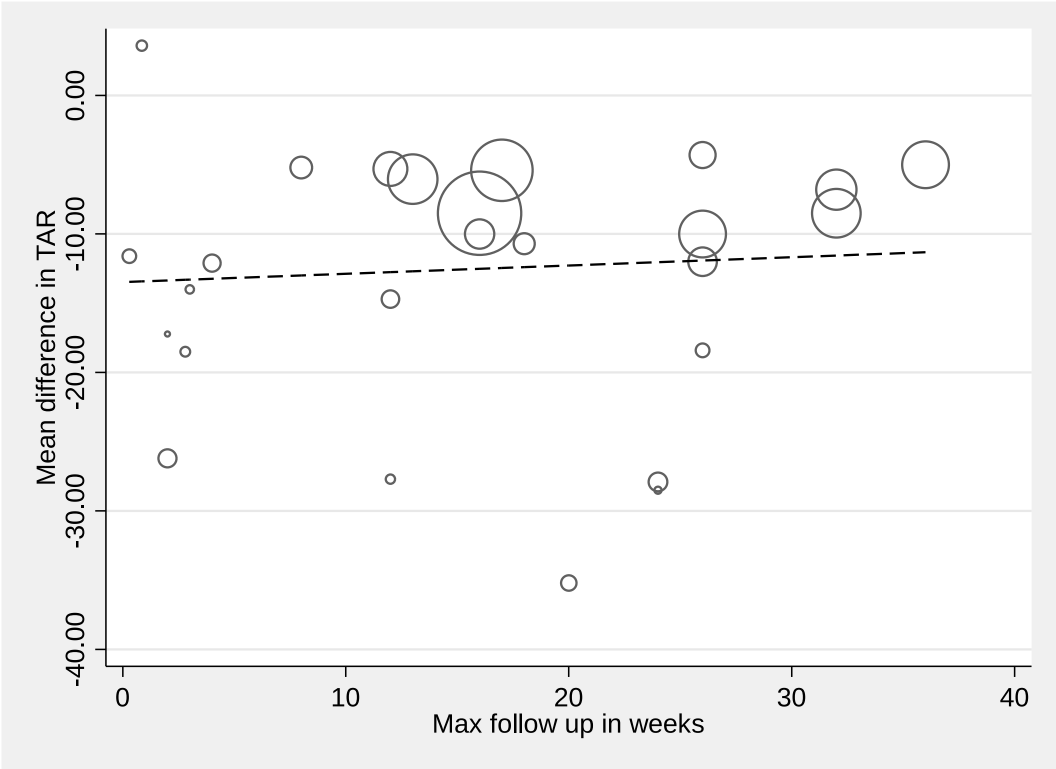
Difference in time with sensor values above target range (TAR) (%) by percentage of males



Difference in time with sensor values above target range (TAR) (%) by diabetes duration

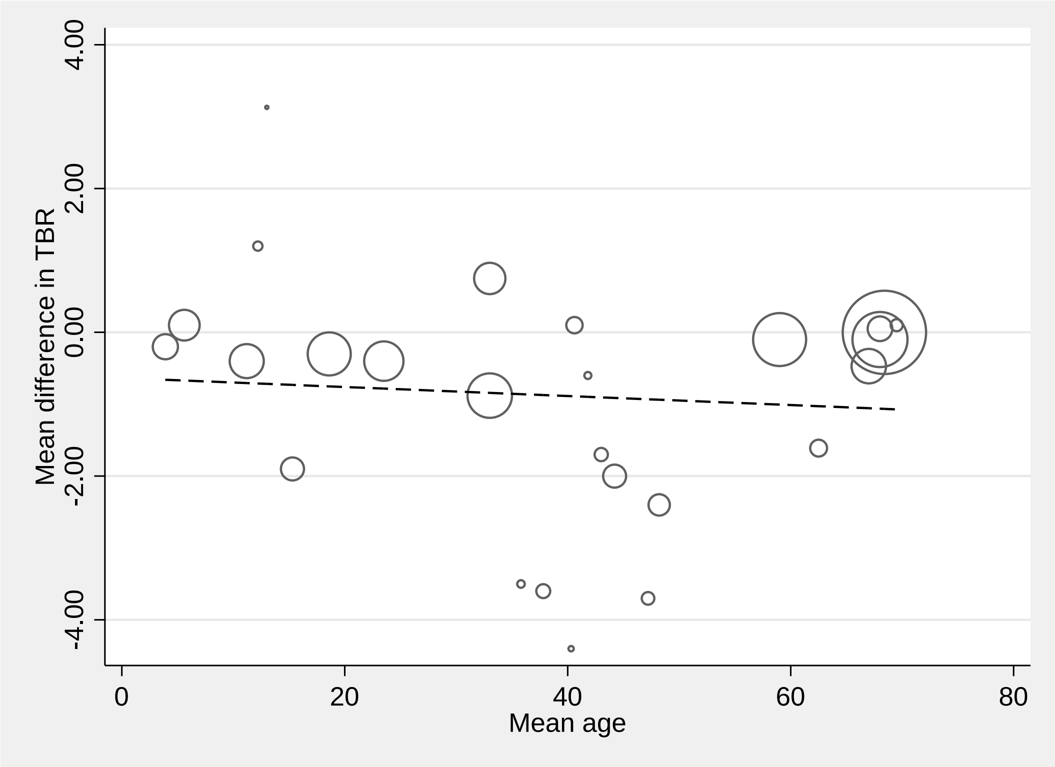


Difference in time with sensor values above target range (TAR) (%) by maximum follow-up (in weeks)

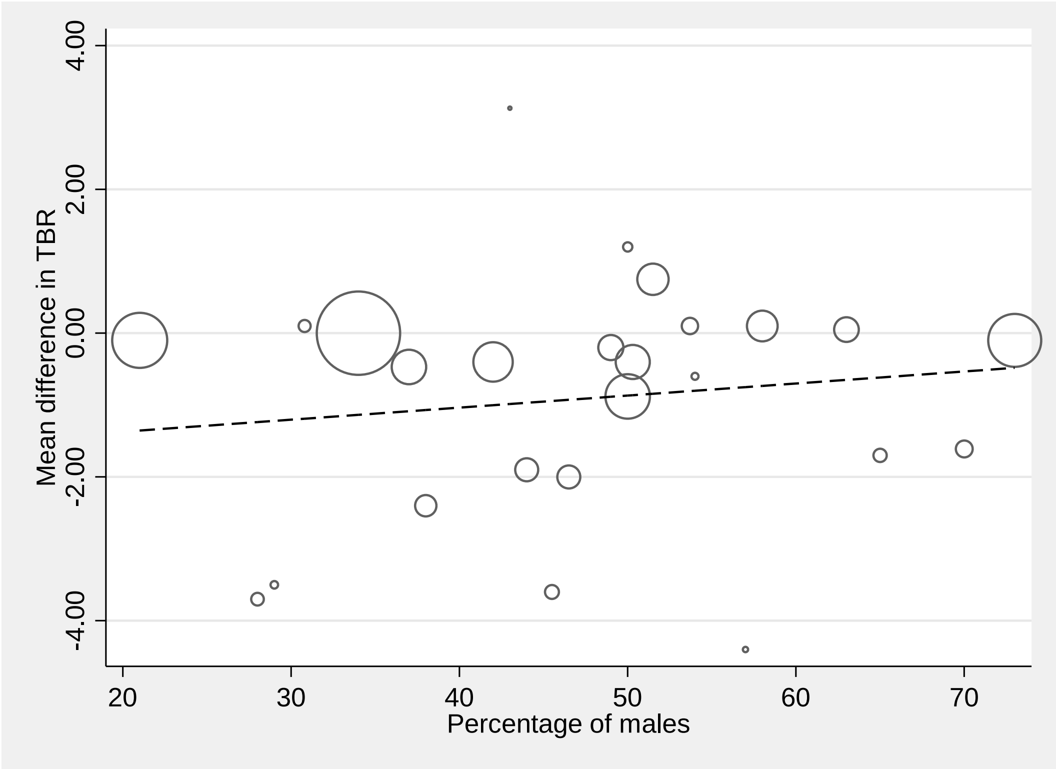


Supplemental figure 4d

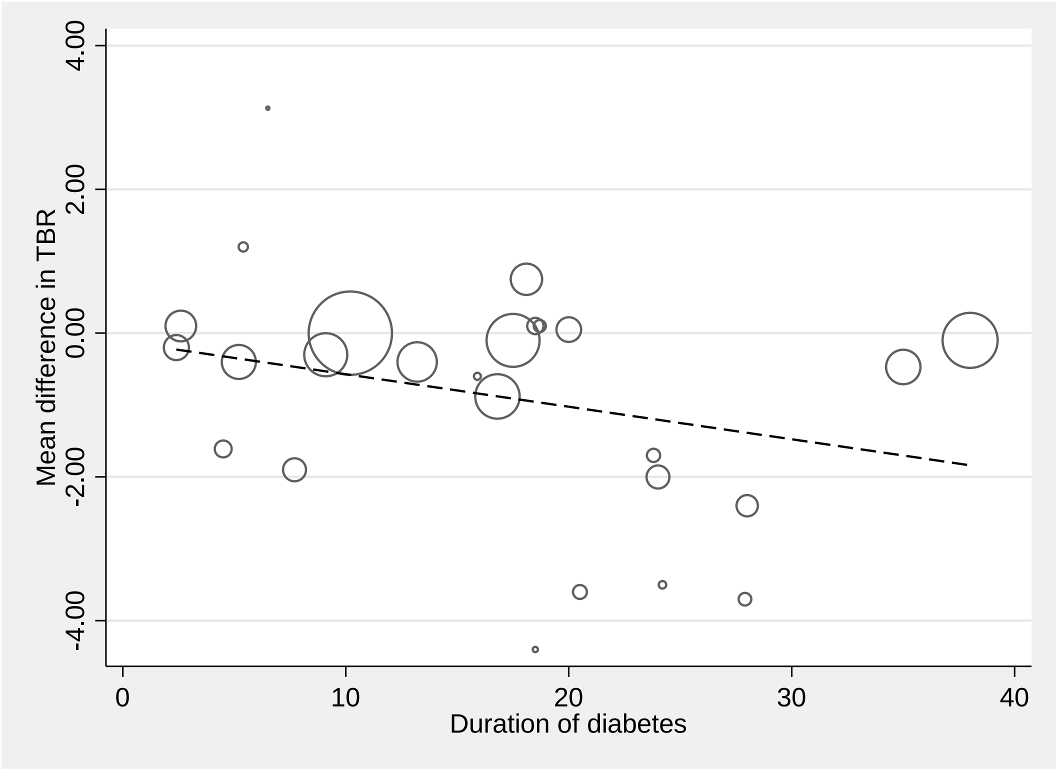
Difference in time with sensor values below target range (TBR) (%) by mean age



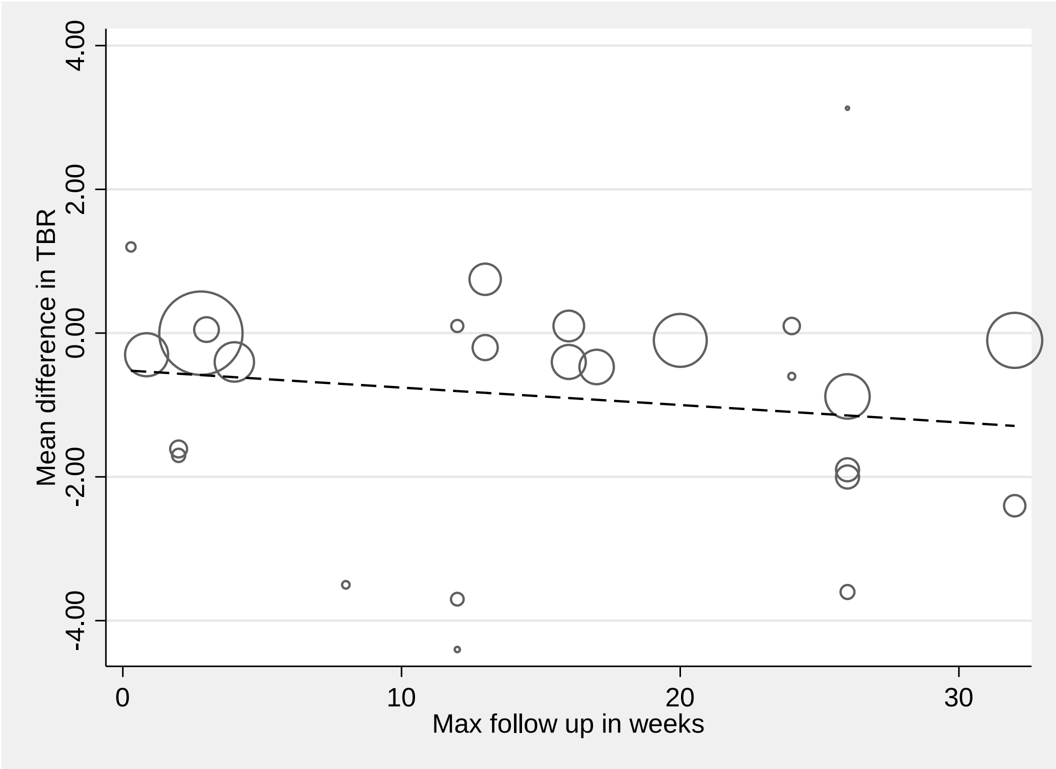
Difference in time with sensor values below target range (TBR) (%) by percentage of males



Difference in time with sensor values below target range (TBR) (%) by diabetes duration

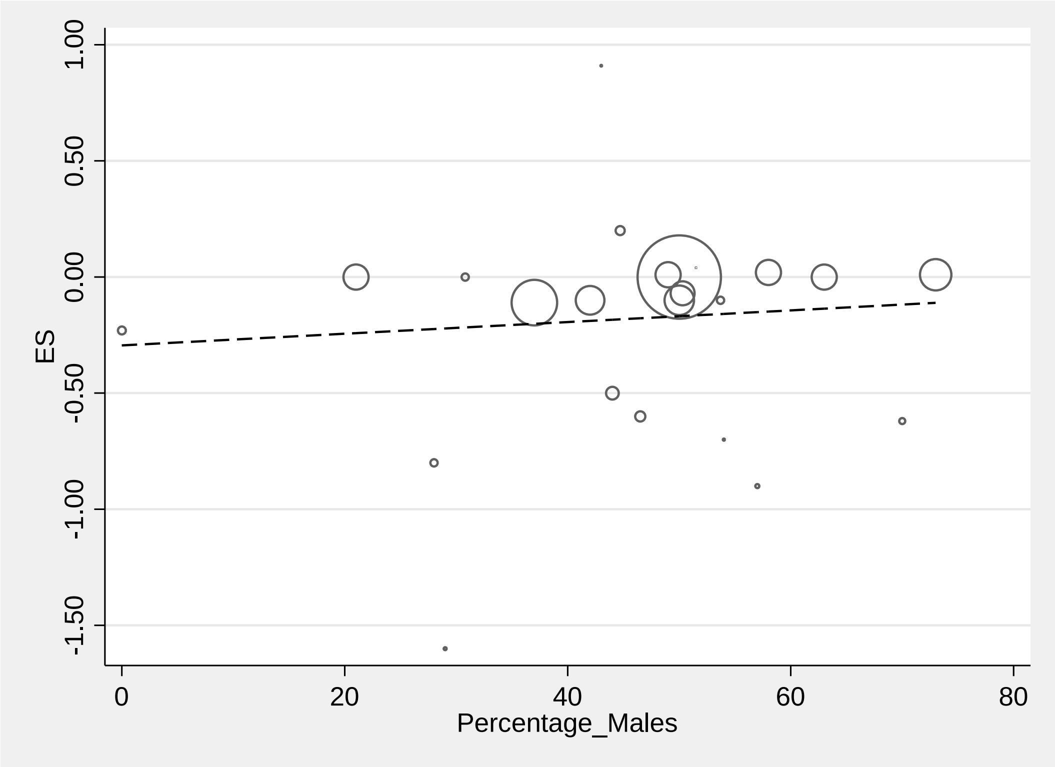


Difference in in time with sensor values below target range (TBR) (%) by maximum follow-up (in weeks)

