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Comparative characteristics of older people with type 1 diabetes treated with continuous subcutaneous insulin infusion or insulin injection therapy: data from the German/Austrian DPV registry

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Abstract

Aim To compare clinical characteristics and outcomes in adults with type 1 diabetes aged ≥ 60 years using continuous subcutaneous insulin infusion (CSII) vs. insulin injection therapy. Further, to determine the percentage of older adults with type 1 diabetes using CSII.

Research design and methods Retrospective study using data of the Diabetes Prospective Follow-up Registry (DPV). Including percentage CSII use from 2008 to 2018, and the characteristics of 9547 individuals extracted from the DPV in March 2019 (N = 1404 CSII; N = 8143 insulin injection therapy). Wilcoxon rank sum tests were used for continuous variables and chi-square tests for categorical variables to compare clinical characteristics of people using CSII vs. insulin injection therapy. Adjusted analyses used generalized linear models to compare diabetes-related outcomes.

Results CSII usage has increased in older adults (from 12% in 2008 to 23% in 2018). After adjustment, CSII was associated with lower HbA_{1c} [60.7 mmol/mol (7.7 ± 0.1%) vs. 62.8% (7.9 ± 0.1%)], lower daily insulin dose (0.49 ± 0.02 vs. 0.61 ± 0.01 IU/kg), fewer days in hospital (8.1 ± 0.12 vs. 11.2 ± 0.11 days/person-year), fewer severe hypoglycaemic events (0.16 ± 0.02 vs. 0.21 ± 0.03 events/person-year) and fewer diabetic ketoacidosis (0.06 ± 0.01 vs. 0.08 ± 0.01 events/person-year). Individuals on CSII showed lower rates of microalbuminuria and also have a diagnosis of depression and neuropathy.

Conclusions A growing number of older adults are using insulin pumps. Older age in itself should not be seen as a contraindication for CSII.

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Introduction

The prevalence of diabetes is rising worldwide. With better treatment options and increasing life expectancy, the population of older people with type 1 diabetes is growing [1]. This leads to increasing demand for treatment options tailored to the needs of older adults with type 1 diabetes. Among the available treatment options for type 1 diabetes, continuous subcutaneous insulin infusion (CSII; insulin pump therapy) has become increasingly popular and has gained widespread acceptance in diabetes care [2,3]. The total number of people with diabetes treated with CSII worldwide remains unclear, estimations based on financial reports from the diabetes technology industry suggest that the number may approach 0.75–1 million users globally, with an estimate of > 500 000 users with type 1 diabetes in the USA alone [4]. Further, the percentage of older adults using CSII will increase because

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What's new?

- Diabetes technologies have to be individually tailored to the needs, wishes, clinical characteristics and capabilities of users. Research on older people with type 1 diabetes using continuous subcutaneous insulin infusion CSII is scarce.
- CSII usage has increased in adults aged ≥ 60 years.
- People using CSII report slightly better glycaemic control and fewer acute diabetes complications.
- CSII usage in older people with type 1 diabetes is a topic of increasing importance. More emphasis should be put on the needs and wishes of this specific age group. Older age in itself should not be seen as a contraindication for CSII.

discontinuation rates for pump therapy in adults are generally low [5]. Little is known, however, about the characteristics of adults aged ≥ 60 years using CSII. There are many studies examining the effectiveness and use of CSII in adults and children [6,7]. However, research on the benefits of insulin pump use in older individuals with type 1 diabetes is scarce. Because of concerns about cognitive deficits and multiple comorbidities, people aged 65 years and older are often excluded from clinical trials. The few available studies focusing on older individuals suggest that CSII is valuable clinically and can be used effectively and safely, with similar positive outcomes to those observed in younger people [8–15]. A recent cluster randomized controlled trial (RCT) that compares the effectiveness of insulin pumps with multiple daily injections for adults with type 1 diabetes included participants aged 18–78 years (mean age 42 ± 14.2 years) (REPOSE trial). Retrospective subgroup analyses of the REPOSE trial showed no reliable statistical differences between age groups (< 35, 35–49 and ≥ 50 years) with regard to differences in HbA_{1c} for CSII vs. insulin injection therapy [16]. Only two smaller studies have compared CSII and insulin injection therapy in older individuals [8,10]. The lack of research on CSII usage in older people suggests this may be an overlooked and underrated topic. Thus, it is of interest to examine CSII use among older adults in specialized diabetes care over recent years and to determine the need for research and technical solutions adapted for this group.

