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Health Technology Assessment

Continuous glucose monitoring in type 2 diabetes treated with insulin

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Key messages

Type 2 diabetes (T2D) is a chronic condition in which some individuals require insulin treatment. While self-monitoring of blood glucose (SMBG) is the traditional method for monitoring glucose levels, continuous glucose monitoring (CGM) systems have been introduced as an alternative. However, the advantages of CGM use compared to SMBG in insulin-treated T2D remain uncertain.

We assessed the clinical effectiveness and safety of CGM compared to SMBG in individuals with insulin-treated T2D. Additionally, we evaluated cost-effectiveness, calculated budget impact, analysed implications for healthcare personnel requirements related to the implementation of CGM, considered organisational implications, and patient perspectives.

We included nine randomised controlled trials (RCTs) and three non-RCTs, all involving participants with poorly controlled insulin-treated T2D. Relevant outcomes are summarised below, along with our assessment of the confidence in the results. Among individuals with uncontrolled, insulin-treated T2D, compared to SMBG:

- CGM probably reduces HbA1c levels (RCTs: moderate certainty), but not sufficiently to reach the predefined threshold for a minimal clinically important difference.
- It is uncertain whether there is a difference in severe hypoglycaemia between CGM and SMBG (RCTs: very low certainty).
- CGM probably increases the time spent in the glycaemic target range (TIR) (RCTs: moderate certainty).
- CGM probably reduces hospitalisations for stroke, myocardial infarction, and heart failure for patients followed up in specialist healthcare services (non-RCT data: moderate certainty).

For the entire insulin-treated T2D population, the use of CGM may result in an increase in costs without clear extra health benefits.

For insulin-treated T2D patients requiring specialist follow-up, CGM use provides an incremental health benefit (0.34 quality-adjusted life years; QALYs) at an additional cost of NOK [redacted] resulting in an incremental cost-effectiveness ratio of NOK [redacted] per QALY. This result is based on the assumption that the clinical benefits persist with long-term and consistent use. However, a shorter time horizon leads to less cost-effectiveness results ([redacted] for a 5-year time horizon).

An insulin-treated T2D patient requiring specialist follow-up at age 67 years using SMBG would have an absolute prognosis loss of 5.38 good life years.

Over five years (2026-2030), the additional costs for the Regional Health Authorities (RHAs) associated with implementing and following up CGM within the specialist healthcare sector were estimated to range from NOK [redacted]. For a larger population of insulin-treated individuals with T2D using multiple daily injections, the total cost of implementing CGM for RHAs was estimated between NOK [redacted] in 2026 and NOK [redacted] in 2030 based on the collaboration between the specialist and primary healthcare sectors.

National implementation of CGM may require 21–32 specialist nurses full-time equivalents (FTEs) for specialist healthcare or a total of 91-128 FTEs for collaboration between the specialist and primary healthcare.

Title:
Continuous glucose monitoring in type 2 diabetes treated with insulin: a Health Technology Assessment

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Publisher:
Norwegian Medical Products Agency conducted the HTA based on a commission from the Ordering Forum

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When was the literature search conducted?

November 2024 and February 2025 (seach in trial registries)

Executive summary

Introduction

Type 2 diabetes (T2D) is a chronic condition characterised by persistently elevated blood glucose levels and disruptions in energy metabolism. Achieving and maintaining glycaemic control is important for managing this condition, alongside addressing other key factors, such as hypertension, dyslipidaemia, and obesity. Treatment typically involves lifestyle modifications, such as following a healthy diet and engaging in regular physical activity, often combined with oral blood glucose-lowering medications, injection of GLP-1 analogues, and, when necessary, insulin therapy.

Regular monitoring of blood glucose levels is recommended in insulin-treated T2D. The conventional method for measuring blood glucose levels is self-monitoring of blood glucose (SMBG) using a blood glucose meter. However, continuous glucose monitoring (CGM) systems has demonstrated favourable results in managing type 1 diabetes (T1D) when also considering the resource utilisation. It remains uncertain whether comparable benefits of CGM over SMBG can be achieved in individuals with insulin-treated T2D.

Objectives

The aims of this health technology assessment (HTA) were to:

- evaluate the clinical effectiveness and safety of CGM compared to SMBG in individuals with insulin-treated T2D
- assess the health economic consequences, including both a cost-utility analysis and a budget impact analysis for specialist healthcare and the overall healthcare system, as well as relevant subpopulations
- analyse the implications for healthcare personnel requirements associated with the implementation of CGM
- describe the organisational implications of introducing CGM in the Norwegian healthcare system
- summarise patient experiences with CGM

Methodology

We conducted a systematic search of medical databases and trial registries to identify relevant randomised controlled trials (RCTs) and non-RCTs. Our inclusion criteria focused on adults aged 18 years or older with insulin-treated T2D, comparing the use of CGM with SMBG. The outcomes assessed included measures of clinical effectiveness and safety. We evaluated the risk of bias for RCTs and non-RCTs on the outcome level. When feasible, we synthesised data through meta-analyses. We assessed the certainty of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. We applied the minimal clinically important difference (MCID) thresholds of 5.5 mmol/mol for HbA1c and 5% for TIR, as suggested by the National Institute for Health and Care Excellence. The expert group identified subgroups of interest, including individuals with insulin-treated T2D who experience recurrent or severe hypoglycaemia, have intellectual disabilities, are planning pregnancy, are currently pregnant, or are in the postpartum period.

We did not identify data for diabetes-related late complications for the entire insulin-treated T2D individuals. Therefore, the outcomes were insufficient to perform a model-based analysis for this population. Consequently, the relationship between health benefits and resource use related to the introduction of CGM for the entire population of insulin-treated T2D was assessed based on the results of the systematic review, using HbA1c as a surrogate endpoint.

To assess the cost-effectiveness of CGM compared to SMBG in individuals with insulin-treated T2D who need clinical follow-up at the specialist healthcare, a decision-analytic model was developed. The analysis was conducted as a cost–utility analysis from an extended healthcare perspective within the

Norwegian context, applying a lifetime time horizon. Efficacy estimates were derived from a recently published Swedish registry study that directly compared the effects of CGM versus SMBG on both acute and late diabetes-related complications. Transition probabilities and quality-of-life data were obtained from published sources. The costs of CGM were based on the latest procurement price provided by the Norwegian Hospital Procurement Trust, while other costs were derived from official Norwegian unit prices. To address parameter uncertainty, sensitivity and scenario analyses were performed.

Disease severity was assessed using the absolute shortfall approach, which estimates the expected loss of healthy life years (quality-adjusted life years; QALYs) due to illness compared with the general population. Further, we conducted a budget impact analysis to estimate the additional costs associated with implementing CGM compared to SMBG over a five-year period. The analysis included relevant costs related to glucose monitoring methods and additional healthcare personnel requirements for initiation, training, and device follow-up. Two organisational models were assessed, using different assumptions about the number of eligible patients and collaboration between the specialist and primary healthcare sectors. The budget impact was estimated for both the overall insulin-treated T2D individuals and predefined subpopulations.

The impact of implementing CGM on healthcare personnel demand was assessed by estimating incremental labour requirements, expressed in full-time equivalents (FTEs). Estimates were based on data on FTE utilisation per patient for both the new and current interventions and the number of eligible patients. The impact of implementing CGM on healthcare personnel demand was estimated for both organisational models: Model 1, with all activities conducted within specialist healthcare, and Model 2, involving collaboration between specialist and primary healthcare sectors.

We described the organisational implications based on input from the expert group, relevant guidelines and literature, as well as current practices for CGM allocation in Norway. The Norwegian Diabetes Association provided input regarding patient experiences.

Results

Relative effectiveness and safety

We included 12 unique studies reported in 13 publications: nine RCTs and three non-RCTs. The studies were published between 2016 and 2024 and included a total of 1,119 participants in the RCTs and 166,884 in the non-RCTs. Participants' average age at baseline was approximately 61 years, while the average duration of T2D at baseline was approximately 16 years. The mean baseline HbA1c level was approximately 70 mmol/mol (8.6%), indicating suboptimal or poorly controlled diabetes. All studies received industry funding.

For individuals with poorly controlled, insulin-treated T2D, the main outcomes are:

HbA1c
CGM probably reduces HbA1c compared to SMBG in individuals with poorly controlled blood glucose (RCTs: mean difference (MD): -2.19 mmol/mol; 95% confidence interval (CI): -3.92 to -0.47; moderate certainty), but not sufficiently to meet the predefined MCID threshold of 5.5 mmol/mol.

Severe Hypoglycaemia
It is uncertain whether there is difference in severe hypoglycaemia between CGM and SMBG because the results are based on very low certainty evidence (RCTs: risk ratio: 2.53; 95% CI: 0.53 to 12.10; very low certainty).

Time in range
CGM probably increases time in range (TIR) compared to SMBG (RCTs: MD: 5.5%; 95% CI: 1.68 to 9.32; moderate certainty). While the mean TIR increase surpasses the MCID threshold of 5%, the confidence interval includes values below this threshold, indicating some uncertainty about whether the increase consistently meets the predefined MCID.

Time below range
It is uncertain whether CGM reduces time below range (TBR) compared to SMBG because the results are based on very low certainty evidence (RCTs: TBR <3.9 mmol/L threshold: MD: -0.86%; 95% CI: -1.40 to -0.33; very low certainty, and TBR ≤3.0 mmol/L threshold (MD: -0.34%; 95% CI: -0.69 to 0.02; very low certainty).

Time above range
There is probably no difference in time above range (TAR) at the >10.0 mmol/L threshold between CGM and SMBG (RCTs: MD: -2.36%; 95% CI: -5.55 to 0.83, moderate certainty) but CGM may reduce TAR at the >13.0 mmol/L threshold (RCTs: MD: -4.07%; 95% CI: -7.67 to -0.47; low certainty).

Quality of Life
There may be no difference in quality of life between CGM and SMBG (RCTs: standardised mean difference: 0.1; 95% CI: -0.24 to 0.45; low certainty).

Diabetes-related late vascular complications
It is uncertain whether there is a difference in diabetes-related late vascular complications between CGM and SMBG because the results are based on very low certainty evidence (RCTs: overall very low certainty).

Evidence from one non-RCT suggests that CGM probably reduces diabetes-related late vascular complications compared to SMBG in individuals receiving follow-up care in the specialist healthcare services (non-RCT: overall moderate certainty).

Safety related to the CGM device
CGM demonstrated a favourable safety profile in RCTs, with mild to moderate skin reactions as the most reported adverse events in RCTs.

Subgroup assessment

None of the included studies specifically investigated the effectiveness of CGM compared to SMBG in the predefined subgroups.

Health economic evaluation of prioritisation criteria

Using HbA1c as a surrogate outcome, no clinically meaningful difference was observed between CGM and SMBG for individuals with uncontrolled insulin-treated T2D. Considering the higher cost of CGM compared to SMBG, the introduction of CGM may result in higher costs without clear additional health benefits for the entire insulin-treated T2D population.

The health economic analysis indicated that CGM provides extra health benefits compared with SMBG, with an incremental gain of 0.34 QALYs and additional costs of approximately NOK [redacted], resulting in an incremental cost-effectiveness ratio (ICER) of about NOK [redacted] per QALY gained for insulin-treated T2D patients requiring specialist follow-up at the hospital. The cost-effectiveness of CGM is strongly dependent on user adherence and sustained impact on reducing diabetes-related complications. The cost-effectiveness results were therefore most sensitive to shorter time perspectives, resulting in an ICER of approximately [redacted] per QALY (a 5-year time horizon). Sensitivity analyses confirmed that results were also sensitive to assumptions about device costs, the cost of managing late complications, such as end-stage renal disease, and mortality risk associated with advanced complications.

An insulin-treated T2D patient requiring specialist follow-up at age 67 years using the current glucose measuring method (SMBG) would have an absolute prognosis loss of 5.38 good life years (QALY).

The budget impact analysis estimated additional costs of NOK [redacted] over five years for individuals requiring specialist follow-up within the specialist healthcare. For predefined subpopulations, we have estimated the total costs to be around NOK [redacted] in 2026 and NOK [redacted] in 2030. These estimates would have a limited financial impact on the Regional Health Authorities (RHAs), as a subset of insulin-treated T2D patients already use CGM under the current group exemption scheme. However, expanding access to a larger population of insulin-treated T2D

individuals using multiple daily injections, through collaboration between the specialist and primary healthcare sectors, would increase the total costs of implementing CGM for the RHAs between NOK [redacted] in 2026 and NOK [redacted] in 2030.

Implementation of CGM for insulin-treated T2D individuals may require 21–32 FTE specialist nurses within the specialist healthcare sector, or a total of 91–128 FTEs under a collaborative model between specialist and primary healthcare sectors for a larger population of insulin-treated T2D individuals using multiple daily injections.

Organisational implications

In Norway, CGM is allocated by diabetes teams within specialist healthcare services to eligible candidates with both T1D and T2D, under the current group exemption for T2D. The expert group emphasised that the allocation of CGM for individuals with insulin-treated T2D should remain the responsibility of the specialist healthcare sector, as is currently the case. Successful implementation will require effective patient training and ongoing follow-up. Additionally, it will be important to establish clear criteria to identify the most suitable candidates for CGM use.

Patient experiences

The Norwegian Diabetes Association emphasised that insulin-treated T2D impacts individuals' quality of life physically, mentally, socially, and economically. According to the Association, CGM can help individuals by improving disease management, reducing stress, and enhancing safety. As such, the Norwegian Diabetes Association advocates for expanded access to CGM for individuals with insulin-treated T2D who are undergoing multiple daily injection therapy with insulin or using 1–2 doses of long-acting insulin and experiencing recurrent hypoglycaemia that cannot be resolved through adjustments to their treatment. They added that CGM should also be used as an educational tool for certain individuals with T2D. Furthermore, they stressed the importance of tailoring solutions to meet the needs of vulnerable groups, including older adults, individuals with low health literacy, and immigrants.

Discussion

This HTA provided the first Norwegian health economic evaluation of using CGM for insulin-treated T2D, directly incorporating diabetes-related late complications rather than relying solely on HbA1c.

The results of the health economic analysis are sensitive to key assumptions regarding long-term adherence, persistence of glycaemic benefit, and the time horizon used to capture clinical effects. Shorter follow-up periods substantially reduce the estimated health benefits and increase the cost per QALY, highlighting the importance of sustained use for achieving cost-effectiveness. Uncertainty remains around several model parameters, including the long-term risk of complications, mortality, and quality-of-life effects in insulin-treated patients with T2D.

The health economic model relied on data from a large Swedish registry study rather than randomised controlled trials, which may introduce residual confounding. Norwegian data on complications and mortality risks were not available, requiring the use of evidence from comparable European sources. These limitations, along with assumptions related to workforce capacity and future treatment pathways, should be considered when interpreting the results and their implications for implementation within the Norwegian healthcare system.

Specialist nurse full-time equivalents for the introduction of CGM were estimated at the national level, but data on hospital-level requirements were not accessible and depend on both existing resource capacity and how each hospital organises its workforce.

Continued data collection from Norwegian registries and real-world practice will be essential to refine estimates of clinical benefit, resource use, and workforce needs in future evaluations.

Conclusion

According to RCT data, CGM may offer certain advantages over SMBG for adults with poorly controlled, insulin-treated T2D, particularly in improving TIR. However, evidence for most other outcomes was uncertain or showed little to no relevant difference between CGM and SMBG. Non-RCT data suggest that CGM use may provide potential vascular benefits for individuals with uncontrolled, insulin-treated T2D who are managed in specialist healthcare services, compared to SMBG, after adjustment for relevant confounding factors. No evidence was identified related to the predefined subgroups.

CGM may provide additional health benefits at an increased cost for selected insulin-treated T2D individuals, with long-term gains likely outweighing costs for those requiring specialist follow-up. The cost-effectiveness of CGM depends on long-term adherence and sustained clinical benefit.

Introducing CGM for insulin-treated individuals with T2D will increase resource requirements and demand for healthcare personnel, particularly specialist nurses. The budgetary impact for the Regional Health Authorities will therefore depend on how CGM follow-up is organised and the extent of patient uptake. When limited to the currently prioritised individual groups, implementation is expected to formalise existing practice rather than impose substantial new financial or organisational burdens on the healthcare system.

Hovedbudskap (Norwegian key messages)

Diabetes type 2 (T2D) er en kronisk sykdom der noen personer har behov for insulinbehandling. Selv om egenmåling av blodglukose (SMBG) er den tradisjonelle metoden for å overvåke blodglukosenivået, har kontinuerlige vevsglukosemålingssystemer blitt introdusert som et alternativ. Fordelene med kontinuerlig vevsglukosemåling sammenlignet med SMBG hos personer med insulinbehandlet T2D er imidlertid usikre.

Vi vurderte klinisk effekt og sikkerhet av kontinuerlige glukosemålere sammenlignet med SMBG. I tillegg evaluerte vi kostnadseffektivitet, beregnet budsjettpåvirkning, analyserte implikasjoner for helsepersonellbehov knyttet til innføring av kontinuerlige glukosemålere, vurderte organisatoriske konsekvenser og brukerperspektiver.

Vi inkluderte ni randomiserte forsøk (RCT-er) og tre ikke-RCT-er, alle med deltakere som hadde dårlig regulert glukose ved insulinbehandlet T2D. Relevante resultater er presentert under sammen med vår vurdering av tiltro til resultatene.

Resultatene for personer med dårlig regulert, insulinbehandlet T2D var:

- Bruk av kontinuerlige vevsglukosemålere kan muligens redusere HbA1c-nivåer sammenlignet med SMBG (RCT data: moderat tillit), men ikke tilstrekkelig til å nå den forhåndsdefinerte terskelen for en minimalt klinisk viktig forskjell.
- Det er usikkert om det er forskjell i alvorlig hypoglykemi mellom kontinuerlige vevsglukosemålere og SMBG (RCT data: svært lav tillit).
- Bruk av kontinuerlige vevsglukosemålere kan trolig øke tid i glukosemålområdet sammenlignet med SMBG (RCT data: moderat tillit).
- Bruk av kontinuerlige vevsglukosemålere kan trolig redusere sykehusinnleggelser for hjerneslag, hjerteinfarkt og hjertesvikt sammenlignet med SMBG hos personer som følges opp i spesialisthelsetjenesten (moderat tillit basert på data fra en registerstudie*)*.

For alle insulinbehandlede T2D-pasienter fører muligens bruken av kontinuerlige vevsglukosemålere til økte kostnader uten tydelige tilleggseffekter på helse

For personer med T2D som behandles med insulin og følges opp i spesialisthelsetjenesten gir kontinuerlige vevsglukosemålere en inkrementell helseeffekt på 0,34 kvalitetsjusterte leveår (QALYs) til en merkostnad på [redacted] kroner, noe som resulterer i en kostnad på om lag [redacted] kroner per vunnet QALY. Resultatet er basert på forutsetningen om at de kliniske fordelene opprettholdes ved langvarig og konsekvent bruk. På kortere sikt blir imidlertid kostnadseffektiviteten redusert ([redacted] for en tidshorisont på 5 år).

En 67 år gammel insulinbehandlet T2D-pasient som trenger oppfølging fra spesialist og benytter SMBG har et absolutt prognosetap på 5,38 gode leveår.

Over en femårsperiode (2026-2030) er de anslåtte kostnadene for de regionale helseforetakene (RHF-ene) knyttet til implementering og oppfølging av kontinuerlige vevsglukosemålere i spesialisthelsetjenesten beregnet til mellom [redacted] kroner. For en større populasjon av personer med T2D som behandles med flere daglige insulininjeksjoner er kostnadene for RHF-ene beregnet til mellom [redacted] kroner i 2026 og [redacted] kroner i 2030, basert på en samarbeidsmodell mellom spesialist- og primærhelsetjenesten.

Nasjonal implementering av kontinuerlige vevsglukosemålere kan kreve mellom 21 og 32 spesialsykepleierårsverk i spesialisthelsetjenesten, eller totalt mellom 91 og 128 årsverk ved en samarbeidsmodell mellom spesialist- og primærhelsetjenesten.

Tittel:
Kontinuerlig vevsglukosemåling ved diabetes type 2 som behandles med insulin: en fullstendig metodevurdering

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Hvem står bak denne publikasjonen?
Direktoratet for medisinske produkter, på oppdrag fra Bestillerforum for nye metoder

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Når ble litteratursøket utført?
November 2024 og februar 2025 (studieregistersøk)

Sammendrag (Norwegian summary)

Innledning

Diabetes type 2 (T2D) er en kronisk sykdom som kjennetegnes av vedvarende høye blodglukosenivåer og forstyrrelser i energimetabolismen. Å oppnå og opprettholde best mulig glykemisk kontroll er viktig for god sykdomshåndtering. Like viktig er det å behandle andre følgetilstander, som hypertensjon, dyslipidemi og fedme. T2D-behandlingen innebærer hovedsakelig livsstilsendringer, som å følge et sunt kosthold og delta i regelmessig fysisk aktivitet, ofte i kombinasjon med orale blodglukosesenkende medikamenter, injeksjon av GLP-1 analoger og, ved behov, insulinbehandling.

Regelmessig måling av blodglukosenivåer anbefales for personer med insulinbehandlet T2D. Den tradisjonelle metoden for å måle blodglukose er egenmåling av blodglukose (SMBG) ved hjelp av et blodglukoseapparat. Kontinuerlige vevsglukosemålingssystemer har vist gode resultater i sykdomshåndtering blant personer med diabetes type 1 (T1D) når det også tas hensyn til ressursbruk. Det er usikkert om sammenlignbare fordeler ved bruk av kontinuerlige vevsglukosemålere sammenlignet med SMBG kan oppnås hos personer med insulinbehandlet T2D.

Hensikt

Målet med denne metodevurderingen var å:

- vurdere klinisk effekt og sikkerhet av kontinuerlige vevsglukosemålere sammenlignet med SMBG hos personer med insulinbehandlet T2D
- vurdere de helseøkonomiske konsekvensene, inkludert både en kostnadseffektivitetsanalyse og en budsjettkonsekvensanalyse for spesialisthelsetjenesten og den samlede helsetjenesten og relevante subpopulasjoner, samt implikasjoner for behovet for helsepersonell ved implementering av kontinuerlige vevsglukosemålere
- vurdere organisatoriske konsekvenser ved å introdusere kontinuerlige vevsglukosemålere i til personer med insulinbehandlet T2D
- oppsummere brukernes erfaringer med kontinuerlige vevsglukosemålere

Metodikk

Vi gjennomførte systematiske søk i medisinske databaser og studieregisterdatabaser for å identifisere relevante randomiserte kontrollerte forsøk (RCT-er) og ikke-RCT-er. Inklusjonskriteriene inkluderte voksne i alderen 18 år eller eldre med insulinbehandlet T2D, der bruk av kontinuerlige vevsglukosemålere ble sammenlignet med SMBG. Utfallsmålene var klinisk effekt og sikkerhet. Vi vurderte risiko for skjevhet i studiene på utfallsnivå. Data ble sammenstilt i metaanalyser der dette var hensiktsmessig. Vi vurderte tiltro til resultatene ved hjelp av GRADE-rammeverket (Grading of Recommendations Assessment, Development and Evaluation). Vi benyttet 5,5 mmol/mol for HbA1c og 5 % for tid i glukoseområdet (TIR) som terskelverdier for minimal klinisk viktig forskjell som foreslått av the National Institute for Health and Care Excellence. Ekspertgruppen forhåndsdefinerte undergrupper som kan ha spesiell nytte av kontinuerlige vevsglukosemålere. Disse inkluderer personer med insulinbehandlet T2D som opplever tilbakevendende eller alvorlig hypoglykemi, har utviklingshemming, planlegger graviditet, er gravide eller er i postpartumperioden.

Vi identifiserte ikke data knyttet til diabetes-relaterte senkomplikasjoner for hele populasjonen av insulinbehandlede T2D. Derfor var resultatene ikke tilstrekkelige til å gjennomføre en modellbasert analyse for denne populasjonen. Forholdet mellom nytte og ressursbruk ved eventuelt innføring av CGM for hele populasjonen av insulinbehandlede T2D-pasienter ble dermed vurdert basert på resultatene fra den systematiske oversikten, med HbA1c som et surrogatendepunkt.

For å vurdere kostnadseffektiviteten av kontinuerlige vevsglukosemålere sammenlignet med SMBG hos pasienter med T2D som behandles med insulin og krever oppfølging i spesialisthelsetjenesten, ble det utviklet en beslutningsanalytisk modell. Analysen ble gjennomført som en kostnads–nytte-analyse fra et utvidet helsetjenesteperspektiv i norsk kontekst, med et livstidsperspektiv. Effektdata ble

hentet fra en nylig publisert svensk registerstudie som direkte sammenlignet effekten av ulike glukosemålingsmetoder på både akutte og sene diabetesrelaterte komplikasjoner. Overgangssannsynligheter og livskvalitetsdata ble basert på publiserte kilder. Kostnader for kontinuerlige vevsglukosemålere ble basert på siste innkjøpspris fra Sykehusinnkjøp HF, mens øvrige kostnader ble hentet fra offisielle norske enhetspriser. For å håndtere usikkerhet i parameterverdier ble det gjennomført sensitivitetsanalyser.

Sykdommens alvorlighetsgrad ble vurdert ved bruk av absolutt helsetap (absolute shortfall), som estimerer forventet tap av friske leveår (kvalitetsjusterte leveår; QALYs) sammenlignet med den generelle befolkningen. Videre ble det gjennomført en budsjettkonsekvensanalyse for å beregne de tilleggskostnadene som er forbundet med implementering av kontinuerlige vevsglukosemålere sammenlignet med dagens praksis (SMBG) over en femårsperiode. Analysen inkluderte relevante kostnader knyttet til glukosemåling samt behov for ekstra personell til opplæring, oppstart og oppfølging av utstyret. To organisatoriske modeller ble vurdert, med ulike forutsetninger om antall pasienter og ansvarsfordeling for finansiering mellom spesialist- og primærhelsetjenesten. Budsjettkonsekvensene ble estimert både for hele populasjonen av insulinbehandlede T2D-pasienter og for de predefinerte undergruppene.

Effekten av å innføre kontinuerlige vevsglukosemålere på behovet for helsepersonell ble vurdert ved å estimere økt arbeidskraftbehov uttrykt i årsverk. Estimatene var basert på data om ressursbruk per pasient for både dagens og ny intervensjon, samt antall aktuelle pasienter. Arbeidskraftbehovet ble beregnet for begge de organisatoriske modellene: Modell 1, der alle aktiviteter utføres i spesialisthelsetjenesten, og Modell 2, der oppgaver fordeles mellom spesialist- og primærhelsetjenesten.

Vurderingen av de organisatoriske konsekvensene er basert på innspill fra ekspertgruppen, relevante retningslinjer og litteratur, samt gjeldende praksis for distribusjon av kontinuerlige vevsglukosemålere i Norge. Diabetesforbundet ga innspill om brukererfaringer.

Resultater

Relativ effekt og sikkerhet

Vi inkluderte 12 studier fordelt på 13 publikasjoner, hvorav ni RCT-er og tre ikke-RCT-er. Studiene var publisert mellom 2016 og 2024 og inkluderte totalt 1119 deltakere i RCT-ene og 166 884 i ikke-RCT-ene. Gjennomsnittsalderen på deltakerne ved studiestart var ca. 61 år, mens gjennomsnittlig varighet av T2D-diagnosen ved oppstart av studien var ca. 16 år. Gjennomsnittlig HbA1c-nivå ved studiestart var ca. 70 mmol/mol (8.6%), noe som indikerer en dårlig regulert diabetes. Alle studiene mottok finansiering fra industrien.

Hovedutfall fra RCT-er for personer med dårlig regulert, insulin-behandlet T2D:

HbA1c
Bruk av kontinuerlige vevsglukosemålere kan trolig senke HbA1c sammenlignet med SMBG hos de med dårlig regulert glukosekontroll (RCT-data: gjennomsnittlig forskjell (MD): -2,19 mmol/mol; 95% konfidensintervall (KI): -3,92 til -0,47; moderat tillit), men ikke nok til å nå den forhåndsdefinerte terskelen for minimal klinisk viktig forskjell på 5,5 mmol/mol.

Alvorlig hypoglykemi
Det er usikkert om det er forskjell i alvorlig hypoglykemiske hendelser mellom kontinuerlige vevsglukosemålere og SMBG fordi resultatene er basert på data med svært lav tillit (RCT-data: risk ratio (RR): 2,53; 95% KI: 0,53 to 12,1; svært lav tillit).

Tid i glukosemålområdet
Bruk av kontinuerlige vevsglukosemålere kan trolig øke tid i glukosemålområdet (TIR) sammenlignet med SMBG (RCT-data: MD: 5,5 %; 95% KI: 1,68 til 9,32; moderat tillit). Selv om den gjennomsnittlige økningen i TIR overstiger den forhåndsdefinerte terskelen for minimal klinisk viktig forskjell på 5 %,

inkluderer konfidensintervallet verdier under denne terskelen, noe som indikerer usikkerhet rundt hvorvidt økningen konsekvent oppfyller den predefinerte klinisk meningsfulle forskjellen.

Tid under glukosemålområdet
Det er usikkert om kontinuerlige vevsglukosemålere reduserer tid under glukosemålområdet (TBR) sammenlignet med SMBG fordi resultatene er basert på data med svært lav tillit (TBR <3.9 mmol/L terskel: RCT-data: MD: -0,86 %; 95 % KI: -1,40 til -0,33; svært lav tillit, og TBR ≤3.0 mmol/L terskel: RCT-data: MD: -0,34 %; 95 % KI: -0,69 to 0,02; svært lav tillit).

Tid over glukosemålområdet
Det er trolig ingen forskjell i tid over glukoseområdet (TAR) ved terskelen >10,0 mmol/L mellom kontinuerlige vevsglukosemålere og SMBG (RCT-data: MD: -2,36 %; 95 % KI: -5,55 til 0,83, moderat tillit), men kontinuerlige vevsglukosemålere kan muligens redusere TAR ved terskelen >13,0 mmol/L (RCT-data: MD: -4,07 %; 95 % KI: -7,67 til -0,47; lav tillit).

Livskvalitet
Det er muligens ingen forskjell i livskvalitet mellom kontinuerlige vevsglukosemålere og SMBG (RCT-data: standardisert gjennomsnittlig forskjell: 0,1; 95 % KI: -0,24 til 0,45; lav tillit).

Diabetesrelaterte vaskulære senkomplikasjoner
Det er usikkert om det er forskjell i diabetes-relaterte vaskulære senkomplikasjoner mellom kontinuerlige vevsglukosemålere og SMBG fordi resultatene er basert på data med svært lav tillit (RCT-data: generelt svært lav tillit).

Data fra en ikke-RCT antyder at bruk av kontinuerlige vevsglukosemålere trolig reduserer diabetes-relaterte vaskulære senkomplikasjoner blant personer som følges opp i spesialisthelsetjenesten (ikke-RCT-data (registerstudie): generelt moderat tillit).

Sikkerhet knyttet til utstyret
Kontinuerlige vevsglukosemålere hadde en gunstig sikkerhetsprofil, med milde til moderate hudreaksjoner som de mest rapporterte bivirkningene i RCT-ene.

Subgruppevurdering

Ingen av de inkluderte studiene undersøkte spesifikt effekten av kontinuerlige vevsglukosemålere sammenlignet med SMBG i de predefinerte undergruppene.

Helseøkonomisk evaluering av prioriteringskriterier

Når HbA1c ble brukt som surrogatutfall, ble det ikke observert noen klinisk relevant forskjell mellom kontinuerlige vevsglukosemålere og SMBG for personer med ukontrollert, insulin-behandlet T2D. Gitt at kontinuerlige vevsglukosemålere er mer kostbart enn SMBG, vil innføringen av kontinuerlige vevsglukosemålere muligens føre til høyere kostnader uten tydelige tilleggseffekter på helse for hele populasjonen av insulinbehandlede personer med T2D.

Den helseøkonomiske analysen viser at bruk av kontinuerlige vevsglukosemålere gir økt helsegevinst sammenlignet med SMBG, med en inkrementell gevinst på 0,34 QALYs og en merkostnad på om lag [redacted] kroner. Dette tilsvarer en inkrementell kostnadseffektivitetsratio (IKER) på rundt [redacted] kroner per vunnet QALY. Kostnadseffektiviteten av kontinuerlige vevsglukosemålere er sterkt avhengig av pasientenes etterlevelse og en vedvarende effekt på reduksjon av diabetesrelaterte komplikasjoner. Resultatene var derfor særlig følsomme for kortere tidshorisonter, der IKER oversteg [redacted] per QALY (en 5-års tidshorisont). Sensitivitetsanalysene viste også at resultatene var følsomme for antakelser om kostnader knyttet til utstyr, kostnader for senkomplikasjoner (som terminal nyresvikt) og dødelighet ved alvorlige komplikasjoner.

En 67 år gammel insulinbehandlet T2D-pasient som trenger oppfølging fra spesialist og benytter dagens målemetode (SMBG), har et absolutt prognosetap på 5,38 gode leveår (QALYs).

Budsjettanalysen estimerte merkostnader på mellom [redacted] kroner over en femårsperiode for pasienter som krever oppfølging i spesialisthelsetjenesten. For de predefinerte subpopulasjonene har vi estimert at de totale kostnadene vil være rundt [redacted] kroner i 2026

og [redacted] kroner i 2030. Disse anslagene viste at det er en begrenset økonomisk effekt for de regionale helseforetakene (RHF-ene), ettersom en andel av pasientene allerede bruker kontinuerlige vevsglukosemålere gjennom dagens gruppeunntaksordning. Imidlertid vil utvidelse av tilgangen til en større populasjon av insulinbehandlede T2D-individer som bruker flere daglige injeksjoner, gjennom samarbeid mellom spesialisthelsetjenesten og primærhelsetjenesten, øke de totale kostnadene for implementering av kontinuerlige vevsglukosemålere for RHF-ene til mellom [redacted] kroner i 2026 og [redacted] kroner i 2030.

Implementering av kontinuerlige vevsglukosemålere for insulinbehandlede T2D-pasienter kan kreve mellom 21 og 32 årsverk for spesialsykepleiere i spesialisthelsetjenesten, eller totalt mellom 91 og 128 årsverk ved en samarbeidsmodell mellom spesialist- og primærhelsetjenesten for en større populasjon av personer med T2D som behandles med flere daglige insulininjeksjoner.

Organisatoriske konsekvenser

Etter dagens norske praksis tildeles kontinuerlige vevsglukosemålere av diabetesteamene i spesialisthelsetjenesten til kvalifiserte kandidater, både T1D og T2D under det gjeldende gruppeunntaket for T2D. Ekspertgruppen understreket at tildeling av kontinuerlige vevsglukosemålere til personer med insulinbehandlet T2D fortsatt bør skje i regi av spesialisthelsetjenesten, slik praksis er i dag. For å sikre en vellykket implementering vil det være nødvendig med god brukeropplæring og -oppfølging. I tillegg vil det være viktig å etablere klare kriterier for å identifisere de mest egnede kandidatene for bruk av CGM.

Brukererfaringer

Diabetesforbundet understreker at insulinbehandlet T2D påvirker livskvaliteten på flere måter, både fysisk, mentalt, sosialt og økonomisk. Ifølge Diabetesforbundet kan kontinuerlige vevsglukosemålere hjelpe mange ved å forbedre sykdomshåndteringen, redusere stress og øke tryggheten. Diabetesforbundet ønsker utvidet tilgang til kontinuerlige vevsglukosemålere for personer med insulinbehandlet T2D som bruker insulin i mangeinjeksjonsbehandling, eller som bruker 1-2 doser langtidsvirkende insulin og er plaget med tilbakevendende hypoglykemier hvor problemet ikke lar seg løse ved å justere behandlingen. I tillegg ønsker de kortvarig bruk av kontinuerlige vevsglukosemålere som et opplæringsverktøy for enkelte med en T2D-diagnose. De fremhever også viktigheten av å skreddersy løsninger for å møte behovene til sårbare grupper, inkludert eldre, personer med lav helsekompetanse og innvandrere.

Diskusjon

Denne HTA-en er den første norske helseøkonomiske evalueringen av bruk av kontinuerlige vevsglukosemålere for insulinbehandlet T2D, der langtidskomplikasjoner er direkte inkludert, i stedet for kun å basere seg på HbA1c.

Resultatene fra den helseøkonomiske analysen er følsomme for sentrale antakelser knyttet til langvarig etterlevelse, vedvarende effekt på blodsukkerkontroll og valgt tidshorisont for å fange opp kliniske effekter. Kortere oppfølgingsperioder reduserer de estimerte helsegevinstene betydelig og øker kostnaden per vunnet QALY, noe som understreker betydningen av vedvarende bruk for å oppnå kostnadseffektivitet. Det er fortsatt usikkerhet knyttet til flere av modellens parametere, blant annet risiko for langtidskomplikasjoner, dødelighet og livskvalitet hos insulinbehandlede personer med T2D.

Den helseøkonomiske modellen bygget på data fra en stor svensk registerstudie snarere enn randomiserte kontrollerte studier, noe som kan medføre gjenværende konfunderende faktorer. Norske data for komplikasjons- og dødelighetsrisiko var ikke tilgjengelige, og det var derfor nødvendig å benytte evidens fra sammenlignbare europeiske kilder. Disse begrensningene, sammen med antakelser om fremtidig bemanningskapasitet og behandlingsforløp, bør tas i betraktning ved tolkningen av resultatene og deres implikasjoner for implementering i norsk helsetjeneste.

Antallet spesialistsykepleieres årsverk ved en eventuell innføring av CGM ble estimert på nasjonalt nivå. Data for å beregne årsverksbehovet på sykehusnivå er imidlertid ikke tilgjengelige, da dette avhenger av både eksisterende kapasitet og hvordan hvert enkelt sykehus organiserer bemanningen.

Fortsatt datainnsamling fra norske registre og reell klinisk praksis vil være avgjørende for å forbedre estimatene for klinisk effekt, kostnader og personellbehov i fremtidige vurderinger.

Konklusjon

I følge RCT-data kan bruk av kontinuerlige vevsglukosemålere gi visse fordeler sammenlignet med SMBG for voksne med dårlig kontrollert glukose ved insulinbehandlet T2D, spesielt forbedring av TIR. Kunnskapsgrunnlaget for de fleste andre utfall var enten usikkert eller viste liten eller ingen relevant forskjell mellom tiltaket og SMBG. Data fra en ikke-RCT antyder at bruk av kontinuerlige vevsglukosemålere kan gi mulige vaskulære fordeler for personer med dårlig regulert, insulinbehandlet T2D som følges opp i spesialisthelsetjenesten, sammenlignet med SMBG, etter justering for relevante konfunderende faktorer. Ingen av studiene undersøkte effekten av kontinuerlige vevsglukosemålere i de predefinerte undergruppene.

Kontinuerlige vevsglukosemålere kan gi økte helsemessige gevinster til en høyere kostnad for utvalgte personer med T2D som behandles med insulin, der de langsiktige gevinstene sannsynligvis vil oppveie de økte kostnadene for pasienter som krever oppfølging i spesialisthelsetjenesten. Kostnadseffektiviteten avhenger av langvarig etterlevelse og vedvarende klinisk effekt.

Innføring av kontinuerlige vevsglukosemålere for insulinbehandlede personer med T2D vil øke ressursbehovet og etterspørselen etter helsepersonell, særlig spesialsykepleiere. De budsjettmessige konsekvensene for de regionale helseforetakene vil derfor avhenge av hvordan oppfølgingen av kontinuerlige vevsglukosemålere organiseres og hvor mange pasienter som tar teknologien i bruk. Dersom innføringen begrenses til de allerede prioriterte pasientgruppene, forventes tiltaket i hovedsak å formalisere eksisterende praksis snarere enn å medføre vesentlig nye økonomiske eller organisatoriske belastninger for helsetjenesten.

Preface

The Division of Health Economics and Analysis at the Norwegian Medical Products Agency (NOMA) was commissioned in October 2024 to perform a health technology assessment (HTA) on continuous and flash glucose monitoring for individuals with type 2 diabetes treated with insulin (1). For this HTA, we have chosen to refer to both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM), also called flash glucose monitoring, as "continuous glucose monitoring" (CGM).

The HTA was commissioned within the National System for Managed Introduction of New Health Technologies (called 'Nye metoder' in Norwegian). The health technology assessment will be used as a tool for informed decision-making by the regional health authorities in the Decision Forum in the national system.

The Division of Health Economics and Analysis follows an established framework when conducting HTAs, described in the methodology manual (called «Slik oppsummerer vi forskning») (2). This framework enables the use of standardised formulations when describing methods, presenting results, and discussing findings.

NOMA supports transparency in HTAs but is, as an administrative agency, obliged to protect commercially sensitive information in accordance with the Public Administration Act. The analyses in this report are based on confidential prices, and are therefore subject to confidentiality, cf. Section 13, paragraph 1.

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Disclaimer: Use of artificial intelligence

As part of NOMA's commitment to innovation and efficiency in preparing HTAs, we have utilised artificial intelligence (AI) tools to assist our work. We followed the principles outlined on the Reporting of AI in medical research (RAISE) (4).

In this HTA, we primarily used ChatDMP, a secure AI-powered language model developed by NOMA, to summarise text and enhance the clarity, consistency, and readability of several sections of the document. Additionally, we used other AI tools to assist with figure generation and data extraction for this report. The additional AI tools we used are ChatGPT, Gemini, Copilot, NotebookLM and Elicit. Authors review all outputs and take full responsibility for the accuracy and integrity of the final content.

Declared conflicts of interest

All project members, clinical experts, and reviewers have completed a declaration of interest according to NOMA policies. No conflicts of interest were reported. However, patient representatives, representing the Norwegian Diabetes Association, may have some conflict of interest (see Section 5.2 for details).

The Norwegian Medical Products Agency (NOMA) is solely responsible for the content of this report.

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List of abbreviations

Abbreviation	Explanation
AGP	Ambulatory glucose profile
BGM	Blood glucose monitoring
CGM	Continuous glucose monitoring
CI	Confidence interval
CSII	Continuous subcutaneous insulin infusion
CV	Coefficient of variation
DDS	Diabetes distress scale
DiD	Difference-indifference analysis
DMP	Direktoratet for medisinske produkter (NOMA in English)
DNS	Diabetes nurse specialist
DRG	Diagnosis related groups
eGFR	Estimated glomerular filtration rate
EHR	Electronic health records
EQ-5D	EuroQol-5 dimension
GLP-1	Glucagon-like peptide-1 agonists
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
GV	Glycaemic variability
HbA1c	Glycated haemoglobin
HCP	Healthcare professionals
HTA	Health technology assessment
HTAi	Health technology assessment international
HRQoL	Health related quality of life
ICER	Incremental cost-effectiveness ratio
isCGM	Intermittently scanned continuous glucose monitoring
ITT	Intention to treat
LEA	Lower extremity amputation
MARD	Mean absolute relative effectiveness
MCID	Minimal clinically important difference
MD	Mean difference
MDI	Multiple daily (insulin) injections
NDR	National Diabetes Register in Sweden
NICE	National institute for health and care excellence
NOMA	Norwegian Medical Products Agency
NOK	Norwegian kroner
Non-RCT	Non-randomised controlled trial (also known as an observational study)
OGTT	Oral glucose tolerance test
PCP	Primary care physician
PICO	Population, Intervention, Comparison, Outcome
PROMS	Patient-reported outcome measures
PS-IPTW	Propensity-score inverse probability of treatment weighting
QALYs	Quality-adjusted life years
QoL	Quality of life
RCT	Randomised controlled trial
RoB	Risk of bias

RR	Relative risk
rtCGM	Real-time continuous glucose monitoring
SGLT2	Sodium-glucose cotransporter-2
SMBG	Self-monitoring of blood glucose
SMD	Standardised mean difference
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TAR	Time above the glucose target range
TBR	Time below the glucose target range
TIR	Time within the glucose target range
VA / VHA	Veteran Health / Veteran Health Administration
WHO-5	World health organization five well-being index

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1. Introduction

1.1 Diabetes

Diabetes is a metabolic disorder characterised by elevated blood glucose levels (5), resulting from the body's reduced ability to produce insulin or respond effectively to it (6). If left untreated or poorly managed, diabetes can lead to severe complications, chronic vascular conditions, and an increased risk of mortality (5).

The prevalence of diabetes in Norway has increased in recent years, though there are indications of stabilisation due to a decline in incidence rates (7). In 2020, it was estimated that 260,000 to 280,000 individuals in Norway had a confirmed diagnosis of diabetes (8). A 2022 estimate further suggested that an additional 11% of cases remained undiagnosed (9).

While there are multiple subtypes of diabetes, the three main categories are type 1 diabetes (T1D), type 2 diabetes (T2D), and gestational diabetes. Of these, T2D is the most common, accounting for 90–95% of all cases (6).

1.1.1 Diabetes diagnostic criteria

Major health organisations worldwide, including the American Diabetes Association, officially recognise and recommend the use of haemoglobin A1c (HbA1c) as a diagnostic marker for T2D (10). HbA1c measures the proportion of blood glucose bound to haemoglobin. It reflects an individual's average plasma glucose levels over the preceding eight to twelve weeks (11). In contrast, plasma glucose concentrations provide a snapshot of current blood glucose levels.

The Norwegian Directorate of Health's diabetes guideline (12) specify the following criteria for diagnosing diabetes:

- HbA1c ≥48 mmol/mol (≥6.5%), or
- fasting plasma glucose ≥7.0 mmol/L, and/or
- plasma glucose ≥11.1 mmol/L two hours after an oral glucose tolerance test (OGTT)

To confirm a diagnosis, a follow-up test must verify a result exceeding the diagnostic threshold (12). However, according to the guideline, no additional testing is required if the patient presents with random plasma glucose levels of ≥11.1 mmol/L alongside symptoms of diabetes (12), such as increased thirst, frequent urination, and fatigue.

While HbA1c is a cornerstone of diabetes diagnosis, it is not without limitations. For instance, its accuracy can be compromised in conditions that affect red blood cells. HbA1c is not suitable for diagnosing gestational diabetes (13). Instead, the diagnosis is based on plasma glucose concentrations. Gestational diabetes can be confirmed at any stage of pregnancy if, during an OGTT, fasting plasma glucose is between 5.3 and 6.9 mmol/L and/or the 2-hour plasma glucose level is between 9.0 and 11.0 mmol/L (13).

1.1.2 Type 2 diabetes

T2D is a complex metabolic disorder that develops progressively over time. In its initial stages, the condition is marked by insulin resistance, where the body's cells become less responsive to the hormone insulin (6). To counteract this reduced sensitivity, the pancreas compensates by producing higher amounts of insulin. However, as the disease progresses, the pancreas loses its ability to produce sufficient insulin due to dysfunction of the pancreatic β-cells. This decline in insulin production, combined with ongoing insulin resistance, leads to impaired blood glucose regulation and persistently elevated blood glucose levels, a state known as hyperglycaemia (14).

The development of T2D is influenced by a combination of environmental and genetic factors (7). Key risk factors include a sedentary lifestyle, ethnicity, genetic predisposition, and obesity (7). Smoking is also recognised as a risk factor for T2D (7). The incidence of T2D rises with age, with the average age of diagnosis in Norway being approximately 65 years and is more prevalent among individuals from

lower socioeconomic backgrounds (7). Additionally, certain ethnic groups, particularly those of Asian and African descent, face a heightened risk of developing T2D (7).

Annually, an estimated 14,000 to 18,000 new cases of T2D are diagnosed in Norway, equating to an average of around 40 new cases per day (7). A 2017 Norwegian study by Bakke and colleagues (15) analysed data from 2005 to 2014 and reported that approximately 14.7% of individuals with T2D were treated with insulin. However, the proportion of individuals with T2D receiving insulin treatment is expected to decline as the use of newer blood glucose-lowering medications, such as glucagon-like peptide-1 agonists (GLP-1) and sodium-glucose cotransporter-2 (SGLT2) inhibitors, continues to rise (16).

1.2 Type 2 diabetes management

In Norway, the diagnosis, treatment, and follow-up care of T2D for most individuals are primarily provided by their general practitioner (12), regardless of whether insulin therapy is required. However, individuals with poorly controlled blood glucose levels or complex comorbidities are typically referred to multidisciplinary diabetes teams within specialist healthcare services for either periodic or long-term management (12). Nevertheless, as the day-to-day management of diabetes is predominantly self-directed, healthcare professionals emphasise the importance of individuals taking an active role in managing their own health (17).

The management of T2D usually begins with lifestyle modifications, such as changes in diet and physical activity, and may progress to the use of oral glucose-lowering medications (7). When these interventions fail to maintain optimal blood glucose control, insulin therapy may become necessary (7). Insulin therapy for T2D generally falls into two main categories: long-acting insulin analogues and rapid-acting insulin analogues. Long-acting insulin is sufficient for most individuals (18) and is typically administered once or twice daily to provide stable glucose control. However, some individuals may also require rapid-acting insulin (18), which is taken at mealtimes to manage postprandial blood glucose spikes.

In insulin-treated T2D, regular blood glucose monitoring is recommended to identify when therapeutic adjustments are required to minimise the risk of hypoglycaemia or hyperglycaemia (19;20). While the initiation of insulin therapy increases the risk of hypoglycaemia in T2D (12), most individuals still have residual endogenous insulin secretion and preserved counter-regulation. This glucose-regulated insulin secretion helps buffer mismatches between insulin dose, food intake, and physical activity, resulting in an overall lower risk of severe hypoglycaemia compared to individuals with little or no endogenous insulin (indicated by low C-peptide levels), whose risk closely resembles that seen in T1D.

Achieving glycaemic control in T2D should not come at the expense of addressing other equally important aspects of treatment and management, such as hypertension, dyslipidaemia, and obesity. In line with the recommendations outlined in the Norwegian diabetes guidelines (12), the focus should remain on education, motivation, a healthy diet, physical activity, and weight reduction in cases of excess weight throughout the entire course of management.

Although a holistic approach is vital for managing T2D, capillary blood glucose monitoring—performed through self-monitoring of blood glucose (SMBG) levels either multiple times daily or weekly—remains a cornerstone of diabetes management for individuals receiving insulin therapy (21). SMBG involves pricking the skin to obtain a capillary blood sample, which may cause needle-stick anxiety, discomfort, and inconvenience for some individuals (22;23). Furthermore, SMBG has inherent limitations, including insufficient data due to infrequent testing and the absence of nocturnal readings (24). Innovations in glucose monitoring have led to the development of less invasive technologies and tools, such as personal continuous glucose monitoring (CGM) devices, which provide more comprehensive data. CGM aim to empower individuals with diabetes to manage their condition more effectively (19).

1.3 Description of the technology

Sensor-based CGM systems typically consist of a subcutaneous glucose sensor connected to a transmitter and an external interface for data visualisation (19;25). The data visualisation interface may take the form of either a dedicated receiver or a mobile application (19;25). There are two principal types of personal CGM systems: real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) (19;25), the latter is also referred to as flash glucose monitoring systems (25). rtCGM devices measure glucose levels continuously and automatically transmit the data at regular intervals, typically every 1 to 5 minutes, to a receiver or a smartphone application (19;25;26). By contrast, isCGM systems require the user to actively scan the sensor throughout the day using a device reader or a smartphone application to access glucose measurements and related information (19).

Unlike traditional capillary blood glucose testing, CGM devices equipped with electrochemical sensors measure glucose levels in the interstitial fluid of the subcutaneous tissue (26). Once the electrochemical sensor is inserted subcutaneously, glucose concentrations in the interstitial fluid are measured and wirelessly transmitted to a receiver or smartphone. Under stable conditions, the average lag time between blood glucose and interstitial glucose concentrations is 8 to 10 minutes (27). This delay occurs because glucose must first diffuse from the capillaries into the interstitial fluid before being measured (27). Software algorithms are designed to compensate for the lag between blood and interstitial glucose concentrations under stable conditions; however, the delay can become clinically significant during periods of rapid glucose fluctuations (27). Advanced CGM systems, featuring enhanced calibration algorithms, are increasingly capable of predicting critical events such as hypoglycaemia and hyperglycaemia, thereby enhancing patient safety (26). Modern CGM devices also provide alerts and alarms in response to rising or falling glucose levels, allowing users to take timely action (28).

Nevertheless, when symptoms do not align with CGM readings, users are advised to confirm their glucose levels using capillary blood glucose monitoring (SMBG), as this method reflects the actual circulating glucose levels, including those in critical tissues such as the brain (27;29-31). Additionally, many CGM devices now offer remote data-sharing capabilities, enabling users to share their glucose data with family members, caregivers, and healthcare providers. This feature not only provides reassurance to all parties involved but also facilitates collaborative management of diabetes, allowing individuals to share the responsibilities of their care (28).

To evaluate the accuracy of a CGM system in measuring glucose levels, a statistical performance measure called MARD (Mean Absolute Relative Difference) is used. MARD quantifies the difference between CGM readings and simultaneous measurements from a highly accurate reference source, with lower values (expressed as a percentage) indicating greater accuracy (32). Generally, a CGM system with a MARD of less than 10% is considered to have good analytical performance. For example, the FreeStyle Libre 3 has a MARD of 8.9% in adults, while the Dexcom G7 achieves a slightly lower MARD of 8.2% in adults (32).

A CGM device is not a standalone tool for managing diabetes; however, the glucose data it generates can offer detailed insights into blood glucose patterns. These insights enable individuals and their healthcare providers to make informed adjustments to other management strategies, such as diet, physical activity, and medications, to optimise diabetes control.

In Norway, three manufacturers supply the four CGM models covered by the current public framework agreement, which is valid until 2026 (33) These devices are intended for use by individuals with T1D and, in specific cases, individuals with insulin-treated T2D who have been prescribed a device following evaluation by a specialist healthcare provider (12). The available models are: Freestyle Libre 3 Plus and 2 Plus (Abbott) (29), Simplera (Medtronic) (31), and Dexcom G7 (Nordic Infucare) (30). Table 1 provides a summary of the key features of these devices, based on publicly available information from the manufacturers (29-31).

Table 1. CGM devices listed in the Norwegian public framework agreement, effective until 2026

	Freestyle Libre 3 Plus (29)	Freestyle Libre 2 Plus (29)	Simplera (31)	Dexcom G7 (30)
Type of system	rtCGM	isCGM with some rtCGM functions	rtCGM	rtCGM
Frequency of glucose testing	Every 1 minute	Every 1 minute	Every 5 minutes	Every 5 minutes
Calibration with SMBG is required	No	No	No	No
Allows optional calibrations	-	-	-	Yes
Warm-up time†	60 minutes	60 minutes	120 minutes	30 minutes
Sensor wear time‡	15 days	15 days	6 days (and a 24-hour grace period#)	10 days (and a 12-hour grace period#)
Provides trend arrows*	Yes	Yes	Yes	Yes
Provides alarms for hyper- and hypoglycaemia	Yes	Yes	Yes	Yes
Connects with insulin pumps	Yes	NA	No	Yes
Compatibility with mobile devices	Yes	Yes	Yes	Yes
Real-time remote data sharing	Yes	Yes	Yes	Yes
Indicated for use in pregnancy	Yes	Yes	No	Yes
Minimum age for use	2 years	2 years	2 years	2 years

NA: not assessable, meaning no information easily available; rtCGM: real-time continuous glucose monitoring; isCGM: intermittently scanned continuous glucose monitoring; SMBG; self-monitoring of blood glucose

† The period required for calibration after placement under the skin. During this time, users must rely on finger-prick blood glucose checks for treatment decisions (34).

‡ The maximum duration a sensor can be worn before it needs to be replaced (34).

The grace period gives users extra time and flexibility to change their CGM sensor (30).

* Trend arrows show the direction of glucose levels, enabling proactive adjustments to prevent hyper- or hypoglycaemia (34).

1.4 Why is it important to conduct this HTA?

The use of CGM as an alternative to SMBG has been shown to improve glycaemic control in systematic reviews involving individuals with T1D (35-37). However, it remains uncertain whether comparable outcomes can be achieved in individuals with insulin-treated T2D.

In recent years, several randomised trials and observational studies have been published comparing the effectiveness and safety of CGM with SMBG in individuals with insulin-treated T2D (3;38-42). However, to the best of our knowledge, no systematic reviews have exclusively focused on this comparison for individuals with insulin-treated T2D.

Moreover, an assessment of the cost-effectiveness of CGM compared to SMBG for individuals with insulin-treated T2D in the Norwegian healthcare context has not yet been undertaken. The organisational implications of introducing CGM for this population within the Norwegian healthcare system remain unexplored. Lastly, there appears to be no published overview of the experiences of Norwegian CGM user experiences.

1.4.1 Group exemption until the HTA is finalised

Under the 'Nye metoder' framework, medical products undergoing assessment are generally not authorised for implementation (43). However, the medical directors of the regional health authorities have agreed to grant a group exemption for CGM use among individuals with T2D until the HTA is completed. At the Interregional Medical Directors' Meeting on 19 June 2023 (44), the following group exemption for T2D was approved:

> CGM devices may be allocated in the following cases (translated directly from Norwegian):
>
> 1. **Patients with insulin-requiring diabetes** who, despite long-term follow-up and significant self-management efforts, still experience highly challenging blood sugar regulation and

recurrent episodes of hypoglycaemia. The Norwegian Directorate of Health's recommendation of a target HbA1c of 53–64 mmol/mol (7.0–8.0%) should not, on its own, serve as a criterion for allocating CGM devices to this patient group.

2. **Pregnant women with known diabetes** where there is a medical indication to use a CGM device instead of the nationally recommended practice of SMBG. This also applies to women with gestational diabetes, where a medical indication for CGM use is identified.
3. **Patients with severe chronic kidney failure** who are on multiple daily insulin injections and have an increased risk of hypoglycaemia due to impaired glucose production in the kidneys could be considered under a slightly more liberal indication.

Under the group exemption, the provision of CGM devices to patients with T2D requires approval from either an established expert group or the medical director of the relevant healthcare institution (44).

1.5 Objectives and research question

The objectives of this HTA are to evaluate the clinical effectiveness, safety, health economic implications, organisational aspects, and patient perspectives of CGM compared to SMBG in individuals with T2D treated with insulin.

Additionally, the commissioner has tasked NOMA with conducting subgroup analyses for insulin-treated T2D populations previously identified as particularly well-suited for CGM use (1). These are groups that Norwegian endocrinologists consider particularly suitable for the use of CGM from a clinical perspective (45).

These groups are:

- Individuals with T2D on multiple daily injections (MDI) with rapid-acting insulin who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses.
- Individuals with T2D on insulin therapy who have experienced more than one episode of severe hypoglycaemia in the past year.
- Individuals with T2D on insulin therapy whose profession involves significant risks if hypoglycaemia occurs.
- Younger individuals with T2D on insulin therapy who have intellectual disabilities.
- Women with T2D using MDI of insulin, during preconception planning and throughout pregnancy. Continuous use may also be considered during the postpartum period if the MDI regimen is maintained and there is a risk of hypoglycaemia.

1.6 Metrics for assessing glycaemic control

There are several metrics for assessing glycaemic control in diabetes, with HbA1c, blood glucose levels, time in the target blood glucose range (TIR), time below the target range (TBR), time above the target range (TAR), and glycaemic variability (GV) being the most relevant and commonly used.

1.6.1.1 HbA1c

HbA1c is measured in millimoles of glycated haemoglobin per mole (mmol/mol) or percentage of glycated haemoglobin (%). As of 30 September 2019, HbA1c has been reported in Norway using mmol/mol, rather than as a percentage (46).

For assessing metabolic control, HbA1c monitoring is considered the gold standard. According to the Norwegian diabetes guideline (12), the treatment goal for most individuals with T2D is an HbA1c level of approximately 53 mmol/mol (7%). However, an HbA1c level between 53–64 mmol/mol (7.0–8.0%)

may be appropriate for individuals with a prolonged disease duration, significant comorbidities (particularly reduced renal function with an estimated Glomerular Filtration Rate (eGFR) < 45 ml/min/1.73 m²), or an elevated risk of hypoglycaemia (12).

1.6.1.2 Blood glucose levels

Blood glucose levels refer to the concentration of glucose in the bloodstream at a given moment and are measured in millimoles per litre (mmol/L) or milligrams per decilitre (mg/dL). These measurements are widely used for monitoring glucose levels, often through finger-prick tests (SMBG). This method provides an immediate snapshot of blood glucose levels at the time of testing.

CGM devices measure glucose levels in the interstitial fluid surrounding cells, rather than directly in the bloodstream. While their readings are correlated with blood glucose levels, there is a time lag between changes in blood glucose and corresponding changes in glucose levels within the subcutaneous interstitial fluid (47), as described in Section 1.3.

1.6.1.3 TIR

TIR quantifies the proportion of time individuals with diabetes maintain blood glucose levels within the target range, typically defined as 3.9–10.0 mmol/L (70–180 mg/dL) (48). While TIR is primarily assessed using CGM, it can also be estimated as derived TIR (dTIR) from SMBG profiles (49).

A TIR of 70% or higher is the recommended target for most adults with T2D (50), corresponding to approximately 16.8 hours or more per day within the target glycaemic range.

With the increased use of CGM, TIR has emerged as a complementary metric to HbA1c for assessing diabetes control, making comparisons between these metrics relevant. Although there may be considerable variability in the change in HbA1c for a given change in TIR, on average, a TIR (3.9–10.0 mmol/L) of 70% roughly corresponds to an HbA1c of 53 mmol/mol (7.0%), while a TIR of 50% corresponds to an HbA1c of approximately 64 mmol/mol (51).

1.6.1.4 TBR

TBR measures the proportion of time individuals with diabetes spend below the target glucose range, indicating periods of hypoglycaemia, and is most often assessed using CGM. Hypoglycaemia is typically defined as <3.9 mmol/L (<70 mg/dL) (48).

For most adults with T2D, the recommended TBR target is less than 4%, which corresponds to 58 minutes per day (50). Severe hypoglycaemia, generally defined as <3.0 mmol/L (<54 mg/dL), has a recommended TBR target of less than 1% (14 minutes) for most adults with T2D (50).

1.6.1.5 GV

GV refers to fluctuations in blood glucose levels over time. It encompasses changes that occur throughout the day, including episodes of hypoglycaemia, postprandial peaks following meals, and daily variations in blood glucose levels (52).

GV tends to be relatively high in individuals with impaired blood glucose regulation (52). The recommended target for GV is a coefficient of variation (CV) of 36% or lower (48).

1.7 Project plan

A project plan for this HTA is publicly available: id2023_075-kontinuerlig-glukosemaling.pdf.

The project plan did not specify primary outcome measures. However, it did outline the outcomes deemed relevant for assessment using the GRADE framework. These included HbA1c, TIR, TAR, TBR, severe hypoglycaemic events, quality of life, diabetes-related late vascular complications, and mortality. Consequently, we consider these to be the main outcomes of this HTA.

The project plan did not explicitly specify the time points at which the effectiveness of the outcomes should be evaluated. For the primary outcomes listed above, we identified the latest reported time points from the included studies and used these in the meta-analyses. Additionally, we pooled

outcome data at specific intervals in the meta-analyses: ≤3 months, 4–8 months, 12 months, and >12 months. Where a high degree of heterogeneity was present, we conducted exploratory sensitivity analyses and thus deviated slightly from the specific criteria outlined in the project plan.

In the project plan, we outlined the following diabetes-related late vascular complications: nephropathy, retinopathy, neuropathy, coronary heart disease, peripheral vascular disease, and stroke. During the data extraction phase, no data related to nephropathy were identified; however, kidney disease was reported in one study. While not identical, nephropathy involves damage or disease of the kidneys, and we included kidney disease in the analysis as it was relevant to the health economic evaluation. Similarly, foot ulcers, which were not included in the PICO, were incorporated into the analysis due to their relevance to the health economic evaluation. Foot ulcers—localised wounds or sores on the feet—are associated with neuropathy and/or peripheral vascular disease (53), linking them to two PICO-included outcomes.

1.8 External experts

At the start of the project, we engaged clinical experts specialised in endocrinology, general practice, and diabetes care to contribute to its development. The primary role of the expert group has been to assist in defining the inclusion criteria within the PICO framework (Population, Intervention, Comparator, and Outcome). Additionally, they have provided input on the technologies under consideration, relevant publications, organisational factors, and to the health economic evaluation, all within the context of Norwegian clinical practice. The expert group has also contributed to the interpretation of the results and offered insights for the discussion chapter of the report.

We also enlisted two patient representatives from the Norwegian Diabetes Association's Central Board. Their contributions included sharing insights into the experiences of association members living with T2D, offering perspectives on current management practices, and outlining expectations for the CGM technology under evaluation. Furthermore, they were invited to review and provide feedback on the HTA report prior to its finalisation.

2. Clinical effectiveness and safety

We conducted a systematic review to evaluate the clinical effectiveness and safety of CGM compared to SMBG in individuals with insulin-treated T2D, following the guidelines from the Norwegian Institute of Public Health (2) and the Cochrane Handbook (54). We also aimed to conduct subgroup analyses for insulin-treated T2D populations identified by clinical experts as particularly suitable for CGM use.

2.1 Methods

2.1.1 Inclusion criteria

The inclusion criteria are described in Table 2.

Table 2. Inclusion criteria

Population	**Main population:**
	Individuals 18 years and older with T2D treated with insulin
	
	Subgroups (delimited from the definitions described in chapter 1.5):
	• Individuals with T2D on MDI therapy with rapid-acting insulin.
	  ○ **Condition**: documented persistent hypoglycaemia, defined as ≥2 episodes of symptomatic hypoglycaemia per week despite insulin dose adjustments for optimisation.
	• Individuals with T2D on any form of insulin therapy.
	  ○ **Condition**: history of ≥2 severe hypoglycaemic episodes in the past 12 months, where "severe hypoglycaemia" is defined as requiring third-party assistance in the specialist healthcare service (hospital).
	• Individuals with T2D on insulin therapy whose profession involves safety-critical roles (e.g., drivers, machine operators, pilots, healthcare professionals).
	  ○ **Condition**: evidence of hypoglycaemia-related risks in the workplace, such as documented hypoglycaemia episodes during work hours or professions where hypoglycaemia might endanger themselves or others.
	• Individuals aged <60 years with T2D on insulin therapy and diagnosed with intellectual disabilities, defined by standardised criteria (e.g., IQ <70 or adaptive functioning limitations).
	  ○ **Condition**: documented challenges in managing diabetes due to cognitive or functional impairments.
	• Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period.
	  ○ **Condition**: risk of hypoglycaemia during pregnancy or postpartum due to MDI therapy using CGM tailored to pregnancy.

Intervention	Personal continuous glucose monitoring (CGM); real-time (rtCGM) and intermittently scanned CGM (isCGM)
Comparator	Self-monitoring of blood glucose (SMBG)
Outcomes	• HbA1c • Total hypoglycaemia events (i.e., including both severe and nocturnal hypoglycaemia) • Severe hypoglycaemia events (i.e., blood glucose level below 3.1 mmol/L and requiring third-party assistance) • Nocturnal hypoglycaemia events (i.e., blood glucose level below 3.9 mmol/L during sleep) • TIR, 3.9-10.0 mmol/L (48)) • TBR, 3.0-3.8 mmol/L (48)) • TAR, 10.1-13.9 mmol/L (48)) • GV, %CV, target ≤36% (48)) • Quality of life (overall and psychological subdomain(s)), both disease-specific PROMS and general measures (e.g., EQ-5D) • Diabetes-related late vascular complications (nephropathy, retinopathy, neuropathy, coronary heart disease, peripheral vascular disease, stroke)

	• Mortality • Adverse events associated with the CGM device (e.g., contact dermatitis, hypersensitivity reactions, scarring, lipodystrophy, false low glucose readings) • Mental health outcomes associated with the use of the CGM device (e.g., anxiety, depression, distress)
Study design	RCTs Non-RCTs (prospective and retrospective) with a control group and a follow-up period of 12 months or more Trial registry records
Publication year	No limit
Country/context	No limit
Language	English, Spanish, Norwegian, Swedish, Danish

2.1.2 Exclusion criteria

We excluded the following:

- Cross-sectional, non-controlled, and non-RCT studies with less than 12 months of follow-up.
- Editorials, commentaries, letters, brief reports, and conference abstracts.
- Systematic reviews, review articles and HTAs (although they were used or screened for relevant primary studies related to any section of this HTA).
- Guidelines, position papers, and recommendations (however, guidelines and recommendations were relevant to the organisational aspects chapter).
- Studies including both T1D and T2D, where data is reported in aggregate form and not provided separately for T2D.
- Head-to-head comparisons of one CGM versus another CGM.
- Professional CGM devices, meaning that the involvement of a healthcare professional is required.
- Continuous glucose monitors for use only in a hospital setting.

2.1.3 Literature search

2.1.3.1 Search in databases

The team information retrieval specialist (GEN) developed a search strategy in collaboration with the project team and, following best practices in the field (55;56), conducted the literature searches. The search strategies were tailored to suit the specific interface of each electronic bibliographic database. For the population and intervention concepts, the search strategy incorporated both keywords and controlled vocabulary, such as MeSH (Medical Subject Headings) from the National Library of Medicine. Boolean operators "OR" and "AND" were used to combine search terms and concepts appropriately. The search was not restricted by language, publication year, study design, or publication type.

A second information retrieval specialist (EH) reviewed and proofread the search strategies prior to the literature search being conducted. Documentation of the search process and results is provided in Appendix 1.

The main literature search was conducted using the following sources:

- Medline (Ovid)
- Embase (Ovid)
- Epistemonikos
- The international HTA database (INAHTA)

The search results from bibliographic databases and trial registries were exported to the reference management tool EndNote. Duplicates were removed using a standardised, semi-automated method (57). The unique records were then uploaded to EPPI-Reviewer (58) for relevance assessment against the inclusion and exclusion criteria.

2.1.3.2 Literature search in other sources

To supplement the main search, the information retrieval specialist (EH) executed another search in two of the most relevant study registers. The following study registers were used:

- ClinicalTrials.gov (National Institutes of Health)
- International Clinical Trial Registry Platform (World Health Organization)

For more details on the search strategy and number of hits, see Appendix 1.

2.1.4 Selection of studies

To reviewers (JB, IKØE) independently selected publications in a step-by-step process (2), utilising the data tool EPPI Reviewer (59) throughout. In the first step, the title and abstract of all identified references were evaluated against the selection criteria. In the second step, relevant publications were obtained in full text for final assessment. Any disagreements regarding inclusion or exclusion at any stage were resolved through discussion or, when necessary, with the assistance of a third project member.

2.1.5 Risk of bias assessment

Two reviewers (JB, IKØE) independently assessed the risk of bias at the outcome level for the included studies. Any disagreements in the assessments were resolved through discussion or by consulting a third project member. For RCTs, we used the Cochrane's Risk of Bias tool version 2 (RoB v2) (60), while for non-RCTs, we used the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool (61).

The five domains included in RoB v2 (62) are: 1) bias arising from the randomisation process; 2) bias due to deviations from intended interventions; 3) bias due to missing outcome data; 4) bias in the measurement of the outcome; and 5) bias in the selection of the reported result.

In ROBINS-I, seven domains of bias are addressed (61). These are: 1) bias due to confounding; 2) bias in the selection of participants into the study; 3) bias in classification of interventions; 4) bias due to deviations from intended interventions; 5) bias due to missing data; 6) bias in measurement outcomes; and 7) bias in the selection of the reported results.

In non-RCTs, adjustments for systematic bias are particularly important. We expected that the studies would measure a minimum set of confounding factors, including age, sex, duration of diabetes, comorbidities, body mass index, and baseline HbA1c level. Studies that did not adjust for these confounding factors were downgraded in the ROBINS-I assessment.

2.1.6 Data extraction

We used a custom-made Excel sheet for data extraction, supported by the AI tool Google NotebookLM (63) to streamline the process. Google NotebookLM is an online AI tool based on Gemini 2.0, designed to assist users in interacting with documents (63). Table 3 provides an overview of the data extracted from the included studies.