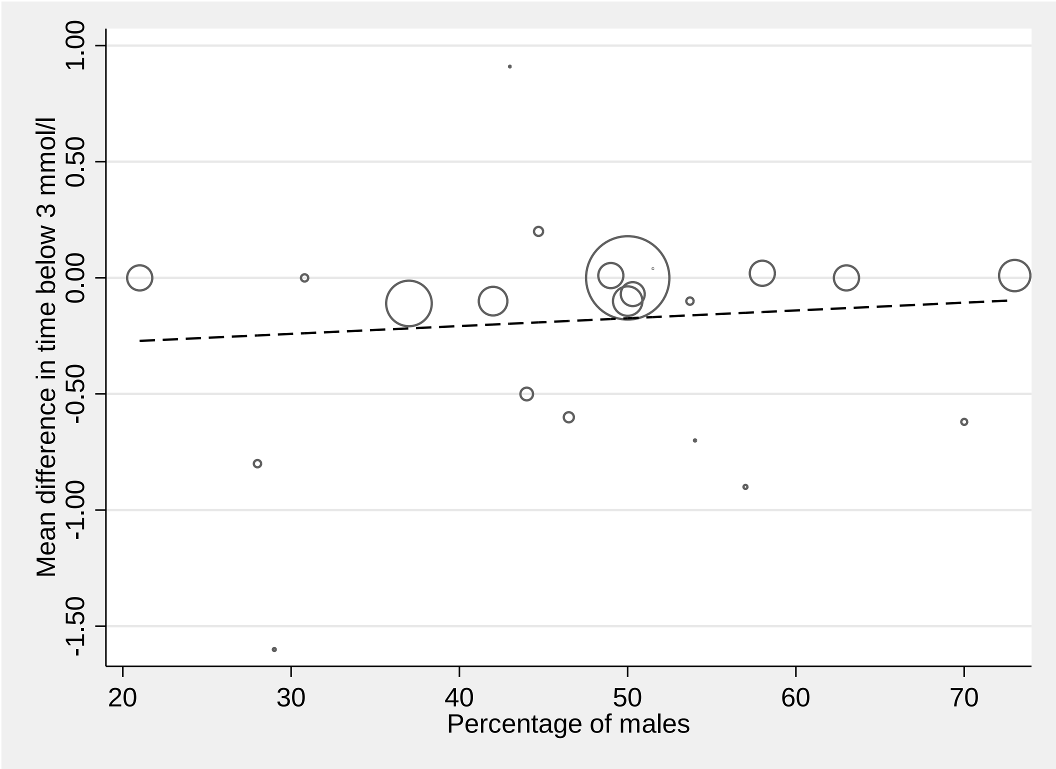


Supplemental figure 4e

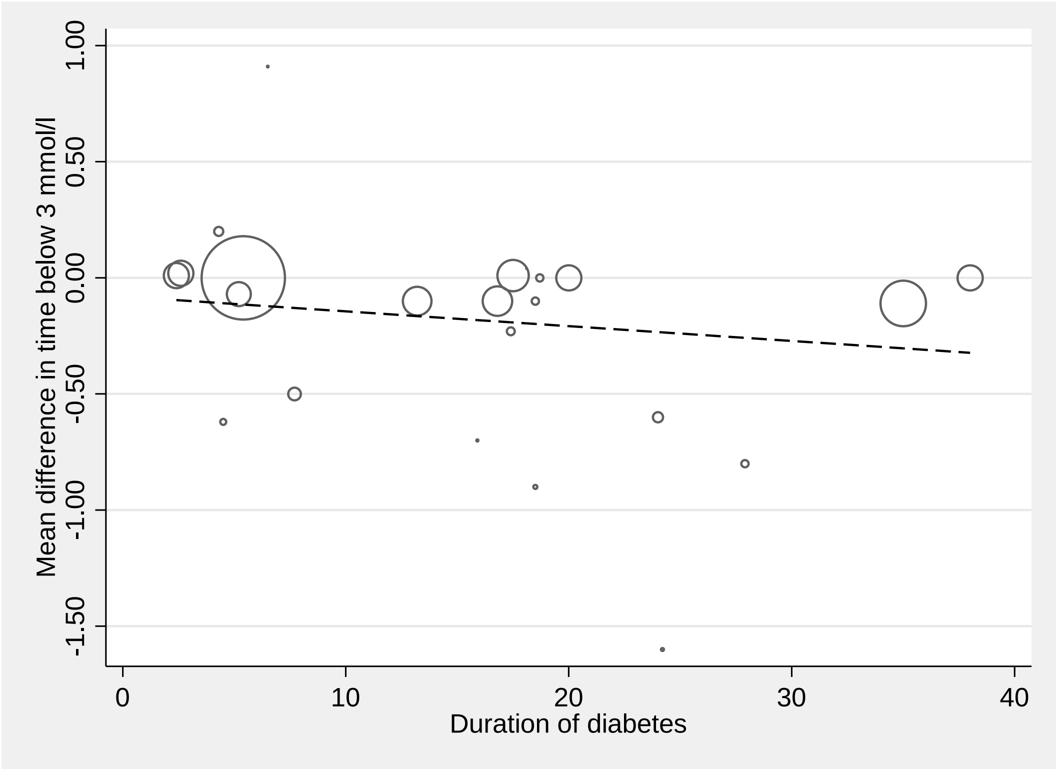
Difference in time with sensor values below 3 mmol/l (%) by mean age



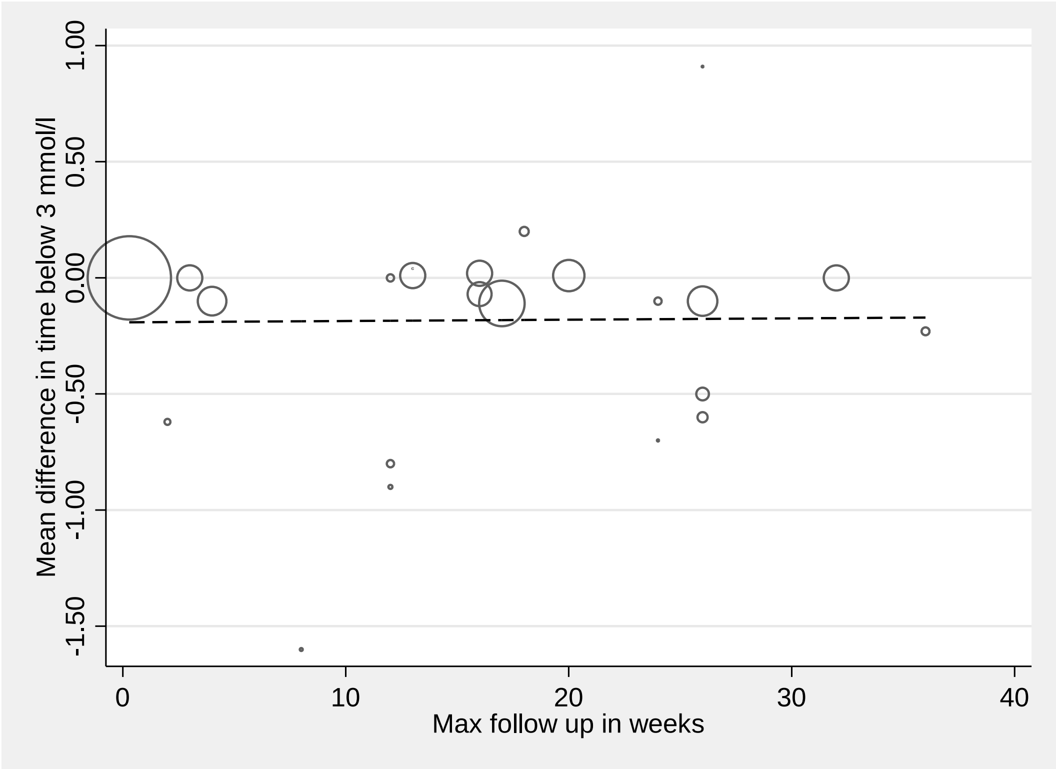
Difference in time with sensor values below 3 mmol/l (%) by percentage of males



Difference in time with sensor values below 3 mmol/l (%) by diabetes duration



Difference in in time with sensor values below 3 mmol/l (%) by maximum follow-up (in weeks)

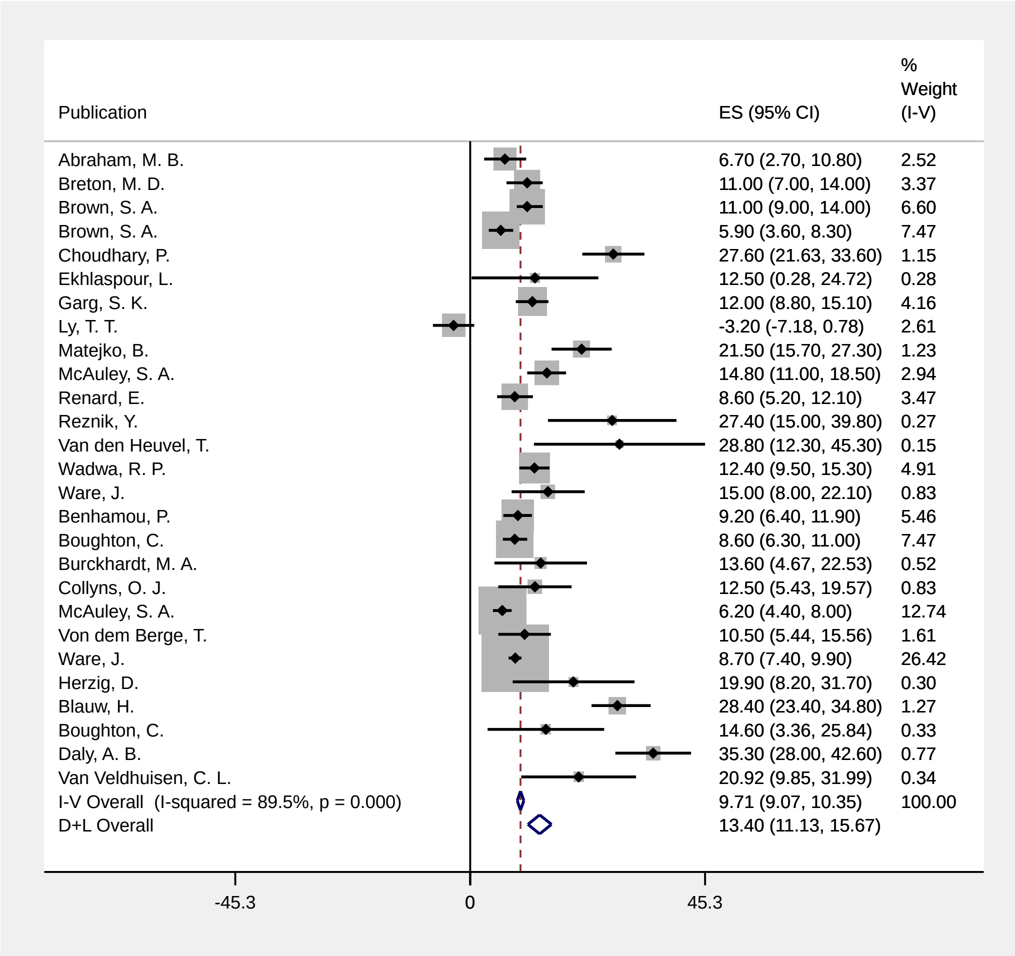


Supplemental figure 5

Meta-analysis on AID systems and TIR (%). Abbreviations: AID, automated insulin delivery; ES (95% CI), mean difference (95% confidence interval); TIR, time with sensor values in target range.

Supplemental figure 5a

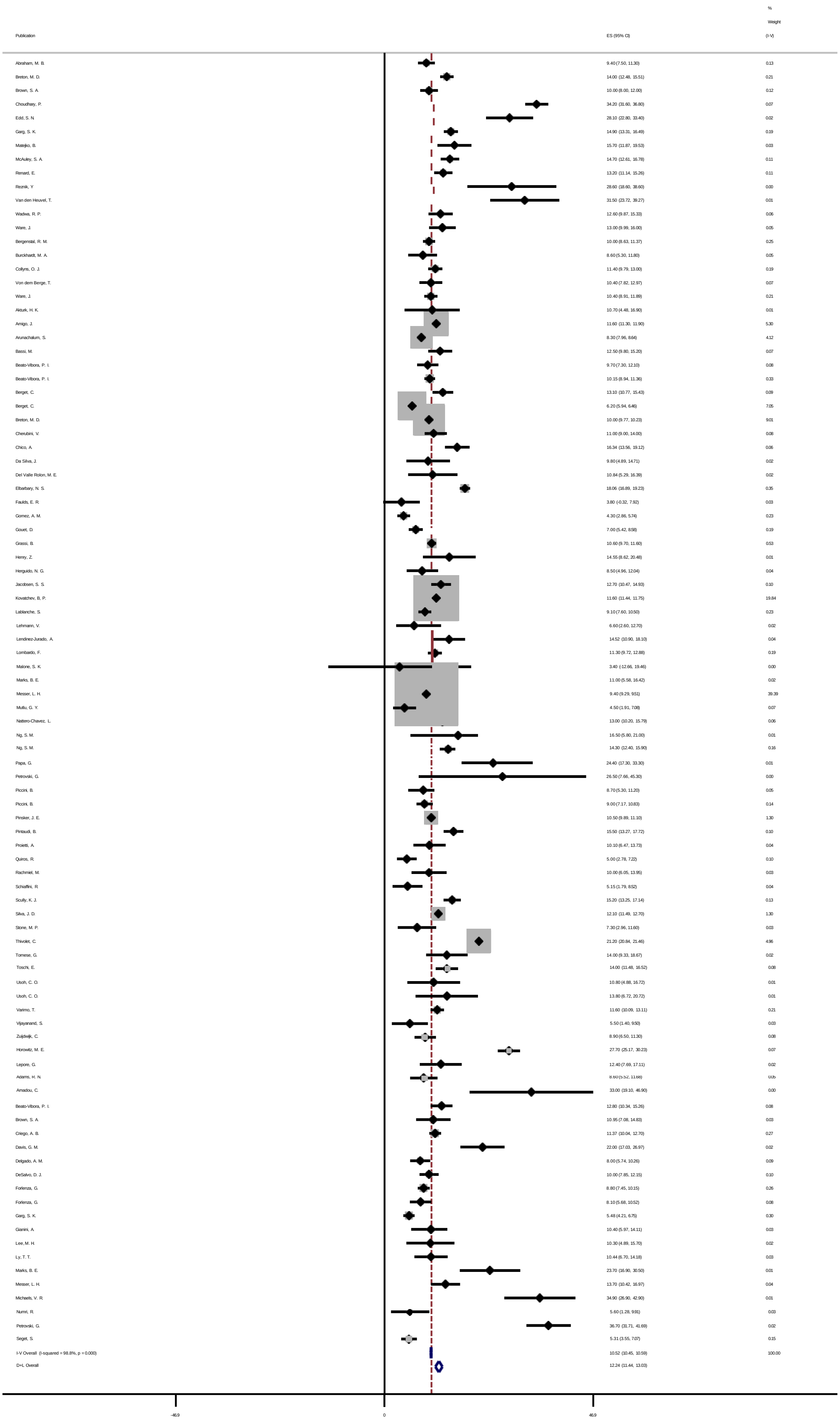
Randomized clinical trials. Randomized clinical trials evaluating the impact of AID systems on time in range percentage. The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices. Additional note. Two studies, by Ekhlaspour et al [PMID 31099946] and Forlenza et al [PMID 30888835] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Ekhlaspour et al [PMID 31099946] because it included a larger number of participants. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants.



Supplemental figure 5b

Studies of any design. Studies of any design comparing time in range percentages before (Reference) vs after utilization of AID systems (i.e., pre vs post intervention). Baseline treatment (before utilization of AID system) includes any other diabetes treatment methods (including standard diabetes therapy, multiple daily injection insulin therapy with/without glucose sensing-device, continuous subcutaneous insulin infusion with/without sensor augmentation with/without [predictive] low glucose suspend).

Additional note. Two studies, by Petrovski et al [PMID 33044604] and Petrovski et al [PMID 31953687] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Petrovski et al [PMID 33044604] because of the longer follow-up. Two studies, by Petrovski et al [PMID 35072781] and Petrovski et al [PMID 35351095] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the results of only one of the studies. Two studies, by Beato-Vibora et al [PMID 33784187] and Beato-Vibora et al [PMID 34329691] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Beato-Vibora et al [PMID 34329691] because of the longer follow-up. Two studies, by Lendínez-Jurado et al[PMID 37959415] and Lendínez-Jurado et al [PMID 37337407] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Lendínez-Jurado et al [PMID 37337407] because of the longer follow-up. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants. Two studies, by DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by DeSalvo et al [PMID 38277156] because of the longer follow-up. Two studies, by Boucsein et al [PMID 36689621] and Michaels et al [PMID 37823890] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Michaels et al [PMID 37823890] because of the longer follow-up.