Diabetes management in general, and the use of diabetes technologies such as insulin pumps in particular, has to be individually tailored to the needs, wishes, clinical characteristics and capabilities of users to be successful. This is particularly true for elderly people who may be affected by age-associated impairments such as cognitive decline, and visual or sensorimotor impairment [17]. With increasing age, the ability to use insulin pumps may vary considerably between people, and an individual's characteristics should be taken into account when choosing therapeutic options. To be able to individually tailor insulin pump therapy to the needs of older adults with diabetes who may experience age-associated impairments, and to support diabetes care teams in educating users, extensive data from large patient registries and specialized diabetes care centres on the characteristics of older people using CSII compared with individuals using insulin injection therapies are very much needed.

To address this important topic, this study extracted data from the German/Austrian Diabetes Prospective Follow-up Registry (Diabetes-Patienten-Verlaufsdokumentation, DPV) on people with type 1 diabetes who were aged ≥ 60 years in March 2019. To investigate the trend in CSII use, percentages of current CSII users and number newly initiated users for each year from 2008 to 2018 were retrieved. Further, data on clinical characteristics of older individuals (≥ 60 years) using CSII in the most recent year of treatment were compared with individuals of the same age using insulin injection therapy.

Research design and methods

Participants and data collection

The DPV registry was established in 1995 by the Institute of Epidemiology and Medical Biometry at the University of Ulm and is based on a freely available software that offers standardized, prospective, multicentre documentation of diabetes care and outcomes. DPV participating centres reflect all levels of specialized diabetes care. Some 485 specialized diabetes care centres, diabetes departments at university hospitals, community-based general hospitals and rehabilitation units in Germany, Austria, Switzerland and Luxembourg regularly report anonymized data for central analyses and benchmarking. For more details see the DPV website (www.d-p-v.eu). The DPV initiative has been approved by the ethics committee at the University of Ulm and by the local review boards at each participating site. The study design complies with the Declaration of Helsinki ethical standards. The ethics committee of the University of Ulm has authorized the DPV Initiative as well as the analyses of anonymized data related to quality of care. The local review board of each participating center has approved the anonymized data collection.

In March 2019, anonymous data of the most recent year of treatment of people with type 1 diabetes aged ≥ 60 years using CSII or insulin injection therapy were retrieved from the DPV. Individuals were diagnosed with type 1 diabetes by qualified diabetologists only and the majority of cases were confirmed by antibodies against β cells or glutamic acid decarboxylase. Metabolic control was assessed by HbA_{1c}. HbA_{1c} values were standardized mathematically to the reference range of the Diabetes Control and Complications Trial (DCCT) using the multiple of the mean method [18]. In line with the report of the American Diabetes Association (ADA) Workgroup on Hypoglycemia, severe hypoglycaemia

Table 1 Percentage of CSII and MDI in people aged ≥ 60 years in the period 2008 to 2018

	All	Age group		
Year	≥ 60 years % (*N*, *n*)	60 to < 70 years % (*N*, *n*)	70 to < 80 years % (*N*, *n*)	≥ 80 years % (*N*, *n*)
2008	12 (1503, 183)	16 (823, 131)	9 (554, 50)	2 (126, 2)
2009	11 (1580, 168)	14 (798, 115)	8 (683, 48)	4 (144, 5)
2010	13 (1683, 216)	18 (835, 143)	10 (681, 68)	3 (167, 5)
2011	16 (1772, 272)	23 (812, 177)	12 (784, 87)	5 (176, 8)
2012	15 (1731, 254)	22 (771, 161)	12 (751, 79)	7 (209, 14)
2013	16 (1351, 211)	23 (631, 139)	12 (563, 62)	6 (157, 10)
2014	19 (1417, 262)	27 (686, 189)	14 (557, 74)	4 (174, 8)
2015	21 (1558, 302)	29 (707, 207)	15 (573, 87)	5 (168, 8)
2016	20 (1443, 298)	27 (725, 204)	15 (524, 81)	7 (194, 13)
2017	22 (1335, 298)	31 (732, 230)	14 (421, 59)	5 (182, 9)
2018	23 (1307, 296)	31 (672, 205)	18 (449, 80)	6 (186, 11)

