

Appendix C Data synthesis

Table C.1 Conceptual framework

Final conceptual framework of the recommended diabetes specific PROs.

Patient reported outcome	Definition	Patient reported outcome measure(s)	Type of diabetes patient reported outcome recommended for	No. studies endorsing patient reported outcome	Evidence endorsing patient reported outcome (study identifier)
PSYCHOLOGICAL: Diabetes specific psychological well-being					
Diabetes distress (multidimensional and aspect of diabetes specific psychological well-being)	Emotional response to aspects of living with and managing diabetes	Problem Areas in Diabetes (PAID); Problem Areas in Diabetes-1 (PAID-1); Problem Areas in Diabetes-5 (PAID-5); Problem Areas in Diabetes-11 (PAID-11); Diabetes Distress Scale (DDS); Diabetes Distress Scale-2 (DDS-2); Diabetes Distress Scale-4 (DDS-4); Type 1 Diabetes Distress Scale (T1-DDS); Diabetes Questionnaire (Swedish National Diabetes Register (SNDR)) (Free of worries sub-scale; items 6-8); D-SMART tool (American Association of Diabetes Educators)	Both	17	AADE (2003); Byrne (2017); Chen (2019); Eigenmann (2009); Glasgow (1999); Hermanns (2013); Kalra (2019); Marrero (2019); Nano (2020); Nicolucci (2013); Rubin (2006); Skovlund (2019); Speight (2009); Svedbo Engström (2018); Ventura (2016); Vieta (2011); Young-Hyman (2016)
Fear/worry about hypoglycemia (aspect of diabetes distress)	Fears and worry related to hypoglycemia	Hypoglycemia Fear Survey-II (HFS-II) (full and worry sub-scale only); Hypoglycemia Fear Survey-II Short Form (HFS-II SF)	Both	3	Bradley (2018); Skovlund (2019); Young-Hyman (2016)
Diabetes specific psychological well-being (multidimensional)	Aspects of mental health related to diabetes including but not limited to negative well-being (e.g. feeling depressed because of diabetes: also diabetes distress, diabetes related positive well-being, etc.)	Well-Being Questionnaire 28 (W-BQ28), Diabetes Questionnaire (SNDR) (Mood and energy sub-scale; items 3-5 <i>(but also incl. 1 depression item)</i>)	Both	3	Reaney (2016); Speight (2009); Svedbo Engström (2018)
Fear of complications (aspect of diabetes distress)	Fears related to complications (i.e. general, specific (e.g. blindness), lifestyle, hypoglycemia and weight gain)	Fear of Complications Questionnaire (FCQ)	Both	NA	Identified by core team
PSYCHOLOGICAL: Diabetes specific quality of life					
Diabetes specific quality of life (multi-dimensional)	The perceived impact of diabetes on one's life (not just his/her health) in ways that are important to the individual (i.e. on life domains important to them). It reflects a cognitive response (i.e. considered thoughts).	Audit of Diabetes-Dependent Quality of Life (ADDQoL); Diabetes-39 (D-39); Diabetes Quality of Life (DQoL) measure; DAWN Impact of Diabetes Profile (DIDP); World Health Organization quality of life scale WHOQOL-BREF DMQoL (diabetes module)	Both	11	Bradley (2018); Byrne (2017); Chen (2019); Donald (2012); Glasgow (1999); Huang (2008); Nicolucci (2013); Skovlund (2019); Speight (2009); Ventura (2016); Vieta (2011)
Impact of diabetes on productivity (aspect/dimension of diabetes specific quality of life)	The impact of diabetes on life/work productivity	Diabetes Impact on Productivity (DPM)	Both	1	Skovlund (2019)

PSYCHOLOGICAL: Diabetes self-management behaviours: Am I doing it? (Performance)