Statistically adjusted effect estimates are preferred over unadjusted effect estimates (such as the number of events), and these were the data extracted. Adjustments are essential for addressing both precision and systematic bias.

Relative effect estimates were extracted directly from the included studies. Where data were presented in alternative formats, such as figures or graphs, the relevant information was extracted either manually or by using the software tool PlotDigitizer (64), a free web-based tool designed to extract data from 2D plots, bar graphs, scatter plots, and other types of visualisations. An online meta-converter tool (65) was utilised to convert data where necessary to enable pooling in meta-analyses.

One reviewer (JB) extracted and transformed data from the included studies, while another reviewer (IKØE) cross-checked the data against the relevant publications and double-checked the transformed data. Any disagreements were resolved through consensus.

The corresponding author of one publication (3) was contacted to clarify a potential error in the published article. Additionally, two articles (42;66) were publications from the same trial and were therefore treated as a single RCT.

Table 3. Extracted data from the included studies

Concerning	Extracted information
The study	Authors, publication year, study design, total duration of study, details of any 'run-in' period, number of study centres and locations, setting, funding, clinical identification number
The participants	Number of participants in each group, age range, sex, duration of T2D, ethnicity
The intervention	Type of CGM device, CGM usage patterns
The comparator	Type of glucose measurement, measurement frequency, measurement time (mealtime, bedtime, etc.)
The outcomes	Definitions of outcomes, means, medians, standard deviations, or confidence intervals at baseline and post-intervention and follow-up assessment(s), contextual information if provided, and variables adjusted for in the analyses related to all outcomes (see Table 2 for details)

2.1.7 Analyses

We categorised studies and results based on outcome measures and study design and analysed the RCTs and non-RCTs separately. All analyses and calculations were conducted using the software Review Manager (RevMan) Web (67).

2.1.7.3 Effect estimates

We used group post-test results to calculate effect sizes.

Dichotomous outcomes

For dichotomous outcomes, we calculated the relative risk (RR) with 95% confidence intervals (CI). The RR, also referred to as the risk ratio, quantifies the probability of an event occurring in the exposed group compared to the probability of the same event occurring in the unexposed group (68).

Continuous outcomes

For continuous outcomes measured on the same scale, we calculated the mean differences (MD) with 95% CI. For continuous outcomes measured with different scales, we computed the standardised mean differences (SMD) with 95% CI. SMD were interpreted using Cohen's *d* as follows: small effect size = 0.2, medium effect size = 0.5, and large effect size = 0.8 (69).

2.1.7.4 Meta-analyses

We synthesised the results from the included studies into meta-analyses, where feasible.

Meta-analysing data requires the studies to be sufficiently homogeneous with respect to study design, participants, interventions, comparisons, and outcome measures. As the populations, interventions, and outcomes in the included studies were unlikely to be identical, we employed a random-effects model for the analyses. The random-effects model accounts for potential systematic differences between individual studies, assuming that there is no single true effect but rather that each study may exhibit slightly different effects. This approach calculates an average effect and typically results in wider confidence intervals compared to the fixed-effect model. Pairwise meta-analyses are presented in forest plots with pooled effect estimates for each meta-analysis.

We assessed potential sources of statistical heterogeneity in study outcomes by examining CIs and calculating Chi^2 and I^2 (67). Wide CIs were noted as potentially indicating variability in effect estimates across studies, with poor overlap of CIs generally suggesting heterogeneity (70). The Chi^2 test was used to evaluate whether observed differences in results were greater than would be expected by chance (70). A significant p-value (<0.05) indicates heterogeneity, though we acknowledged that this test is sensitive to the number or size of studies (70). The I^2 statistic was employed to quantify the percentage of variability in effect estimates attributable to heterogeneity rather than chance. I^2 values were interpreted as follows: 0–40% as unlikely to be important, 30–60% as potentially indicating

moderate heterogeneity, 50–90% as potentially indicating substantial heterogeneity, and 75–100% as suggesting considerable heterogeneity (70).

Where a high degree of heterogeneity was identified, we conducted exploratory leave-one-out sensitivity analyses to evaluate whether any single study disproportionately affected the heterogeneity or the pooled effect. These analyses were considered to be potentially hypothesis-generating only. We reported CIs, Chi², p-values, and I² statistics for heterogeneity and downgraded our confidence in the effect estimates where high heterogeneity was observed.

We planned to conduct subgroup analyses for populations identified as particularly relevant to CGM use (specified in Sections 1.5 and 2.1.1).

2.1.7.5 Narrative synthesis

In instances where meta-analyses were not feasible, we calculated and presented effect estimates for relevant outcomes reported in the included studies. In these cases, we summarised and illustrated the effect estimates using forest plots without an "overall effect estimate" and provided additional context in the accompanying text.

2.1.8 Assessing the certainty in the evidence

When assessing the certainty of the evidence (confidence in effect estimates), we refer to the extent to which the research findings can be relied upon to represent the "true" or "actual" effects of the interventions under investigation. In other words, it reflects how well-documented and reliable the research results are.

To evaluate the confidence in the evidence, we employed the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) (71). We used the digital tool GRADEpro (72). While the level of confidence is a continuous measure, it is categorised into four levels for practical purposes: high, moderate, low, and very low. These categories are defined in Table 4.

Table 4. The GRADE categories of the degree of confidence in the evidence

GRADE level	Symbol	Description
High certainty	⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty	⊕⊕⊕◯	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. We use the term *probably* to express our confidence in the result.
Low certainty	⊕⊕◯◯	We have limited confidence in the effect estimate: The true effect might be substantially different from the estimated effect. We use the term *may* to express our confidence in the result.
Very low certainty	⊕◯◯◯	We have very low confidence that the effect estimate is close to the true effect. We use the term *unclear/uncertain* to express our confidence in the result.

Following the GRADE Handbook (71), we used the study design as a starting point and then evaluated five criteria to determine the level of confidence in the evidence: risk of bias, inconsistency, imprecision, indirectness, and publication bias. When incorporating observational studies, it is also possible to upgrade the certainty of the evidence if the initial GRADE assessment begins at a low level. This is achieved by evaluating three additional criteria: strong or very strong associations between interventions and outcomes (where the calculated effect is so substantial that it is unlikely to be due to chance), large or very large dose-response effects, and situations where all likely confounders would have contributed to reducing the effect estimate.

We assessed the certainty in evidence for the following outcomes: HbA1c, TIR, TAR, TBR, severe hypoglycaemic episodes, quality of life, diabetes-related late vascular complications, and mortality.

Two reviewers (JB, IKØE) evaluated the confidence in the results. Any disagreements in assessments were resolved through discussion or by consulting a third project member.

2.1.9 Minimal clinically important differences

When interpreting the results and drawing conclusions, we adopted the same thresholds for minimal clinically important differences (MCIDs) as those specified in the NICE guideline, “Type 2 diabetes in adults: diagnosis and management” (73), Table 5.

Table 5. Thresholds for MCIDs

Outcome	MCID
HbA1c (presented as a percentage or mmol/l)	5.5 mmol/mol or 0.5 percentage points
TIR (%)	5% change in TIR

As outlined in the NICE guideline (73), when no specific MCID was available, a MCID of 0.5 of the median standard deviation of the comparison arms was applied. For dichotomous outcomes, such as relative risk, default MCIDs of 0.8 and 1.25 were used when no other MCID was available. We followed these same MCIDs in our HTA.

2.2 Results

2.2.1 Results of the literature search and study selection

The initial search yielded 8,297 results prior to duplicate removal (see Figure 1). Additionally, we identified four references via citations in other publications: one published protocol and three trial registries. After removing duplicates, 6,222 references remained to be screened. Of these, 6,104 references were excluded as they clearly did not meet the inclusion criteria. We reviewed 118 full-text publications, excluding 94 (see Appendix 2). The most common reasons for exclusion were incorrect population and intervention. Ultimately, 24 records were included: 12 studies reported across 13 publications (3;24;38;40-42;66;74-79), two published protocols (80;81) and nine study registries.

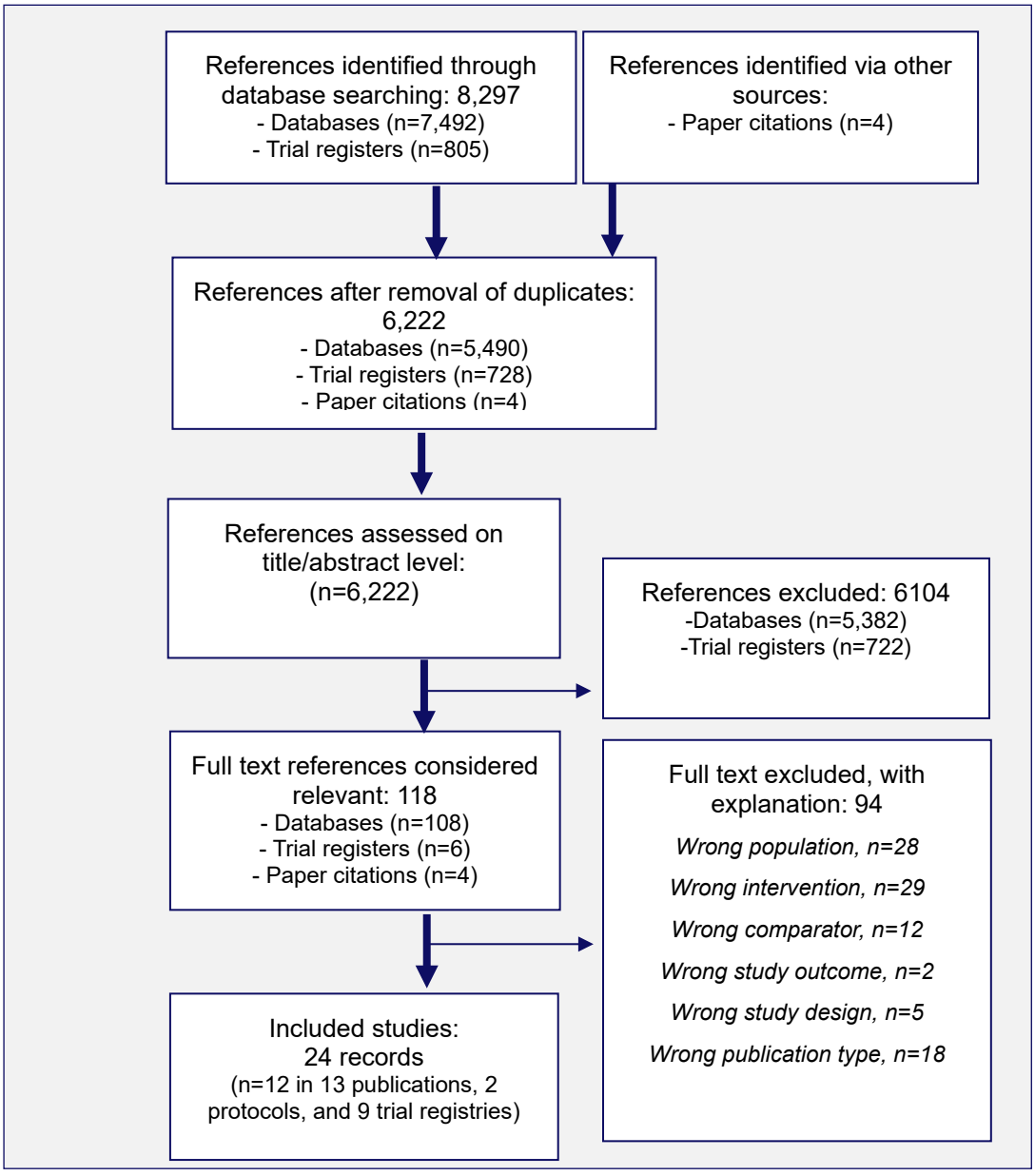


Figure 1: Flow chart on selection of studies

2.2.1.1 Ongoing trials

The trial registry search identified seven ongoing trials with the potential to meet the inclusion criteria for future updates of the systematic review, as presented in Appendix 3.

2.2.2 Description of the included studies

We included 12 unique studies detailed across 15 publications (3;24;38;40-42;66;74-81), including two protocols (80;81). Nine were RCTs (24;38;40-42;66;74-77) (in ten publications), and three were non-RCTs (3;78;79), as described in Table 6 and Appendix 3.

The studies were conducted in Denmark (40), Sweden (3), the United Kingdom (74), Germany, France and the United Kingdom (75), Israel (41), the United States of America (24;38;42;66;78;79), New Zealand (77), and South Korea (76). They were published between 2016 and 2024 and included 1,119 participants (ranging from 45 to 224) in the RCTs and 166,884 participants (ranging from 36,080 to 45,618) in the non-RCTs. Measurement periods ranged from 10 weeks to two years. One RCT (76) included three study arms, and one non-RCT (3) included three cohorts (MDI, basal insulin and control), while the remaining studies had two study arms or cohorts. One RCT was reported in two publications: the first publication (42) included an 8-month follow-up, and the second publication (66) included a 14-month follow-up. All studies received industry funding (see Appendix 3 for details), which included funding for the study or its pilot, the provision of CGM devices, and/or the involvement of a co-author affiliated with the device manufacturer whose product was being evaluated for effectiveness.

The average baseline age of participants was approximately 61 years, while the average duration of T2D at baseline was approximately 16 years. The mean baseline HbA1c levels was approximately 70 mmol/mol (8.6%), indicating suboptimal or poorly controlled T2D, as the target HbA1c level for most adults with T2D is typically at or below 53 mmol/mol (7.0%) (12).

Table 6. Description of the included studies

Author/year, NCT and study name	Country and follow up	Population	Intervention (CGM device)	Comparison	Outcome(s)
Randomised controlled trials					
Ajjan 2016 (74) NCT01713348 **SIGN study**	United Kingdom 3 months 10 days (100 days)	T1D and T2D on MDI	FreeStyle Navigator (isCGM)	SMBG	Difference in time with glucose in target range [3.9–10.0 mmol/L). Time spent in euglycemia and hypoglycaemia, difference in HbA1c, Adverse events related to the device and study.
Beck 2017 (38) NCT02282397 **DIAMOND study**	USA 3 and 6 months	T2D on MDI	Dexcom G4 Platinum (rtCGM)	SMBG	Change in HbA1c, TIR, TAR, TBR, GV, QoL, Adverse events.
Bergenstal 2022 (24) NCT01237301 **REACT3 study**	USA 2 and 4 months	T2D on insulin ± metformin	Dexcom Seven Plus (rtCGM)	SMBG	HbA1c change, TBR, TIR, GV, TAR, Adverse events.
Haak 2017 (75) NCT02082184 **REPLACE study**	Germany, France, and United Kingdom 6 months	T2D on prandial, prandial + basal or CSII	FreeStyle Libre (isCGM)	SMBG	Difference in HbA1c, TBR, hypoglycaemic events, TIR, GV, Nighttime hypoglycaemia QoL, Adverse events, severe hypoglycaemia device related AEs.
Kim 2024 (76) NCT04926623 **FreEdoM-2 study**	South Korea 6 months	T2D on MDI	FreeStyle Libre 1 (isCGM)	SMBG	HbA1c, TIR, TBR, TAR, GV Severe hypo & hyperglycaemia, number of adverse events, especially hypoglycaemia.
Lever 2024 (77) ACTRN 12621000889853 Lever 2023 (80) **2GO-CGM study**	New Zealand 3 months	T2D daily insulin use of >0.2 units of insulin/kg/day	Dexcom G6 (rtCGM)	SMBG	TIR, HbA1c, TAR, TBR, Severe hypoglycaemia, severe adverse event, GV.

Lind 2024 (40) NCT04331444 Lind 2021 (81) **Steno2tech study**	Denmark 6 and 12 months	T2D, treatment with insulin injections at least once daily	Dexcom G6 (rtCGM)	SMBG	TIR, TAR, TBR, GV, severe hypoglycaemic episodes, QoL, HbA1c, DDS.
Martens 2021 (42), **Aleppo 2021** (66) NCT03566693 **MOBILE study**	USA 8 and 14 months	T2D on basal insulin	Dexcom G6 (rtCGM)	SMBG	HbA1c, TIR, metrics during daytime and nighttime, Percentage of participants achieving specific HbA1c targets (<7.0%, <7.5%, <8.0%), Severe Hypoglycaemic Events, Diabetic Ketoacidosis Events, Other Serious Adverse Events, and Other Non-serious Adverse Events.
Yaron 2019 (41) NCT02809365	Israel 2.5 months (10 weeks)	T2D on two or more insulin injections daily (with at least one prandial insulin injection)	FreeStyle Libre (isCGM)	SMBG	HbA1c changes, frequency of hypoglycaemic events, QoL, severe hypoglycaemic episodes.
Non-randomised studies					
Karter 2021 (78)	USA Kaiser Permanente Northern California claim registry 12 months	T1D and T2D, insulin treated patients	Not specified – "Real-time CGM device" *	SMBG	HbA1c mean change. Proportion of patients with HbA1c <7%, <8%, and >9%. Acute metabolic events (emergency department or hospital utilisation): General healthcare utilisation: emergency department visits for any reason, hospitalisations for any reason, number of outpatient visits, and number of telephone visits.
Nathanson 2025 (3)	Sweden National Diabetes Register, the Swedish Prescribed Drug Register, and the Swedish National Patient Register 6,12, and 24 months	T2D on basal or MDI	Not specified**	SMBG	Changes in mean HbA1c. Hospital admission rates for Diabetes-Related Complications: Overall hospitalisation: hospitalisation for any reason.
Reaven 2023 (79)	USA Veterans' Health Care Administration (VHA) health care system 12 months	T1D and T2D T2D on basal + bolus, basal, or bolus insulin therapy	Dexcom (34%) FreeStyle Libre (63%) Medtronic (3%)	SMBG	Change in Hb1Ac, percentages of patients achieving HbA1c <7%, 8% and 9%. Acute metabolic events (hypo and hyperglycaemia), overall hospitalisations.

CGM: continuous glucose monitoring; MDI: multiple daily injections (of insulin); CSII: continuous subcutaneous insulin infusion; HbA1c: haemoglobin A1c; isCGM: intermittently scanned continuous glucose monitoring; rtCGM: real-time continuous glucose monitoring; SMBG: self-monitoring of blood glucose; T1D: type 1 diabetes; T2D: type 2 diabetes; TAR: time above range; TBR: time below range; TIR: time in range; GV: glycaemic variation; USA: United States of America; NCT: the ClinicalTrials.gov identifier; ACTRN: Australian New Zealand Clinical Trials Registry

* Specific brand names are not provided, though Dexcom is mentioned as a funder; **The supplementary materials imply "FSL" (likely FreeStyle Libre) in the selection process diagram.

2.2.3 Risk of bias in the included RCTs

Risk of bias was assessed for 12 of the 13 included outcomes described in Section 2.1.1 using RoB v2 (60) for each included trial. Mortality was the only outcome not assessed, as it was reported in the trial registries rather than in the published trials, and RoB 2 is not applicable for evaluating outcomes reported in trial registries.

The overall risk of bias for each outcome was determined based on the criteria outlined in the Cochrane Handbook (62). An overall high risk of bias for an outcome was assigned if at least one domain was rated as having a high risk of bias, or if multiple domains were rated as having some concerns, considerably reducing confidence in the trial's outcome result. Detailed results of all RoB outcome assessments are presented in the text and in Table A4-1 in Appendix 4. A summary of the overall RoB for each outcome in each trial is provided below.

For HbA1c, the overall RoB was judged as having some concerns in six RCTs (38;40;42;66;75-77) and as high in three RCTs (24;41;74). The main concern was the possibility that behavioural changes—such as insulin adjustments based on feedback from the CGM device—may have influenced HbA1c outcomes more in the CGM group than in the SMBG group due to the continuous feedback provided by the CGM device.

The outcomes of total, nocturnal, and severe hypoglycaemic events, as well as TIR, TBR, TAR, and GV, were consistently rated as having overall some concerns across all RCTs (24;38;40-42;66;74;75;77). Although the judgements varied between trials, the main concerns were related to behavioural differences that could bias the true values of these metrics. Specifically, users may act differently when continuously viewing readings, and the continuous data provided by CGM devices can lead to behavioural changes that affect the outcomes, inherently biasing the outcome measurements in favour of the CGM group compared to the SMBG group.

QoL was rated as having overall some concerns (38;40;75) across all trials, primarily due to the lack of participant blinding and the subjective nature of its evaluation. However, the use of validated questionnaires somewhat mitigated the risk of bias. The mental health outcome was rated as having some concerns in one RCT (38) and as having an overall high risk of bias in another (75) due to the same issues identified for QoL.

Adverse events associated with the CGM device were generally rated as having some concerns (38;40;42;66;76), with two RCTs (74;77) receiving overall high risk of bias. This was mainly due to potential slight differential bias, where mild or subjective events may have been underreported in the SMBG group compared to the CGM group, as well as the lack of prespecification of the outcome in the trial registries in some RCTs.

Diabetes-related late vascular complications were rated as having overall some concerns in four RCTs (40;42;66;75;76), while two RCTs (24;77) were assessed as having an overall high risk of bias. This was primarily due to both the lack of blinding and potential performance bias arising from differential management between the two groups, as well as the absence of preregistration of the outcome in trial registries.

2.2.4 Risk of bias in the included non-RCTs

The risk of bias in non-RCTs was assessed using the ROBINS-I tool (61) across seven domains for each outcome in each study. The RoB judgments for the outcomes in each non-RCT are summarised in Table 7, with detailed descriptions provided in Appendix 4.

The overall risk of bias for each study was assessed based on predefined criteria (61). A judgement of overall moderate risk of bias was assigned if at least one domain was rated as moderate risk, but no domains were rated as serious or critical risk of bias. Studies were considered to have an overall serious risk of bias if at least one domain was rated as serious risk, or if multiple domains were rated as moderate risk, leading to a cumulative judgment of serious risk.

The overall RoB was judged as serious for HbA1c and severe hypoglycaemic events in Karter (78), serious for HbA1c in Nathanson (3), and serious for severe hypoglycaemic events in Reaven (79). Other outcomes in Nathanson (3), as well as HbA1c in Reaven (79), were judged as having an overall moderate risk of bias. The most prominent drivers of concern were the possibility of unmeasured confounders, potential misclassification of participants, and potential differences in follow-up care.

Table 7. Risk of bias assessment using the ROBINS-I tool

	D1	D2	D3	D4	D5	D6	D7	Overall
Karter 2021								
HbA1c	😐	😐	😐	😐	😐	🙂	😐	☹
Severe hypo events	😐	😐	😐	😐	😐	🙂	😐	☹
Nathanson 2025								
HbA1c	😐	😐	😐	😐	😐	🙂	😐	☹
Severe hypo events	😐	🙂	🙂	😐	🙂	😐	😐	😐
Diabetes-related late vascular complications	😐	🙂	🙂	😐	🙂	🙂	😐	😐
Reaven 2023								
HbA1c	😐	😐	😐	🙂	🙂	🙂	😐	😐
Severe hypo events	😐	😐	😐	🙂	😐	😐	😐	☹

D1: bias due to confounding; D2: bias in the selection of participants into the study; D3: bias in classification of interventions; D4: bias due to deviations from intended interventions; D5: bias due to missing data; D6: bias in measurement outcomes; D7: bias in the selection of the reported results; green: low risk of bias; yellow: moderate risk of bias; red: serious risk of bias

2.2.5 Clinical effectiveness and safety of the intervention

We compiled studies containing effect and safety data for all 13 outcomes presented in Table 2 in Section 2.1.1.

Where necessary, we performed various calculations and transformations to facilitate the meta-analysis, including reversing the direction of scales for consistency, transforming medians to means, or conducting other calculations as required. These adjustments, along with any underlying assumptions (if applicable), are detailed in the footnotes of the analyses.

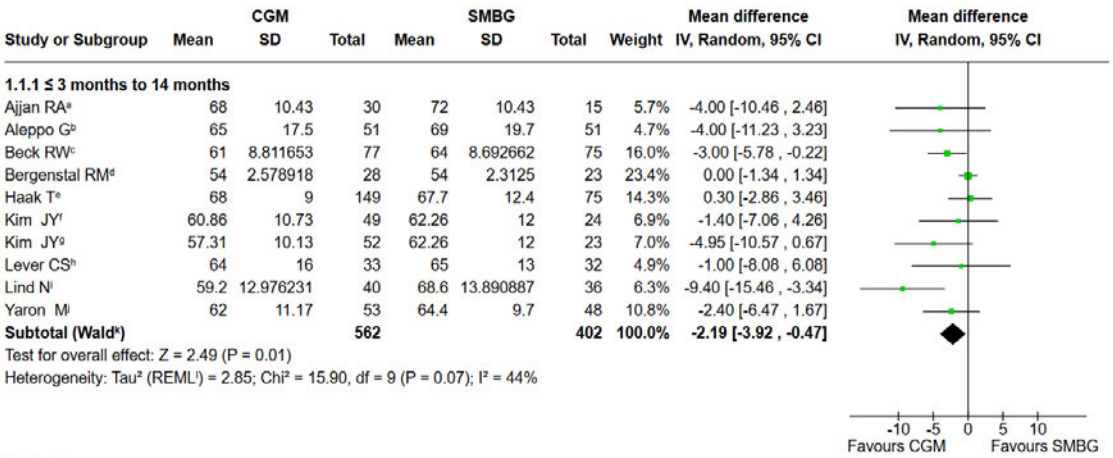
2.2.5.2 HbA1c

Nine RCTs (24;38;40-42;66;74-77) and three non-RCTs (3;78;79), provided data for HbA1c. To ensure standardisation and consistency, data are presented as millimoles of glycated haemoglobin per mole (mmol/mol).

2.2.5.2.1 Results from randomised controlled trials

When all RCTs (24;38;40;41;66;74-77) with end-of-intervention follow-up were pooled, the overall estimate for HbA1c showed a statistically significant reduction in the CGM group compared to the control group (MD: -2.19; 95% CI: -3.92 to -0.47; p = 0.01; I^2 = 44%; see Figure 2). The analysis included 964 participants. The interventions lasted between 3 and 14 months.

Although the reduction observed in the meta-analysis was statistically significant, it did not meet the prespecified threshold for the minimal clinically important difference of 5.5 mmol/mol, as outlined in Section 2.1.9.



Footnotes

[a]SIGN study, the pooled SD was calculated from the SE of the adjusted mean difference in the ANCOVA analysis; 3 months.
[b]MOBILE study, continue CGM vs SMBG; 14 months
[c]DIAMOND study, % converted to mmol/mol using the HbA1c net calculator https://www.hba1cnet.com/hba1c-calculator/; 6 months.
[d]REACT3 study, data extracted with WebPlotDigitizer-4.8; % converted to mmol/mol using the HbA1c net calculator https://www.hba1cnet.com/hba1c-calculator/ ; 4 months
[e]REPLACE study; 6 months
[f]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[g]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[h]2GO-CGM study; 3 months
[i]Steno2tech study; 12 months
[j]Post-intervention SDs were estimated from baseline and change SDs, assuming a high correlation (r = 0.9); 2.2 months.
[k]CI calculated by Wald-type method.
[l]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 2: Effect of CGM versus SMBG on HbA1c across RCTs at end of intervention

HbA1c results at different time points are presented in Appendix 5.

2.2.5.2.2 Results from non-randomised studies

The included non-randomised studies employed a difference-in-differences methodology, a statistical approach that estimates the causal effect of an intervention by comparing changes in outcomes over time between groups. However, pooling estimates across studies can be challenging due to variations in time periods, model specifications, contexts, and populations. As a result, the findings from the non-RCTs are presented narratively. Additionally, results from individual non-RCTs are illustrated in a graph designed to compare the direction and magnitude of the difference-in-differences estimates across studies (see Figure 3).

Karter (78) conducted a 12-month exploratory retrospective cohort study to evaluate outcomes before and after real-time CGM initiation. The study employed propensity score overlap weighting to balance baseline characteristics and applied statistical adjustments for key confounders, such as pre-baseline insulin treatment and glycaemic control. Furthermore, the authors stated that their “models were not adjusted for multiple comparisons and were thus exploratory,” highlighting the need for caution when interpreting the statistical significance of the findings. The total number of participants included in the HbA1c analysis was 41,753 insulin-treated patients, of whom 36,080 had T2D (344 CGM initiators and 35,736 non-initiators).

Difference in difference at 12 months

- The weighted and adjusted net change in HbA1c was −6.12 mmol/mol (95% CI, −7.87 to −4.48 mmol/mol; p < 0.001), corresponding to −0.56% (95% CI, −0.72% to −0.41%).

The analysis results met the prespecified threshold for the minimal clinically important difference of 5.5 mmol/mol. However, these findings should be interpreted with caution due to limitations in the study design.

Nathanson (3) investigated the impact of isCGM versus SMBG on HbA1c levels in adults with insulin-treated T2D using a retrospective comparative cohort design. The study linked data from several national healthcare registries in Sweden, as follows:

a) The National Diabetes Register, used to identify individuals with T2D,
b) The Swedish Prescribed Drug Register, which provided data on all prescribed and dispensed medicines nationwide and
c) The Swedish National Patient Register, which supplied administrative data on inpatient care, including hospital admissions and their associated diagnoses, coded according to ICD-10.

Key adjustments included propensity score-based inverse probability of treatment weighting (PS-IPTW), adjusted for baseline HbA1c and various confounders. The results of this study are reported for two cohorts: those treated with multiple daily insulin injections (T2D-MDI) and those on basal insulin (T2D-B). The total number of participants in the isCGM group was 6,800 (T2D-MDI: 2,876; T2D-B: 2,292), while the SMBG group included 78,386 participants (T2D-MDI: 33,584; T2D-B: 43,424).

Table 8 shows the results per group at 6, 12, and 24 months. In describing the analysis, Nathanson (3) characterised the outcome as the baseline-adjusted difference in the change in mean HbA1c for isCGM and SMBG participants. This statistical approach was designed to produce an estimate akin to a difference-in-differences analysis, accounting for baseline differences and comparing changes over time between groups. Although the reduction observed in the analyses was statistically significant, it did not meet the prespecified threshold for the minimal clinically important difference of 5.5 mmol/mol, as outlined in Section 2.1.9.

Table 8. Baseline-adjusted difference in change in HbA1c levels (Nathanson study)

Metric / Cohort	Timepoint	T2D-MDI	T2D-B	Results
HbA1c mmol/mol	Baseline	66 ±15.08 vs. 59.45±13.12	66.01±16.07 vs.62.62 ±13.01	Change was statistically significant for all observations (p<0.001). *Publication printing error in CI (confirmed by correspondence with Nathanson)
	6 months	-3.7 (-4.8 to -2.5)*	-3.5 (-3.9 to -3)	
	12 months	-3.4 (-4.4 to -2.5)*	-3.2 (-3.8 to -2.6)	
	24 months	-3.6 (-4.6 to -2.5)	-3.7 (-4.3 to -3.1)	

HbA1c: glycated haemoglobin; mmol/mol: millimoles per mole of total haemoglobin; T2D-B: type 2 diabetes treated with basal insulin only; T2D-MDI: type 2 diabetes treated with multiple daily injections (of insulin); CI: confidence interval.

Reaven (79) utilised a retrospective observational study to compare initiators of CGM with non-CGM users, with follow-up conducted at 6 and 12 months. Key adjustments included propensity score overlap weighting to balance baseline characteristics. The total sample size for the HbA1c analysis was 43,759 patients (15,292 CGM users and 28,467 non-users). These results were obtained using propensity score overlap weighting and linear mixed models/generalised estimating equations, with the difference-in-differences calculated to assess the change in HbA1c. The results were as follows:

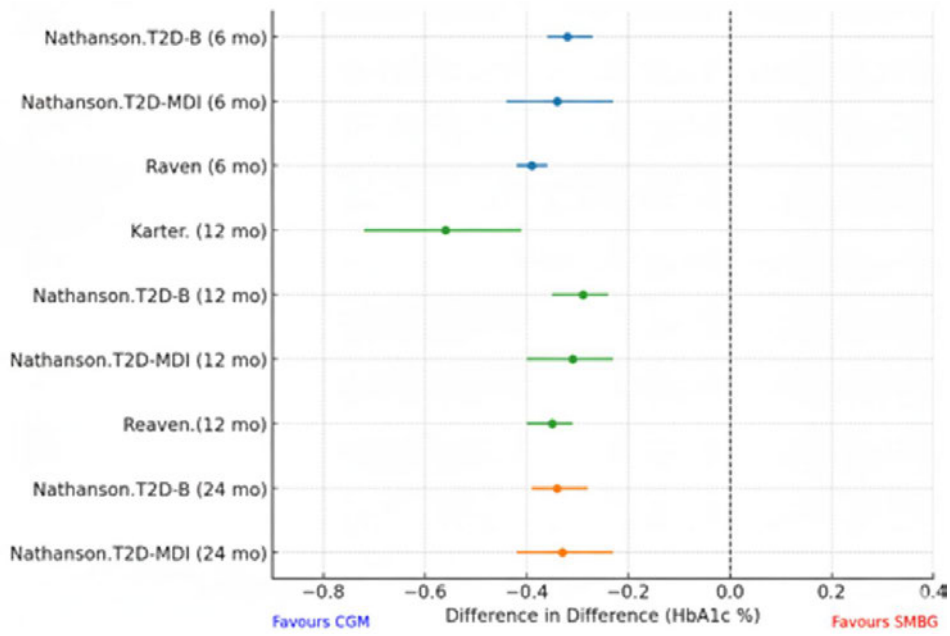
Difference-in-Differences

- At 6 months: −4.26 mmol/mol (95% CI −4.59 to −3.93 mmol/mol; −0.39%, 95% CI −0.42 to −0.36), p < 0.001
- At 12 months: −3.83 mmol/mol (95% CI −4.37 to −3.39 mmol/mol; −0.35%, 95% CI −0.40 to −0.31), p < 0.001

While the analyses revealed a statistically significant reduction, the decrease fell short of the predefined minimal clinically important difference of 5.5 mmol/mol, as specified in Section 2.1.9.

Summary of HbA1c results in non-randomised studies

As illustrated in Figure 3, all included non-RCT studies reported a reduction in HbA1c among CGM users compared with non-initiators or SMBG users. The difference-in-differences estimates indicated that the most significant improvement occurred at 12 months.



The figure was generated with the assistance of ChatGPT (v5.0) and has been reviewed and verified for accuracy by the authors.

Figure 3: Difference-in-differences for HbA1c at 6, 12, and 24 months as reported by the non-RCTs

Subgroup reported by the non-RCTs

Karter (78) identified uncontrolled diabetes by the proportion of patients with HbA1c levels higher than 74.9 mmol/mol (>9%) at baseline. There were 23.8% of patients in the rtCGM group and 24.8% in the non-initiator group. The authors found that, among those who started using rtCGM, there was a significant decrease in the proportion of patients whose HbA1c remained above 74.9 mmol/mol. After accounting for changes in the non-CGM user group, 11.5% fewer CGM initiators with T2D had an HbA1c greater than 74.9 mmol/mol (confidence interval for the net change: 16.7% fewer to 6.2% fewer).

Nathanson (3) investigated isCGM users with suboptimal glycaemic management, defining this subgroup based on baseline HbA1c levels. Suboptimal glycaemic management was defined as a baseline HbA1c ≥58.5 mmol/mol (≥7.5%). An additional analysis was performed for individuals with higher baseline HbA1c levels of ≥70 mmol/mol (≥8.6%). The study's findings are presented in Table 9.

Table 9. Baseline-adjusted difference in change HbA1c for isCGM vs SMBG users

	T2D-MDI Cohort	T2D-B Cohort
For baseline HbA1c ≥ 58.5 mmol/mol (≥7.5%) (p<0.001 in all instances).		
6 months	- 4.3 mmol/mol, -4.7 to-3.7	−4.6 mmol/mol, -5 to -4
12 months	- 4.6 mmol/mol, -4.9 to -4.3	–4.0 mmol/mol, -4.5 to -3.5
24 months	-4.1 mmol/mol, -4.9 to -3.5	−4.5 mmol/mol, -6.1 to -3.9
For baseline HbA1c ≥70 mmol/mol (≥8.6%)		
6 months	Both cohorts achieved greater reductions from baseline after starting isCGM with a mean decrease of 14.3 mmol/mol at 6 months (p<0.001 in both cases), which was maintained at 24 months.	
12 months		
24 months		

HbA1c: glycated haemoglobin; isCGM: intermittently scanned continuous glucose monitoring; mmol/mol: millimoles per mole; T2D-B: type 2 diabetes treated with basal insulin only; T2D-MDI: type 2 diabetes treated with multiple daily injections (of insulin)

The study by Reaven (79) examined subgroups with higher baseline HbA1c values to evaluate the potential for greater benefits from CGM initiation. However, the study did not specify a numerical threshold for what constitutes "higher baseline HbA1c values." The authors emphasised that CGM was particularly effective for patients with less controlled diabetes at baseline.

- Overall weighted baseline HbA1c for insulin users (indicating suboptimal control), both non-users and CGM users had an average HbA1c of 69 mmol/mol (8.5%).
- Improvement in HbA1c for subsets with higher baseline values: Up to −12.46 mmol/mol (calculated from a −1.14% decline).

Clinical Meaningfulness

Although we set our threshold for MCID at 5.5 mmol/mol, in alignment with the threshold established by NICE (73), several RCTs reported their own criteria for clinically meaningful results.

Haak (75) noted that the trial was powered to detect a difference of 3.8 mmol/mol (0.35%) in HbA1c between groups, indicating that this was considered a relevant threshold for the trial's objective.

Martens (42) defined a 4.4 mmol/mol (0.4%) treatment group difference in HbA1c as a clinically meaningful shift. The results stated that "in adults with poorly controlled T2D treated with basal insulin, CGM use, when compared to SMBG, resulted in a statistically significant adjusted difference of −0.4% (95% CI, −0.8% to −0.1%) at 8 months."

Yaron (41) reported that the trial's sample size calculation was based on detecting a 5.5 mmol/mol (0.5%) difference in HbA1c. Furthermore, a non-prespecified post-hoc analysis examined a "significant reduction" in HbA1c, defined as at least 5.5 mmol/mol (0.5%) and at least 10.9 mmol/mol (1%).

Reaven (79) noted that the observed declines in HbA1c in patients with T2D "approached 0.4%" (approximately 4.4 mmol/mol) and described these changes as "clinically meaningful," but did not report a specific minimally clinical important difference. The overall decline in HbA1c in T2D associated with CGM initiation (a weighted difference in differences of −4.26 mmol/mol [−0.39%] at 6 months and −3.83 mmol/mol [−0.35%] at 12 months) was considered clinically meaningful, especially as changes approached 0.4%.

2.2.5.3 Total hypoglycaemic events

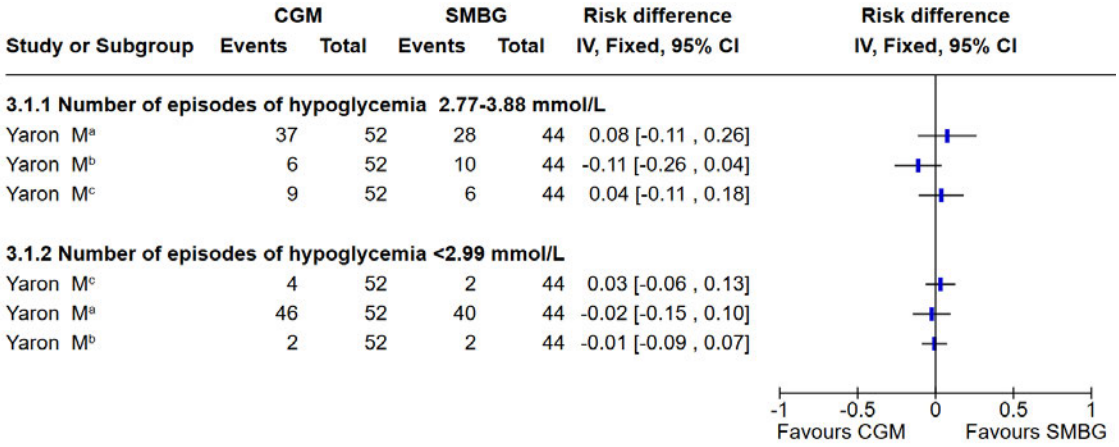
We defined total hypoglycaemic events as a single measure explicitly termed or assessed as 'total hypoglycaemia event,' combining both severity and time-of-day aspects into one metric for the entire cohort. Of the 12 included studies, only Yaron (41) provided data for this outcome.

Yaron (41) reported on hypoglycaemia events, distinguishing between different glucose ranges and thresholds. The study indicated that episodes could be symptomatic or asymptomatic and provided details on the number of documented symptomatic and/or self-reported hypoglycaemic episodes for two key glucose ranges and thresholds: 2.77 – 3.88 mmol/L and <2.99 mmol/L. No significant differences were observed between CGM and SMBG across the two glycaemic ranges or thresholds. The overall direction of effect was inconsistent across categories, with confidence intervals crossing zero, indicating no clear advantage of CGM over SMBG in reducing the total number of hypoglycaemic events at either range or threshold. The results are presented in Table 10 and Figure 4.

Table 10. Number of episodes of documented symptomatic and/or self-reported hypoglycaemia

	CGM (n=52)	SMBG (n=44)	p-value
Number of episodes of hypoglycaemia 2.77–3.88 mmol/L			
0 episodes	37	28	0.34
1 episode	6	10	
2+ episodes	9	6	
Number of episodes of hypoglycaemia <2.99 mmol/L			
0 episodes	46	40	0.89
1 episode	2	2	
2+ episodes	4	2	

CGM: continuous glucose monitoring; SMBG: self-monitoring of blood glucose; mmol/L: millimoles per litre



Footnotes

[a]Defined "total hypoglycemia incidence" as changes in total hypoglycemic events, no of episodes '0'

[b]Defined "total hypoglycemia incidence" as changes in total hypoglycemic events, no of episodes '1'

[c]Defined "total hypoglycemia incidence" as changes in total hypoglycemic events, no of episodes '2+'

Figure 4: Number of total hypoglycaemic events

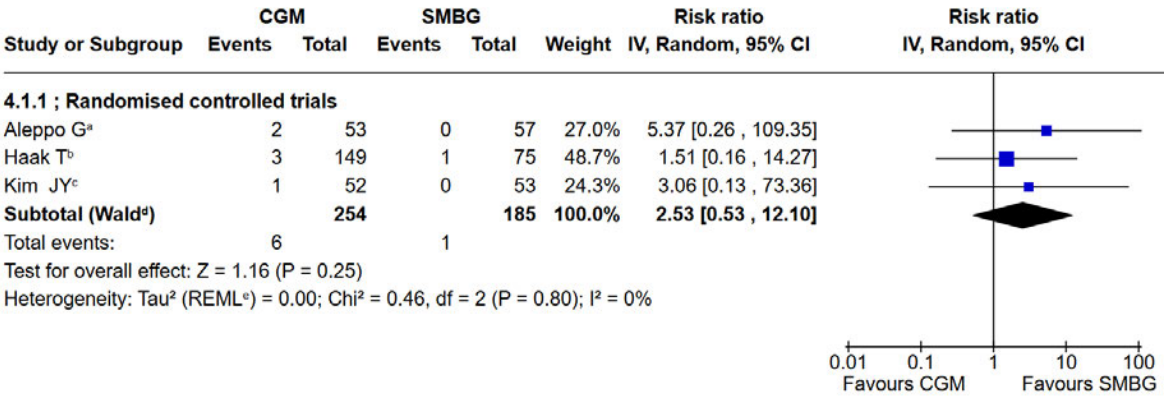
2.2.5.3.3 Severe hypoglycaemic events

We defined severe hypoglycaemic events as a blood glucose level below 3.1 mmol/L requiring third-party assistance.

Severe hypoglycaemic events reported in RCTs

Five RCTs, reported that no severe hypoglycaemic events occurred during the study period (24;38;40;76;77). Additionally, two RCTs (41;74) provided a definition of severe hypoglycaemia, but the reporting was unclear (see Table 11 for details).

Three RCTs (66;75;76), were included in the meta-analysis. The meta-analysis estimated the RR for severe hypoglycaemia at 2.53, with a 95% CI ranging from 0.53 to 12.10, $I^2 = 0\%$, p = 0.25, see Figure 5. This point estimate suggests a potential 153% increase in the risk of severe hypoglycaemia in the CGM group compared to the SMBG group. However, the result was not statistically significant, and the wide confidence interval includes the possibility of both benefit and harm.



Footnotes

[a]MOBILE study; ... events requiring assistance from another person to administer carbohydrates or other resuscitative action; 14 months

[b]REPLACE study, … an event requiring third-party assistance; 6 months

[c]FreEdoM-2 study, defines ***adverse events*** as any undesirable medical occurrences ; 6 months

[d]MOBILE study; ...events requiring assistance from another person to administer carbohydrates or other resuscitative action; 8 months

[e]CI calculated by Wald-type method.

[f]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 5: Relative risk for severe hypoglycaemia across RCTs at end of intervention

Severe hypoglycaemic events reported in non-RCTs

Among the non-RCTs, both Karter (78) and Nathanson (3) reported the impact of CGM on reducing severe hypoglycaemia. Karter (78) observed a 4% reduction in the event rate (−4.0% reduction in the

proportion of patients; 95% CI, −7.8% to −0.2%; p = 0.04). Nathanson (3) further differentiated outcomes by insulin regimen, showing a 49% relative risk reduction in the MDI group (RR 0.51; 95% CI 0.27 to 0.95; p = 0.034), but no statistically significant results in the basal-only group (RR 0.69; 95% CI 0.31 to 1.44; p = 0.305). Reaven (79), found no statistically significant difference between CGM users and non-users (HR 0.93; 95% CI 0.74 to 1.16; p = 0.52).

Definitions of severe hypoglycaemia in included studies

We summarised the definition of severe hypoglycaemia by study design (RCTs and non-RCTs) in Table 11, including the type of insulin and length of intervention, as different insulin types have varying pharmacokinetic profiles that influence hypoglycaemia risk. It is important to note that the studies did not specify a blood glucose level (e.g., below 3.1 mmol/L) for this outcome.

Table 11. Studies detailing definitions and outcomes of severe hypoglycaemia

Author, year	Length Type of insulin	Severe hypoglycaemia definition	Results
Randomised controlled trials			
Ajjan 2016 (74)	~3 month MDI	… an event requiring the assistance of a third party	Ajjan did not report new severe hypoglycaemic events.
Beck 2017 (38)	6 months MDI	… an event that required the assistance of another person to administer carbohydrates or other resuscitative action	**No severe hypoglycaemia events** occurred during the study.
Bergenstal 2022 (24)	~3.7 month Insulin (or sulfonylurea or incretin therapies)	The study focused on "clinically important hypoglycaemia (<2.8 mmol/L)".	There were **no reported adverse events for this study**.
Haak 2017 (75)	6 months Intensive insulin therapy or CSII	… an event requiring third-party assistance	Four hypoglycaemia serious adverse events were experienced by four participants (three intervention and one control).
Kim 2024 (76)	6 months MDI	Defines *adverse events* as any undesirable medical occurrences, but it does not provide a specific definition for "severe hypoglycaemia"	**No severe hypoglycaemia events** occurred during the study in any of the groups.
Lever 2024 (77)	3 months Using ≥0.2 units/kg/day of insulin (basal and bolus)	… an event requiring assistance from another person	There were **no episodes** of severe hypoglycaemia in either group.
Lind 2024 (40)	12 months 83% basal insulin without prandial insulin, 17% MDI	… "a hypoglycaemic event serious enough to require the help of another person (self-reported)"	There were **no episodes** of severe hypoglycaemia in either group.
Martens 2021 (42) / Aleppo 2021 (66)	8 and 14 months Basal insulin	… an event that required assistance from another person to administer carbohydrates or other resuscitative action	Two severe hypoglycaemic events occurred in one participant in the CGM group, none in the SMBG group.
Yaron 2019 (41)	2.2 months MDI	… events requiring third-party assistance	The study reports overall hypoglycaemic episodes (not specified as severe) based on glucose thresholds of <3.0 mmol/L and 3.0–3.9 mmol/L. e.g., glucose <3.0mmol/L, 4.5% of the

			control group and 3.8% of the intervention group experienced 1 episode, while 4.5% of the control group and 7.7% of the intervention group experienced 2+ episodes.
Non-Randomised controlled trials			
Karter 2021 (78)	12 months before and 12 after baseline index data Insulin-treated patients	Hypoglycaemia events were defined by a primary diagnosis from an emergency department encounter or a principal diagnosis from an inpatient admission using ICD-9-CM or IDC-10-CM codes, indicating severe events requiring medical attention	CGM initiation was associated with a −4.0% reduction in proportion of patients (95% CI, −7.8% to −0.2%; p = 0.04) experiencing hypoglycaemia event rates (ED or hospitalisation). NNT to avoid 1 hypoglycaemic event: 25 (95% CI, 13-476).
Nathanson 2025 (3)	Analysis span over 6,12, and 24 months Insulin-treated therapy, specifically differentiating between those on MDI and those on T2D-B	Severe hypoglycaemia was identified through hospital admissions for hypoglycaemia (based on ICD-10 diagnostic codes). The supplementary materials list "Hypoglycaemia without/with coma"	The event rate for isCGM was 0.17 per 100 person-years, compared to 0.33 per 100 person-years for SMBG users. T2D- MDI compared to SMBG, isCGM users had a 49% lower risk of admission for severe hypoglycaemia (RR 0.51; 95% CI 0.27 to 0.95; p=0.034). The event rate for isCGM was 0.27 per 100 person-years, compared to 0.44 per 100 person-years for SMBG users. T2D-B The study did not find a significant reduction in *hospitalisation* for severe hypoglycaemia in this cohort (RR 0.69; 95% CI 0.31 to 1.44; p=0.305). The event rate for isCGM was 0.18 per 100 person-years, compared to 0.25 per 100 person-years for SMBG users.
Reaven 2023 (79)	12 months before and 12 after baseline index data	Hypoglycaemia events were defined as the first occurrence of an ED or hospital admission if hypoglycaemia was listed as one of the diagnostic codes. A broader definition, including an outpatient blood glucose level <54 mg/dL (<3.0 mmol/L), was used for sensitivity analyses.	The study found no significant difference in *risk of admission* for hypoglycaemia between CGM users and nonusers (HR 0.93; 95% CI 0.74 to 1.16; p=0.52).

BGM: blood glucose monitoring; CGM: continuous glucose monitor; CI: confidence interval; CSII: continuous subcutaneous insulin infusion; ED: emergency department; HbA1c: glycated haemoglobin; HR: hazard ratio; ICD: international classification of disease; isCGM: intermittently scanned continuous glucose monitoring; MDI: multiple day (insulin) injections; mmol/mol: millimoles of glycated haemoglobin per mole of total haemoglobin; NNT: number needed to treat; RR: relative risk; T2D-B: type 2 diabetes treated with basal insulin only; T2D-MDI: Type 2 diabetes treated with multiple daily injections.

2.2.5.3.4 Nocturnal hypoglycaemic events

We defined nocturnal hypoglycaemic events as the number of occurrences where blood glucose levels fell below 3.9 mmol/L during sleep. The events of nocturnal hypoglycaemia, expressed as a rate per 100 person-years, was not reported in the included articles. However, three RCTs (38;42;66;75), provided data on nocturnal hypoglycaemia using alternative metrics, such as the percentage of time spent in hypoglycaemia below defined thresholds (e.g., 3.9 mmol/L) during specific hours (e.g., 23:00 to 06:00), event rates, or the frequency of events (counts) with glucose levels below certain thresholds (e.g., 3.9 or 3.1 mmol/L). The trials defined “nocturnal hypoglycaemia” as occurring over periods of 6, 7, or 8 hours. Table 12 presents an overview of the definitions and metrics used for reporting nocturnal hypoglycaemia.

Table 12. Definitions and metrics of nocturnal hypoglycaemia reported in the included RCTs

Study year	Nocturnal hypoglycaemia period definition	Metrics reported
Beck 2017	Defined as 22:00 to 6:00am (a 8-hour period)	% time <70 mg/dL and % time <60 mg/dL; % time <50 mg/dL, Area Under the Curve (h x mg/dL) of 70 mg/dL
Haak 2017	Defined nighttime as the period from 23:00 to 06:00 (a 7-hour period)	Events per day, time (in hours), Area Under the Curve (h x mg/dL) for different glucose thresholds i.e., 70 mg/dL, 50 mg/dL, 45 mg/dL
Martens 2021 / Aleppo 2021	Defined nighttime as 12:00 AM – 05:59 AM (or 12AM to 6AM) (a 6-hour period)	% time <70 mg/dL and % time <54 mg/dL; hypoglycaemia event rate (per week)*, time in range, coefficient of variation, hyperglycaemia (% time >180, 250, 300 mg/dL, mean glucose mg/dL

*A CGM-measured hypoglycaemic event was defined as at least two sensor values below 54 mg/dL, 15 or more minutes apart, with no intervening values above 54 mg/dL. The end of an event required at least 30 consecutive minutes with a sensor glucose concentration above 70 mg/dL

Time spent in nocturnal hypoglycaemia

Among the outcome measures reported in the RCTs, we synthesised the percentage of time/hours spent in hypoglycaemia for two different thresholds (3.9 mmol/L and 3.1 mmol/L). Challenges for these analyses included differences in how data were reported, such as varying concentration units (mg/dL and mmol/L), discrepancies in metrics (hours vs percentage), and variations in the defined 'nocturnal' time window (6, 7, or 8 hours). Additionally, the RCT by Beck (38) presented data in medians and interquartile ranges (IQR).

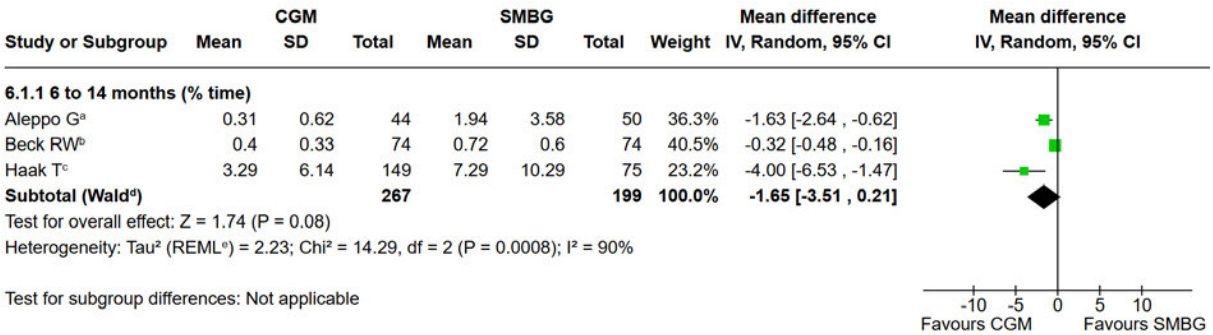
To ensure consistency, we first converted all glucose values to mmol/L, as done in previous analyses, and then standardised time values to percentage time based on the defined nocturnal window (e.g., 7 hours). Medians and IQR were used to estimate means and standard deviations (SD) using the online tool https://meta-converter.com/conversions.

Nocturnal hypoglycaemic events (3.9 mmol/L) reported in RCTs

The meta-analysis reports the effect of CGM versus SMBG on nocturnal hypoglycaemia (as percentage time), across two thresholds: 3.9 mmol/L (see Figure 6) and 3.1 mmol/L (see Figure 7).

The results of the analysis for 3.9 mmol/L were as follows:

Three RCTs (38;66;75) provided data for the 3.9 mmol/L threshold of nocturnal events at the end of the intervention follow-up, ranging from 6 to 14 months. The combined result showed a non-statistically significant difference between CGM and SMBG of -1.65 (95% CI -3.51 to 0.21; 466 participants; $I^2 = 90\%$; p = 0.08; see Figure 6). Heterogeneity in the analysis was explored but remained considerable (analysis not shown), indicating substantial variability among the included studies, which may limit the generalisability of the findings.



Footnotes

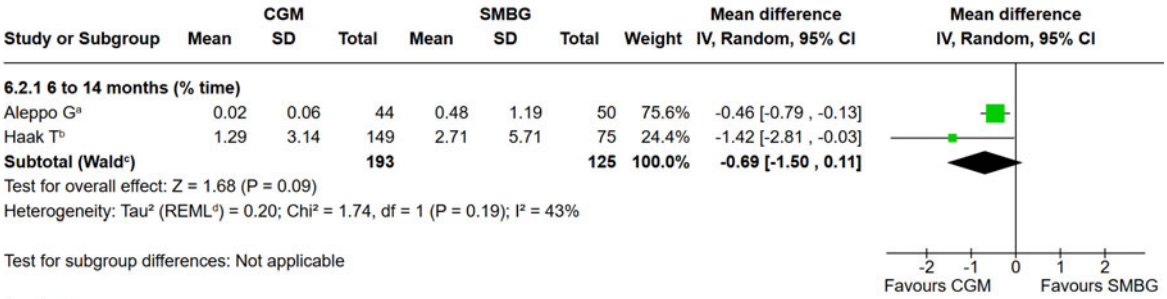
[a]MOBILE study, outcome measured from 12:00 AM to 05:59 (6 hrs), data winsorized (10th - 90th percentiles) - continue CGM vs. SMBG; 14 months.
[b]DIAMOND study, nighttime 10:00 p.m. to <6:00 a.m. (8 hrs); % time, medians and IQR (mg/dL) converted via meta-converter.com
[c]REPLACE study, nighttime: 23:00–06:00 (7 hrs), % time = (hours ÷ 7) × 100, SDs scaled similarly; 6 months.
[d]CI calculated by Wald-type method.
[e]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 6: Percentage of time on nocturnal hypoglycaemia for 3.9 mmol/L threshold at end of intervention

Nocturnal hypoglycaemic events (3.1 mmol/L) reported in RCTs

Results for 3.1 mmol/L were as follows:

Two RCTs (66;75) provided data for the 3.1 mmol/L threshold of nocturnal events at the end of the intervention follow-up, ranging from 6 to 14 months. The combined result showed a non-statistically significant effect of -0.69 (95% CI -1.50 to 0.11; 318 participants; I² = 43%; p = 0.09; see Figure 7).



Footnotes

[a]MOBILE study, defined as 6 hours from 12:00 AM – 05:59 AM and <54mg/dL
[b]REPLACE study; defined as 7 hours from 23:00 to 06:00; 55mg/dL. Hours converted to percentage using the formula: (hours ÷ 7) × 100; 6 months.
[c]CI calculated by Wald-type method.
[d]Tau² calculated by Restricted Maximum-Likelihood method.

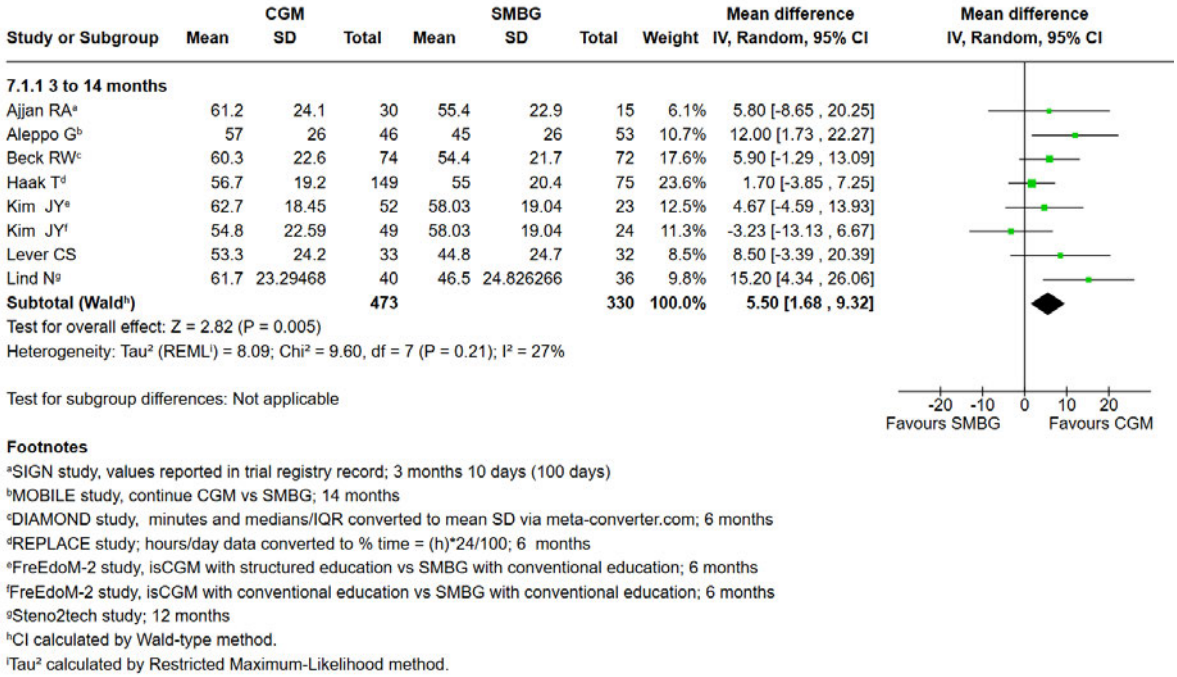
Figure 7: Percentages of time on nocturnal hypoglycaemia for 3.1 mmol/L threshold at end of intervention

2.2.5.4 TIR

We defined TIR as 3.9–10.0 mmol/L. Seven RCTs (38;40;42;66;74-77) provided data for this outcome. Data are presented as percentage time, followed by hours per day.

When data from all RCTs were pooled at the end of the intervention, the overall mean difference in TIR was 5.50% (95% CI: 1.68% to 9.32%; 803 participants; I² = 27%; p = 0.005; Figure 8). This indicates that the CGM group had approximately 1 hour and 20 minutes more time in range per day compared to the SMBG group. The length of the interventions ranged from 3 to 14 months.

The MCID for this outcome was set at a 5-percentage point change in TIR. While the point estimate exceeds this threshold, the confidence interval includes values below 5 percentage points, meaning the result suggests the potential for a clinically meaningful difference but does not confirm it with certainty.



Footnotes

[a]SIGN study, values reported in trial registry record; 3 months 10 days (100 days)
[b]MOBILE study, continue CGM vs SMBG; 14 months
[c]DIAMOND study, minutes and medians/IQR converted to mean SD via meta-converter.com; 6 months
[d]REPLACE study; hours/day data converted to % time = (h)*24/100; 6 months
[e]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[f]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[g]Steno2tech study; 12 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 8: Percentage of TIR across RCTs at end of intervention

TIR results at different time points are presented in Appendix 5.

2.2.5.5 TBR

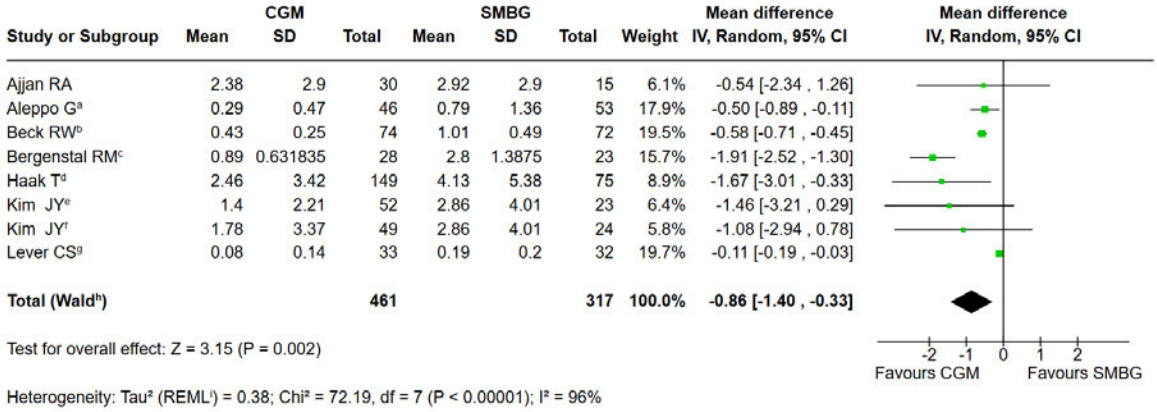
We defined TBR as 3.0–3.8 mmol/L. TBR was analysed separately for two hypoglycaemia thresholds: <3.9 mmol/L and ≤3.0 mmol/L. Nine RCTs (24;38;40-42;66;74-77) provided data for TBR, with one RCT by Yaron (41) focusing on the frequency of hypoglycaemic events, which is also described in Section 2.2.6.2 and Appendix 5.

2.2.5.5.5 TBR <3.9 mmol/L

Seven RCTs (24;38;66;74-77) reported results on TBR <3.9 mmol/L at the end of the intervention follow-up, ranging from 3 to 14 months. The meta-analysis showed a statistically significant reduction in percentage TBR, favouring CGM (MD: -0.86; 95% CI: -1.40 to -0.33; 778 participants; $I^2 = 96\%$; $p = 0.002$; Figure 9), equivalent to approximately 12 minutes fewer per day in hypoglycaemia. The substantial heterogeneity ($I^2 = 96\%$) warranted further exploration, detailed in Appendix 5.

Clinically important difference of TBR

When no specific MCID was available, we applied a MCID of 0.5 times the median standard deviation of the comparison arms (73), as described in Section 2.1.9. Based on this criterion, the meta-analysis indicated that the mean reduction in TBR favouring CGM exceeded the threshold for clinical importance. However, it should be noted that the confidence interval does not consistently meet the predefined threshold for MCID, introducing some uncertainty regarding the robustness of this finding.



Footnotes

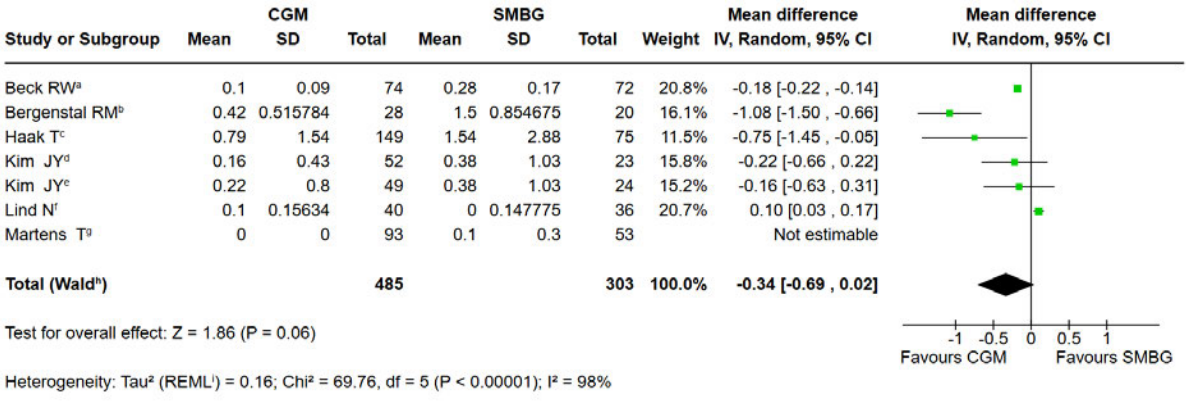
[a]MOBILE study, data reported as winsorized (10th - 90th percentiles) prior to reporting summary statistics; 14 months
[b]DIAMOND study, medians and IQR, transformed to mean and SD via meta-converter.com, and from min to %Time; 6 months
[c]REACT3 study, digital data extracted with WebPlotDigitizer-4.7 for subgroup using insulin, data reported as hypoglycemia rates with SE; 4 months
[d]REPLACE study, h converted to % time; 6 months
[e]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[f]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[g]2GO-CGM; authors noted the data were very skewed, medians and IQR transformed via meta-converter.com; 3 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 9: Percentage of TBR <3.9 mmol/L across RCTs at end of intervention

TBR <3.9 mmol/L results at different time points are presented in Appendix 5

2.2.5.5.6 TBR ≤3.0 mmol/L

Six RCTs (24;38;40;42;75;76) provided data for TBR ≤3.0 mmol/L. When statistically combined, the percentage of TBR was not statistically significant (MD: -0.34; 95% CI: -0.69 to 0.02; 788 participants; p = 0.06, see Figure 10). Due to considerable heterogeneity (I² = 98%), a sensitivity analysis was conducted, see details in Appendix 5.



Footnotes

[a]DIAMOND study, medians and IQR converted via meta-converter.com and min to %; 6 months
[b]REACT3 study; data reported as hypoglycemia rates and SE; 4 months
[c]REPLACE study; h converted to % time; 6 months
[d]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]Steno2tech study, authors state TBR was very low for both groups, limiting their ability to assess hypoglycemia; 12 months
[g]MOBILE study, data winsorized at the 10th and 90th percentiles prior reporting; 8 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 10: TBR ≤3.0 mmol/L across RCTs at end of intervention

TBR <3.0 mmol/L results at different time points are presented in Appendix 5

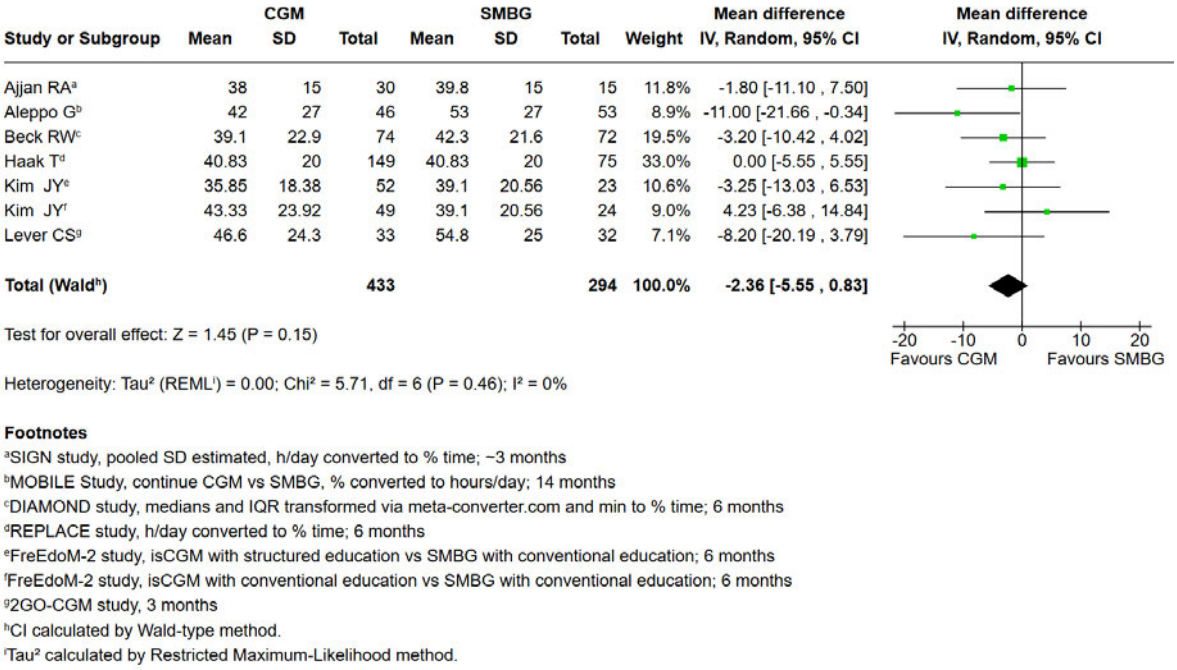
2.2.5.6 TAR

We defined TAR as 10.1–13.9 mmol/L. In one RCT (75), the TAR threshold was set at 13.3 mmol/L, whereas in the remaining RCTs, it was set at 13.9 mmol/L.

TAR was analysed separately for two glucose thresholds: >10.0 mmol/L and >13.0 mmol/L (hours/day). The results are described below.

2.2.5.6.7 TAR >10.0 mmol/L

Six RCTs (38;66;74-77) provided data for TAR >10.0 mmol/L. The overall percentage time mean difference for TAR was -2.36 (95% CI: -5.55 to 0.83; 727 participants; I^2 = 0%; p = 0.15; see Figure 11), equivalent to 34 minutes per day less time above range. This suggests a trend towards a reduction in TAR >10.0 mmol/L in the CGM group compared to the SMBG group; however, the confidence interval indicates that this difference was not statistically significant.