N, total number of individuals with type 1 diabetes; *n*, number of individuals using continuous subcutaneous insulin infusion (CSII); MDI, multiple daily injections.

was defined as an event requiring the assistance of another person to actively administer carbohydrates, glucagon or other resuscitative actions [19]. To select individuals with comorbid depression, the registry was searched for a diagnosis using International Statistical Classification of Diseases and Related Health Problems (ICD)-10 codes (e.g. F32.1) and Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV, as well as specific search terms (e.g. anhedonia, melancholia, sadness). Furthermore, we searched for every available antidepressant, using both trademark and generic nomenclature (e.g. fluoxetine and Prozac) as the use of antidepressant medication is strongly associated with depressed mood. This method has been applied successfully in previous studies on comorbid psychiatric disorders [20].

Statistical analyses

SAS 9.4 statistical software package (SAS Institute Inc., Cary, NC, USA) was used for data analysis. The percentage of people aged ≥ 60 years using CSII vs. insulin injection therapy over the past 11 years w as determined based on age group: ≥ 60 years (all individuals), 60 to < 70 years, 70 to < 80 years and ≥ 80 years. Statistical differences between groups (CSII vs. insulin injection therapy) were assessed by Wilcoxon tests for continuous variables and χ^2 tests for dichotomous variables. Effect size measures used were Cramer's φ (χ^2) and Cohen's *r* (Wilcoxon test). Severe hypoglycaemic events, diabetic ketoacidosis and hospitalization were summarized during the most recent year of observation. Event rates for hypoglycaemic events and ketoacidosis were modelled in a negative binomial regression model. Hospitalization was modelled by a Poisson regression based on the individual time under risk in each person and expressed as events per person-year. Bonferroni step-down correction (Holm-method) was used to adjust all *P*-values for multiple comparisons. A *P*-value < 0.01 was considered statistically significant. Results are presented as median and upper/lower quartile (Q1; Q3) for continuous variables and as proportions for dichotomous variables. Multivariable regression models were used to compare CSII vs. insulin injection therapy with regard to the outcome variables HbA_{1c}, insulin dose, hospitalization, diabetic ketoacidosis, severe hypoglycaemia, diabetic retinopathy, microalbuminuria, diabetic neuropathy, history of stroke, history of myocardial infarction and depression controlled for differences in age, sex, and diabetes duration between treatment groups (Table 1).

Results

CSII use in the elderly and old

To investigate the trend in CSII usage, numbers of people with type 1 diabetes aged ≥ 60 years using CSII or initiating CSII over the period 2008 to 2018 were retrieved (Table 2). The trend shows an increase in the percentage of all people aged ≥ 60 years from 12% (2008) to 23% (2018).

Table 2 Numbers of users aged ≥ 60 years who newly initiated CSII in the period 2008 to 2018

	All	Age groups		
Year	≥ 60 years	60 to < 70 years	70 to < 80 years	≥ 80 years
2008	51	35	15	1
2009	49	36	13	0
2010	73	50	21	2
2011	99	69	28	2
2012	70	43	21	6
2013	70	47	20	3
2014	71	48	21	2
2015	88	62	25	1
2016	74	48	25	1
2017	59	49	10	0
2018	67	48	17	2

CSII, continuous subcutaneous insulin infusion.

In the group of individuals aged 60 to < 70 years, CSII usage increased gradually and almost doubled over a period of 11 years (from 16% in 2008 to 31% in 2018); approximately one-third of this population used CSII in 2017 (31%). The percentage of individuals using CSII among people aged 70 to < 80 years increased from 9% (2008) to 18% (2018). Regarding individuals aged ≥ 80 years CSII usage increased slowly from 2% in 2008 to a maximum of 7% in 2012 and 2016.

Participant characteristics

For this analysis, 9547 individuals (1404 CSII; 8143 insulin injection therapy) from 187 DPV centres in Germany, Austria and Switzerland were included. Data were retrieved in March 2019 and comprised the most recent year of treatment for individuals with type 1 diabetes aged ≥ 60 years. In case of discontinuation of insulin pump therapy before March 2019, data on the most recent year of treatment using CSII were retrieved.