Physical activity (aspect of performance of diabetes self-management behaviour)	Performance of physical activity behaviour	Summary of Diabetes Self-Care Activities (SDSCA); Diabetes Self-Management Questionnaire (DSMQ); International Physical Activity Questionnaire, short form (IPAQ-SF); D-SMART tool (AADE)	Both	11	AADE (2003); Chen (2019); Donald (2012); Eigenmann (2009); Moffet (2009); Nicolucci (2013); Rubin (2006); Schoenthaler (2020); Skovlund (2019); Ventura (2016); Young-Hyman (2016)
Diet (aspect of performance of diabetes self-management behaviour)	Performance of diet related behaviour	SDSCA; DSMQ; Brief-type self-administered diet history questionnaire (BDHQ); D-SMART tool (AADE)	Both	11	AADE (2003); Chen (2019); Donald (2012); Eigenmann (2009); Moffet (2009); Nicolucci (2013); Rubin (2006); Schoenthaler (2020); Skovlund (2019); Ventura (2016); Young-Hyman (2016)
Self-monitoring blood glucose (aspect of performance of diabetes self-management behaviour)	Performance of self-monitoring of blood glucose behaviour	SDSCA; DSMQ; D-SMART tool (AADE)	Both	9	AADE (2003); Chen (2019); Eigenmann (2009); Moffet (2009); Nicolucci (2013); Rubin (2006); Skovlund (2019); Ventura (2016); Young-Hyman (2016)
Foot care (aspect of performance of diabetes self-management behaviour)	Performance of foot care behaviour (e.g. self-foot exam)	SDSCA	Both	5	Eigenmann (2009); Moffet (2009); Nicolucci (2013); Skovlund (2019); Young-Hyman (2016)
Medication taking (including oral and injectable) (aspect of performance of diabetes self-management behaviour)	Performance of diabetes related medication taking behaviour (i.e. taking and refilling of diabetes related medications)	Adherence to Refills and Medications Scale (ARMS-D); SDSCA; D-SMART tool (AADE)	Both	8	AADE (2003); Chen (2019); Moffet (2009); Nicolucci (2013); Rubin (2006); Schoenthaler (2020); Ventura (2016); Young-Hyman (2016)
Engaging with health services (aspect of performance of diabetes self-management behaviour)	Engagement with and optimal use of diabetes services (incl. attending diabetes appointments, non-scheduled interaction, and routine diabetes screening)	DSMQ; D-SMART tool (AADE)	Both	3	AADE (2003); Rubin (2006); Skovlund (2019)
Diabetes self-management behaviour performance (multi-dimensional)	Performance of health behaviours (i.e. behaviours that relate to health maintenance, restoration and improvement) specifically prescribed for managing diabetes	DSMQ	Both	3	Byrne (2017); Glasgow (1999); Kalra (2019)
Oral health (aspect of performance of diabetes self-management behaviour)	Performance of oral self-care (i.e. to prevent periodontitis)	None suggested	Both	1	Moffet (2009)
PSYCHOLOGICAL: Diabetes self-management behaviours: Am I doing it? (Capacity)					
Diet (aspect of capacity for diabetes self-management behaviour)	Subjective perception of one's current capacity in terms of performing individualised recommendations for	Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - diet and exercise sub-scale; Items 12+13)	Both	1	Svedbo Engström (2018)

Physical activity (aspect of capacity for diabetes self-management behaviour)	diet (i.e. how one feels are currently managing to perform this behaviour - rather than tracking performance of this behaviour) Subjective perception of one's current capacity in terms of performing individualised recommendations for physical activity (i.e. how one feels are currently managing to perform this behaviour - rather than tracking performance of this behaviour)	Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - diet and exercise sub-scale; Items 12+13)	Both	1	Svedbo Engström (2018)
PSYCHOLOGICAL: Diabetes self-management behaviours: Can I do it? (Patient activation)					
Patient activation (multidimensional)	Believing that the patients' role is important and possessing the knowledge, skills/competencies, and confidence to take action and maintain this in terms of managing one's own health and well-being	Patient Activation Measure (PAM); Health Education Impact Questionnaire (heiQ)	Both	2	Donald (2012); Skovlund (2019)
PSYCHOLOGICAL: Diabetes self-management behaviours: Do I want to do it? (Perceived importance)					
Diet (aspect of perceived importance of diabetes self-management behaviour)	How important diet is perceived to be	None suggested	Both	1	Ventura (2016)
Physical activity (aspect of perceived importance of diabetes self-management behaviour)	How important physical activity is perceived to be	None suggested	Both	1	Ventura (2016)
Self-monitoring blood glucose (aspect of perceived importance of diabetes self-management behaviour)	How important self-monitoring of blood glucose is perceived to be	None suggested	Both	1	Ventura (2016)
PSYCHOLOGICAL: Diabetes self-management behaviours: Do I want to do it? (Perceived motivation)					
Motivation	Motivational orientation to performing diabetes self-management behaviours (i.e. whether this is 'autonomous/intrinsic' (and the behaviour is self-determined because it is consistent with internal goals and satisfies innate psychological needs) or 'controlled' (and the behaviour is determined by a	Treatment Self-Regulation Questionnaire-diabetes (TSRQ-diabetes)	Type 2	1	Chen (2019)