Footnotes

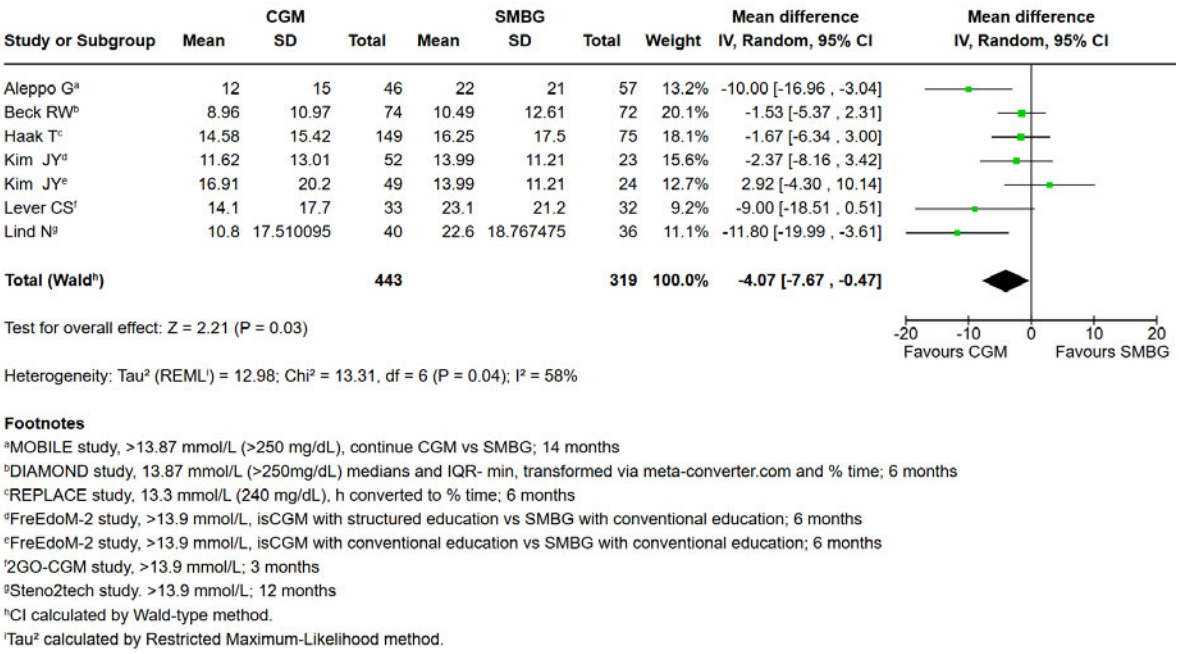
[a]SIGN study, pooled SD estimated, h/day converted to % time; ~3 months
[b]MOBILE Study, continue CGM vs SMBG, % converted to hours/day; 14 months
[c]DIAMOND study, medians and IQR transformed via meta-converter.com and min to % time; 6 months
[d]REPLACE study, h/day converted to % time; 6 months
[e]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[f]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[g]2GO-CGM study, 3 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 11: Analysis of TAR >10 mmol/L across RCTs at end of intervention

TAR >10 mmol/L results at different time points are presented in Appendix 5

2.2.5.6.8 TAR >13.0 mmol/L

Six RCTs (38;40;66;75-77) provided data for TAR >13.0 mmol/L. The overall percentage time mean difference for TAR >13.0 mmol/L was -4.07 (95% CI: -7.67 to -0.47; 762 participants; I^2 = 58%; p = 0.03; Figure 12), indicating a significant reduction in TAR >13.0 mmol/L in the CGM group compared to the SMBG group. This corresponds to approximately 59 minutes per day less TAR (>13.0 mmol/L) in the CGM group. However, an I^2 of 58% indicates moderate to substantial heterogeneity. This was explored with a sensitivity analysis, detailed in Appendix 5.



Footnotes

[a]MOBILE study, >13.87 mmol/L (>250 mg/dL), continue CGM vs SMBG; 14 months
[b]DIAMOND study, 13.87 mmol/L (>250mg/dL) medians and IQR- min, transformed via meta-converter.com and % time; 6 months
[c]REPLACE study, 13.3 mmol/L (240 mg/dL), h converted to % time; 6 months
[d]FreEdoM-2 study, >13.9 mmol/L, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, >13.9 mmol/L, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]2GO-CGM study, >13.9 mmol/L; 3 months
[g]Steno2tech study. >13.9 mmol/L; 12 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 12: Analysis of TAR >13.0 mmol/L across RCTs at end of intervention

Clinically important difference of TAR

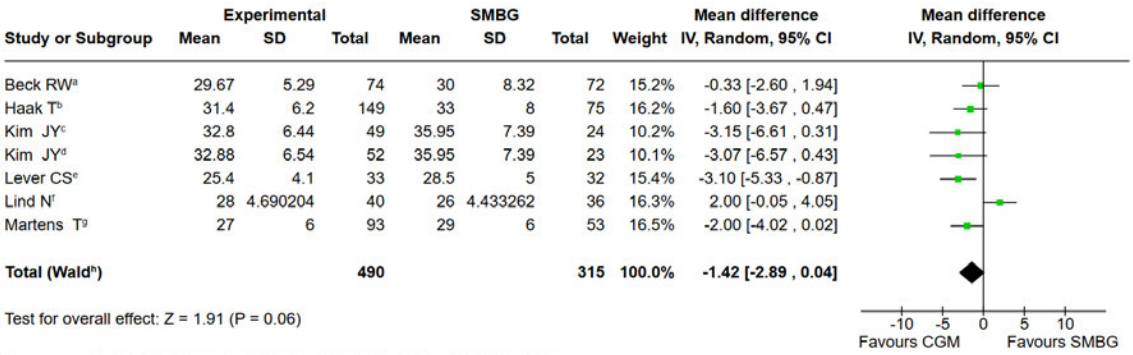
When no specific MCID was available, we applied a MCID of 0.5 times the median standard deviation of the comparison arms (73), as previously described. The MD of -4.07 exceeds this threshold, suggesting a clinically meaningful reduction in TAR (>13.0 mmol/L) in the CGM group compared to the SMBG group. However, the lower bound of the 95% CI (-0.47) does not exceed the predefined MCID threshold, introducing some uncertainty regarding the robustness of the observed reduction.

TAR >13.0 mmol/L results at different time points are presented in Appendix 5.

2.2.5.7 GV

We defined GV as fluctuations in blood glucose levels, with the recommended target being a coefficient of variation (CV) of 36% or lower (%CV, target ≤36%) (48).

Six RCTs (38;40;42;75-77) provided data for GV and were included in the meta-analysis. The results showed no statistically significant reduction in GV in the CGM group compared to the SMBG group. The overall mean difference was -1.42 (95% CI: -2.89 to 0.04; 805 participants; $I^2 = 61\%$; $p = 0.06$; see Figure 13). Heterogeneity was moderate to substantial ($I^2 = 61\%$). We therefore conducted a sensitivity analysis, detailed in Appendix 5.



Footnotes

[a]DIAMOND study, medians and IQR converted based on the assumption of approximate normality via https://meta-converter.com/conversions/mean-sd-iqr., 6 months
[b]REPLACE study; 6 months
[c]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education: 6 months
[d]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months.
[e]2GO-CGM study; 3 months
[f]Steno2tech study, data converted to %; 12 months
[g]MOBILE Study (CGM vs BGM); number of participants reflect participants with sufficient CGM data at the 8-month visit; 8 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure 13: Analysis of GV across RCTs at end of intervention

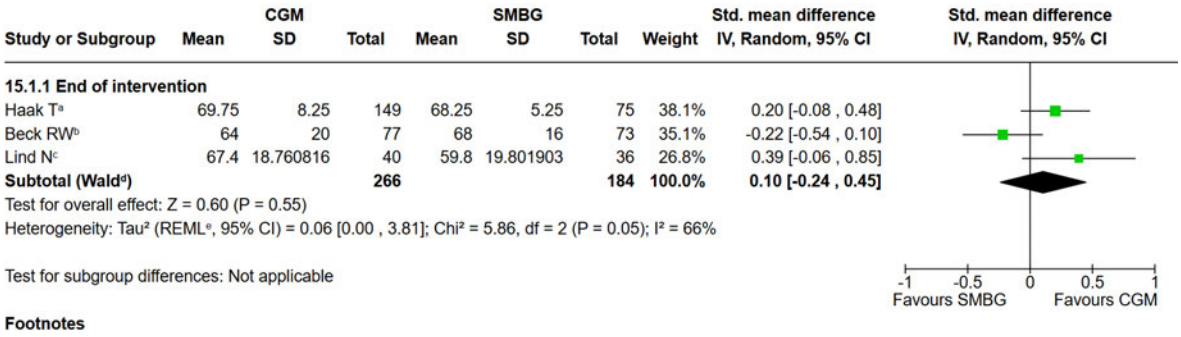
The MD of -1.42 suggests that, on average, the CGM group experienced a 1.42 percentage point reduction in CV compared to the SMBG group. However, this result was not statistically significant. Notably, across the included studies, the CGM groups consistently reported mean GV values well below the 36% threshold (ranging from 25.4% to 32.88%), while the SMBG groups often approached the upper limit of the recommended target (up to 35.95%). Even a modest additional reduction of approximately 1.5% with CGM could play an important role in helping individuals remain safely below the 36% cutoff.

2.2.5.8 Quality of life

We defined QoL across overall and psychological subdomains, incorporating both disease-specific PROMS and general measures (e.g., EQ-5D).

Three RCTs (38;40;75) reported QoL using different instruments: one used the EuroQol 5 Dimensions (EQ-5D) and the World Health Organization Five Well-Being Index (WHO-5) (38), another used the Short Form Health Survey -36 items (SF-36) and WHO-5 (40), and the third applied the Diabetes Quality of Life (DQoL) scale (75). To enable quantitative synthesis, the WHO-5 Well-Being Index was selected as the common metric. This decision allowed the combination of two of the three studies that reported overlapping WHO-5 data, maximising the sample size and ensuring consistency of measurement across datasets. The DQoL data from the third study were retained, with the score inverted (multiplied by -1) before pooling to align with the direction of the other instruments. Consequently, EQ-5D and SF-36 outcomes were excluded from the meta-analysis to prevent heterogeneity introduced by incomparable scales.

The overall QoL results indicated a standardised mean difference (SMD) of 0.1 higher (95% CI: -0.24 to 0.45; 450 participants; $I^2 = 66\%$; $p = 0.55$), suggesting no significant impact of CGM on QoL (see Figure 14). The substantial heterogeneity ($I^2 = 66\%$) indicated variability across studies, prompting us to conduct a sensitivity analysis, detailed in Appendix 5.



Footnotes

[a]DIAMOND study, WHO-5 total score, scale of 0-5 over the past 2 weeks (scale 0-25) - higher scores = better quality of life; WHO-5 scores reported by Beck were originally presented as raw totals. For consistency with Lind, these have been converted to percentage scores (range: 0–100) by multiplying the mean and SD by 4.
[b]REPLACE study, DQoL - total score -scores range from 1 to 5, high scores = dissatisfaction, frequent impact, or frequent worry. Inverted score (6-original mean), so higher values indicate better quality of life. These inverted scores were then linearly transformed to a 0–100 scale using the formula: (score – 1) × 25, for consistency with WHO-5. Data extracted using WebPlotDigitizer-4.7.
[c]Steno2tech study; 12 months

Figure 14: Overall QoL across RCTs at end of intervention

2.2.5.9 Diabetes-related late vascular complications

Diabetes-related late vascular complications included conditions such as nephropathy, retinopathy, neuropathy, coronary heart disease, peripheral vascular disease, and stroke.

2.2.5.9.9 Results from the RCTs

Evidence for diabetes-related late vascular complications in the included RCTs was limited. Two RCTs, Yaron (41) and Bergenstal (24), reported no adverse events, while the three-arm RCT by Kim (76) reported a single stroke in the comparison group. The results of three RCTs (40;42;66;77), are presented in a forest plot to provide a graphical representation of the findings (see Figure 15). The effect estimates showed no significant differences between the CGM and SMBG groups.

For stroke (8 and 12 months), the OR was 1.15 (95% CI: 0.14 to 9.21; 251 participants; $I^2 = 0\%$; p = 0.9) based on data from Lind (40) and Martens (42).

For arterial stenosis at 14 months, the OR was 3.29 (95% CI: 0.13 to 82.43; 110 participants; p = 0.47) as reported by Aleppo (66).

Arteriosclerotic heart disease at 8 months showed an OR of 1.55 (95% CI: 0.06 to 38.52; 175 participants; p = 0.79) based on Martens (42).

Peripheral vascular disease, using necrosis of toes as a surrogate outcome at 3 months, had an OR of 0.31 (95% CI: 0.01 to 7.98; 65 participants; p = 0.48) as reported by Lever (77).

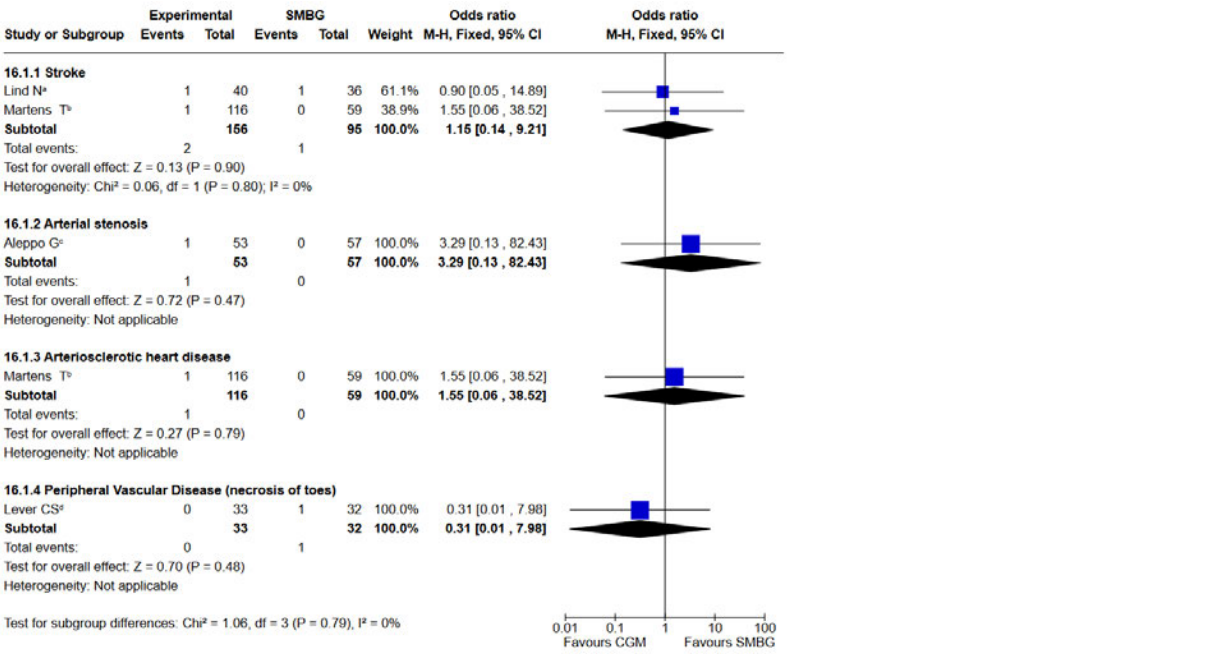
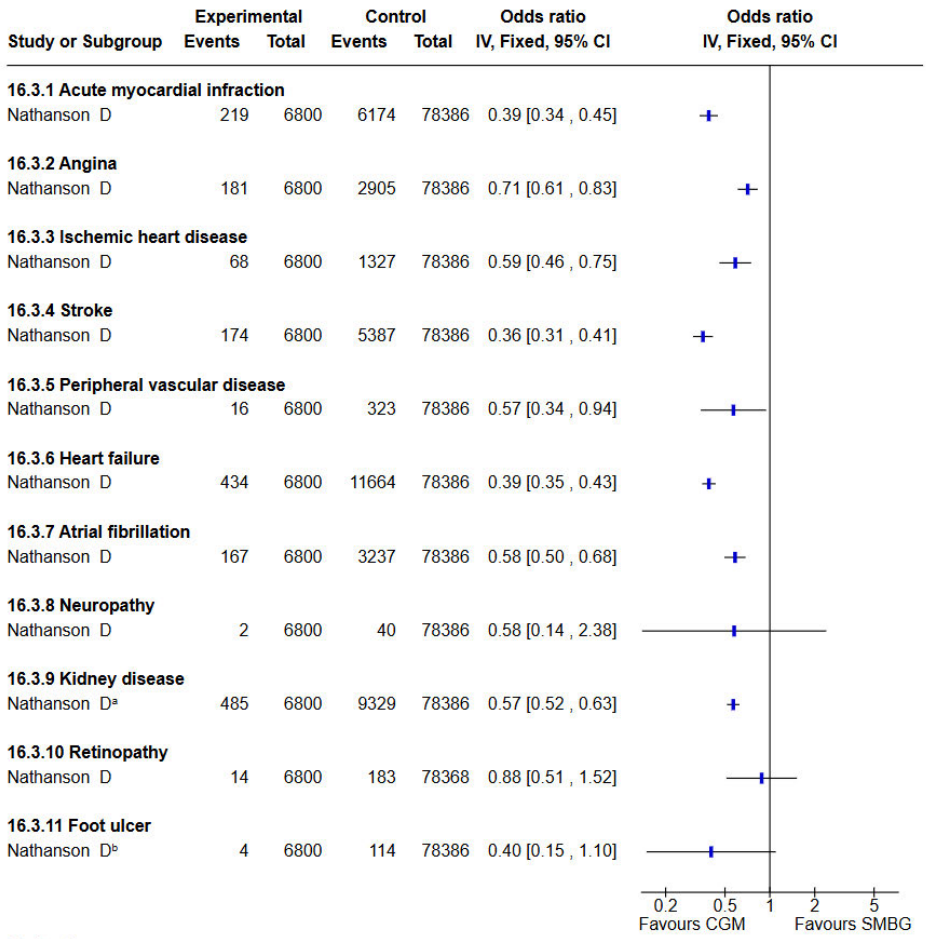


Figure 15: Diabetes-related late vascular complications across RCTs

2.2.5.9.10 Results from non-RCTs

Two non-RCTs (Karter (78) and Reaven (79)) did not provide specific information on diabetes-related late vascular complications as a measured outcome. Instead, the authors focused on acute metabolic events, such as hypoglycaemia and hyperglycaemia requiring urgent care, as well as changes in HbA1c.

Nathanson (3) utilised hospital data for various diabetes-related complications sourced from the Swedish National Patient Register. The findings were presented for all adults with T2D using isCGM, as well as for two subgroups: T2D-MDI and T2D-B. We present these data as odds ratio (OR) in Figure 16.



Footnotes

[a]Nephropathy was included as an outcome in the PICO, rather than specifically kidney disease.

[b]Foot ulcer was not included as a separate outcome in the PICO. However, foot ulcers may be associated with neuropathy and/or peripheral vascular disease .

Figure 16: Diabetes-related late vascular complications derived from non-RCT data

Diabetes-related late vascular complications for individuals with T2D on MDI

Results of isCGM users compared to SMBG in the T2D-MDI cohort (3) demonstrated the following:

- A significantly lower relative risk (RR) of admission for stroke (RR: 0.54; 95% CI: 0.39 to 0.73; $p < 0.001$).
- A significantly lower RR of admission for acute non-fatal myocardial infarction (RR: 0.75; 95% CI: 0.57 to 0.99; $p = 0.047$).
- No statistically significant RR for hospital admissions due to angina (RR: 1.37; 95% CI: 1.00 to 1.87; $p = 0.051$).
- No statistically significant change in RR for ischaemic heart disease, peripheral vascular disease, heart failure, kidney disease (nephropathy), retinopathy, or foot ulcer. Neuropathy had insufficient events for analysis.

Diabetes-related late vascular complications for T2D patients on basal insulin with isCGM

Results of isCGM users compared to SMBG in the T2D-B cohort (3) demonstrated the following:

- A significantly lower RR of admission for heart failure (RR: 0.63; 95% CI: 0.46 to 0.87; $p = 0.006$).
- A significantly increased RR of admission for angina (RR: 1.75; 95% CI: 1.24 to 2.47; $p = 0.002$).

- No statistically significant change in RR for stroke, acute non-fatal myocardial infarction, ischaemic heart disease, peripheral vascular disease, kidney disease (nephropathy), retinopathy, or neuropathy.
- Foot ulcer had insufficient events for analysis.

2.2.5.10 Mortality

None of the full-text publications reported data on mortality. However, information available in some trial registry records indicated that mortality was listed as a study endpoint. We documented this discrepancy under the risk of bias domain for selective reporting. Specifically, the trial registries for Ajjan (74), Bergenstal (24), and Haak (75) included mortality as an outcome, yet none of the corresponding publications reported these data. In all cases, the results posted in the trial registries indicated that there were no deaths in either study group.

2.2.5.11 Adverse events associated with the CGM device

Adverse events associated with the CGM device included issues such as contact dermatitis, hypersensitivity reactions, scarring, lipodystrophy, and false low glucose readings. All nine RCTs reported on adverse events associated with the device. The findings were as follows:

Three RCTs reported no adverse events. Beck (38) and Bergenstal (24) specified that reportable adverse events included “all device or study-related adverse events.” Yaron (41), however, did not provide details beyond a general statement indicating no serious adverse events.

The safety analysis by Ajjan (74) included all participants screened and enrolled, for whom at least one attempt was made to insert the device. The authors reported that 48 out of 56 participants (87.3%) experienced sensor insertion site symptoms but did not provide a breakdown of specific events.

One device-related adverse event was reported by Lever (77) among all participants. This involved a minor skin reaction to the sensor adhesive, which required antihistamine treatment.

Kim (76) reported one device adhesion problem in one of the intervention groups.

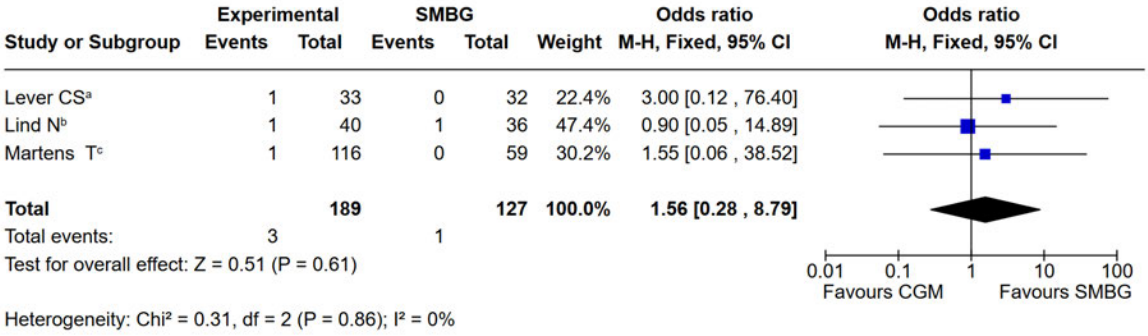
In Haak (75), device-related adverse events in the intervention group were categorised as sensor-adhesive reactions. Six participants (4.0%) reported a total of nine device-related events. The severity of these events was as follows: 2 severe, 6 moderate, and 1 mild. Specific events included erythema and itching, sensor insertion site reactions, sensor site allergic reactions, necrosis at the sensor insertion site, infection at the sensor site (two events), rash at the sensor site (two events), and sensor allergy. No device-related adverse events were reported in the control group.

Across the MOBILE trial (Martens (42) and Aleppo (66)), five non-serious adverse events were reported in the CGM group. These included two cases of bruising, one case of itching, and two cases of rash.

Two device-related adverse events were reported by Lind (40) across all participants. One participant in the CGM group experienced a skin reaction (rash) after the removal of the first blinded CGM, while one participant in the SMBG group also experienced a skin reaction (rash) after the removal of the first blinded CGM.

Skin lesions or reactions

Three RCTs (40;42;77) reported on skin lesions or reactions. We summarised these findings in a meta-analysis. The results showed no statistically significant difference between the groups (OR 1.56, 95% CI 0.28 to 8.79, p=0.61, I^2 = 0%, 316 participants; see Figure 17).



Footnotes

[a]2GO-CGM study, minor skin reaction to sensor adhesive, which required antihistamine treatment; 3 months

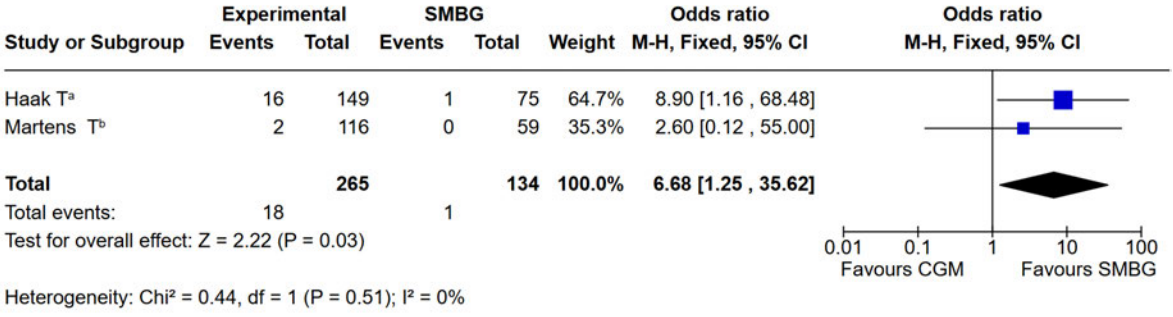
[b]Steno2tech study. Skin reaction (rashes) after removal of the first blinded CGM); baseline 10 days of blinded CGM wear in both group

[c]MOBILE study, skin lesion; 8 months

Figure 17: Skin lesions or reactions reported across RCTs

Rash

Two RCTs reported on rash at or near the sensor site. The results indicated a statistically significant difference between the groups, favouring the control group (OR 6.68, 95% CI 1.25 to 35.62, p=0.03, I^2 = 0%, 399 participants; see Figure 18). However, the wide confidence interval (1.25 to 35.62) suggests substantial uncertainty in the effect estimate, likely due to the relatively small number of events (18 in the CGM group and 1 in the control group). This underscores the need for caution when interpreting the results, as the true effect may vary considerably.



Footnotes

[a]REPLACE study, CGM 6 months, BGM 4 weeks masked use

[b]MOBILE study; 8 months

Figure 18: Rash reported across RCTs

2.2.5.12 Mental health outcomes associated with the CGM device

The mental health outcome included device-related anxiety, depression, distress, and related conditions.

Three RCTs (38;40;75) reported mental health outcome, using the Diabetes Distress Scale, where lower scores indicate less distress and higher scores reflect greater distress. Additionally, one of these RCTs (40) assessed fear of hypoglycaemia using the Hypoglycaemia Fear Survey-II at 6 and 12 months, where lower scores indicate less fear and higher scores reflect greater fear of hypoglycaemia.

2.2.5.12.11 Diabetes Distress Scale (Overall)

At 6 months, the results for the mental health outcome measured using the Diabetes Distress Scale showed no statistically significant differences between CGM and control groups (38;40;75) (MD: -0.11; 95% CI: -0.23 to 0.00; p = 0.06; I^2 = 44%; 450 participants; see Figure 19). Similarly, at 12 months, no

statistically significant difference was observed in one RCT (40), (MD: -0.40; 95% CI: -0.81 to 0.01; 76 participants; see Figure 19).

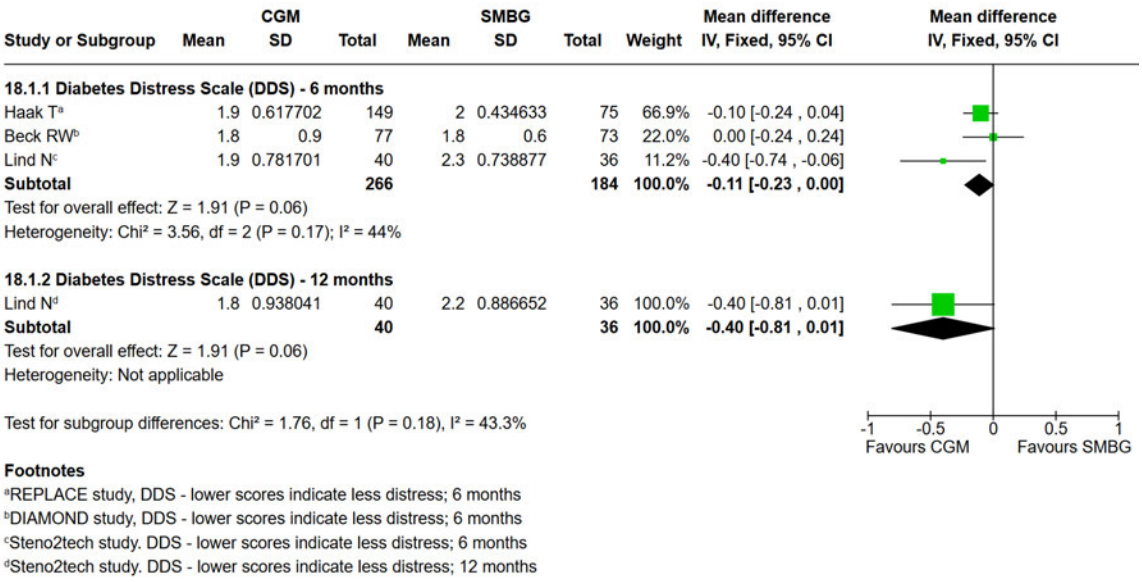


Figure 19: Overall mental health outcomes across RCTs at 6 and 12 months

2.2.5.12.12 Diabetes Distress Scale – Emotional Burden

Two RCTs reported on the Diabetes Distress Scale – Emotional Burden. At 6 months, there was no statistically significant difference between the intervention and control groups (MD: -0.08; 95% CI: -0.37 to 0.21; I² = 46%; 374 participants; 2 studies; see Figure 20).

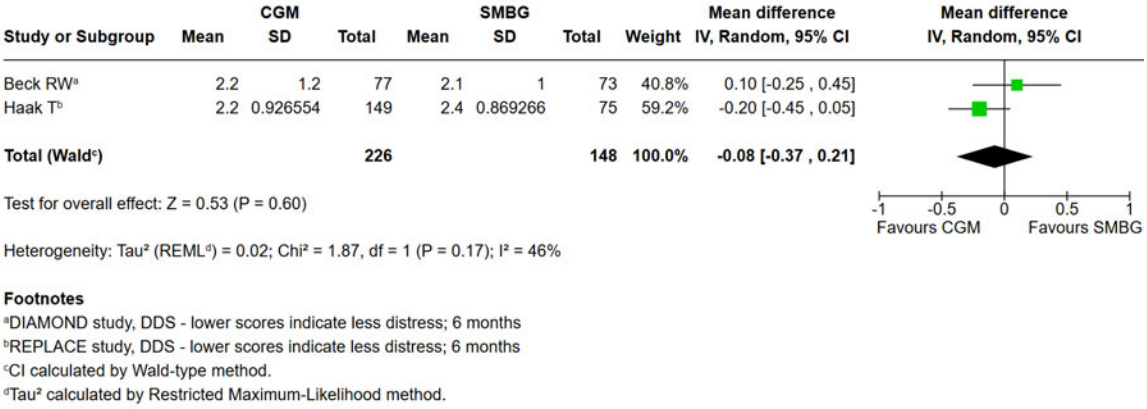


Figure 20: Diabetes Distress Scale – Emotional burden

2.2.5.12.13 Diabetes Distress Scale – Interpersonal Distress

Two RCTs (38;75) reported on the Diabetes Distress Scale – Interpersonal Distress. At 6 months, there was no statistically significant difference between the intervention and control groups (MD: -0.06; 95% CI: -0.25 to 0.13; I² = 0%; 374 participants; see Figure 21).

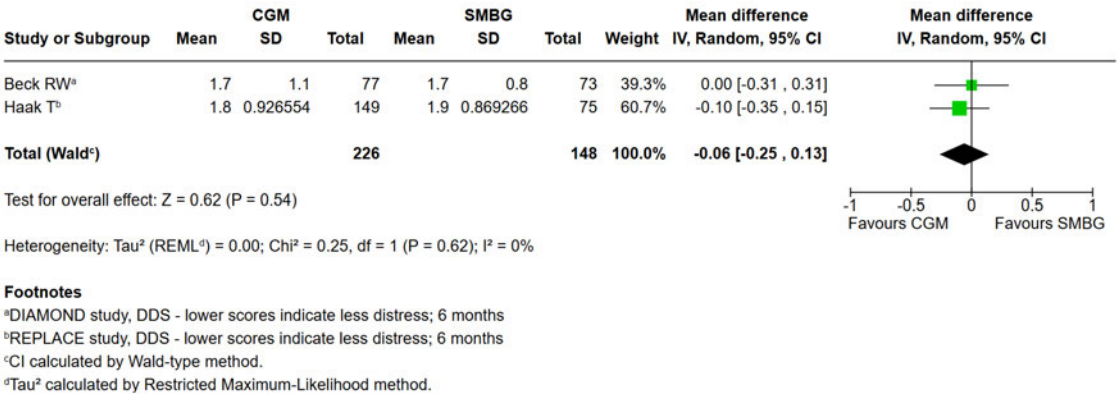


Figure 21: Diabetes Distress Scale – Interpersonal Distress

2.2.5.12.14 Hypoglycaemia Fear Survey-II (HFS-II)

One RCT (40) reported on hypoglycaemia fear. At 6 and 12 months, there was no statistically significant difference between CGM and control (6 months: MD: -0.70; 95% CI: -3.23 to 1.83, and 12 months: MD: -0.30; 95% CI: -2.68 to 3.28; 76 participants; see Figure 22).

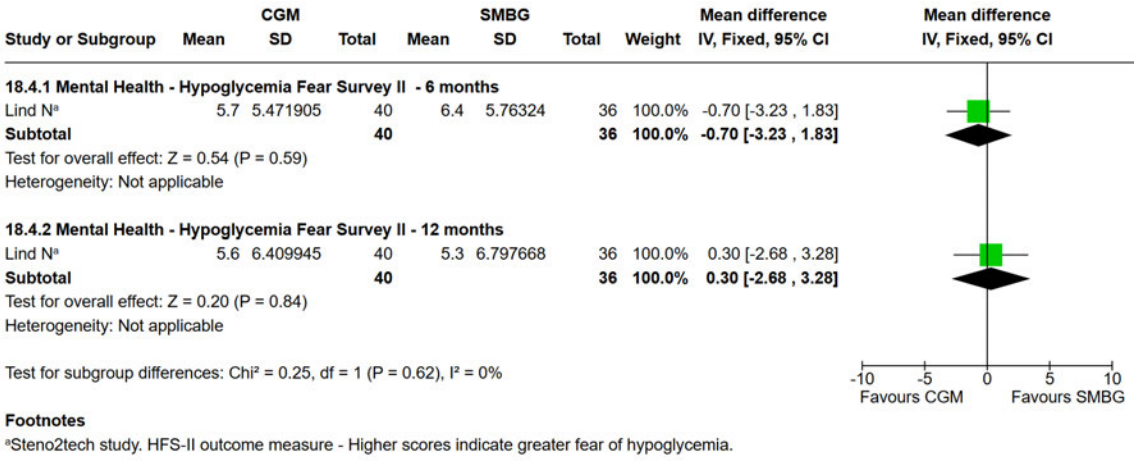


Figure 22: Hypoglycaemia Fear Survey-II

2.2.5.13 Assessment of effectiveness of CGM in predefined subgroups

The commissioner tasked NOMA with conducting subgroup analyses for insulin-treated T2D populations previously identified as particularly well-suited for CGM use. These subgroups are described in Section 1.5, and the results regarding these populations are summarised below.

2.2.5.13.15 *Individuals with T2D on multiple daily injections (MDI) with rapid-acting insulin who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses*

None of the included studies specifically focused on participants with T2D on MDI with rapid-acting insulin who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses. However, six RCTs (38;41;74-77) and one non-RCT (3) included participants on either MDI, intensive insulin therapy, or continuous subcutaneous insulin infusion (CSII).

As summarised in Table 13, the RCTs primarily investigated populations with suboptimal or poorly controlled T2D as their main cohorts. A key finding across these studies was that the observed improvements in glycaemic control in these populations were achieved without an increased risk of

hypoglycaemia (24;38;40-42;66;74-77). Table 13 provides an overview of the eligibility criteria and baseline HbA1c values of the RCTs.

Table 13. HbA1c parameters for study inclusion and baseline profile

Author year	Hb1Ac inclusion criteria	Baseline HbA1c Mean HbA1c ± SD mmol/mol (%)	Other
Ajjan 2016	The inclusion criteria specified an HbA1c between 58 and 108 mmol/mol (7.5% and 12.0%).	CGM group 76.5 ± 15.0 mmol/mol (9.2% ± 1.4%), SMBG group, 77.4 ± 13.7 mmol/mol (9.2% ± 1.3%).	Focus on individuals receiving MDI, typically indicating poorly controlled diabetes
Beck 2017	Eligibility criteria defined the study population as having HbA1c levels between 58 to 86 mmol/mol (7.5% to 10%)	CGM group was 76.4 ± 14.1 mmol/mol (9.1% ± 1.3%), and SMBG group 74.8 ± 13.9 mmol/mol (8.9% ± 1.2%)	The focus is on individuals receiving MDI, typically indicating poorly controlled diabetes.
Bergenstal 2022	Inclusion criteria specified uncontrolled T2D defined as HbA1c 53 mmol/mol (≥7.0%)	CGM Group 66 ± 13.1 mmol/mol (8.19% ± 1.2%), and SMBG group 62 ± 8.63 mmol/mol (7.85% ± 0.79%)	
Haak 2017	Inclusion criteria stipulated an HbA1c level between 58 and 108 mmol/mol (7.5% and 12.0%).	CGM group 72.0 ± 10.6 mmol/mol (8.7% ± 0.97%) and SMBG group 73.5 ± 11.3 mmol/mol (8.8% ± 1.04%)	The study specifies intensive insulin therapy
Kim 2024	Inclusion criteria: HbA1c level of 58 to 97 mmol/mol (7.5% to 12%)	The overall weighted baseline HbA1c for the T2D cohort was 69 mmol/mol (8.5%)	Individuals with MDI or an insulin pump for 12 weeks or more
Lever 2024	Inclusion: adults with T2D who had elevated HbA1c ≥64 mmol/mol (8.0%)	CGM group: 85 ± 18 mmol/mol (10.0% ±1.7%) SMBG group: 81 ± 12 mmol/mol (9.6% ±1.1%)	The study aimed at high-risk individuals.
Lind 2021	Inclusion: participants were included if their HbA1c was ">58 mmol/mol (7.5%)	The median baseline HbA1c for the overall cohort was 67 mmol/mol (8.3%).	Subgroup analysis planned for subgroups with baseline HbA1c ≥8.5%, ≥9.0%, ≥9.5%, ≥10.0% but not reported
Martens 2021 / Aleppo 2021	Inclusion specified HbA1c of 62 mmol/mol to 102 mmol/mol (7.8% to 11.5%). The study states its focus on adults with "poorly controlled type 2 diabetes."	The mean HbA1c for the overall cohort at baseline (initial randomization) was 76 mmol/mol (9.1% ± 0.9%).	Additional subgroups changes in HbA1c are reported based on their baseline HbA1c values: "≥8.5%", "≥9.0%", "≥9.5%", and "≥10.0%
Yaron 2019	Inclusion: HbA1c values of 58 to 86 mmol/mol (7.5%-10%), later slightly expanded (due to recruitment and time constraints) to 57–88 mmol/mol (7.4% – 10.2%).	CGM group: 71 ± 9.5 mmol/mol (8.6% ± 0.87%) SMBG group: 68 ± 8.1 mmol/mol (8.3% ± 0.74%)	Focus on individuals receiving MDI, typically indicating poorly controlled diabetes

SMBG: self-monitoring of blood glucose; CGM: continuous glucose monitoring; HbA1c: haemoglobin A1c; MDI: multiple day injections; mmol/mol: millimoles per mole; SD: standard deviation; T2D: type 2 diabetes.

2.2.5.13.16 Individuals with T2D on insulin therapy who have experienced more than one episode of severe hypoglycaemia in the past year.

None of the included studies specifically focused on participants with T2D on insulin therapy who have experienced more than one episode of severe hypoglycaemia.

2.2.5.13.17 Individuals with T2D on insulin therapy whose profession involves significant risks if hypoglycaemia occurs.

None of the included studies specifically focused on participants with T2D on insulin therapy whose profession involves significant risks if hypoglycaemia occurs.

2.2.5.13.18 Younger individuals with T2D on insulin therapy who have intellectual disabilities.

None of the included studies specifically focused on participants with T2D on insulin therapy who have intellectual disabilities.

2.2.5.13.19 Women with T2D using MDI of insulin, during preconception planning and throughout pregnancy. Continuous use may also be considered during the postpartum period if the MDI regimen is maintained and there is a risk of hypoglycaemia.

None of the included studies specifically focused on women with T2D using MDI of insulin, during preconception planning, throughout pregnancy, or on CGM use during the postpartum period when an MDI regimen is maintained and the risk of hypoglycaemia persists.

2.2.6 GRADE – assessment of certainty in the evidence

We assessed the certainty in the evidence using the GRADE framework. Main outcomes are presented in Table 14. However, the full assessment can be found in Appendix 6.

Table 14: SoF table of CGM compared to SMBG

Outcomes	Expected absolute effects (95% CI)		No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with SMBG	Risk with CGM			
HbA1c	NA	MD 2.19 lower (3.92 lower to 0.47 lower)	964 (9 RCTs)	⊕⊕⊕◯ MODERATE [a]	Did not reach MICD of 5.5 mmol/mol
HbA1c	NA	DiD_1: -6.12, 95% CI, -7.87 to -4.48 mmol/mol, 12 months DiD_2: −3.83, 95%CI −4.37 to -3.39 mmol/mol, 12 months DiD_3: T2D-MDI -3.6, 95%CI -4.6 to -2.5 and T2D-B -3.7, 95%CI -4.3 to -3.1, mmol/mol, 24 months	(3 non-RCTs)	⊕⊕◯◯ LOW [b]	Results not pooled. Difference in Difference (DiD) reported for each study. Only one study (Karter 2021) reached the predefined MICD of 5.5 mmol/mol. However, the authors emphasise that this outcome should be regarded as exploratory evidence.
Severe hypoglycaemic events	NA	RR 1.71 (0.44 to 6.66), 6 more per 1000 (from 5 fewer to 46 more)	614 (3 RCTs in meta-analysis) 532 (5 RCTs narratively described)	⊕◯◯◯ VERY LOW [a,g]	*No severe hypoglycaemia*, defined as "requiring third-party assistance," was reported in 5 RCTs
Severe hypoglycaemic events	NA	Karter:4% event rate drop, 95% CI, −7.8% to −0.2%, p = 0.04. Reaven: HR 0.93; 95% CI 0.74 to 1.16, p=0.52. Nathanson: T2D-MDI RR 0.51; 95% CI 0.27 to 0.95; p=0.034, T2D-B: RR 0.69; 95% CI 0.31 to 1.44; p=0.305	165,025 (3 non-RCTs)	⊕◯◯◯ VERY LOW [b,c,f]	Two studies reported statistically significant reductions in severe hypoglycaemia, while one study found no statistically significant difference
Time In Range 3.9-10.0 mmol/L	NA	MD 5.5% higher (1.68 higher to 9.32 higher)	803 (7 RCTs)	⊕⊕⊕◯ MODERATE [a]	Length ranged from 3 to 14 months
Time Below Range <3.9 mmol/L	NA	MD 0.86 lower (1.4 lower to 0.33 lower)	778 (7 RCTs in meta-analysis) 101 (1 RCT narratively described)	⊕◯◯◯ VERY LOW [a,d]	One RCT examined hypoglycaemia frequency and is described narratively.

Outcomes	Expected absolute effects (95% CI)		No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with SMBG	Risk with CGM			
Time Below Range <3.0 mmol/L	NA	MD 0.34 lower (0.69 lower to 0.02 higher)	788 (6 RCTs)	⊕◯◯◯ VERY LOW [a,d]	No statistically significant difference
Time Above Range >10.0 mmol/L	NA	MD 2.36 lower (5.55 lower to 0.83 higher)	727 (6 RCTs)	⊕⊕⊕◯ MODERATE [a]	No statistically significant difference
Time Above Range >13.3 mmol/L	NA	MD 4.07 lower (7.67 lower to 0.47 lower)	762 (6 RCTs)	⊕⊕◯◯ LOW [a,c]	-
Quality of life	NA	SMD 0.1 higher (0.24 lower to 0.45 higher)	450 (3 RCTs)	⊕⊕◯◯ LOW [a,c]	No statistically significant difference
Diabetes-related late vascular complications - stroke	NA	OR 1.15 (0.14 to 9.21) 2 more per 1,000 (from 9 fewer to 79 more)	251 (2 RCTs)	⊕⊕◯◯ LOW [a,g]	No statistically significant difference
Diabetes-related late vascular complications - arterial stenosis	NA	OR 3.29 (0.13 to 82.43) 0 fewer per 1,000 (from 0 fewer to 0 fewer)	110 (1 RCT)	⊕◯◯◯ VERY LOW [a,g]	No statistically significant difference
Diabetes-related late vascular complications - arteriosclerotic heart disease	NA	OR 1.55 (0.06 to 38.52) 0 fewer per 1,000 (from 0 fewer to 0 fewer)	175 (1 RCT)	⊕◯◯◯ VERY LOW [a,g]	No statistically significant difference
Diabetes-related late vascular complications - peripheral vascular disease (necrosis of toes)	NA	OR 0.31 (0.01 to 7.98) 21 fewer per 1,000 (from 31 fewer to 173 more)	65 (1 RCT)	⊕◯◯◯ VERY LOW [a,e,f]	No statistically significant difference
Diabetes-related late vascular complications - stroke	NA	OR 0.36 (0.31 to 0.41) 43 fewer per 1,000 (from 47 fewer to 39 fewer)	85,186 (1 non-RCT)	⊕⊕⊕◯ MODERATE [a]	Non-RCT from Sweden
Diabetes-related late vascular complications – acute myocardial infarction	NA	OR 0.39 (0.34 to 0.45) 46 fewer per 1,000 (from 51 fewer to 42 fewer)	85,186 (1 non-RCT)	⊕⊕⊕◯ MODERATE [a]	Non-RCT from Sweden
Diabetes-related late vascular complications – heart failure	NA	OR 0.39 (0.35 to 0.43) 85 fewer per 1,000 (from 91 fewer to 79 fewer)	85,186 (1 non-RCT)	⊕⊕⊕◯ MODERATE [a]	Non-RCT from Sweden
Mortality	NA	Not pooled. No deaths in either study group were reported in the trial registries	393 (3 RCTs)	NA	Not feasible to GRADE because mortality was only reported in trial registries

[a] Downgraded one level due to an overall moderate risk of bias in the outcome measurement
[b] Downgraded two levels due to overall serious risk of bias in the outcome measurement
[c] Downgraded one level due to serious inconsistency in the results or meta-analysis for this outcome (I^2 of between 50% and 70%, potentially indicating substantial heterogeneity)
[d] Downgraded two levels due to very serious inconsistency in the meta-analysis for this outcome (I^2 of between 70% and 100%, suggesting considerable heterogeneity)
[e] Downgraded one level due to the outcome being a surrogate endpoint
[f] Downgraded one level due to wide confidence interval, suggesting some uncertainty in the effect estimate
[g] Downgraded two levels due to very wide confidence interval, suggesting substantial uncertainty in the effect estimate
NA: not assessable; MD: mean difference; SMD: standardised mean difference: OR: odds ratio; MDI: multiple daily injections (of insulin); B: basal insulin

3. Health economic evaluation

The healthcare sector, like society in general, is restricted by limited resources and budget constraints. Health economic evaluations aim to ensure that available resources are used to achieve the greatest possible health benefit, supporting informed decision-making.

In Norway, decisions regarding the introduction, use, or phasing out of health interventions are based on three prioritisation criteria: health benefit, resource use, and disease severity (82;83). These criteria should be considered together and balanced against one another. Greater resource use may be justified when an intervention provides substantial health benefits or addresses a more severe condition (82;83).

The priority-setting criteria are to be evaluated together and weighed against each other (82;83). In practice, the three priority-setting criteria are considered by weighing costs against benefits in a health economic analysis. A health economic evaluation is a comparative analysis of treatment options where the health effects and costs of the treatment alternatives are measured and compared. Results of economic evaluations can be expressed as an incremental cost-effectiveness ratio (ICER), which is defined by the following equation:

$$ICER = \frac{Cost_{\text{intervention}} - Cost_{\text{comparator}}}{Effect_{\text{intervention}} - Effect_{\text{comparator}}} = \frac{\Delta C}{\Delta E}$$

The ICER must be compared to a threshold of cost-effectiveness to decide if the intervention is cost-effective or not, except in the case that either a) the intervention is both more effective and less costly than the comparator (i.e., intervention is a dominant alternative) or b) the intervention is both less effective and more costly than the comparator (i.e., intervention is a dominated alternative).

Health economic evaluations are often based on decision models (such as Markov models) that calculate results from various input parameters. Because there are always uncertainties related to the values of these parameters, sensitivity analysis is an important feature of any economic evaluation based on a decision model framework. In short, sensitivity analysis illustrates how much the results vary when model parameters are changed. Probabilistic sensitivity analysis (PSA) is a kind of sensitivity analysis. The advantage of PSA is that it allows uncertainties in all model parameters to be accounted for simultaneously. The basic approach in PSA is to assign probability distributions to all uncertain model parameters, which replaces the “fixed” values of the parameters with values generated by random draws from the distributions. The calculation is based on the alternative that renders the highest values of net monetary benefit (NMB) or net health benefit (NHB). Results from PSAs are often presented as scatter plots, which show point estimates of the ICER for all iterations in the cost-effectiveness plane, and are also presented as cost-effectiveness acceptability curves (CEACs), which show the probability of the alternatives being cost-effective subject to changing values of the threshold value. The calculation is based on the alternative that renders the highest values of net monetary benefit (NMB) or net health benefit (NHB).

3.1 Methods

3.1.1 General

The systematic review results did not identify data related to the diabetes late complications for the entire insulin-treated T2D individuals. Therefore, the outcomes were insufficient to perform a model-based analysis for this population. Consequently, the relationship between health benefits and resource use related to the introduction of CGM for the entire population of insulin-treated T2D individuals was assessed based on the results of the systematic review, using HbA1c as a surrogate endpoint.

To assess the cost-effectiveness of CGM compared with self-SMBG in individuals with T2D treated with insulin requiring hospital follow-up, we conducted a cost-utility analysis (CUA) within the Norwegian healthcare context. The model adopted a lifetime time horizon with health effects expressed in terms of quality-adjusted life years (QALYs). The relevant costs were expressed in 2024 Norwegian kroner (NOK). Both costs and effects were discounted using an annual discount rate of 4% as recommended by the guidelines for health economic evaluation in the health sector (84). The analysis was carried out from an extended healthcare perspective. This approach includes all relevant healthcare costs across both specialist and primary healthcare services in the Norwegian setting but excludes broader societal costs, such as productivity losses. This perspective aligns with the priorities established within a fixed healthcare budget, as outlined in the priority-setting white paper (82;83). We expressed the probabilistic results as the mean ICER from 10,000 model runs in the base case. Moreover, we addressed uncertainties in the model parameters by conducting different scenario analyses, including deterministic and probabilistic sensitivity analyses, which were designed as a Monte Carlo simulation with 10,000 iterations.

3.1.2 Population, intervention, and model structure

3.1.2.1 Population

We developed a cost-effectiveness model for individuals with insulin-treated T2D requiring hospital follow-up, assuming a mean age of 67 years, as recommended by clinical experts.

3.1.2.2 Intervention

As described earlier in the report, there are two main types of personal CGM systems: real-time CGM (rtCGM), which continuously transmits glucose data, and intermittently scanned CGM (isCGM), which requires users to scan the sensor to access glucose readings. According to experts' opinion, there is no clinically relevant difference in effect between the two CGM types for this population. In addition, the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF) conducts a joint tender for all CGM devices. Therefore, we evaluated them as a single intervention, using CGM as the intervention in the model.

3.1.2.3 Model structure

We developed a decision-analytic model in TreeAge Pro 2025. The model is a Markov model in which a cohort of patients is followed over a defined time horizon. A Markov modelling approach was considered appropriate, as T2D is a chronic condition requiring continuous treatment.

We assessed the costs and utilities associated with CGM and SMBG in adults with insulin-treated T2D on insulin therapy over a lifetime horizon. The model used a cycle length of one year, meaning that any transitions between health states could occur only once per year. A half-cycle correction was applied to improve accuracy.

The structure of the applied Markov model is similar to previously published health economic evaluations of CGM in individuals with diabetes (85). The validity of the model structure and its

assumptions for the Norwegian context was discussed and assessed by clinical experts with experience in treating individuals with insulin-treated T2D in Norway.

The model incorporates multiple health states, during which various late complications may arise. These complications are expected to influence both cost and health outcomes, as well as the progression of T2D and the associated risk of future complications. Additionally, the model accounts for the possibility of acute complications. The primary distinction between CGM and SMBG lies in the varying probabilities, costs, and effect parameters associated with each option.

The health states were primarily defined based on complications reported in a Swedish publication that examined diabetes-related complications in adults with insulin-treated T2D, comparing those using CGM with those using SMBG (3). At any given time, patients could be in only one of the predefined states. Upon completion of each cycle, patients could, depending on transition probabilities, move to another state or remain in the same state until death. Each health state and event is associated with specific health outcomes and costs. Death was modelled as an absorbing state; once an individual transitions into this state, no further transitions occur, and no additional costs or health outcomes are recorded. The following late complication health states were included in the model (Figure 23):

- Retinopathy
- Neuropathy
- Nephropathy

- Cardiovascular disease (CVD), as defined in this model, encompasses several prevalent conditions, including stroke, peripheral artery disease (PAD), heart failure (HF), ischaemic heart disease, atrial fibrillation, acute myocardial infarction (AMI), and angina
- Additionally, the model includes health states for concurrent and/or more severe disease:
  - Retinopathy and neuropathy
  - Retinopathy and nephropathy
  - Retinopathy and CVD
  - Neuropathy and nephropathy
  - Neuropathy and CVD
  - Nephropathy and CVD
  - Blindness
  - Lower extremity amputation (LEA)
  - End-stage renal disease (ESRD accompanied by another late complication (e.g., CVD)
  - More than two concurrent diseases, excluding ESRD and LEA, e.g., simultaneous presence of retinopathy, CVD (e.g., PAD), and neuropathy

For CVD complications, we applied different mortality risks, disutilities, and costs for the first year compared with subsequent years to reflect the higher burden immediately following disease onset. Furthermore, for health states involving two late complications in individuals without prior CVD, it was assumed that the additional risk of developing further complications encompassed the probability of experiencing CVD.

In addition, based on the advice of the clinical experts, we included acute diabetic complications such as severe hypoglycaemia and diabetic foot ulcers in the model as events. These events do not lead to transitions between health states but are relevant for the accumulation of costs and effects. Severe

hypoglycaemia can occur in all health states, whereas diabetic foot ulcers are restricted to health states that involve neuropathy, nephropathy, CVD, LEA, or ESRD.

Figure 23 presents a simplified overview of the Markov model and the possible transitions between health states. Straight arrows represent transitions to other health states, while circular arrows indicate that patients can remain in the same state from one cycle to the next. Patients can develop new complications over time. For instance, a patient who develops neuropathy moves to the neuropathy health state; if nephropathy occurs later, they transition to the combined neuropathy and nephropathy state (a two-complications health state), and this applies to all combinations of complications.

Moreover, as presented in Figure 23, patients with nephropathy alone or with nephropathy as one of the complications can progress to ESRD. The transition to the ESRD health state retains any existing complications. Patients who develop more than two late complications (excluding ESRD and LEA) transition to an aggregated "≥2 complications" health state, representing advanced disease without specifying exact combinations. Transition to LEA can occur from any health state except retinopathy and blindness, but these transition arrows are omitted from the figure for clarity. Patients in the ESRD or LEA states with concurrent complications can only transition to death, which is possible from all health states. If disease progression stops, patients remain in their current health state.

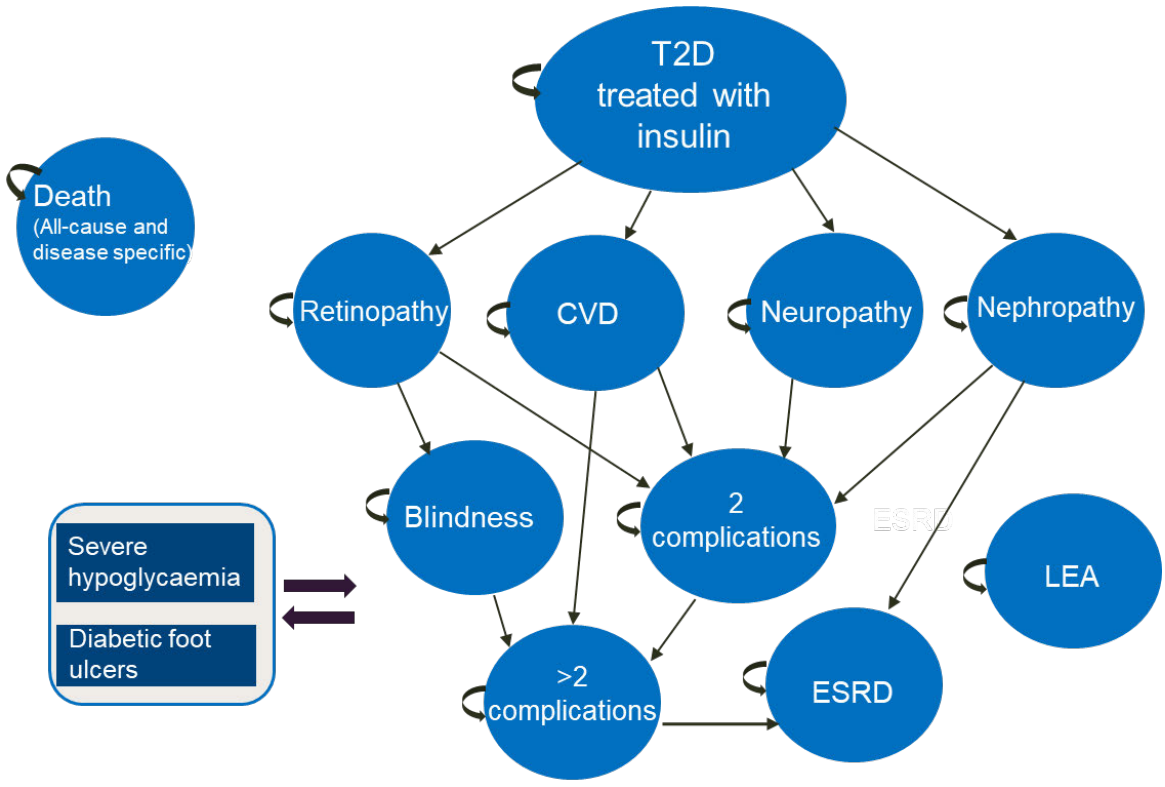


Figure 23*:* Simplified model structure

T2D: Type 2 diabetes; CVD: Cardiovascular disease; LEA: Lower extremity amputation; ESRD: End-stage renal disease
Note: Transition to the LEA health state can occur from any health state except retinopathy and blindness. Severe hypoglycaemia can occur in all health states. Diabetic foot ulcers can only occur in health states where one or more of the following late complications are present: neuropathy, nephropathy, CVD, LEA, and ESRD. Transition to death is possible from all health states.

3.1.3 Model parameters

The model was developed as a probabilistic model, in which all uncertain parameters, including efficacy, costs, utility-weights, and epidemiological inputs, were represented by probability distributions rather than fixed point estimates. This approach allows uncertainty in the input parameters to be reflected in the results and enables PSA. The data sources and methods used to derive these parameter estimates are described below.

3.1.3.1 Transitional probabilities

Transition probabilities between health states were primarily derived from a recently published Swedish study (3). This retrospective cohort study assessed the impact of CGM compared to SMBG in insulin-treated T2D treated with MDI, including basal and/or bolus insulin regimens. The study, as described in 2.2.2, evaluated the effect of using SMBG to isCGM on both glycaemic control and hospitalisations due to diabetes-related complications.

Authors of the Swedish study (3) employed a propensity score-based inverse probability of treatment weighting to adjust for baseline differences across treatment groups. This method enables the full retention of the cohort while minimising confounding. Additionally, a double-robust approach was employed to further adjust for covariates that remained imbalanced after weighting. The covariates used in the propensity score model included age, sex, BMI, baseline HbA1c, lipid profile, renal function, smoking status, physical activity, diabetes duration, pre-baseline comorbidities, insulin delivery method, and complications. Most covariates were balanced after weighting was performed.

Unlike previous health economic models that have typically used HbA1c reduction as a surrogate outcome, the Swedish study provides direct comparative data on clinical outcomes for insulin-treated T2D patients, such as hospital admissions for severe hypoglycaemia, micro- and macrovascular complications (3).

We used event-based outcomes reported by the Swedish study (3) rather than total event counts, to reduce uncertainty in estimating the timing and frequency of complications in the model. CVD complications, including myocardial infarction (MI), stroke, angina, peripheral vascular disease, HF, and atrial fibrillation, were aggregated into a single CVD health state in the model. Other complications, such as retinopathy, nephropathy, and neuropathy, were modelled independently based on event rates directly from the Swedish study (3) presented in Table 15.

Hypoglycaemia and foot ulcers were modelled as events and applied to relevant health states where clinically appropriate, as described in the previous section.

Event rates reported per 100 person-years were converted to annual transition probabilities using standard methods (86). All probabilities were incorporated in the model as beta distributions.

Table 15: Diabetes-related complications rates in the comparator (SMBG) cohort

Type of condition	Estimate, per 100 person-years of follow-up	SE
Acute myocardial infarction	2.20	0.00028
Angina	1.03	0.00020
Ischaemic heart disease	0.47	0.00013
Stroke	1.92	0.00026
Peripheral vascular disease	0.12	0.00008

Heart failure	4.16	0.00038
Atrial fibrillation	1.16	0.00020
Nephropathy	3.33	0.00036
Retinopathy	0.07	0.00005
Neuropathy	0.01	0.00005
Hypoglycaemia	0.33	0.00010
Foot ulcer	0.04	0.00005

SMBG: Self-monitoring blood glucose; SE: Standard error
Source: (3)

3.1.3.2 Risk estimates of secondary late complications

We did not have access to data to estimate the risk of secondary late complications in individuals with insulin-treated T2D. Therefore, risk estimates for secondary complications in individuals with a single complication were derived from relevant epidemiological studies of the general T2D population deemed applicable to the Norwegian context. The risk estimates for all pairwise combinations are presented in Table 16.

The selection of studies reporting relative risk estimates to develop secondary or more than two complications followed a structured framework based on the following criteria: systematic reviews, studies considered relevant for Norway, and the most recently published literature.

These risks were multiplied by relevant base probabilities (following conversion from event rates to probabilities) sourced from the Swedish study (Table 15) to maintain internal consistency. Dirichlet distributions were used to ensure probabilities are normalized to 1 after applying the risk estimates.

For individuals who may develop a second complication, a common risk estimate was assumed across several pairwise combinations when no specific risk estimates were available, based on the sequence of complication onset. In these cases, the risk estimate was considered symmetric, regardless of the order of occurrence (i.e., Relative Risk (RR) [Xj|Xi] = RR[Xi|Xj]). For other complications, separate risk estimates were applied whenever such data were available. The risk estimates, along with supporting references, are detailed in Table 16. All risk estimates were incorporated in the model as log-normal distributions.

Table 16: Relative effect used in the model

Type of condition	Developing a second complication	Risk estimate	SE	Source
Retinopathy	CVD	1.81	0.106	(87)
	Nephropathy	4.64	0.323	(87)
	Neuropathy	2.22*	0.136	(87)
CVD	Retinopathy	1.81	0.106	(87)
	Nephropathy	2.18	0.336	(88)

	Neuropathy	2.32	0.414	(89)
Nephropathy	Retinopathy	2.37	0.144	(87)
	CVD	2.18	0.336	(88)
	Neuropathy	6.38	0.561*	(90)
Neuropathy	Retinopathy	1.73	0.190	(87)
	CVD	2.32	0.414	(89)
	Nephropathy	6.38	0.561*	(90)

SE: Standard error; CVD: Cardiovascular disease

*SE is adjusted based on the published value for developing a second complication in patients with neuropathy or nephropathy.

Complications not included in the Swedish study (3), such as blindness, ESRD, and LEA, were modelled using data from additional published literature (Table 17). These transitions were assumed to occur conditionally, dependent on progression from relevant precursor health states. Specifically, blindness was modelled to occur only following retinopathy, and ESRD was modelled after nephropathy, or from health states involving more than two complications, including nephropathy as an underlying risk factor for ESRD. LEA was modelled as a separate health state accessible from all health states except for the “retinopathy” and “blindness” states.

The probability of transitioning to LEA was assumed to be constant across all relevant health states and derived from external sources representative of the modelled patient population, as presented in Table 17.

As described earlier, we defined patients with more than two complications as a separate “>2 complications” health state. Transitions from combinations of two complication health states to more than two complication health state were estimated using a multiplicative joint probabilistic approach, which calculates the joint likelihood of experiencing a third or fourth complication, assuming conditional independence between the risks of subsequent complications (91). The estimation approach is presented in Appendix 7, Table A7 1.

The probability of having more than two complications after blindness is estimated to be based on the highest risk of having the subsequent complication after retinopathy, such as CVD (Table 17).

An exception was made for patients in the CVD health state. These patients were allowed to experience recurrent or secondary CVD events (e.g., a second myocardial infarction or other CVD events), which triggered a transition to the more than two complications health state. This was justified by the aggregation of CVD events in the primary CVD health state. Patients who remained stable after experiencing CVD events stayed in the CVD state but retained eligibility to progress to additional complications based on their respective risk estimates for further complications, based on the preceding complication.

To estimate the proportion of ESRD patients with more than two complications, we applied the cumulative risk reported by Saeed et al (2022) (92), which is approximately 0.05 (Table 17).

Table 17: Other complication rates used in the model

Type of condition	Rate	SE	Source
Blindness	0.007	0.0007*	(93)
ESRD	0.029	0.0028*	(92)

LEA**	0.004	0.0020	(94)
Recurrence of CVD	0.126	0.0009	(85)
Blindness to ">2 complication"	0.190	0.0070	Assumption***
>2 complications to ESRD	0.050	0.0050	(95)

CVD: Cardiovascular disease; ESRD: End-stage renal disease; LEA: Lower extremity amputation; SE: Standard error
*SE is calculated as 10% of P
** The transition probability of LEA was constant across all health states, sourced externally from the modelled patient population.
***The transition probability of having more than two complications after blindness is estimated based on the highest risk of having the subsequent complication after retinopathy.

3.1.3.3 Mortality

3.1.3.3.1 All-cause mortality for insulin-treated T2D

We did not have access to Norwegian mortality data for individuals with T2D treated with insulin. Consequently, in the absence of such data, baseline mortality was estimated by adjusting age-specific background mortality rates from Statistics Norway (SSB) for 2023 (96) and combining these with diabetes-specific mortality from the Norwegian Institute of Public Health's Cause of Death Registry for the same year (97). Diabetes-specific mortality was stratified by age group and applied as an additional risk on top of baseline age-specific mortality to estimate all-cause mortality rates among individuals with diabetes.

3.1.3.3.2 Disease-specific mortality for insulin-treated T2D

All-cause mortality estimates for insulin-treated T2D were adjusted for individual complications for disease-specific mortality using published relative risks that were deemed appropriate for the Norwegian context. These risk estimates, including those for CVD, retinopathy, nephropathy, and neuropathy, are presented in Table 18.

Notably, for CVD, a higher mortality rate was applied in the first year following the event to reflect elevated risk during the acute and post-acute phase Table 18.

Table 18: Complication-specific relative risk for mortality

Type of condition	RR	Ln (RR)	SE(Ln(RR))	Source
Retinopathy	1.55	0.44	0.08	(98)
Neuropathy	1.46	0.38	0.08	(99)
Nephropathy	1.60	0.47	0.16	(92)
CVD	1.72	0.54	0.03	(100)
Blindness	1.68	0.52	0.16	(101)
LEA	3.14	1.14	0.13	(102)
ESRD	3.14	1.14	0.13	(102)

More than two complications	3.14	1.14	0.13	(102)

	Probability	SE	
CVD 1st year	0.20	0.037	(103)

CVD: Cardiovascular disease; ESRD: End-stage renal disease; LEA: Lower extremity amputation; Ln(RR): Natural log of (RR)
RR: Relative risk; SE: Standard error

3.1.3.3.3 Disease-specific mortality for insulin-treated T2D with 2 or more than 2 complications

For patients experiencing two complications, the RR of mortality with the highest value was applied, based on the assumption that mortality would be primarily driven by the most severe complication (Table 18). For instance, if an individual has both retinopathy and nephropathy, the RR of 1.6 (for nephropathy) was used instead of the RR of 1.55 (for retinopathy) to adjust for the additional condition-specific mortality.

This assumption reduces the risk of overstating mortality due to joint complications and avoids the double-counting of risk.

Furthermore, all-cause mortality was adjusted for an additional risk of mortality for more than 2 complications, ESRD, and LEA, using an RR estimate derived from a UK-based study (102). We used an RR of 3.14 (95% CI: 2.43–4.03) in the economic model, reflecting the elevated mortality risk associated with advanced multimorbidity in the model.

3.1.3.4 Clinical efficacy parameters in the model

Unlike previous economic models that used HbA1c reduction as a surrogate outcome, our model directly applies relative risks for included complications to compare isCGM users with SMBG for clinical outcomes. The clinical inputs are based on a Swedish study (3) as previously described, which included insulin-treated T2D patients with either MDI or basal insulin. To address potential confounding, the study applied propensity score–based inverse probability of treatment weighting using baseline characteristics such as age, sex, diabetes duration, HbA1c, BMI, comorbidities, and lifestyle factors. Weighted regression models were then used to estimate the treatment effect between CGM and SMBG users.

We applied the RR estimates for isCGM users from the T2D-MDI group to the corresponding transition probabilities in the model to capture the observed differences in complication rates between monitoring strategies.

We added the RRs to the model as probability distributions and therefore used lognormal distributions, according to the methodology described by Briggs and co-authors (86). Standard errors for the log-normal distributions were calculated based on confidence intervals for efficacy estimates. The estimates of the calculations of distributions for efficacy parameters used in the model are presented in Table 19.

Table 19: Efficacy estimates used in the model (log-normal distribution)

Type of condition	Relative risk	Ln (RR)	SE(Ln(RR))
Acute myocardial infarction	0.67	-0.40	0.10
Angina	1.27	0.24	0.11
Ischaemic heart disease	1.08	0.08	0.15

Stroke	0.56	-0.58	0.10
Peripheral vascular disease	0.98	-0.02	0.36
Heart failure	0.63	-0.46	0.09
Atrial fibrillation	1.00	0	0.11
Nephropathy	0.89	0.12	0.08
Retinopathy	1.55	0.44	0.33
Neuropathy	1.05	0.05	0.83
Hypoglycaemia	0.43	-0.84	0.24
Foot ulcer	0.71	-0.34	0.56

Ln(RR): Natural log of (RR); SE: Standard error
Source: (3)

3.1.3.5 Costs

We calculated an annual cost per patient associated with different alternatives for each health state and event in the model. All costs included in the model were measured in 2024 Norwegian kroner (NOK). The costs measured before 2024 were adjusted to 2024 prices using the Consumer Price Index (104). The uncertainty surrounding cost parameters was assessed by using gamma distributions, with variation limited to 30% of the base-case value.

