Boucher, 2020

Bibliographic Reference	Boucher, Sara E.; Galland, Barbara C.; Tomlinson, Paul A.; Rose, Shelley; Gray, Andrew R.; Wiltshire, Esko J.; de Bock, Martin I.; Mackenzie, Karen E.; Rayns, Jenny A.; Chan, Huan; Wheeler, Benjamin J.; Effect of 6 months of flash glucose monitoring in youth with type 1 diabetes and high-risk glycemic control: A randomized controlled trial; Diabetes Care; 2020; vol. 43 (no. 10); 2388-2395

Study details

Secondary publication of another included study- see primary study for details	
Other publications associated with this study included in review	
Trial registration number and/or trial name	ACTRN12618000320257
Study type	Randomised controlled trial (RCT)
Study location	New Zealand
Study setting	multi-centre
Study dates	April 2018 - May 2019
Inclusion criteria	Age 13-20 years Duration of diabetes

	>= 12 months HbA1c level >=9% 6 months prior to enrolment
Exclusion criteria	Previous CGM use Current or in previous 4 months (not including intermittent hospital or clinic based use) Comorbidity any severe diabetes related complication, other uncontrolled medical comorbidity Pregnancy
Intervention(s)	
Outcome measures	HbA1c (%) + mmol/mol % of CGM data captured Glucose monitor checks / day Adverse events DKA Severe hypoglycemia Hospitalisations QoL (validated tools) PedsQL generic PedsQL Diabetes HFS DTSQ
Number of participants	64
Type of insulin delivery system	MDI 55 (86) CSII 9 (14)
SMBG checks per day	1.9 +/- 2.7
CGM use per day	

Duration of follow-up	3 months 6 months
Loss to follow-up	3 months -1 6 months - 0
Methods of analysis	ITT (subset: pp)

Study arms

isCGM (N = 33)
FreeStyle Libre system; Abbott Diabetes Care - 1 additional visit with sensor education

SMBG (N = 31)
Self-monitored blood glucose concentrations using their usual glucometer.

Characteristics

Arm-level characteristics

Characteristic	isCGM (N = 33)	SMBG (N = 31)
% Female Nominal	16	15
Mean age (SD) Mean (SD)	16.5 (1.9)	16.7 (2.2)
BMI (z score) Mean (SD)	0.67 (1.05)	0.73 (0.96)
Time since diabetes diagnosis (years) Mean (SD)	7 (3.5)	8 (4)

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Normal RCT - CYP

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(In line with T1 guideline, knowledge of treatment for subjective markers was seen as one intended consequence of intervention and thus study not marked down for this.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(per protocol analysis conducted for HbA1c but not used to replace ITT and not significant)*
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable *(Inclusion criteria 13-20 years)*

Burckhardt, 2018

Bibliographic Reference	Burckhardt, Marie-Anne; Roberts, Alison; Smith, Grant J; Abraham, Mary B; Davis, Elizabeth A; Jones, Timothy W; The Use of Continuous Glucose Monitoring With Remote Monitoring Improves Psychosocial Measures in Parents of Children With Type 1 Diabetes: A Randomized Crossover Trial.; Diabetes care; 2018; vol. 41 (no. 12); 2641-2643

Study details

Trial registration number and/or trial name	ACTRN12616000463471
Study type	Crossover RCT

Study location	Australia
Study setting	At home with visits to children's hospital
Study dates	
Sources of funding	This work was performed at the Children's Diabetes Centre in Perth, a JDRF/National Health and Medical Research Council–funded Centre of Research Excellence (APP1078190).
Inclusion criteria	People with T1D + 1 parent Age 2 - 12 Duration of diabetes More than 1 year No previous CGM use last 6 months
Outcome measures	QoL (validated tools) PArental HFS PedsQL generic PedsQL diabetes Dass STAI PSQI
Number of participants	49
Type of insulin delivery system	MDI 20 (36%) CSII 29 (64%)
CGM use per day	minimum of 80% over 2 weeks
Duration of follow-up	3 months