Comparisons of the clinical characteristics of people using CSII compared with insulin injection therapy are presented in Table 3. Mean (SD) CSII duration was 6 (4.7) years. In the most recent year of treatment, 7% of CSII users had a patch pump ($N = 635$). Individuals on CSII were younger compared with the insulin injection group, with a lower percentage of people aged ≥ 70 years. Age at diabetes onset was younger in the CSII group with longer diabetes duration and a greater number of individuals with duration of diabetes ≥ 30 years. The CSII group had a higher BMI compared with the insulin injection group.

Glycaemic management and control

Adjusted comparisons of clinical outcome variables are presented in Table 4. After adjustment for sex, age and duration of diabetes, the difference in metabolic control in the group using CSII compared with the insulin injection therapy group remained significant. The CSII group had a lower HbA_{1c}; sex and diabetes duration were significant covariates. People on CSII used a significantly lower daily insulin dose and reported fewer events of severe hypoglycaemia and ketoacidosis.

Chronic diabetes complications

Despite a significantly lower HbA_{1c}, the CSII group was more likely to have an associated diagnosis of neuropathy and depression. Individuals using CSII were hospitalized less often, with diabetes duration, sex and age serving as significant covariates. The main reasons for hospitalization were diabetes education/therapy adjustment, reasons unrelated to diabetes, severe hypoglycaemia and ketoacidosis.

Conclusions

This study aimed to investigate CSII use in people with type 1 diabetes age ≥ 60 years over the past 11 years (2008–2018) and to examine the clinical characteristics of older individuals with type 1 diabetes treated with CSII compared with insulin injection therapy.

Our results show an increase of insulin pump usage over the past 11 years. In 2008, ~ 12% of all individuals aged ≥ 60 years in the DPV registry used CSII, whereas in 2018 ~ 23% of participants used CSII. In particular, individuals aged 60 to < 70 years contributed to this trend: the percentage of elderly people treated with CSII almost doubled over the 11 years, with approximately one-third of people (31%) in this age group using CSII in 2018 compared with 16% in 2008. Our results show that the population of people with

Table 3 Demographic and clinical characteristics: comparison of CSII and insulin injection therapy

	CSII		Insulin injection therapy		
	N	Median (Q1, Q3)	*N*	Median (Q1, Q3)	*P*-value
Age; years	1404	66.4 (62.8, 71.5)	8143	70.5 (65.0, 76.7)	< 0.001
Age at onset; years	1404	31.0 (20.9, 42.8)	8143	45.0 (30.6, 57.9)	< 0.001
Age ≥ 70 years; %	1404	31	8143	52	< 0.001
Women; %	1404	52	8143	51	1.00
BMI; kg/m^2	1343	26.5 (23.8, 29.8)	7735	25.6 (22.9, 29.1)	< 0.001
BMI > 30 kg/m^2; %	1343	24	7735	20	0.008
Diabetes duration; years	1404	36.8 (24.5, 46.8)	8143	25.7 (13.1, 40.4)	< 0.001
Diabetes duration ≤ 10 years; %	1404	5.3	8143	19	
Diabetes duration 10 to < 30 years; %	1404	30	8143	39	
Diabetes duration ≥ 30 years; %	1404	65	8143	43	
HbA_{1c}; mmol/mol	1260	56.3 (50.8, 63.9)	7482	58.2 (49.5, 68.8)	< 0.001
HbA_{1c}; %	1260	7.3 (6.8, 8.0)	7482	7.5 (6.7, 8.5)	
HbA_{1c} < 58 mmol/mol (7.5%)	1260	57	7482	50	
HbA_{1c} < 69 mmol/mol (8.5%)	1260	85	7482	76	
CGM/FGM use; %	1404	15	8143	10	< 0.001
SMBG/day	1031	4.5 (4.0, 6.0)	6940	4.0 (3.0, 4.0)	< 0.001

CSII: continuous subcutaneous insulin infusion; SMBG: self-monitoring of blood glucose. Non-adjusted comparisons; dichotomous variables are presented as percentages; continuous variables are presented as median and quartiles (Q1, Q3); Bonferroni-Holm adjusted *P*-values.