Based on feedback from clinical experts, it was assumed that individuals with T2D who are treated with insulin perform an average of three blood glucose measurements per day. The estimate includes expenses related to test strips and lancets (105). We have estimated the annual costs associated with capillary blood glucose monitoring at approximately NOK 8,000 per patient per year.

The average annual costs associated with the use of CGM are based on the latest procurement price provided by the Norwegian Hospital Procurement Trust, which is NOK [redacted] (106). This estimate is based on assumptions of average usage and replacement of sensors and does not account for training, follow-up, or situations where the measuring device (sensors) needs to be replaced earlier than every two weeks. Additionally, we have included the costs associated with supplementary blood glucose measurements using SMBG. Based on expert opinion, we assumed that approximately 50% of patients require SMBG once per week to address discrepancies between CGM readings and the patient's symptoms.

The annual diabetes treatment cost was estimated to be NOK 8,250 per patient based on data from a Norwegian publication (107)

Costs associated with the initiation of the device, training, technical support, and the interpretation and follow-up of CGM data at the hospital's outpatient clinic were also included in the analysis, based on information provided by the expert group. The personnel costs were calculated for two different organisational models; however, the personnel costs related to the specialist healthcare organisational model were used in the health economic model to ensure consistency with the population defined in the model (Table 20). For more details on the organisational models, please see Section 3.1.5.

Table 20: Personnel costs associated with implementing CGM per patient

	Initiate and training (hours/year)	Follow-up and technical support (hours/year)	Wage (NOK/hour)*	Total costs per year (NOK)
Specialist healthcare**				
Specialist nurse	1	8	628	5,652
Specialist physician	0.25	0.75	1,085	1,085
Secretary/administration staff	1/year		440	440
Healthcare worker***	0.75	0.5	450	540
Collaboration between specialist and primary healthcare**	**Specialist Healthcare (SHC)**	**Primary Healthcare (PHC)**		
Specialist nurse	1	8	SHC: 628 PHC: 580	SHC: 628 PHC: 4,640
Specialist physician General practitioner	0.25	1	SHC: 1,085 PHC: 910	SHC: 271 PHC: 910
Secretary/administration staff	0.25	0.75	SHC: 440 PHC: 442	SHC: 110 PHC: 332
Healthcare worker***	1.2	-	450	SHC: 540
Total Costs				SHC: 1,549 PHC: 5,882

CGM: Continuous glucose monitoring; SHC: Specialist healthcare; PHC: Primary healthcare
*Source: (108)
** More information about the organizational models is presented in Section 3.1.5. In the health economic model, we have included personnel costs associated with specialist healthcare to ensure consistency with the population defined in the model.
*** Health care worker at *Behandlingshjelpemidler* units.

Table 21 presents the costs associated with acute and late complications, along with their corresponding sources.

Table 21: Costs associated with acute and late complications

Type of condition	Costs (NOK)	Comment/Source*
Acute myocardial infarction	1. year: 218,701 Follow-up years: 4,614	(109) (110)
Angina	1. year: 117,650 Follow-up years: 4,614	(111) (110)
Ischaemic heart disease	1. year: 418,027 Follow-up years: 62,867	Assumption**
Stroke	1. year: 392,365 Follow-up years: 203,313	(112)
Peripheral vascular disease	1. year: 151,392 Follow-up years: 69,368	(113)

Heart failure	1. year: 81,676 Follow-up years: 53,639	(114)
Atrial fibrillation	1. year: 28,873 Follow-up years: 17,742	(115)
Nephropathy* **	75,235	(116)
Retinopathy	1. year: 4,964 Follow-up years: 1,515	DRG code: 293O DRG code: 902O (117)
Neuropathy	1. year: 62,489 Follow-up years: 3,657	DRG:18 and 19 DRG: 901C (117)
ESRD	782,466	DRG code: 317 (117), assumed 156 sessions per year
LEA	1. year: 294,261 Follow-up years: 1,724	DRG codes: 285 and 910A (117)
Blindness	68,292	(118)
Hypoglycaemia	7,730	(119)
Foot ulcer	150,589	(85) DRG code: 271 (117)

CVD: Cardiovascular disease; LEA: Lower extremity amputation; ESRD: End-stage renal disease; DRG: Diagnosis-Related Groups
*All costs were adjusted to 2024 prices using the Consumer Price Index (104).
**Based on the costs estimated for acute myocardial infarction, angina, and heart failure, this approach was previously used in a Norwegian health economic study (111).
***The costs were calculated based on the weighted average, assuming 50% of CKD1-3 and 50%of CKD 4-5 based on a Norwegian source (116).

We calculated the costs of CVD based on the costs associated with the relevant cardiovascular diseases, presented in Section 3.1.2, and we weighted them according to the event rates presented by the Swedish study (3).

When patients develop more than one complication, simply adding the individual costs would overestimate the total burden, as patients with multiple complications would otherwise be counted more than once. To address this, we applied an overlap adjustment factor. The adjustment combines the baseline probability of each complication with the RR of developing one complication given the presence of another. In this way, the model identifies the proportion of patients who may experience both complications, or at least one, and scales down the combined costs to avoid double-counting (see Appendix 7 Table A7 2).

We extended the same principle to multiple complications. For each complication, the baseline probability was multiplied by the RR of developing it given the presence of other complications. The overlapping factor was then derived by subtracting the joint probability distribution of not experiencing the complications from 1, ensuring a consistent and accurate estimation of costs across multiple comorbidities.

3.1.3.6 Health-related quality of life

Due to the lack of a Norwegian study, the utility value associated with using CGM compared to SMBG for insulin-treated T2D individuals was derived from the results of a systematic review. A randomised study was identified, which reported health-related quality of life using the EQ-5D instrument. The study concluded that there were no significant differences between CGM and SMBG regarding quality-of-life outcomes (15). Therefore, we did not include the potential effect of different glucose measurement methods on patients' utility. The utility value, estimated to be 0.82, was age-adjusted for the insulin-treated T2D individuals using the NOMA guidelines (84).

HRQoL values associated with acute and late complications included in the model were primarily based on studies included in the recently published systematic review of health state utility values for type 2 diabetes-related complications (120).

All utility values are measured based on EQ-5D. We used Beta or Gamma distributions for utility/disutility values in the model, respectively, with variation limited to 10% of the base-case value.

The disutility values for each complication and group of combinations, more than two complications, ESRD, and disutility values for multiple complications are presented in Table 22.

Table 22: Disutility* associated with complications

Type of Condition	Disutility	Comment/Source
Retinopathy	-0.040	(121)
Neuropathy	-0.084	(121)
Nephropathy	-0.049	(122)
CVD	1. year: -0.164 Follow-up years: -0.110	(120) (122)
Blindness	-0.083	(122)
ESRD	-0.301	Assumption based on the value reported by (121)**
LEA	-0.351	Assumption based on the value reported by (120)***
Two complications (CVD + Neuropathy) ****	-0.185	Assumption
More than 2 complications*****	-0.256	Assumption
Hypoglycaemia (Event)	-0.051	Assumed severe hypoglycaemia affects health-related quality of life for a duration of 5.5 days (85;120)
Foot Ulcer (Event)	-0.170	Diabetic foot ulcers are expected to have a healing time of 6.6 months (85;120;123)

CVD: Cardiovascular disease; LEA: Lower extremity amputation; ESRD: End-stage renal disease
*Disutility in health economic models refers to the negative impact or reduction in quality of life associated with a specific health state or event, often quantified as a decrease in utility scores (QALYs).
**Additional complications: retinopathy, nephropathy, neuropathy, and CVD, excluding LEA, were assumed. 0.5 dampening factor was used to adjust the joint disutility of ESRD and existing other complications.
*** Additional complications: nephropathy, neuropathy, and CVD, excluding ESRD, were assumed. 0.3 dampening factor was used to adjust the joint disutility of ESRD and existing other complications.
****The example of two complications is based on CVD and neuropathy disutilities; results will vary depending on the specific combination of complications.
***** For health states with more than two complications, the multiplicative method was extended across all four major complications (retinopathy, nephropathy, neuropathy, CVD).

The model applied a multiplicative approach to estimate health state utility values (HSUVs) for patients experiencing multiple concurrent diabetes-related complications. This method, adapted from Brazier et al. (91), recognises that the impact of an additional complication on HRQoL depends on the level of health remaining after accounting for existing conditions. In contrast to additive methods, which may

exaggerate utility loss and generate implausibly low values, the multiplicative framework preserves proportionality and ensures that combined HSUVs remain clinically realistic.

The approach was applied to the four major complications considered in the model: retinopathy, nephropathy, neuropathy, and CVD. For health states involving more than one complication, we calculated combined utilities by multiplying the relative utilities of each condition, with disutility expressed as the difference between perfect health (1.0) and the combined utility estimate.

For severe complications with a dominant impact on HRQoL, specifically ESRD and LEA, we introduced an extension of the multiplicative method. This incorporated applying a dampening factor to reflect diminishing marginal disutility, consistent with economic theory and clinical evidence of adaptation to severe health states (91). We assumed dampening factors of 0.5 for ESRD and 0.3 for LEA and applied it in all scenarios, reducing the incremental weight of additional complications once these conditions were present.

The above methods and the approach are further explained in Appendix 7 Table A7 3.

3.1.4 Severity – absolute shortfall

According to the severity criterion, priority increases with the expected future health loss due to illness. Severity is measured as "absolute shortfall", defined as the anticipated future loss of healthy life years (in QALYs) associated with a specified diagnosis. For the treatment of a diagnosed disease, severity is the average expected absolute shortfall loss for the specific patient group, given the current standard treatment. In general, the larger the absolute shortfall associated with an illness, the more resources per QALY gained the authorities may be willing to allocate.

Absolute shortfall is calculated as the difference between expected healthy life years (QALYs) at a given age (A) without the disease (s_A), and prognosis with the disease with current treatment (P_A), and is calculated as follows:

$$AS = QALYs_A - P_A$$

3.1.5 Budget impact analysis

Budget impact is defined as the additional costs incurred by introducing the new technology minus the total cost of maintaining the current practices (84).

To conduct budget impact analyses, it is necessary to estimate the number of individuals who may be eligible for CGM. The responsibility regarding the financing of CGM for patients with T2D treated with insulin remains unclear. We have therefore estimated the budget impact, using a recommended time horizon of five years, for two different organisational models.

The budget impact was estimated using the relevant costs, including the costs associated with glucose monitoring methods, the additional personnel costs for initiation, training, and follow-up of CGM, as applied in the cost-effectiveness analysis (see Table 20). The analysis was conducted for both the insulin-treated T2D population and predefined subpopulations.

3.1.5.1 Number of individuals with T2D treated with insulin eligible for CGM

According to data from the Norwegian Health Economics Administration (Helfo), in 2024, approximately 224,000 people in Norway had T2D, of whom over 41,000 were treated with insulin (124). Of these, about 20,000 received multiple daily injections (MDI) with rapid-acting insulin, which the clinical experts consider the most relevant group for CGM use/adoption. In addition, approximately 21,000 individuals were treated with long-acting insulin.

It should also be noted that around 3,200 insulin-treated T2D individuals are currently using CGM under the Group exemption (43;125).

Based on different organisational models, we have attempted to estimate the potential need for CGM and presented it in two different scenarios (Table 23). Our estimates are based on input from clinical experts.

The clinical expert's joint consensus indicated that CGM is probably not beneficial for all T2D individuals treated with insulin.

The majority of clinical experts suggested that insulin-treated T2D individuals who could benefit from CGM should be managed within specialist healthcare, as treatment adjustments based on CGM findings are most effectively carried out by specialists. Based on the clinical experts' opinions, our estimate for this group ranges between 3,000 and 5,000 people per year.

On the contrary, some experts believe that CGM could benefit a larger insulin-treated T2D group, estimated to be between 12,000 and 20,000 people. The lower estimate is based on the assumption that approximately 50% of those using MDI and some on long-acting insulin, while the upper estimate assumes that all T2D individuals on MDI would be eligible. Such a large number of patients would exceed the current outpatient capacity and would therefore require close collaboration between specialist and primary care services.

Table 23: Number of individuals with insulin-treated T2D eligible for CGM (2024)

Organisational model	Number of individuals eligible for CGM
Specialist healthcare	3,000-5,000
Collaboration between the specialist and primary healthcare	12,000-20,000

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring

Approximately 14,000 to 18,000 new cases of T2D are diagnosed annually in Norway (7). We have assumed that approximately 1,400-1,800 new individuals will be treated with MDI, of whom approximately 400 (new cases) will need follow-up at the hospital and may be eligible for CGM each year. Table 24 presents the projected number of insulin-treated individuals eligible for CGM use over the next five years based on the different organisational models of specialist healthcare (SHC) and the collaborative model for the SHC and primary healthcare (PHC).

Table 24: Number of individuals with insulin-treated T2D eligible for CGM over the next five years

Organisational model	2025	2026	2027	2028	2029	2030
Specialist healthcare	3,400 - 5,400	3,800 - 5,800	4,200 - 6,200	4,600 - 6,600	5,000 - 7,000	5,400 - 7,400
Collaboration between the specialist and primary healthcare	13,600 - 19,600	15,200 - 21,200	16,800 - 22,800	18,400 - 24,400	20,000 - 26,000	21,600 - 27,600

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring

3.1.5.2 Estimated number of individuals eligible for CGM in subpopulations

As mentioned, in 2024, about 20,000 individuals received MDI with rapid-acting insulin. Based on the advice from clinical experts, we have estimated the number of individuals eligible for CGM within the subpopulations (Table 25). Further, we have assumed that approximately 1,400-1,800 new individuals will be treated with MDI each year.

In addition, we have estimated the number of patients eligible for the temporary use of CGM for educational purposes (Table 25). Further details about the subpopulation are provided in Sections 1.5, 2.1.1, and 2.2.5.12, and our previous publication (1).

Table 25: Number of insulin-treated T2D individuals eligible for CGM in subpopulations per year

Subpopulations	Number of individuals eligible for CGM
Individuals with T2D on MDI who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses (≈10%)*	2,000
Individuals with insulin-treated T2D who have experienced more than one episode of severe hypoglycaemia in the past year (≈1%)*	200
Individuals with insulin-treated T2D whose profession involves safety-critical roles (≈5%)*	400
Individuals aged <60 years, insulin-treated T2D and diagnosed with intellectual disabilities (≈1%)*	200
Women with MDI-T2D who are planning pregnancy, currently pregnant, or in the postpartum period. (≈4%)*	400

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; MDI: Multiple daily injections
*Based on experts' opinions
**Source: (7)

3.1.6 Healthcare personnel utilisation

Assessing the implications for healthcare personnel demand is an integral part of evaluating new health technologies. The Norwegian government has mandated that workforce consequences be systematically assessed to inform decision-making on the implementation of new technologies within the healthcare system (83).

Effective planning and allocation of healthcare personnel are essential to realising the potential health gains of new interventions. Resource availability determines the extent to which patients can access the technology and, consequently, the additional health benefits measured in QALYs.

Following the principles outlined by the National Health Care Institute in the Netherlands (126), we estimated the impact of implementing CGM for individuals with T2D treated with insulin on healthcare personnel utilisation. The analysis measured incremental personnel requirements, expressed in full-time equivalents (FTEs) [1], representing the difference in labour needed to implement CGM compared with current practice. Subsequently, the overall impact on healthcare resources was estimated by calculating the total FTEs required to deliver/manage the use of CGM to all eligible patients relative to the existing standard of care.

We estimated FTE requirements separately for both organisational models: initiation, training, and follow-up within specialist healthcare (model 1, SHC alone) and a collaborative approach between specialist and primary healthcare (model 2), as outlined earlier in the budget impact methodology.

[1] Full-Time Equivalent (FTE**)** is a way to measure the workload of employees in a standardized manner. It allows organizations to compare workloads even when some employees work part-time, e.g., 1 FTE = one employee working full-time (usually 37.5 hours/week in Norway, but it can vary by company or country.

3.2 Results

Our systematic review found that there was no difference between CGM and SMBG in cardiovascular late complications for individuals with uncontrolled insulin-treated T2D. When using HbA1c as a surrogate endpoint, the results also indicated no clinically meaningful difference between the two glucose monitoring methods. Given that CGM is more costly than SMBG, it is less probable to be cost-effective for the entire insulin-treated T2D population.

3.2.1 Probabilistic base-case results- insulin-treated T2D patients requiring follow-up at the hospital

We conducted a model-based cost-effectiveness analysis of CGM compared with SMBG for patients with severe insulin-treated T2D requiring specialist follow-up at the hospital.

Table 26 presents the expected total and incremental costs and QALYs for CGM compared with SMBG in patients with insulin-treated T2D and followed up at the hospital. Over a lifetime horizon, CGM was associated with higher total costs than SMBG, resulting in an incremental cost of NOK [redacted]. CGM also produced additional health benefits, with an incremental gain of 0.34 QALYs compared with SMBG. The resulting ICER was approximately NOK [redacted] per QALY gained.

Table 26: Expected total costs and effects for the different alternatives from a lifetime perspective (discounted)

Intervention	Costs (NOK)	Incremental costs (NOK)	Effect (QALYs)	Incremental effect (QALYs)	ICER (NOK/QALY)
SMBG	1,000,454		7.20		
CGM	[redacted]	[redacted]	7.54	0.34	[redacted]

SMBG: Self-monitoring blood glucose; CGM: Sensor-based glucose monitoring; QALY: Quality-Adjusted Life Year; ICER: Incremental Cost-Effectiveness Ratio

Figure 24 presents the results of the PSA, illustrating the joint distribution of costs and health effects from 10,000 Monte Carlo simulations. Each point represents one simulated cost and QALY outcome for CGM and SMBG. The scatter plot shows that most iterations for CGM are more costly and more effective than SMBG. The spread of points reflects the variation in model outcomes for both cost and QALY estimates due to the uncertainty in model parameters.

Figure 24: Cost-Effectiveness Scatter Plot for Self-monitoring blood glucose vs Continuous glucose monitoring

The probability that each strategy is cost-effective at WTP thresholds per QALY gained is presented in Figure 25. At lower WTP thresholds, SMBG has the highest probability of being cost-effective. However, as the WTP increases, the probability that CGM is cost-effective rises, surpassing SMBG at approximately NOK [redacted] per QALY. Beyond this threshold, CGM remains the preferred option for most WTP values.

Figure 25: Cost-Effectiveness Acceptability Curve for SMBG vs CGM
CGM: Continuous glucose monitoring; SMBG: Self-monitoring blood glucose

3.2.2 Sensitivity analyses

3.2.2.1 One-way sensitivity analysis (OWS)

The results of the OWS (deterministic) are presented in Figure 26 which illustrates the changes in ICER values across various parameters.

The most significant impact on ICER was observed with the reduction in the cost of SMBG tests. As the cost of SMBG tests approaches zero, the ICER for the intervention shifts from approximately NOK [redacted] (base case) to NOK [redacted] per QALY and to NOK [redacted] per QALY for an increase in the cost of SMBG tests.

Other key factors influencing ICER include the cost of ESRD treatment (NOK [redacted] per QALY) and the risk of mortality associated with ESRD, LEA, and individuals with more than two complications (NOK [redacted] per QALY). An increase in the cost of ESRD treatment decreases the ICER, as adherence to CGM helps mitigate progression to ESRD, and the reverse relationship also applies. On the other hand, a higher risk of mortality reduces QALY gains, as elevated mortality rates diminish the potential for life expectancy improvements among individuals with multiple comorbidities. For instance, a 2.5-fold increase in RR of mortality for ESRD, LEA, and more than two complications resulted in an ICER of approximately NOK [redacted] per QALY, and the reverse relationship also applies if it is decreased.

Furthermore, the effect of CGM to reduce the rates of complications such as nephropathy, HF, and AMI in terms of relative risk was identified as one of the top 10 variables impacting ICER, with values ranging between approximately NOK [redacted] per QALY (nephropathy and HF) and approximately NOK [redacted] per QALY for AMI. The cost of CVD follow-up was also highlighted as a significant factor influencing ICER from approximately NOK [redacted] per QALY.

The frequency of SMBG self-tests also affects ICER, with values ranging between NOK [redacted] and NOK [redacted] per QALY. A reduction in the cost of CGM demonstrates substantial sensitivity, lowering the ICER to approximately NOK [redacted] per QALY. Additionally, the increased costs associated with healthcare personnel due to CGM usage were among the top 10 variables that influenced the ICER (NOK [redacted] per QALY).

Figure 26: Top 10 variables in the Tornado diagram for One-Way Sensitivity Analysis

SMBG: Self-monitoring of blood glucose; CGM: Continuous glucose monitoring; RR: relative risk; ESRD: End-stage renal disease; LEA: Lower extremity amputation; HF: Heart failure; CVD: Cardiovascular disease; AMI: Acute myocardial infarction
Note: Low RR-values correspond to an increase in the clinical effect of the intervention

3.2.3 Scenario analyses

We present the results of the scenario analysis in Table 27, ordered according to their impact on the ICER from the highest to the lowest value. We calculated the incremental cost and incremental QALYs with respect to the comparator values for each scenario and also presented the total incremental change in costs and health benefits.

We also included a presentation of all ICER results from the scenario analyses in Figure 27 to illustrate the relative variation in ICERs across scenarios, from the lowest to the highest value.

The first two scenarios examined the effect of CGM over shorter time horizons instead of lifetime, as used in the base-case, specifically 5 and 10 years, to assess the health benefits of CGM based on the available short-term follow-up data from the Swedish (2-year) study (3). The ICER ranged from approximately NOK [redacted] for 10 years (scenario 2) and NOK [redacted] per QALY for 5 years (scenario 1). The results indicate that if CGM benefits and costs are limited to a shorter time horizon, it inflates the ICER significantly. Therefore, sustained compliance of CGM over a longer time horizon is deemed necessary for an increase in the overall effectiveness of the intervention with respect to the additional costs.

The age of the patients at CGM initiation (scenario 3) has some impact on the ICER. The ICER changes from approximately NOK [redacted] per QALY if the age of CGM initiation is increased from 67 to 75 years old (Figure 27).

Limiting the treatment effect to 10 years (scenario 4) has a downward impact on the ICER. This scenario reflects the changes in the compliance behaviour of individuals using CGM, resulting in limited direct benefits associated with CGM up to 10 years. The increase in ICER (approximately NOK

[redacted] per QALY) is moderate, with a limited 10-year effect of CGM in the model that is run from a lifetime perspective, hence implying that there is continuity in the indirect benefits of the first 10 years of using CGM across the remaining subsequent years.

The analysis indicated that it is only scenario 5 leading to a reduction in ICER when we consider additional gain in QALYs associated with CGM (0.03; (85)) in the analysis.

Table 27: Summary of Scenario Analyses (CGM versus SMBG)

Scenario	Assumption	Total costs, CGM (NOK)	Total QALY, CGM (QALYs)	Incremental (NOK)	Incremental effect (QALYs)	ICER (NOK/ QALY)
Base-case		[redacted]	7.54	[redacted]	0.34	[redacted]
Scenario 1*	Time horizon= 5 years	[redacted]	3.44	[redacted]	0.047	[redacted]
Scenario 2**	Time horizon= 10 years	[redacted]	5.71	[redacted]	0.14	[redacted]
Scenario 3***	Starting age =75 years	[redacted]	5.63	[redacted]	0.26	[redacted]
Scenario 4****	Treatment effect = 10 years	[redacted]	7.50	[redacted]	0.29	[redacted]
Scenario 5****	Additional CGM utility = 0.03	[redacted]	7.60	[redacted]	0.39	[redacted]

CGM: Continuous glucose monitoring; QALY: Quality-Adjusted Life Year; ICER: incremental cost-effectiveness ratio; SBMG: Self-monitoring blood glucose.
Note: Incremental cost and effect were calculated as the difference from base-case values.
*SMBG Total Cost = 159,426 and Total QALYs= 3.40 for model time horizon 5 years
**SMBG Total Cost = 429,780 and Total QALYs= 5.56 for model time horizon 10 years
***SMBG Total Cost = 472,956 and Total QALYs= 5.36 for starting age = 75 year
***'SMBG Total Cost and Total QALYs are unchanged for scenario 4 and scenario 5 and equivalent to base-case values.

Figure 27*:* Cost-effectiveness frontier results of scenario analyses

3.2.4 Severity – absolute shortfall

We assumed that the average age of patients who may be relevant for treatment with CGM is 67 years. At this age, an individual without T2D is expected to have 14.96 healthy years of life remaining. With SMBG, the current standard glucose measuring method, expected healthy life years were estimated to be 9.58.

Compared to the general population, a patient with insulin-treated T2D using the current glucose measuring method would have a loss of 5.38 years in good health (QALY) (Table 28).

Table 28: Calculation of the absolute shortfall

Explanation	Year / QALYs
Average age at start of treatment (A)	67
Expected remaining QALYs (undiscounted) for the general population without the disease (QALYSA)	14.96
Remaining QALYs (undiscounted) for those with insulin-treated T2D treated with current standard care (PA)	9.58
Loss of QALYs due to T2D (absolute shortfall, AS)	5.38

3.2.5 Budget impact analysis

We have estimated the budget impact, using a recommended time horizon of five years for two different organisational models. The unit costs, including the costs associated with interventions and personnel costs, used in the analyses, are presented in Section 3.1.3.5 and Appendix 8 Table A8 1. The analysis does not account for potential downstream savings associated with improved glycaemic control, reduced complications, or fewer hospital admissions.

3.2.5.1 Initiating and device follow-up in specialist healthcare

The clinical experts recommend that T2D individuals who benefit from CGM should be followed in specialist healthcare for treatment adjustments based on CGM findings.

Table 29 presents the projected number of individuals with insulin-treated T2D who need follow-up from the specialist at the hospital and are eligible for CGM under a specialist healthcare organisational model from 2025 to 2030. This estimate is close to the number of T2D patients who already use CGM under the group exemption, approximately 3,200 (125).

Table 30 summarises the estimated annual costs associated with implementing CGM for the Regional Health Authorities (RHAs). The additional annual costs of implementing CGM are projected to range from NOK [redacted] in 2026 to NOK [redacted] in 2030.

We have also presented the additional cost of implementing CGM for insulin-treated T2D individuals who need follow-up at the hospital for the Norwegian healthcare sector. For comparison, the estimated annual costs associated with SMBG (covered by the national insurance scheme, Helfo) are expected to range from NOK 30–46 million in 2026 to NOK 43–58 million in 2030. The incremental budget consequences for the Norwegian healthcare sector overall are thus estimated between NOK [redacted] in 2026 and NOK [redacted] in 2030.

Table 29: Number of insulin-treated T2D requiring specialist follow-up at the hospital and who are eligible for CGM over the next five years

Organisational model	2026	2027	2028	2029	2030
Specialist healthcare	3,800 - 5,800	4,200 - 6,200	4,600 - 6,600	5,000 - 7,000	5,400 - 7,400

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring

Table 30: Budget impact for the Regional Health Authorities and for the healthcare sector overall of implementing CGM for insulin-treated T2D requiring specialist follow-up at hospital (NOK)*

	2026	2027	2028	2029	2030
Budgetary consequences for the RHAs	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Current budget for SMBG**	30,000,000 - 45,800,000	33,200,000 - 49,000,000	36,300,000 - 52,100,000	39,500,000 - 55,300,000	42,600,000 - 58,400,000
Budgetary consequences for the Norwegian Healthcare sector**	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; RHA: Regional Health Authorities; SMBG: Self-monitoring blood glucose
*Numbers are rounded.
**Funded by Norwegian Health Economics Administration (Helfo).
***For the calculation of budget consequences for the Norwegian healthcare sector, we have included the cost of SMBG (1 per/week) for those individuals using CGM.

3.2.5.2 Collaboration between specialist healthcare and primary healthcare

We have also estimated the budgetary consequences for both the Regional Health Authorities and the Norwegian healthcare sector overall of implementing CGM for a larger group of individuals with MDI T2D. Such a high number of individuals would exceed current outpatient capacity and would therefore require collaboration between specialist and primary healthcare services.

Table 31 presents the projected number of individuals with T2D treated with insulin who could be eligible for CGM in a collaborative organisational model between the specialist and primary healthcare for a 5-year period. The total estimated number of eligible individuals increases gradually from approximately 15,200 – 21,200 in 2026 to 21,600 – 27,600 in 2030.

Under this model, initiation and training are conducted in specialist healthcare, while device follow-up is divided between sectors based on patient severity. Severe patients, defined as those requiring regular follow-up at the hospital, receive device follow-up in specialist healthcare, while the remaining majority are managed in primary healthcare. The estimated number of individuals followed up in specialist healthcare remains stable over time (approximately 4,800–6,400 individuals), whereas the number of patients followed up in primary healthcare increases proportionally with total uptake, reaching 15,200–21,200 by 2030.

Table 31: Number of individuals with insulin-treated T2D potentially eligible for CGM through collaboration between specialist and primary healthcare sectors over the next five years*

	2026	2027	2028	2029	2030
Total estimate of insulin-treated T2D eligible for CGM	15,200 - 21,200	16,800 - 22,800	18,400 - 24,400	20,000 - 26,000	21,600 - 27,600
Specialist healthcare					
Initiating and training	15,200 - 21,200	1,400 - 1,800	1,400 - 1,800	1,400 - 1,800	1,400 - 1,800
Device follow-up for severe patients**	4,800	5,200	5,600	6,000	6,400
Primary healthcare					
Device follow-up**	10,400 - 16,400	11,600 - 17,600	12,800 - 18,800	14,000 - 20,000	15,200 - 21,200

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring
*Numbers are rounded
**Severe patients who require clinical follow-up by specialists at the hospital.

Table 32 presents the estimated annual costs associated with implementing CGM under the collaborative organisational model. Due to organisational, logistical, and financial considerations, the cost estimates assume that procurement and financing of CGM is assumed to be handled by the Norwegian Hospital Procurement Trust and funded by the Regional Health Authorities. This approach aligns with current practice, where CGM devices are procured through national tenders and distributed by *Behandlingshjelpemidler*[2]. If CGM were instead sold through pharmacies, the overall cost to society would likely be substantially higher compared to the existing tender-based procurement system.

For specialist healthcare, total costs, including initiation, training, and device follow-up of severe patients, are estimated to range from NOK [redacted] in 2026 to NOK [redacted] in 2030. For primary healthcare, follow-up costs are expected to rise from NOK [redacted] in 2026 to NOK [redacted] in 2030.

When both sectors are combined, the total cost of implementing CGM (specialist and primary care) is estimated between NOK [redacted] in 2026 and NOK [redacted] in 2030. For comparison,

[2] Behandlingshjelpemidler (treatment aids) are medical-technical devices used in the treatment of chronic illnesses or long-term health conditions. These devices are provided on loan to patients by the specialist healthcare services.

the costs of self-monitoring of blood glucose are estimated at NOK 120–167 million in 2026 and NOK 171–218 million in 2030.

The resulting budgetary consequences for the Norwegian healthcare sector are estimated between NOK [redacted] in 2026 and NOK [redacted] in 2030. These figures represent the additional cost of transitioning from SMBG to CGM in an integrated care model, where initiation and complex follow-up remain in specialist care, while routine device management is largely shifted to primary care.

Table 32*:* Budget impact for the Regional Health Authorities and for the healthcare sector overall of implementing CGM for insulin-treated T2D individuals, based on collaboration between specialist and primary healthcare (NOK)*

	2026	2027	2028	2029	2030
Specialist healthcare (SHC)					
Initiating and training	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Device follow-up (severe patients) **	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Yearly cost of the device for RHAs for those followed up at PHC	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Budgetary consequences for the RHAs	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Primary healthcare (PHC)					
Device Follow-up	61,200,000 - 96,500,000	68,200,000 - 103,500,000	75,300,000 - 110,600,000	82,300,000 - 117,600,000	89,400,000 - 124,700,000
Total Costs of implementing CGM (SHC + PHC) * **	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Current budget for SMBG** **	120,000,000 - 167,400,000	132,700,000 - 180,100,000	145,300,000 - 192,700,000	158,000,000 - 205,300,000	170,600,000 - 218,000,000
Budgetary consequences for the Norwegian Healthcare sector	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; RHA: Regional Health Authorities; SMBG: Self-monitoring blood glucose; SHC: Specialist healthcare; PHC: Primary healthcare

*Numbers are rounded.

**Severe patients who require follow-up by specialists at the hospital.

***It is assumed that RHAs are responsible for financing the CGM costs. Additionally, we assumed that some individuals with CGM have a cost of SMBG, and these are added to the total costs, incidence extracted from Table 31 (Initiate and training) at NOK 187.5 for CGM patients.

**** Funded by Norwegian Health Economics Administration (Helfo).

Figure 28 provides a summary of the total budgetary consequences for the RHAs of implementing CGM for insulin-treated individuals, based on different organisational models. The results indicated

that if CGM is implemented only for individuals requiring follow-up from the specialists at hospitals, the costs were estimated to range approximately between NOK [redacted] million over a 5-year period. Conversely, if CGM implementation is expanded to include a larger group, almost all individuals treated with MDI, the budget impact would be substantially higher, ranging between NOK [redacted] This scenario assumed collaboration between the specialist and primary health care sectors.

Figure 28*:* Budgetary consequences for the Regional Health Authorities of implementing CGM for insulin-treated T2D, based on different organisational models
T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; SHC: Specialist healthcare; PHC: Primary healthcare
*SHC model: The budget impact is calculated for T2D individuals treated with insulin who require follow-up by specialists at the hospital.
** Collaboration between SHC and PHC model: The budget impact is calculated for T2D individuals treated with insulin who are potentially eligible for CGM.

Figure 29 provides a summary of the total net budgetary impact for the entire Norwegian healthcare sector of implementing CGM for insulin-treated T2D individuals compared to the current care, based on different organisational models, when considering the costs associated with SMBG. The results indicate that if CGM is implemented only for individuals requiring follow-up from the specialists at hospitals, the budget impact was estimated to range approximately between NOK [redacted] over a 5-year period. Conversely, if CGM implementation is expanded to include a larger group, namely, almost all individuals treated with MDI, the budget impact would be substantially higher, ranging between NOK [redacted]. This scenario assumes collaboration between the specialist and primary healthcare sectors. It should be noted that the estimated costs for the first year of implementation (2026) are considerably higher, as a large number of individuals will incur device-related costs during the initial rollout.

Figure 29*:* Budgetary impact for the entire Norwegian Healthcare system of implementing CGM for insulin-treated T2D, based on different organisational models
T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; SHC: Specialist healthcare; PHC: Primary healthcare
*SHC model: The budget impact is calculated for T2D individuals treated with insulin who require follow-up by specialists at the hospital.
** Collaboration between SHC and PHC model: The budget impact is calculated for T2D individuals treated with insulin who are potentially eligible for CGM.

3.2.5.3 Budget impact analyses for subpopulations

Table 33 presents the estimated number of individuals within specific subpopulations of people with T2D on MDI therapy who are considered eligible for CGM. The estimates are based on expert opinions and reflect clinical judgment regarding groups who may derive particular benefit from CGM.

The estimated number of eligible individuals across all subgroups is projected to increase moderately over the five-year period, from approximately 4,900 in 2026 to 6,200 individuals in 2030. These individuals are assumed to initiate and follow up on CGM use within specialist healthcare settings, given their clinical complexity and the need for close monitoring.

As presented in Section 3.2.5.1, the total number of eligible individuals in the subpopulations is within the estimated range of those who require initiation and device follow-up in the specialist healthcare sector. There may also be overlap between the individuals estimated in the subpopulations and those requiring specialist follow-up.

Table 33: Number of individuals eligible for CGM in subpopulations; CGM initiation and device follow-up at the hospital

Subpopulations	2026	2027	2028	2029	2030
Individuals with T2D on MDI who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses	2,320	2,480	2,640	2,800	2,960
Individuals with insulin-treated T2D who have experienced more than one episode of severe hypoglycaemia in the past year	232	248	264	280	296
Individuals with insulin-treated T2D whose profession involves safety-critical roles	1,160	1,240	1,320	1,400	1,480
Individuals aged <60 years with insulin-treated T2D and diagnosed with intellectual disabilities	232	248	264	280	296
Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period	928	992	1,056	1,120	1,184

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; MDI: Multiple daily insulin

The estimated budget impact for the Regional Health Authorities of implementing CGM for the identified subpopulations who would receive training, initiation, and follow-up at hospitals is presented in Table 34.

The total costs of providing CGM for these subgroups are projected to increase gradually from approximately NOK [redacted] in 2026 to NOK [redacted] in 2030. Among the subgroups, the largest budget impact is associated with individuals with persistent insulin dosing challenges (estimated NOK [redacted] annually) and individuals in safety-critical occupations (estimated NOK [redacted] annually).

Table 34*: Budget impact for the Regional Health Authorities of implementing CGM for the subpopulations (NOK)**

Subpopulation	2026	2027	2028	2029	2030
Individuals with T2D on MDI who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Individuals with insulin-treated T2D who have experienced more than one episode of severe hypoglycaemia in the past year	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Individuals with insulin-treated T2D whose profession involves safety-critical roles	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Individuals aged <60 years with insulin-treated T2D and diagnosed with intellectual disabilities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total additional cost for RHAs, including all subgroups	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; RHA: Regional Health Authorities
*The costs, including device and personnel costs, were estimated for two weeks.

The costs of SMBG for subpopulations and the budgetary consequences for the Norwegian healthcare sector for each subgroup are presented in Appendix 8 Table A 8.2 and Table A8.3 , respectively. The results showed that extending CGM access to clinically prioritised subpopulations with high medical need would result in additional costs for the Norwegian healthcare sector of approximately NOK [redacted] in 2026, increasing to NOK [redacted] in 2030.

3.2.6 Healthcare personnel utilisation

We estimated the impact of implementing CGM for insulin-treated T2D individuals by assessing national healthcare personnel utilisation in FTEs to capture the workforce requirements for 2026. The analysis focuses on labour capacity constraints to reflect the feasibility of large-scale implementation within Norway's healthcare system. Estimates were based on two organisational models: one with initiation and device follow-up conducted entirely within specialist healthcare, and another involving collaboration between specialist healthcare and primary healthcare if CGM were implemented for a larger number of insulin-treated T2D individuals. The analysis focused specifically on specialist nurses, as they were identified as the most resource-demanding personnel group in the implementation of CGM.

National estimates of healthcare workforce availability were sourced from the NOMA's unit cost database (2025), which reports 1,663 annual work hours per FTE for all personnel care workers.

We estimated that between 3,800 and 5,800 individuals/year would be eligible for CGM initiation, training, and follow-up within specialist healthcare (SHC) in 2026.

Based on national patient projections and assumptions of collaboration between SHC and PHC, the model includes between 15,200 and 21,200 individuals eligible for CGM initiation and training within specialist healthcare, 4,800 severe patients requiring specialist follow-up, and between 10,400 and 16,400 individuals for follow-up in PHC in 2026.

Based on expert-validated process times of one hour per patient for initiation and training and approximately eight hours per patient for annual follow-up, the national FTE requirements for specialist nurses were estimated for two organisational models. In Model 1, where initiation, training, and device follow-up are conducted entirely within SHC, the estimated workforce requirement includes between 3 and 4 FTE specialist nurses for initiation and training and between 18 and 28 FTE specialist nurses for follow-up, resulting in a total of approximately 21 to 32 FTE specialist nurses within SHC at the national level (Table 35).

Table 35: Specialist nurse workforce requirement for CGM implementation in insulin-treated T2D (Specialist healthcare)

	Full-Time Equivalent (FTE)*	
	Lower range	**Upper range**
Annual work hours per FTE for all personnel care workers **	1,663	
Total estimate of eligible individuals for CGM (SHC)	3800	5800
Number of patients (SHC)- Initiation and training	3800	5800
Specialist nurses (SHC) for initiating and training (all patients), hour	1.00	1.00
Specialist nurses FTE (SHC) for initiating and training, % of total FTE	0.0006	0.0006
Required number of specialist Nurses (FTE) for implementing CGM for T2D treated with Insulin-initiating and training (SHC)	**3**	**4**
Specialist nurses (SHC) for device follow-up	8.00	8.00
Specialist nurse FTE/per year (SHC) for device follow-up, % of total FTE	0.0048	0.0048
Required number of specialist nurses for implementing CGM for T2D patients- device follow-up (SHC)	**18**	**28**
Total required number of specialist nurses (FTE) for implementing CGM for T2D treated with (SHC)	**21**	**32**

T2D: Type 2 diabetes; CGM: Sensor-based glucose monitoring; SHC: Specialist healthcare; PHC: Primary healthcare
*Full-Time Equivalent (*årsverk* in Norwegian): represents the workload of a full-time employee over a specified period (one year)
**Source: (84)

In Model 2, representing collaboration between specialist healthcare and primary healthcare, the estimated requirement for specialist nurses in SHC is between 9 and 13 FTE for initiation and training and 23 FTE for follow-up, yielding a total of 41 to 49 FTE specialist nurses in SHC. For PHC, the required number of specialist nurses for follow-up is estimated to range between 50 and 79 FTE, reflecting the larger number of patients managed at the primary care level in this model (Table 36).

Overall, the national implementation of CGM for insulin-treated T2D patients is estimated to require between ninety-one and one hundred twenty-eight FTE across the healthcare sector.

Table 36*:* Specialist nurse workforce requirement for CGM implementation in insulin-treated T2D (Specialist and Primary healthcare sector)

	Full-Time Equivalent (FTE)*	
	Lower range	**Upper range**
Annual work hours per FTE for all personnel care workers **	1,663	
Total estimate of eligible individuals for CGM (collaboration model between PHC and SHC)	15,200	21,200
Number of patients (SHC)- Initiation and training	15,200	21,200
Number of patients (SHC)- device Follow-up (severe patients)	4,800	4,800
Total number of patients (PHC)- device follow-up	10,400	16,400
Specialist nurses (SHC) for initiating and training (all patients), hour	1.00	1.00
Specialist nurses FTE (SHC) for initiating and training, % of total FTE	0.0006	0.0006
Required number of specialist Nurses (FTE) for implementing CGM for T2D treated with Insulin-initiating and training (SHC)	**9**	**13**
Specialist nurses (SHC) for device follow-up of severe patients, hour	8.00	8.00
Specialist nurses FTE/per year (SHC) for device follow-up, % of total FTE	0.0048	0.0048
Required number of specialist Nurses (FTE) for T2D treated with Insulin (SHC)	23	23
Required number of specialist Nurses for implementing CGM for severe T2D patients-device follow-up (SHC)	**32**	**36**
Total required number of specialist Nurses (FTE) for implementing CGM for T2D treated with (SHC)	**41**	**49**
Specialist nurses for device follow-up (PHC), hour	8.00	8.00
Specialist nurses FTE/per year (PHC) for device follow-up, % of total FTE	0.0048	0.0048
Required number of specialist Nurses (FTE) for implementing CGM for T2D treated with Insulin- follow-up (PHC)	**50**	**79**

T2D: Type 2 diabetes; CGM: Sensor-based glucose monitoring; SHC: Specialist healthcare; PHC: Primary healthcare
*Full-Time Equivalent (*årsverk* in Norwegian): represents the workload of a full-time employee over a specified period (one year)
**Source: (84)

4. Organisational aspects

In this chapter, we describe organisational aspects that could potentially be influenced by expanding the availability of CGMs to a wider group of individuals with T2D, compared to current levels.

Of particular interest are:

1. How is the management of T2D organised within the Norwegian healthcare system?
2. What is the current practice for assigning CGM to individuals with T2D?
3. What organisational aspects will be affected if the provision of CGM is expanded to more individuals with T2D than is the case today?

4.1 Methodology for obtaining information

Our approach adheres to the methodology outlined in the Norwegian Institute of Public Health's manual "Slik oppsummerer vi forskning" (2).

The chapter is based on input from the expert group and information from guidelines to outline current practices (12). We also incorporated relevant information available online from healthcare institutions (127-129) and the Norwegian Diabetes Association (130). To gather insights into CGM allocation routines for T2D in other countries, we contacted HTA agencies in Sweden, Denmark, and Finland. Furthermore, we used literature identified through our systematic literature search, as described in Section 2.1.3, along with additional references found in the bibliographies of these publications.

4.1.1.1 Limitations

Our methodological approach has certain limitations, as it relies on published literature and input from the expert group. As the clinical experts represent the Norwegian health trusts, it is assumed that they have a comprehensive understanding of the organisational aspects of the healthcare system, allowing them to provide valuable insights into the issue at hand. However, it should be emphasised that the interpretation of the literature and clinician input is the responsibility of NOMA.

4.2 Organisation of diabetes care in Norway

According to the Norwegian guideline for diabetes (12), the treatment and follow-up of individuals with T2D should primarily occur under the care of their general practitioner (GP), regardless of whether they are treated with insulin or not. However, individuals with poor blood glucose control or complex comorbidities should be referred to multidisciplinary teams (diabetes teams) within the specialised healthcare services for treatment either periodically or permanently (12). In such instances, responsibility for the patient’s care is shared between the GP and the specialist healthcare service (12).

4.2.1 Diabetes teams: composition and responsibilities

According to the Norwegian guideline for diabetes (12), a diabetes team should consist of a senior consultant with specialised expertise in diabetes, a diabetes nurse, and a clinical dietitian. Other specialists may also be part of or affiliated with the team (12).

The responsibilities of the diabetes team (12) include patient care (i.e., consultations, referrals, and development of individual treatment plans), education and training for patients, their relatives, and healthcare professionals, as well as other diabetes-related activities. These additional activities involve collaboration with primary healthcare providers, community institutions, biomedical engineers for laboratory quality assurance, and pharmacists regarding medication use and medical aids (12). Furthermore, the diabetes teams are expected to support research on diabetes prevention and treatment in partnership with university hospitals (12).

4.3 Current practice for assigning CGM to individuals with T2D

In Norway, individuals with T2D may, in specific cases, be eligible to receive a CGM if they require daily insulin and struggle to achieve optimal glucose levels (12). However, when a medical product (including both pharmaceuticals and medical devices) is under national assessment within 'Nye metoder,' it should not be implemented (43). For this reason, as outlined in Section 1.4.1, a group exemption allows the provision of CGM to individuals with insulin-treated T2D (44) while NOMA's HTA is ongoing.

Eligibility for CGM in T2D requires either treatment in a hospital outpatient clinic ("diabetesklinikk") or referral to the specialist healthcare services by a GP (130). A hospital doctor or diabetes nurse applies for a CGM device on behalf of the user (130). According to the clinical experts, applications for CGMs are assessed by the diabetes team at hospitals, with decisions often made in collaboration with the hospital specialist director. The devices are supplied through Treatment Aid ("Behandlingshjelpemidler") at hospitals. An overview of devices included in the current financial agreement, negotiated by the Norwegian Hospital Procurement Trust ("Sykehusinnkjøp HF"), is provided in Table 1, Section 1.3.

According to the clinical experts, individuals using CGMs distributed through Treatment Aid are followed up by specialist healthcare services, primarily through diabetes outpatient clinics. Experts further note that CGM training is provided by diabetes nurses, and follow-up care involves both nurses and doctors.

Data from the 2024 diabetes outpatient clinics' report, provided by clinical experts, indicate that 9,362 individuals with T2D visited the clinics, of whom 97% were receiving insulin treatment and 34.5% were using CGM, corresponding to approximately 3,200 individuals. However, the clinical experts also note that some individuals purchase CGMs out of pocket, though they do not have an overview of the number of such cases.

The Norwegian Diabetes Association notes that practices for allocating CGM devices to individuals with insulin-treated T2D vary across Norway (130). They are therefore calling for clearer guidelines regarding the allocation of such devices for this population (130).

4.4 Potential consequences of expanding the use of CGM in insulin-treated T2D

The clinical experts recommend that decisions regarding the allocation of CGM for individuals with insulin-treated T2D continue to be managed by diabetes teams in hospitals, as is currently the case. Additionally, specialists often adjust treatment regimens, simplify them, and may even recommend reduced glucose monitoring for less complex regimens.

Based on the clinical experts' experience, it is estimated that selected individuals using a combination of basal and rapid-acting insulin could benefit from CGM use, either for a short period or a longer duration. In this context, 'benefit' refers to the ability of these individuals to use CGM to achieve improved glycaemic regulation. The experts noted that individuals who already have good glycaemic control are unlikely to derive substantial benefits from CGM. Offering CGM to individuals with insulin-treated T2D who are likely to benefit is expected to result in either a similar or modest increase in device allocation compared to current levels.

To facilitate a comparison of practices in Norway with international guidelines, Table 37 provides an overview of recommendations for CGM use in individuals with T2D on insulin therapy across Scandinavia (131-135), alongside the clinical guideline from the National Institute for Health and Care Excellence (NICE) (136).

Although CGM recommendations for individuals with T2D vary between countries, they generally support CGM use for those on intensive insulin therapy (e.g., multiple daily injections or basal-bolus regimens) who experience recurrent hypoglycaemia, impaired awareness of hypoglycaemia, or difficulties with self-monitoring (see Table 37). Some recommendations also suggest the short-term or

periodic use of CGM to optimise treatment or address specific needs, such as supporting behavioural adjustments or medication changes.

Table 37. Recommendations for CGM use among individuals with insulin-treated T2D

Guidelines	Recommendations
The National Board of Health and Welfare (Socialstyrelsen), Sweden (131)	• Swedish healthcare services may offer isCGM to individuals with T2D who are treated with both mealtime and basal insulin and experience recurrent issues with hyperglycaemia or hypoglycaemia (priority 6)*. • In exceptional cases, Swedish healthcare services may offer rtCGM to individuals with T2D who are treated with both mealtime and basal insulin and experience recurrent issues with hyperglycaemia or hypoglycaemia (priority 8)*.
The Swedish Medical Technologies Product Council (MTP Council) (132)	Updated recommendation on FreeStyle Libre and FreeStyle Libre 2 (2025-04-24) #: • isCGMs may be used by patients with T2D who are treated with basal insulin in combination with mealtime insulin and have an HbA1c level exceeding 60 mmol/mol, or who experience recurrent severe hypoglycaemic episodes despite efforts to adjust insulin doses. ○ Attempts at lifestyle changes and optimisation of treatment with non-insulin antidiabetic medications should have been undertaken. • Use for a limited period to optimise treatment may also be considered. • In other cases, refrain from using continuous glucose monitors for individuals with T2D.
Duodecim, Good medical practice, Finland (133)	Working group appointed by the Finnish Medical Association Duodecim, the Association for Internal Medicine in Finland and the Medical Council of the Diabetes Association recommends: • CGM for individuals with T2D treated with multiple daily insulin injections. For individuals with T2D not treated with insulin or who are treated with basal insulin, routine CGM is not recommended. • In these cases, a few weeks of targeted monitoring may be considered with careful deliberation.
Treatment council (Behandlingsrådet), Denmark (134)	The Danish Health Technology Council has no recommendation for CGM use in T2D.
Danish Endocrinological Society, Denmark (135)	The Danish Endocrinological Society recommends: • Permanent or periodic CGM use for motivated individuals with T2D who are on a basal-bolus insulin treatment plan and receiving ongoing care in a diabetes clinic. • Periodic CGM use for individuals with T2D who are not on insulin or not following a basal-bolus treatment plan, to support behavioural adjustments and/or medication changes in cases of dysregulation.
NICE (136)	The NICE guideline recommends offering isCGM to adults with T2D on multiple daily insulin injections if any of the following criteria are met: • They experience recurrent or severe hypoglycaemia. • They have impaired awareness of hypoglycaemia. • They have a condition or disability (such as a learning disability or cognitive impairment) that prevents them from self-monitoring blood glucose using capillary blood glucose testing but would allow them to use an isCGM device (or have it scanned on their behalf). • They would otherwise require self-monitoring of blood glucose at least 8 times per day.

isCGM: intermittently scanned continuous glucose monitoring; rtCGM: real-time continuous glucose monitoring; T2D: type 2 diabetes

* A higher number indicates a lower priority

The MTP Council has decided to conduct a new evaluation of CGM devices for patients with type 2 diabetes. Until the evaluation is completed, the current recommendation remains in effect

The clinical experts expressed concern that some older individuals may struggle to use the CGM device, particularly as the average age of individuals with insulin-treated T2D in Norway is approximately 67 years. The experts highlight potential issues such as the misapplication of the device, technical problems, and an increased need for follow-up in cases of incorrect measurements, which could place additional pressure on specialist healthcare services.

It should be noted that the older population with diabetes varies widely in health status due to differences in age, physical condition, and social factors (137). This calls for tailored goals and approaches for diabetes management involving technology. Regular assessments of functional and cognitive status may be needed to understand their impact on the ability to use diabetes devices, along with the need for educational support and/or caregiver involvement (137).

4.4.1 Training of individuals with insulin-treated T2D and their relatives

Research indicates that training in the use of CGM can lead to improved blood glucose regulation compared to conventional training or no training (76;138-140). The Norwegian guideline for diabetes (12) states that specialist healthcare services should provide education to all individuals newly diagnosed with diabetes about the condition and its management. However, most individuals with insulin-treated T2D who will require CGM training are likely to have lived with T2D for an extended period before starting insulin therapy. Consequently, dedicated training courses will likely be necessary for those deemed eligible for CGM use.

All RCTs in this HTA included some form of educational support to participants using CGM and SMBG, as detailed in Table 38. A full overview of the training provided in each study is available in Appendix 9. In summary, CGM groups received education focused on interpreting CGM data, adjusting insulin doses, carbohydrate counting, and making lifestyle changes. SMBG groups, on the other hand, received training in traditional diabetes management methods, including using SMBG devices, adjusting insulin doses, and general diabetes care.

Table 38. Overview of training and education provided in the HTA included studies

Study and aim	Group	Educational component
Ajjan 2016 (74)	CGM group	• Educational discussions with HCPs focused on adjusting insulin doses. • Topics included hypoglycaemia management, re-education on carbohydrate counting, and the effects of exercise. • Insulin adjustments were tailored to fasting hyperglycaemia and post-prandial glucose levels
	SMBG group	• No specific educational intervention: standard care recommendations were provided by HCPs.
Beck 2017 (38)	CGM group	• Participants received general counselling about CGM use and individualised recommendations for incorporating CGM data into blood glucose management.
	SMBG group	• No specific educational intervention beyond general counselling and recommendations based on SMBG data.
Bergenstal 2022 (24)	CGM group	• Basic education on CGM data usage for dietary and medication adjustments. • Clinicians reviewed Ambulatory Glucose Profile (AGP) reports with participants during each visit to assist with therapy changes
	SMBG group	• Structured SMBG education (four tests daily) • Participants received practical learning through 7-point blood glucose profiles for clinical decision-making
Haak 2017 (75)	CGM group	• No specific training on interpreting sensor glucose data. • Discussions during visits included glucose control, diet/lifestyle effects on glucose trends, and insulin dose modifications.
	SMBG group	• Participants were instructed to record blood glucose levels and other events (e.g., severe hypoglycaemia) in a diary. • No formal education beyond standard SMBG practices.
Kim 2024 (76)	CGM group 1	• Structured education sessions (five in total) focused on insulin dose and timing adjustments, carbohydrate counting, and reviewing CGM patterns.
	CGM group 2	• Participants learned how to achieve postprandial glucose targets and ensure glucose levels returned to target after meals.
	SMBG group	• Conventional education sessions (three in total) focused on insulin dose adjustments based on SMBG data.
Lever 2024 (77)	CGM group	• Participants received training on the Dexcom G6 system, including interpretation of alerts, trend arrows, and graphs. • Insulin dosing advice was provided based on blinded CGM data.

	SMBG group	• Training on SMBG devices was provided, including the use of SmartLog® software to view and export glucose results.
Lind 2024 (40) (see also elaboration below)	CGM group	• Participants received interactive, hands-on CGM education. • Instructions were provided on interpreting CGM data and understanding the relationship between glucose and diabetes self-management.
	SMBG group	• Peer support sessions facilitated by the primary investigator involved participatory methods and peer exchange.
Martens 2021 (42) / **Aleppo 2021** (66)	CGM group	• Participants received individualised glucose targets, basal insulin titration, meal planning basics, hypoglycaemia management, and medication adherence guidance. • Study clinicians provided advisory expertise on glucose data interpretation and therapy adjustments.
	SMBG group	• Participants attended general diabetes education sessions (individual or group) consistent with the site's usual program. • Topics included glucose targets, insulin titration, meal planning, and hypoglycaemia management.
Yaron 2019 (41)	CGM group	• Counselling included diabetes management instructions and detailed carbohydrate counting consultation by trained diabetes nurses and a dietitian.
	SMBG group	• Participants received the same counselling and carbohydrate counting consultation as the CGM group.

CGM: continuous glucose monitoring; SMBG: self-monitoring of blood glucose via finger-pricks; HPC: healthcare professionals; AGP: ambulatory glucose profile

Kim and colleagues (76) investigated the impact of CGM combined with structured education, CGM with conventional education, and SMBG with conventional education on HbA1c as the primary outcome. Their findings revealed that isCGM leads to a greater reduction in HbA1c in adults with T2D on MDI when education on interpreting graphical patterns in CGM data is provided.

Of particular interest to the Norwegian healthcare service may be the trial by Lind and colleagues (40) which demonstrated that the use of CGM, combined with structured education, led to improved self-reported health behaviours among participants. As part of the trial, the researchers developed and implemented a three-hour training programme tailored specifically for individuals with insulin-treated T2D (141). This programme was well-received by participants, and the authors suggested that it could be integrated into the initiation of CGM use outside the context of a clinical trial (141). Elements of the programme appear similar to the training offered to individuals newly diagnosed with diabetes in specialist healthcare services in Norway (127). However, Lind and colleagues' course includes specific training in the use of CGM, such as practical instruction on device insertion, handling, and data interpretation (141).

Norwegian healthcare services could potentially adapt elements of Lind and colleagues' course to tailor training programmes to the Norwegian context. Furthermore, as specialist healthcare services already possess expertise in training individuals with T1D on CGM use, this expertise could be leveraged and expanded to provide training for individuals with insulin-treated T2D and their relatives. However, an important consideration when educating individuals with insulin-treated T2D is their digital and health literacy levels (142;143), which must be taken into account to ensure the training is appropriately designed and delivered.

4.4.2 Competence among healthcare personnel

To ensure effective education on the use of CGM devices for individuals with insulin-treated T2D, it is important that healthcare personnel—particularly newly trained diabetes nurses or those with limited experience in diabetes care—have a thorough understanding of the device's technical functionalities. Diabetes teams at outpatient diabetes clinics play a key role in providing education to healthcare professionals on diabetes-related topics (12). While the technical aspects of CGM devices may be less complex compared to other diabetes technologies, training may still be required to ensure that the workforce is adequately prepared to support patients.

Most research on the educational needs of healthcare personnel regarding the technical specifications of CGM devices and related equipment primarily focuses on their use for individuals with T1D (144-148).

Qualitative research conducted among healthcare personnel responsible for the follow-up of individuals with T1D highlights that their competence in managing various types of technical diabetes devices may sometimes be limited (144-147). Healthcare professionals have expressed a need for further training in technology and standardised clinical guidance (145-147). Such training would enable them to provide optimal support to users in their daily lives, as well as in situations where non-critically ill individuals with personal CGM devices are admitted to the hospital (149).

In a Norwegian qualitative study on diabetes nurses' experiences with patient education in insulin pump therapy for individuals with T1D, the nurses reported both a need and a desire to stay informed about the medical devices available for individuals with diabetes (148). They also emphasised the importance of sharing experiences with other diabetes nurses, as not all diabetes outpatient clinics have fully developed diabetes teams to facilitate discussions about various challenges (148). The Norwegian Diabetes Association supports the view that healthcare personnel should receive training on how to use the functionalities of diabetes devices as effectively as possible (130).

4.4.3 Digital follow-up and secure digital solutions

Personal CGM devices allow data sharing with family members and healthcare professionals (29-31). Wireless transmission of data from CGM devices to healthcare professionals can pave the way for broader use of e-consultations. An e-consultation is a user-initiated message to a healthcare provider, which may contain sensitive information and attachments, with responses typically provided within five working days (150). Telemedicine extends the concept of e-consultations by enabling real-time monitoring of users by healthcare providers. Currently, there is limited evidence to support telemedicine as being more effective than standard practice for various conditions, including diabetes (151). However, telemedicine is regarded as a safe alternative for providing self-management support in diabetes (151).

A study on telemonitoring of individuals with insulin-treated T2D is planned in Denmark (the DiaMonT study), where participants will be provided with CGM devices monitored by healthcare personnel, who will maintain contact via phone throughout the study period (152). The researchers behind the DiaMonT study believe it has the potential to serve as a foundation for implementing telemedicine for patients with insulin-treated T2D in Denmark (152). In Norway, at Vestre Viken Hospital Trust, digital follow-up for individuals with T1D in diabetes outpatient clinics was introduced in 2024 (129). This service involves users answering questions via an application every four months. Along with recorded blood glucose values, the data are sent from the application to the hospital for assessment and follow-up by a diabetes nurse or doctor. Individuals are contacted for further follow-up if the data indicates a worsening of their condition. If no deterioration is observed, in-person hospital check-ups can be postponed (129). The application also enables individuals to send messages and communicate with the hospital when needed. However, the digital follow-up service does not currently appear to include patients with insulin-treated T2D.

Notably, both medical devices with wireless data transmission (153) and healthcare institutions (154) are vulnerable to cyberattacks. Protecting diabetes devices requires robust cybersecurity measures (153) and collaboration among regulatory bodies, certification agencies, solution providers, and manufacturers (153). Additionally, secure IT systems and digital safety training for healthcare staff are essential within the healthcare sector (154). The Norwegian Diabetes Association highlights the need for secure data transfer from devices to healthcare providers (130). They suggest that combining safe data transmission with staff training could promote e-consultations, save time, and reduce costs for both users and healthcare services (130).

5. Patient perspectives

In this chapter, we describe and discuss patient perspectives related to the use of CGMs for individuals with insulin-treated T2D.

Of particular interest are:

1. The burden of living with insulin-treated T2D
2. Experience of current T2D management
3. Experience with and expectations of the CGM device (in particular, what would be valued most about the technology and issues regarding managing technology administration and side effects)

5.1 Methodology for obtaining information

Our approach adheres to the methodology outlined in the Norwegian Institute of Public Health's manual "Slik oppsummerer vi forskning" (2).

The chapter is primarily based on information provided by the Norwegian Diabetes Association. We arranged a meeting with the Association and utilised our Norwegian adaptation of the HTAi questionnaire for patient input (155) to gather information. Two members of the Central Board ("Sentralstyret") of the Norwegian Diabetes Association completed the questionnaire on behalf of its members. We summarised the input from the Association using AI. The process started by uploading the input into NOMAs secure Large Language Model (ChatDMP) and applying a prompt that had been developed and verified by NOMA. The resulting summary was then reviewed and quality-checked by the project manager, who initiated an iterative process involving edits and multiple interactions with ChatDMP until the final product was achieved. For the sake of transparency, the full input is provided in Appendix 10.

We used relevant systematic reviews and qualitative studies identified through the screening process outlined in Section 2.1.3 to compare and discuss the findings from our questionnaire responses with those from published literature in Section 6.4.

5.1.1 Limitations

Our approach has some limitations, as it does not involve conducting a systematic review of patient experiences, nor does it constitute primary research. Consequently, the description is confined to insights provided by the Norwegian Diabetes Association, which are viewed in the context of the published literature in Section 6.4.

5.2 Input from the Norwegian Diabetes Association

The Norwegian Diabetes Association is an independent, non-profit organisation that represents individuals with diabetes, as well as those affected by or interested in the condition. As of 2025, it has approximately 32,700 members, including 14,000 with T2D and 11,000 with T1D. Its membership also includes 1,900 healthcare professionals and 1,600 relatives. Additionally, 57% of members are aged over 60, and 55% are women.

The Association is funded through membership fees, donations, inheritances, sponsorships from pharmaceutical and device suppliers, and grants from entities such as the Directorate of Children, Youth and Family Affairs, the Norwegian Directorate of Health, Norsk Tipping, and the DAM Foundation.

The Association's understanding of the T2D population, its needs, and the potential benefits of CGM is informed by statistics from inquiries to the Diabetes Line helpline (an information service of the Norwegian Diabetes Association), insights shared by individuals with T2D interacting with expert councils and committees composed of healthcare professionals and user representatives, as well as internal surveys, and research.

5.2.1 The burden of living with insulin-treated T2D

The Norwegian Diabetes Association did not provide information solely related to the burden of living with insulin-treated T2D. Instead, they provided information on the burden of living with T2D in general.

The Association highlighted that T2D is a chronic condition requiring continuous self-management and follow-up, substantially impacting individuals' quality of life. Daily life revolves around demanding choices related to diet, physical activity, medication, and stress management. Many individuals experience physical and mental exhaustion, social limitations, and financial strain as a result of the condition. For those with insulin-treated T2D, constant vigilance is required to assess how various factors influence blood glucose levels, which can be both mentally and physically draining.

Psychological challenges are common, with fear of hypoglycaemia, guilt over poor regulation, and social stigma dominating daily life for many individuals. These factors often contribute to reduced work capacity and the need for workplace accommodations. Socially, individuals may face challenges explaining their condition during meals or managing spontaneity in social settings, further limiting their participation in daily activities.

The Norwegian Diabetes Association emphasised that certain groups face heightened challenges in managing T2D. Older individuals with multiple chronic diseases, those with reduced cognitive or physical function, and individuals with low health literacy often struggle with effective self-management. Socially and economically vulnerable groups may lack access to necessary equipment and healthy food, while immigrants and minorities often encounter language barriers and cultural differences that complicate adherence to treatment recommendations.

Relatives of individuals with T2D also face difficulties. Caregivers often struggle to provide effective support due to limited influence on treatment decisions and lack of access to blood glucose data. Acute concerns, such as hypoglycaemia, and the need to balance the individual's autonomy with their care needs can lead to stress, negatively impacting caregivers' own health and well-being.

5.2.2 Experience with current management of T2D

The Norwegian Diabetes Association addressed not only the experiences of individuals with insulin-treated T2D but also those living with T2D in general.

The Association noted that current treatment options for T2D include lifestyle changes, oral medication, and finger-prick blood glucose monitoring when initiating insulin therapy. While these measures can be effective, many individuals encounter challenges in implementing them. Adjusting diet and physical activity can be difficult without adequate guidance, and insulin therapy carries the risk of hypoglycaemia, which can negatively impact quality of life.

Finger-prick blood glucose monitoring is widely used but perceived by many individuals as painful, inconvenient, and disruptive to daily life. Traditional monitoring methods provide only snapshots of blood glucose levels rather than continuous data, which can lead to uncertainty and inappropriate treatment decisions, such as taking too much or too little insulin.

Certain groups face additional challenges in using existing treatments and equipment for T2D. Physical limitations, psychological barriers, and social stigma often interfere with effective management. Vulnerable groups, such as older individuals, those with cognitive or physical impairments, and economically disadvantaged individuals, may struggle to access or use treatment effectively, further exacerbating health disparities.

5.2.3 Experiences and expectations of CGM devices

The Norwegian Diabetes Association highlighted CGM as a technology with the potential to substantially improve the daily lives of individuals with insulin-treated T2D. CGM provides real-time data and trend information, enabling individuals to adjust their treatment promptly and avoid glucose fluctuations. The reduced reliance on finger-prick testing and alerts for hypo- and hyperglycaemia

enhance safety and reduce stress and increase the patients understanding of how their blood glucose levels are affected by food, activity and other circumstances.

Feedback shared with the Association from individuals with insulin-treated T2D who have used CGM indicates fewer episodes of hypoglycaemia, improved HbA1c levels, and greater peace of mind, particularly at night. Relatives also benefit, as CGM reduces their worry and enhances their ability to provide support. The Association noted that CGM can positively impact quality of life by reducing fatigue, dizziness, and headaches, while increasing confidence in physical activity and decreasing anxiety. Newly diagnosed individuals with T2D may also benefit from using CGM temporarily to better understand how food and physical activity affect blood glucose levels.

Despite its advantages, the Norwegian Diabetes Association acknowledges that CGM devices are not without challenges. Some individuals report discomfort from wearing the device, as well as skin irritation at the sensor site. Financial barriers remain a significant obstacle, as access to reimbursement for CGM is limited. The Association observes that more affluent individuals with T2D often choose to fund CGM privately, contributing to a growing socioeconomic divide within the healthcare system. Over time, such inequality risks exacerbating existing health disparities, leaving economically disadvantaged individuals with greater difficulties in managing their condition effectively compared to those with stronger financial resources.

Position statement from the Norwegian Diabetes Association

The Norwegian Diabetes Association has prepared a position statement on access to CGM for individuals with T2D, developed in consultation with the Executive Committee of the Medical Advisory Council (156):

The Norwegian Diabetes Association recommends that the following individuals with T2D should have access to CGM:

- Patients undergoing multiple daily injection therapy with insulin.
- Patients using 1–2 doses of long-acting insulin who experience recurring hypoglycaemia that cannot be resolved through adjustments to their treatment.

The Norwegian Diabetes Association also supports the short-term use of CGM (e.g., 2–4 weeks) for certain individuals with T2D in the following situations:

- During educational sessions and/or when there is a need for increased motivation to adopt healthier lifestyle habits. Users can benefit from observing how their glucose levels are influenced by daily activities, particularly diet and physical activity.
- When investigating unsatisfactory blood glucose regulation. CGM can provide valuable insights into specific times of day and situations where blood glucose levels are particularly high or low.

6. Discussion

6.1 Discussion of effectiveness and safety

The clinical effectiveness and safety of CGM use were evaluated across multiple outcomes compared to SMBG in individuals with insulin-treated T2D.

6.1.1 Key findings from the systematic review of effectiveness and safety

The systematic review included nine RCTs and three non-RCTs to assess clinical outcomes related to the use of CGM compared to SMBG in individuals with insulin-treated T2D. The findings from the systematic review and meta-analyses indicate that CGM offers certain advantages over SMBG for adults with poorly controlled insulin-treated T2D. However, no evidence was identified specifically for the predefined subgroups. Furthermore, no evidence was available regarding the use of CGM in individuals with well-controlled or optimally managed insulin-treated T2D. All studies received industry funding.

6.1.1.1 Findings from RCTs

Based on RCTs, CGM demonstrated a statistically significant reduction in HbA1c compared to SMBG (moderate certainty), though the reduction did not meet the predefined MCID. CGM also increased TIR (moderate certainty), with clinically meaningful improvements suggested, though not confirmed with certainty. TBR and diabetes-related late vascular complications results were inconclusive due to the evidence mainly being of very low certainty. No statistically significant differences were found between CGM and SMBG for total, severe, or nocturnal hypoglycaemia, TAR (>10.0 mmol/L threshold), glycaemic variation, QoL, or mental health outcomes, with varying degrees of confidence in the evidence. None of the trials reported mortality in the published reports. CGM demonstrated a favourable safety profile with mild to moderate adverse events, such as skin reactions.

6.1.1.2 Findings from non-RCTs

Non-RCTs reported statistically significant reductions in HbA1c among CGM users compared to non-users, with the greatest improvements observed at 12 months. However, these findings were based on low-certainty evidence and did not consistently meet the predefined MCID. Some studies reported statistically significant reductions in severe hypoglycaemia among CGM users. However, the results were inconclusive due to the evidence being of very low certainty. One study reported statistically significant reductions in hospitalisations for stroke, myocardial infarction, and heart failure in CGM users (moderate certainty evidence), but no statistically significant changes in neuropathy (very low certainty evidence) were observed.

6.1.2 Is the evidence comprehensive and applicable?

All included RCTs and non-RCTs investigated the effectiveness of CGM use compared to SMBG, which is sometimes referred to as standard care, in individuals with insulin-treated T2D. This aligns with the inclusion criteria and the commission from ‘Nye metoder.’ While all our prespecified outcomes were addressed by the included studies, not every study covered all outcomes. The outcome of mortality was only reported in the trial registries of three RCTs. Importantly, none of the included studies specifically investigated the prespecified subgroups defined by the commissioner, and as a result, outcomes for these subgroups could not be addressed in this HTA.