Loss to follow-up	0
Methods of analysis	Continuous outcomes were analyzed using linear mixed models. Least squares means (LSM), based on the fixed terms in the model, and differences in LSM along with their 95% CIs were calculated. To analyze the change in frequency of SMBG, a generalized linear mixed model with a negative binomial distribution and log link was used. All data were analyzed on an intent-to-treat basis.P values,0.05 were considered statistically significant.
Additional comments	Most parents chose a low alert between 3.1 and 5.3 mmol/L and a high alert between 8.0 and 20.0 mmol/L

Study arms

rtCGM (N = 49)
Dexcom G5 mobile CGM system

SMBG (N = 49)
conventional blood glucose monitoring

Characteristics

Study-level characteristics

Characteristic	Study (N = 49)
% Female Nominal	31
Mean age (SD) Mean (SD)	9.5 (1.9)
Time since diabetes diagnosis (years) Mean (SD)	3.9 (2.5)
HbA1c (%)	7.7 (0.7)

Characteristic	Study (N = 49)
Mean (SD)	

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Cross-over trial - CYP

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2: Risk of bias due to deviations from intended interventions (effect of assignment to intervention)	Risk of bias judgement for deviations from intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low *(In line with T1 guideline, knowledge of treatment for subjective markers was seen as one intended consequence of ntervention and thus study not marked down for this.)*
Domain 5. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Directly applicable

Deiss, 2006

Bibliographic Reference Deiss, D; Hartmann, R; Schmidt, J; Kordonouri, O; Results of a randomised controlled cross-over trial on the effect of continuous subcutaneous glucose monitoring (CGMS) on glycaemic control in children and adolescents with type 1 diabetes.; Experimental and clinical endocrinology & diabetes : official journal, German Society of Endocrinology [and] German Diabetes Association; 2006; vol. 114 (no. 2); 63-7

Study details

Secondary publication of another included study- see primary study for details	
Study location	Berlin, Germany
Study setting	Diabetes outpatient clinic
Study dates	July 2002 to April 2003
Sources of funding	research grant from Medtronic MiniMed Inc., Germany
Inclusion criteria	People with T1D Age "children and adolescents"
Outcome measures	HbA1c (%) mean [take post crossover data only!] Hypoglycaemia >180 [10] 3 months not a crossover % of CGM data captured Adverse events mild local side effects
Type of insulin delivery system	MDI 3 or more
SMBG checks per day	Capillary self-monitoring blood glucose was comparable between the arms A and B (median 175 mg/dl [99 – 260] vs. 191 mg/dl [117 – 320], p = 0.384) without any significant change from baseline (p = 0.776 and p = 0.112, respectively)
Additional comments	v poor crossover study have to treat 1st bit as poor RCT

Study arms

rtCGM (N = 15)

A continuous glucose monitoring system (CGMS, Medtronic MiniMed Inc., Northridge, CA, USA)

SMBG (N = 15)
SMBG only

Characteristics

Arm-level characteristics

Characteristic	rtCGM (N = 15)	SMBG (N = 15)
% Female Nominal	5	9
Mean age (SD) Custom value	Median 10.3 range 2-16	Median 12.4 range 3-16
BMI Custom value	Median 17.6 range 14.6 - 21.8	Median 19.7 range 13.6 - 28.3
Time since diabetes diagnosis (years) Custom value	Median 1.7 range 0.4 - 7.1	Median 2.6 range 0.2 - 6.0

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Normal RCT - CYP

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No information on randomisation)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Concerns due to timepoints being measured in this crossover*

Section	Question	Answer
		feasibility study. Timepoint only take pre-crossover and no data taken after crossover before both arms put on unblinded treatment.)
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(Data not shown at second timepoint prior to both arms being given unblinded treatment. Could be due to nature of feasibility studies but still presents a risk.)*
Overall bias and Directness	Risk of bias judgement	High *(No randomisation data and concerns about timepoints reported compared to study flow. Cannot be used as crossover study as would introduce unit of analysis errors due to only pre crossover data being reported as if a parallel RCT)*
Overall bias and Directness	Overall Directness	Direct