demand or threat from an external agent, e.g. a family member or healthcare provider or shame)). Autonomously motivated people are more likely to be successful in self-regulating behaviour and hence performing it (see Self Determination Theory)

PSYCHOLOGICAL: Diabetes satisfaction

Diabetes treatment satisfaction ⁱⁱⁱ	An individual's subjective appraisal of their experience of treatment (both process and outcomes), including ease of use, side effects and efficacy	Diabetes Treatment Satisfaction Questionnaire (DTSQ); DSQoLs; Global Diabetes Satisfaction Treatment (GDST)	Both	6	Bott (1998); Bradley (2018); Chen (2019); Skovlund (2019); Speight (2009); Vieta (2011)
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Perceived autonomy in diabetes care	How much choice one has in their decisions concerning meals and activities related to their medication	Treatment Flexibility Scale (TFS)	Both	NA	Identified by core team
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Satisfaction with living with diabetes ^{iv}	Contentment with aspects of physical or emotional health related to diabetes (e.g. body weight, energy or ability to have social interactions)	Current Health Satisfaction Questionnaire (CHES-Q)	Type 2	1	Chen (2019)
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PSYCHOLOGICAL: Diabetes treatment goals

Diabetes treatment goals ^v	Motivational structures relating to diabetes treatment (to be considered while treating, educating, or counselling)	DSQoLs	Type 1	1	Bott (1998)
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PSYCHOLOGICAL: Diabetes specific health beliefs

Perceived control over diabetes (multidimensional and aspect of diabetes specific health beliefs)	Appraisal of the extent to which one feels as though they have their diabetes and blood sugar under control (comprising self-efficacy for performing diabetes self-management behaviours and locus of control; motivational orientation and perception of how much control one has over the conditions of their life (e.g. perception that life outcomes arise from factors out of one's control and behaviour in response to external circumstances (external locus of control) versus perception of life outcomes arising from one's own agency and abilities and behaviour in response to internal	None suggested	Both	2	Rubin (2006); Schoenthaler (2020)
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	states (internal locus of control)) (see Modified Social Learning Theory)				
Self-efficacy (aspect of perceived behavioural control)	Perceived capability to perform diabetes self-management behaviours (see Social Cognitive Theory)	Perceived Competence for Diabetes Scale (PCDS); Confidence In Diabetes Self-Care (CIDS) (insulin-using); CIDS (non-insulin using); Diabetes Self-efficacy Scale (DSES); D-SMART tool (AADE)	Both	6	AADE (2003); Chen (2019); Glasgow (1999); Skovlund (2019); Ventura (2016); Young-Hyman (2016)
Patient empowerment (aspect of diabetes specific health beliefs)	Perceived ability to manage psychosocial issues related to diabetes (e.g. stress, obtaining family support, negotiating with health care, professionals/ employers, and dealing with uncomfortable emotions) (i.e. akin to diabetes related psychosocial self-efficacy)	Diabetes Empowerment Scale-DAWN Short Form (DES-SF); D-SMART tool (AADE)	Both	5	AADE (2003); Byrne (2017); Glasgow (1999); Nicolucci (2013); Skovlund (2019)
Diabetes specific health beliefs (multi-dimensional)	Attitudes and beliefs about diabetes	None suggested	Both	1	Moffet (2009)
Diabetes specific health beliefs (theoretical model)	Attitudes and beliefs about diabetes based on a theoretical model of health behaviour; see Health Belief Model (predictors of behaviour incl. perceived severity, perceived susceptibility to the disease process, perceived benefits and costs/barriers, and cues to action (i.e. internal (e.g. symptoms) or external (e.g. health education)	None suggested	Type 2	1	Chen (2019)
PSYCHOLOGICAL: Diabetes related cognition					
Diabetes-related problem solving and decision making	The cognitive aspect of diabetes self-management behaviour (i.e. relating to glucose regulation, managing hypo/sick days, and managing diabetes in general i.e. when routines are difficult to follow)	Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - capabilities to manage diabetes sub-scale; item 9-11); D-SMART tool (ADDE)	Both	3	AADE (2003); Svedbo Engström (2018); Ventura (2016)
PSYCHOLOGICAL: Diabetes related skills and competencies					
Skills and techniques for managing diabetes	Knowledge based skills and techniques (including the use of aids) that help participants manage their diabetes	heiQ; Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - capabilities to manage diabetes sub-scale; items 9-11)	Both	2	Skovlund (2019); Svedbo Engström (2018)
PSYCHOLOGICAL: Diabetes knowledge					
Diabetes knowledge	Level of knowledge about and understanding of	CHES-Q	Both	3	Chen (2019); Moffet (2009); Skovlund (2019)