6.1.2.3 Participants

All participants in the included studies were individuals with insulin-treated T2D. However, none of the studies included participants who matched the descriptions of the predetermined subgroups.

The HbA1c inclusion criteria in the RCTs required a minimum level of 53 mmol/mol (7%). Baseline HbA1c levels across all included studies (RCTs and non-RCTs) were approximately 70 mmol/mol (8.6%), suggesting that the findings are primarily relevant to individuals with uncontrolled, insulin-

treated T2D. However, determining the exact baseline HbA1c level was challenging, as one trial reported the median instead of the mean.

The mean age of participants across the studies was approximately 61 years, although the exact mean age was difficult to determine because one trial reported median values rather than the mean. Nonetheless, this approximate mean age was slightly lower than the average age of individuals with insulin-treated T2D in Norway (approximately 67 years), which was used in the health economic analysis. This value is also closely aligned with the mean age reported in the Swedish study by Nathanson and colleagues (3).

Similarly, determining the exact duration of T2D was challenging, as two trials reported median values rather than mean values, and one study did not provide any information about the duration of T2D in the study population. Nevertheless, the approximate mean duration of T2D at baseline across the remaining studies was approximately 16 years. This likely reflects the prolonged progression of T2D to an advanced stage requiring insulin therapy to regulate blood glucose levels. We believe these findings are representative of individuals with insulin-treated T2D in Norway.

6.1.2.4 Clinical applicability

Two of the included studies, one RCT and one non-RCT, were conducted in Denmark (40) and Sweden (3), respectively. Two RCTs were conducted in South Korea (76) and New Zealand (77), while the remaining RCTs and non-RCTs were carried out in high-income countries in Europe and the United States. For the RCTs, we consider the results likely transferable to Norway. However, when accounting for similarities and differences in health systems, which are more relevant for non-RCTs, the results may not be fully transferable to Norway, except for the non-RCT conducted in Sweden (3), which was used in the health economic model.

An evident limitation of the HTA's findings is that some of the CGM devices used are older models compared to those currently available. Manufacturers are continuously improving their products, enhancing both accuracy and user-friendliness. However, the concept of continuous glucose monitoring of interstitial fluid, as compared to standard self-monitoring of blood glucose, remains relevant. In this regard, the results are likely applicable to the use of more modern devices.

Data from the included RCTs suggest that CGM has a favourable safety profile, with mild to moderate adverse events such as skin reactions. However, from January to October 2025, 77 serious events were reported with the FreeStyle Libre 3 Plus (400,000 units on the Norwegian market) and 88 with the Simplera CGM (59,000 units) to NOMA (157). While the number of events is low relative to the number of devices in use, manufacturers are required to investigate and report serious incidents to NOMA (157). Users are advised to have blood glucose meters available for capillary blood glucose measurements when CGM readings do not match symptoms (29;31;157).

It is important to emphasise that CGM devices do not treat or manage diabetes or directly prevent hypo- or hyperglycaemia. Their effectiveness relies on the user's ability to respond appropriately to the alarms and trend indicators provided by the device. Therefore, comprehensive and personalised education is important to ensure proper use of the devices and to maximise their potential benefits. This point is also emphasised by clinical experts and the Norwegian Diabetes Association, who highlight the importance of user education in achieving optimal outcomes.

6.1.3 Can we trust the evidence?

The certainty of evidence indicates the level of confidence we have that the effect estimates closely reflect or accurately represent the "true" impact of an intervention on a specific outcome (158). One of the key benefits of the GRADE approach is its ability to make our assessments transparent and open to critique. While GRADE provides a structured framework for systematically evaluating the certainty of evidence, the final assessments still rely on subjective judgement. As a result, we acknowledge that others may interpret or evaluate the certainty of evidence differently.

Details on the GRADE assessment are provided in Section 2.2.6 and Appendix 6. All results were downgraded by at least one level, with “moderate certainty” being the highest confidence rating assigned.

6.1.3.5 Risk of bias and grading of certainty in the evidence in included RCTs

The risk of bias assessment is instrumental in determining the certainty of the evidence using the GRADE framework. We conducted a thorough assessment of the risk of bias in the included RCTs using the ROB v2 tool (60). While many of the trials were well conducted, several concerns regarding the risk of bias were identified, as detailed in Appendix 4. Issues related to bias were identified across all assessed domains in the RCTs, with the lack of blinding being the most prominent concerns. This limitation likely contributed to differential self-management of T2D, as CGM provides a continuous range of data, whereas SMBG only offers snapshots of blood glucose levels. However, it is important to note that this continuous feedback is also the key advantage of CGM and may represent the very effect that the studies aim to capture. While this feature could inherently bias the outcomes in favour of CGM, it simultaneously reflects the intended benefit of the technology in potentially promoting more effective self-management behaviours.

GRADE assessment of RCT outcomes

The identified risks of bias were the primary factors contributing to the downgrading of confidence in the effect estimates of RCT outcomes, as assessed using the GRADE framework. Downgrading solely due to risk of bias resulted in moderate certainty for three outcomes: HbA1c, TIR, and TAR >10 mmol/L, with the latter showing no statistically significant difference between groups. Other effect estimates derived from synthesising data across RCTs were judged to have low or very low certainty. This additional downgrading was mainly due to a combination of 1) risk of bias, 2) inconsistency (heterogeneity in the meta-analyses), and/or 3) imprecision caused by wide confidence intervals, which indicate some or substantial uncertainty in the effect estimates.

6.1.3.6 Risk of bias and grading of certainty in the evidence in non-RCTs

We assessed the risk of bias in the included non-RCTs using the ROBINS-I tool (61). Although the studies were generally well conducted, several concerns regarding the risk of bias were identified, as detailed in Appendix 4. The primary reasons for downgrading the risk of bias in HbA1c, severe hypoglycaemia, and diabetes-related late vascular complications outcomes in non-RCTs were confounding and selection bias. Additional factors, including measurement bias, deviations from intended interventions, and missing data, also contributed to the downgrading.

GRADE assessment of non-RCT outcomes

The identified risks of bias were the main contributors to the downgrading of confidence in the effect estimates for non-RCT outcomes, as evaluated using the GRADE framework. This led to moderate certainty ratings for outcomes such as acute myocardial infarction, angina, ischemic heart disease, heart failure, atrial fibrillation, and stroke. All other outcomes were assessed as having low or very low certainty.

6.1.3.7 Study design and evidence reliability

We included RCTs, as they are widely regarded as the “gold standard” for assessing clinical effectiveness (159). However, RCTs often have strict inclusion criteria that may limit their generalisability, and they typically feature relatively short follow-up durations (159). To address these limitations and better capture potential long-term complications of insulin-treated T2D, we also included observational studies with both an intervention and a control group, and follow-up durations of 12 months or longer. Nevertheless, non-RCTs are inherently more susceptible to biases in selection, confounding, and measurement, which restrict their ability to establish causal relationships.

For example, while major risk factors for cardiovascular disease—such as lipid levels, blood pressure, and kidney function—were adjusted for in the analysis conducted by Nathanson and colleagues, the authors acknowledged that these factors may still have influenced the results (3). Furthermore, it cannot be ruled out that factors other than CGM use contributed to the observed outcomes. Notably,

the study by Nathanson and colleagues lacked data on the extent and type of training provided to individuals using CGM (3), as well as their motivation for behavioural changes. The authors also highlighted that the observed risk reductions are unlikely to be solely attributable to improved glycaemic control following CGM initiation, considering the modest difference in HbA1c between the CGM and control groups and the relatively short follow-up period in their study (3). A potential explanation proposed by the authors is that CGM use may have contributed to a reduction in severe hypoglycaemia, including nocturnal hypoglycaemia, which could be associated with a lower risk of severe cardiovascular events (3). Other possible factors contributing to the reduced incidence of vascular events may include increased TIR and reduced GV (3). However, the authors emphasised that these hypotheses require further investigation and detailed analyses of CGM data, which were not available in their study (3).

6.1.4 Strengths and limitations

The strength of the systematic review lies in its adherence to international standards for conducting systematic reviews, as outlined in the guidelines from the Norwegian Institute of Public Health (2) and the Cochrane handbook (54). We conducted comprehensive a literature search across multiple databases and developed a detailed protocol, which was largely adhered to. Deviations from the protocol, outlined in Section 1.6. Two team members were actively involved throughout the process, including screening and selecting studies, assessing risk of bias, and grading the certainty of evidence. Data extraction and meta-analyses were performed by one team member and subsequently verified by another. Additionally, both the search strategy and meta-analyses underwent internal review by other department members before finalisation.

The limitations of this review include the timing of the main literature search, which was conducted in November 2024, and the search of trial registries, conducted in February 2025. Consequently, we cannot rule out the possibility that relevant studies may have been published after these dates. During the review process, a relevant non-RCT came to our attention, linking CGM use among individuals with insulin-treated T2D to reduced mortality (160). This study's population appears to overlap with parts of the population included in one non-RCT (79) assessed in this HTA. However, the specific population, drawn from the Veterans Affairs (VA) Health Care System and consisting of 94% men, makes the results less likely to be generalisable to a broader T2D population, particularly when compared to the Norwegian population.

This limited generalisability arises from several factors. The Norwegian insulin-treated T2D population has a more balanced gender distribution compared to the VA T2D population, with an average of eight women for every ten men with diabetes (including both T1D and T2D) in Norway (44.4% women vs. 55.6% men) (7). Additionally, over 20% of US veterans are living with diabetes (161), whereas only around 5% of the Norwegian population has a known diabetes diagnosis (7). Furthermore, the healthcare systems of the two countries differ considerably: Norway's universal healthcare system guarantees equitable access to resources for all citizens (162), while the VA operates within a system designed specifically for veterans, offering varying levels of access and support (161). Differences in living conditions between the two countries—including income inequality (163), social welfare systems, and cultural attitudes towards health (164)—further restrict the generalisability of VA-based findings to the Norwegian T2D population.

Another limitation of the HTA is that our initial search of trial registries did not capture three registries for the included RCTs. A thorough investigation was conducted to identify the reasons for this discrepancy, as detailed below: The registry search was structured similarly to the bibliographic database search (type 2 diabetes AND insulin AND CGM). The three missing ClinicalTrials.gov records contained less information in the "Brief Summary" and "Detailed Description" fields than is typical. In two of the records, insulin was mentioned only in the inclusion criteria and not in the "Brief Summary" or "Detailed Description," which appears to have caused them to be excluded from the search results. It seems that inclusion criteria are not searched when using the "Other terms" search field, which was applied in our search. The third registry used a CGM-related term that was missing from our search strategy ("sensor-based glucose monitoring"). The search functionality of trial

registries is less advanced than bibliographic databases such as Ovid and capturing all possible variants without proximity operators is challenging. However, following this investigation, the issue was resolved, and the reason for the missing records were identified. Despite this limitation in the trial registry search, we are confident that the main literature search successfully captured all relevant studies.

We interpreted the scope of the commission as an assessment of CGM use among individuals with insulin-treated T2D in private settings, primarily as a self-management tool for managing the condition, with follow-up care in primary or specialist healthcare services. As such, we did not include studies examining CGM use in hospitalised individuals, during transitions from hospital to home, in telemonitoring contexts, or among individuals with T2D who are not on a medical treatment plan or are following treatment plans other than insulin (e.g., oral medications, GLP-1, or SGLT2). Consequently, the conclusions of this review are limited to individuals with insulin-treated T2D using CGM in private settings for self-management purposes.

Moreover, we did not conduct any analysis on the effectiveness of isCGM versus rtCGM and are unable to provide information in that regard. Additionally, participants were using a combination of insulin regimens and, given their age, had other concomitant medications or diseases that were not accounted for in this HTA.

Two out of the three non-RCTs provided limited information regarding the type of device used and the concomitant educational programmes that may have been implemented alongside CGM initiation. Furthermore, no information was available on how the ‘diabetic teams’ or care were provided, apart from our general understanding of the country’s healthcare system.

All studies were sponsored by industry in some capacity. The RCTs were registered in trial registries, ensuring public access to the full protocols. Additionally, the roles and responsibilities of industry were fully disclosed in the published studies. However, financial relationships between industry, scientific researchers, and academic institutions have been shown to influence research outcomes, with findings more likely to favour the products developed by the sponsoring company compared to those from research funded by other sources (165). Future research should focus on assessing CGM devices independently of industry influence.

6.1.5 Consistency with other literature reviews and studies

In this HTA, we investigated the use of CGM compared to SMBG among individuals with insulin-treated T2D. To our knowledge, no other systematic reviews have exclusively focused on insulin-treated T2D. However, several systematic reviews have examined CGM use in T2D populations regardless of treatment regimen.

A 2024 systematic review by Jancev and colleagues (166), reported that the use of CGM compared to SMBG across 12 RCTs was associated with improvements in glycaemic control in adults with T2D. The findings included a MD in HbA1c of −3.43 mmol/mol (moderate-certainty evidence), an increase in TIR of 6.36%, a decrease in TBR of −0.66%, TAR of −5.86%, and GV of −1.47%. These results were either slightly higher than or comparable to those observed in our analyses. Jancev and colleagues (166) also highlighted that outcome data on incident severe hypoglycaemia (non-statistically significant difference) and incident microvascular and macrovascular complications (non-statistically significant difference) were limited, which aligns with our findings.

In a systematic review by Seidu and colleagues (167), comparing CGM or isCGM to SMBG in T2D, the authors reported that CGM use was associated with a reduction in HbA1c, with a MD of -0.19% (equivalent to -2.08 mmol/mol). This reduction is slightly smaller than the one observed in our analysis. For isCGM, the authors found a reduction of -0.31% (equivalent to -3.39 mmol/mol), which is slightly higher than our result. Seidu and colleagues (167) also reported that the use of CGM or isCGM did not have a significant impact on body composition, blood pressure, or lipid levels. Although we did not investigate these outcomes in our HTA, these findings are consistent with the Norwegian diabetes guideline (12) and feedback from clinical experts, who emphasised the importance of adopting a holistic approach to T2D management rather than focusing solely on glycaemic control.

The input from clinical experts regarding the need for a holistic approach is consistent with findings from a 2025 narrative review by Luca and colleagues (168), which examined the historical evolution of the relationship between T2D and cardiovascular disease. The authors highlighted a significant shift in diabetes management, transitioning from a glucose-centred approach to a more comprehensive strategy that prioritises personalised cardiovascular risk assessment and multidisciplinary care to optimise patient outcomes. However, CGM use may still play an important role in the management of insulin-treated T2D, particularly in individuals with poorly controlled insulin-treated T2D.

The studies included in our HTA (24;38;40-42;66;74-77) focused on participants with poorly controlled insulin-treated T2D, with mean baseline HbA1c levels ranging from 62 to 86 mmol/mol (7.8% to 10%). A registry study conducted in Sweden, which included individuals with T2D on various treatment regimens, found that incident users of the FreeStyle Libre system with better initial glycaemic control (baseline HbA1c <8.0%) did not achieve any significant change six months after the index date, regardless of whether they were on insulin or non-insulin treatment (169). These findings suggest that individuals with poorly regulated or uncontrolled diabetes may derive the greatest benefit from CGM use.

6.2 Discussion of health economics

Using HbA1c as a surrogate outcome, no clinically meaningful difference was observed between CGM and SMBG for individuals with uncontrolled insulin-treated T2D. Given that CGM is more costly than SMBG, it is less probable to be cost-effective compared to SMBG for the total T2D population treated with insulin.

The results of our model-based analysis, which assessed the cost-effectiveness of CGM compared to SMBG in patients with T2D treated with insulin and requiring follow-up care within specialist healthcare services, indicate that CGM provides an extra health benefit (QALYs), with an incremental gain of 0.34 QALYs at an additional cost of NOK [redacted], corresponding to an ICER of approximately NOK [redacted] per QALY. This result is, however, based on some assumptions that the clinical benefits are maintained through long-term and consistent use. The cost-effectiveness of CGM is therefore strongly dependent on user adherence and sustained impact on reducing diabetes-related complications. As the results of scenario analysis indicated, the cost-effectiveness ratio is highly sensitive to the time perspective for considering the additional effect for CGM, which results in an ICER as high as [redacted] per QALY gained. Hence, the long-term cost of complications is highly influenced by disease severity and progression with regard to the time horizon, and cost savings may vary according to individual risk profiles over the long term. In particular, survival among patients with ESRD or multiple complications has a substantial effect on the ICER, and the risk estimates may be subject to uncertainty in the long term. Given that the model relies on short-term data from a more severe population, the estimated health benefits of CGM for this group may be overestimated.

The estimated budgetary impact of implementing CGM for individuals with T2D treated with insulin and requiring specialist follow-up at hospitals is projected to range between NOK [redacted] over a five-year period (2026-2030) for the Regional Health Authorities. However, approximately 3,200 such patients are already using CGM under the current group exemption scheme. This suggests that the incremental financial impact on the Regional Health Authorities would be limited, as a large share of the target population is already covered within existing budgets. Moreover, the number of patients currently using CGM is within the estimated range of the predifined subpopulations, indicating that the implementation would largely formalise and standardise current practice for these clinically eligible groups rather than introduce a substantial new financial burden.

Expanding CGM access to a larger group of individuals treated with MDI, through collaboration between the specialist and primary healthcare, would increase total costs for the Regional Health Authorities to NOK [redacted] in 2026 and NOK [redacted] in 2030. It should be noted that, based on experts' opinion, the number of individuals with T2D treated with insulin, and thus eligible for

CGM, is expected to gradually decline over time, as newer treatment options and therapeutic advancements reduce the need for insulin therapy in this population.

Workforce modelling estimated that implementation of CGM for T2D patients treated with insulin may require 21–32 FTE specialist nurses within the specialist healthcare sector, or a total of 91–128 FTEs under a collaborative model between specialist and primary healthcare sectors for a larger population of insulin-treated T2D individuals.

6.2.1 Strengths and limitations

This is the first health economic model evaluating CGM in individuals with T2D within the Norwegian context. To our knowledge, it is also the first model to use evidence from a direct comparison between CGM and SMBG that includes long-term diabetes complications, rather than relying solely on HbA1c as a surrogate endpoint, as in previous studies. This approach allows for a more comprehensive estimation of both health outcomes and lifetime costs, capturing the clinical and economic implications of CGM use.

The model is informed by a robust real-world study from a recent Swedish study that directly compared CGM and SMBG using linked national registers, including the Swedish National Diabetes Register, the Prescribed Drug Register, and the National Patient Register. This large dataset, covering over 6,800 CGM users and more than 78,000 SMBG users, provides robust and generalisable evidence. The close similarities between the Swedish and Norwegian healthcare systems, diabetes management practices, and population characteristics enhance the relevance and transferability of these findings.

Additional strengths include the use of a transparent, model-based framework that allows for lifetime projections and systematic exploration of parameter uncertainty through both deterministic and probabilistic sensitivity analyses. Similarly, the model allows for measuring the variation in CGM adherence effects through their direct impact on major complications, as well as potential reductions in late complications following severe events or multiple comorbidities. This provides a comprehensive framework for assessing and monitoring long-term changes in costs and effects at the patient level. The model is adaptive and can be readily updated as new evidence on CGM effectiveness becomes available, allowing assessment of adherence variability, subgroup-specific effects, and future interventions along the diabetes treatment pathway. It has also been applied by other Nordic HTA bodies (85), supporting its relevance and transferability.

Furthermore, for the first time, this assessment includes a separate analysis of the impact of introducing a new health technology on national healthcare workforce requirements in Norway, providing valuable insights into the personnel resources needed for large-scale implementation. By expressing resource needs for the most critical healthcare personnel as incremental FTEs required for implementation, this approach aligns with Norway’s prioritisation principles by integrating system-level feasibility and workforce sustainability into the broader assessment of cost-effectiveness and disease severity. It thereby supports more balanced, evidence-informed decisions about the introduction and scaling of CGM within Norway’s healthcare system.

To model real-life outcomes is very complex; hence, any simulation is a simplification. We have tried to find the most robust and best evidence available, but limitations associated with the data and the simplifications of our health economic model should be considered when interpreting the results.

The relative effect estimates applied in our health economic model were derived from a recent Swedish registry-based study (3), which directly compared CGM and SMBG in individuals with type 2 diabetes. Although this study represents the most comprehensive and relevant real-world evidence currently available, it was not a randomised controlled trial (RCT). Nevertheless, the diabetes-related late vascular complications outcome was assessed to have an overall moderate risk of bias. Consequently, potential confounding and selection bias cannot be fully ruled out, as discussed in Section 6.1.3. These methodological limitations may influence the estimated relative effects, particularly for outcomes related to late complications. Nonetheless, the hospitalisation outcomes associated with the diabetes-related late vascular complications were assessed as having moderate

certainty according to the GRADE framework (Section 2.2.6), providing a reasonable basis for model parameterisation. In the context of health economic evaluation, this level of evidence is considered acceptable when higher-quality data are unavailable, particularly given the real-world relevance and consistency of the Swedish data with clinical practice in Norway.

A key limitation is the lack of access to Norwegian data on mortality, complication risks, costs, and quality of life for insulin-treated individuals with T2D. Consequently, the model relied on the best available published evidence, including recent Norwegian studies, systematic reviews, and data from European countries with healthcare systems comparable to Norway. While this approach ensured methodological consistency and clinical plausibility, access to national registry data would have allowed for more precise parameterisation and strengthened the external validity of the results.

Data on the risk of secondary or combined late complications (i.e., individuals experiencing more than two concurrent complications) were not available. To address this gap, a transparent and clinically reasonable multimorbidity framework was applied to ensure that the combined disease burden was represented in the estimation of costs. Health-related quality of life adjustments were derived using the Brazier method (91), which is consistent with international best practice for preference-based utility estimation.

Where direct and consistent risk estimates were unavailable, we applied the best available evidence using different effect measures, including hazard ratios (HR), relative risks (RR), and odds ratios (OR), depending on the data source. While this approach may introduce some uncertainty due to variations in study design and outcome reporting, it is consistent with standard health economic modelling practice when evidence is limited. All estimates were applied transparently and tested through sensitivity analyses to ensure robustness of results.

In line with previous health technology assessments, treatment costs related to ongoing diabetes management were excluded from the complication health states to avoid double-counting, as these costs were assumed to be similar across both the intervention and comparator arms.

Moreover, we did not include the CGM costs for earlier replacement of the sensor (less than 14 days) in our analysis, which might have underestimated the CGM costs. However, One-way sensitivity analysis showed that if we increase the cost of CGM by 30%, the conclusion may not change.

We did not include the direct effect of the device on mortality in the health economic analysis, as a systematic review of the literature did not identify any studies relevant to the Norwegian context that reported differences in mortality outcomes between these glucose monitoring methods (Section 6.1.4).

While different data sources were used to populate the model, priority was given to the most recent and contextually relevant evidence. Future analyses should aim to incorporate national registry data once available, allowing for further refinement of local cost, outcome, and epidemiological estimates.

Finally, the budget impact analyses were based on estimated numbers of eligible patients and available information regarding healthcare personnel requirements. These estimates are subject to uncertainty, as future changes in financing responsibilities, care pathways, and workforce capacity may affect the practical implementation of CGM within the Norwegian healthcare system. This uncertainty also applies to the estimation of specialist nurse full-time equivalents required for the introduction of CGM. While our analysis was conducted at the national level, data on hospital-level requirements were not accessible. These requirements are likely to depend on both existing resource capacity and the specific ways in which each hospital organises its workforce.

6.2.2 Consistency with other health economic studies

We conducted a scoping search to identify previous economic evaluations of sensor-based glucose monitoring in individuals with T2D that may be relevant to the Norwegian context. It is essential to acknowledge that economic evaluations are highly context-dependent; therefore, results and conclusions from international studies cannot be directly applied to the Norwegian setting due to differences in healthcare systems, clinical pathways, resource utilisation, and cost structures.

Five cost–utility analyses were identified: two from the United Kingdom (73;170), one from Sweden (171), one from France (172), and one from Spain (173). The study populations in all analyses consisted of individuals with T2D treated with insulin. Four of the studies applied the commercially available Core Diabetes Model developed by IQVIA, using HbA1c as a surrogate endpoint for clinical outcomes (73;170-172). Similarly, the Spanish analysis employed a Markov model that linked HbA1c to complication risks using UKPDS equations but excluded hypoglycaemia-related utilities (173).

These studies concluded that sensor-based glucose monitoring systems were associated with health gains but also resulted in higher costs compared with SMBG. The results were most sensitive to assumptions related to long-term effectiveness, device costs, and persistence of treatment effects. These findings align with our own sensitivity analyses, confirming that cost-effectiveness is highly dependent on sustained clinical benefit and realistic cost assumptions over time. However, as all the identified studies used HbA1c as a surrogate endpoint, direct comparison with our analysis, where late complications were explicitly modelled, is not feasible. Whether the interventions were deemed cost-effective in each study depended on the incremental cost per QALY gained and the willingness-to-pay threshold applied in the respective country.

6.3 Discussion of organisational implications

Despite advancements in glucose-lowering therapies and improved clinical guidance, achieving and maintaining glycaemic control in T2D remains challenging. Pitak and colleagues (174) found that the estimated prevalence of glycaemic control among individuals with insulin-treated T2D in high-income countries was 32.76%. They also found that the prevalence of glycaemic control among individuals in hospital settings (23.29%) was lower than the prevalence among individuals in primary care settings (31.56%). This suggests that individuals receiving follow-up care in specialist healthcare settings may face greater challenges in achieving glycaemic control, underscoring the potential need for supportive tools, such as CGM devices, to improve outcomes. Currently, in Norway, under the existing group exemption for T2D, CGM devices are allocated to individuals treated in the specialist healthcare sector, highlighting this practice in the Norwegian healthcare system.

During the preparation of this HTA, we reviewed CGM allocation guidelines from neighbouring countries, including Sweden, Denmark, and Finland. These guidelines (131-133;135) recommend CGM for individuals with T2D who are on intensive insulin regimens, such as basal-bolus therapy, particularly those with poorly controlled glycaemic levels or recurrent hypoglycaemic episodes. For individuals with T2D who are not on intensive insulin therapy, periodic or limited CGM use may be considered to optimise treatment or support behavioural changes and medication adjustments, especially in cases of dysregulation (131-133;135). Most recommendations are supported by the findings of our HTA, which suggest that individuals with poorly controlled T2D are the primary beneficiaries of CGM use. The guideline from the Norwegian Endocrinology Society (45) also highlights recurrent hypoglycaemic episodes as a key criterion for CGM reimbursement under the national healthcare system. However, any new standard practice should be supported by a clear prioritisation framework and national guidelines to ensure consistency across Norway.

The successful implementation of CGM use will probably require some organisational adjustments, including the development of tailored training programmes for users and their families. Several of the trials included in this HTA incorporated rigorous or structured educational components alongside CGM use, with trials by Kim and colleagues (76) and Lind and colleagues (40) offering the most robust educational interventions. Notably, Lind and colleagues (40) provided a tailored 3-hour training programme specifically designed to help participants interpret CGM results (141). This trial consistently demonstrated better outcomes for the CGM group compared to other trials, particularly in HbA1c, TIR, and TAR, suggesting that education may play a significant role in optimising CGM benefits. However, this aspect has not been thoroughly assessed in our HTA and warrants further investigation in future trials.

Given that many individuals with T2D in Norway—beyond those who are insulin-treated—may have low health and technology literacy (142;143), education and support from healthcare professionals

and caregivers (175;176) are crucial for the effective implementation of CGM use and lifestyle changes among individuals with insulin-treated T2D. Although there is no definitive evidence directly linking low health literacy to poor glycaemic control or health behaviours (143), it is likely crucial for healthcare professionals to tailor education and support to each patient's health literacy level to optimise outcomes. Currently, such support may be insufficient, underscoring the need for greater focus on educational initiatives and interpersonal assistance.

6.4 Discussion of patient perspectives

A common characteristic of many chronic diseases, including diabetes, is that treatment is largely individual-focused, supplemented by periodic support from health services. However, the Norwegian Diabetes Association emphasises that many people with diabetes struggle to manage the condition effectively and achieve glycaemic control.

Tong and colleagues (177) conducted a qualitative study involving 17 individuals with insulin-treated T2D in Malaysia to investigate factors contributing to poor glycaemic control. The study identified key barriers, including difficulties adhering to regular meal and medication schedules, fear of hypoglycaemia, aversion to needles and pain, and a lack of knowledge and self-efficacy in diabetes management (177). CGM has the potential to address some of these perceived barriers, such as alleviating the fear of hypoglycaemia and reducing the need for frequent finger-prick testing (29-31). However, findings from our HTA do not indicate that the fear of hypoglycaemia is statistically significantly different between CGM users and SMBG users. Nevertheless, CGM can enhance users' understanding of their condition by providing real-time insights into blood glucose trends, such as when levels are rising or falling (29-31).

Sergel-Stringer and colleagues (178) conducted a qualitative study to understand the experiences of individuals with insulin-treated T2D who were initiating rtCGM use. This study was conducted alongside the RCT led by Lever and colleagues (77). The authors concluded that adults with insulin-treated T2D found rtCGM systems broadly acceptable and easier to use than traditional SMBG, with perceived benefits in glycaemic control, self-efficacy, and convenience (178). However, they also noted persistent challenges related to technological performance, skin-related complications, cost, and equity (178).

A central approach to self-management is the concept of empowerment, a strategy designed to enhance an individual's ability to recognise and address their own challenges rather than depend solely on externally provided solutions (179). The Norwegian Diabetes Association advocates for CGM as a valuable tool to empower individuals in managing their condition more effectively. Lind and colleagues (40) observed that self-reported health behaviours improved when CGM was combined with comprehensive education. Their findings suggest that CGM can enable individuals with insulin-treated T2D to make more informed decisions by providing insights into how insulin, dietary choices, and physical activity affect glycaemic control (40). Supporting this, an RCT by Polonski and colleagues (180) demonstrated that the introduction of CGM led to greater patient engagement in diabetes self-management compared to the use of SMBG.

However, as previously mentioned, the potential benefits of CGM may be constrained by low levels of health and technology literacy among certain individuals (142;143). To address these challenges, the healthcare sector could prioritise screening patients for health literacy levels and provide tailored education and training to maximise the benefits of this technology, as demonstrated in a study by Evans and colleagues (181). Additional support for this approach comes from a qualitative study by Ni and colleagues (175), which reported high acceptance of CGM among a low-income, diverse patient population with T2D. The study underscored the importance of personalised clinician support and family involvement in overcoming barriers related to health and technology literacy, thereby facilitating both the initiation and sustained use of CGM (175).

Ensuring equitable access to technologies and training that support glycaemic control for individuals with low health and technology literacy may be crucial for reducing health-related social inequalities in Norway. Without such measures, individuals with higher health literacy and greater financial resources

may choose to purchase CGM devices privately, potentially worsening disparities in health outcomes between those with better and poorer health (182). However, addressing social inequalities requires more than simply providing access to the technology. Ensuring equitable capability to benefit from CGM demands a multi-faceted approach. This underscores that technology alone cannot solve the broader issues tied to these inequalities. Investments in skills, inclusion, trust, human resources, and the broader social determinants of health are vital—not just financial access to purchase CGM.

6.5 Implications of the findings for clinical practice

This HTA found that the use of CGM offers some advantages over SMBG in adults with suboptimal or poorly controlled insulin-treated T2D. However, healthcare professionals and patient representatives emphasise the need for clear and standardised criteria to allocate CGM to eligible individuals, which should be developed following this HTA.

Based on the results of the cost-effectiveness analysis, the HTA findings suggest that the long-term benefits of CGM in insulin-treated T2D patients requiring clinical follow-up are primarily dependent on sustained adherence and appropriate patient selection; therefore, integration of the technology is crucial to be structured into a clinical follow-up approach. The use of CGM may lead to some improvements in the short term, such as glycaemic control; however, the full impact is recognised over time through a reduction in complication rates.

To ensure that technology effectively supports behavioural management and medical adherence, it is essential to establish enhanced and ongoing diabetes education, improve health and diabetes literacy, and develop robust support systems. These measures will enable both healthcare providers and individuals to utilise the technology effectively and maximise its potential benefits and long-term cost-effectiveness.

We propose monitoring CGM use in T2D through the Norwegian Quality Improvement of Laboratory Examinations (Noklus), including details such as the patient's diabetes type, treatment regimen, HbA1c levels, type of technology used, diabetes-related late complications, and mortality. This practice may facilitate future studies on diabetes-related late complications for this population in Norway.

6.6 Knowledge gaps

More studies with longer follow-up periods are needed to assess diabetes-related late complications and mortality in T2D, which are essential for evaluating health economic consequences.

Adherence to CGM guidance was not part of our research question, however, the health economic evaluation highlights the need for further research on adherence and treatment persistence.

Future research should also aim to assess the effects of CGM devices independently of industry funding.

7. Conclusion

This HTA found that the use of CGM may offer certain advantages over SMBG in adults with suboptimal or poorly controlled, insulin-treated T2D, particularly in improving TIR. For most other outcomes, the results did not provide definitive conclusions. However, non-RCT evidence suggests that CGM may reduce hospital admissions for some diabetes-related late vascular complications in individuals with poorly controlled, insulin-treated T2D who receive follow-up care within specialist healthcare services, after adjustments for relevant confounding factors. Notably, no evidence was available for the use of CGM in individuals within the predefined subgroups. All included studies received industry funding.

For the entire population of individuals with T2D treated with insulin, the introduction of CGM may result in higher costs without measurable additional health benefits.

For adults with T2D treated with insulin and requiring clinical follow-up in specialist healthcare, the incremental health benefits associated with CGM are likely to outweigh the additional costs. However, the results are substantially sensitive to key assumptions regarding long-term adherence and sustained glycaemic benefits, which have a strong influence on projected health outcomes and costs, which makes the incremental cost-effectiveness ratio exceed [redacted] per QALY gained (for a 5-year time horizon).

The budgetary consequences of implementing CGM for the Regional Health Authorities over a 5-year period (2026-2030) depend on the chosen organisational model, whether CGM is implemented and followed up within specialist healthcare (NOK [redacted] or through a collaborative approach between the specialist and primary healthcare (NOK [redacted] in 2026 and NOK [redacted] in 2030), as well as on the level of uptake among patients receiving multiple daily insulin injections. If CGM is implemented only for individuals with T2D treated with insulin who require clinical follow-up in specialist healthcare, the budgetary consequences for the specialist healthcare sector would likely remain at a similar level to that of patients using CGM under the current group exemption scheme and likely consist of the total cost estimated for the implementation of CGM for the predefined subpopulations.

Implementation of CGM for T2D patients treated with insulin may require 21–32 full-time equivalents (FTE) specialist nurses within the specialist healthcare sector, or a total of 91–128 FTEs under a collaborative model between specialist and primary healthcare sectors for a larger population of insulin-treated T2D individuals.

The Norwegian Diabetes Association requests expanded access to CGM for certain individuals with insulin-treated T2D and short-term use for educational purposes for specific individuals with T2D, while emphasising the importance of addressing the needs of vulnerable groups, such as older adults, those with low health literacy, and immigrant populations.

8. References

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180. Polonsky WH, Soriano EC, Levrat-Guillen F, Chichmarenko M, Sandoval H, Bastian A, et al. Does Continuous Glucose Monitoring Use Prompt Greater Engagement in Self-Management? A Randomized Controlled Trial Focusing on Adults With Type 2 Diabetes. J Diabetes Sci Technol 2025:19322968251361031. DOI: 10.1177/19322968251361031
181. Evans EI, Pincus KJ, Seung H, Rochester-Eyeguokan CD. Health literacy of patients using continuous glucose monitoring. J Am Pharm Assoc (2003) 2024;64(4):102109. DOI: 10.1016/j.japh.2024.102109

182. Øversveen E. Teknologisk utvikling og sosial ulikhet i helse: Tilgjengeligheten av medisinsk teknologi i behandlingen av en kronisk sykdom. Norsk sosiologisk tidsskrift 2019;3(4):269-83. DOI: 10.18261/issn.2535-2512-2019-04-03
183. Hong Y. On computing the distribution function for the Poisson binomial distribution. Computational Statistics & Data Analysis 2013;59:41-51.
184. Smitth MWB, P.G.; Phibbs C.S.; Wanger, T.H. Guidebook. Microcost Methods for determining VA healthcare costs. Health Economics Resource Center; 2010.

Appendix 1: Search strategy

Search performed on: 21 November 2024

Embase <1974 to 2024 November 19>

1	Non Insulin Dependent Diabetes Mellitus/ or Diabetes Mellitus/	1069174
2	(((diabetes or DM) and (adult-onset or ketosis-resistant or maturity-onset or slow-onset or type2 or typeII or typeii or type 2 or type II or T2 or T-2 or TII or T-II)) or dm2 or t2d? or mody).ti,bt. or (diabet* or insulin).jn.	290855
3	Insulin/ or (insulin adj4 (daily or dose* or dosing or injection* or take* or taking or therap* or treat*)).tw,bt,kf.	426712
4	Continuous Glucose Monitoring System/ or Continuous Glucose Monitoring/ or Self-Monitoring Blood Glucose/	7715
5	(((continuous* or flash or intermittent* or real-time or realtime) adj4 (bloodglucose or glucose) adj4 (measur* or monitor* or selfmonitor* or sensor*)) or ((continuous* or flash or intermittent* or real-time or realtime) adj4 (measur* or monitor* or selfmonitor* or sensor*) adj4 (bloodglucose or glucose))).tw,bt,kf.	17363
6	(CGM or CGMs or CBGM or rtCGM or RT CGM or R-CGM or RCGM or FGM or F-GM).tw,bt,kf.	14614
7	((Medtrum adj2 TouchCare*) or (Dexcom adj2 (G6 or G7 or Seven Plus)) or GlucoMen* or (Guardian* adj2 (Connect or "3" or "4")) or (Freestyle adj (Libre or Navigator)) or Simplera* or (Medtronic adj (Enlite or iPro2))).mp,bt.	3497
8	(1 or 2) and 3 and (4 or 5 or 6 or 7)	7365
9	(rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and Animal experiment/	1275917
10	Animal experiment/ not (human experiment/ or human/)	2685603
11	(conference abstract or preprint).pt.	5426859
12	8 not (9 or 10 or 11)	3875

Ovid MEDLINE(R) ALL <1946 to November 19, 2024>

1	exp Diabetes Mellitus, Type 2/ or Diabetes Mellitus/	327044
2	(((diabetes or DM) and (adult-onset or ketosis-resistant or maturity-onset or slow-onset or type2 or typeII or typeii or type 2 or type II or T2 or T-2 or TII or T-II)) or dm2 or t2d? or mody).ti,bt. or (diabet* or insulin).jn.	176911
3	Insulin/ or (insulin adj4 (daily or dose* or dosing or injection* or take* or taking or therapy or treat*)).tw,bt,kf.	228744
4	Continuous Glucose Monitoring/ or Blood Glucose Self-Monitoring/	11028
5	(((continuous* or flash or intermittent* or real-time or realtime) adj4 (bloodglucose or glucose) adj4 (measur* or monitor* or selfmonitor* or sensor*)) or ((continuous* or flash or intermittent* or real-time or realtime) adj4 (measur* or monitor* or selfmonitor* or sensor*) adj4 (bloodglucose or glucose))).tw,bt,kf.	9993

6	(CGM or CGMs or CBGM or rtCGM or RT-CGM or R-CGM or RCGM or FGM or F-GM).tw,bt,kf.	7584
7	((Medtrum adj2 TouchCare*) or (Dexcom adj2 (G6 or G7 or Seven Plus)) or GlucoMen* or (Guardian* adj2 (Connect or "3" or "4")) or (Freestyle adj (Libre or Navigator)) or Simplera* or (Medtronic adj (Enlite or iPro2))).mp,bt.	868
8	(1 or 2) and 3 and (4 or 5 or 6 or 7) [DM2 AND insulinbeh. AND CGM/FGM]	3503
9	exp animals/ not humans.sh.	5278796
10	preprint.pt.	32242
11	8 not (9 or 10)	3467

Epistemonikos

(Advanced search)

Title/Abstract:] (((diabetes OR DM) AND (adult-onset OR "adult onset" OR ketosis-resistant OR "ketosis resistant" OR maturity-onset OR "maturity onset" OR slow-onset OR "slow onset" OR type2 OR typeII OR "type 2" OR "type II" OR type-2 OR type-II OR T2 OR T-2 OR TII OR T-II)) OR DM2 OR DMII OR T2D* OR mody)
AND

[Title/Abstract:] (((continuous* OR flash OR intermittent* OR real-time OR realtime OR "real time") AND (bloodglucose OR blood-glucose OR glucose) AND (measur* OR monitor* OR self-monitor* OR selfmonitor* OR sensor*)) OR CGM OR CGMs OR CBGM OR rtCGM OR RT-CGM OR "RT CGM" OR R-CGM OR RCGM OR "R CGM" OR FGM OR F-GM)
Filters: Systematic Review + Broad Synthesis

Total number of hits: 121 + 7

INAHTA

((((diabetes OR DM) AND (adult-onset OR "adult onset" OR ketosis-resistant OR "ketosis resistant" OR maturity-onset OR "maturity onset" OR slow-onset OR "slow onset" OR type2 OR typeII OR "type 2" OR "type II" OR type-2 OR type-II OR T2 OR T-2 OR TII OR T-II)) OR DM2 OR DMII OR T2D* OR mody) AND (((continuous* OR flash OR intermittent* OR real-time OR realtime OR "real time") AND (bloodglucose OR blood-glucose OR glucose) AND (measur* OR monitor* OR self-monitor* OR selfmonitor* OR sensor*)) OR CGM OR CGMs OR CBGM OR rtCGM OR RT-CGM OR "RT CGM" OR R-CGM OR RCGM OR "R CGM" OR FGM OR F-GM))
Basic search

Number of hits: 22

Search strategy for study registers

ClincalTrials.gov 2025-02-17	[Other:] ((((diabetes OR DM) AND (adult-onset OR "adult onset" OR ketosis-resistant OR "ketosis resistant" OR maturity-onset OR "maturity onset" OR slow-onset OR "slow onset" OR type2 OR typeII OR "type 2" OR "type II" OR type-2 OR type-II OR T2 OR T-2 OR TII OR T-II)) OR dm2 OR t2d OR mody) AND insulin AND ("continuous glucose" OR "flash glucose" OR "intermittent glucose" OR "real-time glucose" OR "realtime glucose" OR "real time glucose" OR "continuous blood glucose" OR "flash blood glucose" OR "intermittent blood glucose" OR "real-time blood glucose" OR "realtime blood glucose" OR "real	596

	time blood glucose" OR "continuous blood-glucose" OR "flash blood-glucose" OR "intermittent blood-glucose" OR "real-time blood-glucose" OR "realtime blood-glucose" OR "real time blood-glucose" OR Medtrum OR TouchCare OR Dexcom OR GlucoMen OR Guardian OR Freestyle OR Simplera OR Medtronic OR Enlite OR iPro2))	
ICTRP 2025-02-17	[Standard search interface:] ((((diabetes OR DM) AND (adult-onset OR "adult onset" OR ketosis-resistant OR "ketosis resistant" OR maturity-onset OR "maturity onset" OR slow-onset OR "slow onset" OR type2 OR typeII OR "type 2" OR "type II" OR type-2 OR type-II OR T2 OR T-2 OR TII OR T-II)) OR dm2 OR t2d OR mody) AND insulin AND ("continuous glucose" OR "flash glucose" OR "intermittent glucose" OR "real-time glucose" OR "realtime glucose" OR "real time glucose" OR "continuous blood glucose" OR "flash blood glucose" OR "intermittent blood glucose" OR "real-time blood glucose" OR "realtime blood glucose" OR "real time blood glucose" OR "continuous blood-glucose" OR "flash blood-glucose" OR "intermittent blood-glucose" OR "real-time blood-glucose" OR "realtime blood-glucose" OR "real time blood-glucose" OR Medtrum OR TouchCare OR Dexcom OR GlucoMen OR Guardian OR Freestyle OR Simplera OR Medtronic OR Enlite OR iPro2))	209

Appendix 2: Excluded studies

Study	Reason for exclusion
Ajjan (2019) Ajjan RA, Jackson N, Thomson SA. Reduction in HbA1c using professional flash glucose monitoring in insulin-treated type 2 diabetes patients managed in primary and secondary care settings: A pilot, multicentre, randomised controlled trial. Diabetes & Vascular Disease Research 2019;16(4):385-95. DOI: https://dx.doi.org/10.1177/1479164119827456	Intervention
Ajjan (2022) Ajjan R, Bilir SP, Hellmund R, Souto D. Cost-Effectiveness Analysis of Flash Glucose Monitoring System for People with Type 2 Diabetes Receiving Intensive Insulin Treatment. Diabetes Therapy Research, Treatment and Education of Diabetes and Related Disorders 2022;13(11-12):1933-45. DOI: https://dx.doi.org/10.1007/s13300-022-01325-w	Publication type (cost-effectiveness)
Ajjan (2023) Ajjan RA, Heller SR, Everett CC, Vargas-Palacios A, Higham R, Sharples L, et al. Multicenter Randomized Trial of Intermittently Scanned Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Individuals With Type 2 Diabetes and Recent-Onset Acute Myocardial Infarction: Results of the LIBERATES Trial. Diabetes Care 2023;46(2):441-9. DOI: https://dx.doi.org/10.2337/dc22-1219	Population (not all on insulin)
Al Hayek (2023) Al Hayek AA, Al Dawish MA. Use of Flash Glucose Monitoring and Glycemic Control in Patients with Type 2 Diabetes Mellitus Not Treated with an Intensive Insulin Regimen: 1-Year Real-Life Retrospective Cohort Study. Advances in Therapy 2023;40(6):2855-68. DOI: https://dx.doi.org/10.1007/s12325-023-02508-y	Comparator (retrospective – no control group)
Alshannaq (2023) Alshannaq H, Isitt JJ, Pollock RF, Norman GJ, Cogswell G, Lynch PM, et al. Cost-utility of real-time continuous glucose monitoring versus self-monitoring of blood glucose in people with insulin-treated Type 2 diabetes in Canada. Journal of Comparative Effectiveness Research 2023;12(10):e230075. DOI: https://dx.doi.org/10.57264/cer-2023-0075	Publication type (cost utility)
Alshannaq (2024) Alshannaq H, Pollock RF, Joubert M, Ahmed W, Norman GJ, Lynch PM, et al. Cost-utility of real-time continuous glucose monitoring versus self-monitoring of blood glucose in people with insulin-treated Type II diabetes in France. Journal of Comparative Effectiveness Research 2024;13(3):e230174. DOI: https://dx.doi.org/10.57264/cer-2023-0174	Publication type (cost utility)
Anonymous (2010) Anonymous. Validation of measures of satisfaction with and impact of continuous and conventional glucose monitoring. Diabetes Technology & Therapeutics 2010;12(9):679-84. DOI: https://dx.doi.org/10.1089/dia.2010.0015	Study design (non-RCT < 12 months)
Argento (2014) Argento NB, Nakamura K, Sala RD, Simpson P. Hemoglobin A1C, mean glucose, and persistence of glycation ratios in insulin-treated diabetes. Endocrine Practice 2014;20(3):252-60. DOI: https://dx.doi.org/10.4158/EP13079.OR	Comparator (retrospective – no control group)
Bailey (2022) Bailey R, Calhoun P, Chao C, Walker TC. With or Without Residual C-Peptide, Patients with Type 2 Diabetes Realize Glycemic Benefits from Real-Time Continuous Glucose Monitoring. Diabetes Technology & Therapeutics 2022;24(4):281-4. DOI: 10.1089/dia.2021.0384	Publication type (subgroup of the Mobile study)
Baker (2022) Baker M, Musselman ME, Rogers R, Hellman R. Practical implementation of remote continuous glucose monitoring in hospitalized patients with diabetes. American Journal of Health-System Pharmacy 2022;79(6):452-8. DOI: https://dx.doi.org/10.1093/ajhp/zxab456	Intervention (remote CGM)

Bao (2022) Bao S, Bailey R, Calhoun P, Beck RW. Effectiveness of Continuous Glucose Monitoring in Older Adults with Type 2 Diabetes Treated with Basal Insulin. Diabetes Technology & Therapeutics 2022;24(5):299-306. DOI: https://dx.doi.org/10.1089/dia.2021.0494	Publication type (subgroup of the Mobile study)
Baumstark (2017) Baumstark A, Jendrike N, Pleus S, Haug C, Freckmann G. Evaluation of Accuracy of Six Blood Glucose Monitoring Systems and Modeling of Possibly Related Insulin Dosing Errors. Diabetes Technology & Therapeutics 2017;19(10):580-8. DOI: https://dx.doi.org/10.1089/dia.2016.0408	Comparator
Beck (2022) Beck SE, Kelly C, Price DA. Non-adjunctive continuous glucose monitoring for control of hypoglycaemia (COACH): Results of a post-approval observational study. Diabetic Medicine 2022;39(2):e14739. DOI: 10.1111/dme.14739	Study design (6 mo SMBG and 6 mo CGM)
Bennion (2002) Bennion N, Christensen NK, McGarraugh G. Alternate site glucose testing: a crossover design. Diabetes Technology & Therapeutics 2002;4(1):25-33; discussion 45. DOI: https://dx.doi.org/10.1089/15209150252924058	Study design (non-RCT < 12 months)
Bergenstal (2012) Bergenstal RM, Bode BW, Tamler R, Trence DL, Stenger P, Schachner HC, et al. Advanced meter features improve postprandial and paired self-monitoring of blood glucose in individuals with diabetes: results of the Actions with the CONTOUR Blood Glucose Meter and Behaviors in Frequent Testers (ACT) study. Diabetes Technology & Therapeutics 2012;14(10):851-7. DOI: https://dx.doi.org/10.1089/dia.2012.0051	Population (not separate data for T2D)
Billings (2018) Billings LK, Parkin CG, Price D. Baseline Glycated Hemoglobin Values Predict the Magnitude of Glycemic Improvement in Patients with Type 1 and Type 2 Diabetes: Subgroup Analyses from the DIAMOND Study Program. Diabetes Technology & Therapeutics 2018;20(8):561-5. DOI: https://dx.doi.org/10.1089/dia.2018.0163	Publication type (subgroup of the Diamond study)
Blackberry (2014) Blackberry ID, Furler JS, Ginnivan LE, Derraz H, Jenkins A, Cohen N, et al. An exploratory trial of insulin initiation and titration among patients with type 2 diabetes in the primary care setting with retrospective continuous glucose monitoring as an adjunct: INITIATION study protocol. BMC Family Practice 2014;15:82. DOI: https://dx.doi.org/10.1186/1471-2296-15-82	Intervention (study protocol)
Brown (2023) Brown M, Roberts J, Smith C, Eash D. Safety and Effectiveness of the Use of an Electronic Glucose Monitoring System Versus Weight-Based Dosing Nomogram for Treatment of Diabetic Ketoacidosis and Hyperglycemic Hyperosmolar Syndrome in a VA Hospital. Journal of Diabetes Science & Technology 2023;17(3):727-32. DOI: https://dx.doi.org/10.1177/19322968221074710	Population (not separate data for T2D)
Bujnowska-Fedak (2011) Bujnowska-Fedak MM, Puchala E, Steciwko A. The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in Poland. Telemedicine Journal & E-Health 2011;17(3):153-63. DOI: 10.1089/tmj.2010.0113	Intervention
Cai (2023) Cai L, Wang W, Dai L. Risk factors for hypoglycemia in patients with type 2 diabetes mellitus after intensive insulin therapy and blood glucose monitoring strategy. African Health Sciences 2023;23(2):499-508. DOI: https://dx.doi.org/10.4314/ahs.v23i2.58	Intervention
Chico (2003) Chico A, Vidal-Rios P, Subira M, Novials A. The continuous glucose monitoring system is useful for detecting unrecognized hypoglycemias in patients with type 1 and type 2 diabetes	Comparator

but is not better than frequent capillary glucose measurements for improving metabolic control. Diabetes Care 2003;26(4):1153-7. DOI: https://dx.doi.org/10.2337/diacare.26.4.1153	
Chu (2024) Chu C, Li J, Yang X, Zhao H, Wu Z, Xu R, et al. Continuous glucose monitoring versus conventional glucose monitoring in the ICU: A randomized controlled trial. Journal of Critical Care 2024;84(no pagination). DOI: https://dx.doi.org/10.1016/j.jcrc.2024.154894	Population
Cooke (2009) Cooke D, Hurel SJ, Casbard A, Steed L, Walker S, Meredith S, et al. Randomized controlled trial to assess the impact of continuous glucose monitoring on HbA(1c) in insulin-treated diabetes (MITRE Study). Diabetic Medicine 2009;26(5):540-7. DOI: https://dx.doi.org/10.1111/j.1464-5491.2009.02723.x	Intervention
Cosson (2009) Cosson E, Hamo-Tchatchouang E, Dufaitre-Patouraux L, Attali JR, Paries J, Schaepelynck-Belicar P. Multicentre, randomised, controlled study of the impact of continuous sub-cutaneous glucose monitoring (GlucoDay) on glycaemic control in type 1 and type 2 diabetes patients. Diabetes and Metabolism 2009;35(4):312-8. DOI: https://dx.doi.org/10.1016/j.diabet.2009.02.006	Intervention
Davis (2020) Davis GM, Spanakis EK, Migdal AL, Singh LG, Albury B, Urrutia MA, et al. Accuracy of Dexcom G6 Continuous Glucose Monitoring in Non-Critically Ill Hospitalized Patients With Diabetes. Diabetes Care 2021;44(7):1641-6. DOI: https://dx.doi.org/10.2337/dc20-2856	Study design (non-RCT < 12 months)
Davis (2021) Davis G, Bailey R, Calhoun P, Price D, Beck RW. Magnitude of Glycemic Improvement in Patients with Type 2 Diabetes Treated with Basal Insulin: Subgroup Analyses from the MOBILE Study. Diabetes Technology & Therapeutics 2022;24(5):324-31. DOI: https://dx.doi.org/10.1089/dia.2021.0489	Outcome (MARD)
Davis 2022 Davis G, Bailey R, Calhoun P, Price D, Beck RW. Magnitude of Glycemic Improvement in Patients with Type 2 Diabetes Treated with Basal Insulin: Subgroup Analyses from the MOBILE Study. Diabetes Technology & Therapeutics 2022;24(5):324-31. DOI: https://dx.doi.org/10.1089/dia.2021.0489	Publication type (subgroup of the Mobile study)
De Block (2015) De Block CE, Gios J, Verheyen N, Manuel-y-Keenoy B, Rogiers P, Jorens PG, et al. Randomized Evaluation of Glycemic Control in the Medical Intensive Care Unit Using Real-Time Continuous Glucose Monitoring (REGIMEN Trial). Diabetes Technology & Therapeutics 2015;17(12):889-98. DOI: https://dx.doi.org/10.1089/dia.2015.0151	Intervention
Del Prato (2012) Del Prato S, Nicolucci A, Lovagnini-Scher AC, Turco S, Leotta S, Vespasiani G. Telecare Provides comparable efficacy to conventional self-monitored blood glucose in patients with type 2 diabetes titrating one injection of insulin glulisine-the ELEONOR study. Diabetes Technology & Therapeutics 2012;14(2):175-82. DOI: https://dx.doi.org/10.1089/dia.2011.0163	Intervention
Eeg-Olofsson (2022) Eeg-Olofsson K, Svensson AM, Franzen S, Ahmed I, Tornblom M, Levrat-Guillen F. Real-world study of flash glucose monitoring among adults with type 2 diabetes within the Swedish National Diabetes Register. Diabetes and Vascular Disease Research 2022;19(1). DOI: https://dx.doi.org/10.1177/14791641211067418	Comparator (before-and-after; no control group)
Ehrhardt (2011) Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. Journal of Diabetes Science & Technology 2011;5(3):668-75. DOI: https://dx.doi.org/10.1177/193229681100500320	Population

Everett (2020) Everett CC, Reynolds C, Fernandez C, Stocken DD, Sharples LD, Sathyapalan T, et al. Rationale and design of the LIBERATES trial: Protocol for a randomised controlled trial of flash glucose monitoring for optimisation of glycaemia in individuals with type 2 diabetes and recent myocardial infarction. Diabetes & Vascular Disease Research 2020;17(5):1479164120957934. DOI: https://dx.doi.org/10.1177/1479164120957934	Population (study protocol)
Garg (2006) Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. Diabetes Care 2006;29(1):44-50. DOI: https://dx.doi.org/10.2337/diacare.29.01.06.dc05-1686	Population (not separate data for T2D)
Grady (2018) Grady M, Katz LB, Levy BL. Use of Blood Glucose Meters Featuring Color Range Indicators Improves Glycemic Control in Patients With Diabetes in Comparison to Blood Glucose Meters Without Color (ACCENTS Study). Journal of Diabetes Science & Technology 2018;12(6):1211-9. DOI: https://dx.doi.org/10.1177/1932296818775755	Intervention
Gunawardena (2019) Gunawardena KC, Jackson R, Robinett I, Dhaniska L, Jayamanne S, Kalpani S, et al. The Influence of the Smart Glucose Manager Mobile Application on Diabetes Management. Journal of Diabetes Science & Technology 2019;13(1):75-81. DOI: https://dx.doi.org/10.1177/1932296818804522	Intervention
Halimi (2001) Halimi S, Charpentier G, Grimaldi A, Grenier JL, Baut F, Germain B, et al. Effect on compliance, acceptability of blood glucose self-monitoring and HbA(1c) of a self-monitoring system developed according to patient's wishes. The ACCORD study. Diabetes & Metabolism 2001;27(6):681-7.	Intervention
Hangaard (2022) Hangaard S, Kronborg T, Hejlesen O, Aradottir TB, Kaas A, Bengtsson H, et al. The Diabetes teleMonitoring of patients in insulin Therapy (DiaMonT) trial: study protocol for a randomized controlled trial. Trials [Electronic Resource] 2022;23(1):985. DOI: 10.1186/s13063-022-06921-6	Intervention (study protocol)
Harris (2023) Harris SB, Levrat-Guillen F. Use of the FreeStyle Libre system and diabetes treatment progression in T2DM: Results from a retrospective cohort study using a Canadian private payer claims database. Diabetes, Obesity & Metabolism 2023;25(6):1704-13. DOI: https://dx.doi.org/10.1111/dom.15025	Population
Hermanns (2019) Hermanns N, Ehrmann D, Schipfer M, Kroger J, Haak T, Kulzer B. The impact of a structured education and treatment programme (FLASH) for people with diabetes using a flash sensor-based glucose monitoring system: Results of a randomized controlled trial. Diabetes Research & Clinical Practice 2019;150:111-21. DOI: 10.1016/j.diabres.2019.03.003	Comparator
Homko (2007) Homko CJ, Santamore WP, Whiteman V, Bower M, Berger P, Geifman-Holtzman O, et al. Use of an internet-based telemedicine system to manage underserved women with gestational diabetes mellitus. Diabetes Technology & Therapeutics 2007;9(3):297-306. DOI: https://dx.doi.org/10.1089/dia.2006.0034	Population
Hunter (2015) Hunter B, R N, Mathieson K, Leafman JS, Feinglos MN. The Effect of Blood Glucose Self-Monitoring Among Inmates With Diabetes. Journal of Correctional Health Care 2015;21(4):343-54. DOI: https://dx.doi.org/10.1177/1078345815599782	Population (not separate data for T2D)
Haak (2017)	Comparator (follow-up study by Haak

Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Therapy Research, Treatment and Education of Diabetes and Related Disorders 2017;8(3):573-86. DOI: 10.1007/s13300-017-0255-6	(2017), without a control group)
Idrees (2024) Idrees T, Castro-Revoredo IA, Oh HD, Gavaller MD, Zabala Z, Moreno E, et al. Continuous Glucose Monitoring-Guided Insulin Administration in Long-Term Care Facilities: A Randomized Clinical Trial. Journal of the American Medical Directors Association 2024;25(5):884-8. DOI: https://dx.doi.org/10.1016/j.jamda.2024.01.031	Intervention
Ilany (2018) Ilany J, Bhandari H, Nabriski D, Toledano Y, Konvalina N, Cohen O. Effect of prandial treatment timing adjustment, based on continuous glucose monitoring, in patients with type 2 diabetes uncontrolled with once-daily basal insulin: A randomized, phase IV study. Diabetes, Obesity & Metabolism 2018;20(5):1186-92. DOI: https://dx.doi.org/10.1111/dom.13214	Intervention
Isitt (2022) Isitt JJ, Roze S, Sharland H, Cogswell G, Alshannaq H, Norman GJ, et al. Cost-Effectiveness of a Real-Time Continuous Glucose Monitoring System Versus Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Therapy in the UK. Diabetes Therapy Research, Treatment and Education of Diabetes and Related Disorders 2022;13(11-12):1875-90. DOI: https://dx.doi.org/10.1007/s13300-022-01324-x	Publication type (cost-effectiveness)
Jecht (2024) Jecht M. Continuous glucose monitoring or conventional blood glucose monitoring in insulin-treated people with type 2 diabetes?: Results of the Steno2tech study. [German]. Diabetologie 2024;20(5):632-4. DOI: https://dx.doi.org/10.1007/s11428-024-01215-8	Publication type (comment on the Steno2teck study)
Jedlowski (2019) Jedlowski PM, Te CH, Segal RJ, Fazel MT. Cutaneous Adverse Effects of Diabetes Mellitus Medications and Medical Devices: A Review. American Journal of Clinical Dermatology 2019;20(1):97-114. DOI: https://dx.doi.org/10.1007/s40257-018-0400-7	Publication type
Jendle (2021) Jendle J, Eeg-Olofsson K, Svensson AM, Franzen S, Lamotte M, Levrat-Guillen F. Cost-Effectiveness of the FreeStyle Libre ® System Versus Blood Glucose Self-Monitoring in Individuals with Type 2 Diabetes on Insulin Treatment in Sweden. Diabetes Therapy Research, Treatment and Education of Diabetes and Related Disorders 2021;12(12):3137-52. DOI: https://dx.doi.org/10.1007/s13300-021-01172-1	Publication type (cost-effectiveness)
Jungheim (2002) Jungheim K, Koschinsky T. Glucose monitoring at the arm: risky delays of hypoglycemia and hyperglycemia detection. Diabetes Care 2002;25(6):956-60. DOI: 10.2337/diacare.25.6.956	Intervention
Katalenich (2015) Katalenich B, Shi L, Liu S, Shao H, McDuffie R, Carpio G, et al. Evaluation of a Remote Monitoring System for Diabetes Control. Clinical Therapeutics 2015;37(6):1216-25. DOI: https://dx.doi.org/10.1016/j.clinthera.2015.03.022	Intervention
Kataoka (2023) Kataoka Y, Kitahara S, Funabashi S, Makino H, Matsubara M, Matsuo M, et al. The effect of continuous glucose monitoring-guided glycemic control on progression of coronary atherosclerosis in type 2 diabetic patients with coronary artery disease: The OPTIMAL randomized clinical trial. Journal of Diabetes & its Complications 2023;37(10):108592. DOI: https://dx.doi.org/10.1016/j.jdiacomp.2023.108592	Comparator
Kestila (2007) Kestila KK, Ekblad UU, Ronnemaa T. Continuous glucose monitoring versus self-monitoring of blood glucose in the treatment of gestational diabetes mellitus. Diabetes Research & Clinical Practice 2007;77(2):174-9. DOI: https://dx.doi.org/10.1016/j.diabres.2006.12.012	Population

Kim (2024) Kim JY, Ilham S, Alshannaq H, Pollock RF, Ahmed W, Norman GJ, et al. Real-time continuous glucose monitoring vs. self-monitoring of blood glucose: cost-utility in South Korean type 2 diabetes patients on intensive insulin. Journal of Medical Economics 2024;27(1):1245-52. DOI: https://dx.doi.org/10.1080/13696998.2024.2405293	Publication type (cost-effectiveness)
Klarskov (2022) Klarskov CK, Windum NA, Olsen MT, Dungu AM, Jensen AK, Lindegaard B, et al. Telemetric Continuous Glucose Monitoring During the COVID-19 Pandemic in Isolated Hospitalized Patients in Denmark: A Randomized Controlled Exploratory Trial. Diabetes Technology & Therapeutics 2022;24(2):102-12. DOI: https://dx.doi.org/10.1089/dia.2021.0291	Intervention
Krouwer (2022) Krouwer JS. Adverse Event Data for Years 2018 to 2020 for Diabetes Devices. Journal of Diabetes Science and Technology 2022;16(5):1299-302. DOI: https://dx.doi.org/10.1177/19322968211011688	Publication type (adverse events)
Mader (2024) Mader JK, Waldenmaier D, Mueller-Hoffmann W, Mueller K, Angstmann M, Vogt G, et al. Performance of a Novel Continuous Glucose Monitoring Device in People With Diabetes. Journal of Diabetes Science and Technology 2024;18(5):1044-51. DOI: 10.1177/19322968241267774	Comparator
Matoba (2020) Matoba K, Hayashi A, Shimizu N, Moriguchi I, Kobayashi N, Shichiri M. Comparison of accuracy between flash glucose monitoring and continuous glucose monitoring in patients with type 2 diabetes mellitus undergoing hemodialysis. Journal of Diabetes and its Complications 2020;34(11) (no pagination). DOI: https://dx.doi.org/10.1016/j.jdiacomp.2020.107680	Outcome (MARD)
Mukherjee (2013) Mukherjee JJ, Majumdar S, Ray S. Assessment of glycaemic control in patients with diabetes mellitus on insulin therapy. Journal of the Indian Medical Association 2013;111(11):761-5.	Publication type
Nakagawa (2022) Nakagawa Y, Hirota Y, Yamamoto A, Takayoshi T, Takeuchi T, Hamaguchi T, et al. Accuracy of a Professional Continuous Glucose Monitoring Device in Individuals with Type 2 Diabetes Mellitus. Kobe Journal of Medical Sciences 2022;68(1):E5-E10.	Intervention
New (2015) New JP, Ajjan R, Pfeiffer AFH, Freckmann G. Continuous glucose monitoring in people with diabetes: the randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). Diabetic Medicine 2015;32(5):609-17. DOI: 10.1111/dme.12713	Population (not separate data for T2D)
New (2016) New JP, Ajjan R, Pfeiffer AFH, Freckmann G. Continuous glucose monitoring in people with diabetes: The randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). Diabetes Technology and Therapeutics 2016;18(Supplement 1):S11-S2. DOI: https://dx.doi.org/10.1089/dia.2016.2502	Publication type (comment on the GLADIS study)
Newman (2009) Newman SP, Cooke D, Casbard A, Walker S, Meredith S, Nunn A, et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technology Assessment (Winchester, England) 2009;13(28):iii-iv, ix. DOI: https://dx.doi.org/10.3310/hta13280	Population (not separate data for T2D)
O'Connor (2024) O'Connor MJ, Ding X, Hernandez C, Hubacz L, Church RJ, O'Connor L. A Pilot Trial of Continuous Glucose Monitoring Upon Emergency Department Discharge Among People With Diabetes Mellitus. Endocrine Practice 2024;30(2):122-7. DOI: https://dx.doi.org/10.1016/j.eprac.2023.11.001	Population

Olsen (2024) Olsen MT, Klarskov CK, Pedersen-Bjergaard U, Hansen KB, Kristensen PL. Summary of clinical investigation plan for The DIATEC trial: in-hospital diabetes management by a diabetes team and continuous glucose monitoring or point of care glucose testing - a randomised controlled trial. BMC Endocrine Disorders 2024;24(1):60. DOI: https://dx.doi.org/10.1186/s12902-024-01595-4	Population
Paramasivam (2018) Paramasivam SS, Chinna K, Singh AKK, Ratnasingam J, Ibrahim L, Lim LL, et al. Continuous glucose monitoring results in lower HbA_{1c} in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. Diabetic Medicine 2018;35(8):1118-29. DOI: https://dx.doi.org/10.1111/dme.13649	Population
Peters (2021) Peters A, Cohen N, Calhoun P, Ruedy KJ, Beck RW, Martens TW, et al. Glycaemic profiles of diverse patients with type 2 diabetes using basal insulin: MOBILE study baseline data. Diabetes, Obesity & Metabolism 2021;23(2):631-6. DOI: 10.1111/dom.14238	Publication type (baseline data MOBILE study)
Pyl (2020) Pyl J, Dendooven E, Van Eekelen I, den Brinker M, Dotremont H, France A, et al. Prevalence and Prevention of Contact Dermatitis Caused by FreeStyle Libre: A Monocentric Experience. Diabetes Care 2020;43(4):918-20. DOI: https://dx.doi.org/10.2337/dc19-1354	Population (adults and paediatric patients)
Rama (2024) Rama C, Rahman N, Gandhi M, Tan NC, Phoon IKY, Seah DEJ, et al. Intermittently scanned continuous glucose monitoring provides no benefit over structured self-monitoring of blood glucose in type 2 diabetes not on prandial insulin, in the context of diabetes self-management education: GLucose monitoring programme SingaporE (GLiMPSE). Diabetes Research & Clinical Practice 2024;211:111678. DOI: https://dx.doi.org/10.1016/j.diabres.2024.111678	Population
Roussel (2021) Roussel R, Riveline JP, Vicaut E, de Pouvourville G, Detournay B, Emery C, et al. Important Drop in Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study. Diabetes Care 2021;44(6):1368-76. DOI: https://dx.doi.org/10.2337/DC20-1690	Study design
Ruedy (2017) Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C. Continuous Glucose Monitoring in Older Adults With Type 1 and Type 2 Diabetes Using Multiple Daily Injections of Insulin: Results From the DIAMOND Trial. Journal of Diabetes Science & Technology 2017;11(6):1138-46. DOI: https://dx.doi.org/10.1177/1932296817704445	Population (not separate data for T2D)
Sampaio (2012) Sampaio CR, Franco DR, Goldberg DJ, Baptista J, Eliaschewitz FG. Glucose control in acute myocardial infarction: a pilot randomized study controlled by continuous glucose monitoring system comparing the use of insulin glargine with standard of care. Diabetes Technology & Therapeutics 2012;14(2):117-24. DOI: https://dx.doi.org/10.1089/dia.2011.0157	Population
Sato (2016) Sato J, Kanazawa A, Ikeda F, Shigihara N, Kawaguchi M, Komiya K, et al. Effect of treatment guidance using a retrospective continuous glucose monitoring system on glycaemic control in outpatients with type 2 diabetes mellitus: A randomized controlled trial. Journal of International Medical Research 2016;44(1):109-21. DOI: https://dx.doi.org/10.1177/0300060515600190	Comparator
Schipfer (2018) Schipfer M, Albrecht C, Ehrmann D, Haak T, Kulzer B, Hermanns N. Makes FLASH the difference between the intervention group and the treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on intensive insulin therapy: study protocol for a randomised controlled trial. Trials [Electronic Resource] 2018;19(1):91. DOI: https://dx.doi.org/10.1186/s13063-018-2479-9	Comparator (study protocol)