Hommel 2014

Study details

Trial registration number and/or trial name	SWITCH; NCT00598663
Study type	Cross-over randomised controlled trial
Study location	Europe
Study setting	Four adult sites in Europe with experience in the use of insulin pumps and CGM.
Study dates	January 2008 to July 2010
Sources of funding	The study was funded by Medtronic International Trading Sarl, Tolochenaz, Switzerland.
Inclusion criteria	People with T1D Duration of diabetes >1 year Adults Participants were aged <= 18 years

	Treatment with continuous subcutaneous insulin infusion (CSII) therapy with rapid-acting insulin analogues for more than 6 months HbA1c between 7.5% and 9.5% (58.5 and 80.3 mmol/mol) Naive to CGM Had successfully completed a five-question multiple choice test concerning pump therapy and general understanding of diabetes
Exclusion criteria	Hypoglycaemia unawareness (i.e. hypoglycaemia without symptoms) Concomitant chronic illness known to affect diabetes control and any pharmacological treatment that might modify glycaemic values ≥3 incidents of severe hypoglycaemia in the last 12 months
Intervention(s)	"During a 1-month run-in phase, participants used a glucometer (Bayer Ascensia Contour; Bayer Diabetes Care, Basel, Switzerland) and an insulin pump system (Mini-Med Paradigm REAL-Time System; Medtronic, Tolochenaz, Switzerland) able to integrate CGM in the study phase. All participants received structured training on diabetes management and device use and had their knowledge assessed. Each treatment period was 6 months long, with a 4-month washout phase between the two periods. All participants wore a continuous glucose monitor (Guardian REAL-Time Clinical; Medtronic, Tolochenaz, Switzerland), which they were blinded to (the device screen was turned off), for 2 weeks prior to randomisation and prior to crossover. Participants in the Sensor Off arm wore the device for 2 weeks prior to each study visit. No common treatment protocols or fixed algorithms were provided to the centres, and therapy adjustments were made in consultation with participants at clinic visits. Participants were individually encouraged to make self-adjustments to their treatment using real-time CGM values, hyper- and hypoglycaemic alerts and trends, or to incorporate self-monitoring of blood glucose (SMBG) results into treatment adjustments, with written examples of therapy changes provided in the optional patient diary. Participants completed a ten-question test to demonstrate technical knowledge on the pump (4 weeks before randomisation) and a 12-question test on CGM (at visit 1 of the On/Off sequence or visit 6 of the Off/On sequence)."
Outcome measures	PEDs-QL (children and parents) DTSQ
Number of participants	Continuous glucose monitoring Sensor On/Sensor Off N=72 Continuous glucose monitoring Sensor Off/Sensor On N=72
IGNORE	
Type of insulin delivery system	Continuous subcutaneous insulin infusion Insulin pump

Type of insulin regimen	Rapid acting
Duration of follow-up	6 months
Loss to follow-up	Reported for all participants without separate information for adults.
Additional comments	Sensor data for the secondary endpoints were extracted from CareLink Clinical (CareLink Therapy Management System for Diabetes-Clinical, Medtronic, Tolochenaz, Switzerland) during the 15-day period prior to the end-of period (6-month) visit. For the Sensor On arm, 100% sensor use was calculated as the number of days in the Sensor On period multiplied by 288, the maximum number of sensor readings per day. The study also included children but only data from adults was extracted for this evidence review.

Study arms

Continuous glucose monitoring Sensor Off/Sensor On (N = 72)

Guardian REAL-Time Clinical; Medtronic, Tolochenaz, Switzerland

Continuous glucose monitoring Sensor On/Sensor Off (N = 72)

Guardian REAL-Time Clinical; Medtronic, Tolochenaz, Switzerland

Characteristics

Arm-level characteristics

No specific arm level characteristics for children were given.