%
Weight
Publication
ES (95% CI)
(I-V)
Abraham, M. B. 9.40 (7.50, 11.30) 0.13
Breton, M. D. 14.00 (12.48, 15.51) 0.21
Brown, S. A. 10.00 (8.00, 12.00) 0.12
Choudhary, P. 34.20 (31.60, 36.80) 0.07
Edd, S. N. 28.10 (22.80, 33.40) 0.02
Garg, S. K. 14.90 (13.31, 16.49) 0.19
Matejko, B. 15.70 (11.87, 19.53) 0.03
McAuley, S. A. 14.70 (12.61, 16.78) 0.11
Renard, E. 13.20 (11.14, 15.26) 0.11
Reznik, Y 28.60 (18.60, 38.60) 0.00
Van den Heuvel, T. 31.50 (23.72, 39.27) 0.01
Wadwa, R. P. 12.60 (9.87, 15.33) 0.06
Ware, J. 13.00 (9.99, 16.00) 0.05
Bergenstal, R. M. 10.00 (8.63, 11.37) 0.25
Burckhardt, M. A. 8.60 (5.30, 11.80) 0.05
Collyns, O. J. 11.40 (9.79, 13.00) 0.19
Von dem Berge, T. 10.40 (7.82, 12.97) 0.07
Ware, J. 10.40 (8.91, 11.89) 0.21
Akturk, H. K. 10.70 (4.48, 16.90) 0.01
Amigo, J. 11.60 (11.30, 11.90) 5.30
Arunachalum, S. 8.30 (7.96, 8.64) 4.12
Bassi, M. 12.50 (9.80, 15.20) 0.07
Beato-Vibora, P. I. 9.70 (7.30, 12.10) 0.08
Beato-Vibora, P. I. 10.15 (8.94, 11.36) 0.33
Berget, C. 13.10 (10.77, 15.43) 0.09
Berget, C. 6.20 (5.94, 6.46) 7.05
Breton, M. D. 10.00 (9.77, 10.23) 9.01
Cherubini, V. 11.00 (9.00, 14.00) 0.08
Chico, A. 16.34 (13.56, 19.12) 0.06
Da Silva, J. 9.80 (4.89, 14.71) 0.02
Del Valle Rolon, M. E. 10.84 (5.29, 16.39) 0.02
Elbarbary, N. S. 18.06 (16.89, 19.23) 0.35
Faulds, E. R. 3.80 (-0.32, 7.92) 0.03
Gomez, A. M. 4.30 (2.86, 5.74) 0.23
Gouet, D. 7.00 (5.42, 8.58) 0.19
Grassi, B. 10.60 (9.70, 11.60) 0.53
Henry, Z. 14.55 (8.62, 20.48) 0.01
Herguido, N. G. 8.50 (4.96, 12.04) 0.04
Jacobsen, S. S. 12.70 (10.47, 14.93) 0.10
Kovatchev, B, P. 11.60 (11.44, 11.75) 19.84
Lablanche, S. 9.10 (7.60, 10.50) 0.23
Lehmann, V. 6.60 (2.60, 12.70) 0.02
Lendinez-Jurado, A. 14.52 (10.90, 18.10) 0.04
Lombardo, F. 11.30 (9.72, 12.88) 0.19
Malone, S. K. 3.40 (-12.66, 19.46) 0.00
Marks, B. E. 11.00 (5.58, 16.42) 0.02
Messer, L. H. 9.40 (9.29, 9.51) 39.39
Mutlu, G. Y. 4.50 (1.91, 7.08) 0.07
Nattero-Chavez, L. 13.00 (10.20, 15.79) 0.06
Ng, S. M. 16.50 (5.80, 21.00) 0.01
Ng, S. M. 14.30 (12.40, 15.90) 0.16
Papa, G. 24.40 (17.30, 33.30) 0.01
Petrovski, G. 26.50 (7.66, 45.30) 0.00
Piccini, B. 8.70 (5.30, 11.20) 0.05
Piccini, B. 9.00 (7.17, 10.83) 0.14
Pinsker, J. E. 10.50 (9.89, 11.10) 1.30
Pintaudi, B. 15.50 (13.27, 17.72) 0.10
Proietti, A. 10.10 (6.47, 13.73) 0.04
Quiros, R. 5.00 (2.78, 7.22) 0.10
Rachmiel, M. 10.00 (6.05, 13.95) 0.03
Schiaffini, R. 5.15 (1.79, 8.52) 0.04
Scully, K. J. 15.20 (13.25, 17.14) 0.13
Silva, J. D. 12.10 (11.49, 12.70) 1.30
Stone, M. P. 7.30 (2.96, 11.60) 0.03
Thivolet, C. 21.20 (20.84, 21.46) 4.96
Tornese, G. 14.00 (9.33, 18.67) 0.02
Toschi, E. 14.00 (11.48, 16.52) 0.08
Usoh, C. O. 10.80 (4.88, 16.72) 0.01
Usoh, C. O. 13.80 (6.72, 20.72) 0.01
Varimo, T. 11.60 (10.09, 13.11) 0.21
Vijayanand, S. 5.50 (1.40, 9.50) 0.03
Zuijdwijk, C. 8.90 (6.50, 11.30) 0.08
Horowitz, M. E. 27.70 (25.17, 30.23) 0.07
Lepore, G. 12.40 (7.69, 17.11) 0.02
Adams, R. N. 8.60 (5.52, 11.68) 0.05
Amadou, C. 33.00 (19.10, 46.90) 0.00
Beato-Vibora, P. I. 12.80 (10.34, 15.26) 0.08
Brown, S. A. 10.95 (7.08, 14.83) 0.03
Criego, A. B. 11.37 (10.04, 12.70) 0.27
Davis, G. M. 22.00 (17.03, 26.97) 0.02
Delgado, A. M. 8.00 (5.74, 10.26) 0.09
DeSalvo, D. J. 10.00 (7.85, 12.15) 0.10
Forlenza, G. 8.80 (7.45, 10.15) 0.26
Forlenza, G. 8.10 (5.68, 10.52) 0.08
Garg, S. K. 5.48 (4.21, 6.75) 0.30
Gianini, A. 10.40 (5.97, 14.11) 0.03
Lee, M. H. 10.30 (4.89, 15.70) 0.02
Ly, T. T. 10.44 (6.70, 14.18) 0.03
Marks, B. E. 23.70 (16.90, 30.50) 0.01
Messer, L. H. 13.70 (10.42, 16.97) 0.04
Michaels, V. R. 34.90 (26.90, 42.90) 0.01
Numri, R. 5.60 (1.28, 9.91) 0.03
Petrovski, G. 36.70 (31.71, 41.69) 0.02
Seget, S. 5.31 (3.55, 7.07) 0.15
I-V Overall (I-squared = 98.8%, p = 0.000) 10.52 (10.45, 10.59) 100.00
D+L Overall 12.24 (11.44, 13.03)
-46.9
0
46.9

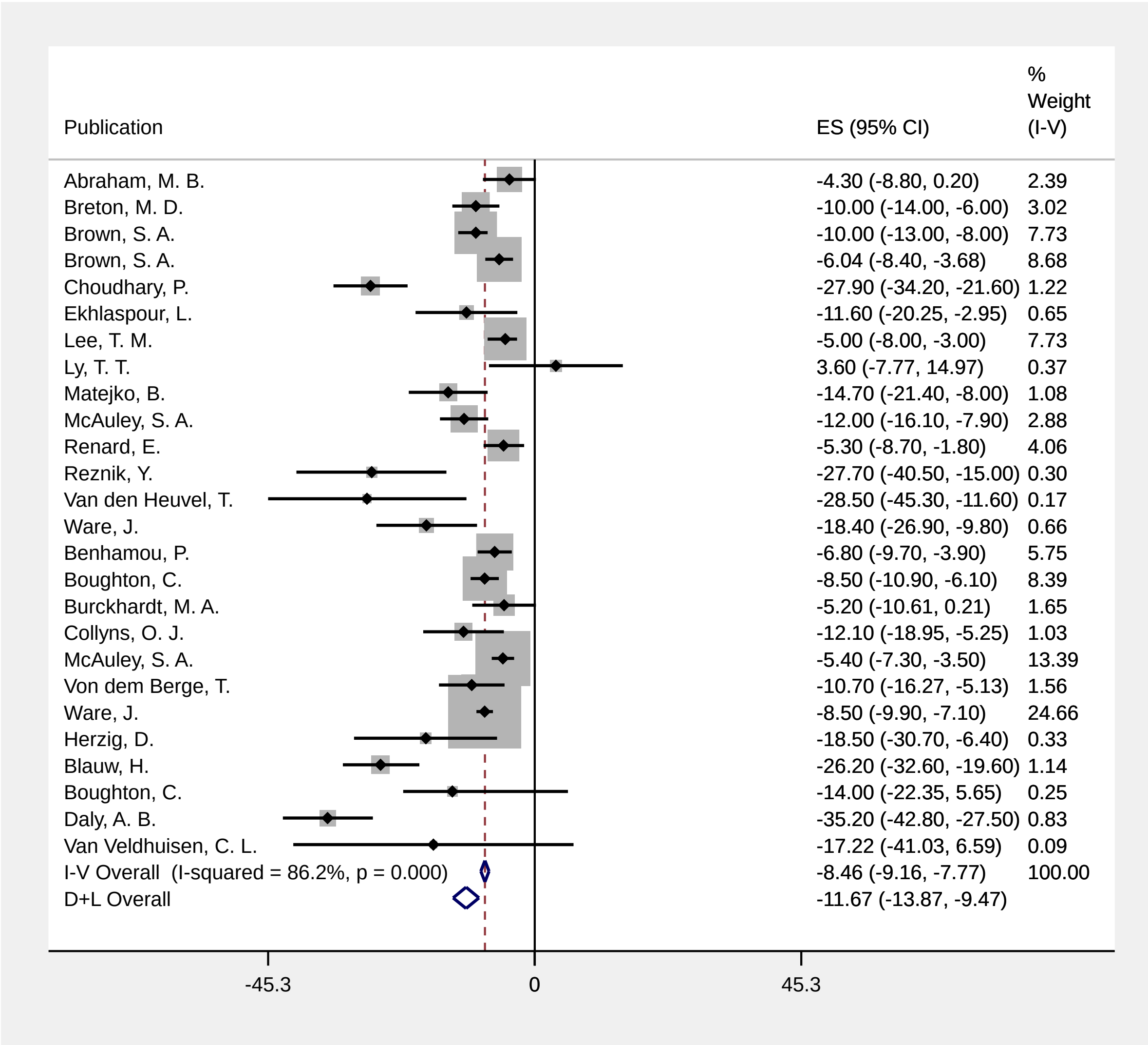
Supplemental figure 6

Meta-analysis on AID systems and TAR (%). Abbreviations: AID, automated insulin delivery; ES (95% CI), mean difference (95% confidence interval); TAR, time with sensor values above target range.

Supplemental figure 6a

Randomized clinical trials. Randomized clinical trials evaluating the impact of AID systems on time above range percentage. The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices.

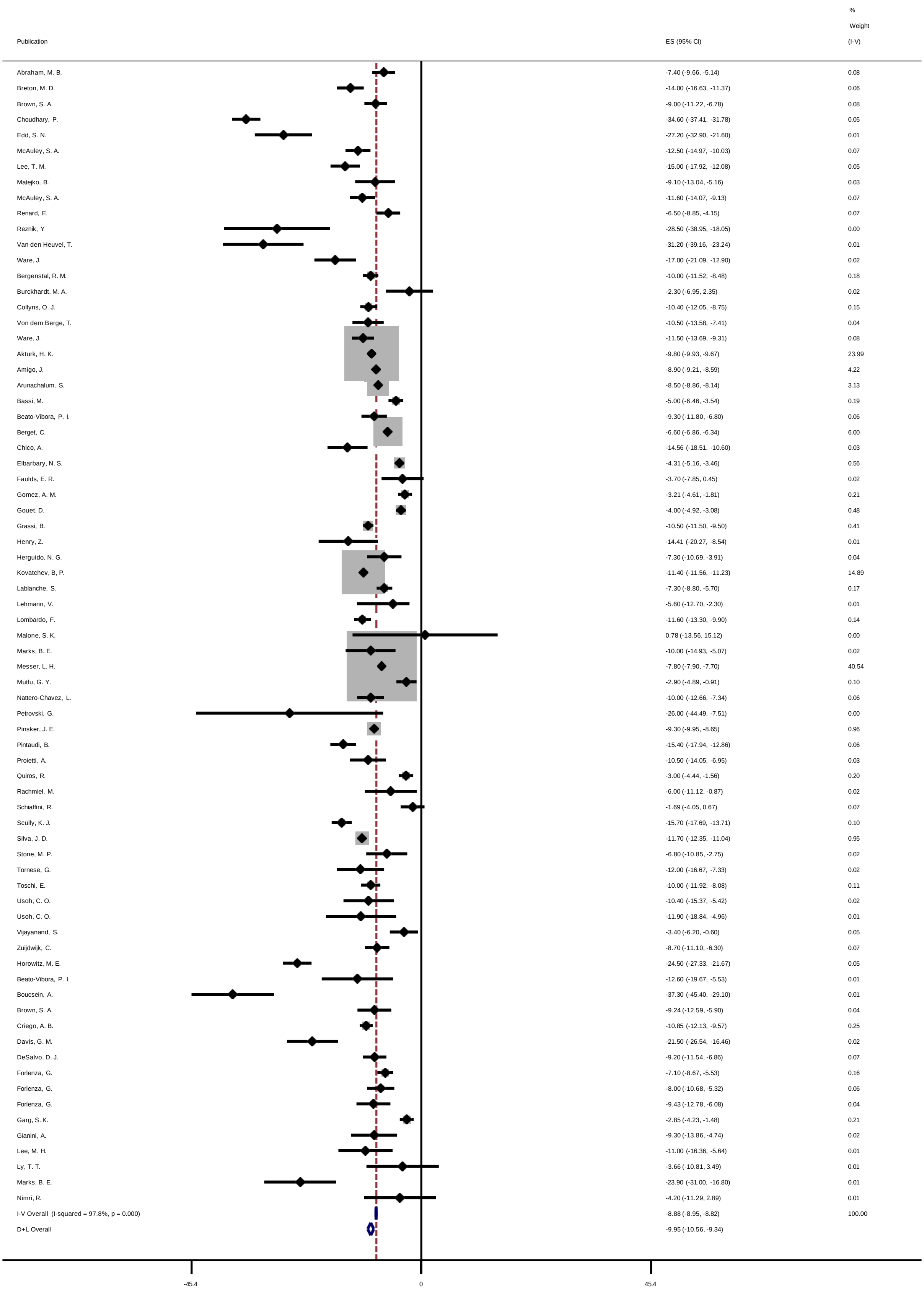
Additional note. Two studies, by Ekhlaspour et al [PMID 31099946] and Forlenza et al [PMID 30888835] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Ekhlaspour et al PMID 31099946] because it included a larger number of participants. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants.



Supplemental figure 6b

Studies of any design. Studies of any design comparing time above range percentages before (Reference) vs after utilization of AID systems (i.e., pre vs post intervention). Baseline treatment (before utilization of AID system) includes any other diabetes treatment methods (including standard diabetes therapy, multiple daily injection insulin therapy with/without glucose sensing-device, continuous subcutaneous insulin infusion with/without sensor augmentation with/without [predictive] low glucose suspend).

Additional note. Two studies, by Beato-Vibora et al [PMID 33784187] and Beato-Vibora et al [PMID 34329691] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Beato-Vibora et al [PMID 34329691] because of the longer follow-up. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants. Two studies, by DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by DeSalvo et al [PMID 38277156] because of the longer follow-up.