Scott (2020) Scott EM, Feig DS, Murphy HR, Law GR. Continuous Glucose Monitoring in Pregnancy: Importance of Analyzing Temporal Profiles to Understand Clinical Outcomes. Diabetes Care 2020;43(6):1178-84. DOI: https://dx.doi.org/10.2337/dc19-2527	Population
Seibold (2021) Seibold A. Minimizing Adverse Skin Reactions to Wearable Continuous Glucose Monitoring Sensors in Patients With Diabetes. Journal of Diabetes Science and Technology 2021;15(3):713-4. DOI: https://dx.doi.org/10.1177/1932296820984763	Publication type (adverse events)
Singh (2020) Singh LG, Levitt DL, Satyarengga M, Pinault L, Zhan M, Sorkin JD, et al. Continuous Glucose Monitoring in General Wards for Prevention of Hypoglycemia: Results From the Glucose Telemetry System Pilot Study. Journal of Diabetes Science & Technology 2020;14(4):783-90. DOI: https://dx.doi.org/10.1177/1932296819889640	Intervention
Singh (2020) Singh LG, Satyarengga M, Marcano I, Scott WH, Pinault LF, Feng Z, et al. Reducing Inpatient Hypoglycemia in the General Wards Using Real-time Continuous Glucose Monitoring: The Glucose Telemetry System, a Randomized Clinical Trial. Diabetes Care 2020;43(11):2736-43. DOI: https://dx.doi.org/10.2337/dc20-0840	Intervention
Spanakis (2022) Spanakis EK, Urrutia A, Galindo RJ, Vellanki P, Migdal AL, Davis G, et al. Continuous Glucose Monitoring-Guided Insulin Administration in Hospitalized Patients With Diabetes: A Randomized Clinical Trial. Diabetes Care 2022;45(10):2369-75. DOI: https://dx.doi.org/10.2337/dc22-0716	Population (not separate data for T2D)
Tanenberg (2004) Tanenberg R, Bode B, Lane W, Levetan C, Mestman J, Harmel AP, et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin-treated diabetes: A randomized controlled trial. Mayo Clinic Proceedings 2004;79(12):1521-6. DOI: https://dx.doi.org/10.4065/79.12.1521	Population (not separate data for T2D)
Tang (2014) Tang TS, Digby EM, Wright AM, Chan JH, Mazanderani AB, Ross SA, et al. Real-time continuous glucose monitoring versus internet-based blood glucose monitoring in adults with type 2 diabetes: a study of treatment satisfaction. Diabetes Research & Clinical Practice 2014;106(3):481-6. DOI: https://dx.doi.org/10.1016/j.diabres.2014.09.050	Comparator
Thabit (2024) Thabit H, Rubio J, Karuppan M, Mubita W, Lim J, Thomas T, et al. Use of real-time continuous glucose monitoring in non-critical care insulin-treated inpatients under non-diabetes speciality teams in hospital: A pilot randomized controlled study. Diabetes, Obesity & Metabolism 2024;26(11):5483-7. DOI: https://dx.doi.org/10.1111/dom.15885	Population
Thielen (2010) Thielen V, Scheen A, Bringer J, Renard E. Attempt to improve glucose control in type 2 diabetic patients by education about real-time glucose monitoring. Diabetes & Metabolism 2010;36(3):240-3. DOI: https://dx.doi.org/10.1016/j.diabet.2010.03.002	Publication type (short report, pilot study)
Thomsen (2024) Thomsen CHN, Norlev JTD, Hangaard S, Jensen MH, Hejlesen O, Cohen SR, et al. The intelligent diabetes telemonitoring using decision support to treat patients on insulin therapy (DiaTRUST) trial: study protocol for a randomized controlled trial. Trials [Electronic Resource] 2024;25(1):744. DOI: https://dx.doi.org/10.1186/s13063-024-08588-7	Intervention (telemonitoring)
Thomsen (2024) Thomsen CHN, Norlev JTD, Hangaard S, Jensen MH, Kristensen SNS, Aradottir TB, et al. Intelligent Diabetes Telemonitoring for Patients on Insulin Therapy: A Randomized Controlled	Intervention (telemonitoring)

Trial Protocol. Studies in Health Technology & Informatics 2024;316:1737-8. DOI: https://dx.doi.org/10.3233/SHTI240762	
Tildesley (2010) Tildesley HD, Mazanderani AB, Ross SA. Effect of Internet therapeutic intervention on A1C levels in patients with type 2 diabetes treated with insulin. Diabetes Care 2010;33(8):1738-40. DOI: https://dx.doi.org/10.2337/dc09-2256	Intervention
Tildesley (2013) Tildesley HD, Wright AM, Chan JH, Mazanderani AB, Ross SA, Tildesley HG, et al. A comparison of internet monitoring with continuous glucose monitoring in insulin-requiring type 2 diabetes mellitus. Canadian Journal of Diabetes 2013;37(5):305-8. DOI: https://dx.doi.org/10.1016/j.jcjd.2013.05.006	Intervention
Tildesley (2015) Tildesley HD, Wright AM, Chan JH, Mazanderani AB, Ross SA, Tildesley HG, et al. A comparison of Internet monitoring with continuous glucose monitoring in insulin-requiring type 2 diabetes mellitus. Diabetes Technology and Therapeutics 2015;17(Supplement 1):S17-S8. DOI: https://dx.doi.org/10.1089/dia.2015.1502	Intervention
Tildesley (2016) Tildesley HD, Wright AM, Chan JHM, Mazanderani AB, Ross SA, Tildesley HG, et al. A Comparison of Internet Monitoring with Continuous Glucose Monitoring in Insulin-Requiring Type 2 Diabetes Mellitus. Canadian Journal of Diabetes 2016;40(1 Supplement 1):24-7. DOI: https://dx.doi.org/10.1016/j.jcjd.2016.04.003	Intervention **Note:** Retracted publication
Voormolen (2012) Voormolen DN, DeVries JH, Franx A, Mol BW, Evers IM. Effectiveness of continuous glucose monitoring during diabetic pregnancy (GlucoMOMS trial); a randomised controlled trial. BMC Pregnancy & Childbirth 2012;12:164. DOI: https://dx.doi.org/10.1186/1471-2393-12-164	Population (not separate data for T2D)
Voormolen (2018) Voormolen DN, DeVries JH, Sanson RME, Heringa MP, de Valk HW, Kok M, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): A multicentre randomized controlled trial. Diabetes, Obesity & Metabolism 2018;20(8):1894-902. DOI: https://dx.doi.org/10.1111/dom.13310	Intervention
Wang (2024) Wang Y, Lu J, Wang M, Ni J, Yu J, Wang S, et al. Real-time continuous glucose monitoring-guided glucose management in inpatients with diabetes receiving short-term continuous subcutaneous insulin infusion: a randomized clinical trial. The Lancet Regional Health - Western Pacific 2024;48(no pagination). DOI: https://dx.doi.org/10.1016/j.lanwpc.2024.101067	Population
Wei (2015) Wei NJ, Nathan DM, Wexler DJ. Glycemic control after hospital discharge in insulin-treated type 2 diabetes: a randomized pilot study of daily remote glucose monitoring. Endocrine Practice 2015;21(2):115-21. DOI: https://dx.doi.org/10.4158/EP14134.OR	Intervention
Yoo (2008) Yoo JH, Kim G, Lee HJ, Sim KH, Jin SM, Kim JH. Effect of structured individualized education on continuous glucose monitoring use in poorly controlled patients with type 1 diabetes: A randomized controlled trial. Diabetes Res Clin Pract 2022;184:109209. DOI: 10.1016/j.diabres.2022.109209	Population
Zaharieva (2020) Zaharieva DP, Teng JH, Ong ML, Lee MH, Paldus B, Jackson L, et al. Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose to Assess Glycemia in Gestational Diabetes. Diabetes Technology and Therapeutics 2020;22(11):822-7. DOI: https://dx.doi.org/10.1089/dia.2020.0073	Population

Appendix 3: List of included studies

The HTA's included studies are presented below:

Studies
RCTs
Ajjan 2016 Ajjan RA, Abougila K, Bellary S, Collier A, Franke B, Jude EB, et al. Sensor and software use for the glycaemic management of insulin-treated type 1 and type 2 diabetes patients. Diabetes & Vascular Disease Research 2016;13(3):211-9. DOI: https://dx.doi.org/10.1177/1479164115624680
Beck 2017 Beck RW, Riddlesworth TD, Ruedy K, Ahmann A, Haller S, Kruger D, et al. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Annals of Internal Medicine 2017;167(6):365-74. DOI: 10.7326/M16-2855
Bergenstal 2022 Bergenstal RM, Mullen DM, Strock E, Johnson ML, Xi MX. Randomized comparison of self-monitored blood glucose (BGM) versus continuous glucose monitoring (CGM) data to optimize glucose control in type 2 diabetes. J Diabetes Complications 2022;36(3):108106. DOI: 10.1016/j.jdiacomp.2021.108106
Haak 2017 Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. Diabetes Ther 2017;8(1):55-73. DOI: 10.1007/s13300-016-0223-6
Kim 2024 Kim JY, Jin SM, Sim KH, Kim BY, Cho JH, Moon JS, et al. Continuous glucose monitoring with structured education in adults with type 2 diabetes managed by multiple daily insulin injections: a multicentre randomised controlled trial. Diabetologia 2024;67(7):1223-34. DOI: 10.1007/s00125-024-06152-1
Lever 2024 Lever CS, Williman JA, Boucsein A, Watson A, Sampson RS, Sergel-Stringer OT, et al. Real time continuous glucose monitoring in high-risk people with insulin-requiring type 2 diabetes: A randomised controlled trial. Diabetic Medicine 2024;41(8):e15348. DOI: https://dx.doi.org/10.1111/dme.15348
Lind 2024 Lind N, Christensen MB, Hansen DL, Norgaard K. Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial. Diabetes Care 2024;47(5):881-9. DOI: 10.2337/dc23-2194
Martens 2021 / Aleppo 2021 Martens T, Beck RW, Bailey R, Ruedy KJ, Calhoun P, Peters AL, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA 2021;325(22):2262-72. DOI: 10.1001/jama.2021.7444 Aleppo G, Beck RW, Bailey R, Ruedy KJ, Calhoun P, Peters AL, et al. The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin. Diabetes Care 2021;44(12):2729-37. DOI: https://dx.doi.org/10.2337/dc21-1304
Yaron 2019 Yaron M, Roitman E, Aharon-Hananel G, Landau Z, Ganz T, Yanuv I, et al. Effect of Flash Glucose Monitoring Technology on Glycemic Control and Treatment Satisfaction in Patients With Type 2 Diabetes. Diabetes Care 2019;42(7):1178-84. DOI: 10.2337/dc18-0166
Non-RCTs
Karter 2021 Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes. JAMA 2021;325(22):2273-84. DOI: https://dx.doi.org/10.1001/jama.2021.6530

Nathanson 2025

Nathanson D, Eeg-Olofsson K, Spelman T, Bulow E, Kyhlstedt M, Levrat-Guillen F, et al. Intermittently scanned continuous glucose monitoring compared with blood glucose monitoring is associated with lower HbA1c and a reduced risk of hospitalisation for diabetes-related complications in adults with type 2 diabetes on insulin therapies. Diabetologia 2025;26:26. DOI: https://dx.doi.org/10.1007/s00125-024-06289-z

Reaven 2023

Reaven PD, Newell M, Rivas S, Zhou X, Norman GJ, Zhou JJ. Initiation of Continuous Glucose Monitoring Is Linked to Improved Glycemic Control and Fewer Clinical Events in Type 1 and Type 2 Diabetes in the Veterans Health Administration. Diabetes Care 2023;46(4):854-63. DOI: https://dx.doi.org/10.2337/dc22-2189

Overview of included studies

Author, year, reference, trial registry number	Study population, setting	Mean age / median age	Duration of T2D (years) mean / median	Baseline HbA1c (%) mean / median	Study duration, run-in period	Intervention	Control	CGM system type	CGM wear time protocol	Calibration protocol	Total CGM wear	Funding
RCTs												
Ajjan, 2016, (74), **NCT01713348**	87 T1D and T2D 45 T2D on MDI (≥2) 9 hospitals in the UK	*Mean:* isCGM: 57.8±8.8 SMBG: 55.5±10.9	*Mean:* isCGM: 13.9±7.9 SMBG: 15.8±7.5	*Mean:* isCGM: 9.2±1.4 SMBG: 9.2±1.3	14 weeks + 2 days (100 days) 15-day run-in period	isCGM + reviewing and explaining the ambulatory glucose profile with HCP	SMBG, mean 3.4 times/ day at baseline (with masked CGM in the final 15 days)	FreeStyle Navigator	NA. Wear with the alarm function turned off	NA	NA, but only those who had 50% CGM data from the 15-day run-in period were included	Abbott Diabetes Care
Beck, 2017, (38) **NCT02282397**	158 T2D receiving MDI 25 endocrine clinics (USA and Canada)	*Mean:* rtCGM: 60±11 SMBG: 60±9	*Median:* rtCGM: 17 (11-23) SMBG: 18 (12-23)	*Mean:* rtCGM: 8.5 ± 0.6 SMBG: 8.5 ± 0.7	24 weeks, 14 days run-in period	rtCGM + basic education on CGM data usage	SMBG at least 4 times/day, blinded CGM for x2 one week	DexCom™ G4 Platinum	Daily wear (168 days)	Calibrate 2x daily and SMBG 4x daily	159.5 of 168 days (mean)	Dexcom, Inc., with one co-author from Dexcom.
Bergenstal, 2022, (24) **NCT01237301**	114 T2D, either: (1) sulfonylurea ± metformin, (2) incretin (DPP4 inhibitor or GLP-1 agonist) ± metformin, or (3) insulin ± metformin. Endocrinology clinic setting	*Mean:* rtCGM: 59.3±8.9 SMBG: 58.8±10	*Mean:* rtCGM: 11.8±6.5[a] SMBG: 12.7±7[a]	*Mean:* rtCGM: 8.19 (1.2) SMBG: 7.85 (0.79)	16 weeks, 2-4 weeks run-in period	rtCGM + basic education on CGM data usage	Structured SMBG 4 times/day and periodic blinded CGM	Dexcom™ Seven plus	Daily wear, continuous	SMBG: 4x daily	NA	Roche Diagnostic Diabetes Care
Haak, 2017, (75) **NCT02082184**	224 T2D on prandial, prandial + basal, or CSII	*Mean:* isCGM 59.0±9.9 SMBG: 59.5±11	*Mean:* isCGM: 17±8 SMBG: 18±8	*Mean:* isCGM: 8.74±0.97 SMBG: 8.88±1.04	24 weeks, 2 weeks run-in period	isCGM; no instruction in interpreting CGM data was given.	SMBG (mean 3.9 times/day at baseline) + glucose diary. Blinded	FreeStyle Libre™ Abbott	14-day continuous wear time	isCGM: scan every 8 hours Both groups:	14 days	Abbott Diabetes Care

	26 diabetes clinics in Germany, France, and the UK						CGM for the last 2 weeks			SMBG daily		
Kim, 2024, (76) **NCT04926623**	159 T2D on MDI 8 tertiary medical centres in South Korea	*Mean:* isCGM 1: 59.51±9.82 isCGM 2: 56.58± 11.86 SMBG: 57.11±9.94	*Mean:* isCGM 1: 18.29± 12.31 isCGM 2: 16.51±9.6 SMBG: 16.46±7.91	*Mean:* isCGM 1: 8.41±1.05 isCGM 2: 8.30±0.92 SMBG: 8.47±1.02	24 weeks, 2 weeks run-in period	I1) isCGM with structured education I2) isCGM with standard education	SMBG, standard education, blinded isCGM for the last 2 weeks	FreeStyle Libre 1	NA	NA	isCGM 1: mean scan 11.34±5.36 /day isCGM 2: mean scan 9.51±6.25 /day SMBG: 2.43±1.20 /day	Daewoong Pharmaceutical Co., Ltd.
Lever, 2024, (77) **ACTRN 12621000889853**	67 T2D, minimum daily insulin use of ≥0.2 units of insulin/kg/day New Zealand	*Median*: rtCGM: 51, range 22-70 SMBG: 56, range 16-65	*Median* rtCGM: 13.0 (9.0, 16.0) SMBG: 13.0 (9.0, 18.0)	*Mean:* rtCGM: 9.2 (8.9, 10.3) SMBG: 9.7 (8.6, 10.2)	12 weeks, 2 weeks run-in period	rtCGM, 3-4 h CGM training session	SMBG, 4-7 x day, standard care, 2 weeks blinded CGM for the last 2 weeks	Dexcom™ G6	Use above 70% NB: five participants were excluded due to ≤70% sensor wear	No calibration SMBG: BGM at least 2 times/day + if symptoms of hypo-/ hyperglycaemia	Median percentage of active sensor time at 96% (90, 98) of total available time	Dexcom, Inc.
Lind, 2024, (40) **NCT04331444**	76 T2D, inadequately controlled, treatment with insulin injections at least once daily (basal or MDI) Outpatient clinic, Copenhagen, Denmark	*Mean:* rtCGM: 61.1 (8.1) SMBG: 61.3 (8.6)	*Mean:* rtCGM: 18.8 (7.1) SMBG: 17.4 (6.5)	*Median* rtCGM: 8.2 (7.8, 9.1) SMBG: 8.4 (7.8, 9.1)	12 months, 10 days blinded CGM run-in period	rtCGM, 3-h education course	SMBG, 3-h education 10-day blinded CGM at baseline and after 6 and 12 months	Dexcom™ G6	NA	No calibration	The mean active sensor time assessed during the last blinded CGM at 12 months follow-up was 96.3% (SMBG group 97.7%, CGM group 95.2%).	Steno Diabetes Center Copenhagen, Dexcom funded the devices

Martens, 2021, (42) **NCT03566693**	175 T2D, poorly controlled, basal insulin treatment 1-phase: CGM 116; SMBG: 59 2-phase: CGM 53; SMBG 53 15 primary care settings in the USA	*Mean:* 1-phase: rtCGM: 56±9 SMBG: 59±9	*Mean:* rtCGM: 14±9 SMBG: 15±10	*Mean:* 1-phase: rt:CGM: 9.1±1.0 SMBG: 9.0±0.9	8 months, up to a 10-day run-in period using Dexcom G6	rtCGM	SMBG + blinded CGM at 3 months and 8 months	Dexcom™ G6	Daily wear (continuously)	SMBG: fasting and postprandial testing 1-3x daily	Median CGM use was 6.2 d (IQR 5.0-6.7) at month 14 (with no available data for 3 participants)	Dexcom, Inc.
Aleppo, 2021, (66) (continuation of Martens et al. 2021) **NCT03566693**		2-phase (all) 58±9		2-phase (all) 9.1±0.9	6 months	rtCGM	SMBG	Dexcom™ G6				Dexcom, Inc.
Yaron, 2019, (41) **NCT02809365**	101 T2D on two or more insulin injections daily (with at least one prandial insulin injection) 2 medical institutions, Israel	*Mean.* isCGM: 67.55 (6.69) SMBG: 65.94 (8.42)	*Mean:* isCGM: 22.1 (7.0) SMBG: 21.53 (8.29)	*Mean:* isCGM: 8.68 (0.87) SMBG: 8.34 (0.74)	10 weeks, 2 weeks run-in period	isCGM + counselling and diabetes management instructions	SMBG + counselling and diabetes management instructions	FreeStyle Libre	CGM: scan at least every 8 h SMBG: at least four times a day.	both groups were asked to assess BG 7 times a day 1 day each week	NA	Abbott Laboratories USA
Non-RCTs												
Karter, 2021, (78) **NR**	5673 T1D; 36,080 T2D on insulin Kaiser Permanente Northern California claim registry, USA	*Mean:* rtCGM: 59.1 (14.5) SMBG: 64.6 (12.1)	*Mean:* rtCGM: 17.1 (11.1) SMBG: 15.8 (8.8)	*Mean:* rtCGM: 8.20 (1.5) SMBG: 8.27 (1.6)	12 months	rtCGM	SMBG	Not specified, probably Dexcom	NA	NA	NA	Dexcom + National Institute of Diabetes and Digestive and Kidney Diseases
Nathanson, 2024, (3) **NR**	85,186 T2D on basal insulin or MDI	*Mean*: isCGM: 63.5±12.7	*Mean*: isCGM: 15.81±9.87	*Mean*: isCGM: 7.82±1.42	24 months	isCGM	SMBG	Not specified, probably	NA	NA	NA	Abbott Diabetes Care, with one author being an

	Sweden	SMBG: 70.11± 11.31	SMBG: 15.72±8.82	SMBG: 7.83±1.23				FreeStyle Libre				Abbott Laboratories Ltd. employee
Reaven, 2023, (79) **NR**	45,618 T2D on basal+bolus, basal, or bolus USA	*Mean*: CGM. 66.7 (9.8) SMBG: 68.3 (9.5)	*Mean*: CGM: NA SMBG: NA	*Mean* CGM: 8.7 (1.7) SMBG: 8.1 (1.6)	12 months	CGM	SMBG	Dexcom (34%) FreeStyle Libre (63%) Medtronic (3%)	NA	NA	NA	Department of Veterans Affairs The work was supported by pilot funding from Dexcom, Inc.

[a] reported as T2D onset age in the publication

CGM: continuous glucose monitoring; isCGM: intermittently scanned continuous glucose monitoring; rtCGM: real-time continuous glucose monitoring; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes; CSII: continuous subcutaneous insulin infusion (insulin pump therapy); NA: not assessable; HCP: healthcare provider; IQR: interquartile range; MDI: multiple daily injections (of insulin); NCT: the ClinicalTrials.gov identifier; ACTRN: Australian New Zealand Clinical Trials Registry; NR: not registered

Identified ongoing trials that have the potential to be included in future updates

The trial registries were assessed following the search conducted in February 2025 and revisited in October 2025. During the review in October 2025, we found that one study had been published in July 2025, while another is expected to be published soon. An assessment of these studies will need to be conducted to determine their relevance for inclusion.

The following trials may be considered for inclusion in future updates of this report:

Trial number	Title	Status	NOMA's comment
ISRCTN17386990 (2021)	Type 2 diabetes self-management using continuous glucose monitoring	Published (July 2025)	Has the potential to be included in an update of the report
NCT05222815 (2022)	Comparing Fingerstick Blood Glucose Monitoring Versus Continuous Glucose Monitoring in Primary Care	Active, not recruiting	Relevant: is supposed to be published soon. Has the potential to be included in an update of the report.
ACTRN12616000413426 (2016)	An evaluation of the performance and user acceptance of a mobile real-time continuous glucose monitoring system in people with type 1 and type 2 diabetes treated with multiple daily injections of insulin.	Recruiting	May be relevant.
CTRI (2021)	A Study to compare glycemic control achieved by Flash Glucose Monitoring and Self Monitoring of blood Glucose in pregnant women with Diabetes Mellitus	Not yet recruiting	May be relevant (T2D treated with insulin)
NCT05944432 (2023)	Real-Time Glucose Monitoring Using FreeStyle Libre 3 in Adults With Type 2 Diabetes On Basal Insulin Plus SGLT2 Inhibitor and/or GLP-1	Active, not recruiting	Relevant
NCT06296485 (2024)	Pragmatic Clinical Trial of Continuous Glucose Monitoring-based Interventions for Safe Insulin Use in High-Risk Older Adults With Type 2 Diabetes	Recruiting	Probably relevant.
NCT06311019 (2024)	The Effects of Continuous Glucose Monitoring and Connected Insulin Pens on Glycemic Control in Patients With Type 2 Diabetes Treated With Multiple Daily Insulin Injections	Active, not recruiting.	Relevant. From Denmark,

Appendix 4: Assessment of risk of bias in included studies

Risk of bias in the included RCTs

Risk of bias in RCTs was assessed using the RoB v2 tool for 12 of the 13 outcomes described in Section 2.1.1, in each trial. However, it was not possible to assess the risk of bias for the mortality outcome, as this was only reported in the trial registries of three RCTs (24;74;75). Notably, the RoB v2 tool is not designed to evaluate outcomes registered solely in trial registries.

A summary of the risk of bias across all outcomes in each trial is provided in Table A4-1. We have also included the overall judgement used for the GRADE assessment, where applicable, in Table A4-1. See also the results of the GRADE assessment in Section 2.2.6 and Appendix 6.

Table A4-1. Detailed risk of bias assessment for all outcomes in RCTs

	D1	D2	D3	D4	D5	Overall
HbA1C						GRADE: downgraded 1
Ajjan 2016	?	?	?	-	-	+
Beck 2017	-	?	-	-	-	?
Bergenstal 2022	-	?	+	-	-	+
Haak 2017	-	?	-	-	-	?
Kim 2024	-	?	-	-	-	?
Lever 2024	?	?	-	-	-	?
Lind 2024	-	?	-	-	-	?
Martens/Aleppo 2021	-	?	-	-	-	?
Yaron 2021	+	?	-	-	-	+
Total hypoglycaemic events						No GRADE
Haak 2017	-	?	-	?	-	?
Martens/Aleppo 2021	-	?	-	?	-	?
Yaron 2021	+	?	-	?	-	+
Severe hypoglycaemic events						GRADE: downgraded 1
Beck 2017	-	?	-	-	-	?
Haak 2017	-	?	-	-	-	?
Lever 2024	?	?	-	-	?	+
Lind 2024	-	?	-	-	-	?
Martens/Aleppo	-	?	-	-	-	?
Yaron 2021	+	?	-	-	?	+
Nocturnal hypoglycaemic events						No GRADE
Beck 2017	-	?	-	?	-	?
Haak 2017	-	?	-	?	?	+
Martens/Aleppo 2021	-	?	-	?	?	+
TIR						GRADE downgraded 1
Ajjan 2016	?	?	?	?	?	+
Beck 2017	-	?	-	?	-	?
Bergenstal 2022	-	?	+	?	?	+
Haak 2017	-	?	-	?	-	?
Kim 2024	-	?	-	?	?	+
Lever 2024	?	?	-	?	-	+
Lind 2024	-	?	-	?	-	?
Marens/Aleppo 2021	-	?	-	?	-	?
TBR						GRADE: downgraded 1
Ajjan 2016	?	?	?	?	-	+
Beck 2017	-	?	-	?	-	?

Bergenstal 2022	-	?	+	?	-	+
Haak 2017	-	?	-	?	-	?
Kim 2024	-	?	-	?	-	?
Lever 2024	?	?	-	?	-	+
Lind 2024	-	?	-	?	-	?
Martens/Aleppo 2021	-	?	-	?	-	?
Yaron 2021	+	?	-	?	?	+
TAR						GRADE: downgraded 1
Ajjan 2016	?	?	?	?	-	+
Beck 2017	-	?	-	?	-	?
Bergenstal 2022	-	?	+	?	?	+
Haak 2017	-	?	-	?	-	?
Kim 2024	-	?	-	?	-	?
Lever 2024	?	?	-	?	-	+
Lind 2024	-	?	-	?	-	?
Martens/Aleppo 2021	-	?	-	?	-	?
Glycaemic variability						No GRADE
Beck 2017	-	?	-	?	-	?
Haak 2017	-	?	-	?	-	?
Kim 2024	-	?	-	?	-	?
Lever 2024	?	?	-	?	-	+
Lind 2024	-	?	-	?	-	?
Martens/Aleppo 2021	-	?	-	?	-	?
Diabetes-related late vascular complications						GRADE: downgraded 1
Bergenstal 2022	-	?	+	-	?	+
Haak 2017	-	?	-	-	?	?
Kim 2024	-	?	-	-	?	?
Lever 2024	?	?	-	-	?	+
Lind 2024	-	?	-	-	?	?
Martens/Aleppo 2021	-	?	-	-	-	?
QoL						GRADE: downgraded 1
Beck 2017 (disease-specific)	-	?	-	?	-	?
Beck 2017 (general)	-	?	-	?	-	?
Haak 2017 (disease-specific)	-	?	-	?	-	?
Lind 2024 (general, SF-36)	-	?	-	?	-	?
Lind 2024 (general, WHO 5)	-	?	-	?	-	?
Adverse events associated with CGM						No GRADE
Ajjan 2016	?	-	?	?	-	+
Beck 2017	-	-	-	?	-	?
Kim 2024	-	-	-	?	?	?
Lever 2024	?	-	-	?	?	+
Lind 2024	-	-	-	?	?	?
Mental health outcomes associated with CGM						No GRADE
Beck 2017	-	?	-	?	-	?
Haak 2017	-	?	-	?	?	+

D1: bias arising from the randomisation process; D2: bias due to deviations from intended interventions; D3: bias due to missing outcome data; D4: bias in the measurement of the outcome; D5: bias in the selection of the reported result; -: low risk of bias; ?: some concerns; +: high risk of bias

Domain 1 (D1): bias arising from the randomisation process

D1 assessed bias arising from the randomisation process. If the randomisation process was adequately described and allocation concealment was ensured, this domain was rated as having a low risk of bias. Six RCTs were assessed as having a low risk of bias in D1 (24;38;40;42;66;75;76), two RCTs were deemed to have some concerns (74;77), and one RCT was judged to have a high risk of bias (41). The reasons for these judgements varied between trials. In Ajjan 2016 (74), a computer-

generated randomisation sequence was used; however, information regarding allocation concealment was missing. In Lever 2024 (77), despite the randomisation process and allocation being well-executed, discrepancies remained in group composition after randomisation. These weaknesses contributed to both studies being rated as having some concerns. In Yaron 2021 (41), information on the randomisation process and allocation concealment was absent, resulting in a high risk of bias in D1.

Domian 2 (D2): bias due to deviations from intended interventions

D2 addresses bias due to deviations from intended interventions. Health-related behaviours are more likely to vary between intervention groups if participants are aware of the intervention they have been assigned (62).

For the HbA1c outcome, all RCTs were assessed as having some concerns. This was primarily due to the lack of blinding of participants and researchers. Additionally, behavioural changes, such as insulin adjustments based on information from the CGM device, could have influenced HbA1c outcomes.

The outcomes of total, severe, and nocturnal hypoglycaemic events were judged to have some concerns in D2 for RCTs that included one or more of these outcomes (38;40-42;66;75;77). This judgement was attributed to lack of blinding and performance bias, stemming from differential management. Specifically, CGM devices display continuous glucose levels and, in some instances, provide alarms, which may prompt users to take actions to prevent low glycaemic levels, thereby influencing event rates.

For the objectively measured sensor-based outcomes TIR, TAR, and TBR recorded by CGM, derivations are unlikely to introduce bias into the measurement. However, behavioural differences, as described for glycaemic events, could bias the true values of these metrics, as users may act differently when continuously viewing readings or being alerted by alarms. These considerations resulted in some concerns in D2 for these outcomes across all (24;38;40-42;66;74-77) RCTs that included one or more of these outcomes.

The GV outcome, which measures fluctuations in blood glucose levels and encompasses TIR, TBR, and TAR, was similarly judged to have some concerns in D2 across all RCTs that included this outcome (38;40;42;66;75-77), based on the same considerations as described for TIR, TBR, and TAR.

The QoL outcomes, both general and disease-specific, regardless of the questionnaire used to assess them, were rated as having some concerns in D2 across RCTs that included one or more of these outcomes (38;40;75). This judgement was attributed to the lack of blinding, as knowledge of intervention assignment almost certainly influences responses for subjectively rated outcomes. The same judgement was applied to subjectively measured mental health outcomes associated with the CGM device in D2 across all RCTs that included this outcome.

We rated the adverse events associated with the CGM device as having a low risk of bias in D2 (38;42;66;74;76;77). This rating was given despite the lack of blinding, primarily because events such as skin reactions are directly caused by the device or the adhesive used to attach it to the body.

We rated the diabetes-related late vascular complications outcome as having some concerns in D2 for all RCTs that assessed this outcome (24;40;42;66;75-77). This judgement was attributed to the lack of blinding and performance bias resulting from differential management. Specifically, long-term management adjustments influenced by CGM readings could potentially affect the risk of diabetes-related late vascular complications; however, this impact is likely to be minimal during shorter trial periods.

Domain 3 (D3): bias due to missing outcome data

In D3, bias due to missing outcome data is evaluated. For an intention-to-treat (ITT) analysis, all randomised participants constitute the appropriate study population (62). RCTs that do not use ITT analysis—meaning they exclude some participants from the analysis—are assessed as having at least some concerns for D3. Seven of the included RCTs (38;40-42;66;75-77) used an appropriate ITT

analysis to evaluate the effectiveness of CGM versus SMBG and were therefore assessed as having a low risk of bias in D3.

In Ajjan 2016 (74), ITT analysis was mentioned; however, not all participants were included in the analysis. The ITT approach was undermined by adherence-based exclusions, leading to an assessment of some concerns. In Bergenstal 2022 (24), the statistical analysis was poorly described, but according to the trial registry, the study employed a per-protocol analysis. Participants who discontinued the study, including those who experienced side effects, were excluded from the analysis. This missingness was plausibly related to the study outcomes, resulting in a high risk of bias for D3.

Domain 4 (D4): bias in the measurement of the outcome

One goal of D4 is to identify performance measurement techniques that are unsuitable for assessing intended outcomes (62). Measurement errors can bias intervention effect estimates (62).

For HbA1c, there is only one objective method for measuring this outcome. HbA1c is typically assessed using standardised laboratory methods that are blinded to CGM or SMBG allocations in most studies. Because the outcome is not influenced by participants or researchers, it was rated as having a low risk of bias in all RCTs.

The outcomes of TIR, TBR, TAR, and GV were all judged to have some concerns in D4 for all RCTs including these outcomes. Although being an objective measure, TIR, TBR, TAR, and GV metrics can only be measured continuously using CGMs, whereas SMBG provides sparse measurements that may underestimate these outcomes. Consequently, the data provided by CGM devices can lead to behavioural changes that affect the outcomes, inherently biasing the outcome measurement in favour of the CGM group.

The nocturnal hypoglycaemic events outcome was judged as having some concerns in D4 because the detection of nocturnal hypoglycaemia is likely to be more frequent in the CGM group as the CGM group uses the device continuously, while the SMBG group measures only intermittently. This introduces differential measurement bias. The severe hypoglycaemia events outcome, however, was judged as having a low risk of bias in D4 because severe hypoglycaemia is typically clinically apparent and defined as requiring third-party assistance. For the total hypoglycaemic event outcome, which includes both nocturnal and severe hypoglycaemic events, it was also judged as having some concerns in D4 across the RCTs that assessed this outcome.

QoL was judged as having some concerns in D4 across RCTs that assessed these outcomes. This outcome is measured subjectively, and participants cannot be blinded to CGM, which may have influenced their responses. The use of validated questionnaires helps to mitigate this risk to some extent. A similar judgement of some concerns in D4 was also applied to the mental health outcome associated with the CGM device in all RCTs that assessed this outcome.

The outcome of adverse events associated with the CGM device was judged as having some concerns. This judgement was made because physical events are often easy to verify, whereas mild or subjective events may be underreported in the SMBG group compared to the CGM group, potentially resulting in slight differential bias.

The outcome of diabetes-related late vascular complications was judged as having a low risk of bias in D4. This judgement was made because these outcomes are objectively measured and unlikely to be influenced by the intervention. They are typically assessed through standard clinical procedures (e.g., lab tests, imaging) that are independent of CGM or SMBG assignment. While blinding of outcome assessors is ideal, it is not critical, as objective endpoints are less susceptible to bias.

Domain 5 (D5): bias in the selection of the reported result

D5 addresses bias arising from the selective reporting of results based on their direction, magnitude, or statistical significance (62). For an outcome to be judged as having a low risk of bias in D5, its definition and measurement should be described in a prespecified and publicly available protocol or

study register. Across the various RCTs, most outcomes were prespecified in a protocol or study register and were therefore rated as having a low risk of bias.

However, outcomes that were not prespecified in a protocol or study register were rated as having some concerns. While these outcomes could have been rated as having a high risk of bias, we opted for a slightly more lenient judgement. An exception was found in one RCT (42;66), where the outcome of QoL was prespecified in the trial registry but not included in the published articles. This specific outcome was judged as having a high risk of bias in D5.

Overall assessment of the risk of bias of outcomes in each RCT

The overall risk-of-bias judgement for each outcome was based on the following criteria (62):

- **Low risk of bias**: The study is assessed as having a low risk of bias across all domains for the given result.
- **Some concerns**: The study raises some concerns in at least one domain for the given result, but it is not considered to be at high risk of bias in any domain.
- **High risk of bias**: The study is assessed as having a high risk of bias in at least one domain for the given result, or it raises some concerns in multiple domains in a way that significantly reduces confidence in the result.

Because an outcome judged as having some concerns in certain domains can result in an overall judgement of some concerns, while multiple domains with the judgement of some concerns can lead to an overall judgement of high risk of bias, we interpreted 1–2 instances of "some concerns" as an overall judgement of "some concerns," whereas 3 or more instances were judged as an overall high risk of bias.

The overall risk of bias across outcomes and trials are described in Section 2.2.3 and displayed in Table A4-1 above.

Risk of bias in the included non-RCTs

The risk of bias in the non-RCTs was assessed for each outcome in each study using the ROBINS-I tool, as detailed in Table A4-2. The judgments are based on extensive assessments that are described in more detail below.

Table A4-2. Risk of bias assessment using the ROBINS-I tool

	D1	D2	D3	D4	D5	D6	D7	Overall
Karter 2021								
HbA1c	?	?	?	?	?	-	?	+
Severe hypo events	?	?	?	?	?	-	?	+
Nathanson 2025								
HbA1c	?	?	?	?	?	-	?	+
Severe hypo events	?	-	-	?	-	?	?	?
Diabetes-related late vascular complications	?	-	-	?	-	-	?	?
Reaven 2023								
HbA1c	?	?	?	-	-	-	?	?
Severe hypo events	?	?	?	?	?	?	?	+

D1: bias due to confounding; D2: bias in the selection of participants into the study; D3: bias in classification of interventions; D4: bias due to deviations from intended interventions; D5: bias due to missing data; D6: bias in measurement outcomes; D7: bias in the selection of the reported results; -: low risk of bias; ?: moderate risk of bias; +: serious risk of bias

Domain 1 (D1): bias due to confounding

All non-RCTs (3;78;79) were judged to have a moderate risk of bias due to confounding across all outcomes (D1 in Table A4-3). The rationale for this judgment is detailed below for each study.

Karter (78) used propensity score weighting and adjusted for baseline covariates, but residual confounding remained possible due to unmeasured factors such as patient motivation and

socioeconomic status. Differences in race/ethnicity and neighbourhood deprivation index suggested potential unmeasured confounders that could have biased the results. Confounding was addressed using overlap weighting in the design phase and statistical adjustments in the analysis. Race/ethnicity and preferred spoken language were considered confounders due to historically lower technology uptake, poorer adherence, and worse diabetes outcomes in minority groups and non-English speakers. This judgement applied to both HbA1c and severe hypoglycaemic events, as shown in Table A4-3.

In Nathanson (3), limitations included potential unmeasured confounders, such as device training and insulin use duration, which were not recorded. While propensity-score inverse probability of treatment weighting (PS-IPTW) achieved good balance for most baseline variables, small imbalances in age, diastolic blood pressure, and estimated Glomerular Filtration Rate (eGFR) remained, potentially impacting HbA1c and varying between groups. For severe hypoglycaemic events, the PS-IPTW approach achieved similar balance as for HbA1c, but unmeasured factors such as education, hypoglycaemia awareness, and socioeconomic status could still influence isCGM uptake and hypoglycaemia risk. For diabetes-related late vascular complications, PS-IPTW achieved good balance on measured covariates, though unmeasured confounding (e.g., smoking intensity, socioeconomic status, secondary prevention care, cardioprotective medication adherence, and diabetes education) remained plausible, as these factors may affect vascular outcomes and correlate with isCGM use.

In Reaven (79), key unmeasured confounders were plausible in the context of care-seeking and device adoption. However, the extensive design and analytical controls support a judgement of moderate rather than serious risk of bias. The authors modelled CGM initiation using over 40 covariates, applied propensity-score overlap weighting (demonstrating excellent model discrimination with post-weighting standardised mean differences [SMDs] ≈<0.1), and utilised negative-control outcomes, providing robust—though not definitive—control of confounding. This judgement applied to both HbA1c and severe hypoglycaemic events, as shown in Table A4-3.

Domain 2 (D2): bias in the selection of participants into the study

Bias in the selection of participants into the study (D2) was assessed for each outcome in each study. The judgements (as shown in Table A4-3) and their rationale are summarized below.

In Karter (78), misclassification was possible if patients did not consistently use their assigned device, leading to a judgement of moderate risk of bias for both outcomes.

In Nathanson (3), participant selection was based on prescription/electronic health records (EHR), though actual adherence or use could differ. isCGM use and SMBG status were determined from the Swedish National Diabetes Register (NDR) and pharmacy dispensing data, with incident isCGM defined by the first recorded use and prior CGM excluded. While the risk of misclassification was limited and unlikely to be differential for HbA1c, it still warranted a judgement of moderate risk of bias. For severe hypoglycaemic events and diabetes-related late vascular complications, the risk of bias was judged as low, despite the potential for adherence or use to vary from prescription records.

In Reaven (79), both outcomes were judged as moderate risk of bias. Administrative classification is generally reliable, but non-differential misclassification was possible. Misclassification could occur if CGM was obtained outside the Veteran Health Administration (VHA) or if prescriptions did not reflect actual use at baseline. Differences in device brands may have influenced outcomes, but exposure was defined as “initiation of any CGM” based on CGM sensor prescriptions versus no CGM. While administrative definitions are reliable, they allow for some misclassification of actual use.

Domain 3 (D3): bias in classification of interventions

Bias in classification of interventions (D3) was assessed for each outcome in each study, with judgements summarized in Table A4-3 and detailed below.

In Karter (78), both outcomes were judged to have moderate risk of bias due to notable baseline differences between initiators and non-initiators in the T2D group before weighting, including age,

diabetes duration, race/ethnicity, preferred language, neighbourhood deprivation index, Charlson Comorbidity Index score, hypoglycaemia risk, insulin type, delivery method, and non-insulin medication use. Exclusions (e.g., incomplete EHR data) could lead to selection bias. Remaining imbalances (|d|≥0.1) were included as covariates in the difference-in-differences models.

In Nathanson (3), the HbA1c outcome was judged as having moderate risk of bias. Participants were selected from a defined population, requiring EHR and lab/CGM availability. Exclusions for missing data may bias the sample toward more adherent or tech-savvy patients. Diabetes type, recorded at the person level in NDR, was reliably classified, minimising confounding by errors in diabetes type. Cohort inclusion required adults with T2D initiating isCGM after June 1, 2017, excluding prior CGM users. Controls were SMBG users matched via weighting. However, HbA1c analysis required lab values in specific windows, and only a subset of incident isCGM users had complete pre- and post-index HbA1c, introducing potential bias related to care engagement. Severe hypoglycaemic events and diabetes-related late vascular complications were judged as low risk of bias, as registry-based cohorts ensured broad inclusion and outcome capture did not depend on post-baseline clinic attendance or lab availability.

In Reaven (79), both outcomes were judged as having moderate risk of bias. For HbA1c, restriction to insulin users not on pumps improved exchangeability but narrowed the target population. Non-users were randomly downsampled to 10% to aid balance, introducing selection concerns despite being prespecified for comparability. Severe hypoglycaemic events required ≥2 years pre-index VHA activity, ≥1 primary/endocrine visit before index, and post-index VHA interaction, ensuring engaged VHA patients but limiting representativeness. Patients with unstable diabetes may have been more likely to initiate CGM, though propensity weighting mitigated this.

Domain 4 (D4): bias due to deviations from intended interventions

Bias due to deviations from intended interventions (D4) was assessed for each outcome in each study, with judgements summarized in Table A4-3 and detailed below.

In Karter (78), adherence to devices may have varied, and deviations may have correlated with patient characteristics, leading to a judgement of moderate risk of bias for both outcomes.

In Nathanson (3), the outcome of HbA1c was rated as having a moderate risk of bias. Adherence to isCGM varied in real-world use, and co-interventions such as education intensity, clinic follow-up, and treatment titration were uncontrolled and may have influenced outcomes. These deviations, plausibly related to both exposure and HbA1c, increased the risk of bias. For severe hypoglycaemic events, the risk of bias was also judged as moderate. Post-initiation co-interventions (e.g., education changes) may have reduced hypoglycaemia as part of the real-world “package” of isCGM, but differential co-interventions could have biased effects upward. Similarly, the diabetes-related late vascular complications outcome was judged to have a moderate risk of bias. isCGM initiation might have triggered increased healthcare contact or therapy adjustments (e.g., antihypertensives, statins), which could influence diabetes-related late vascular complications. While these co-interventions are part of the pathway for “as-used” effects, differential intensification unrelated to glucose control may have exaggerated the effects.

In Reaven (79), the outcome of HbA1c was rated as having a low risk of bias. The study targeted the “effect of assignment at baseline,” with no evidence of analytic bias from post-baseline adjustments affecting the primary estimate. Similarly, the outcome of severe hypoglycaemic events was rated as low risk of bias, as analyses targeted the effect of assignment/initiation without conditioning on post-index care patterns.

Domain 5 (D5): bias due to missing data

Bias due to missing data (D5) was assessed for each outcome in each study, with judgements summarized in Table A4-3 and detailed below.

In Karter (78), both outcomes were rated as having moderate risk of bias. The authors did not consistently explain how missing CGM data were handled. Missing data were rare, accounting for only

0.4% of approximately 4.3 million data points. Median values were imputed for continuous variables, and missing categorical variables were flagged in propensity score models. However, imputation was not applied to difference-in-differences models or the statistics presented in Tables 1 and 2 of the study.

In Nathanson (3), HbA1c was rated as having moderate risk of bias. Missingness was acknowledged but not fully addressed, with missing values arising from unrecorded or unperformed assessments. HbA1c is typically recorded annually in NDR, but the analysis included only participants with measurements within prespecified windows (3–14 months pre-index; closest values to 6-, 12-, and 24-months post-index). This “available cases” approach risks bias if measurement frequency differs by exposure or outcome, such as more frequent assessments for engaged isCGM users. No multiple imputation for HbA1c trajectories was reported. Severe hypoglycaemic events were rated as low risk of bias, as data were captured from the Swedish National Patient Register (NPR) with >90% national coverage for inpatient events. However, events managed in outpatient or emergency departments without admission were not captured. The outcome of diabetes-related late vascular complications was also rated as low risk of bias, as hospitalisations for vascular events were captured via the Swedish NPR, with minimal risk of missingness for inpatient events.

In Reaven (79), HbA1c was rated as having low risk of bias due to multiple imputation using chained equations with five datasets, and HbA1c availability was sufficient for primary analyses. Severe hypoglycaemic events were rated as moderate risk of bias. Events were captured from emergency room/inpatient ICD-9/10 codes, with all VHA encounters recorded. However, patients seeking care outside VHA could have unobserved events, introducing a slight risk of under-ascertainment.

Domain 6 (D6): bias in measurement outcomes

Bias in measurement outcomes (D6) was assessed for each outcome in each study, with judgements summarised in Table A4-3 and detailed below.

In Karter (78), both outcomes in D6 were rated as having low risk of bias. Clinical outcomes (HbA1c, severe hypoglycaemic episodes) were derived from lab/EHR data, which is considered reliable.

In Nathanson (3), HbA1c was rated as having low risk of bias, as it is a lab-based measure recorded annually in the NDR for individuals with diabetes. Severe hypoglycaemic events were rated as having moderate risk of bias due to reliance on hospital admission data from the Swedish NPR, which may involve reporting errors. Diabetes-related late vascular complications were rated as having low risk of bias, as outcomes were ICD-10-coded primary diagnoses (e.g., stroke, MI, heart failure). While misclassification is possible, it appears non-differential by device use, with results showing both increased and reduced RRs.

In Reaven (79), HbA1c was judged as having low risk of bias, as it is an objective lab measure, unlikely to be influenced by exposure status. Severe hypoglycaemic events were rated as having moderate risk of bias due to potential misclassification in claims-based data. Severe hypoglycaemia was defined via ICD-9/10 codes for emergency room/inpatient admissions, with sensitivity analyses including glucose <54 mg/dL. Coding errors and differential capture remain plausible.

Domain 7 (D7): bias in the selection of the reported results

Bias in the selection of reported results (D7) was assessed for each outcome in each study and rated as having a moderate risk of bias across studies. None of the included non-RCTs had a published protocol or were registered in a study registry. A summary of judgments is provided in Table A4-3, with details below.

In Karter, there was no strong evidence of outcome suppression, but reporting may favour positive findings.

In Nathanson, no preregistered protocol was cited. While a wide set of outcomes was reported, selective reporting of time windows or subgroups cannot be excluded for HbA1c. For other outcomes, multiple cardiovascular and complication endpoints, including non-significant and adverse findings,

such as angina, were reported. This mitigates but does not eliminate concerns about selective reporting.

In Reaven, there was no explicit prospective registration, and no multiplicity adjustments were made despite multiple outcomes, analyses, and subgroup explorations. Although the protocol/code was available "upon request," no clear public pre-specified analysis plan was provided.

The overall risk of bias of outcomes in non-RCTs

The overall risk-of-bias judgment for each outcome was based on the criteria described in Table A4-3, where all domains are considered. An outcome with a moderate risk of bias in certain domains may result in an overall judgment of moderate risk of bias. However, multiple domains with moderate risk of bias can lead to an overall judgment of serious risk of bias.

We applied the following interpretation: when 1 to 4 domains are rated as having "moderate risk of bias," the overall judgment is considered "moderate risk of bias." Conversely, if 5 to 7 domains are rated as having "moderate risk of bias," the overall judgment is considered "serious risk of bias."

Table A4-3. Judgement description from the ROBINS-I Tool

Judgement	Interpretation	How reached
Low risk of bias except for concerns about uncontrolled confounding	There is the possibility of uncontrolled confounding that has not been controlled for (given the observational nature of the study), but otherwise little or no concern about bias in the result	*Low risk of bias except for concerns about uncontrolled confounding* in Domain 1 and *Low risk of bias* in all other domains
Moderate risk of bias	There is some concern about bias in the result, although it is not clear that there is an important risk of bias	At least one domain is at *Moderate risk of bias*, but no domains are at *Serious risk of bias* or *Critical risk of bias*
Serious risk of bias	The study has some important problems: characteristics of the study give rise to a serious risk of bias in the result	At least one domain is at *Serious risk of bias*, but no domains are at *Critical risk of bias* OR Several domains are at *Moderate*, leading to an additive judgement of *Serious risk of bias*
Critical risk of bias	The study is very problematic: characteristics of the study give rise to a critical of bias in the result, such that the result should generally be excluded from evidence syntheses.	At least one domain is at *Critical risk of bias* OR Several domains are at *Serious risk of bias*, leading to an additive judgement of *Critical risk of bias*

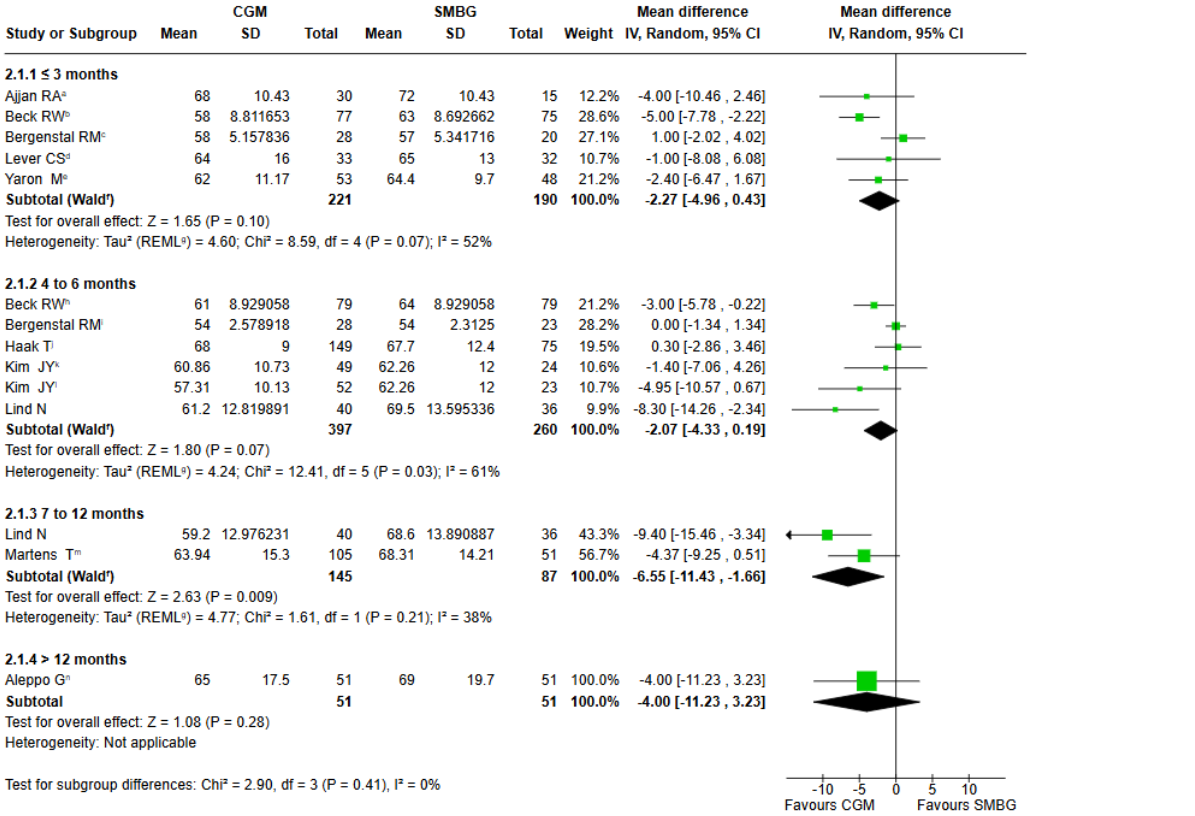
Although none of the studies were judged to have a serious risk of bias in any individual domain, the overall judgment, based on the interpretation criteria mentioned above, indicated a serious risk of bias for HbA1c and severe hypoglycaemic events in the study by Karter (78), HbA1c in the study by Nathanson (3), and severe hypoglycaemic events in the study by Reaven (79). An overall moderate risk of bias was judged for severe hypoglycaemic events and diabetes-related late vascular complications in the study by Nathanson (3), as well as for HbA1c in the study by Reaven (79).

Appendix 5: Meta-analyses – additional information

Additional analyses of HbA1c assessed in RCTs

This section presents additional analyses of HbA1c in RCTs.

To explore the impact of CGM versus control on HbA1c values, the RCTs were analysed based on follow-up duration, allowing for a more detailed understanding of how the intervention's effectiveness varies over time, see Figure A5 1.



Footnotes

[a]SIGN study, the pooled standard deviation was derived from the standard error of the adjusted mean difference reported in the ANCOVA analysis; 3 months 10 days (100 days).
[b]DIAMOND study, % converted to mmol/mol using the HbA1cNet calculator https://www.hba1cnet.com/hba1c-calculator/; 3 months
[c]REACT3 study, data extracted with WebPlotDigitizer-4.8; percentage converted to mmol/mol using the HbA1c net calculator https://www.hba1cnet.com/hba1c-calculator/ ; 2 months
[d]2GO-CGM study; 3 months
[e]Post-intervention SD was estimated using baseline SD, SD of change, and assumed high correlation (r=0.9) for data consistency; 2 months.
[f]CI calculated by Wald-type method.
[g]Tau² calculated by Restricted Maximum-Likelihood method.
[h]DIAMOND study, % converted to mmol/mol using the HbA1c net calculator https://www.hba1cnet.com/hba1c-calculator/; 6 months.
[i]REACT3 study, data extracted with WebPlotDigitizer-4.8; % converted to mmol/mol using the HbA1c net calculator https://www.hba1cnet.com/hba1c-calculator/ ; 4 months
[j]REPLACE study; 6 months
[k]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[l]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[m]MOBILE Study, % converted to mmol/mol with https://www.hba1cnet.com/hba1c-calculator/. SD calculated by multiplying NGSP SD by the conversion formula slope (10.93); 8 months.
[n]MOBILE study, continue CGM vs SMBG; 14 months

Figure A5 1: HbA1c assessed at various time points

≤ 3 months

Five RCTs reported data for the time point of ≤ 3 months. The mean difference between the intervention and control groups was not statistically significant (MD -2.27, 95% CI -4.96 to 0.43, I^2 = 52%, 411 participants; see Figure A5 1.

With an I^2 = 52%, this meta-analysis falls on the borderline between moderate and substantial heterogeneity. Therefore, we conducted a sensitivity analysis to test the robustness of the results and to explore potential sources of variation.

Sensitivity analysis

The removal of Bergenstal 2022 from the analysis led to a reduction in heterogeneity and a statistically

significant result (MD -3.88, 95% CI -5.95 to -1.81, I² = 0%, 363 participants, 4 studies, p = 0.0002; see Figure A5 2).

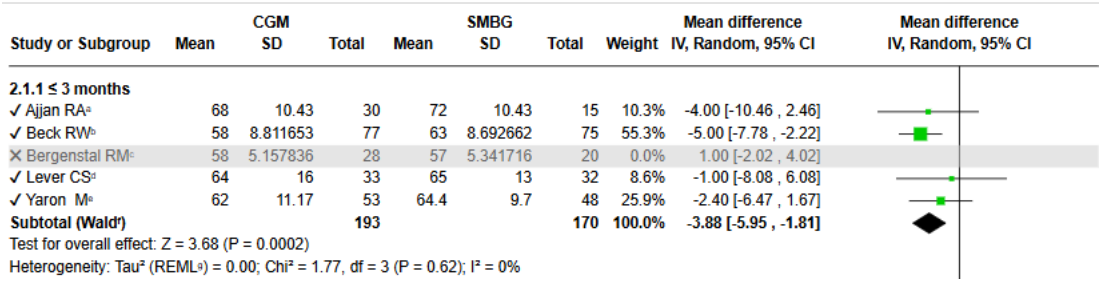


Figure A5 2: Sensitivity analysis of HbA1c ≤ 3 months

4 to 6 months

A total of five RCTs, including one with two arms (Kim), provided data for the time point of 4 to 6 months. One RCT reported 4 months data (Bergenstal), while the others (Beck, Haak, Kim, Lind) provided data for 6 months. The mean difference between CGM and control was non-significant (MD -2.07, 95% CI -4.33 to 0.19, I² = 61%, 657 participants, p = 0.07; see Figure A5 1).

An I² = 61% indicates moderate to substantial heterogeneity, which was further explored through a sensitivity analysis.

Sensitivity analysis

The removal of Bergenstal 2022 from the analysis, led to a reduction in heterogeneity and a statistically significant result (MD, -2.89, 95% CI -5.56 to -0.22, I² = 48%, 606 participants, 4 studies, p = 0.03), see Figure A5 3.

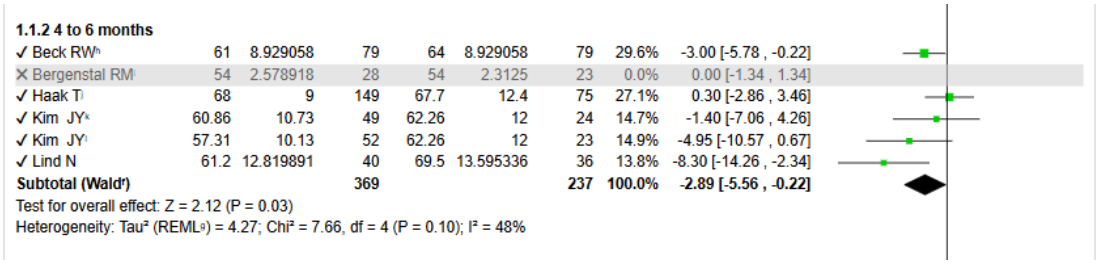


Figure A5 3. Sensitivity analysis of HbA1c at 6 months (a)

When removing Lind, heterogeneity was reduced to I² = 39%; however, the results were no longer statistically significant (MD -1.15 95% CI -2.90 to 0.60, p = 0.20), see Figure A5 4.

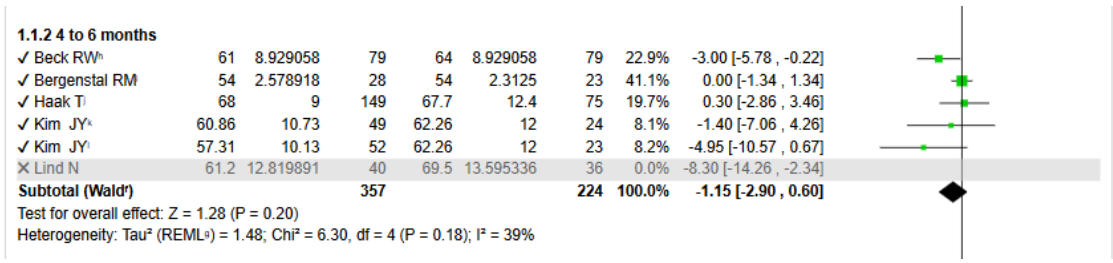


Figure A5 4. Sensitivity analysis of HbA1c at 6 months (b)

8 to 12 months

Two RCTs reported data for the time point of 8 to 12 months: one at 8 months (Martens 2021) and the other at 12 months (Lind 2024). The pooled effect estimate showed statistically significant results (MD -6.55, 95% CI -11.43 to -1.66, 232 participants, I² = 38%, p = 0.009; see Figure A5 1).

>14 months
One small follow-up RCT (Aleppo) reported results for phase 2 of the study at 14 months. Results were not statistically significant (MD -4.00, 95%CI -11.23 to 3.23, 102 participants, p = 0.28, see Figure A5 1).

Comments to the study by Bergenstal and colleagues regarding reasons for heterogeneity

The study by Bergenstal (2022) has several particularities that could explain heterogeneity in HbA1c outcomes when compared in a meta-analysis:

- **Structured SMBG Protocol**: The study utilised a highly structured SMBG protocol, requiring participants to perform SMBG four times daily, download data, and receive detailed 7-point glucose profiles (360 View) for guiding treatment adjustments. The authors state that "structured, consistent use of glucose data regardless of device (structured SMBG or CGM) leads to improvements in A1c control."
- **Use of older CGM systems**: The authors acknowledged as a limitation that the study utilised older CGM systems (e.g., blinded DexCom SevenPlus CGM), noting that current CGM devices have "improved significantly; measurement is more accurate and many no longer need SMBG calibration." The use of more modern, accurate CGM devices might demonstrate different or potentially greater HbA1c reductions due to more precise data guiding therapy adjustments, contributing to heterogeneity.
- **Minimal CGM training**: Subjects in the CGM group received only "basic education on CGM data usage" for making self-care adjustments, which the authors suggest might have "potentially limit[ed] the realized benefits of CGM guided therapy."
- **Specific patient population and therapy stratification (including insulin type)**: The study included adults with uncontrolled T2D (A1c ≥7.0%). The type of insulin the participants were on (e.g., basal, bolus, pre-mixed) was not specified beyond "insulin ± metformin." As different insulin regimens have varying impacts on overall glycaemic control and glucose variability, which directly influence HbA1c, the meta-analysis could show different A1c changes compared to this study's more broadly defined "insulin group," contributing to heterogeneity.

Additional analyses of nocturnal hypoglycaemic events assessed in RCTs

This section presents additional analyses of nocturnal hypoglycaemic events in RCTs.

To explore the impact of CGM versus control on nocturnal hypoglycaemia events, the RCTs were analysed based on follow-up duration, allowing for a more detailed understanding of how the intervention's effectiveness varies over time.

Nocturnal hypoglycaemic events (3.9 mmol/L) at different time points

The meta-analysis reports the effect of CGM versus SMBG on nocturnal hypoglycaemia (as percentage time) at three different follow-up periods: 3 months, 6 and 8 months, and 14 months, across two thresholds: 3.9 mmol/L (see Figure A5 5) and 3.1 mmol/L Figure A5 9).

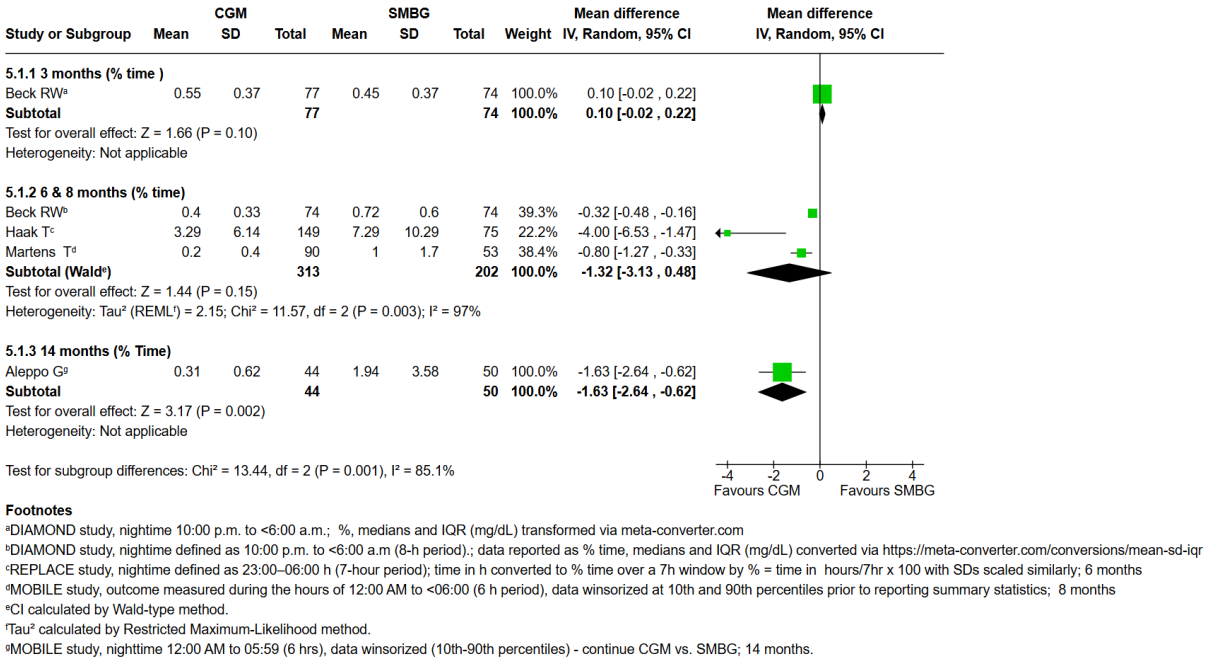
The results of the analysis for 3.9 mmol/L (70 mg/dL) were as follows:

3 months – 8-hour period:
Based on the RCT by Beck (38), there was no statistically significant difference between CGM and SMBG (MD 0.0, 95% CI: -0.00 to 0.1, 151 participants, p = 0.14; see Figure A5 5)

6 and 8 months
Three RCTs (Beck, Haak, Aleppo) provided data for 6 and 8 months, each with a different time window. The pooled results showed a non-significant effect (MD -1.26, 95% CI: -3.27 to 0.74, I^2 = 97%, 515 participants, p = 0.22; see Figure A5 5).

14 months – 6-hour period:

One RCT (Aleppo) showed a statistically significant effect favouring CGM (MD -1.63, 95% CI: -2.64 to -0.62, 94 participants, p = 0.002; see Figure A5 5) at 14 months.



Footnotes

[a]DIAMOND study, nightime 10:00 p.m. to <6:00 a.m.; %, medians and IQR (mg/dL) transformed via meta-converter.com

[b]DIAMOND study, nightime defined as 10:00 p.m. to <6:00 a.m (8-h period).; data reported as % time, medians and IQR (mg/dL) converted via https://meta-converter.com/conversions/mean-sd-iqr

[c]REPLACE study, nightime defined as 23:00–06:00 h (7-hour period); time in h converted to % time over a 7h window by % = time in hours/7hr x 100 with SDs scaled similarly; 6 months

[d]MOBILE study, outcome measured during the hours of 12:00 AM to <06:00 (6 h period), data winsorized at 10th and 90th percentiles prior to reporting summary statistics; 8 months

[e]CI calculated by Wald-type method.

[f]Tau² calculated by Restricted Maximum-Likelihood method.

[g]MOBILE study, nighttime 12:00 AM to 05:59 (6 hrs), data winsorized (10th-90th percentiles) - continue CGM vs. SMBG; 14 months.

Figure A5 5: Nocturnal hypoglycaemia for 3.9 mmol/L threshold

Sensitivity analysis of 6 and 8 months (% time) in 3.9 mmol/L

Sensitivity analysis was performed to assess the heterogeneity (I^2 = 97%) of the 6-to-8-month meta-analysis. In step one, we removed the trial by Haak, as this was as the trial with the most extreme effect size. After excluding Haak, heterogeneity decreased to I^2 = 73%, and the pooled estimate became statistically significant (MD = -0.51, 95% CI: -0.97 to -0.05, 291 participants, p = 0.03; see Figure A5 6).

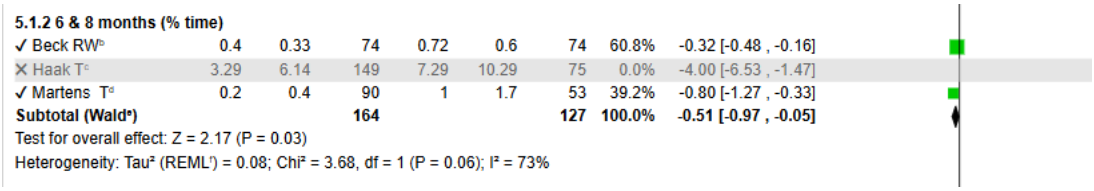


Figure A5 6: Sensitivity analysis of nocturnal hypoglycaemic events at 6 and 8 months (a)

When Haak was included in the analysis and Beck was removed, heterogeneity remained substantial (MD = -2.15, 95% CI: -5.25 to 0.95, 367 participants, p = 0.17, I^2 =83%; see Figure A5 7). Similarly, when Beck and Haak trials were returned and only Martens was removed from the analysis, heterogeneity remained substantial (MD = -1.93, 95% CI: -5.51 to 1.64, 372 participants, p = 0.29, I^2 = 88%; see Figure A5 8).

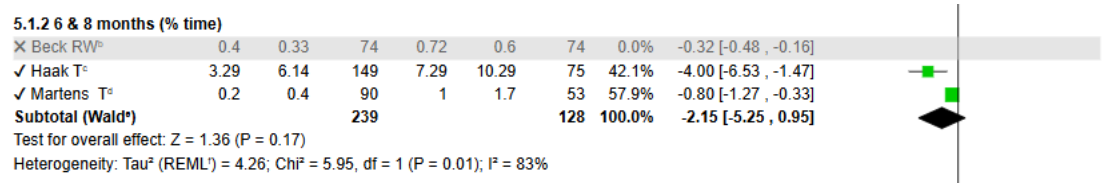


Figure A5 7. Sensitivity analysis of nocturnal hypoglycaemic events at 6 and 8 months (b)

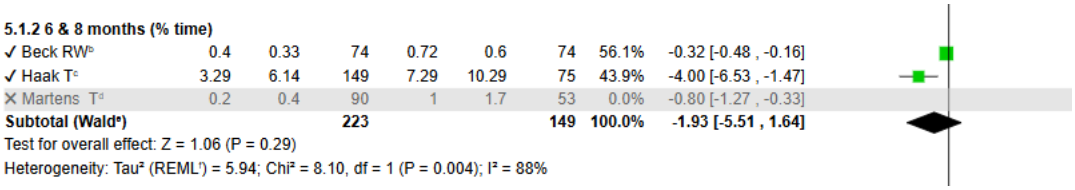


Figure A5 8: Sensitivity analysis of nocturnal hypoglycaemic events at 6 and 8 months (c)

Nocturnal hypoglycaemic events (3.1 mmol/L) at different time points

Results for 3.1 mmol/L (54-55 mg/dL) were as follows:

3 months (3.1 mmol/L)

Beck's results indicate that most participants experienced no recorded nocturnal hypoglycaemia at the 2.77 mmol/L (<50 mg/dL) glucose threshold. At baseline, the median percentage of time spent in nocturnal hypoglycaemia was 0.0% in both groups, indicating minimal exposure to hypoglycaemia prior to the intervention. At 3 months, median values remained at 0.0% (IQR: 0.0–0.0) in both groups (n = 77 vs. n = 74), suggesting no measurable change from baseline.