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) T1 Cross-over trial

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(No information on whether allocation sequence was concealed until participants were enrolled and assigned to interventions.)*

Section	Question	Answer
Domain 2: Risk of bias due to deviations from intended interventions (effect of assignment to intervention)	Risk of bias judgement for deviations from intended interventions (effect of assignment to intervention)	Low *(4 months long enough to lose CGM learning effect? Committee opinion. Unblinded assignment to intervention judged as impossible to avoid and thus not marked down here.)*
Domain 3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(No information on whether allocation sequence was concealed until participants were enrolled and assigned to interventions.)*
Overall bias and Directness	Overall Directness	Directly applicable *(Only data on children was taken from in this study publication.)*

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, 2010

Bibliographic Reference	Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, Group; Beck, Roy W; Lawrence, Jean M; Laffel, Lori; Wysocki, Tim; Xing, Dongyuan; Huang, Elbert S; Ives, Brett; Kollman, Craig; Lee, Joyce; Ruedy, Katrina J; Tamborlane, William V; Quality-of-life measures in children and adults with type 1 diabetes: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring randomized trial.; Diabetes care; 2010; vol. 33 (no. 10); 2175-7

Study details

Secondary publication of another included	Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, Group, Tamborlane, William V, Beck, Roy W et al. (2008) Continuous glucose monitoring and intensive treatment of type 1 diabetes. The New England journal of medicine 359(14): 1464-76

study- see primary study for details	

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, 2008

Bibliographic Reference	Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, Group; Tamborlane, William V; Beck, Roy W; Bode, Bruce W; Buckingham, Bruce; Chase, H Peter; Clemons, Robert; Fiallo-Scharer, Rosanna; Fox, Larry A; Gilliam, Lisa K; Hirsch, Irl B; Huang, Elbert S; Kollman, Craig; Kowalski, Aaron J; Laffel, Lori; Lawrence, Jean M; Lee, Joyce; Mauras, Nelly; O'Grady, Michael; Ruedy, Katrina J; Tansey, Michael; Tsalikian, Eva; Weinzimer, Stuart; Wilson, Darrell M; Wolpert, Howard; Wysocki, Tim; Xing, Dongyuan; Continuous glucose monitoring and intensive treatment of type 1 diabetes.; The New England journal of medicine; 2008; vol. 359 (no. 14); 1464-76

Study details

Other publications associated with this study included in review	Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, Group (2010) Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial. Diabetes care 33(1): 17-22 Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, Group, Beck, Roy W, Lawrence, Jean M et al. (2010) Quality-of-life measures in children and adults with type 1 diabetes: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring randomized trial. Diabetes care 33(10): 2175-7 Tansey, M, Laffel, L, Cheng, J et al. (2011) Satisfaction with continuous glucose monitoring in adults and youths with Type 1 diabetes. Diabetic medicine: a journal of the British Diabetic Association 28(9): 1118-22
Trial registration number and/or trial name	JDRF; NCT00406133
Study type	Randomised controlled trial (RCT)
Study location	US
Study setting	10 participating centres, which included academic, community, and managed care-based practices.
Study dates	February - December 2007
Sources of funding	Supported by grants from the Juvenile Diabetes Research Foundation.
Inclusion criteria	People with T1D

	Duration of diabetes ≥1 year 8 years of age or older Using an insulin pump or receiving at least three daily insulin injections HbA1c level 7.0 to 10.0% Not used continuous glucose monitoring at home in the 6 months leading up to the trial
Intervention(s)	**Continuous glucose monitoring** Each of the devices for CGM consisted of a glucose oxidase–based electrochemical sensor, which was placed subcutaneously and replaced every 3 to 7 days (depending on the type of device), along with a receiver to which interstitial glucose measurements were sent wirelessly and stored. Since the purpose of the study was to evaluate a treatment strategy using the technology of continuous glucose monitoring and not a specific device, a device was assigned to each patient by the clinical centre on the basis of device features and the participants' preferences. Participants were instructed to use the device on a daily basis and to verify the accuracy of the glucose measurement with a home blood glucose meter (provided by the study) before making management decisions, according to the regulatory labelling of the devices. **Intermittent capillary blood glucose monitoring** Participants were given blood glucose meters and test strips and asked to perform home blood glucose monitoring at least four times daily.
Outcome measures	HbA1c Time in range Amount of time per day the glucose level was in the target range (71 to 180 mg per decilitre [3.9 to 10.0 mmol per litre]). Time spent above/below target glucose range Amount of time per day the glucose level was hypoglycaemic (≤70 mg per decilitre or ≤50 mg per decilitre [≤3.9 or ≤2.8 mmol per litre]) or hyperglycaemic (>180 mg per decilitre or >250 mg per decilitre [10.0 or 13.9 mmol per litre]). Hypoglycaemia Severe hypoglycaemia defined as an event that required assistance from another person to administer oral carbohydrate, glucagon, or other resuscitative actions. Glycaemic variability Diabetic ketoacidosis Hyperglycaemia resulting in ketoacidosis. Adverse events Severe hypoglycaemia, ketoacidosis, unexpected study-related or device-related events, and serious adverse events regardless of cause. Quality of life measured by validated tools