Publication
ES (95% CI)
%
Weight
(I-V)
Abraham, M. B. -7.40 (-9.66, -5.14) 0.08
Breton, M. D. -14.00 (-16.63, -11.37) 0.06
Brown, S. A. -9.00 (-11.22, -6.78) 0.08
Choudhary, P. -34.60 (-37.41, -31.78) 0.05
Edd, S. N. -27.20 (-32.90, -21.60) 0.01
McAuley, S. A. -12.50 (-14.97, -10.03) 0.07
Lee, T. M. -15.00 (-17.92, -12.08) 0.05
Matejko, B. -9.10 (-13.04, -5.16) 0.03
McAuley, S. A. -11.60 (-14.07, -9.13) 0.07
Renard, E. -6.50 (-8.85, -4.15) 0.07
Reznik, Y -28.50 (-38.95, -18.05) 0.00
Van den Heuvel, T. -31.20 (-39.16, -23.24) 0.01
Ware, J. -17.00 (-21.09, -12.90) 0.02
Bergenstal, R. M. -10.00 (-11.52, -8.48) 0.18
Burckhardt, M. A. -2.30 (-6.95, 2.35) 0.02
Collyns, O. J. -10.40 (-12.05, -8.75) 0.15
Von dem Berge, T. -10.50 (-13.58, -7.41) 0.04
Ware, J. -11.50 (-13.69, -9.31) 0.08
Akturk, H. K. -9.80 (-9.93, -9.67) 23.99
Amigo, J. -8.90 (-9.21, -8.59) 4.22
Arunachalum, S. -8.50 (-8.86, -8.14) 3.13
Bassi, M. -5.00 (-6.46, -3.54) 0.19
Beato-Vibora, P. I. -9.30 (-11.80, -6.80) 0.06
Berget, C. -6.60 (-6.86, -6.34) 6.00
Chico, A. -14.56 (-18.51, -10.60) 0.03
Elbarbary, N. S. -4.31 (-5.16, -3.46) 0.56
Faulds, E. R. -3.70 (-7.85, 0.45) 0.02
Gomez, A. M. -3.21 (-4.61, -1.81) 0.21
Gouet, D. -4.00 (-4.92, -3.08) 0.48
Grassi, B. -10.50 (-11.50, -9.50) 0.41
Henry, Z. -14.41 (-20.27, -8.54) 0.01
Herguido, N. G. -7.30 (-10.69, -3.91) 0.04
Kovatchev, B, P. -11.40 (-11.56, -11.23) 14.89
Lablanche, S. -7.30 (-8.80, -5.70) 0.17
Lehmann, V. -5.60 (-12.70, -2.30) 0.01
Lombardo, F. -11.60 (-13.30, -9.90) 0.14
Malone, S. K. 0.78 (-13.56, 15.12) 0.00
Marks, B. E. -10.00 (-14.93, -5.07) 0.02
Messer, L. H. -7.80 (-7.90, -7.70) 40.54
Mutlu, G. Y. -2.90 (-4.89, -0.91) 0.10
Nattero-Chavez, L. -10.00 (-12.66, -7.34) 0.06
Petrovski, G. -26.00 (-44.49, -7.51) 0.00
Pinsker, J. E. -9.30 (-9.95, -8.65) 0.96
Pintaudi, B. -15.40 (-17.94, -12.86) 0.06
Proietti, A. -10.50 (-14.05, -6.95) 0.03
Quiros, R. -3.00 (-4.44, -1.56) 0.20
Rachmiel, M. -6.00 (-11.12, -0.87) 0.02
Schiaffini, R. -1.69 (-4.05, 0.67) 0.07
Scully, K. J. -15.70 (-17.69, -13.71) 0.10
Silva, J. D. -11.70 (-12.35, -11.04) 0.95
Stone, M. P. -6.80 (-10.85, -2.75) 0.02
Tornese, G. -12.00 (-16.67, -7.33) 0.02
Toschi, E. -10.00 (-11.92, -8.08) 0.11
Usoh, C. O. -10.40 (-15.37, -5.42) 0.02
Usoh, C. O. -11.90 (-18.84, -4.96) 0.01
Vijayanand, S. -3.40 (-6.20, -0.60) 0.05
Zuijdwijk, C. -8.70 (-11.10, -6.30) 0.07
Horowitz, M. E. -24.50 (-27.33, -21.67) 0.05
Beato-Vibora, P. I. -12.60 (-19.67, -5.53) 0.01
Boucsein, A. -37.30 (-45.40, -29.10) 0.01
Brown, S. A. -9.24 (-12.59, -5.90) 0.04
Criego, A. B. -10.85 (-12.13, -9.57) 0.25
Davis, G. M. -21.50 (-26.54, -16.46) 0.02
DeSalvo, D. J. -9.20 (-11.54, -6.86) 0.07
Forlenza, G. -7.10 (-8.67, -5.53) 0.16
Forlenza, G. -8.00 (-10.68, -5.32) 0.06
Forlenza, G. -9.43 (-12.78, -6.08) 0.04
Garg, S. K. -2.85 (-4.23, -1.48) 0.21
Gianini, A. -9.30 (-13.86, -4.74) 0.02
Lee, M. H. -11.00 (-16.36, -5.64) 0.01
Ly, T. T. -3.66 (-10.81, 3.49) 0.01
Marks, B. E. -23.90 (-31.00, -16.80) 0.01
Nimri, R. -4.20 (-11.29, 2.89) 0.01
I-V Overall (I-squared = 97.8%, p = 0.000) -8.88 (-8.95, -8.82) 100.00
D+L Overall -9.95 (-10.56, -9.34)
-45.4
0
45.4

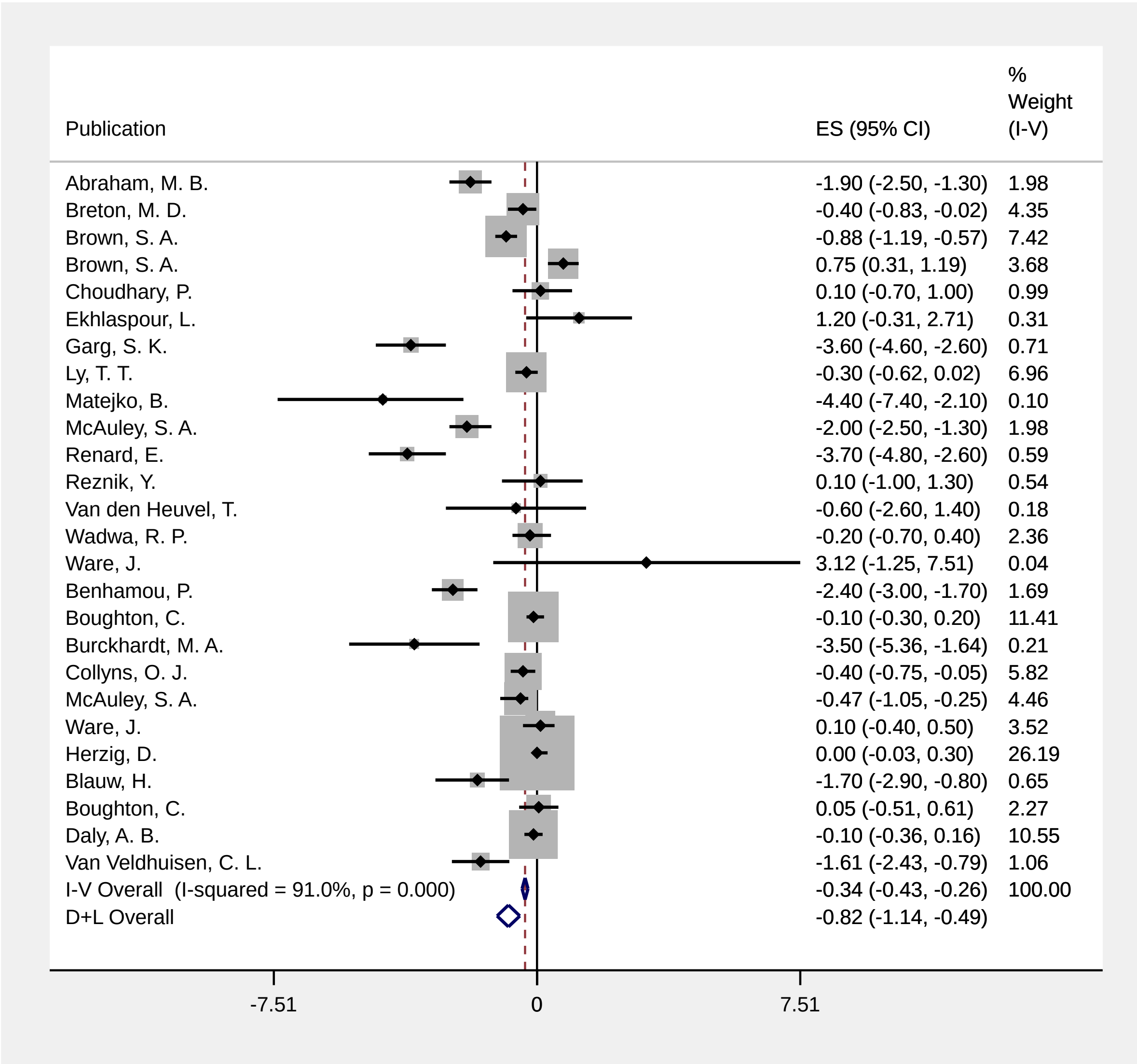
Supplemental figure 7

Meta-analysis on AID systems and TBR (%). Abbreviations: AID, automated insulin delivery; ES (95% CI), mean difference (95% confidence interval); TBR, time with sensor values below target range.

Supplemental figure 7a

Randomized clinical trials. Randomized clinical trials evaluating the impact of AID systems on time below range percentage. The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices.

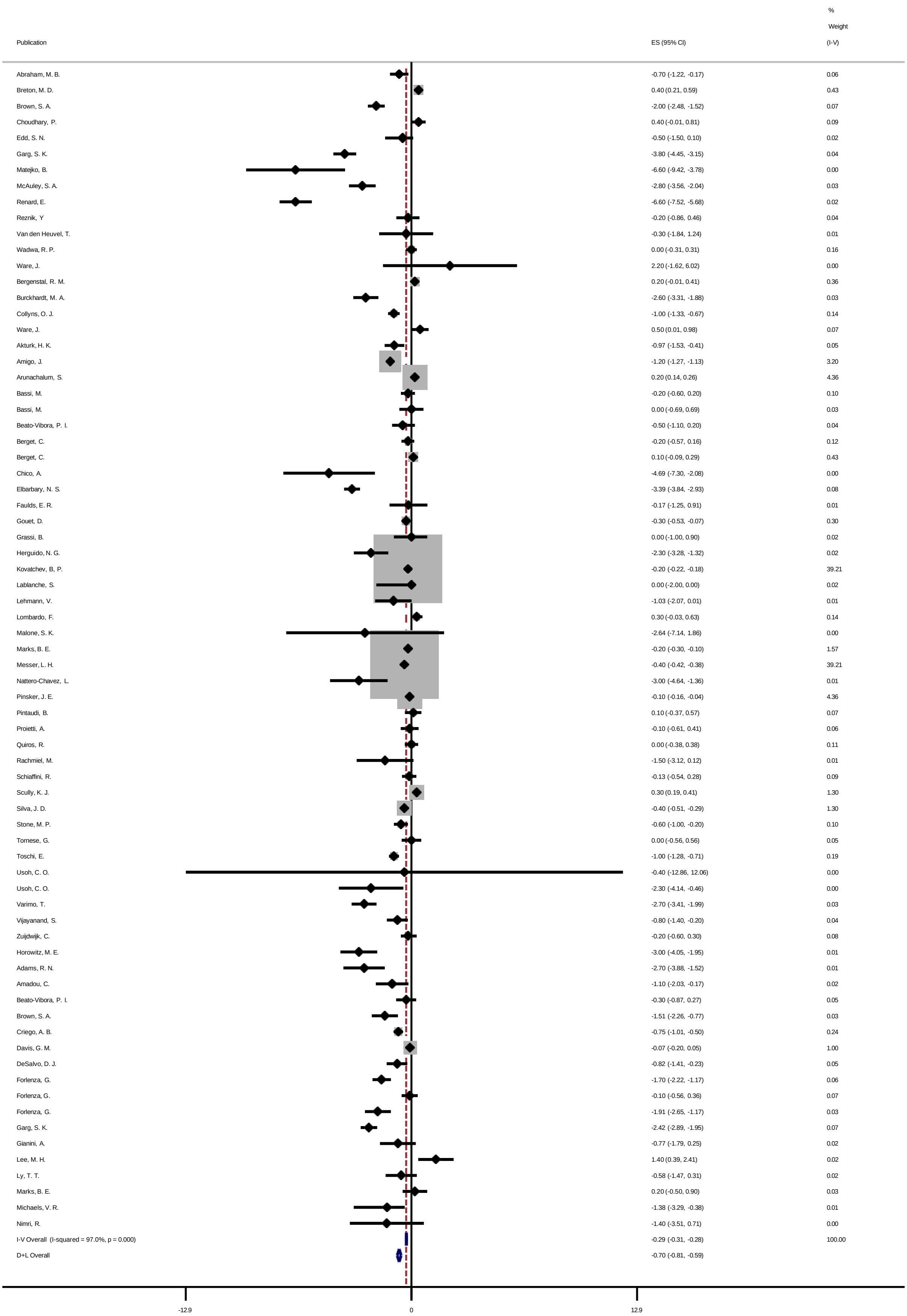
Additional note. Two studies, by Ekhlaspour et al [PMID 31099946] and Forlenza et al [PMID 30888835] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Ekhlaspour et al [PMID 31099946] because it included a larger number of participants. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants.



Supplemental figure 7b

Studies of any design. Studies of any design comparing time below range percentages before (Reference) vs after utilization of AID systems (i.e., pre vs post intervention). Baseline treatment (before utilization of AID system) includes any other diabetes treatment methods (including standard diabetes therapy, multiple daily injection insulin therapy with/without glucose sensing-device, continuous subcutaneous insulin infusion with/without sensor augmentation with/without [predictive] low glucose suspend).

Additional note. Two studies, by Beato-Vibora et al [PMID 33784187] and Beato-Vibora et al [PMID 34329691] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Beato-Vibora et al [PMID 34329691] because of the longer follow-up. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants. Two studies, by DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by DeSalvo et al [PMID 38277156] because of the longer follow-up. Two studies, by Boucsein et al [PMID 36689621] and Michaels et al [PMID 37823890] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Michaels et al [PMID 37823890] because of the longer follow-up.