6 and 8 months follow up (3.1 mmol/L)

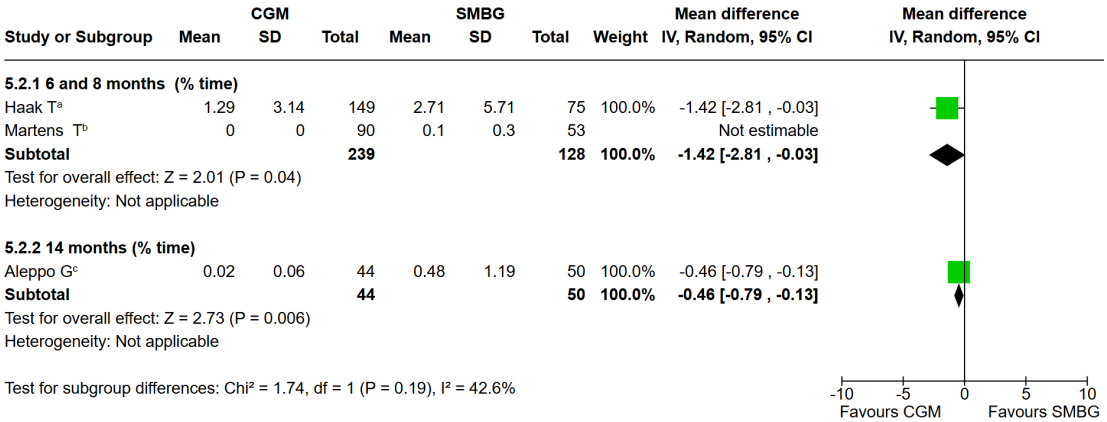
Two RCTs (Haak, Martens) contributed data for the 6- and 8-month follow-up. The effect estimate, derived from Haak, indicates a statistically significant reduction in the percentage of time spent in nocturnal hypoglycaemia for the CGM group compared with the control group (MD = -1.42%, 95% CI: -2.81 to -0.03; p = 0.04; Figure A5 9). Heterogeneity was not applicable due to only one study providing estimable data in this subgroup.

Martens reported the mean percentage of time spent in nocturnal hypoglycaemia as 0.0% at 8 months for the intervention group and 0.1% for the control group at the 3.1 mmol/L threshold. The insulin regimen in this study excludes prandial insulin, which may explain the observed low rates of hypoglycaemia.

At 6 months, Beck reported that both groups maintained a median of 0.0% (IQR 0.0–0.0) (n = 74 vs. n = 72).

14 months follow up (3.1 mmol/L)

One follow-up RCT (Aleppo) showed a significant reduction in nocturnal hypoglycaemia favouring the experimental group (MD = -0.46%, 95% CI: -0.79 to -0.13; 94 participants, p = 0.006; see Figure A5 9.



Footnotes

[a]REPLACE study; outcome defined as 23:00 to 06:00 (7hrs); 55mg/dL. Hours converted to % of nocturnal period: (hours ÷ 7) × 100; 6 months.
[b]MOBILE study: outcome defined as 12AM to <6AM; < 54mg/dL; 8 months
[c]MOBILE study, outcome defined as a 6-hour period from 12:00 AM – 05:59 AM and <54mg/dL

Figure A5 9: Nocturnal hypoglycaemia for 3.1 mmol/L threshold

Additional analyses of TIR assessed in RCTs

This section presents additional analyses of TIR in RCTs.

TIR data were grouped based on follow-up duration: 3 months, 6 to 8 months, and 12 to 14 months, see Figure A5 10. One RCT had three arms (Kim), another utilised a constrained linear mixed-effects model (Lever) adjusted for medication use, and one trial presented its findings across two publications (Aleppo, Martens). The results were as follows:

3 months

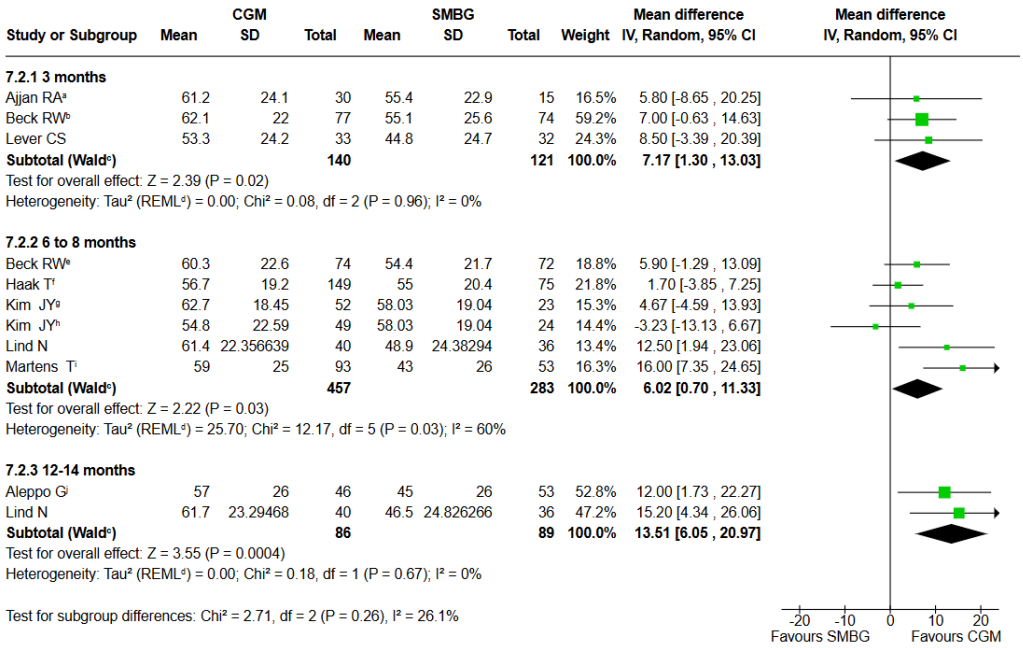
Three RCTs (Beck, Lever, Ajjan) provided data for 3 months. The pooled results showed an overall difference in TIR favouring CGM of 7.17% (95% CI: 1.30 to 13.03; 261 participants; $I^2 = 0\%$; $p = 0.02$, see Figure A5 10), indicating that participants using CGM spent approximately 1.7 hours per day more within the target glucose range compared to those using SMBG.

6 to 8 months

Five RCTs (Beck, Haak, Kim, Lind, Martens) provided data for 6 months. The pooled RCTs showed a statistically significant result, indicating that participants in the intervention group spent 6% more time in range than those in the control group (approximately 1 hour and 27 minutes per day) (MD: 6.02, 95% CI: 0.70 to 11.33; 740 participants; $I^2 = 60\%$; $p = 0.03$; Figure A5 10). Heterogeneity was assessed as ranging between moderate and substantial.

12 to 14 months

Two RCTs (Aleppo and Lind) reported changes in % TIR (3.9–10.0 mmol/L) at 12–14 months. When pooled, the intervention increased TIR by an average of +13.51% (95% CI: 6.05% to 20.97%, $p = 0.0004$; Figure A5 10) compared with the control. This indicates that individuals in the intervention group spent on average, approximately 3.2 hours more per day within the target glucose range than those in the control group. Heterogeneity was low, demonstrating consistency between the studies.



Footnotes

[a]SIGN study, values reported in trial registry record; 3 months 10 days (100 days)
[b]DIAMOND study, minutes and medians/IQR converted to time h = %TIR/100 x 24 and mean SD via meta-converter.com; 3 months
[c]CI calculated by Wald-type method.
[d]Tau² calculated by Restricted Maximum-Likelihood method.
[e]DIAMOND study, values reported in minutes and medians/IQR converted to mean SD following meta-converter.com; 6 months
[f]REPLACE study; 6 months
[g]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[h]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[i]MOBILE study, CGM vs SMBG; 8 months
[j]MOBILE study, continue CGM vs SMBG; 14 months

Figure A5 10. Analysis of TIR at 3 months, 6 to 8 months, and 12 to 14 months

Sensitivity analysis

Once Martens was excluded from the meta-analysis, heterogeneity decreased to 10%, and the result remained statistically significant (MD: 3.75, 95% CI: 0.02 to 7.47; 594 participants; p = 0.05; Figure A5 11).

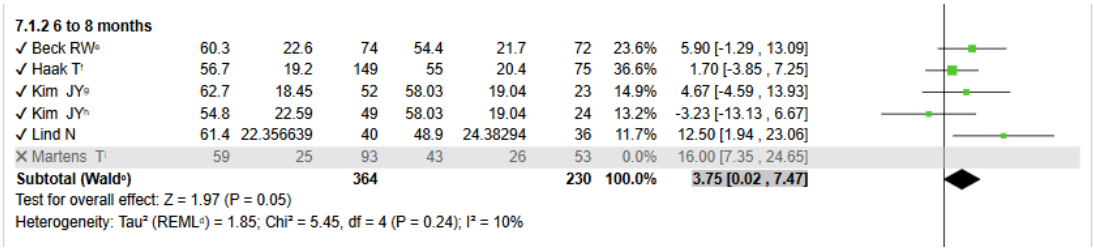
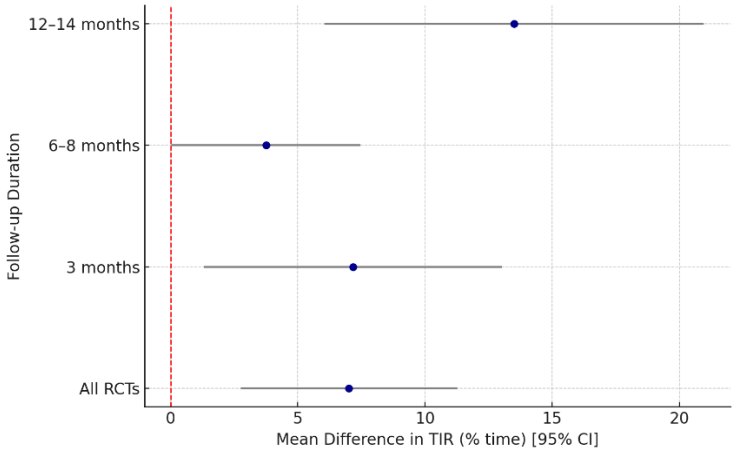


Figure A5 11. Sensitivity analysis of TIR at 6 months

The graphical summary in Figure A5 12 presents the MD in TIR (% time) by follow-up duration, combining all RCTs with 95% CI. It highlights the statistically significant pooled short- and mid-term benefits, as well as potentially large but less certain long-term effects based on pooled data from single trials.



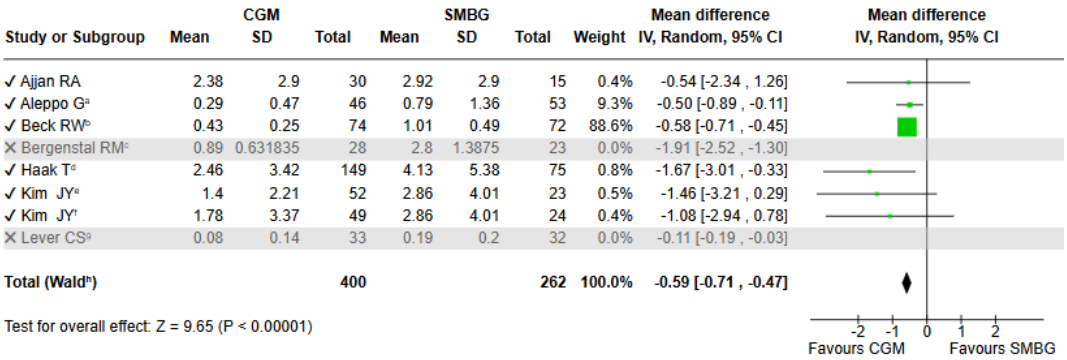
The figure was generated with the assistance of ChatGPT (v5.0) and has been reviewed and verified for accuracy by the authors.

Figure A5 12. Effect of intervention on TIR (% time)

Additional analyses of TBR assessed in RCTs

This section presents additional analyses of TBR in RCTs, first TBR <3.9 mmol/L and then ≤3.0 mmol/L.

The sensitivity analysis of the main meta-analysis for TBR <3.9 mmol/L (Figure A5 13) showed that heterogeneity was resolved (I^2 = 0%) after removing the trials by Bergenstal and Lever, while the result remained statistically significant (MD: -0.59; 95% CI: -0.71 to -0.47; 662 participants; p = 0.00001; see Figure A5 13). This corresponds to approximately 8.5 minutes per day (95% CI: 6.8 to 10.2 minutes per day) spent in hypoglycaemia.



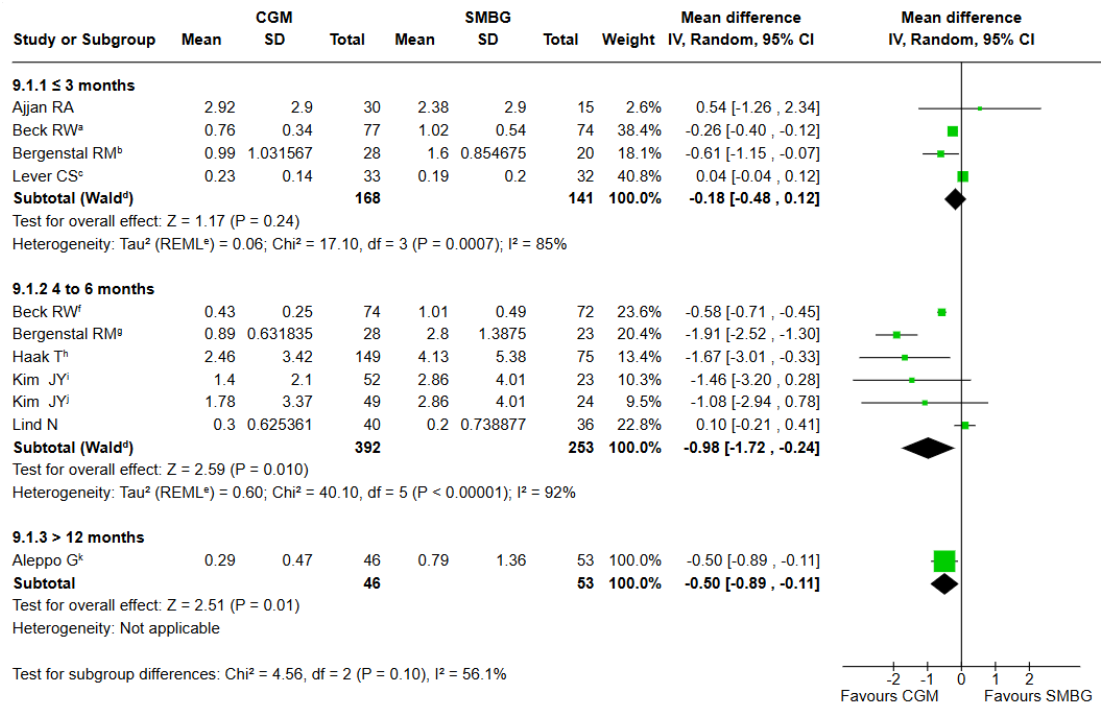
Footnotes

[a]MOBILE study, data reported as winsorized (10th - 90th percentiles) prior to reporting summary statistics; 14 months
[b]DIAMOND study, medians and IQR, transformed to mean and SD via meta-converter.com, and from min to %Time; 6 months
[c]REACT3 study, digital data extracted with WebPlotDigitizer-4.7 for subgroup using insulin, data reported as hypoglycemia rates with SE; 4 months
[d]REPLACE study, h converted to % time; 6 months
[e]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[f]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[g]2GO-CGM; authors noted the data were very skewed, medians and IQR transformed via meta-converter.com; 3 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 13. Sensitivity analysis of TBR <3.9 mmol/L across RCTs at end of intervention

Analyses of TBR <3.9 mmol/L

Data were grouped according to follow-up duration: 3 months, 4 to 6 months, and >12 months, for the outcome of TBR <3.9 mmol/L, see Figure A5 14.



Footnotes

[a]DIAMOND study, medians and IQR, transformed via meta-converter.com, and minutes to hrs/day and % time = (minutes ÷ 1440) × 100; 3 months
[b]REACT3 study, digital data extracted with WebPlotDigitizer-4.7 for subgroup using insuline; 2 months
[c]2GO-CGM; authors wrote data were very skewed, medians and IQR converted via meta-converter.com; 3 months
[d]CI calculated by Wald-type method.
[e]Tau² calculated by Restricted Maximum-Likelihood method.
[f]DIAMOND study, medians and IQR transformed via meta-converter.com and from min to %Time; 6 months
[g]REACT3 study, digital data extracted with WebPlotDigitizer-4.7 for subgroup using insuline; 4 months
[h]REPLACE study, h converted to % time; 6 months
[i]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[j]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[k]MOBILE study, data reported as winsorized at the 10th and 90th percentiles prior to reporting summary statistics; 14 months

Figure A5 14. Assessment of TBR (<3.9 mmol/L) at various time points

≤ 3 months

Five RCTs (Ajjan, Beck, Bergenstal, Lever, Yaron) provided data at ≤ 3 months. One trial (Lever) reported that the "time below range data were very skewed" and noted that, due to low baseline levels, the change in hypoglycaemia could not be meaningfully assessed. Another trial (Yaron) focused on the frequency of events, which is described narratively.

Yaron 2019 included 96 participants. At the end of the intervention (2.2 months, equivalent to 10 weeks), the frequency of <3.9 mmol/L episodes did not significantly differ between groups. The percentage of individuals with T2D who experienced at least one event was 36% (16 patients) in the CGM group versus 28% (15 patients) in the SMBG group (p = 0.51). The mean and standard deviation in the CGM group were 0.69 (1.5) compared to 0.86 (1.97) in the SMBG group (p = 0.63).

The meta-analysis results for the ≤ 3-month follow-up indicated a non-statistically significant reduction in TBR (MD: -0.18; 95% CI: -0.48 to 0.12; 309 participants; I^2 = 85%; p = 0.24; see Figure A5 14). Given the considerable variation among the studies, a sensitivity analysis was conducted.

Sensitivity analysis

In a sensitivity analysis excluding the Lever trial, statistical heterogeneity decreased (I^2 = 10%), and the pooled effect estimate was significant MD −0.30 (95% CI −0.51 to −0.09; 244 participants; p = 0.006; Figure A5 15).

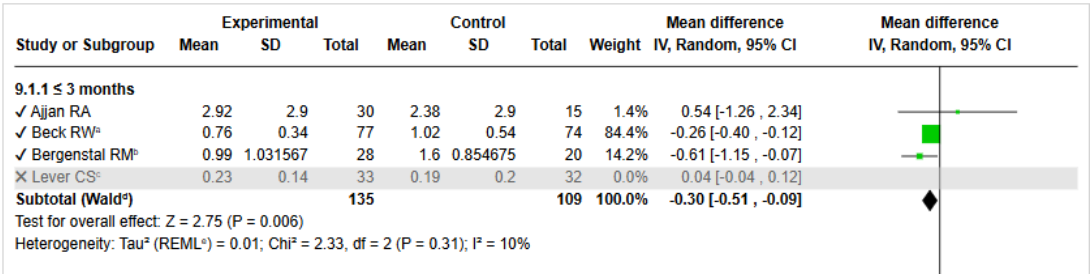


Figure A5 15. Sensitivity analysis of TBR <3.9 mmol/L at ≤ 3 months

4 to 6 months

Five RCTs (Beck, Bergenstal, Haak, Kim, Lind) provided data for the 4 to 6 months and were included in this analysis. The pooled MD was −0.98 95% CI −1.72 to −0.24, p = 0.010 favouring CGM (625 participants, I^2 = 92%; Figure A5 14). The variation among the studies was considerable, for what we conducted a sensitivity analysis.

Sensitivity analysis

In a sensitivity analysis, excluding the Lind and Beck trials eliminated statistical heterogeneity (I^2 = 0%), and the pooled effect estimate remained significant (MD: -1.77; 95% CI: -2.28 to -1.26; 423 participants; p < 0.00001; Figure A5 16).

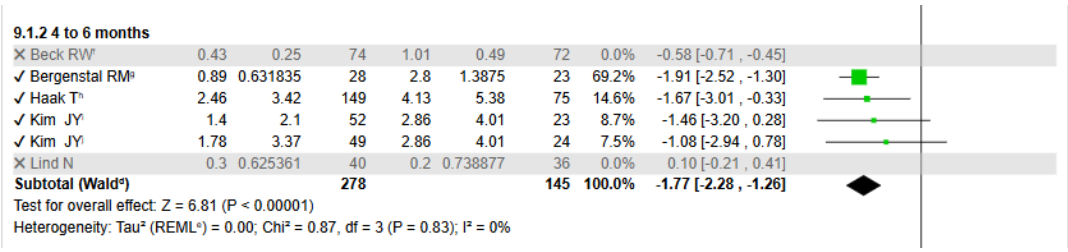


Figure A5 16. Sensitivity analysis of TBR <3.9 mmol/L at 4 to 6 months

8 and 12 months

Two RCTs (Martens and Lind) provided data for TBR at eight and 12 months.

Results from Martens are presented as adjusted mean differences in percentages. When CGM was compared to SMBG intervention, the adjusted mean difference at 8 months was 0.22 (SD 0.41), 93

participants vs 0.5 (SD 0.5) 93 participants. The CGM group spent on average, approximately 4 minutes less per day below 3.9 mmol/L compared to the SMBG group.

In Lind, the author noted that TBR was very low during the study for both groups. The authors reported that due to these very low baseline values, the trial's ability to meaningfully assess the effect of time in hypoglycaemia was limited. At 12 months, when CGM was compared to SMBG intervention, the estimate was 0.01, 95% CI 0.0 to 0.0 hours/day, 40 participants vs. 0, 95% CI 0 to 0.1 hours/day, 36 participants.

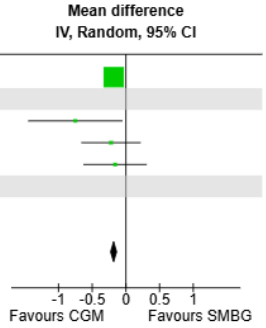
14 months

Aleppo presents follow up data from Martens at 14 months. Participants %time spend below range was MD -0.50 95%CI -0.89 to -0.11, 99 participants, p = 0.01, see Figure A5 14.

TBR ≤3.0 mmol/L

We performed a sensitivity analysis of TBR ≤3.0 mmol/L at the end of the intervention follow-up. Excluding the trials conducted by Lind and Bergenstal eliminated the statistical heterogeneity (I^2 = 0%), and the pooled effect estimate for TBR ≤3.0 mmol/L became statistically significant (MD: -0.18; 95% CI: -0.23 to -0.14; 664 participants; p < 0.00001; see Figure A5 17).

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean difference IV, Random, 95% CI
✓ Beck RW[a]	0.1	0.09	74	0.28	0.17	72	97.7%	-0.18 [-0.22 , -0.14]
✕ Bergenstal RM[b]	0.42	0.515784	28	1.5	0.854675	20	0.0%	-1.08 [-1.50 , -0.66]
✓ Haak T[c]	0.79	1.54	149	1.54	2.88	75	0.4%	-0.75 [-1.45 , -0.05]
✓ Kim JY[d]	0.16	0.43	52	0.38	1.03	23	1.0%	-0.22 [-0.66 , 0.22]
✓ Kim JY[e]	0.22	0.8	49	0.38	1.03	24	0.9%	-0.16 [-0.63 , 0.31]
✕ Lind N[f]	0.1	0.15634	40	0	0.147775	36	0.0%	0.10 [0.03 , 0.17]
✓ Martens T[g]	0	0	93	0.1	0.3	53		Not estimable
Total (Wald[h])			**417**			**247**	**100.0%**	**-0.18 [-0.23 , -0.14]**



Test for overall effect: Z = 8.17 (P < 0.00001)

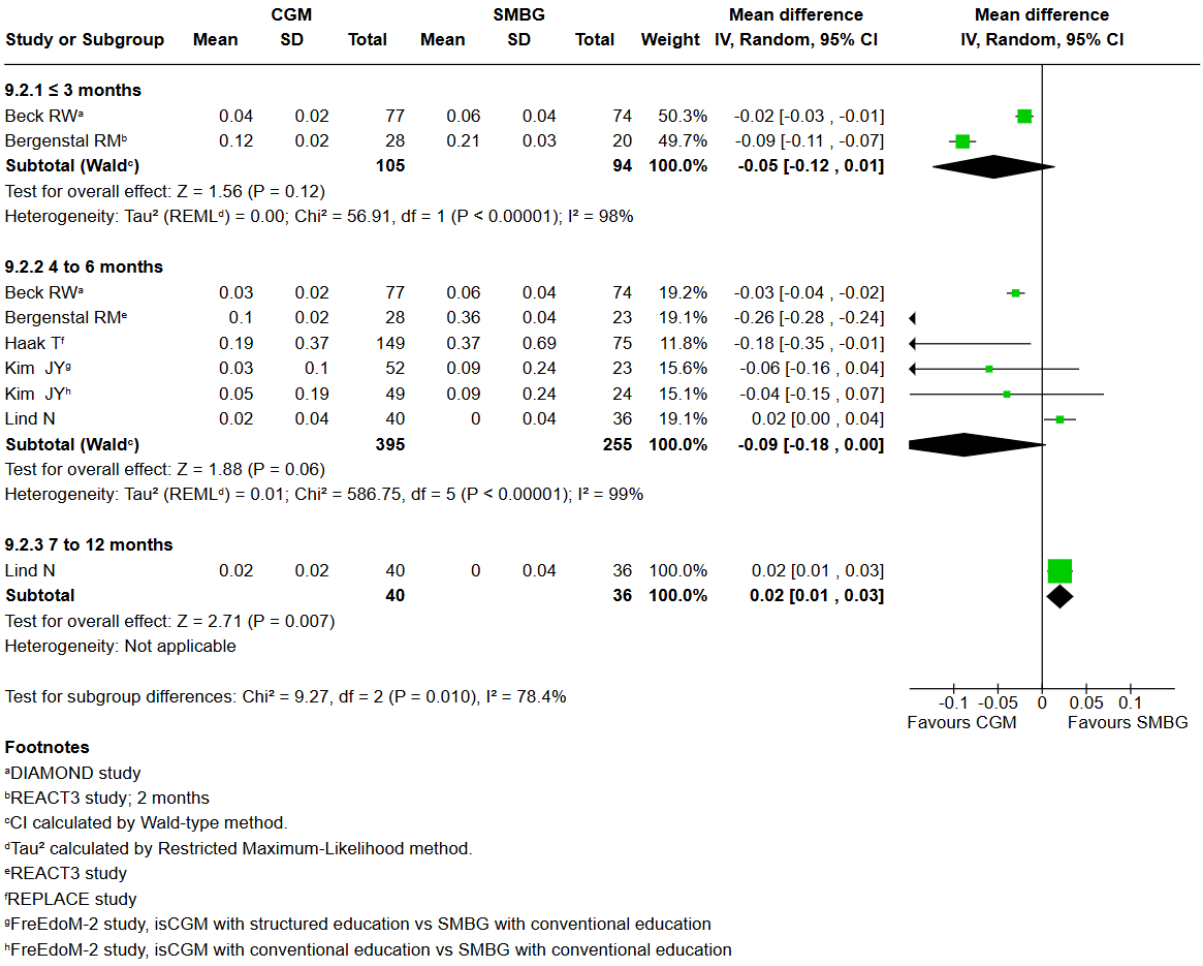
Heterogeneity: Tau² (REML[i]) = 0.00; Chi² = 2.60, df = 3 (P = 0.46); I² = 0%

Footnotes

[a]DIAMOND study, medians and IQR converted via meta-converter.com and min to %; 6 months
[b]REACT3 study; data reported as hypoglycemia rates and SE; 4 months
[c]REPLACE study; h converted to % time; 6 months
[d]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]Steno2tech study, authors state TBR was very low for both groups, limiting their ability to assess hypoglycemia; 12 months
[g]MOBILE study, data winsorized at the 10th and 90th percentiles prior reporting; 8 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 17: Sensitivity analysis of TBR ≤3.0 mmol/L across RCTs at end of intervention

Data were also grouped according to follow-up duration: 3 months, 4 to 6 months, and 7–12 months, see Figure A5 18.



Footnotes

[a]DIAMOND study
[b]REACT3 study; 2 months
[c]CI calculated by Wald-type method.
[d]Tau² calculated by Restricted Maximum-Likelihood method.
[e]REACT3 study
[f]REPLACE study
[g]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education
[h]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education

Figure A5 18. Assessment of TBR (≤3.0 mmol/L) at various time points

≤3 months

Three studies provided data for ≤3 months. Two studies (Beck and Bergenstal) were pooled and showed that TBR in the CGM group did not significantly differ from the control group (MD -0.05, 95% CI -0.12 to 0.01, 194 participants, I² = 98%, p = 0.12, see Figure A5 18). There was considerable variation among studies, indicating pooling of the results may not be appropriate and a single pooled result questionable. The estimate should be interpreted with great caution.

Yaron 2019 study included 96 participants; at the end of 2.2 months (10 weeks) the frequency of <3 mmol/L <54 episodes did not significantly differ between groups. The percentage of individuals with diabetes type 2 with at least one event in the CGM was 11% (6 patients) vs 9% (4 patients) in the SMBG group, p = 0.75, mean and SD CGM 0.38 (1.29) vs 0.2 (1.82), p = 0.43.

4 to 6 months

Five RCTs (Beck Bergenstal, Haak, Kim and Lind) were included in the meta-analysis. The pooled difference was MD −0.09, 95% CI −0.18 to 0.00, 650 participants (see Figure A5 18) which did not reach statistical significance (p=0.06). There was considerable heterogeneity, I² = 99%, thus a sensitivity analysis was conducted.

Sensitivity Analysis

After excluding the trials with fewest participants, Bergenstal and Lind, three trials with 523 participants were included. The pooled MD was −0.03 (95% CI −0.05 to −0.02), favouring CGM, Figure A5 19. This effect was statistically significant (p = 0.0002). Heterogeneity was low (I² = 3%).

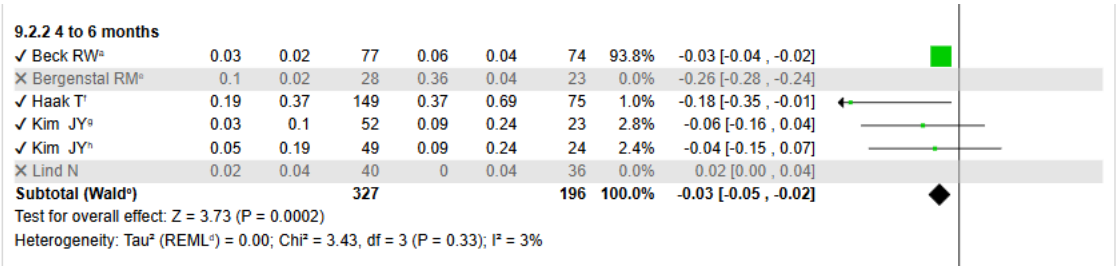


Figure A5 19. Sensitivity analysis of TBR ≤3.0 mmol/L at 4 to 6 months

7 to 12 months

In Martens, when CGM was compared to SMBG intervention, the adjusted MD for TBR ≤3.0 at 8 months was very low (−0.10, 95% CI−0.15 to −0.04, 93 vs 53 participants, p= 0.001), as reported in Martens' trial. The negative difference indicates that the CGM group spent on average, approximately 1.4 minutes less per day (95% CI: 0.6 to 2.2 minutes/day less) below 3.0 mmol/L compared to the SMBG group (1% of 24 hours = 0.24 h= 14.4 minutes, -0.10 x 14.4= -1.44 minutes/day).

In Lind's trial, when CGM was compared to SMBG, the difference in TBR at 12 months was very low 0.1% (0.0 to 0.1 n=40) vs. 0% (0.0 to 0.1 n=36). The absolute difference between groups is about 1.4 minutes/day less TBR for individuals in the SMBG group (1% of 24 hours = 0.24 h = 14.4 minutes, CGM 0.1 x 14.4 = 1.44 minutes/day) compared to the CGM group.

Additional analyses of TAR assessed in RCTs

This section presents additional analyses of TAR in RCTs, first TAR >10 mmol/L and then >13.0 mmol/L.

TAR >10 mmol/L

Analyses by follow-up duration of TAR >10 mmol/L

Data were grouped by follow-up duration for TAR >10 mmol/L into the following categories: 3 months, 6 to 8 months, and 14 months, see Figure A5 20.

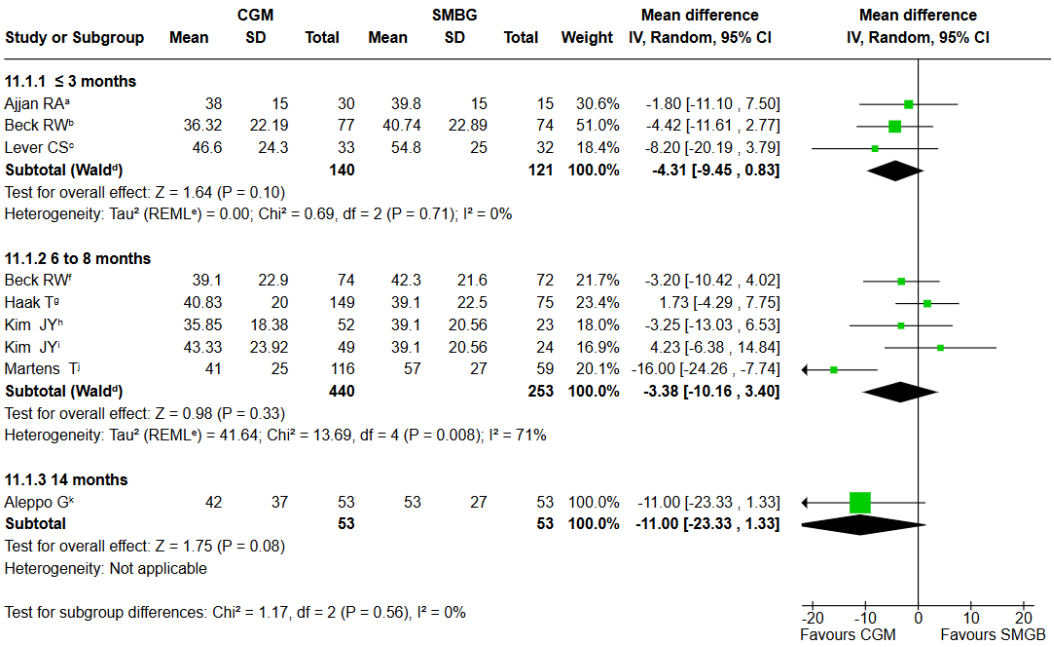


Figure A5 20. Analysis of TAR >10 mmol/L at various time points

≤3 months

Three RCTs provided data for ≤3 months (Ajjan, Beck, Lever). The TAR between CGM and SMBG was not statistically significant -4.31 percentage points, 95% CI -9.45 to 0.83, 261 participants, see Figure A5 20. There was no significant heterogeneity among the studies.

6 to 8 months

Four RCTs (Beck Haak Kim, Martens) provided data for 4 to 6 months. The TAR between CGM and SMBG was not statistically significant (MD -3.38, 95% CI -10.16 to 3.40, 693 participants, I^2 = 71%, p = 0.33). An I^2 = 71%, represents substantial heterogeneity, thus we conducted a sensitivity analysis.

Sensitivity analysis 6 to 8 months (TAR >10 mmol/L) follow-up

When Martens was removed from the analysis, the heterogeneity disappeared, I^2 = 0%; the mean difference between groups remained not statistically significant (MD -0.15, 95%CI -4.04 to 3.74, 518 participants, p = 0.94; see Figure A5 21).

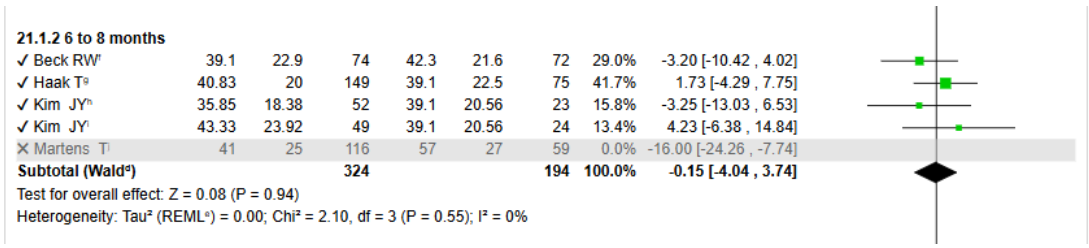


Figure A5 21. Sensitivity analysis of TAR >10 mmol/L at 4 to 6 months

14 months

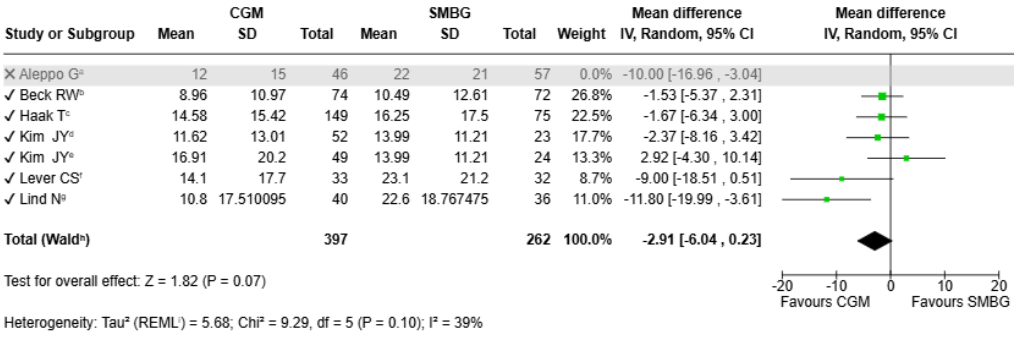
One follow up RCT (Aleppo) presented data for 14 months. The mean results showed no statistical difference between CGM and SMBG at 14 months for TAR (MD -11, 95% CI -23.33 to 1.33, 106 participants, p = 0.08, see Figure A5 20).

TAR >13.0 mmol/L

Sensitivity analysis at the end of intervention of TAR >13.0

When Aleppo or Lind were independently removed from the main analysis, the heterogeneity was reduced but remained moderate, I^2 = 39% and 37%; the mean differences between groups became not statistically significant.

By removing Aleppo, the result was still not statistically significant: MD -2.91, 95%CI -6.04 to 0.23, 659 participants, I^2 = 39%, p = 0.07, see Figure A5 22.



Test for overall effect: Z = 1.82 (P = 0.07)

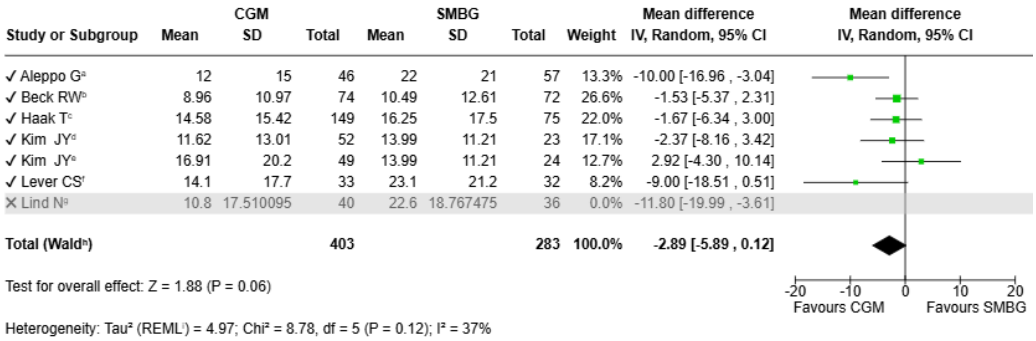
Heterogeneity: Tau² (REML[i]) = 5.68; Chi² = 9.29, df = 5 (P = 0.10); I² = 39%

Footnotes

[a]MOBILE study, >13.87 mmol/L (>250 mg/dL), continue CGM vs SMBG; 14 months
[b]DIAMOND study, 13.87 mmol/L (>250mg/dL) medians and IQR- min, transformed via meta-converter.com and % time; 6 months
[c]REPLACE study, 13.3 mmol/L (240 mg/dL), h converted to % time; 6 months
[d]FreEdoM-2 study, >13.9 mmol/L, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, >13.9 mmol/L, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]2GO-CGM study, >13.9 mmol/L; 3 months
[g]Steno2tech study. >13.9 mmol/L; 12 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 22. Sensitivity analysis of TAR >13.0 mmol/L at the end of intervention (a)

By removing Lind, the analysis was also not statistically significant (MD -2.89, 95%CI -5.89 to 0.12, 686 participants, p = 0.06, see Figure A5 23).



Test for overall effect: Z = 1.88 (P = 0.06)

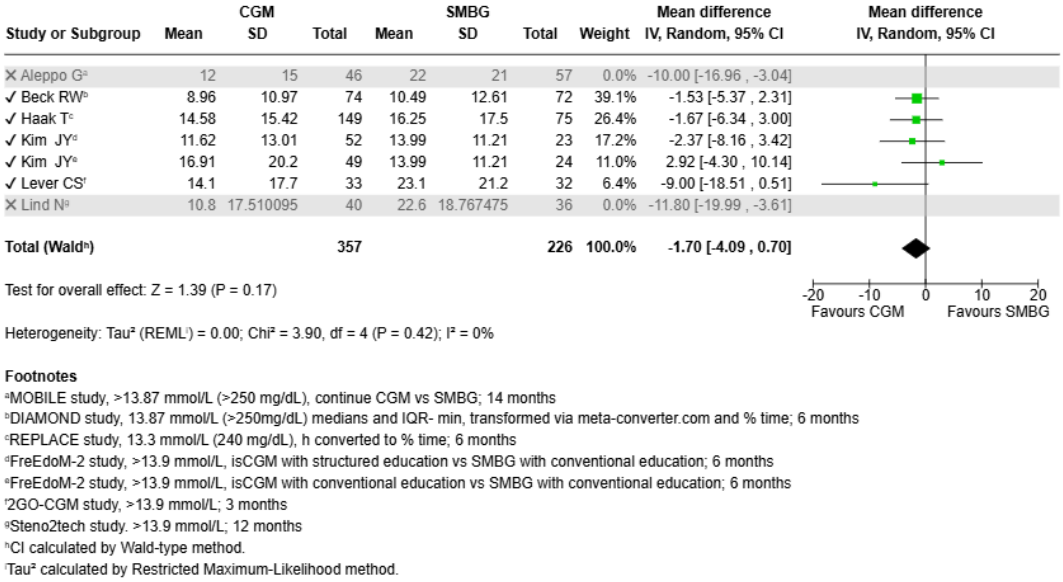
Heterogeneity: Tau² (REML[i]) = 4.97; Chi² = 8.78, df = 5 (P = 0.12); I² = 37%

Footnotes

[a]MOBILE study, >13.87 mmol/L (>250 mg/dL), continue CGM vs SMBG; 14 months
[b]DIAMOND study, 13.87 mmol/L (>250mg/dL) medians and IQR- min, transformed via meta-converter.com and % time; 6 months
[c]REPLACE study, 13.3 mmol/L (240 mg/dL), h converted to % time; 6 months
[d]FreEdoM-2 study, >13.9 mmol/L, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, >13.9 mmol/L, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]2GO-CGM study, >13.9 mmol/L; 3 months
[g]Steno2tech study. >13.9 mmol/L; 12 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 23. Sensitivity analysis of TAR >13.0 mmol/L at the end of intervention (b)

When both Aleppo and Lind were removed from the main meta-analysis (at the end of intervention) the heterogeneity disappeared and the mean difference for TAR time was not statistically significant: MD -1.70, 95%CI -4.09 to 0.70, 583 participants, I^2 = 0%, p = 0.17; see Figure A5 24.



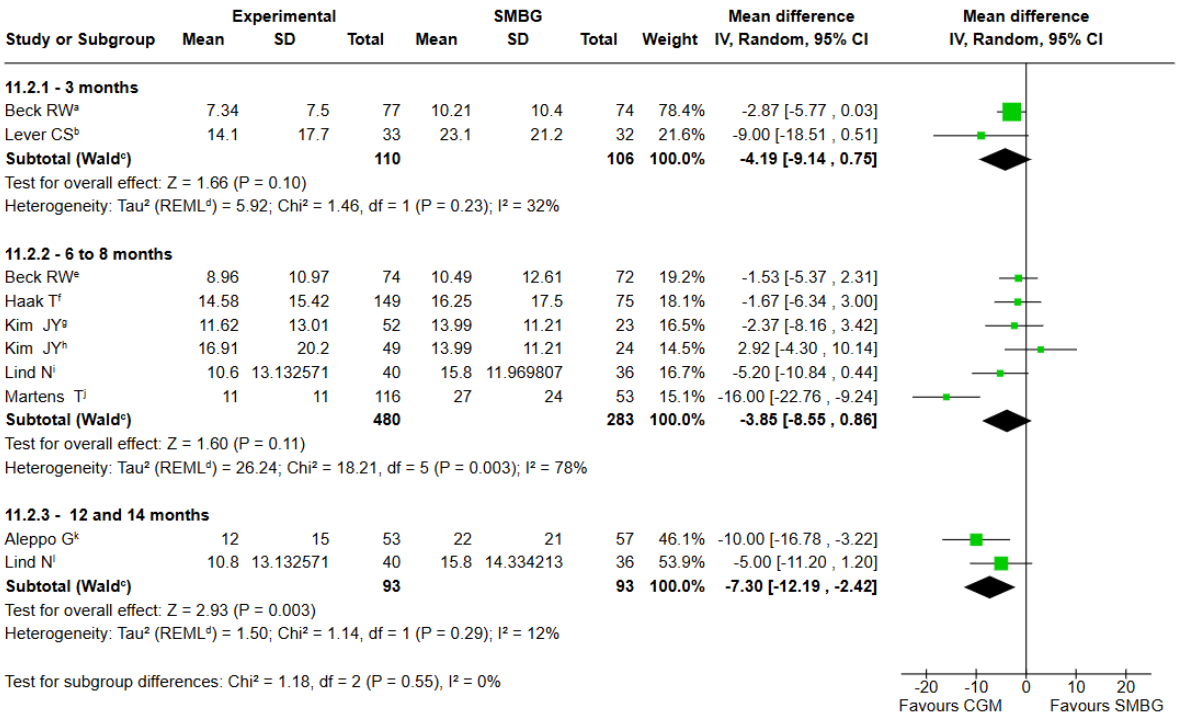
Footnotes

[a]MOBILE study, >13.87 mmol/L (>250 mg/dL), continue CGM vs SMBG; 14 months
[b]DIAMOND study, 13.87 mmol/L (>250mg/dL) medians and IQR- min, transformed via meta-converter.com and % time; 6 months
[c]REPLACE study, 13.3 mmol/L (240 mg/dL), h converted to % time; 6 months
[d]FreEdoM-2 study, >13.9 mmol/L, isCGM with structured education vs SMBG with conventional education; 6 months
[e]FreEdoM-2 study, >13.9 mmol/L, isCGM with conventional education vs SMBG with conventional education; 6 months
[f]2GO-CGM study, >13.9 mmol/L; 3 months
[g]Steno2tech study. >13.9 mmol/L; 12 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 24. Sensitivity analysis of TAR >13.0 mmol/L at the end of intervention (c)

Analyses by Follow-Up Duration of TAR >13.0 mmol/L

Data were grouped by follow-up duration for the outcome of TAR >13.0 mmol/L into the following categories: 3 months, 6 to 8 months, 12 and 14 months, see Figure A5 25.



Footnotes

[a]DIAMOND study, medians and interquartile range, min, transformed to mean SD hours/day via meta-conversions.com
[b]2GO-CGM study, % converted to hours/day
[c]CI calculated by Wald-type method.
[d]Tau² calculated by Restricted Maximum-Likelihood method.
[e]DIAMOND study, medians and IQR, and min transformed to mean SD and %time (conversion assumes normality); 6 months
[f]REPLACE study, h converted to % time; 6 months
[g]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months
[h]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education; 6 months
[i]Steno2tech study, 6 months
[j]MOBILE study; 8 months
[k]MOBILE study, % converted to hours/day; 14 months
[l]Steno2tech study; 12 months

Figure A5 25. Analysis of TAR >13.0 mmol/L at various time points

3 months

Two small RCTs (Beck, Lever) provided data for 3 months follow-up. When combined in the meta-analysis the mean difference between CGM and SMBG was not significant (MD -4.19, 95%CI -9.14 to 0.75, 206 participants, I^2 = 32%, p = 0.10; see Figure A5 25).

6 to 8 months

Five RCTs provided data for 6 to 8 months follow-up (Beck, Haak, Kim, Lind, Martens). At 6 months, the meta-analysis showed a non-significant TAR between groups (MD -3.85, 95% CI -8.55 to 0.86, 763 participants, I^2 = 78%, p = 0.11; see Figure A5 25). Heterogeneity was between substantial and considerable thus we conducted a sensitivity analysis.

Sensitivity analysis

When Martens was removed from the analysis of 6 to 8 months follow-up, the heterogeneity disappeared, I^2 = 0%; the mean difference between groups remains not statistically significant (MD -1.85, 95%CI -4.12 to 0.42, 594 participants, p = 0.11; see Figure A5 26).

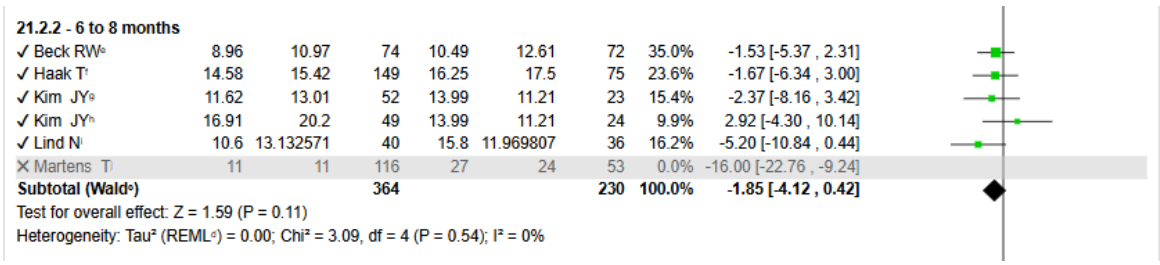


Figure A5 26. Sensitivity analysis of TAR >13.0 mmol/L at 6 to 8 months

12 and 14 months

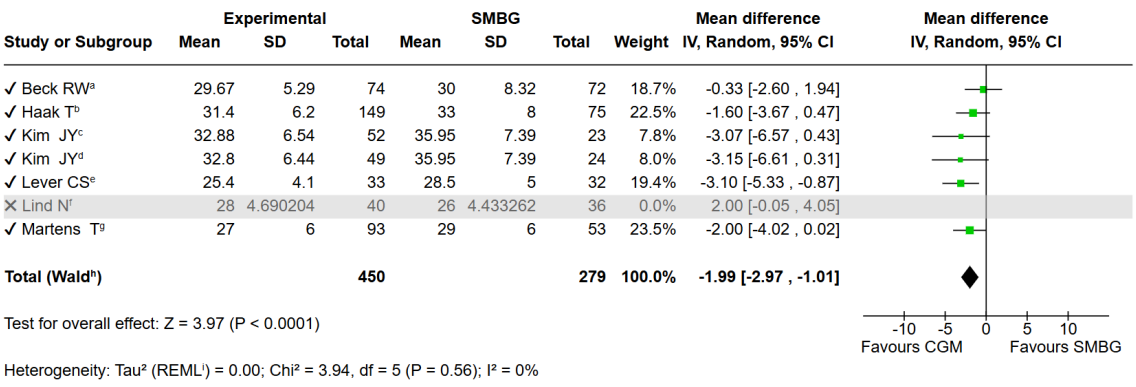
Two small RCTs presented data for 12 and 14 months follow up. The mean results showed a statistical difference between CGM and SMBG for % time in TAR >13.0 mmol/L (MD -7.3, 95% CI -12.19 to –2.42, 186 participants, I^2 = 12%, p = 0.003; see Figure A5 25).

Additional analysis of GV

This section presents additional analysis of GV in RCTs.

Sensitivity analysis of GV

The sensitivity analysis revealed that when excluding Lind from the meta-analysis heterogeneity disappeared (I^2 = 0%). The mean difference between groups became statistically significant, indicating reduced GV in the CGM group compared to the SMBG group (MD: -1.99; 95% CI: -2.97 to -1.01; 729 participants; p < 0.0001; see Figure A5 27).



Footnotes

[a]DIAMOND study, medians and IQR converted based on the assumption of approximate normality via https://meta-converter.com/conversions/mean-sd-iqr., 6 months
[b]REPLACE study; 6 months
[c]FreEdoM-2 study, isCGM with structured education vs SMBG with conventional education; 6 months.
[d]FreEdoM-2 study, isCGM with conventional education vs SMBG with conventional education: 6 months
[e]2GO-CGM study; 3 months
[f]Steno2tech study, data converted to %; 12 months
[g]MOBILE Study (CGM vs BGM); number of participants reflect participants with sufficient CGM data at the 8-month visit; 8 months
[h]CI calculated by Wald-type method.
[i]Tau² calculated by Restricted Maximum-Likelihood method.

Figure A5 27: Sensitivity analysis of GV across RCTs at end of intervention

Additional analysis of QoL

This section presents additional analysis of QoL in RCTs.

Sensitivity analysis of the overall QoL

When Beck was excluded from the analysis, the SMD was 0.25 (95% CI: 0.02 to 0.49) with $I^2 = 0\%$ (300 participants; see Figure A5 28). According to Cohen's *d* criteria (69), an SMD of 0.25 (95% CI: 0.02 to 0.49) represents a small effect size, suggesting that the intervention had a modest positive effect.

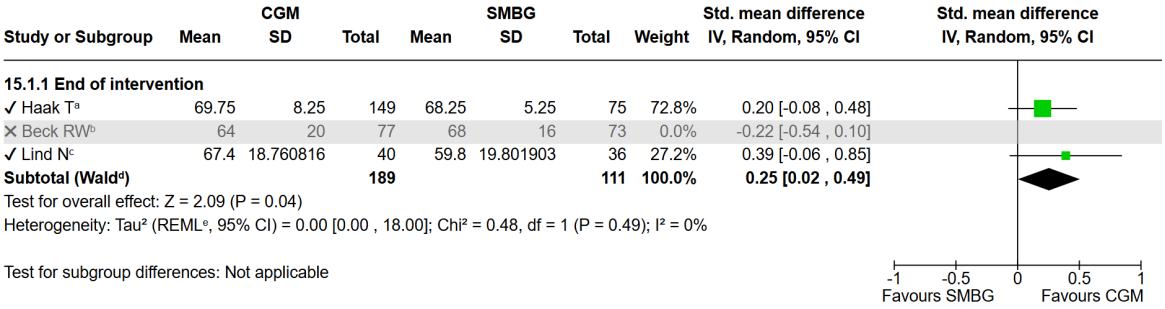


Figure A5 28: Sensitivity analysis of overall QoL

Appendix 6: Grading the certainty of the evidence with GRADE

Question: Should continuous glucose monitoring (CGM) vs blood glucose monitoring (BGM) be used for people with type 2 diabetes on insulin treatment?

Setting: Outpatients with type 2 diabetes using insulin.

Certainty assessment							№ of patients		Certainty		Comments
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CGM	SMBG	Absolute (95% CI)	Certainty	Comments
HbA1c - % (end of intervention)											
9	RCT	Serious [a]	Not serious	Not serious	Not serious	None	562	402	MD 2.19 lower (3.92 lower to 0.47 lower)	Moderate	The result did not meet prespecified MICD of 5.5 mmol/mol
3	Non- RCT	Very serious [b]	Not serious	Not serious	Not serious	Results not pooled. Difference in Difference (DiD) reported for each study	Karter: 344 Reaven: 15,292 Nathanson: 6800 Total: 22,436	Karter: 35,736 Reaven: 28,467 Nathanson: 78,386 Total: 142,589	DiD $_1$: -6.12, 95% CI, -7.87 to -4.48 mmol/mol, 12 months DiD$_2$: −3.83, 95%CI −4.37 to -3.39 mmol/mol, 12 months DiD$_3$: T2D-MDI -3.6, 95%CI -4.6 to -2.5 and T2D-B -3.7, 95%CI -4.3 to -3.1, mmol/mol, 24 months	Low	Karter met prespecified MICD. However, they stated that the outcome should be seen as exploratory.
Severe hypoglycaemia (events) – blood glucose level below 3.1 mmol/L requiring third-party assistance											
8 (3 + 5)	RCT	Serious [a]	Not serious	Not serious	Very serious [g]	None	7/370 (1.9%) (meta-analysis only)	2/244 (0.8%) (meta-analysis only)	3 trials pooled RR 1.71 (0.44 to 6.66), 6 more per 1000 (from 5 fewer to 46 more)	Very low	*No severe hypoglycaemia*, defined as "requiring third-party assistance," was reported in 5 RCTs (N=532)

Certainty assessment							№ of patients		Certainty		Comments
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CGM	SMBG	Absolute (95% CI)	Certainty	Comments
3	Non-RCT	Very serious [b]	Serious [c]	Not serious	Serious [f]	Results not pooled; Results are related to emergency departments or hospitalisation	Karter: 344 Reaven: 15,706 Nathanson: 6800 Total: 22,850	Karter: 35,736 Reaven: 29,912 Nathanson: 78,386 Total: 144,034	Karter:4% event rate drop, 95% CI, −7.8% to −0.2%, p = 0.04. Reaven: HR 0.93; 95% CI 0.74 to 1.16, p=0.52. Nathanson: T2D-MDI RR 0.51; 95% CI 0.27 to 0.95; p=0.034, T2D-B: RR 0.69; 95% CI 0.31 to 1.44; p=0.305	Very low	-
Time in Range - 3.9-10.0 mmol/L, % (end of intervention)											
7	RCT	Serious [a]	Not serious	Not serious	Not serious	Length ranged from 3 to 14 months	473	330	MD 5.5 higher (1.68 higher to 9.32 higher)	Moderate	Reached MCID of 5% change in TIR
Time Below Range - % (end of intervention)											
8 (7+1)	RCT <3.9 mmol/L	Serious [a]	Very serious [d] I^2 = 96%,	Not serious	Not serious		461 (meta-analysis only)	317 (meta-analysis only)	7 trials pooled MD 0.86 lower (1.4 lower to 0.33 lower)	Very low	One RCT examined hypoglycaemia frequency and is described narratively (N=101).
6	RCT <3.0 mmol/L	Serious [a]	Very serious [d] I^2 = 98%,	Not serious	Not serious	None	485	303	MD 0.34 lower (0.69 lower to 0.02 higher)	Very Low	-
Time Above Range - % (end of intervention)											
6	RCT >10.0 mmol/L	Serious [a]	Not serious	Not serious	Not serious	None	433	294	MD 2.36 lower (5.55 lower to 0.83 higher)	Moderate	-

Certainty assessment							№ of patients		Certainty		Comments
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CGM	SMBG	Absolute (95% CI)	Certainty	Comments
6	RCT >13.0 mmol/L	Serious [a]	Serious [c] I^2= 58%,	Not serious	Not serious	None	443	319	MD 4.07 lower (7.67 lower to 0.47 lower)	Low	-
Mortality -											
(3)	RCT Trial registries results	NA	NA	NA	NA	NA	244	149	Not pooled. No deaths in either study group were reported in the trial registries	-	No publications reported this outcome, but 3 trial registries listed mortality as a study endpoint.
Quality of Life – end of intervention (follow-up range from 6 to 12 months; assessed with DQoL and WHO-5, higher scores = better QoL)											
3	RCT	Serious [a]	Serious [c] I^2 = 66%	Not serious	Not serious	None	266	184	SMD 0.1 higher (0.24 lower to 0.45 higher).	Low	-
Diabetes-related late vascular complications (nephropathy, retinopathy, neuropathy, coronary heart disease, peripheral vascular disease, stroke); RCTs follow-up range from X to X; non-RCT follow-up range											
6 (4+2)	RCT	Serious [a]				Two RCTs reported (narratively) no adverse events				Overall, very low	Overall RCTs reporting diabetes-related late vascular complications
2	RCT-Stroke	Serious [a]	Not serious	Not serious	Serious [f]	None	2/156 (1.3%)	1/95 (1.1%)	OR 1.15 (0.14 to 9.21) 2 more per 1,000 (from 9 fewer to 79 more)	Low	-
1	Non-RCT Stroke	Serious [a]	NA	Not serious	Not serious	None	174/6800 (2.6%)	5387/78386 (6.9%)	OR 0.36 (0.31 to 0.41) 43 fewer per 1,000 (from 47 fewer to 39 fewer)	Moderate	Inconsistency not possible to judge - only one included study.

Certainty assessment							№ of patients		Certainty		Comments
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CGM	SMBG	Absolute (95% CI)	Certainty	Comments
1	RCT-Arterial Stenosis	Serious [a]	NA	Not serious	Very serious [g]	None	1/53 (1.9%)	0/57 (0.0%)	OR 3.29 (0.13 to 82.43) 0 fewer per 1,000 (from 0 fewer to 0 fewer)	Very low	As above
1	RCT-Arteriosclerotic heart disease	Serious [a]	NA	Not serious	Very serious [g]	None	1/116 (0.9%)	0/59 (0.0%)	OR 1.55 (0.06 to 38.52) 0 fewer per 1,000 (from 0 fewer to 0 fewer)	Very low	As above
1	RCT-Peripheral Vascular Disease (necrosis of toes)	Serious [a]	NA	Serious [e]	Serious [f]	None	0/33 (0.0%)	1/32 (3.1%)	OR 0.31 (0.01 to 7.98) 21 fewer per 1,000 (from 31 fewer to 173 more)	Very low	As above
1	Non-RCT Peripheral vascular disease	Serious [a]	NA	Not serious	Not serious	None	16/6800 (0.2%)	323/78386 (0.4%)	OR 0.57 (0.34 to 0.94) 2 fewer per 1,000 (from 3 fewer to 0 fewer)	Moderate	As above
1	Acute myocardial infarction	Serious [a]	NA	Not serious	Not serious	None	219/6800 (3.2%)	6174/78386 (7.9%)	OR 0.39 (0.34 to 0.45) 46 fewer per 1,000 (from 51 fewer to 42 fewer)	Moderate	As above
1	Angina	Serious [a]	NA	Not serious	Not serious	None	181/6800 (2.7%)	2905/78386 (3.7%)	OR 0.71 (0.61 to 0.83) 10 fewer per 1,000 (from 14 fewer to 6 fewer)	Moderate	As above
1	Ischemic heart disease	Serious [a]	NA	Not serious	Not serious	None	68/6800 (1.0%)	1327/78386 (1.7%)	OR 0.59 (0.46 to 0.75) 7 fewer per 1,000 (from 20 fewer to 9 fewer)	Moderate	As above
1	Heart failure	Serious [a]	NA	Not serious	Not serious	None	434/6800 (6.4%)	11664/78386 (14.9%)	OR 0.39 (0.35 to 0.43) 85 fewer per 1,000 (from 91 fewer to 79 fewer)	Moderate	As above

Certainty assessment							№ of patients		Certainty		Comments
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CGM	SMBG	Absolute (95% CI)	Certainty	Comments
1	Atrial fibrillation	Serious [a]	NA	Not serious	Not serious	None	167/6800 (2.5%)	3237/78386 (4.1%)	OR 0.59 (0.50 to 0.68) 17 fewer per 1,000 (from 20 fewer to 13 fewer)	Moderate	As above
1	Neuropathy	Serious [a]	NA	Not serious	Very serious [g]	None	2/6800 (0.0%)	40/78386 (0.1%)	OR 0.58 (0.14 to 2.38) 0 fewer per 1,000 (from 0 fewer to 1 more)	Very low	As above
1	Kidney disease	Serious [a]	NA	Not serious	Not serious	None	485/6800 (7.1%)	9329/78386 (11.9%)	OR 0.57 (0.52 to 0.63) 48 fewer per 1000 (from 53 fewer to 41 fewer)	Moderate	As above
1	Retinopathy	Serious [a]	NA	Not serious	Serious [f]	None	14/6800 (0.2%)	183/78386 (0.2%)	OR 0.88 (0.51 to 1.52) 0 fewer per 1000 (from 1 fewer to 1 more)	Low	As above
1	Foot ulcer	Serious [a]	NA	Not serious	Serious [f]	None	4/6800 (0.1%)	114/78386 (0.1%)	OR 0.40 (0.15 to 1.10) 1 fewer per 1000 (form 1 fewer to 0 fewer)	Low	As above

[a] Downgraded one level due to an overall moderate risk of bias in the outcome measurement
[b] Downgraded two levels due to overall serious risk of bias in the outcome measurement
[c] Downgraded one level due to serious inconsistency in the result or in the meta-analysis for this outcome (heterogeneity of between 50% and 70%, potentially indicating substantial heterogeneity)
[d] Downgraded two levels due to very serious inconsistency in the meta-analysis for this outcome (heterogeneity of between 70% and 100%, suggesting considerable heterogeneity)
[e] Downgraded one level due to the outcome being a surrogate endpoint
[f] Downgraded one level due to wide confidence interval, suggesting some uncertainty in the effect estimate
[g] Downgraded two levels due to very wide confidence interval, suggesting substantial uncertainty in the effect estimate
CI: confidence interval; **HbA1c**: glycated hemoglobin or hemoglobin A1c; **MD:** mean difference; **non-RCT**: non-randomized control trial; **RCT**: randomized control trial; **RR:** risk ratio; **SMD**: standardised mean difference; **NA**: not applicable
DiD_1: Difference in Difference provided by Karter 2021; **DiD_2**:Difference in Difference provided by Reaven 2023; **DiD_3**: Difference in difference provided by Nathanson 2024
DQoL: Diabetes Quality of Life questionnaire, 46 items divided into 3 domains, rated on a 5-point Likert scale, lower scores = better QoL
WHO-5: World Health Organization Five Well-Being Index (subjective psychological well-being, 6-point scale from 0 (at no time) to 5 (all of the time), higher scores = better QoL.

Appendix 7: Health economics methods

Estimation of more than 2 complications using event rates from the Swedish Study (3)

Table A7 1: Probabilities for more than 2 complications from 2 complication states

Health state	Complications Remaining	Formula used	Result (Probability)
CVD + Nephropathy	Retinopathy, Neuropathy	(1 - (1 - 0.0007) (1 - 0.0001))	0.0008
CVD + Retinopathy	Nephropathy, Neuropathy	(1 - (1 - 0.0328) (1 - 0.0001))	0.0328
CVD + Neuropathy	Nephropathy, Retinopathy	(1 - (1 - 0.0328) (1 - 0.0007))	0.0335
Nephropathy + Retinopathy	CVD, Neuropathy	(1 - (1 - 0.1048) (1 - 0.0001))	0.1048
Nephropathy + Neuropathy	CVD, Retinopathy	(1 - (1 - 0.1048) (1 - 0.0007))	0.1055
Retinopathy + Neuropathy	CVD, Nephropathy	(1 - (1 - 0.1048) (1 - 0.0328))	0.1368

CVD: cardiovascular disease; ESRD: end-stage renal disease; LEA: lower extremity amputation; Nephropathy: diabetic kidney disease; Neuropathy: diabetic neuropathy; Retinopathy: diabetic retinopathy; T2D: type 2 diabetes.

In Table A7 1 when modelling patients with more than two complications, direct probabilities are rarely available. Therefore, an independent joint probability approach was applied based on methods inspired by binomial distribution functions (183), and using the baseline risks from the Swedish study (3).

The method assumes that each additional complication occurs independently, conditional on the existing complications, and estimates the probability of having at least one of the remaining complications using:

$$P(At\ least\ one\ additional\ complication) = 1 - i = 1\prod n\ (1 - pi)$$

Estimation of the overlapping factor for the cost of two or more than two complications

Figure A7 1 and Table A7 2 provide a figure and numerical example for estimating the overlapping factor. The detailed explanation regarding the method and derivations is outlined below, following the figure and table. It is important to note that the examples are based on an arbitrary number and do not represent the value used as input in the economic model. For the appropriate input value, reference should be made to the method section that presents the cost for various complications.

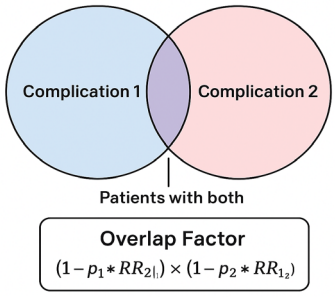


Figure A7 1: Cost overlap adjustment Factor

Table A7 2: Numerical Example of Overlap Factor

Step	Formula	Result
(1)	$(1 - p1 \times RR2\|1) \times (1 - p2 \times RR1\|2) \times (1 - p3 \times RR2\|3)$	0.42768
(2)	Additive cost = = 10,000 + 20,000 + 15,000 = 45,000	45,000
(3)	Adjusted cost = (45,000 × 0.42768)	**19,246 NOK**
(4)	Overlap reduction = 45,000 − 19,246 or 45,000 x (1 – 0.42)	**25,754 NOK (≈57%)**

Description of method

When estimating the combined healthcare costs for patients with two complications, Complication 1 and Complication 2, it is important to account for patients who experience both conditions. Simply adding the costs of Complication 1 and Complication 2 would overestimate total healthcare costs, because patients with both complications would be counted twice.

To correct this, we apply an overlap adjustment factor that incorporates the increased risk of one complication given the presence of the other. The adjusted cost can be calculated as:

$$\{Adjusted\ Cost\} = (c\_1 + c\_2) \times ⊦[\,(1 - p\_1 \times RR\_\{2|1\}) \times (1 - p\_2 \times RR\_\{1|2\})\,⊣]$$

Where:

$\boldsymbol{c1}\ and\ \boldsymbol{c2}$ are the costs of Complication 1 and Complication 2.

$\boldsymbol{p1}\ and\ \boldsymbol{p2}$ are the baseline probabilities of Complication 1 and Complication 2.

$\boldsymbol{RR2|1}$ is the relative risk of Complication 2 given Complication 1.

$\boldsymbol{RR1|2}$ is the relative risk of Complication 1 given Complication 2.

$(1 - p1 \times RR2|1) \times (1 - p2 \times RR1|2)$ estimates the proportion of patients who do not have both complications and is used as the overlap scaling factor for the additive cost of $c1 + c2$, joint cost.

Consequently, $1 - [(1 - p1 \times RR2|1) \times (1 - p2 \times RR1|2)]$ represents the proportion of patients who have at least one of the two complications. By applying this scaling factor to the additive cost, we adjust for the overlap and avoid double-counting the costs for patients with both conditions.

This method was also applied to all joint complication health states in the model for more than two complications. This method conservatively adjusts additive costs by removing the overlap due to patients with both complications, and it is widely recommended in health economic evaluations to adjust costs for multimorbidity (184).

Estimation of joint disutilities for combination of complications, more than two complications, ESRD, and LEA

Table A7 3 provides a numerical example for the estimation of joint disutilities and for other health states that include more than two complications. The example provides an explanation of the method described below. It is important to note that the numbers used in the table are arbitrary and are not input values used in the economic model. The input variables in the model are listed in the method section of the report under Utility values.

Table A7 3: Joint Disutility Estimation for more than one complication

Health states	Input HSUVs	Formula	HSUV combined	Disutilities combined = 1 – HSUV combined	Notes
Two complications	CVD = 0.80 Neuropathy = 0.70	0.80 × 0.70	0.56	0.44	Each new complication reduces remaining health proportionally.
Three complications	CVD = 0.80Neuropathy = 0.70Retinopathy = 0.90	0.80 × 0.70 × 0.90	0.504	0.496	Simple multiplicative model for 3 concurrent conditions.
Four complications	CVD = 0.80Neuropathy = 0.70Nephropathy = 0.75Retinopathy = 0.90	0.80 × 0.70 × 0.75 × 0.90	0.378	0.622	Extends the same logic for all 4 major diabetes complications.
ESRD + 2 others (with dampening)	ESRD = 0.50Neuropathy = 0.70Retinopathy = 0.90B = 0.5	0.50 × (0.70^0.5) × (0.90^0.5)= 0.50 × 0.837 × 0.949	0.397	0.603	Dampening (B=0.5) reduces the marginal effect of added complications.
LEA + 2 others (stronger dampening)	LEA = 0.45Neuropathy = 0.70Retinopathy = 0.90B = 0.3	0.45 × (0.70^0.3) × (0.90^0.3)= 0.45 × 0.899 × 0.965	0.391	0.609	Heavier dampening (B=0.3) limits additional disutility impact.