	diabetes in general and related to one's own clinical outcome measurements					
PSYCHOLOGICAL: Diabetes numeracy						
Diabetes related numeracy	Numeracy skills used in diabetes	Diabetes Numeracy Test (DNT)	Both	1	Young-Hyman (2016)	
PSYCHOLOGICAL: Attitude to insulin						
Attitude to (initiating) insulin treatment	Current appraisal of insulin therapy; both positive and negatives attitudes. Including psychological insulin resistance	Insulin Treatment Appraisal Scale (ITAS)	Type 2	2	Rubin (2006); Ventura (2016)	
PSYCHOLOGICAL: Diabetes-related eating problems/disorders						
Diabetes related eating problems/disorders	Behavioural manifestations of diabetes specific issues related to eating (e.g. intentional medication omission to produce weight loss)	None suggested	Both	2	Skovlund (2019); Young-Hyman (2016)	
PSYCHOLOGICAL: Diabetes related avoidance behaviour						
Hypoglycemia avoidance behaviours	Behaviours aimed at avoiding hypoglycemia owing to fear of its possible negative consequences (increasing risk of hyperglycemia)	HFS-II SF	Both	1	Skovlund (2019)	
Hyperglycemia avoidance behaviours	Behaviours aimed at avoiding hyperglycemia owing to fear of complications etc. (increasing risk of hypoglycemia)	None suggested	Both	1	Ventura (2016)	
PHYSICAL AND FUNCTIONAL: Diabetes symptoms (incl. symptoms of complications)						
Diabetes symptoms (presence and/or burden) (multi-dimensional)	The subjective experience of physical and psychological symptoms related to diabetes and its possible complications	Diabetes Symptom Checklist-Revised (DSC-R); Type 2 Diabetes Symptom Checklist (DSC-2); Diabetes Symptom Measure (DSM)	Both	5	Harman (2019); McColl (1995); Moffet (2009); Skovlund (2019); Vieta (2011)	
Sexual dysfunction (presence) (aspect of diabetes symptoms)	Ways in which one is unable to participate in a sexual relationship (incl. related to desire, arousal, orgasm, and pain)	None suggested	Both	2	Kalra (2019); Moffet (2009)	
Gastroparesis (presence) (aspect of diabetes symptoms)	The presence of physical symptoms associated with gastroparesis (e.g. abdominal pain)	Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)	Both	1	Skovlund (2019)	
Female urinary incontinence (presence) (aspect of diabetes symptoms)	The unintentional passing of urine	None suggested	Both	1	Moffet (2009)	
Hyperglycemia (presence) (aspect of diabetes symptoms)	The presence of symptoms related to hyperglycemia (e.g. thirst)	None suggested	Both	1	Rubin (2006)	
Hypoglycemia (presence and intensity) (aspect of diabetes symptoms)	The presence and intensity of commonly experienced hypoglycemic symptoms	Edinburgh Hypoglycaemia Survey (EHS)	Both	1	Ventura (2016)	