%
Weight
Publication
ES (95% CI)
(I-V)
Abraham, M. B. -0.70 (-1.22, -0.17) 0.06
Breton, M. D. 0.40 (0.21, 0.59) 0.43
Brown, S. A. -2.00 (-2.48, -1.52) 0.07
Choudhary, P. 0.40 (-0.01, 0.81) 0.09
Edd, S. N. -0.50 (-1.50, 0.10) 0.02
Garg, S. K. -3.80 (-4.45, -3.15) 0.04
Matejko, B. -6.60 (-9.42, -3.78) 0.00
McAuley, S. A. -2.80 (-3.56, -2.04) 0.03
Renard, E. -6.60 (-7.52, -5.68) 0.02
Reznik, Y -0.20 (-0.86, 0.46) 0.04
Van den Heuvel, T. -0.30 (-1.84, 1.24) 0.01
Wadwa, R. P. 0.00 (-0.31, 0.31) 0.16
Ware, J. 2.20 (-1.62, 6.02) 0.00
Bergenstal, R. M. 0.20 (-0.01, 0.41) 0.36
Burckhardt, M. A. -2.60 (-3.31, -1.88) 0.03
Collyns, O. J. -1.00 (-1.33, -0.67) 0.14
Ware, J. 0.50 (0.01, 0.98) 0.07
Akturk, H. K. -0.97 (-1.53, -0.41) 0.05
Amigo, J. -1.20 (-1.27, -1.13) 3.20
Arunachalum, S. 0.20 (0.14, 0.26) 4.36
Bassi, M. -0.20 (-0.60, 0.20) 0.10
Bassi, M. 0.00 (-0.69, 0.69) 0.03
Beato-Vibora, P. I. -0.50 (-1.10, 0.20) 0.04
Berget, C. -0.20 (-0.57, 0.16) 0.12
Berget, C. 0.10 (-0.09, 0.29) 0.43
Chico, A. -4.69 (-7.30, -2.08) 0.00
Elbarbary, N. S. -3.39 (-3.84, -2.93) 0.08
Faulds, E. R. -0.17 (-1.25, 0.91) 0.01
Gouet, D. -0.30 (-0.53, -0.07) 0.30
Grassi, B. 0.00 (-1.00, 0.90) 0.02
Herguido, N. G. -2.30 (-3.28, -1.32) 0.02
Kovatchev, B. P. -0.20 (-0.22, -0.18) 39.21
Lablanche, S. 0.00 (-2.00, 0.00) 0.02
Lehmann, V. -1.03 (-2.07, 0.01) 0.01
Lombardo, F. 0.30 (-0.03, 0.63) 0.14
Malone, S. K. -2.64 (-7.14, 1.86) 0.00
Marks, B. E. -0.20 (-0.30, -0.10) 1.57
Messer, L. H. -0.40 (-0.42, -0.38) 39.21
Nattero-Chavez, L. -3.00 (-4.64, -1.36) 0.01
Pinsker, J. E. -0.10 (-0.16, -0.04) 4.36
Pintaudi, B. 0.10 (-0.37, 0.57) 0.07
Proietti, A. -0.10 (-0.61, 0.41) 0.06
Quiros, R. 0.00 (-0.38, 0.38) 0.11
Rachmiel, M. -1.50 (-3.12, 0.12) 0.01
Schiaffini, R. -0.13 (-0.54, 0.28) 0.09
Scully, K. J. 0.30 (0.19, 0.41) 1.30
Silva, J. D. -0.40 (-0.51, -0.29) 1.30
Stone, M. P. -0.60 (-1.00, -0.20) 0.10
Tornese, G. 0.00 (-0.56, 0.56) 0.05
Toschi, E. -1.00 (-1.28, -0.71) 0.19
Usoh, C. O. -0.40 (-12.86, 12.06) 0.00
Usoh, C. O. -2.30 (-4.14, -0.46) 0.00
Varimo, T. -2.70 (-3.41, -1.99) 0.03
Vijayanand, S. -0.80 (-1.40, -0.20) 0.04
Zuijdwijk, C. -0.20 (-0.60, 0.30) 0.08
Horowitz, M. E. -3.00 (-4.05, -1.95) 0.01
Adams, R. N. -2.70 (-3.88, -1.52) 0.01
Amadou, C. -1.10 (-2.03, -0.17) 0.02
Beato-Vibora, P. I. -0.30 (-0.87, 0.27) 0.05
Brown, S. A. -1.51 (-2.26, -0.77) 0.03
Criego, A. B. -0.75 (-1.01, -0.50) 0.24
Davis, G. M. -0.07 (-0.20, 0.05) 1.00
DeSalvo, D. J. -0.82 (-1.41, -0.23) 0.05
Forlenza, G. -1.70 (-2.22, -1.17) 0.06
Forlenza, G. -0.10 (-0.56, 0.36) 0.07
Forlenza, G. -1.91 (-2.65, -1.17) 0.03
Garg, S. K. -2.42 (-2.89, -1.95) 0.07
Gianini, A. -0.77 (-1.79, 0.25) 0.02
Lee, M. H. 1.40 (0.39, 2.41) 0.02
Ly, T. T. -0.58 (-1.47, 0.31) 0.02
Marks, B. E. 0.20 (-0.50, 0.90) 0.03
Michaels, V. R. -1.38 (-3.29, -0.38) 0.01
Nimri, R. -1.40 (-3.51, 0.71) 0.00
I-V Overall (I-squared = 97.0%, p = 0.000) -0.29 (-0.31, -0.28) 100.00
D+L Overall -0.70 (-0.81, -0.59)
-12.9
0
12.9

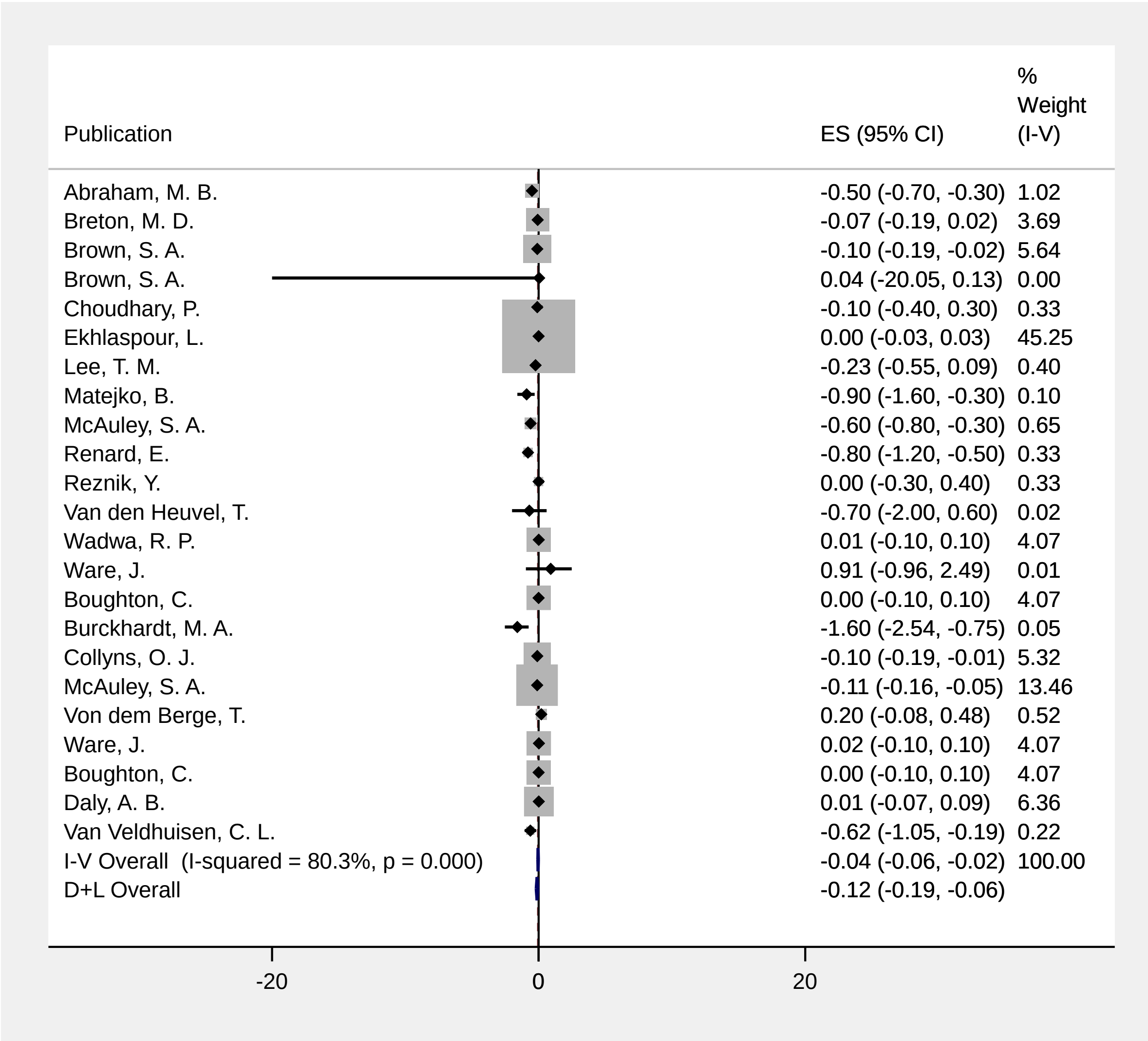
Supplemental figure 8

Meta-analysis on AID systems and time with sensor values below 3 mmol/l (%). Abbreviations: AID, automated insulin delivery; ES (95% CI), mean difference (95% confidence interval).

Supplemental figure 8a

Randomized clinical trials. Randomized clinical trials evaluating the impact of AID systems on time below 3 mmol/l (%). The comparator (Reference) includes any antidiabetic treatment other than high-risk medical devices.

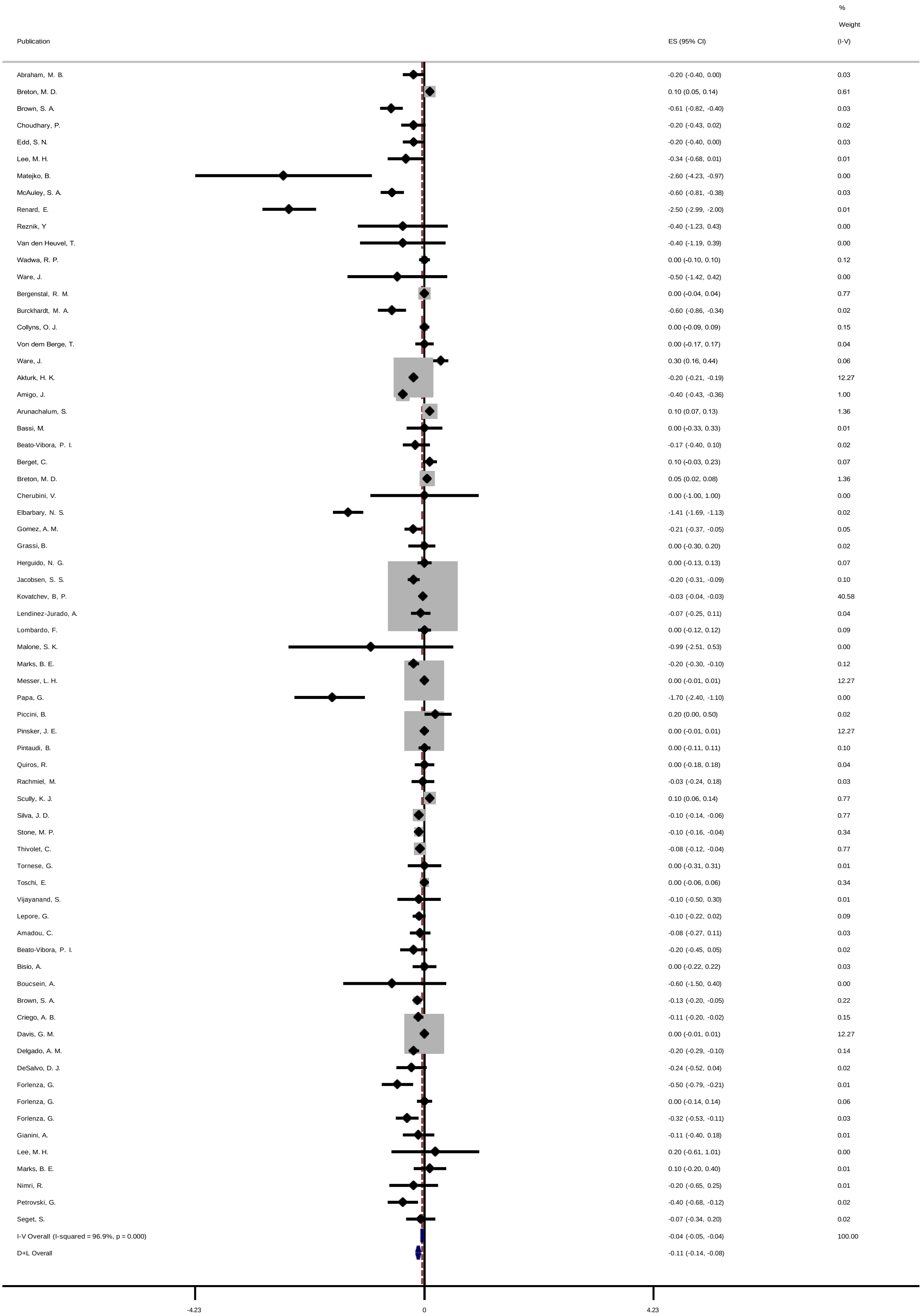
Additional note. Two studies, by Ekhlaspour et al [PMID 31099946] and Forlenza et al [PMID 30888835] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Ekhlaspour et al [PMID 31099946] because it included a larger number of participants. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants.



Supplemental figure 8b

Studies of any design. Studies of any design comparing time below 3 mmol/l percentages before (Reference) vs after utilization of AID systems (i.e., pre vs post intervention). Baseline treatment (before utilization of AID system) includes any other diabetes treatment methods (including standard diabetes therapy, multiple daily injection insulin therapy with/without glucose sensing-device, continuous subcutaneous insulin infusion with/without sensor augmentation with/without [predictive] low glucose suspend).

Additional note. Two studies, by Beato-Vibora et al [PMID 33784187] and Beato-Vibora et al [PMID 34329691] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Beato-Vibora et al [PMID 34329691] because of the longer follow-up. Two studies, by Petrovski et al [PMID 35072781] and Petrovski et al [PMID 35351095] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the results of only one of the studies. Two studies, by Lendínez-Jurado [PMID 37959415] and Lendínez-Jurado [PMID 37337407] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by Lendínez-Jurado et al [PMID 37337407] because of the longer follow-up. Two studies, by Brown et al [PMID 31618560] and Isganaitis et al [PMID 33216667] were performed in overlapping populations, therefore could not be pooled. In this meta-analysis, we included the study by Brown et al [PMID 31618560] because of the larger number of participants. Two studies, by DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population, therefore could not be pooled. In this meta-analysis, we included the study by DeSalvo et al [PMID 38277156] because of the longer follow-up.