	Participants ≥18 years old completed the Hypoglycaemia Fear Survey (HFS) and Social Functioning Health Survey (SF-12) version 2; reported by JDRF (2010). Continuous Glucose Monitoring Satisfaction Scale (CGM-SAT); reported by Tansey (2011).
Number of participants	Continuous glucose monitoring N=52 Intermittent capillary blood glucose monitoring N=46
Type of insulin delivery system	Multiple daily injections (16%) Insulin pump (84%)
Duration of follow-up	26 weeks
Additional comments	Participants completed a run-in phase using a continuous glucose monitor that was modified so that the glucose values were recorded in the receiver but were not visible to the participant; this was referred as a "blinded" continuous glucose monitor. Eligibility required that participants wore a sensor for at least 6 of 7 days before randomisation, with a minimum of 96 hours of glucose values including at least 24 hours overnight, and that home blood glucose monitoring be performed at least three times daily. Data regarding continuous glucose monitoring in both arms after the 26-week visit (blinded monitors in the intermittent capillary blood glucose monitoring arm and unblinded monitors in the continuous glucose monitoring arm) were used to estimate time spent in range, time spent above target glucose range and time spent below target blood glucose range. Type of insulin regimen was not reported.

Study arms

Continuous glucose monitoring (N = 56)

Loss to follow-up	2 participants dropped

Participants were provided with one of the following devices: the DexCom Seven (DexCom), the MiniMed Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System (Medtronic), or the FreeStyle Navigator (Abbott Diabetes Care).

Intermittent capillary blood glucose monitoring (N = 58)

Loss to follow-up	0

Participants were given blood glucose meters and test strips.

Characteristics

Arm-level characteristics

Characteristic	Continuous glucose monitoring Sensor Off/Sensor On (N = 41)	Continuous glucose monitoring Sensor On/Sensor Off (N = 40)
% Female Nominal	48	50
Mean age (SD) (years) Mean (SD)	11.4 (2)	11.6 (2.1)
Time since diabetes diagnosis (kg/m²) Mean (SD)	6.2 (3.1)	5.3 (2.8)

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Normal RCT T1

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(No information on whether allocation sequence was concealed until participants were enrolled and assigned to interventions.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Unblinded assignment to intervention judged as impossible to avoid and thus not marked down here.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Committee discretion regarding the risk of bias for subjective outcomes. Impossible to really blind for intervention in this study.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns *(Unblinded assignment to intervention judged as impossible to avoid and thus not marked down here.)*
Overall bias and Directness	Overall Directness	Directly applicable *(The JDRF trial included children, young people and adults but data was reported separately for adults ≥25 years old.)*

Laffel, 2020

Bibliographic Reference Laffel, Lori M; Kanapka, Lauren G; Beck, Roy W; Bergamo, Katherine; Clements, Mark A; Criego, Amy; DeSalvo, Daniel J; Goland, Robin; Hood, Korey; Liljenquist, David; Messer, Laurel H; Monzavi, Roshanak; Mouse, Thomas J; Prahalad, Priya; Sherr, Jennifer; Simmons, Jill H; Wadwa, R Paul; Weinstock, Ruth S; Willi, Steven M; Miller, Kellee M; CGM Intervention in Teens and Young Adults with T1D (CITY) Study, Group; CDE10; Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial.; JAMA; 2020; vol. 323 (no. 23); 2388-2396