Table 4 Clinical outcomes: comparison of CSII and insulin injection therapy

	CSII		Insulin injection therapy		
	N	Mean (SE)	*N*	Mean (SE)	Adjusted *P*-value
HbA_{1c}; %	1260	7.7 (0.1)	7482	7.9 (0.1)	< 0.001
HbA_{1c}; mmol/mol	1260	60.7 (22.4)	7482	62.8 (22.4)	
Insulin dose; IU/kg day^{-1}	1347	0.49 (0.02)	7788	0.61 (0.01)	< 0.001
History of myocardial infarction; %	1404	7.2 (1.2)	8143	7.4 (1.1)	0.813
History of stroke; %	1404	6.7 (1.0)	8143	8.5 (0.8)	0.029
Retinopathy (any); %	769	25 (2.6)	3987	22 (2.0)	0.128
Neuropathy; %	1404	65 (2.0)	8143	60 (1.6)	0.001
Microalbuminuria; %	790	14 (1.9)	5829	19 (1.9)	< 0.001
Depression; %	1404	11 (1.4)	8143	6.4 (0.7)	< 0.001
	N	Rate (95% CI)	*N*	Rate (95% CI)	Adjusted *P*-value
Severe hypoglycaemia/person-year	1404	0.16 (0.02)	8143	0.21 (0.03)	0.001
Diabetic ketoacidosis/person-year	1404	0.06 (0.01)	8143	0.08 (0.01)	0.003
Days in hospital/person-year	1404	8.1 (0.1)	8143	11.2 (0.1)	< 0.001

CSII, continuous subcutaneous insulin infusion.
Adjusted for sex, age and diabetes duration; dichotomous variables are presented as proportions (%); continuous variables are presented as adjusted mean and standard error.

type 1 diabetes aged ≥ 60 years using CSII is increasing and emphasize the importance of more studies to provide a tailored approach to insulin therapy for this vulnerable group of individuals. The relevance of CSII for older individuals with type 1 diabetes is further backed up by data on the percentage of elderly and old people using CSII in the USA, as reported by the T1D Exchange Clinical Registry [21].

In line with previous research, our results suggest that individuals using CSII have slightly better glycaemic control and need a lower daily insulin dosage [7]. About half of the individuals in both treatment modalities met the glycaemic goals of the ADA for otherwise healthy older adults (< 58 mmol/mol; < 7.5%) [22].

People on CSII experience less severe hypoglycaemia compared with people on insulin injection therapy [7,8,12]. Older people are at a particular risk of hypoglycaemia [23], consequently the risk of severe hypoglycaemia was increased for both treatment modalities compared with younger people [24]. People with frequent, severe hypoglycaemia and/or hypoglycaemia unawareness in particular, may benefit from insulin pumps, which may also apply to older individuals. Rates of severe hypoglycaemia associated with CSII use (0.16 episodes/person-year) were comparable with those reported for participants age > 65 years in the T1D Exchange (0.168 episodes/person-year) [25], but were significantly higher in the insulin injection group (0.21 episodes/person-year). As shown in previous studies, diabetes duration (but not sex and age) was a significant covariate for the effect of CSII vs. insulin injection therapy on severe hypoglycaemia [24,25].

In line with research on younger individuals using CSII, fewer episodes of ketoacidosis were reported in the CSII group compared with individuals using insulin injection therapies, even though ketoacidosis is considered to be one of the most serious adverse events associated with CSII [7].

People using CSII spent fewer days in hospital compared with individuals with insulin injection therapy. Unsurprisingly, hospital days per person-year were substantially higher than in younger populations with type 1 diabetes [26]. Especially for older people who may be more vulnerable to deterioration of their condition within a hospital setting, it is of utmost importance that clear policies and procedures are in place to decide whether they can safely continue CSII or not.

Despite the consensus recommendation that people with mental health issues such as depression or severe anxiety are not good candidates for CSII, people on CSII in our study were diagnosed with depression more often than those on insulin injection therapy, as shown in previous research on younger individuals [20]. It has been suggested that higher levels of psychiatric comorbidity may lead to poorer glycaemic control that could not be managed using insulin injection therapy and thus lead to CSII [27]. However, it is conceivable that increasing age-related impairments and lack of insulin pumps tailored for the needs of older individuals facilitate feelings of being overwhelmed and depressed. Compared with other studies on depression in elderly people with diabetes, the rate of clinically recognized depression among the T1D population studied is low. The diagnosis of depression in our study is clinician-based and not in all cases informed by standardized measures (e.g. WHO-5 cut-off scores). This could lead to depression being undetected and thus underestimated. Further, depression is often overlooked in routine diabetes care, especially in elderly people.