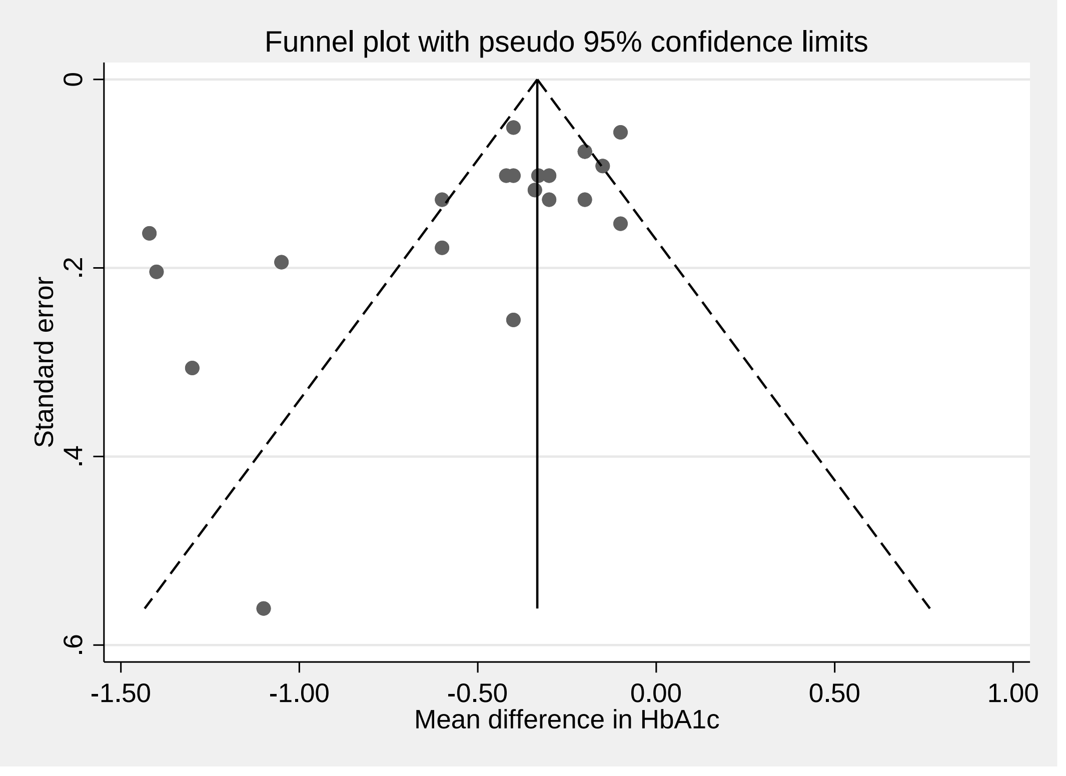

Publication
ES (95% CI)
% Weight (I-V)
Abraham, M. B. -0.20 (-0.40, 0.00) 0.03
Breton, M. D. 0.10 (0.05, 0.14) 0.61
Brown, S. A. -0.61 (-0.82, -0.40) 0.03
Choudhary, P. -0.20 (-0.43, 0.02) 0.02
Edd, S. N. -0.20 (-0.40, 0.00) 0.03
Lee, M. H. -0.34 (-0.68, 0.01) 0.01
Matejko, B. -2.60 (-4.23, -0.97) 0.00
McAuley, S. A. -0.60 (-0.81, -0.38) 0.03
Renard, E. -2.50 (-2.99, -2.00) 0.01
Reznik, Y -0.40 (-1.23, 0.43) 0.00
Van den Heuvel, T. -0.40 (-1.19, 0.39) 0.00
Wadwa, R. P. 0.00 (-0.10, 0.10) 0.12
Ware, J. -0.50 (-1.42, 0.42) 0.00
Bergenstal, R. M. 0.00 (-0.04, 0.04) 0.77
Burckhardt, M. A. -0.60 (-0.86, -0.34) 0.02
Collyns, O. J. 0.00 (-0.09, 0.09) 0.15
Von dem Berge, T. 0.00 (-0.17, 0.17) 0.04
Ware, J. 0.30 (0.16, 0.44) 0.06
Akturk, H. K. -0.20 (-0.21, -0.19) 12.27
Amigo, J. -0.40 (-0.43, -0.36) 1.00
Arunachalum, S. 0.10 (0.07, 0.13) 1.36
Bassi, M. 0.00 (-0.33, 0.33) 0.01
Beato-Vibora, P. I. -0.17 (-0.40, 0.10) 0.02
Berget, C. 0.10 (-0.03, 0.23) 0.07
Breton, M. D. 0.05 (0.02, 0.08) 1.36
Cherubini, V. 0.00 (-1.00, 1.00) 0.00
Elbarbary, N. S. -1.41 (-1.69, -1.13) 0.02
Gomez, A. M. -0.21 (-0.37, -0.05) 0.05
Grassi, B. 0.00 (-0.30, 0.20) 0.02
Herguido, N. G. 0.00 (-0.13, 0.13) 0.07
Jacobsen, S. S. -0.20 (-0.31, -0.09) 0.10
Kovatchev, B, P. -0.03 (-0.04, -0.03) 40.58
Lendinez-Jurado, A. -0.07 (-0.25, 0.11) 0.04
Lombardo, F. 0.00 (-0.12, 0.12) 0.09
Malone, S. K. -0.99 (-2.51, 0.53) 0.00
Marks, B. E. -0.20 (-0.30, -0.10) 0.12
Messer, L. H. 0.00 (-0.01, 0.01) 12.27
Papa, G. -1.70 (-2.40, -1.10) 0.00
Piccini, B. 0.20 (0.00, 0.50) 0.02
Pinsker, J. E. 0.00 (-0.01, 0.01) 12.27
Pintaudi, B. 0.00 (-0.11, 0.11) 0.10
Quiros, R. 0.00 (-0.18, 0.18) 0.04
Rachmiel, M. -0.03 (-0.24, 0.18) 0.03
Scully, K. J. 0.10 (0.06, 0.14) 0.77
Silva, J. D. -0.10 (-0.14, -0.06) 0.77
Stone, M. P. -0.10 (-0.16, -0.04) 0.34
Thivolet, C. -0.08 (-0.12, -0.04) 0.77
Tornese, G. 0.00 (-0.31, 0.31) 0.01
Toschi, E. 0.00 (-0.06, 0.06) 0.34
Vijayanand, S. -0.10 (-0.50, 0.30) 0.01
Lepore, G. -0.10 (-0.22, 0.02) 0.09
Amadou, C. -0.08 (-0.27, 0.11) 0.03
Beato-Vibora, P. I. -0.20 (-0.45, 0.05) 0.02
Bisio, A. 0.00 (-0.22, 0.22) 0.03
Boucsein, A. -0.60 (-1.50, 0.40) 0.00
Brown, S. A. -0.13 (-0.20, -0.05) 0.22
Criego, A. B. -0.11 (-0.20, -0.02) 0.15
Davis, G. M. 0.00 (-0.01, 0.01) 12.27
Delgado, A. M. -0.20 (-0.29, -0.10) 0.14
DeSalvo, D. J. -0.24 (-0.52, 0.04) 0.02
Forlenza, G. -0.50 (-0.79, -0.21) 0.01
Forlenza, G. 0.00 (-0.14, 0.14) 0.06
Forlenza, G. -0.32 (-0.53, -0.11) 0.03
Gianini, A. -0.11 (-0.40, 0.18) 0.01
Lee, M. H. 0.20 (-0.61, 1.01) 0.00
Marks, B. E. 0.10 (-0.20, 0.40) 0.01
Nimri, R. -0.20 (-0.65, 0.25) 0.01
Petrovski, G. -0.40 (-0.68, -0.12) 0.02
Seget, S. -0.07 (-0.34, 0.20) 0.02
I-V Overall (I-squared = 96.9%, p = 0.000) -0.04 (-0.05, -0.04) 100.00
D+L Overall -0.11 (-0.14, -0.08)
-4.23
0
4.23

Supplemental figure 9

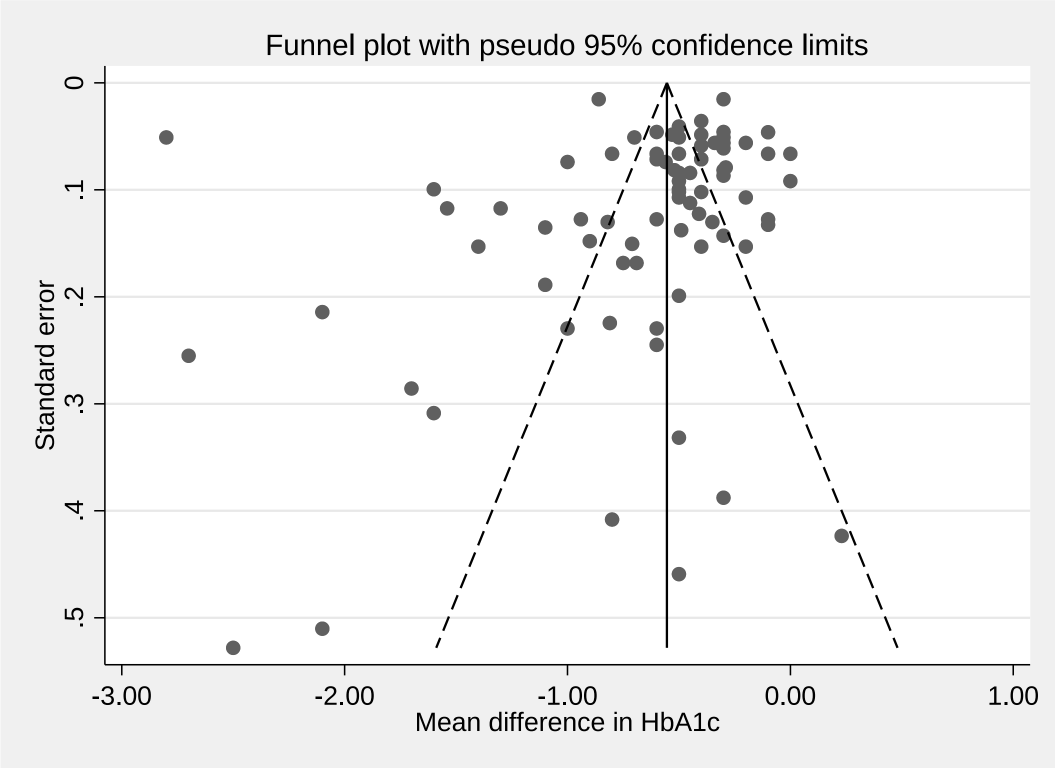
Funnel plots for detection of publication bias. The mean difference is plotted against the standard error of the mean difference. The dashed lines depict the summary mean difference with its 95% confidence interval. Abbreviations: HbA1c, glycated hemoglobin; TIR, time in range.

Supplemental figure 9a

Funnel plot for glycated hemoglobin (HbA1c). Randomized clinical trials are presented. Egger test p-value 0.006

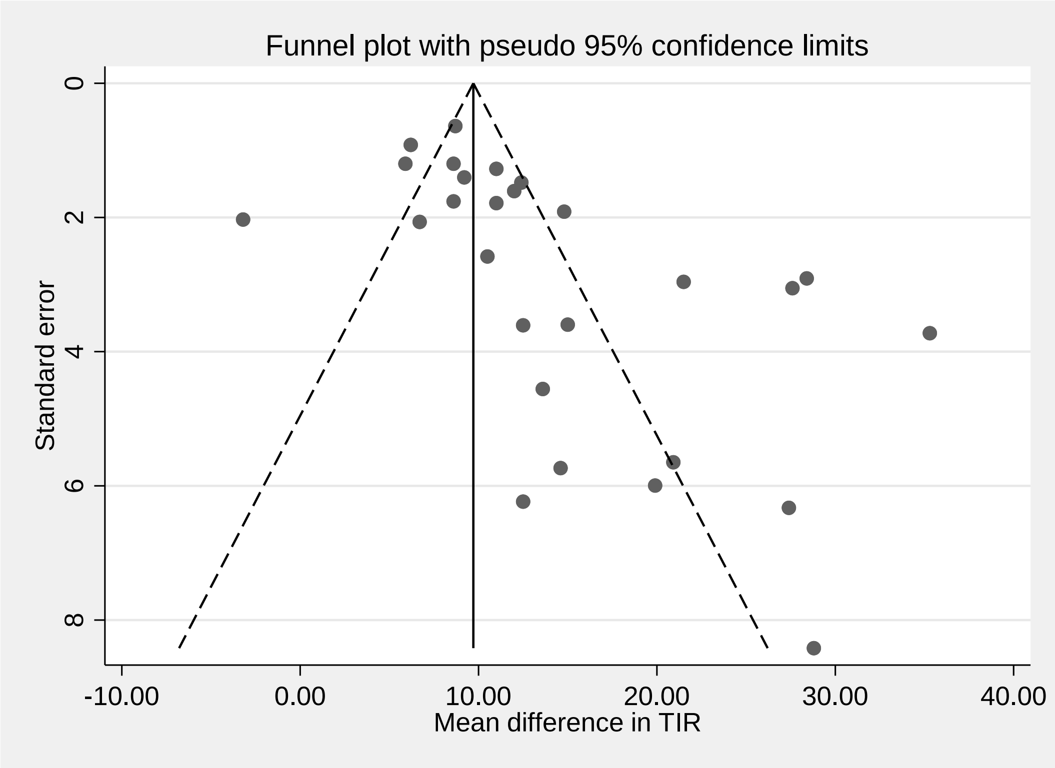


Funnel plot for glycated hemoglobin (HbA1c). Studies of any design comparing HbA1c before (Reference) vs after utilization of AID systems (i.e., pre-post intervention) are presented. Egger test p-value 0.54

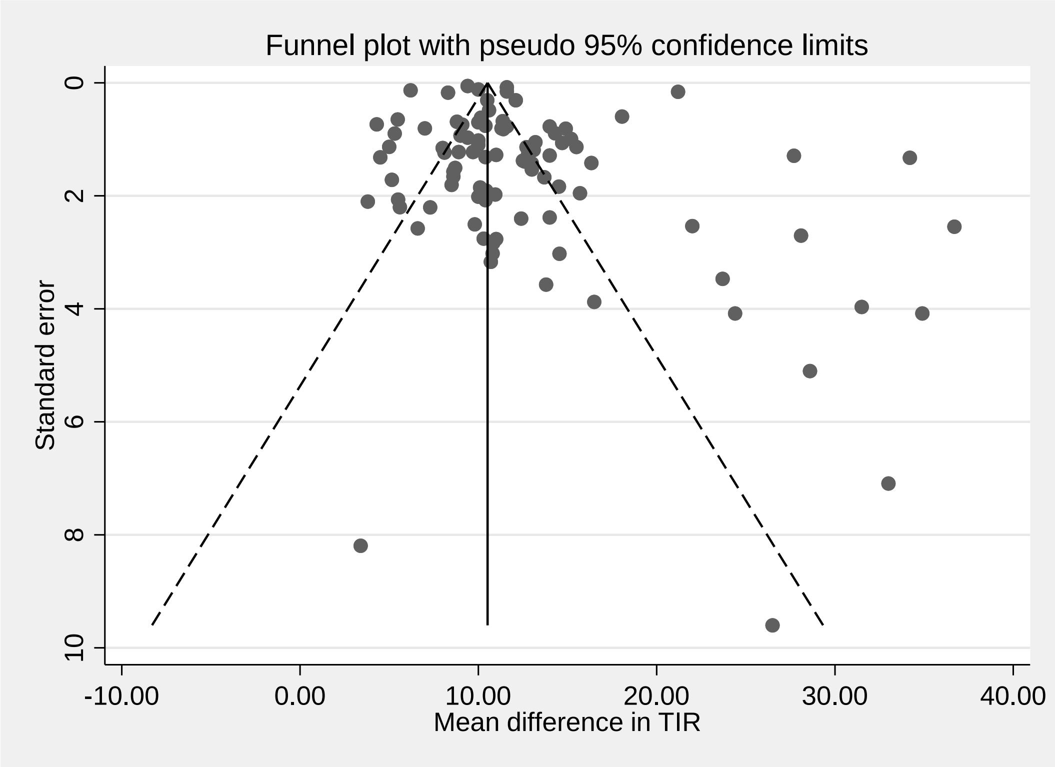


Supplemental figure 9b

Funnel plot for time with sensor values in target range (TIR). Randomized clinical trials are presented. Egger test p-value 0.002

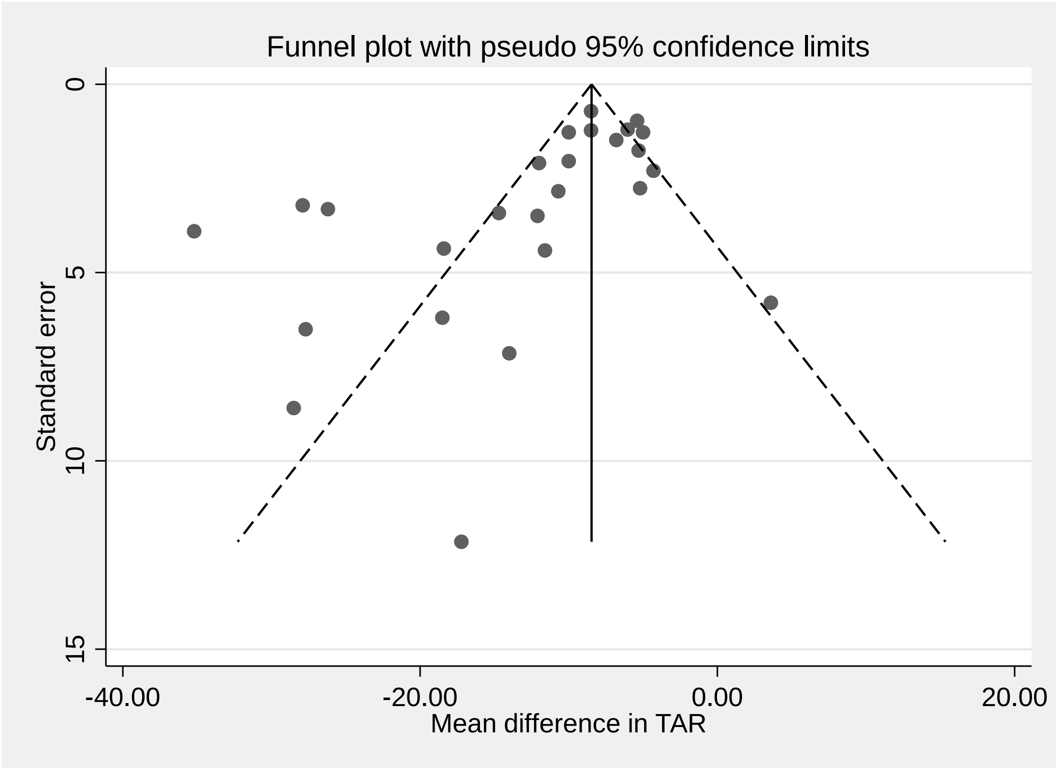


Funnel plot for time with sensor values in target range (TIR). Studies of any design comparing TIR before (Reference) vs after utilization of AID systems (i.e., pre-post intervention) are presented.
Egger test p-value 0.15

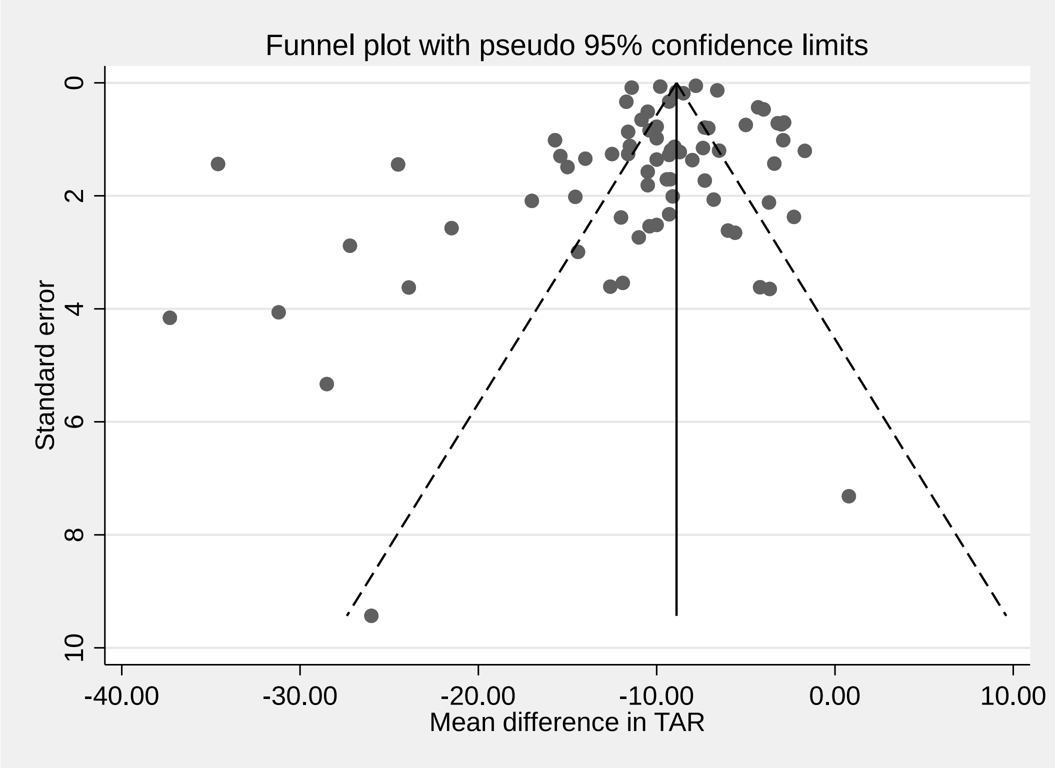


Supplemental figure 9c

Funnel plot for time with sensor values above target range (TAR). Randomized clinical trials are presented. Egger test p-value 0.005