Study details

Secondary publication of another included study- see primary study for details	
Trial registration number and/or trial name	NCT03263494
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	14 endocrinology practices
Study dates	January 2018 - May 2019

Sources of funding	This study was funded by a grant provided by the Leona M. and Harry B. Helmsley Charitable Trust given to the Jaeb Center for Health Research. Dexcom Inc provided nonfinancial support by providing continuous glucose monitoring devices and sensors for the study.
Inclusion criteria	People with T1D Age 14 - 24 No previous CGM use for 3 months Insulin regimen total daily insulin of at least 0.4 units/kg/d HbA1c level >7.5% to <11%
Intervention(s)	
Outcome measures	HbA1c (%) Time in range 70 to 180mg/dL Time above/below target glucose range Time in hyper >180 / >250 Time in hypo Glycemic variability CV Diabetic ketoacidosis % of CGM data captured CGM use days/week hours of CGm data Adverse events Severe hypoglycemia DKA SAE QoL (validated tools) PAID-P GMSS

	Hypoglycemia confidence Sleep quality
Number of participants	153
Type of insulin delivery system	MDI 38 (54%) 32 (41%) CSII CGM: 36 (49%) SMBG: 47 (59%)
SMBG checks per day	
CGM use per day	
Duration of follow-up	26 weeks
Loss to follow-up	0
Methods of analysis	All participants were analyzed according to their randomization group and included in the primary analysis. For the primary analysis, the difference in change in HbA1c from baseline to 26 weeks between the 2 treatment groups was assessed in a longitudinal linear regression model including the HbA1c value at baseline, 13 weeks, and 26 weeks and clinical center as a random effect. Missing data were handled by direct likelihood, which maximizes the likelihood function integrated over possible values of the missing data.

Study arms

CGM (N = 74)
Dexcom G5, Dexcom, Inc

SMBG (N = 79)
Continue BGM with a blood glucose meter without CGM

Characteristics

Arm-level characteristics

Characteristic	CGM (N = 74)	SMBG (N = 79)
% Female Nominal	33	43
Mean age (SD) Mean (SD)	17 (3)	18 (3)
14 - <19 Nominal	48	53
19 - <25 Nominal	26	26
Time since diabetes diagnosis Mean (SD)	9 (5)	10 (5)
Past but not current Nominal	24	30
Never Nominal	50	49

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Normal RCT - CYP

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(In line with T1 guideline, knowledge of treatment for subjective markers was seen as one intended consequence of intervention and thus study not marked down for this.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
Overall bias and Directness	Overall Directness	Partially applicable *(~34% 19 - <25 years old)*

Xu, 2021

Bibliographic Reference Xu, Yuejie; Xu, Lei; Zhao, Weijing; Li, Qing; Li, Ming; Lu, Wei; Zeng, Hui; Pan, Jiemin; Liu, Fang; Yan, Jinhua; Yang, Daizhi; Weng, Jianping; Wu, Wei; Effectiveness of a wechat combined continuous flash glucose monitoring system on glycemic control in juvenile type 1 diabetes mellitus management: Randomized controlled trial; Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy; 2021; vol. 14; 1085-1094

Study details

Trial registration number and/or trial name	ChiCTR1900025495
Study type	Randomised controlled trial (RCT)
Study location	Shanghai, China
Study setting	department of Endocrinology and Metabolism of Shanghai Jiao Tong University Affiliated Sixth People's Hospital
Study dates	Recruitment January 2019 - June 2019
Sources of funding	supported by grants from the National key Research and development program (2017YFC1309601 for Fang Liu), National Science Foundation Items of China (81770802 for Fang Liu), and Shanghai Municipal Education Commission-Gaofeng Clinical Medicine (20152232 for Fang Liu)