Neuropathic pain ⁱⁱ	The assessment of sensory descriptors and signs of pain identified via bedside sensory examination	Douleur Neuropathique 4 Questions (DN-4) (<i>but this is part PRO, part clinician assessed and outdated; pin prick is no longer used</i>)	Both	1	Skovlund (2019)
PHYSICAL AND FUNCTIONAL: Diabetes treatment side effects					
Insulin injection side effect (lypodystrophy)	Abnormal amount and distribution of fat under the skin leading to enlarged areas of tissue/lumps (lipohypertrophy) or to tissue loss (lipoatrophy)	None suggested	Both	1	Nano (2020)
Diabetes treatment side effects	Side effects of diabetes treatment	None suggested	Type 2	1	Harman (2019)
PHYSICAL AND FUNCTIONAL: Hypoglycemia unawareness					
Hypoglycemia unawareness	The failure to sense a fall in blood glucose below normal levels	Gold score	Both	1	Ventura (2016)
SOCIAL: Diabetes specific social support					
Diabetes specific social support	Perceived support received from others in relation to diabetes (including peer support)	Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - support from others sub-scale; items 19-21); Diabetes Support Scale (DSS); D-SMART tool (AADE)	Both	5	AADE (2003); Glasgow (1999); Nicolucci (2013); Svedbo Engström (2018); Ventura (2016)
SOCIAL: Diabetes related stigma					
Diabetes related stigma	Feeling disqualified from full social acceptance related to having diabetes (i.e. felt/self-stigma (perceived) or enacted (discriminatory behaviour that is actually experienced)	Type 1 Diabetes Stigma Assessment Scale (DSAS-1); Type 2 Diabetes Stigma Assessment Scale (DSAS-2)	Both	2	Nicolucci (2013); Ventura (2016)
PSYCHOLOGICAL, PHYSICAL/FUNCTIONAL AND SOCIAL: Diabetes burdens and restrictions					
Diabetes and treatment burdens and restrictions ⁱ	Perceived burdens and restrictions related to diabetes and its management	Diabetes-Specific Quality of Life Scale (DSQoLs) (Burdens and restrictions sub-scale); Diabetes Questionnaire (SNDR) (Abilities to manage diabetes - not limited by diabetes/blood sugar sub-scales; items 14-18)	Both	5	Agiostratidou (2017); Bott (1998); Marrero (2019); Svedbo Engström (2018); Ventura (2016)
Hypoglycemia burdens and restrictions	Perceived burdens and restrictions related to non-severe hypoglycemia	Treatment-Related Impact Measure-Non-severe Hypoglycemic Events (TRIM-HYPO)	Both	1	Skovlund (2019)
Diabetes symptom restrictions	Perceived restrictions related to diabetes symptoms (i.e. the Impact of diabetes symptoms on functional goals, e.g. work, school, family, leisure activities)	None suggested	Type 2	1	Marrero (2019)

ⁱ Aspect of diabetes distress if emotional response to burden or restriction elicited (e.g. DSQoLs 'burdens and restrictions' – certain subscales).

ⁱⁱ Included as a diabetes specific patient reported outcome because the biggest cause is diabetes.

ⁱⁱⁱ We consider this concept a patient reported outcome rather than an outcome that would be elicited by a patient reported experience measure given the focus on efficacy of and side effects (i.e. symptoms) associated with diabetes treatment; other aspects such as the ease of use of treatments may be more aligned with a patient reported experience measure (although these measures typically focus on experience of care in a wider context).

^{iv} Aspect of diabetes specific quality of life: reflects 'contentment with health related to diabetes' (positively worded); diabetes related quality of life reflects the impact of diabetes on the individual's life (not just his/her health) in ways that are important to the individual (negatively worded)

^vCan be used to inform interpretation of treatment satisfaction, e.g. a person's satisfaction with a particular treatment will be influenced by whether it achieves their treatment goal(s)