The ability to monitor real-time glucose data and receive hypoglycaemia alerts using continuous glucose monitoring has been shown to improve glycaemic control and reduce

severe hypoglycaemia in people aged > 65 years [28]. Real-time glucose monitoring may contribute to better glycaemic control, regardless of longer diabetes duration. Sensor use was more common in those using CSII (15% vs. 10%). However, we did not differentiate between continuous glucose monitoring and FGM, and data on sensor use in older adults with diabetes is not complete, thus sensor use may be underreported in the DPV for this age group.

CSII is a proven safe and effective treatment option for older people with type 1 diabetes. Hence older age in itself should not be seen as an exclusion criterion for the use of CSII. An individual's diabetes self-management skills and possible impairments have to be taken into account [29]. Although many older individuals with type 1 diabetes remain highly functional and demand intensive therapy options such as new diabetes technologies for optimized glycaemic control, other older people may potentially benefit from CSII but are affected by geriatric syndromes, which can complicate intensive therapy approaches and increase the risk of adverse outcomes [24]. It is conceivable that despite suboptimal glycaemic control, physicians might opt to continue insulin injection therapy or discontinue CSII due to age-related barriers that complicate CSII initiation, and a lack of elderly-friendly insulin pumps and reliable data on CSII usage in older people [11]. Although there is a strong need for customizable options [24], such as adaptable displays, voice output or simplified menus, the design of current devices still does not offer enough personalized solutions to be most usable and thus effective and safe for the elderly [29]. Actions targeted at healthcare professionals and the diabetes technology market that aim at the usability of devices and raise awareness for the needs of older people using CSII are essential.

Very few specific recommendations on use of new diabetes technologies for older individuals exist and there are no 'official' criteria to decide about discontinuation of CSII [30]. Discontinuation rates for insulin pumps are generally low, because CSII is an effective treatment option for achieving and maintaining good glycaemic control in people with type 1 diabetes, and treatment satisfaction can be better compared with insulin injection therapy [6]. A recent longitudinal analysis of the T1D Exchange Registry on pump discontinuation rates reported that discontinuation rates among adults aged ≥ 26 years were < 1% [5]. Being forced to give up CSII may severely decrease an individual's well-being, promote a feeling of loss of autonomy and increase worries about deterioration of clinical outcomes after converting to insulin injection therapy. Therefore, people who are no longer able to use CSII require practical, and possibly emotional, support to ensure successful transition to insulin injection therapy [30].

A key strength of this study is the large sample size of older people using CSII and insulin injection therapy. This is the first study to compare CSII with insulin injection therapy in older individuals with type 1 diabetes in a primary care setting, using extensive data from a multicentre register (DPV register). Results from patient registries with unselected cases may, of course, differ from the results of clinical trials. However, care data substantially add valuable knowledge about clinical outcomes in daily life. Because data in the DPV were collected from specialized diabetes care centres they are not population-based and may not be generalizable to all older people with type 1 diabetes in other practice settings. The DPV registry was the first nationwide benchmarking launched in Germany and its coverage rates of children and youth with type 1 diabetes are high, but data for older age groups are presumably far less complete because DPV data collection began only in the mid-1990s. Further, duration of CSII was 6 years (SD = 4.7 years), thus most of the individuals included in the analyses on diabetes-related outcomes initiated CSII relatively late in life and we did not differentiate between users who had just initiated CSII and those who were more experienced with CSII. Nonetheless, the DPV is one of the most representative available data sets on older adults with type 1 diabetes in Germany and our results offer greater generalizability than those of previous studies on CSII in the older population. There is the possibility of a survival bias in our data. We used a retrospective design and did not include longitudinal data. Hence, we are not able to model trajectories between treatment modalities and outcomes.

More extensive research in different settings on effectiveness, safety and person-reported outcomes (such as well-being) regarding CSII in older individuals with type 1 diabetes and evidence-based guidelines are needed to help identify those who would most likely benefit from CSII.

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Competing interests

None declared.

Author contributions

JG wrote the manuscript. JG and TK designed the study. RWH and EB analysed the study data. RWH, TK, EK, AD, IS-F, J-CK, MH and SZ contributed to the discussion and reviewed and edited the manuscript. RWH is the guarantor of this work and, as such, had full access to all the data in the

study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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