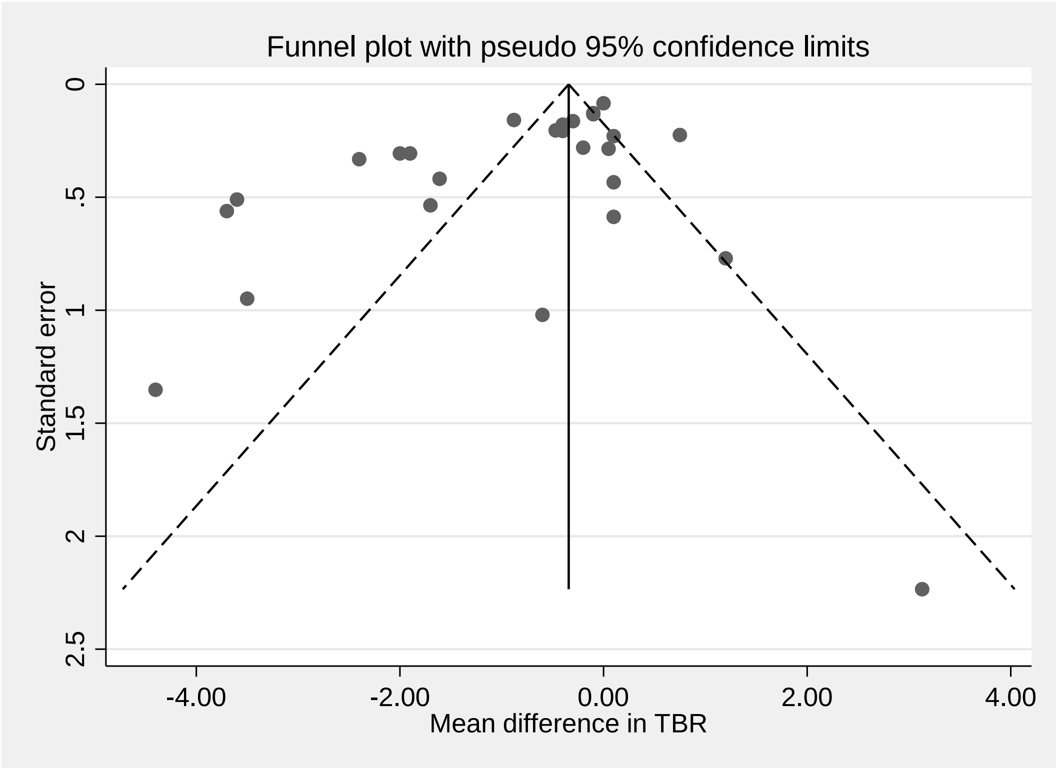


Funnel plot for time with sensor values above target range (TAR). Studies of any design comparing TAR before (Reference) vs after utilization of AID systems (i.e., pre-post intervention) are presented. Egger test p-value 0.4

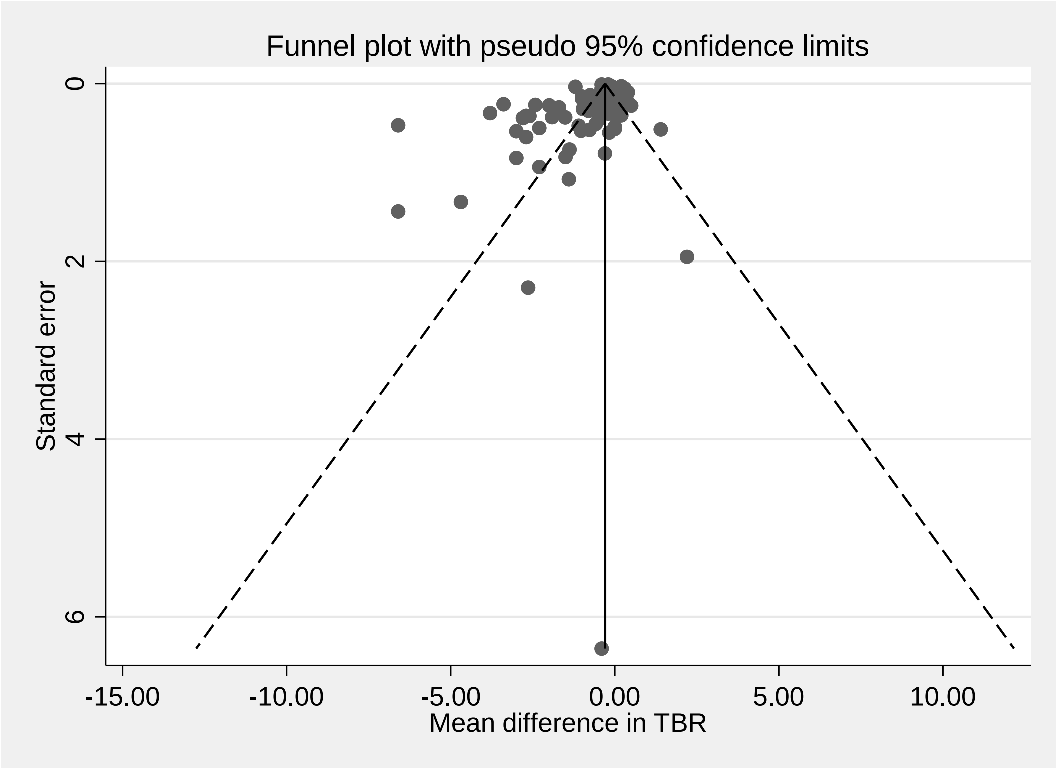


Supplemental figure 9d

Funnel plot for time with sensor values below target range (TBR). Randomized clinical trials are presented. Egger test p-value 0.01

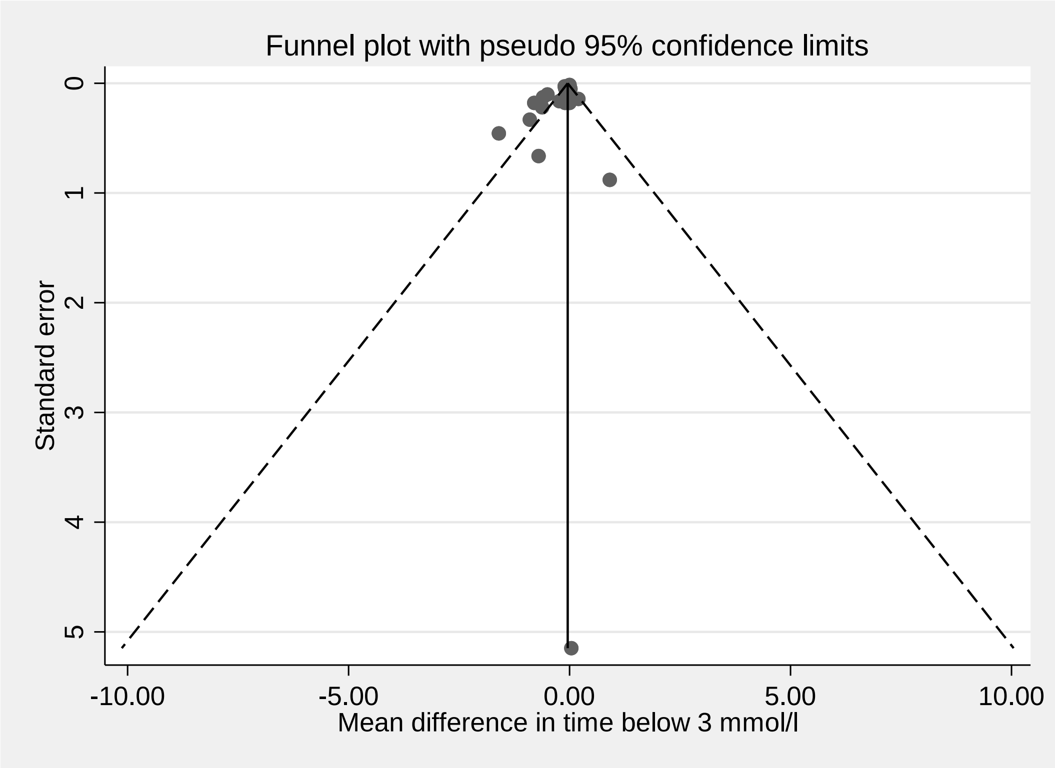


Funnel plot for time with sensor values below target range (TBR). Studies of any design comparing TBR before (Reference) vs after utilization of AID systems (i.e., pre-post intervention) are presented. Egger test p-value 0.05

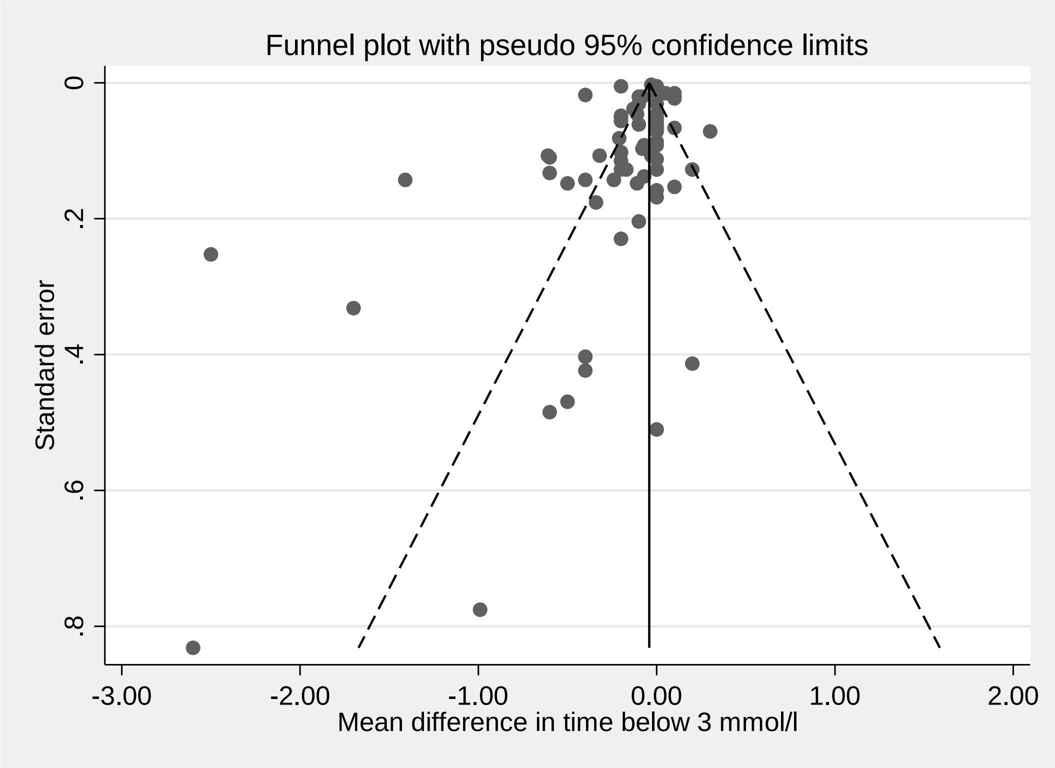


Supplemental figure 9e

Funnel plot for time with sensor values below 3 mmol/l. Randomized clinical trials are presented. Egger test p-value 0.01



Funnel plot for time with sensor values below 3 mmol/L. Studies of any design comparing time below 3 mmol/l before (Reference) vs after utilization of AID systems (i.e., pre-post intervention) are presented. Egger test p-value 0.13



Appendix 1

Databases, coverage and search strategy

We searched the following information sources: Embase (Elsevier), Medline All (Ovid), Cochrane Library (Wiley), Science Citation Index Expanded and Emerging Sources Citation Index (Web of Science) from inception to March 27th 2024. Study design search filters were incorporated and adapted from the BMJ Best Practice: https://bestpractice.bmj.com/info/toolkit/learn-ebm/study-design-search-filters/ The Cochrane Handbook RCT search filter (sensitivity max. version 2008) was applied to the Medline All (Ovid) search: https://training.cochrane.org/handbook/current/chapter-04#section-4-4-7

Embase (Elsevier), Coverage 1947-Present

#13 #9 AND #12

#12 #10 OR #11

#11 'cohort analysis'/exp OR 'longitudinal study'/exp OR 'prospective study'/exp OR 'follow up'/exp OR 'retrospective study'/de OR 'cross-sectional study'/de OR 'observational study'/de OR 'population research'/de OR 'case control study'/exp OR 'major clinical study'/de OR cohort*:ab,ti OR (((prospectiv* OR populat* OR observ* OR retrospect* OR epidemiologic*) NEAR/3 (stud* OR trial*)):ab,ti) OR ((case* NEAR/3 control*):ab,ti) OR ((case* NEAR/3 series):ab,ti) OR ((cross NEAR/1 section*):ab,ti) OR 'case cohort*':ab,ti OR 'nested case control*':ab,ti OR prospectiv*:ab,ti OR retrospectiv*:ab,ti OR longitudinal*:ab,ti OR 'follow up':ab,ti OR followup:ab,ti OR population-based:ab,ti

#10 random*:ti,ab OR placebo*:ti,ab OR 'single blind*':ti,ab OR 'double blind*':ti,ab OR 'triple blind*':ti,ab OR ((clinical NEXT/1 trial*):ti,ab) OR 'randomized controlled trial'/exp

#9 #7 NOT #8

#8 [animals]/lim NOT [humans]/lim

#7 #5 AND #6

#6 #3 OR #4

#5 #1 OR #2

#4 'ambulatory insulin infusion pump*':ti,ab OR 'artificial pancreas':ti,ab OR 'artificial endocrine pancreas':ti,ab OR 'automated pancreas':ti,ab OR 'automated insulin delivery':ti,ab OR 'automated insulin therapy':ti,ab OR 'automated insulin dosing':ti,ab OR 'bionic pancreas':ti,ab OR 'closed-loop control':ti,ab OR 'closed-loop system':ti,ab OR 'continuous intraperitoneal insulin infusion*':ti,ab OR 'do-it-yourself automated pancreas':ti,ab OR 'hybrid closed-loop':ti,ab OR 'implantable glucose monitor*':ti,ab OR 'implantable continuous glucose monitor*':ti,ab OR 'implanted insulin pump*':ti,ab OR 'implantable insulin pump*':ti,ab OR 'implanted infusion pump*':ti,ab OR 'implantable infusion pump*':ti,ab OR 'implantable cgm*':ti,ab OR 'sensor-augmented pump*':ti,ab OR 'implantable glucose sensor*':ti,ab OR 'medtronic 670g':ti,ab,dn,df OR minimed*:ti,ab,dn,df OR diaport*:ti,ab,dn,df OR 'control iq*':ti,ab,dn,df OR diabeloop*:ti,ab,dn,df OR tidepool*:ti,ab,dn,df OR 'omnipod* 5':ti,ab,dn,df OR 'ilet bionic pancreas*':ti,ab,dn,df OR eversense*:ti,ab,dn,df OR 'camaps hx*':ti,ab,dn,df OR 'camaps fx*':ti,ab,dn,df OR dblg1*:ti,ab,dn,df OR (((closed OR hybrid) NEAR/3 (insulin OR glucose) NEAR/3 (system* OR delivery OR device* OR therapy OR algorithm)):ti,ab)

#3 'artificial pancreas'/exp OR 'closed loop control'/de OR 'closed loop control system'/de OR 'closed loop insulin delivery'/de OR 'closed loop insulin delivery system'/de OR 'continuous glucose monitoring device'/de OR 'glucose monitoring/insulin pump system'/de OR 'hybrid closed loop system'/de OR 'implantable drug delivery system'/de OR 'implantable infusion pump'/de OR 'insulin delivery device'/de OR 'insulin implant'/exp OR 'insulin pump therapy'/de

#2 diabet*:ti,ab OR hypoglycemi*:ti,ab OR hypoglycaemi*:ti,ab OR hyperglycemi*:ti,ab OR hyperglycaemi*:ti,ab OR 'iddm':ti,ab OR 'niddm':ti,ab OR 't1dm':ti,ab OR 't2dm':ti,ab

#1 'diabetes mellitus'/de OR 'insulin dependent diabetes mellitus'/exp OR 'non insulin dependent diabetes mellitus'/de

Medline All (Ovid), Coverage 1946-Present

1 diabetes mellitus/ or diabetes mellitus, type 1/ or diabetes mellitus, type 2/

2 (diabet* or hypoglycemi* or hypoglycaemi* or hyperglycemi* or hyperglycaemi* or iddm or niddm or t1dm or t2dm).ti,ab.