Inclusion criteria	People with T1D WHO 1999 criteria Age 10-19 Duration of diabetes >1 year No previous CGM use 3 months before study Insulin regimen use of multiple daily insulin (MDI) and continuous subcutaneous insulin infusion (CSII) for at least 3 months, stable diabetes medication regimen for 3 months before study entry (change in insulin <= 20%), previous documentation of blood glucose level self-monitoring regularly for 2 months (at least three times per day) and willingness to continue for at least 6 months HbA1c level >7 - <10 % Willingness to wear CGM Language Can speak, read, and write Chinese Ability to use WeChat program
Exclusion criteria	Comorbidity severe diabetic complications such as diabetic retinopathy and diabetic nephropathy, recent severe diseases like myocardial infarction, stroke, psychiatric diseases (historical/recent), malignant tumor, kidney disease (defined as eGFR <45), dermatosis, decided by the investigator any condition that could impact the reliability of the HbA1c measurement (eg, hemoglobinopathy, hemolytic anemia, chronic liver disease), decided by the investigator. abuse of illicit drugs, alcohol or prescription drugs Pregnancy Allergy to CGm device or adhesive
Outcome measures	HbA1c (%) Hypoglycaemia number of episodes <3.9mmol

	QoL (validated tools) DMTSQ DQoL CHFSII
Number of participants	80
Duration of follow-up	6 months
Loss to follow-up	Flash = 5 Flash and we chat = 5 SMBg = 10
Methods of analysis	Data with a normal distribution were presented as mean and standard deviations (SD), and data with a non-normal distribution were presented as median with interquartile ranges (IQR). Analyses of variance (ANOVA) and covariance were used for intergroup comparisons of normally distributed data, whereas nonparametric analysis was used for non-normally distributed data.
Additional comments	Really unclear what n they analysed

Study arms

Flash Glucose monitoring (N = 25)

(Libre 1, Abbott Diabetes Care) - A specialist applied the flash glucose monitor to the back of the upper arm through a simple disposable applicator: a thin wire (flexible probe) was subcutaneously implanted, and the sensor was fixed to the application site with an adhesive film. It recorded the blood glucose value at 15-minute intervals automatically, and the blood glucose value can be determined at any time from the display

Flash glucose monitoring with WeChat (N = 25)

n Group C, patients with the Abbott FreeStyle Libre monitor were asked to subscribe to a WeChat Official Account named “KongTangTianDi,” which disseminates scientific diabetes-related information once a week. Furthermore, the WeChat Official Account platform was also used for real-time patient-doctor interactions. A thirdparty health manager was involved in interactive management with patients through the platform. Further, a nurse who specialized in diabetes helped analyze, evaluate, and review the glycemic monitoring data

SMBG (N = 30)
a conventional home glucometer was used to monitor blood glucose ≥ three times a day, and the blood glucose monitoring values were uploaded to the Wenjuan survey platform.

Characteristics

Arm-level characteristics

Characteristic	Flash Glucose monitoring (N = 25)	Flash glucose monitoring with WeChat (N = 25)	SMBG (N = 30)
% Female Nominal	9	13	7
Mean age (SD) Mean (SD)	12.65 (1.73)	13.6 (1.27)	12.65 (1.73)
BMI Mean (SD)	20.01 (2.42)	20.83 (1.71)	20.25 (2.1)
Time since diabetes diagnosis (years) Mean (SD)	2.42 (1.75)	3.33 (2.46)	2.11 (1.82)

Critical appraisal - GUT Cochrane Risk of Bias tool (RoB 2.0) Normal RCT - CYP

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	High *(Unclear whether an ITT or PP analysis was performed, discontinuation rates higher in control arm could be due to participants being unhappy with not receiving treatment.)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Due to unclear analysis type cannot say for sure whether all HbA1c data or QoL data was included.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(In line with T1 guideline, knowledge of treatment for subjective markers was seen as one intended consequence of itnevrentionintervention and thus study not marked down for this.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(No information on whether ITT or PP analysis performed and thus unclear whether analysis is appropriate so high risk.)*
Overall bias and Directness	Overall Directness	Direct *19 year old threshold accepted as acceptable in protocol*