B: dampening factor applied to moderate the impact of additional complications; CVD: cardiovascular disease; ESRD: end-stage renal disease; HSUV: health state utility value; LEA: lower extremity amputation; Nephropathy: diabetic kidney disease; Neuropathy: diabetic neuropathy; Retinopathy: diabetic retinopathy.

Description of the method

In Table A7 3 model adjusted health state utility values (HSUVs) for multiple concurrent complications using a multiplicative approach adapted from Brazier et al. (91). This method accounts for the fact that the impact of each additional condition on HRQoL depends on the remaining health after accounting for other conditions, rather than applying absolute reductions or additive reductions.

For health states comprising **two complications**, the disutility (DU) was calculated using the following formula:

$$AHSUV_{combined} = HSUV_{base} \times \prod_{i=1}^{n} \frac{HSUV_i}{HSUV_{base}}$$

$HSUV_{base}$ = baseline utility (no complications) assumed to be 1 for simplification as DU generated are applied in the model built in TreeAge pro.

$HSUV_i$= utility value for each complication I calculated as $(1 - disutility)$ for each complication j

n = number of complications in the combination

The combined disutility was then expressed as:

$$DUcombined = 1 - HSUVcombined$$

For health states with **three or more complications**, the multiplicative approach was extended to incorporate all four major diabetes-related complications in the model — retinopathy, nephropathy, neuropathy, and cardiovascular disease (CVD). The combined HSUV was calculated as:

$$HSUV_{combined} = HSUV_{base} \times \prod_{i=1}^{4} \frac{HSUV_i}{HSUV_{base}}$$

The disutility was then obtained as $DUcombined = 1 - HSUVcombined\ where\ HSUVbase = 1$ for simplification. This preserves proportionality while avoiding implausibly low utility values for multimorbidity.

For severe complications that have a substantial impact on HRQoL, specifically ESRD and LEA, we developed an original extension of the multiplicative method that incorporates a dampening factor to account for diminishing marginal disutility.

This approach is based on the economic principle of diminishing marginal utility, which suggests that the incremental negative effect of an additional adverse condition is reduced when an individual has already experienced a severe health loss. Clinically, this reflects both adaptation to severe health states and ceiling effects in utility loss, consistent with observed patterns in QALY estimation [ref: health state adaptability].

In this approach:

$$HSUV_{\text{combined}} = HSUV_{Severe} \times \prod_{j=1}^{m} \left(HSUV_j\right)^B$$

Expanded: $HSUVcombined = HSUVS \times (HSUV_1)^B \times (HSUV_2)^B \times (HSUV_3)^B \times (HSUV_4)^B \ldots . j$

Where:

$HSUVS$= $HSUV$ of the severe complication (e.g., ESRD, LEA)

$HSUVj$= $HSUV$ of each additional coexisting complication

B = dampening factor $(0 < B \leq 1)$

m = number of additional complications

In this approach $HSUVS$ the utility value for the health state resulting after adjusting for the disutility from the severe complication, $HSUVj$ are the utilities of after adjusting for additional coexisting complications, and B is a dampening factor $(0 < B \leq 1)$. For LEA, B was set to 0.3, and for ESRD, B

was set to 0.5. This formulation ensures that the dominant impact of severe complications is preserved as the high-impact conditions dominate utility loss, while the marginal effect of additional conditions is proportionally reduced. The combined disutility is estimated by the subtraction of $HSUV\ combined$ from a perfect health state value of 1.

Appendix 8: Budget Impact

Table A8 1: Unit Cost of summary for budget impact

	Costs (NOK)
Initiating and training costs (personnel costs)	1,340
CGM	[redacted]
SMBG cost for intervention	188
Follow-up cost (personnel costs at hospital)	6,372
Follow-up (personnel costs at primary healthcare)	5,882
SMBG (annual cost)	7,898

CGM: Continuous glucose monitoring; SMBG: Self-monitoring blood glucose
Numbers are rounded.

Subpopulations

Table A8 2: Cost for SMBG for subpopulations

Cost of SMBG	2026	2027	2028	2029	2030
Individuals with T2D on MDI who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses	18,300,000	19,600,000	20,800,000	22,100,000	23,400,000
Individuals with insulin-treated T2D who have experienced more than one episode of severe hypoglycaemia in the past year	1,800,000	2,000,000	2,100,000	2,200,000	2,300,000
Individuals with insulin-treated T2D whose profession involves safety-critical roles	9,200,000	9,800,000	10,400,000	11,100,000	11,700,000
Individuals aged <60 years with insulin-treated T2D and diagnosed with intellectual disabilities	1,800,000	2,000,000	2,100,000	2,200,000	2,300,000
Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period	7,300,000	7,800,000	8,300,000	8,800,000	9,400,000

Total Cost of SMBG	38,500,000	41,100,000	43,800,000	46,400,000	49,100,000

T2D: Type 2 diabetes; SMBG: Self-monitoring blood glucose
Numbers are rounded.

Table A8 3: Budget Impact for each subpopulation for the Norwegian Healthcare System

Budget Impact (CGM vs. SMBG)	2026	2027	2028	2029	2030
Individuals with T2D on MDI who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Individuals with insulin-treated T2D who have experienced more than one episode of severe hypoglycaemia in the past year	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Individuals with insulin-treated T2D whose profession involves safety-critical roles	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Individuals aged <60 years with insulin-treated T2D and diagnosed with intellectual disabilities	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total budget impact (all subgroups) for the Norwegian healthcare	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

T2D: Type 2 diabetes; CGM: Continuous glucose monitoring; SMBG: Self-monitoring blood glucose
Numbers are rounded.

Appendix 9: Education Component and/or contact (visits) for CGM vs SMBG groups

Author	Baseline/both groups	Education and/or visits intervention	Education and/or visits control
Ajjan 2016 SIGN study Follow up: ~3 months (100 days)	This study evaluated a structured approach combining CGM with reviewing and explaining the ambulatory glucose profile (AGP) by a Health Care Professional (HCP), followed by appropriate adjustment in insulin therapy. All patients participated in 15-day baseline phase. Individuals have previous experience with insulin management and carbohydrate counting. Contact at days 30 and 45 to adjust their insulin therapy.	FreeStyle Libre was unmasked Educational discussions with HCPs focused on adjusting insulin doses, with priority given to hypoglycaemic episodes through insulin reduction, re-education on carbohydrate counting, and addressing the effects of exercise. Adjustments were also made to long-acting insulin for fasting hyperglycaemia and bolus insulin for post-prandial elevated glucose levels. The CGM devices in this group had alarms switched off to focus on the effect of profile review.	FreeStyle Freedom Lite. FreeStyle Libre was masked. Patients relied on capillary glucose testing for daily glucose assessment HCPs conducted reviews and made recommendations in line with current standards of care
Aleppo/Martens 2021 MOBILE study Two-phase study, basal insulin, primary care management Follow up; 8 months, + 6 months.	The study involved substantial contact with study clinicians who provided advisory expertise, HCP included a physician, nurse Practitioner, physician's assistant, or diabetes educator experienced in glucose data review, and communication directed toward the patient's community treating clinician (Primary Care Physician/PCP). All participants underwent an initial study entry and run-in visit, during which they wore a blinded CGM for 10 days to collect baseline data. Participants were trained on a study-assigned blood glucose meter. Participants were scheduled for, or referred to, one or two general diabetes education sessions (individual or group) consistent with the site's usual diabetes educational program during the run-in period.	The study clinicians' role was advisory, providing insights and interpretations of glucose data and formally communicating recommendations to participants and their PCPs. PCPs were responsible for making actual medication changes. Phase 1 Visits/Contacts: This group had 4 scheduled clinic visits (at Week 2, Month 1, Month 3, and Month 8) and had scheduled 3 phone/remote contacts (at Months 2, 4, and 6) with the study team. At each visit/contact (except Month 3), study clinicians discussed device issues, uploaded glucose data, provided suggestions on self-titration of basal insulin, offered treatment guidelines based on observed glucose patterns, and encouraged lifestyle experimentation and modifications to minimise glycaemic excursions.	Participants received training on how to use a study-assigned Bluetooth-enabled blood glucose meter. The group wore blinded CGM devices periodically (at month 3 and pre-month 8) for data collection purposes only. Phase 1 The SMBG group had 5 scheduled clinic visits (Week 2, Month 1, Month 3, Pre-Month 8, and Month 8). This included an additional visit (Pre-Month 8) compared to the CGM group during Phase 1 Device Use: performing tests 1-3 times daily, including fasting and post-prandial measurements. Educational/Management activities: Participants managed blood glucose using the provided standard SMGM. Study clinicians troubleshot devices and provided suggestions on self-titration

	Key aspects of diabetes management covered included: • Individualised glucose targets (fasting, pre-meal, and post-meal ranges). • Basics of basal insulin titration. • Basics of meal planning. • Hypoglycaemia management. • The importance of medication adherence	Communication with PCPs: After most clinic or virtual visits, study clinicians sent a letter to the participant's PCP, including the glucose data record and management suggestions. Phase 2 Visits/Contacts: This group had 1 phone contact (at Month 11) and 1 clinic visit (at Month 14). Educational/Management Activities: participants received similar guidance from study clinicians regarding therapy adjustments, lifestyle, and interpretation of glucose patterns. Communication letters were sent to PCPs and participants Communication with PCPs: Communication letters containing CGM data interpretation and recommendations were sent to PCPs and participants Participants continued real-time CGM use and were continually encouraged to share their data with followers	of basal insulin, treatment guidelines based on observed glucose patterns, and encouraged lifestyle modifications based on the SMBG data. Data records, interpretation, and recommendations were communicated to PCPs and participants via letters Communication with PCPs: Glucose data records (SMBG data) and management suggestions were communicated via letters to PCPs and participants, similar to the CGM group. Phase 2 This group had one virtual visit by phone after 3 months (Month 11) and a single study follow-up clinic visit after 6 months (Month 14). SMBG groups required an additional visit (Pre-Month 14) to place a blinded CGM sensor for data collection prior to the final visit. Month 11 phone and remote contact Communication with PCP.
Beck 2017 DIAMOND study Follow up: 6 months	All participants underwent a 4-week run-in period to ensure they met study criteria, could consistently upload blood glucose monitoring data, and were able to complete study visits. During this baseline phase, participants performed SMBG testing an average of at least 2 times per day. They were asked to calibrate the blinded CGM device at least twice per day and log blood glucose meter results at least twice per day. They also recorded insulin, food, and exercise.	Dexcom G4 Platinum CGM system Participants received general counselling about using CGM and received individualised recommendations about incorporating CGM data to adjust blood glucose management. The CGM group had 2 additional visits, 1 week before the Week 12 and Week 24 visits (i.e., Week 11 and Week 23), for a total of 4 visits after randomisation (Weeks 4, 12, 24, plus the preceding contacts). Insulin adjustment: the study involved a structured protocol utilizing CGM to optimise insulin dosing - 3 months of high-contact support involving a limited number of phone calls and online contacts.	The control group had 3 visits after randomisation (Weeks 4, 12, and 24). The control group wore a blinded CGM device for 2 weeks before the Week 12 and Week 24 visits for monitoring purposes.

		The intervention provided more frequent visits (4 primary outcome visits vs. 3 for control).	
Bergenstal 2022 REACT3 Follow up: 4 months	Baseline (14 days blinded CGM, following 2–4 weeks run-in): A run-in period (2–4 weeks) occurred before the baseline visit. Participants had a baseline visit following the run-in. Subjects were followed for 16 weeks, with endocrinology clinic visits occurring once every 4 weeks. Therapy adjustments were made during these visits. Participants received instruction on how to use the Aviva blood glucose monitor study meter for calibration measurements four times daily. Subjects wore a blinded DexCom SevenPlus CGM for the 14-day baseline period. During the run-in, subjects received therapy adjustments, such as adding incretins or titrating metformin.	Subjects received basic education on CGM data usage for making dietary or medication adjustments. The clinician and patient reviewed the AGP: CGM report during each visit to assist with therapy changes. This report collapsed 4 weeks of CGM data into a single modal day graphic. Treatment decisions were based on a point of care A1c and the AGP: CGM profile report.	Subjects were asked to perform structured SMBG four times per day. At each visit, SMBG data was downloaded. Subjects received three 7-point blood glucose profiles (the 360 View) at each visit, which serves as a tool for experiential learning and clinical decision-making. Masked CGM was used for 2 weeks prior to the week 8 and week 16 visits, but this CGM data and corresponding AGP reports were not seen by the clinician or the subject. Treatment decisions were based on a point of care A1c and the structured SMBG data
Haak 2017 REPLACE study Follow up: 6 months	All participants wore the flash glucose-sensing system in masked mode (sensor glucose measurements were not visible to participants or investigators). Participants were asked to scan their sensor every 8 hours. Glucose management was supported by continuing their current SMBG regimen using a strip-port built into the reader. Participants were instructed to record blood glucose levels and other events (e.g., severe hypoglycaemia) in a diary.	Participants had two scheduled visits between randomisation and Day 194 (the end of the treatment phase). They also had an unscheduled safety visit on Day 45 because the device was not commercially available when the study began. The sensor system was unblinded for continuous use of sensor glucose data for self-management, including insulin dose decisions, according to product labelling. Crucially, no specific training was provided to these participants regarding the interpretation of sensor glucose data. Historical data was uploaded at subsequent study visits. The HCP reviewed glucose reports (including the AGP) with the participant. Discussions included reviewing glucose control, effects of diet/lifestyle on glucose trends, and insulin dose modifications. Insulin adjustments were guided by common clinical principles (e.g., avoidance of hypoglycaemia, optimizing fasting glucose), reflecting "real-world" practice, as there was no preset algorithm mandated by the protocol.	Participants had two scheduled visits between randomisation and Day 194 (at Day 105 and Day 194). Participants self-managed glucose utilising a standard blood glucose device and recorded values in a glucose diary for the study duration. SMBG frequency remained consistent, averaging approximately 3.8 tests/day. They wore a blinded sensor again for the final 2 weeks of the study for data collection. The HCP reviewed glucose control and discussed insulin dose modifications based on common clinical principles during visits.

Kim 2024 FreEdoM-2 Follow Up> 6 months	All participants underwent blinded CGM. During this baseline period, participants were asked to perform SMBG for 2 weeks.	Participants received structured education delivered by clinicians/educators. Structured education sessions were provided at Baseline, Weeks 4, 8, 12, and 18, resulting in five total sessions over 24 weeks. The sessions at Baseline, 4, 8, and 18 weeks were delivered face-to-face or virtually via telephone calls The intervention involved using isCGM, and the clinician and patient reviewed the graphical patterns of CGM (AGP) during the structured education. The goal was adjustment of the insulin dose and timing. The program included individualised education based on blood glucose levels and the graphical patterns provided by the CGM. The education reviewed the timing and dose of pre-meal rapid-acting insulin bolus to achieve a postprandial glucose excursion. Participants received education on carbohydrate counting and how to review glucose patterns to ensure glucose levels return to target after 4 hours of meal/insulin dose.	Participants received conventional education at Baseline, 12 weeks, and 24 weeks, totalling three sessions over 24 weeks. Sessions were delivered face-to-face or virtually via telephone calls - Conventional education included instructions regarding the adjustment of insulin dose according to blood glucose level
Lever 2024 2GO-CGM Follow up: 3 months	Participants had baseline data collected and underwent a 2-week run-in phase during which a blinded CGM was fitted - participants' diabetes care was assumed by prescribing diabetes nurse specialists (DNS) working under the supervision of an endocrinologist for the study duration. At the baseline appointment and/or during the run-in phase, the prescribing DNS maximised cardiovascular risk and non-insulin glucose-lowering medications for all participants.	Participants received remote reviews with prescribing DNS at Weeks 2 and 8 for further insulin adjustments. Participants received training on the Dexcom G6 system. Training included the interpretation of alerts, trend arrows, and graphs. Insulin dosing/regimen advice was provided by the prescribing DNS based on the blinded CGM data at the randomisation appointment	Participants were trained on and used the CareSens premier meter for SMBG – they used SmartLog® software to view and export glucose results to the DNS. Participants had remote reviews with prescribing DNS at Weeks 2 and 8 for further insulin adjustments. Participants were asked to conduct SMBG four to seven times per day. The DNS advised on insulin dosing/regimen based on blinded CGM data at the randomisation appointment.
Lind 2021 Steno2tech	Participants attended two pre-study visits; wore a blinded CGM device (DexCom G6) for a 10-day period before randomisation; they received both spoken and written information about the blinded CGM, including instructions	Participants were followed by their usual healthcare providers (including 8 endocrinologists and 10 diabetes-specialised nurses) every third month at the outpatient clinic. A total of eight visits during the 12-month study period (plus two pre-study visits). Treatment	Participants attended the same number of clinical visits (five follow-up visits planned during the 60 weeks' study period) and follow-up as the intervention groups, conducted by their usual

Follow up: 12 months	on how to insert and wear the device, and skin preparation. After randomisation, participants attended a 3-hour training course unique for their allocation group. All participants received education on health behaviour, the influence of different food items and exercise on glucose levels, and how to measure SMBG correctly.	intensification was performed by a specialist in diabetology specifically experienced in treating T2D. Participants in the intervention group received a CGM education and training session led by the study investigator. This training was interactive and hands-on, using case studies. Instructions were given on how to insert and wear the DexCom G6 and how to interpret CGM information to better understand the relationship between glucose and diabetes self-management. Group B participants received peer support facilitated by the primary investigator in group sessions (four to six participants). There were three sessions over the study period, each lasting 3 hours. The sessions involved customised participatory methods and peer exchange.	healthcare providers every third month at the outpatient clinic. Participants were asked to measure their blood glucose as usual as agreed with their usual healthcare provider. SMBG measurements varied from 1 to 7 measurements per day, depending on the individual's medical treatment and current glycaemic control, following clinical guidelines. Participants used their own SMBG device and were reinstructed in the test procedure.
Yaron 2019 Follow up: 2.2 months (10 weeks)	The study included an initial visit for screening and a 2-week run-in period for insulin dose stabilisation. Participants were required to be willing to complete daily blood glucose tests, seven times a day, at least 1 day a week. The total contact time (face-to-face and phone visits) with HCPs was kept the same in both groups. Participants had frequent face-to-face visits and telephone calls with HCPs. Scheduled follow-up occurred at Weeks 2, 4, 6, and 10	The intervention group used the FreeStyle Libre system and was instructed to scan at least every 8 hours. The data were downloaded every 2–4 weeks as required by the study protocol. Participants received the same amount of counselling (approximately 30 minutes) as the control group. Counselling included diabetes management instructions and a detailed carbohydrate counting consultation from trained diabetes nurses and a dietitian	Participants were instructed to maintain their routine SMBG using glucometers at least four times a day. They were asked to perform 7-point blood glucose levels 1 day each week to evaluate asymptomatic hypoglycaemic events. The control group received the same amount of counselling and the same detailed carbohydrate counting consultation from trained diabetes nurses and a dietitian.

AGP: ambulatory glucose profile; DNS: diabetes nurse specialist; HCP: health care professional; isCGM: intermittent continuous glucose monitoring; CGM: continuous glucose monitoring; PCP: primary care physician; SMBG: self-monitored blood glucose; T2D: Type 2 diabetes

Appendix 10: Input from the Norwegian Diabetes Association

Spørreskjema for pasient- og brukerorganisasjoner for innsending av innspill til metodevurderinger

(Oversatt og tilpasset versjon av skjemaene utarbeidet av Health Technology Assessment (HTAi) som er tilgjengelig her)

Direktoratet for medisinske produkter

Metodevurdering av

kontinuerlig glukosemåling ved diabetes type 2 som behandles med insulin

Formålet med dette skjemaet

Pasienter og pårørende har unik kunnskap om hvordan det er å leve med en bestemt sykdom eller medisinsk tilstand. De kan beskrive fordeler og ulemper ved behandlingstiltak som ikke blir rapportert i publisert forskning, og i tillegg beskrive hva de vil verdsette mest ved metoden under vurdering. Denne erfaringsbaserte kunnskapen er verdifull for de som gjennomfører metodevurderinger (engelsk: health technology assessment, HTA).

Dette skjemaet er utarbeidet for å hjelpe pasient- og brukerorganisasjoner med å gi erfaringsbasert informasjon til vurdering av en bestemt metode. Skjemaet forsøker å fange opp erfaringskunnskap som er til nytte i vurderingsprosessen til de som utfører selve metodevurderingen.

Informasjon om pasient- eller brukerorganisasjonen

Navn på organisasjon: Diabetesforbundet
Kontaktperson: Cecilie Roksvåg

Rolle: Forbundsleder

Epostadresse: cecilie.roksvaag@diabetes.no Telefon: 41436720

Postadresse: Postboks 6442, Etterstad, 0605 Oslo

Type gruppe (merk alle gjeldende):

☒ Interesseorganisasjon

☐ Uformell selvhjelpsgruppe
☐ Annet, vennligst oppgi: _____

Hensikt med gruppe (merk alle gjeldende):

☐ Støtte ☒
☐ Opplæring ☒
☐ Politisk arbeid ☒
☐ Forskning ☒
☐ Annet, vennligst oppgi: _____

Beskriv organisasjonen (antall og type medlemmer (pasienter, pårørende o.a.), alder, kjønn osv.), finansieringskilder, osv.

Diabetesforbundet er en uavhengig interesseorganisasjon for alle med diabetes og de som er berørt av eller interessert i diabetes. Per 19.03 teller vi cirka 32 700 medlemmer, hvorav 14 000 har diabetes type 2 og 11 000 har diabetes type 1, i tillegg til cirka 1900 medlemmer som er helsepersonell, og 1600 medlemmer som er pårørende. 57 prosent av medlemsmassen vår er over 60 år. 55 prosent er kvinner.

Diabetesforbundet finansieres med medlemskontingent, gaver og arv, sponsing fra legemiddel- og utstyrsleverandører, samt tilskudd knyttet til drift og prosjekter fra eksempelvis Bufdir, Helsedirektoratet, Norsk Tipping og Stiftelsen DAM.

Hvilke informasjonskilder er innspillet i dette skjemaet basert på? Oppgi kilder der det.

Erfaringer fra sekretariatetes kontakt med medlemsmassen, tillitsvalgte og helsepersonell danner grunnlag for mye av vår kunnskap.

Diabeteslinjen er Diabetesforbundets hjelpetelefon som får drøyt 3000 henvendelser i året. 90 prosent av henvendelsene gjelder diabetes type 2. Diabeteslinjen fører statistikk over henvendelser og hva de gjelder. Sykepleierne på Diabeteslinjen er også i kontakt med ulike pasient- og helsepersonellgrupper gjennom foredrag, kursing og deltakelse på faglige seminarer.

Diabetesforbundet har rundt 700 aktive tillitsvalgte som selv har diabetes eller er pårørende til noen med diabetes. Cirka 120 tillitsvalgte er også likepersoner som gir personlig støtte til andre med diabetes og pårørende. Likepersoner og tillitsvalgte er i kontakt med mange med diabetes type 2.

Diabetesforbundet har flere faglige råd og utvalg med bred representasjon fra helsepersonellgruppen, fra endokrinologer og diabetessykepleiere, til allmennleger og psykologer. Det er også brukerrepresentanter i utvalgene. Generelle erfaringer fra fagpersonenes kontakt med pasientene formidles kontinuerlig til oss i Diabetesforbundet gjennom kontakt i jevnlige utvalgsmøter og i øvrig jevnlig dialog.

Mye av vår kunnskap om diabetes type 2-gruppen, dennes demografi og behov, samt potensielle nytte av CGM baserer seg på undersøkelser, studier og forskning, herunder:

- **Demografi og behandling**: I Norge har omtrent 316 000 til 345 000 personer diabetes, ifølge tall fra FHI. Av disse har rundt 90 % diabetes type 2. Diabetes type 2 kan ramme personer i alle aldre, men de fleste utvikler sykdommen når de er over 40 år. Sykdommen er sterkt genetisk betinget, men kan utløses av usunne levevaner og overvekt. Stor ulikhet karakteriserer sykdomsbyrden ved diabetes type 2, hvor spesielt etniske minoriteter og pasienter med lav sosioøkonomisk status har høyere risiko for å utvikle sykdommen – samtidig som lavere helsekompetanse kan føre til mangelfull oppfølging. Det er med andre ord mange svært sårbare grupper som er i en situasjon der de selv skal behandle sykdommen sin, ofte basert på lite til ingenting av forkunnskap, ofte manglende opplæring og i møte med pressede fastleger med varierende innsikt i diabetes.

Kilder:

- Hvor mange har diabetes i Norge i 2020?
- Diabetes og retningslinjer i praksis
- Sosiale helseforskjeller i Norge
- Helsekompetansen i fem utvalgte innvandrergrupper
- Self management of type 2 diabetes among Turkish immigrants in Norway A focus group study

- **Kostnader**: Diabetes type 2 i Norge En analyse av forekomst, sykdomsbyrde, behandling og samfunnsvirkninger – en rapport utviklet av Oslo Economics på oppdrag fra Novo Nordisk
- **Psykisk belastning:**
  - Diabetes distress: the psychological burden of living with diabetes
  - Associations between generalised anxiety disorder, glycaemic management, and demographic factors among adults with diabetes in Europe
  - Forskning om voksne pårørende
- **Relevant øvrig forskning:**
  - Removing barriers to management of adults with type 2 diabetes on insulin using continuous glucose monitoring in UK primary care practice: An expert consensus
  - Effectiveness of continuous glucose monitoring in patient management of Type 2 Diabetes Mellitus: an umbrella review of systematic reviews from 2011 to 2024
  - Experiences With a Novel Micro-Choice-Based Concentrated Group Intervention for People With Type 2 Diabetes: A Qualitative Study
  - High number of hypoglycaemic episodes identified by CGM among home- dwelling older people with diabetes: an observational study in Norway
  - Intermittent use of continuous glucose monitoring in type 2 diabetes is preferred: A qualitative study of patients' experiences. The Science of Diabetes Self-Management and Care

Dersom du svarer på skjemaet som privatperson: hjalp noen deg med å fylle ut dette spørreskjemaet?
JA ☐ / NEI ☒

Hvis ja, vennligst oppgi hvem som hjalp deg og på hvilken måte:

[Svar her]

Vi ønsker å belyse brukerperspektivet i metodevurderingsrapportene. Dette kan gjøres på ulike måter. Hvis aktuelt, godkjenner dere at dette innspillet bli lagt ved metodevurderingsrapporten i sin helhet?
JA ☒ / NEI ☐

Merk: I tråd med hvordan vi behandler alle bidragsytere i metodevurderinger skal taushetserklæring og habilitetsskjema fylles ut.

Tilstandens påvirkning

Hvordan påvirker tilstanden eller sykdommen pasientenes livskvalitet?

Diabetes type 2 er en kronisk sykdom som krever kontinuerlig oppmerksomhet og egenbehandling, noe som kan ha stor innvirkning på pasientenes livskvalitet. Hverdagen preges av en rekke utfordringer knyttet til sykdomshåndtering, psykisk og fysisk helse, sosial deltakelse og økonomiske aspekter.

En kontinuerlig 24-timers utfordring

Diabetes type 2 krever daglige beslutninger knyttet til kosthold, fysisk aktivitet, medisinering og håndtering av stress. Pasienter må konstant vurdere hvordan ulike faktorer påvirker blodsukkeret, noe som kan være både mentalt og fysisk utmattende.

- **Måltider må planlegges nøye**, noe som kan være ekstra krevende i sosiale sammenhenger.
- **Fysisk aktivitet kan være utfordrende**, da feil balanse mellom trening og matinntak kan føre til blodsukkersvingninger.
- **Følelsesmessige svingninger og stress påvirker blodsukkeret**, noe som gjør det vanskelig å opprettholde stabil regulering.

Begrensninger i hverdagen

Diabetes kan føre til at enkelte aktiviteter blir vanskeligere eller må unngås helt:

- **Arbeidssituasjon**: Stress, skiftarbeid og uforutsigbare arbeidsdager kan gjøre det utfordrende å regulere blodsukkeret. Mange opplever redusert arbeidsevne eller må tilrettelegge arbeidshverdagen.
- **Sosialt liv**: Mange synes det er vanskelig å håndtere diabetes i sosiale sammenhenger, spesielt i forbindelse med mat eller spontane aktiviteter. Noen unngår restaurantbesøk eller middager i frykt for å måtte forklare sykdommen.
- **Bilkjøring**: Risikoen for plutselige blodsukkersvingninger kan gjøre enkelte usikre på om de kan kjøre trygt.
- **Fysisk aktivitet**: Trening og mosjon kan være utfordrende hvis blodsukkeret blir for lavt eller høyt, noe som kan føre til redusert deltakelse i sport og fritidsaktiviteter.

Psykisk belastning og stigma

Diabetes type 2 er ikke bare en fysisk sykdom, men påvirker også den mentale helsen:

- **Redsel for lavt blodsukker**: Mange opplever angst knyttet til hypoglykemi, spesielt om natten. Dette kan føre til søvnforstyrrelser og redusert livskvalitet.
- **Skam og sosialt stigma**: Noen føler seg ukomfortable med å måle blodsukker eller sette insulin i det offentlige rom. De kan oppleve fordommer eller misforståelser knyttet til sykdommen.
- **Følelse av utilstrekkelighet**: Når behandlingsmål ikke nås, kan pasienten føle at de ikke gjør en god nok jobb, selv om sykdommen er kompleks og påvirkes av mange faktorer.

Håndtering av diabetes i kombinasjon med andre sykdommer

Mange pasienter med diabetes type 2 har også andre medisinske tilstander, som høyt blodtrykk, hjertesykdom eller depresjon. Dette kan gjøre blodsukkerreguleringen enda vanskeligere:

- **Noen medisiner kan øke blodsukkeret**, noe som gjør behandlingen mer komplisert.

- **Flere helseutfordringer kan øke behovet for støtte og oppfølging**, både fra helsepersonell og pårørende.
- **Fatigue og kroniske smerter** kan redusere evnen til å følge opp behandling og sunn livsstil.
- **Alderdom**: Eldre kan ha nedsatte fysiske eller kognitive evner som gjør det vanskeligere for dem å følge opp egen diabetes. De blir da mer avhengige av sine pårørende eller helsepersonell dersom de har hjemmesykepleier eller bor på institusjon.

Økonomiske utfordringer

Diabetesbehandling kan være kostbar:

- **Måleutstyr kan være dyrt**, og ulik prakis kan føre til uheldige ulikheter i behandling, basert på sosioøkonomisk status. På CGM-området ser vi at flere ressurssterke med type 2 bekoster CGM privat. Dette bidrar til et økt klasseskille i helsetjenesten.
- **Tap av inntekt** kan oppstå dersom pasienten blir sykemeldt eller ufør som følge av komplikasjoner.
- **Samfunnskostnader**: Diabetes type 2 koster helsevesenet milliarder i behandling, sykehusinnleggelser og tapte arbeidsdager.

Hvordan kan ny teknologi som CGM forbedre livskvaliteten?

Flere med type 2 vil kunne oppleve at CGM reduserer stress og forenkler behandlingen. Bruk av kontinuerlig glukosemåling (CGM) kan gi:

- **Mindre behov for fingerstikk**, noe som gjør hverdagen enklere.
- **Tidlig varsling om blodsukkersvingninger**, slik at pasientene kan ta grep før de blir for høye eller lave.
- **Bedre kontroll over blodsukkeret**, noe som kan redusere symptomer som tretthet, humørsvingninger og konsentrasjonsproblemer.
- **Bedre forståelse for eget blodsukker** og hva som påvirker det, som igjen kan gi bedre egenbehandling og økt psykisk trygghet.
- **Lavere risiko for alvorlige komplikasjoner**, som kan føre til færre sykehusinnleggelser og bedre arbeidsevne.

Oppsummering

Diabetes type 2 påvirker livskvaliteten på flere måter – fysisk, psykisk, sosialt og økonomisk. Kontinuerlig oppfølging, egenbehandling og frykt for komplikasjoner kan føre til stress, usikkerhet og begrensninger i hverdagen. Bedre behandlingsalternativer, inkludert bruk av CGM, kan bidra til økt trygghet, bedre sykdomsregulering og redusert belastning på pasientene.

Hvordan påvirker tilstanden pårørende?

Pårørende som støtter pasienter med diabetes type 2, møter flere utfordringer, særlig fordi sykdommen krever kontinuerlig egenbehandling og levevanejusteringer. Her er noen av de viktigste utfordringene de kan oppleve:

Begrenset innflytelse på behandlingen

Diabetes type 2 er en sykdom som krever at pasienten selv tar ansvar for blodsukkerregulering, kosthold og medisinering. Pårørende kan ofte føle seg maktesløse, spesielt når de ser at pasienten sliter med å følge opp anbefalingene fra helsepersonell.

Manglende innsyn i blodsukkerverdier

Uten tilgang til oppdatert informasjon om pasientens blodsukkerverdier, er det vanskelig for pårørende å vite når de skal gripe inn eller tilby støtte. Dette er spesielt utfordrende for eldre pasienter som bruker insulin, da de er mer utsatt for blodsukkersvingninger og akutte komplikasjoner som hypoglykemi.

Bekymring for akutte situasjoner

Pårørende kan være redde for at pasienten får føling (hypoglykemi) eller svært høyt blodsukker (hyperglykemi), særlig hvis pasienten bor alene. Denne bekymringen kan føre til stress og en konstant følelse av å måtte være på vakt.

Pasientens autonomi kontra behovet for støtte

Mange pasienter ønsker å være selvstendige og kan oppleve pårørendes involvering som inntrengende. Dette kan skape konflikter og gjøre det vanskelig å finne en balanse mellom å respektere pasientens autonomi og sikre god oppfølging.

Manglende kunnskap om sykdommen

Pårørende har ofte begrenset medisinsk kunnskap om diabetes type 2 og hvordan ulike faktorer som mat, stress og aktivitet påvirker blodsukkeret. Uten tilstrekkelig opplæring kan det være utfordrende å gi riktig støtte.

Belastning på pårørende

Å være en støttespiller for en diabetespasient kan være krevende, særlig for pårørende til eldre pasienter som trenger omfattende hjelp. Mange pårørende opplever økt stress og følelsesmessig belastning, noe som kan påvirke deres egen helse og livskvalitet.

Teknologiens rolle – Sensorer som støtteverktøy

Bruk av kontinuerlige glukosesensorer kan gi pårørende bedre innsikt i pasientens glukosenivåer og gjøre det enklere å bistå med behandlingen. Dette er spesielt viktig for eldre insulinbrukere, der tidlig oppdagelse av blodsukkersvingninger kan forebygge alvorlige helsekomplikasjoner. Med sanntidsdata kan pårørende bidra på en mer effektiv og trygg måte, samtidig som pasientens selvstendighet respekteres.

Pårørende til personer med diabetes type 2, særlig de som bruker insulin, opplever ofte betydelig belastning i hverdagen. Denne belastningen kan komme til uttrykk på flere måter:

Følelsesmessig og psykisk press

- **Stress og konstant bekymring**: Mange pårørende føler en vedvarende frykt for at deres kjære skal få akutte glukosesvingninger, særlig hypoglykemi, som kan føre til bevisstløshet eller andre alvorlige situasjoner.
- **Angst og uro**: Usikkerhet rundt hvordan sykdommen vil utvikle seg, og om personen følger opp behandlingen sin, kan føre til økt angst hos pårørende.
- **Depresjon og utmattelse**: Langvarig belastning kan føre til depresjon, særlig dersom pårørende føler seg alene om ansvaret eller ikke får nok støtte fra helsevesenet eller andre familiemedlemmer.
- **Skyldfølelse og frustrasjon**: Mange pårørende føler seg maktesløse og kan oppleve skyld dersom personen ikke har god sykdomskontroll. Samtidig kan de også kjenne på frustrasjon hvis personen ikke følger anbefalingene fra helsepersonell.

Trøtthet og søvnforstyrrelser

- Pårørende til eldre med diabetes, spesielt de som bor sammen med personen, kan oppleve søvnforstyrrelser på grunn av nattlige bekymringer eller behov for å hjelpe til med blodsukkermålinger, insulininjeksjoner eller håndtering av symptomer på lavt blodsukker.
- Dersom pårørende også har andre omsorgsoppgaver, som jobb eller barn, kan dette føre til kronisk søvnmangel og utmattelse.

Fysiske utfordringer

- Hvis personen med diabetes har komplikasjoner som nedsatt syn, nevropati eller redusert mobilitet, kan det kreve fysisk hjelp fra pårørende, for eksempel med daglige gjøremål, medisinhåndtering eller insulinadministrasjon.

- Pårørende som selv er eldre eller har helseplager, kan oppleve at omsorgsrollen forverrer egen helse.

Økonomisk press

- Økte utgifter til medisiner, helsetjenester og mat som bidrar til best mulig blodsukkerkontroll kan skape økonomiske utfordringer, spesielt hvis pårørende må redusere arbeidstiden for å gi omsorg.
- I enkelte tilfeller kan pårørende føle seg presset til å ta på seg private utgifter for å sikre best mulig behandling for pasienten.

Påvirkning på sosialt liv og relasjoner

- Mange pårørende prioriterer omsorgsrollen på bekostning av eget sosialt liv, noe som kan føre til isolasjon og ensomhet.
- Relasjoner innen familien kan bli anstrengte, særlig hvis det er uenighet om ansvarsfordeling eller hvordan sykdommen bør håndteres.

Hvordan kan teknologi, som sensorer, bidra til å redusere presset på pårørende?

Mindre bekymring og stress: Med kontinuerlig glukoseovervåkning kan pårørende følge med på personens verdier i sanntid og få varsler ved farlige glukosesvingninger, noe som reduserer angst og usikkerhet. Dersom den med diabetes er en eldre person som har hjemmesykepleier eller bor på insitusjon, kan pårørende oppleve økt trygghet i at helsepersonell har kontroll på blodsukkeret med kontinuerlig måling.

- **Bedre søvn og mindre belastning**: Mindre behov for nattlige oppvåkninger for å sjekke blodsukkeret gir bedre søvnkvalitet.
- **Økt selvstendighet for pasienten**: Sensorer kan hjelpe personen med å ta mer ansvar for egen behandling, noe som kan redusere pårørendes følelsesmessige og praktiske belastning.

Er det grupper av pasienter som spesielt har vanskeligheter med å håndtere tilstanden?

Noen pasientgrupper kan ha særskilte utfordringer med å håndtere diabetes type 2. Dette skyldes blant annet faktorer som alder, helsekompetanse, sosialøkonomiske forhold og funksjonsevne.

Grupper med særskilte utfordringer

Eldre med helseutfordringer

- Mange eldre har flere kroniske sykdommer samtidig, som hjertesykdom, demens eller leddplager, noe som gjør egenbehandling vanskelig.
- De kan ha redusert syn og nedsatt finmotorikk, noe som påvirker evnen til å administrere insulin eller måle blodsukker.
- Kognitive utfordringer som demens kan gjøre det vanskelig å huske medisinering og kostholdsanbefalinger.

Personer med lav helsekompetanse og språkutfordringer

- Pasienter med begrenset kunnskap om sykdommen kan ha vanskeligheter med å forstå hvordan levevanevalg påvirker blodsukkeret.
- Språkbarrierer blant innvandrere og minoritetsgrupper kan føre til misforståelser i møte med helsepersonell og utfordringer med å tolke medisinsk informasjon.
- Kulturforskjeller kan også spille en rolle, for eksempel mattradisjoner som gjør det vanskelig å følge anbefalte kostholdsråd.

Personer med funksjonshemminger

- De med nedsatt syn eller bevegelsesevne kan ha problemer med å utføre

nødvendige egenmålinger og injeksjoner.
- Kognitive funksjonsnedsettelser kan gjøre det vanskelig å forstå og følge opp behandlingen.

Vanskeligstilte og lavinntektsgrupper
- Sunn mat, medisiner og helseoppfølging kan være kostbart, noe som gjør det vanskelig for økonomisk utsatte grupper å prioritere behandling.
- Sosiale utfordringer som ustabil bosituasjon eller manglende støtte fra pårørende kan forverre sykdomshåndteringen.

Menn og kvinner – ulike utfordringer
- **Menn** kan i noen tilfeller ha høyere terskel for å oppsøke hjelp og kan være mindre tilbøyelige til å endre levevaner eller følge opp helseråd.
- **Kvinner** kan oppleve større hormonelle påvirkninger på blodsukkeret (f.eks. under menstruasjon, graviditet og overgangsalder), noe som kompliserer glukosereguleringen.

Barn og unge voksne
- Selv om diabetes type 2 tradisjonelt har vært mest utbredt blant eldre, øker forekomsten blant unge på grunn av levevanefaktorer.
- Unge voksne kan slite med å prioritere sykdommen i en hektisk hverdag, spesielt hvis de har lav sykdomsforståelse eller mangler støtte fra familie.

Disse gruppene kan ha stor nytte av teknologi, som kontinuerlige glukosesensorer, for å forenkle håndteringen av sykdommen og redusere belastningen på både personen med diabetes og pårørende.

Mange pasientgrupper møter betydelige utfordringer når det gjelder å håndtere diabetes type 2 i kombinasjon med andre aspekter av livet. Dette skyldes at sykdommen krever kontinuerlig oppmerksomhet og påvirkes av en rekke faktorer, inkludert mat, aktivitet, stress, følelser, jobbsituasjon og andre helseutfordringer. Her er noen av de største utfordringene spesifikke pasientgrupper kan møte:

Å balansere sykdommen med familieansvar
- **Foreldre med diabetes type 2** må håndtere egen sykdom samtidig som de tar vare på barn, noe som kan føre til at egen helse nedprioriteres.
- **Eldre med omsorgsansvar** for syke ektefeller eller andre kan ha begrenset tid og energi til egenbehandling.
- **Aleneforeldre** har ofte ekstra stor belastning og mindre fleksibilitet til å prioritere egen helse.

Håndtering av diabetes i tillegg til andre sykdommer
- Mange med diabetes type 2 har også **hjertesykdom, høyt blodtrykk, fedme, nyresykdom eller depresjon**, noe som kompliserer behandlingen.
- For eldre pasienter med **demens eller nedsatt kognitiv funksjon** kan det være ekstra vanskelig å følge opp kosthold og medisiner.
- Pasienter med **fysiske funksjonshemminger** kan ha problemer med å måle blodsukker, administrere insulin eller være fysisk aktive.

Tilgang til behandling og økonomiske utfordringer
- Pasienter i lavinntektsgrupper kan ha problemer med å skaffe seg det de trenger til god behandling. Noen har økonomiske begrensninger og opplever egenandelen for

medisiner og/eller insulin belastende nok, om de ikke også skal bekoste egen

blodsukkermåler og et **kosthold** basert på sunne råvarer.

- Noen pasienter bor i områder med **begrenset tilgang til spesialisthelsetjenester**, noe som gjør det vanskelig å få god oppfølging.
- For noen **innvandrere og minoriteter** kan språkbarrierer og lav helsekompetanse gjøre det utfordrende å forstå behandlingsanbefalinger og kommunisere med helsepersonell.

Sosialt stigma og psykiske utfordringer

- Diabetes type 2 er ofte knyttet til **levevaner og vekt**, noe som kan føre til skyldfølelse og stigma, særlig for de som sliter med overvekt.
- Noen opplever at familie og venner **ikke forstår sykdommen**, og at de får kommentarer om hva de spiser eller hvordan de håndterer sykdommen.
- Mange personer med diabetes sliter med **stress, angst og depresjon**, spesielt fordi sykdommen krever konstant oppmerksomhet og påvirker livskvaliteten.

Diabetes krever oppmerksomhet 24/7

- Blodsukkeret påvirkes av **alt fra mat og aktivitet til stress, følelser, søvn og sykdom**, noe som gjør det krevende å holde kontroll hele døgnet.
- Pasienter må ta daglige valg rundt **medisinering, måltider og fysisk aktivitet**, og feilberegninger kan føre til akutte problemer som hypoglykemi (lavt blodsukker) eller hyperglykemi (høyt blodsukker).
- Jobbsituasjonen kan være utfordrende dersom arbeidstider, skiftarbeid eller stress påvirker blodsukkeret, og det kan være vanskelig å forklare behov for pauser til mat eller medisinering.

Hvordan kan teknologi hjelpe?

- **Kontinuerlige glukosemålere (CGM)** kan redusere stress hos pasienten ved å gi varsler om glukosesvingninger og gjøre det enklere å håndtere sykdommen i hverdagen.
  Digitale helseverktøy og apper kan hjelpe personer med å loggføre måltider, trening og medisiner for bedre kontroll.
- **Bedre tilgang til fjernkonsultasjoner med helsepersonell** kan gjøre det lettere for pasienter med begrenset mobilitet eller lang reisevei å få oppfølging.
- **Bruk av CGM i opplæringsøyemed i startfasen av sykdommen,** kan gjøre blodsukkersvingninger lettere å forstå. Dette kan være gunstig for alle med diabetes type 2, men kanskje særskilt for de som sliter med å ta til seg kunnskap om diabetesregulering på grunn av språkvansker eller andre utfordringer.

Erfaringer med eksisterende behandling

Hvor bra håndterer pasientene tilstanden med eksisterende metoder?

(*Metoder* kan være f.eks. legemidler, medisinsk utstyr, prosedyrer, rehabilitering, m.m. Hvis ingen behandlingstiltak er tilgjengelige, bør dette oppgis.)

Pasienter med diabetes type 2 har tilgang til flere behandlingsalternativer, men hvor godt de håndterer sykdommen avhenger av individuell oppfølging, forståelse av egen sykdom, og evne til å følge anbefalte tiltak. Behandlingen består fortrinnsvis av endring i levevaner, blodsukkermåling, medikamentell behandling og i noen tilfeller bruk av medisinsk utstyr.

Eksisterende behandlingstiltak Levevaner og egenbehandling**:**

- Første behandlingsvalg er **endring av kosthold, fysisk aktivitet og vektnedgang**, men mange opplever dette som utfordrende.
- Opplæringen er ofte mangelfull, og fastleger har begrenset kapasitet til å gi individuell veiledning.

- Mange pasienter har **lav helsekompetanse** og strever med å forstå hvordan mat, aktivitet og stress påvirker blodsukkeret.

Medikamentell behandling:

- **Tabletter (for eksempel metformin)** er førstevalget, men gir bivirkninger som mageproblemer og kvalme hos noen pasienter.
- **GLP-1-analoger (injeksjoner)** kan hjelpe med blodsukkerkontroll og vektnedgang, men kan være dyre og vanskelig tilgjengelige.
- **Insulinbehandling** brukes ved behov, men krever regelmessig blodsukkermåling og kan gi risiko for hypoglykemi (lavt blodsukker).

Blodsukkermåling:

- Noen pasienter må måle blodsukker flere ganger daglig med fingerstikk, noe som kan være smertefullt og upraktisk.
- Tradisjonell blodsukkermåling gir kun **øyeblikksbilder**, men sier ikke noe om blodsukkertrender (om det er på vei opp eller ned).
- Noen bruker **kontinuerlig glukosemåling (CGM)**, men ikke alle får dette dekket, spesielt pasienter med diabetes type 2 som ikke bruker insulin.

Hvor godt håndterer eksisterende behandling de mest utfordrende aspektene ved sykdommen?

Fordeler:

- **Tabletter er enkle å ta** og krever ikke mye oppfølging for mange pasienter.
- **Insulin gir god blodsukkerkontroll**, men krever tett oppfølging.
- **Tradisjonell blodsukkermåling er effektiv for de med stabilt blodsukker** og som ikke ønsker å ha utstyr festet på kroppen.

Ulemper:

- **Manglende informasjon om blodsukkertrender** – fingerstikkmålinger gir ikke en helhetlig oversikt.
- **Endringer av levevaner er krevende** – uten god oppfølging kan mange streve med å finne en varig løsning.
- **Insulinbehandling kan være krevende** – feil dosering kan føre til både høyt og lavt blodsukker.

Byrde av behandlingen i hverdagen

- **Avbrudd i arbeid og daglige aktiviteter**: Pasienter må ofte stoppe det de gjør for å måle blodsukker og ta medisiner.
- **Smerte ved fingerstikk**: Mange synes dette er ubehagelig, særlig ved hyppige målinger.
- **Usikkerhet rundt blodsukkernivået**: Pasienter vet ofte ikke om blodsukkeret er på vei opp eller ned, noe som kan føre til usikkerhet og over- eller underbehandling.
- **Begrensninger i sosialt liv**: Noen unngår sosiale situasjoner for å slippe å måle blodsukker eller ta insulin offentlig.

Økonomiske konsekvenser for pasienter og pårørende

- **Høye kostnader for glukosemåling**: Kostnaden kan bli høy for pasienten dersom de selv dekker kostnaden for CGM
- **Tap av inntekt**: Pasienter med dårlig regulert diabetes kan få sykefravær eller nedsatt arbeidsevne.
- **Kostnader ved komplikasjoner**: Dårlig regulert diabetes kan føre til følgesykdommer som krever omfattende behandling og rehabilitering.

Utfordringer med langtidsbruk av eksisterende behandling

- **Fingerstikk gir smerter og ubehag**, særlig for de som må måle ofte.
- **Insulin kan føre til vektøkning, særlig ved blodsukkersvingninger** og gir økt risiko for hypoglykemi.
- **Medikamentelle bivirkninger** som kvalme, fordøyelsesproblemer og lavt blodsukker kan påvirke livskvaliteten.

Hvor fungerer ikke eksisterende behandling optimalt?

- **Når pasienter trenger informasjon om hvor blodsukkeret er på vei** – fingerstikk gir kun øyeblikksbilder.

- **Når pasienter har utfordringer med endring av levevaner uten god veiledning** – mange med diabetes type 2 får lite oppfølging fra helsevesenet.

- **Når pasienter har behov for trygghet og mindre risiko for plutselige blodsukkersvingninger** – tradisjonelle målemetoder krever aktiv testing.

Hvordan kan kontinuerlig glukosemåling (CGM) forbedre behandlingen?

- **Mindre smerte** – færre fingerstikk.
- **Økt trygghet** – pasienter og pårørende kan følge med på glukosenivået i sanntid.
- **Bedre kontroll** – mulighet til å se hvordan glukosenivået utvikler seg over tid.
- **Redusert risiko for komplikasjoner** – bedre regulering gir færre sykehusinnleggelser og komplikasjoner på lang sikt.

Oppsummering

Personer med diabetes type 2 håndterer med varierende suksess dagens behandlingsmetoder. Endringer i levevaner er førstevalg, men mange får ikke god nok oppfølging til å lykkes. Blodsukkermåling er avgjørende, men tradisjonelle metoder gir kun øyeblikksbilder, noe som kan føre til usikkerhet og feiljusteringer av behandling.

For mange pasienter, spesielt de som bruker insulin, kan kontinuerlig glukosemåling (CGM) forbedre behandlingen betydelig ved å gi bedre oversikt over glukosetrender, redusere smerte ved fingerstikk og øke tryggheten i hverdagen. Pasienter med diabetes type 2 som har et behandlingsregime lik personer med type 1, risikerer episoder med hypoglykemi, og CGM kan redusere denne risikoen.

Er det grupper av pasienter som spesielt har vanskeligheter med å bruke eksisterende behandling?

Det er flere grupper av pasienter som har spesielle utfordringer med å bruke eksisterende behandling og utstyr for diabetes type 2. Disse utfordringene kan skyldes fysiske begrensninger, psykiske barrierer, sosial stigma eller andre helseproblemer.

Pasienter med vanskeligheter med å bruke utstyret

- **Personer med stikkevegring** – Noen har en sterk frykt for nåler og blod, noe som gjør daglige blodsukkermålinger og insulininjeksjoner svært stressende eller umulige.
- **Eldre med dårlig funksjonalitet i hendene eller nedsatte kognitive evner** – Redusert finmotorikk på grunn av leddgikt, skjelvinger eller nevropati gjør det vanskelig å bruke blodsukkermålere, stikke seg selv eller håndtere insulinpenner. Nedsatte kognitive evner som følge av alderdom eller demens, kan gi store utfordringer i å håndtere utstyret.
- **Svaksynte eller blinde** – Pasienter med synsnedsettelse har utfordringer med å lese måleresultater, dosere insulin og bruke små medisinske enheter. Mange trenger

spesialtilpassede hjelpemidler som talefunksjon eller app-integrerte målere.

- **Personer med funksjonshemming** – Pasienter med kognitive eller fysiske funksjonsnedsettelser kan ha problemer med å forstå og gjennomføre egenbehandling. Dette gjelder særlig de med utviklingshemming, lammelser eller manglende fingerferdighet.

Pasienter som kan oppleve sosial stigma eller ubehag ved å bruke utstyret offentlig

- **De som er ukomfortable med å måle blodsukker offentlig** – Noen pasienter kvier seg for å bruke utstyr på jobb, skole eller restauranter fordi det kan trekke oppmerksomhet eller vekke ubehag hos andre.
- **De som er sensitive for blod** – Noen pasienter (eller de rundt dem) tåler ikke å se blod, noe som kan gjøre tradisjonelle blodsukkermålinger problematiske.
- **Unge voksne og tenåringer** – Mange ungdommer vil unngå å skille seg ut sosialt og kan derfor hoppe over målinger eller insulininjeksjoner for å slippe å forklare seg.

Pasienter med spesielle sykdommer som gjør eksisterende behandling vanskelig

- **Pasienter med alvorlige hudproblemer eller allergier** – Noen kan ikke bruke insulinpumper eller sensorer på grunn av hudreaksjoner eller eksem.
- **Pasienter med nyresykdom** – Diabetesbehandling må ofte justeres fordi nyresvikt kan påvirke hvordan kroppen håndterer insulin og medisiner.
- **Pasienter med sjeldne genetiske sykdommer** – Noen har metabolske sykdommer som gjør at vanlige behandlingsmetoder for diabetes ikke fungerer optimalt.

Hvordan kan teknologi og tilpasninger hjelpe?

- **Sensorbaserte systemer (CGM)** reduserer behovet for fingerstikk og kan være til stor hjelp for dem med stikkevegring eller dårlig syn.
- **Insulinpenner med smart teknologi** kan gjøre det enklere for personer med motoriske utfordringer å dosere insulin.
- **Diskré måleutstyr og insulininjeksjonssystemer** kan gjøre det lettere for de som føler ubehag ved offentlig bruk.

Erfaringer med metoden som er under vurdering

a) For de <u>med</u> erfaring med den nye metoden eller metoden under vurdering: hvilken forskjell utgjorde det i livene deres?

Bruk av kontinuerlig glukosemåling (CGM) har gjort en betydelig forskjell i hverdagen til mange med diabetes type 2. Teknologien gir en bedre forståelse av blodsukkeret, mer presis egenbehandling og økt trygghet.

1. Hovedgrunner for å bruke CGM

- **Færre fingerstikk**: Mange opplever at hyppige fingerstikk er smertefulle, og CGM reduserer behovet for dette betraktelig.
- **Glukosetrender i sanntid**: Man ser om glukosen er på vei opp, ned eller stabilt, noe som gir mulighet for raskere og mer presise tiltak.
- **Bedre kontroll**: Personene kan lettere unngå høye og lave glukoseverdier ved å handle tidligere.
- **Økt trygghet**: Varslinger gir beskjed om farlige glukoseverdier, spesielt om natten eller under fysisk aktivitet.
- **Bedre egenbehandling**: CGM gir innsikt i hvordan mat, følelser, stress og aktivitet påvirker glukosenivået, noe som hjelper med å ta gode valg for sunnere levevaner.

2. Mål ved oppstart og oppnåelse

Mange pasienter setter seg følgende mål når de begynner med CGM:

- **Bedre langtidsblodsukker (HbA1c)**
- **Færre episoder med hyperglykemi**
- **Mindre hypoglykemier**

Tryggere netter med færre bekymringer for nattlige glukosesvingninger

Oppnåelse:

- Mange rapporterer **bedre HbA1c-verdier** etter å ha brukt CGM en periode.
- Hypoglykemier er **redusert**, ettersom varslinger gir mulighet til å forebygge alvorlig lav glukose.
- Mange føler seg tryggere på natten, spesielt de som tidligere har opplevd nattlige hypoglykemier.

Fordeler og ulemper sammenlignet med andre alternativer Fordeler:

- **Kontinuerlig overvåking** av glukosenivåer, både for pasienten og pårørende.
- **Mindre smerte** – færre fingerstikk.
- **Brukervennlighet** – sensorene sitter på kroppen i opptil 15 dager og er enkel i bruk.
- **Diskré måling** – kan sjekkes via telefon uten at andre legger merke til det.
- **Varslinger** – mulighet for tidlige tiltak før lavt eller høyt glukosenivå.

Ulemper:

- **Følelsen av alltid å ha noe på kroppen** – noen synes det er ubehagelig, og sykdommen føles mer synlig.
- **Stress med å følge med** – enkelte blir for opptatt av glukoseverdier og sjekker for ofte.
- **Hudirritasjon** – noen opplever reaksjoner på sensortapen.
- **Økonomi** – ikke alle får sensorer dekket, og det kan være en stor utgift.

Hvordan hjelper CGM med de vanskeligste aspektene ved diabetes type 2?

- **Bedre regulering**: CGM gir kontinuerlig informasjon om glukosenivået, slik at pasienten kan gjøre riktige tiltak i tide.
- **Mindre bekymring**: Pasienter slipper å gjette på hvordan glukosenivået utvikler seg.
- **Bedre oversikt ved stress, måltider og aktivitet**: Man kan se hvordan ulike faktorer påvirker glukosenivåene og justere deretter.
- **Reduserer usikkerhet**: Mange rapporterer at de føler seg mer selvsikre i egen behandling.

Symptomer som har forbedret seg og påvirkning på livskvalitet

- **Mindre tretthet**: Bedre glukoseregulering gir jevnere energinivåer.
- **Færre episoder med svimmelhet og hodepine**: Redusert forekomst av svingninger mellom høyt og lavt glukosenivå.
- **Økt mobilitet**: Mange føler seg tryggere på fysisk aktivitet.
- **Mindre angst og bekymring**: Både brukere og pårørende føler seg tryggere.

Begrensninger ved CGM

- **Kan gi falske varslinger** – noen ganger kan sensoren varsle for høyt eller lavt glukosenivå unødvendig.
- **Hudirritasjon** – enkelte brukere opplever kløe eller rødhet der sensoren festes.
- **Ikke alltid 100 % presis** – det kan være en liten tidsforsinkelse mellom sensorens målinger og faktisk blodsukker.

Økonomiske konsekvenser

- **Kostnader for pasienten**: Ikke alle med diabetes type 2 får CGM dekket, og utstyr kan bli dyrt.
- **Reisekostnader**: Noen må reise for å få tilgang til sensorer og opplæring.
- **Reduserte utgifter til teststrimler**: CGM-brukere trenger færre teststrimler, noe som kan spare penger på sikt.

Innvirkning på bruk av helsetjenester

- **Færre sykehusbesøk**: Bedre egenbehandling reduserer behovet for akutte innleggelser og legebesøk.
- **Mindre behov for fastlegeoppfølging**: Brukerne får bedre forståelse av sin egen sykdom og trenger mindre tett oppfølging.
- **Forebygging av komplikasjoner**: Jevnere blodsukker reduserer risikoen for langtidskomplikasjoner som nyresykdom og nevropati.

Påvirkning på pårørende

- **Økt trygghet**: Pårørende kan følge med på glukosenivået via delingsfunksjoner i appen.
- **Mindre bekymring for nattlige episoder**: Spesielt viktig for de som tidligere har hatt alvorlige hypoglykemier.
- **Bedre mulighet til å støtte pasienten**: Familie og venner kan hjelpe til med å tolke glukosetrender og gi råd.

Ivaretakelse av brukernes behov

- **CGM gir en mer helhetlig forståelse av glukosenivået og hvordan det påvirkes av levevaner.**
- **Teknologien gjør det enklere å ta gode valg i hverdagen og reduserer behovet for hyppige legebesøk.**
- **Mange rapporterer bedre livskvalitet, økt trygghet og bedre diabeteskontroll.**

Oppsummering

- CGM har gjort en stor forskjell for mange med diabetes type 2 ved å gi bedre innsikt i glukosetrender, færre fingerstikk og økt trygghet.
- Pasientene opplever færre høye og lave glukoseverdier, bedre langtidsblodsukker og større trygghet, spesielt om natten.
- De største utfordringene er følelsen av å alltid ha noe på kroppen, stress ved hyppig sjekking av verdier og økonomiske kostnader.
- Pårørende får økt trygghet og mulighet til å følge med på brukernes glukosenivå.
- CGM kan redusere behovet for helsetjenester og forebygge komplikasjoner, noe som gir besparelser både for brukeren og samfunnet.

b) For de uten erfaring med den nye metoden eller metoden under behandling, men som er klar over kliniske studier: hva er forventninger og begrensninger med metoden?

Forventninger og begrensninger med CGM for personer uten erfaring med metoden:

1. **Forventede fordeler:** Kliniske studier viser at CGM kan gi bedre glukosekontroll, færre hypoglykemier, økt trygghet og forbedret livskvalitet. Mange håper det vil gjøre egenbehandlingen enklere, redusere usikkerhet og gi bedre oversikt over hvordan mat, aktivitet og stress påvirker glukosenivået.

2. **Begrensninger:** Noen kan oppleve stress ved kontinuerlig overvåking, ubehag ved å ha en sensor på kroppen, eller tekniske utfordringer. Det er også usikkerhet rundt hvor stor effekt CGM har for alle pasientgrupper, spesielt de som ikke bruker insulin.

3. **Økonomiske aspekter:** Kostnadene kan være en barriere, særlig for pasienter som ikke får dekket CGM av helsevesenet. På den annen side kan færre sykehusbesøk og bedre glukosekontroll redusere langsiktige kostnader knyttet til diabeteskomplikasjoner.

4. **Påvirkning på helsetjenester:** Bedre egenbehandling kan redusere behovet for lege- og spesialistbesøk, færre akutte sykehusinnleggelser og mindre bruk av andre helsetjenester.

5. **Effekt på pårørende:** CGM kan gi trygghet til pårørende ved at de kan følge med på glukoseverdiene ved behov. Dette er spesielt viktig for eldre, personer med gjentatte hypoglykemier eller de som har vanskeligheter med egenbehandling.

Hvilke grupper av pasienter kan ha mest nytte av metoden under vurdering?

Pasientgrupper med diabetes type 2 som kan ha mest nytte av kontinuerlig glukosemåling (CGM)

Kontinuerlig glukosemåling (CGM) kan være en verdifull teknologi for flere grupper av pasienter med diabetes type 2, spesielt de som har utfordringer med eksisterende behandlingsalternativer eller som trenger bedre innsikt i glukosereguleringen.

Diabetesforbundet har, basert på vår innsikt og våre erfaringer, definert hvilke grupper med type 2 vi mener bør få tilgang på CMG: Diabetesforbundet mener: Kontinuerlig vevsglukosemåling ved diabetes (CGM) ved diabetes type 2

Pasienter med få eller ingen gode behandlingsalternativer

- **Pasienter med stikkevegring eller motoriske utfordringer** – CGM kan redusere behovet for hyppige fingerstikk, noe som er nyttig for dem som har fobi for nåler eller dårlig håndfunksjon.
- **Pasienter med synshemninger** – Svaksynte eller blinde kan ha utfordringer med tradisjonelle blodsukkermålere, og CGM med lydvarsler kan være et bedre alternativ.
- **Eldre med kognitiv svikt eller demens** – De kan ha vanskelig for å følge opp egen måling og medisinering. CGM kan hjelpe pårørende og helsepersonell med å overvåke glukosenivået og forebygge farlige glukosesvingninger.

Pasienter som bruker insulin i mangeinjeksjonsbehandling (MDI)

- CGM gir kontinuerlig innsikt i hvordan **måltider, stress, følelser, søvn og aktivitet påvirker glukosenivået**, noe som kan forbedre insulindoseringen.
- Redusert risiko for **hypoglykemi (lavt blodsukker)**, spesielt om natten. CGM kan varsle pasienten eller pårørende om kritiske glukosefall.
- **Mer presis behandlingstilpasning**, da pasienter kan justere insulindoser basert på reelle målinger fremfor tilfeldige punktmålinger.

Pasienter med tilbakevendende hypoglykemier som bruker 1–2 doser langtidsvirkende insulin

- **Hypoglykemi kan være farlig**, spesielt for eldre eller personer med hjerte- og karsykdommer. CGM kan varsle om fallende glukosenivå og forhindre alvorlige episoder.
- Pasienter med **hypoglykemisk uvitenhet** (manglende evne til å merke lavt blodsukker) vil ha stor nytte av CGM med trendpiler og alarmer.
- Kan bidra til tryggere behandling for dem som **bor alene og ikke har noen til å hjelpe ved hypoglykemi**.

Kortvarig bruk av CGM

- **Ved opplæring og motivasjon til endringer av levevaner**
  - Pasienter kan **se i sanntid hvordan kosthold og aktivitet påvirker glukosenivået**, noe som kan øke forståelsen og motivasjonen for sunne vaner.
  - Gir bedre grunnlag for individuell tilpasning av kosthold og aktivitetsrutiner.
  - Kan være spesielt nyttig for **nydiagnostiserte** som må lære hvordan kroppen reagerer på ulike matvarer og situasjoner.
- **Ved utredning av utilfredsstillende glukoseregulering**
  - CGM kan vise **når på døgnet og i hvilke situasjoner glukosen er for høyt eller lavt**, og dermed hjelpe helsepersonell med å skreddersy behandlingen.
  - Pasienter som sliter med **uforutsigbare glukosesvingninger**, eller der faste blodsukkermålinger ikke gir et klart bilde av reguleringen, kan ha stor nytte av CGM.

2. Ytterligere informasjon

Vennligst oppgi ekstra informasjon dere tror kan være til hjelp for de som gjennomfører metodevurderingen (f.eks. sosiale eller etiske aspekter).

Sårbare grupper med lav helsekompetanse, eldre og personer med språkutfordringer møter ofte betydelige utfordringer i håndteringen av diabetes type 2. Disse barrierene kan føre til dårligere sykdomskontroll, høyere risiko for komplikasjoner og økt belastning på både pasienten og helsevesenet.

Personer med lav helsekompetanse Hva er utfordringen?

- Begrenset forståelse av sykdommens alvorlighet og konsekvenser kan føre til dårlig oppfølging av behandling.
- Manglende kunnskap om hvordan kosthold, aktivitet og medisiner påvirker blodsukkeret.
- Vansker med å tolke blodsukkermålinger, medisinanvisninger eller helseråd fra leger.
- Større risiko for å følge feilinformasjon fra utrygge kilder, som sosiale medier eller bekjente.

Hvordan kan det løses?

- Enkle og visuelle forklaringer fra helsepersonell.
- Bruk av helseapper og digitale løsninger med lettforståelig språk og påminnelser.
- Større satsing på helseinformasjon tilpasset ulike kompetansenivåer.

Eldre pasienter Hva er utfordringen?

- Mange eldre har **flere kroniske sykdommer**, som hjertesykdom og demens, noe som gjør behandlingen komplisert.
- **Nedsatt syn, hørsel og motorikk** kan gjøre det vanskelig å måle blodsukker, bruke insulinpenner eller forstå instruksjoner.
- **Ensomhet og redusert sosial støtte** kan føre til lav motivasjon for å følge opp

behandlingen.
- Noen eldre spiser **for lite eller for uregelmessig**, noe som øker risikoen for hypoglykemi.

Hvordan kan det løses?

- Tilpasset teknologi, som **taleassisterte målere og enklere utstyr** for de med dårlig motorikk.
- Styrket samarbeid med pårørende og hjemmebaserte helsetjenester.
- Individuelle tilpasninger i behandlingen for å gjøre den enklere og tryggere.

Personer med språkutfordringer (innvandrere og minoriteter) Hva er utfordringen?

- Vansker med å forstå helsepersonell, medisinske instrukser og pakningsvedlegg på medisiner.
- Kulturelle forskjeller i kosthold og helseforståelse kan gjøre det utfordrende å følge vanlige behandlingsråd.
- Mange innvandrere har lav helsekompetanse og begrenset tilgang til fastlege eller spesialisthelsetjenester.

Hvordan kan det løses?

- Økt bruk av **tolketjenester og helseinformasjon på flere språk**.
- Tilpassede kostholdsråd som tar hensyn til kulturelle mattradisjoner.
- Bedre tilgjengelighet av helsetjenester i områder med høy innvandrerandel.

Økonomisk og sosialt vanskeligstilte grupper Hva er utfordringen?

- Sunn mat, medisiner og behandlingsutstyr kan være for dyrt.
- Mange sliter med **ustabile boforhold, psykiske lidelser eller rusproblemer**, noe som gjør det vanskelig å prioritere egen helse.
- Mangel på tilgang til fastlege eller diabetesoppfølging.

Hvordan kan det løses?

- Større offentlig støtte for rimeligere medisiner og utstyr.
- Tilpassede tiltak for personer med psykiske lidelser eller rusutfordringer.
- Lavterskeltilbud som **diabetessykepleiere på helsestasjoner eller mobile helsetjenester**.

Oppsummering

Sårbare grupper som eldre, personer med lav helsekompetanse, språkutfordringer og økonomiske utfordringer møter større hindringer i diabetesbehandling. Dette kan føre til dårligere sykdomsmestring, høyere risiko for komplikasjoner og økt press på helsevesenet. Tilpasset teknologi, bedre helseinformasjon og sterkere støtteordninger er nøkkelen til bedre håndtering av diabetes i disse gruppene.

Hovedbudskap

I maks fem punkter, oppgi de viktigste poengene i skjemaet dere vil fremheve.

Økt forståelse av glukoseregulering og bedre glukosekontroll – CGM gir innsikt i glukosetrender, reduserer behovet for fingerstikk og hjelper med å unngå høye/lave glukoseverdier.

Økt trygghet – Varslinger og trendpiler gir mulighet for tidlige tiltak, spesielt om natten, under aktivitet og i forbindelse med måltider, noe som reduserer bekymring både for personen med diabetes og pårørende.

Forbedret livskvalitet – Færre symptomer som tretthet og svimmelhet, mer stabil energi, og bedre mulighet til å tilpasse kosthold og aktivitet.

Økonomiske og praktiske utfordringer – CGM er kostbart for de som dekker det selv, og kan føre til økt klasseskille i helsetjenesten. Fra et brukerperspektiv er det vanskelig å forstå hvorfor dette ikke dekkes av det offentlige da kostnadene i mange tilfeller er sammenlignbare, og CGM har vist seg å være et kostnadseffektivt alternativ.

Mindre bruk av helsetjenester – Bedre egenbehandling reduserer behovet for legebesøk, sykehusinnleggelser og forebygger langtidskomplikasjoner.

Appendix 11: Progress log

LOG	Date/processing time
Proposal for topic sent / horizon scanning alert published on: nyemetoder.no	NA
Commission given by the Ordering Forum in the national system	21.10.2024
Request for recruiting experts sent by NOMA	20.11.2024 – previously recruited experts contacted (4 out of 5 accepted) 22.11.2024 – user representatives contacted 09.12.2024 – additional experts contacted (diabetes nurse and family health specialist)
Recruitment of experts and users completed	10.01.2025
Kick-off meeting held including establishing of PICO	14.01.2025
Need for further clarifications or other factors causing delays (specify in text, including waiting time to obtain necessary data from collaborators)*	Meeting with previously recruited experts, where the need for additional expertise was expressed, 04.12.2024 Final determination of PICO at meeting on 14.01.2025
Project plan published	16.06.2025
First draft of the report sent to the external expert group	10.11.2025
Rapport completed by NOMA	11.12.2025
Processing time at NOMA (days)	331 days (from PICO was finally determined)
HTA sent to commissioner / received by the Secretariat for “Nye metoder”	
*The report has been accepted by the Ordering Forum for “Nye metoder” and forwarded to the Regional Health Authorities for decision	
*Decision by the Decision Forum for “Nye metoder”	