3 infusion pumps, implantable/ or pancreas, artificial/

4 ("ambulatory insulin infusion pump*" or "artificial pancreas" or "artificial endocrine pancreas" or "automated pancreas" or "automated insulin delivery" or "automated insulin therapy" or "automated insulin dosing" or "bionic pancreas" or "closed-loop control" or "closed-loop system" or "continuous intraperitoneal insulin infusion*" or "do-it-yourself automated pancreas" or "hybrid closed-loop" or "implantable glucose monitor*" or

"implantable continuous glucose monitor*" or "implanted insulin pump*" or "implantable insulin pump*" or "implanted infusion pump*" or "implantable infusion pump*" or "implantable cgm*" or "sensor-augmented pump*" or "implantable glucose sensor*" or "medtronic 670g" or minimed* or diaport* or "control iq*" or diabeloop* or tidepool* or "omnipod* 5" or "ilet bionic pancreas*" or eversense* or "camaps hx*" or "camaps fx*" or dblg1* or ((closed or hybrid) adj3 (insulin or glucose) adj3 (system* or delivery or device* or therapy or algorithm))).ti,ab.
5 1 or 2
6 3 or 4
7 5 and 6
8 exp animals/ not humans/
9 7 not 8
10 exp cohort analysis/ or cross-sectional studies/ or observational study/ or case control studies/ or (cohort* or ((prospectiv* or populat* or observ* or retrospect* or epidemiologic*) adj3 (stud* or trial*)) or (case* adj3 control*) or (case* adj3 series) or (cross adj1 section*) or case cohort* or nested case-control* or prospectiv* or retrospectiv* or longitudinal* or follow-up or followup or population-based).ab,ti.
11 randomized controlled trial.pt.
12 controlled clinical trial.pt.
13 randomi?ed.ab.
14 placebo.ab.
15 drug therapy.fs.
16 randomly.ab.
17 trial.ab.
18 groups.ab.
19 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 exp animals/ not humans.sh.
21 19 not 20
22 10 or 21
23 9 and 22

Cochrane Library (Wiley), Coverage 1996-Present
Advanced Search via Search Manager
#1 [mh ^"diabetes mellitus"] OR [mh ^"diabetes mellitus, type 2"] OR [mh ^"diabetes mellitus, type 1"] OR [mh "latent autoimmune diabetes in adults"]
#2 diabet*:ti,ab OR hypoglycemi*:ti,ab OR hypoglycaemi*:ti,ab OR hyperglycemi*:ti,ab OR hyperglycaemi*:ti,ab OR iddm:ti,ab OR niddm:ti,ab OR t1dm:ti,ab OR t2dm:ti,ab
#3 [mh "pancreas, artificial"] OR [mh "infusion pumps, implantable"]
#4 ((ambulatory NEXT insulin NEXT infusion NEXT pump*) OR "artificial pancreas" OR "artificial endocrine pancreas" OR "automated pancreas" OR "automated insulin delivery" OR "automated insulin therapy" OR "automated insulin dosing" OR "bionic pancreas" OR "closed-loop control" OR "closed-loop system" OR (continuous NEXT intraperitoneal NEXT insulin NEXT infusion*) OR "do-it-yourself automated pancreas" OR "hybrid closed-loop" OR (implantable NEXT glucose NEXT monitor*) OR (implantable NEXT continuous NEXT glucose NEXT monitor*) OR (implanted NEXT insulin NEXT pump*) OR (implantable NEXT insulin NEXT pump*) OR (implanted NEXT infusion NEXT pump*) OR (implantable NEXT infusion NEXT pump*) OR (implantable NEXT cgm*) OR (sensor NEXT augmented NEXT pump*) OR (implantable NEXT glucose NEXT sensor*) OR "medtronic 670g" OR minimed* OR diaport* OR (control NEXT iq*) OR diabeloop* OR tidepool* OR (omnipod* NEXT 5) OR (ilet NEXT bionic NEXT pancreas*) OR eversense* OR (camaps NEXT hx*) OR (camaps NEXT fx*) OR dblg1* OR ((closed OR hybrid) NEAR/3 (insulin OR glucose) NEAR/3 (system* OR delivery OR device* OR therapy OR algorithm))):ti,ab
#5 #1 OR #2
#6 #3 OR #4
#7 #5 AND #6

Science Citation Index Expanded and Emerging Sources Citation Index (Web of Science), Coverages, 1900-Present & 2017-Present

1 TS=(diabet* OR hypoglycemi* OR hypoglycaemi* OR hyperglycemi* OR hyperglycaemi* OR iddm OR niddm OR t1dm OR t2dm)

2 TS=("ambulatory insulin infusion pump*" OR "artificial pancreas" OR "artificial endocrine pancreas" OR "automated pancreas" OR "automated insulin delivery" OR "automated insulin therapy" OR "automated insulin dosing" OR "bionic pancreas" OR "closed-loop control" OR "closed-loop system" OR "continuous intraperitoneal insulin infusion*" OR "do-it-yourself automated pancreas" OR "hybrid closed-loop" OR "implantable glucose monitor*" OR "implantable continuous glucose monitor*" OR "implanted insulin pump*" OR "implantable insulin pump*" OR "implanted infusion pump*" OR "implantable infusion pump*" OR "implantable cgm*" OR "sensor-augmented pump*" OR "implantable glucose sensor*" OR "medtronic 670g" OR minimed* OR diaport* OR "control iq*" OR diabeloop* OR tidepool* OR "omnipod* 5" OR "ilet bionic pancreas*" OR eversense* OR "camaps hx*" OR "camaps fx*" OR dblg1* OR ((closed OR hybrid) NEAR/3 (insulin OR glucose) NEAR/3 (system* OR delivery OR device* OR therapy OR algorithm)))

3 TS=((cohort* OR ((prospectiv* OR populat* OR observ* OR retrospect* OR epidemiologic*) NEAR/3 (stud* OR trial*)) OR (case* NEAR/3 control*) OR (case* NEAR/3 series) OR (Cross NEAR/2 section*) OR case-cohort* OR nested-case-control* OR prospectiv* OR retrospectiv* OR longitudinal* OR follow-up OR followup OR population-based))

4 TS=(random* OR placebo* OR "single blind*" OR "double blind*" OR "triple blind*" OR (clinical NEAR/0 trial*) OR "randomized controlled trial" OR RCT)

5 #3 OR #4

6 #1 AND #2 AND #5

Appendix 2

Supplemental Methods

Search strategy

We combined subject headings and free text terms related to: (i) diabetes and hyperglycemia, (ii) device-sensitive search algorithms, and (iii) study design. No language or publication date restrictions were applied.

Study selection

We excluded animal studies, proceedings, reviews, systematic reviews, meta-analyses, letters to the editor, research letters, commentaries, conference abstracts, case studies, or expert opinion documents. Two independent reviewers screened each abstract. Full text articles of identified articles were retrieved. Two independent reviewers performed full-text assessment. In case of disagreement, a third reviewer was consulted. The full texts and reference lists of the selected articles were hand searched in order to identify additional studies for inclusion.

A device-related serious adverse event is defined as any serious adverse event that has a causal relationship with the investigational device or where such causal relationship is reasonably possible (1). A serious adverse event is defined as any adverse event that led to death, serious deterioration in the health of the patient requiring medical assistance including emergency medical services and/or hospitalization (1). A device deficiency is defined as any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer (1). A device deficiency with a serious adverse event potential is defined as any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate (1).

Data extraction

We used a pre-designed data collection form to extract information about journal, first author name, year of publication, funding sources, study design, setting, recruitment period and follow-up duration, sample size, demographics of the population, intervention, comparison, outcome(s) reported, and measures of associations on the outcomes related to efficacy and safety with corresponding 95% confidence intervals (95% CI) or p-values. Moreover, we specified which studies provided information on usability parameters such as technical performance (e.g. % time device was operational) and patient-reported outcomes measures for devices used for disease self-management (e.g. INSPIRE measures and measures of quality of life, fear of hypoglycemia, diabetes distress) (2). The usability of high-risk medical devices for diabetes care is extensively investigated by a separate task within CORE-MD.

Data synthesis

Using descriptive statistics, we summarized study characteristics for the overall sample of studies and for each device class separately. Summary measures of normally distributed continuous variables were reported as mean and standard deviation. Summary measures of non-normally distributed continuous variables were reported as median and interquartile range (IQR). Categorical data were summarized using counts with percentages, and summary tables were used to present the results of the included studies.

Statistical analyses

The statistical analyses were performed in Stata version 15.1 (StataCorp LLC, Texas, USA). We considered p-values lower than 0.05 as statistically significant.

References

1. Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745. https://healtheceuropaeu/system/files/2022-11/md_mdcg_2020-10-1_guidance_safety_reporting_enpdf (Date last accessed 05022023).
2. Weissberg-Benchell J, Shapiro JB, Hood K, Laffel LM, Naranjo D, Miller K, et al. Assessing patient-reported outcomes for automated insulin delivery systems: the psychometric properties of the INSPIRE measures. Diabetic Medicine : a journal of the British Diabetic Association. 2019;36(5):644-52.

Appendix 3

Tools for quality assessment

Appendix 3a

Randomized clinical trials. The quality of evidence of randomized clinical trials (including parallel and cross-over design) was assessed using version 2 of the Cochrane Risk of Bias Assessment Tool, which is based on 5 domains. Domain 1 evaluates bias arising from the randomization process; domain 2 evaluates bias due to deviations from intended interventions; domain 3 evaluates bias due to missing outcome data; domain 4 evaluates bias in measurement of the outcome; domain 5 evaluates bias in selection of the reported result.

Reference publication: Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ (Clinical research ed). 2019;366:l4898.

Reference links: Risk of bias tools (google.com) Risk of bias tools - RoB 2 tool (google.com)

Appendix 3b

Observational studies. The quality of evidence of observational studies was assessed using the Newcastle Ottawa Scale, which is based on three domains, including selection of participants, comparability of study groups, and ascertainment of the outcomes of interest. Each study can be awarded a maximum of nine stars. Based on the thresholds for converting the NOS scores into the Agency for Healthcare Research and Quality (AHRQ) standards, the quality of the studies and risk of bias were categorized as follows: (I) Good quality and low risk of bias: 3 or 4 stars in the selection domain, AND 1 or 2 stars in the comparability domain, AND 2 or 3 stars in the outcome domain. (II) Fair quality and moderate risk of bias: 2 stars in the selection domain, AND 1 or 2 stars in the comparability domain, AND 2 or 3 stars in the outcome domain. (III) Poor quality and high risk of bias: 0 or 1 star in the selection domain, OR 0 star in the comparability domain, OR 0 or 1 stars in the outcome domain. An adapted Scale from the Newcastle-Ottawa quality assessment scale for cohort studies can be found below.

Selection (max 4 stars)

1) *Representativeness of the exposed cohort*
   a. Truly representative of the average in the target population (all subjects or random sampling) *
   b. Somewhat representative of the average in the target population (non-random sampling) *
   c. Selected group of users
   d. No description of the derivation of the cohort
2) *Sample size*
   a. Justified and satisfactory*
   b. Not satisfied
3) *Ascertainment of the exposure (risk factor)*
   a. Secure record (e.g., medical records) *
   b. Structured interview*
   c. Written self-report
   d. No description the measurement tool
4) *Non-respondents*
   a. Comparability between respondents and non-respondents characteristics is established, and the response rate is satisfactory*
   b. The response rate is unsatisfactory, or the comparability between respondents and non-respondents is unsatisfactory
   c. No description of the response rate or the characteristics of the respondents and the non-respondents

Comparability (max 2 stars)

1) *The subjects in the different outcome groups are comparable, based on the study design and analysis. Confounding factors are controlled.*
    a. Study controls for the most important factors (age, sex) *
    b. Study controls for additional relevant factors**
    c. Inadequate degree of control

Outcome (max 3 stars)

1) *Assessment of the outcome*
    a. Definition of AF is in line with the current guidelines **
    b. Definition of AF is provided, but not in line with the current guidelines *
    c. No definition of AF is provided

2) *Statistical test*
    a. The statistical test used to analyze the data is clearly described and appropriate, and the measurement of the association is presented, including the probability level (p-value) *
    b. The statistical test is not appropriate, not described or incomplete.

Appendix 3c

Non-randomized interventional studies with no control group. The quality of evidence of non-randomized interventional studies with no control group was assessed using the validated National Institute of Health assessment tool for Before-After (Pre-Post) studies without control group, with is based on 12 domains.

Domain 1: Was the study question or objective clearly stated?
Domain 2: Were eligibility criteria for the study population prespecified and clearly described?
Domain 3: Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?
Domain 4: Were all eligible participants that met the prespecified entry criteria enrolled?
Domain 5: Was the sample size sufficiently large to provide confidence in the findings?
Domain 6: Was the intervention clearly described and delivered consistently across all study participants?
Domain 7: Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?
Domain 8: Were the people assessing the outcomes blinded to the participants' intervention?
Domain 9: Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?
Domain 10: Did the statistical methods examine changes in outcome measures «from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?
Domain 11: Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention
Domain 12: If the intervention was conducted at a group level, did the statistical analysis take into account the use of individual-level data to determine effects at the group level?
Each study can be awarded a maximum of 12 points. Risk of bias was categorized as follows: 8–12 points indicated low risk, 5–7 points indicated moderate and 1–4 indicated high risk of bias.
Reference link: https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools

Appendix 4

Studies including overlapping populations

Ekhlaspour et al [PMID 31099946] included 48 participants in a setting of ski diabetes camp. Forlenza et al [PMID 30888835] included 24 participants from the study of Ekhlaspour [PMID 31099946], who were investigated further in a home seting.

Petrovski et al [PMID 33044604] is an study including 30 participants, followed-up over 1 year. Petrovski et al [PMID 31953687] is a study including 30 participants followed-up over 3 months. Both studies were performed in the same participants. Petrovski et al [PMID 33044604] is a continuation of Petrovski et al [PMID 31953687]

Beato-Vibora et al [PMID 33784187] is a study performed in 52 participants, followed-up over 4 weeks. Beato-Vibora et al [PMID 34329691] is a study performed in 52 participants, followed-up over 13 weeks. Both studies were performed in the same participants, with different follow-up times.

Breton et al [PMID 32846062 is a randomized clinical trial performed in 101 participants. Kanapka et al [PMID 33355258] is a randomized clinical trial performed performed in 100 participants. The studies are performed in overlapping populations.

Lendínez-Jurado et al [PMID 37959415] and Lendínez-Jurado et al [PMID 37337407] are performed in the same population. Lendínez-Jurado et al [PMID 37959415 has a follow-up time of 3 months and is focused on an analysis stratified by age categories. Lendínez-Jurado et al [PMID 37337407 has a follow-up time of 6 months.

Petrovski et al [PMID 35072781] and Petrovski et al [PMID 35351095] were performed in the same population.

Brown et a [PMID 31618560] and Isganaitis et al[PMID 33216667] were performed in overlapping populations. Isganaitis et al [PMID 33216667] included a subgroup of participants from Brown et al [PMID 31618560].

DeSalvo et al [PMID 38277156] and Sherr et al [PMID 35678724] were performed in the same population. DeSalvo et al [PMID 38277156] had a longer follow-up time.

Boucsein et al [PMID 36689621] and Michaels et al [PMID 37823890] were performed in the same population. Michaels et al [PMID 37823890] had a longer follow-up time.